

BI-ARTICULAR CUP - Modular

MANUFACTURING - DISTRIBUTION: **permedica S.p.a.**
via Como, 38/39 - IT23807 Merate (Lc) - ITALY

REGISTERED TRADEMARKS:



QUALITY CERTIFICATIONIS:



INTENDED PURPOSE

Modular Bi-Articular cup is intended to be used for the prosthetic replacement of the femoral head in hemi-arthroplasty applications, in combination with a femoral stem and an articular head.
It is indicated in partial hip replacement procedures where the acetabular cartilage is not involved in arthrosic disease and therefore an hemi-arthroplasty has been chosen (usually in cases of femoral head fractures).

TECHNICAL INFORMATION

DESIGN:

The liner is provided with a locking ring and presents two holes for extraction with a special pincers. The cup presents a positive eccentricity for the automatic valgus positioning, reducing the risk of dislocation and improving the stress distribution over the acetabular cartilage. Sphericity and roundness of the articular surfaces are compliance with ISO7206-2.

MATERIALS:

METAL SHELL:

- AISI316 stainless steel alloy - ISO5832/1
- PM734 highly Nitrogenized forged stainless steel alloy - ISO5832/9

The device contains percentages of ferromagnetic materials that could be affected by the magnetic fields generated by diagnostic radiology equipments such as Magnetic Resonance Imaging (MRI).

INSERT: Ultra High Molecular Weight Polyethylene, without calcium stearate - ISO5834/1/2.

SURFACE FINISH:

Inner articular surface and outer metal shell: roughness in compliance with ISO7206-2

STERILIZATION:

Method: Ethylene Oxyde (EtO) or irradiation (Beta or Gamma rays - nominal dose 25 kGy) in vacuum.

Validity: 5 years (Beta sterilized products) - 10 years (Gamma/EtO sterilized products).

PACKAGING:

Outer: rigid carton box, with polypropylene protection film and Macrilene foam padding*;

Inner: double bi-laminated polyamide/polyethylene plastic envelope vacuum packed (Beta/Gamma sterilized products).
Double paper/plastic envelope (EtO sterilized products).

Identification labels reporting all necessary information regarding the product can be found both on the outer or inner package; extra detachable labels for application to the clinical chart are enclosed.

* Missing in batches with manufacturing date from 07/2016

CLASSIFICATION:

Class III as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendments.

PRODUCT TECHNICAL INFORMATION SHEET

FURTHER INFORMATION

The Modular Bi-Articular cup consists of a metal shell and its UHMWPE articular liner. It has been conceived to reduce acetabular cartilage wear by distributing the load bearing forces acting on the joint upon a double articular surface. Moreover, the polyethylene liner absorbs impact forces.

The absence of Calcium Stearate ensures that the material's properties are not reduced by the presence of a foreign substance, nevertheless conferring high wear and oxydation resistance.

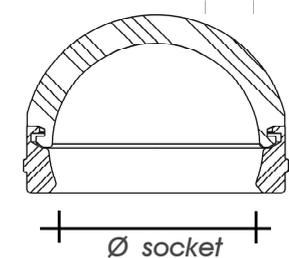
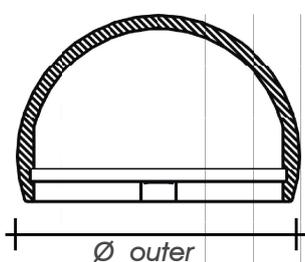
The components, sterilized by irradiation with accelerated electron beam (b-rays) are vacuum-packed, which is particularly relevant for UHMWPE components which are in this way preserved from oxydation.

A wide range of sizes are available, from 39 up to 60mm with 1 mm increasing diameter and inner socket matching \varnothing 28mm ball heads.

AVAILABLE SIZES *References with asterisk are available until stocks last

		METAL SHELL		INSERT
		AISI 316	PM734	socket \varnothing 28mm
Colour code	\varnothing outer	reference	reference	reference
GREEN	39mm	26939*	25939	26971
	40mm	26940*	25940	
	41mm	26941*	25941	
	42mm	26942*	25942	
YELLOW	43mm	26943*	25943	26972
	44mm	26944*	25944	
	45mm	26945*	25945	
BLUE	46mm	26946*	25946	26973
	47mm	26947*	25947	
	48mm	26948*	25948	
	49mm	26949*	25949	
	50mm	26950*	25950	
	51mm	26951*	25951	
	52mm	26952*	25952	
RED	53mm	26953*	25953	26974
	54mm	26954*	25954	
	55mm	26955*	25955	
	56mm	26956*	25956	
	57mm	26957*	25957	
	58mm	26958*	25958	
	59mm	26959*	25959	
	60mm	26960*	25960	

BI-ARTICULAR CUP - Modular



The colour coding of the labelling allows to identify the proper shell/liner combination

RELATED DOCUMENTS *downloadable from our website (registration required)

Product Information Sheet: **SI008EN***

Surgical Technique: **TC004EN***

Instruments Technical Information Sheet: **SSP034EN**



EXACTA

Femoral Stem

SURGICAL TECHNIQUE



Both our Sales Representatives and Product Specialists are at Your complete disposal for any further information and/or explanation about the contents of this Surgical Technique

The EXACTA femoral system by permedica provides two straight femoral stems available in double version:

EXACTA cementless: providing a press-fit stem with bone contact surface finishing in different versions (sandblasted, X-Pore coated, HX-Pore coated);

EXACTA PLUS cemented: mirror polished surface stem with smoothed shape.

Both versions available in Standard 135° and LATERALIZED 127° option.

The stem's design is based upon the principle of a self-locking stem, thus ensuring optimal anchoring guaranteed by a double cortical bone contact in the meta-diaphyseal region on the medial-lateral plane.

Longitudinal and transversal grooves on the anterior and posterior surface guarantees adequate axial and rotational stability.

The stem has a thin rectangular cross-section thus favouring the stem's wedging into the femoral medullary canal. The tapered diaphyseal portion allows for good centering of the implant in the femoral canal avoiding high stresses on the distal cortical walls.

The neck section has a reduced diameter enhancing the range of motion of the joint, avoiding impingement with the inner rim of the acetabular cup.

A special hole on the top allows the insertion of the stem introducer, for the correct alignment and positioning of the stem as well as the coupling with a sliding hammer extraction device.

A niche on the medial region of the prosthetic neck allows the housing of a punch for stem removal if necessary.



NOTE:

Further information are available in the section "Warnings, indication and contraindication for the implant" in the last page of this leaflet.

ATTENTION:

Other than the implementation of a correct Surgical Technique, a good clinical outcome of a THA also depends upon several factors such as bone stock quality, wear values and correct implant sizing.

INDICATION FOR USE

Use of the EXACTA stems is indicated in the following conditions:

- ✓ avascular necrosis of the femoral head;
- ✓ Fractures of the femoral neck/head;
- ✓ rheumatoid arthritis;
- ✓ primary/secondary arthrosis;
- ✓ post-traumatic arthrosis;
- ✓ collagen diseases;
- ✓ displasies and congenital dislocation of the hip joint;
- ✓ epiphysiolisis.

SURGICAL PROCEDURE

ATTENTION:

This Surgical Technique should be considered a guide or example to assist orthopaedic Surgeons already trained in Total Hip Arthroplasty. It's objective is to demonstrate the various instruments used for the implantation of the EXACTA stem by permedica. The knowledge and experience of the Surgeon will guide him throughout the steps of the implantation.

✓ pre-operative planning	page	3
✓ Surgical approach		4
✓ Joint exposure		4
✓ Femoral neck osteotomy		4
✓ Preparing of the medullary canal		4
✓ Broaching		5
✓ Trial reduction		6
✓ Stem implantation - Cementless		7
✓ Stem Implantation - Cemented		8
✓ Head implantation		9
✓ Stem removal		10
✓ Post operative care		10

The aim of preoperative planning is to choose the most suitable prosthesis to implant, determine the ideal anchorage position, establish the correct positioning for good biomechanical reconstruction, correct eventual dysmetria and verify the size.

With these objectives in mind it is necessary to carry out a radiographical exam of the coxo-femoral joint (pelvis and proximal third of the femur) with projected Anterior-Posterior and Latero-Lateral images, with enough focal distance to obtain an enlargement of at least 15%.

In summary, a correct preoperative planning is advisable in order to carry out the following general characteristic evaluation:

CENTER OF ROTATION REPRODUCTION

From the A/P pelvis radiograph the controlateral femoral head center of rotation can be determined, when it is healthy, and the distance from the radiographic U is quantified.

EVALUATION OF EVENTUAL DYSMETRIA

Three horizontal lines are traced: a Bi-ischiatic line (1), between the inferior margins of the ischium; an above acetabular line (2), between the upper margins of the acetabular cavity, and a bi-tronchanteric line (3), between the two lesser trochanters.

If these three lines are parallel amongst themselves, there is no dysmetria.

If lines (1) and (2) are parallel but line (3) is divergent, there is dysmetria due to a deformation of the femur.

If lines (2) and (3) are parallel but (1) is divergent, there is a dysmetria due to a cotyloid deformation.

In the case that all three lines are divergent amongst themselves, there is a combined dysmetria, determined by a cotyloid deformation as well as a femur deformation.

EVALUATION OF THE IMPLANT SIZE

After having studied and evaluated the above mentioned information via radiographic templates (with 15% magnification), choose the optimal size combination for the femoral component as well as the acetabular component (Fig. 1).

It is possible to prepare a traced radiographic lucent of the hip by placing the template over the prosthesis to be implanted.

IMPORTANT!

Determine the correct level of the femoral neck osteotomy by placing the template of the better fitting size over the involved hip x-ray, aligning the line referring to the center of rotation to the top of the *Greater Trochanter*. The Rasp Line marked on the broach will indicate the correct level of the femoral neck resection.

This mark is engraved on each rasp and indicates the precise sinking level.

Please note that the length of the neck (Rasp Line-Center of Rotation) is 41 to 46.5mm depending on the size (refer to table at page 7).

ATTENTION

It would be advisable to evaluate, already in the pre-operative planning phase, the opportunity to use an EXACTA LATERAL stem.

Failing to execute accurate pre-operative planning could lead to poor results. The intervention should be carefully planned based upon X-Ray screening.

Before the operation it is furthermore necessary to investigate the possibility of any possible allergic reactions of the patient towards implantable device materials.



Fig. 1: Pre-operative planning

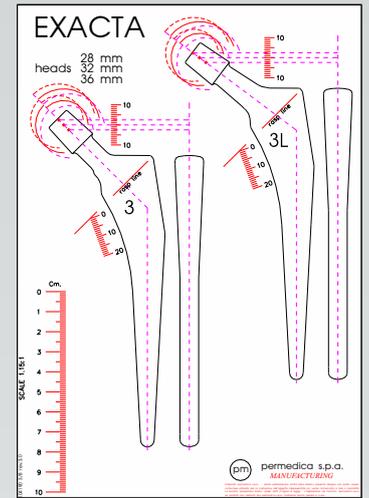
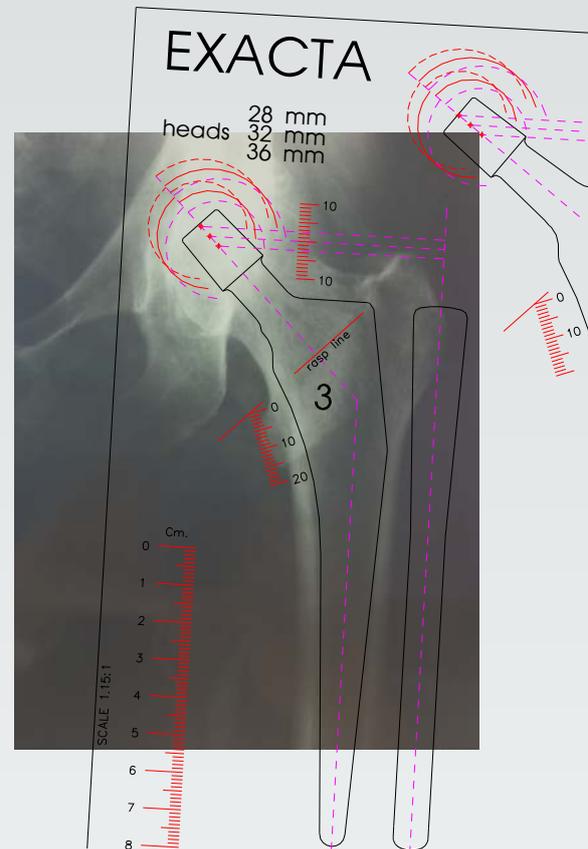


Fig. 1b: size evaluation



2

SURGICAL APPROACH

The initial exposure of the joint for the EXACTA stems implantation can be achieved by following any standard surgical approach, according to Surgeon's preferences and/or habits.

The following illustrated technique refers to an implant realized via a Postero-Lateral Approach.

3

JOINT EXPOSURE

The incision is centered on the posterior half of the *Greater Trochanter* and extended distally along the femoral diaphysis for 10 cm. and proximally following the direction of the *gluteus maximus* fibers.

The *Fascia Lata* is divided in line with the cutaneous incision. The *Gluteus Maximus* is divided longitudinally via a blunt dissection. Cauterize the bleeding points.

Expose the *Short External Rotators muscles* positioning a blunt retractor between the *Capsule* and the *Gluteus Medius*, putting them in tension via internal rotation of the joint. Pass a suturing thread into the *Piriformis Tendon* in order to evidence the position for successive reinsertion. Detach entirely or separately the *External Rotators muscles* by carrying out an incision as close as possible to the bone.

Cut the *Joint Capsule* starting from the *Acetabular Cavity* margin and going till the base of the *Femoral Neck*.

Dislocate the *Femoral Head* turning the joint internally with the knee flexed. In some cases it is necessary to section the *Round ligament* first.

Utilize a double pointed retractor in order to lift the femoral head thus providing optimal exposure.

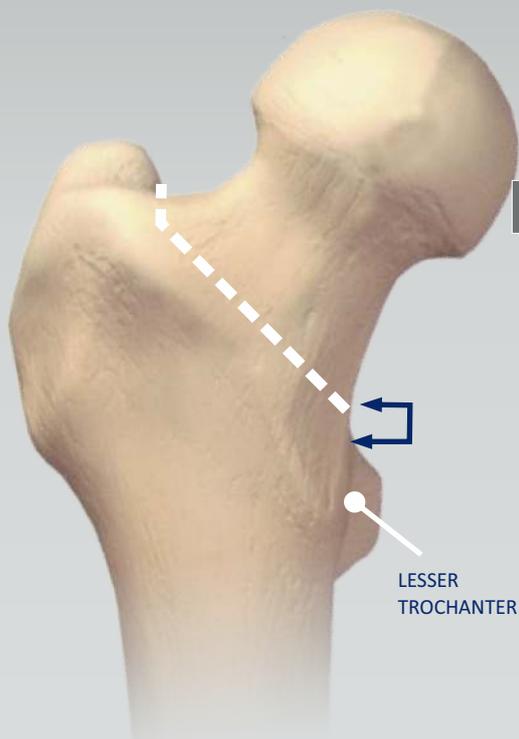


Fig. 2: Resection level

4

FEMORAL NECK OSTEOTOMY

Before proceeding to the osteotomy of the femoral head, it is important to remove any osteophytes and periosteal tissues to allow clear vision of the head/neck limits.

The neck osteotomy is carried out using an oscillating saw, referring to the lesser trochanter and at the distance measured in the pre-operative planning (Fig. 2).

The femoral head is removed and preserved for eventual future bone grafts.

Fig. 3: Starting Chisel

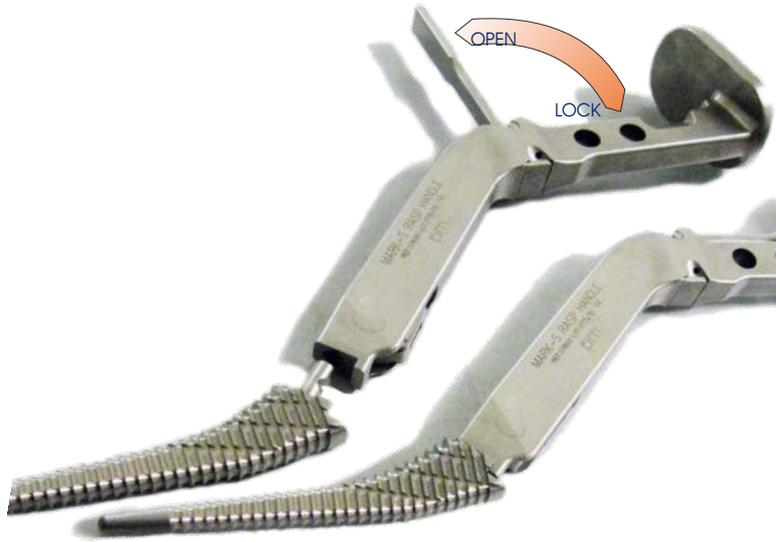


5

STARTING THE FEMORAL CANAL

The medullary canal is initiated utilizing the indicated **Starting Chisel (S12010)**. Striking the chisel, a rectangular cleft is made allowing for the insertion of the first rasp. The chisel must be held as laterally as possible. (Fig. 3)

Identify the axis of the femoral canal using a long curette or a rigid reamer.



BEFORE TO START:
 the EXACTA instruments set can be supplied with both the MARK S broaches (illustrated in this technique) and the CLASSIC broaches (please refer to Surgical Technique TCE045 release 1.2).

CAUTION:
 to lock the Mark S type broaches onto the Impacting Handle, open the locking system by pulling the lever, insert the broach as shown and then close the lever to lock (Fig. 4).

NOTE:
 In addition to the CURVED Impacting Handle (S11600) supplied as standard, it is also available a STRAIGHT Handle and Double Off-set Handles (in LEFT and RIGHT version) to be used with anterior approach. A special Adapter (S11607) is also available to allow broaches impaction by using the Sliding Hammer Impactor (S10012) as well as a pneumatic hammer (Woodpecker).



The smallest size broach is assembled onto the Impacting Handle and inserted into the prepared site. The special design of both the broach and the handle make it possible to preserve the Greater Trochanter, allowing to insert the broach slightly medially (Fig. 5a) and then change the direction to follow the diaphyseal axis by pushing the handle laterally (towards the Greater Trochanter) while hammering the broach.

The broach must be pushed until totally embedded. It may be necessary to repeat the extraction and reinsertion a few times to help removal of bony debris.

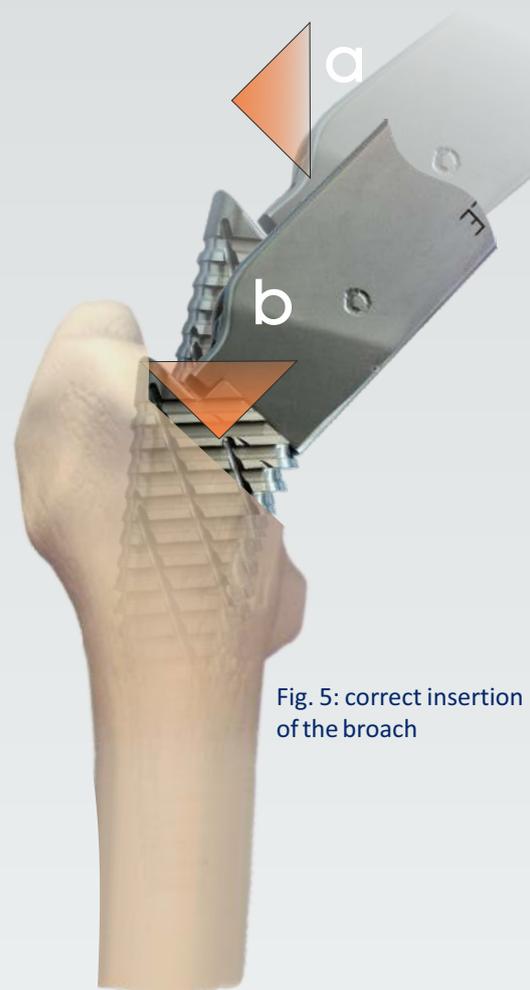


Fig. 5: correct insertion of the broach



Fig. 6: correct sinking of the final broach

Proceed inserting the next broaches, increasing the size until reaching the correct size determined in the pre-op planning (anyway the surgeon should feel the broach locking onto the cortical walls and not sinking any further, stable to torsion and opposing resistance to extraction). If the osteotomy has been made in compliance to the pre-op planning, the Rasp Line mark should be leveled to the osteotomy (Fig. 6). If the broach sinks further, the next size is normally required.

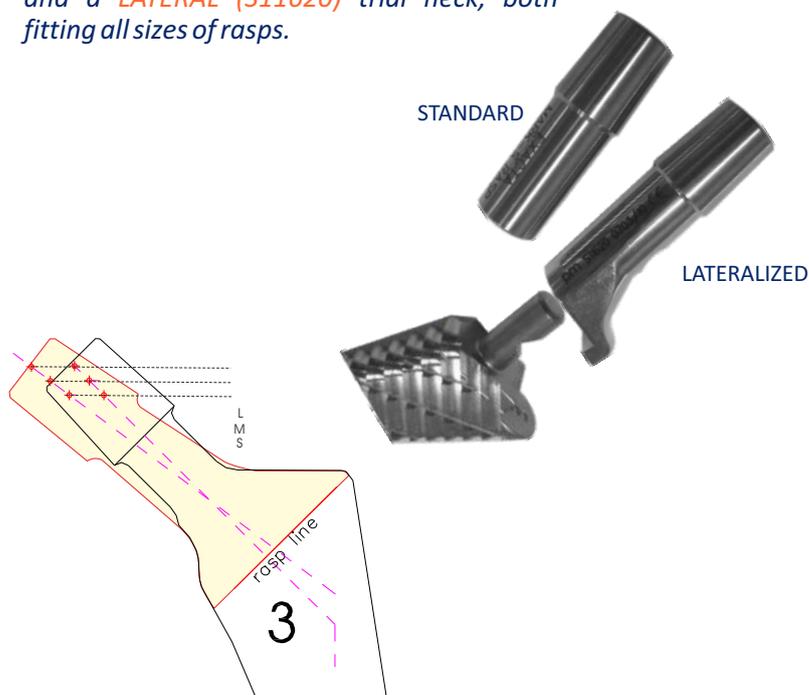
Whenever the final broach should be considerably smaller (two or more sizes) than that evaluated during the pre-operative planning it would be necessary to verify the correct insertion of the rasp within the femoral canal and, if necessary, carry out any corrections before inserting the final implant.

7 TRIAL EVALUATION

Having reached the desired fit, the last broach utilized is left in place. Inserting onto it the apposite Trial Neck for the EXACTA Mark S broach and a Trial Head, it will be possible to carry out a trial reduction. (Fig. 7).

ATTENTION:

The MARK S rasps have STANDARD (S11610) and a LATERAL (S11620) trial neck, both fitting all sizes of rasps.



The Lateralized option allows to change the angle of the neck (127°), increasing the offset and improving muscles tension without changing the limb length.

After inserting a **Medium Neck Trial Head** compatible with the inner diameter of the implanted acetabular cup's liner, reduce the hip to evaluate mobility and stability through a full range of motion (high flexion, external/internal rotation, abduction/adduction) and check for any impingement.

The appropriate neck length of the ball head to be used is determined as well. This is considered optimal if, by extending the limb and applying traction, an excursion of about 10mm is allowed. If the excursion should be different, evaluate the opportunity of using a Short or Long neck ball head.

The neck length of the Trial Heads is identifiable by a colour coding:

- GREEN = SHORT Neck/XL neck
- BLUE = MEDIUM Neck
- GREY = LONG Neck

WARNINGS regarding use of ExtraLong ball-heads:

Although the system foresees the use of Extralong ball heads, this could lead to an alteration of the correct biomechanics, with huge lever arms and high stresses on the implanted components. Therefore, use of this type of ball heads should be carefully evaluated, also considering the patient's weight and morphology.



Fig. 7: Raspa con conetto e testa di prova.

IMPLANTATION OF THE DEFINITIVE STEM

8

PRESS-FIT STEM

EXACTA cementless stems: the definitive Stem to be implanted will be the same size of the last broach utilized.

Once drawn from the sterile packaging, the Stem is manually engaged into the previously prepared femoral site.

Screw the apposite **Stem Impacting End (S11622)** onto the **Universal Impactor Handle (S12011)**.

Lodge the tip into the niche onto extreme top of the stem (Fig. 8) and impact with a hammer until complete seating (fig. 9).



Fig. 8: impactor site



Fig. 9: Stem insertion.

Fig. 10: engagement of the Stem Driver.



Fig. 11a: sinking level referring to the Greater Trochanter

WARNING:

DO NOT USE EXTRALONG BALL HEADS with EXACTA PLUS LATERAL stem

CEMENTED STEM

EXACTA PLUS (cemented): the definitive Stem to be implanted will be the same size of the last rasp utilized.

Once drawn from the sterile packaging, the Stem is engaged onto the **Stem Holder/Driver (S11623)**. Insert the threaded end into the stem and use the integrated knurled knob to screw it into the niche on the top of the stem (Fig. 10) then tighten using the Knob Key.



The prepared femoral cavity is filled with bone cement, following the most favourite cementing technique.

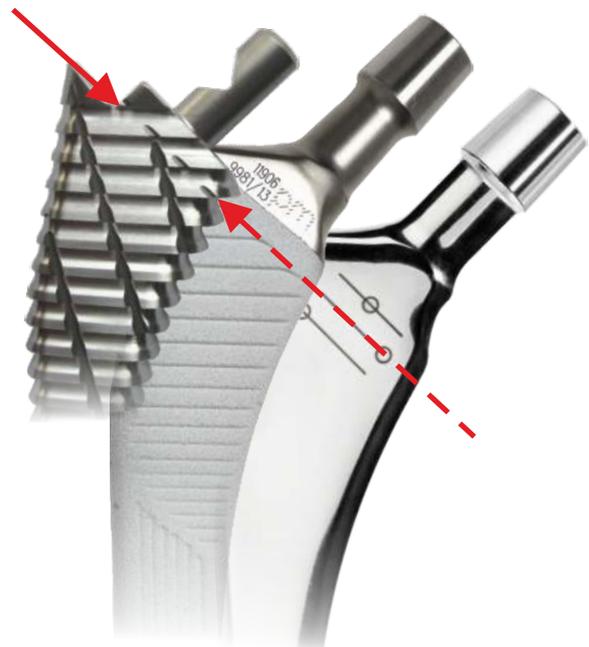
The stem is driven into the femoral canal and sank till it's final seating. For a correct sinking refer to the sinking lines marked on the proximal part of the stem.

ATTENTION:

The central line refers to the resection line marked on the rasp (fig.11b). Please remind anyway that a reliable landmark to refer to is the center of the morse taper (center of rotation) aligned to the *Greater Trochanter* (fig. 11a).

Apply a continuous pressure till complete hardening of the bone cement, removing the bone cement in excess overflowing from the femoral canal.

Fig. 11b: sinking lines.



Once the stem is definitively seated it will be possible to repeat a trial, in case of any doubt, by using the Trial Heads. Once the correct ball head has been established, proceed to implant the definitive one.

Remove the plastic cap protecting the taper and manually insert the selected Ball Head onto the stem taper, applying axial pressure and torsion to achieve perfect locking.

After positioning, the Ball Head is impacted using the apposite **Impacting End (S10014)** assembled on the **Universal Impactor Handle (S12011)** (Fig. 12).



Extra-Long and Excentric ball heads are also available to face any situation during surgery. In case Excentric Ball-Heads $\varnothing 36\text{mm}$, should be used, please refer to Surgical Technique TCE057.

WARNINGS:

- ☑ *Ceramic Ball Heads should be gently impacted. NEVER hit them directly with metal instruments.*
- ☑ *Whenever replacment of a ceramic ball head should be necessary, an accurate investigation of the cone surface should be effected. Any visible damage (i.e. grooves/scratches) would compromise the geometrical/dimensional precision of the cone and use of a new ceramic ball head must be AVOIDED.*

Fig. 12



Whenever it should be necessary to remove the stem, an apposite **Extraction Punch (S10023)** is provided. Screw it onto the **Universal Impactor Handle (S12011)** and insert it into the niche at the base of the stem neck. Impact heavily with an hammer to remove the stem.

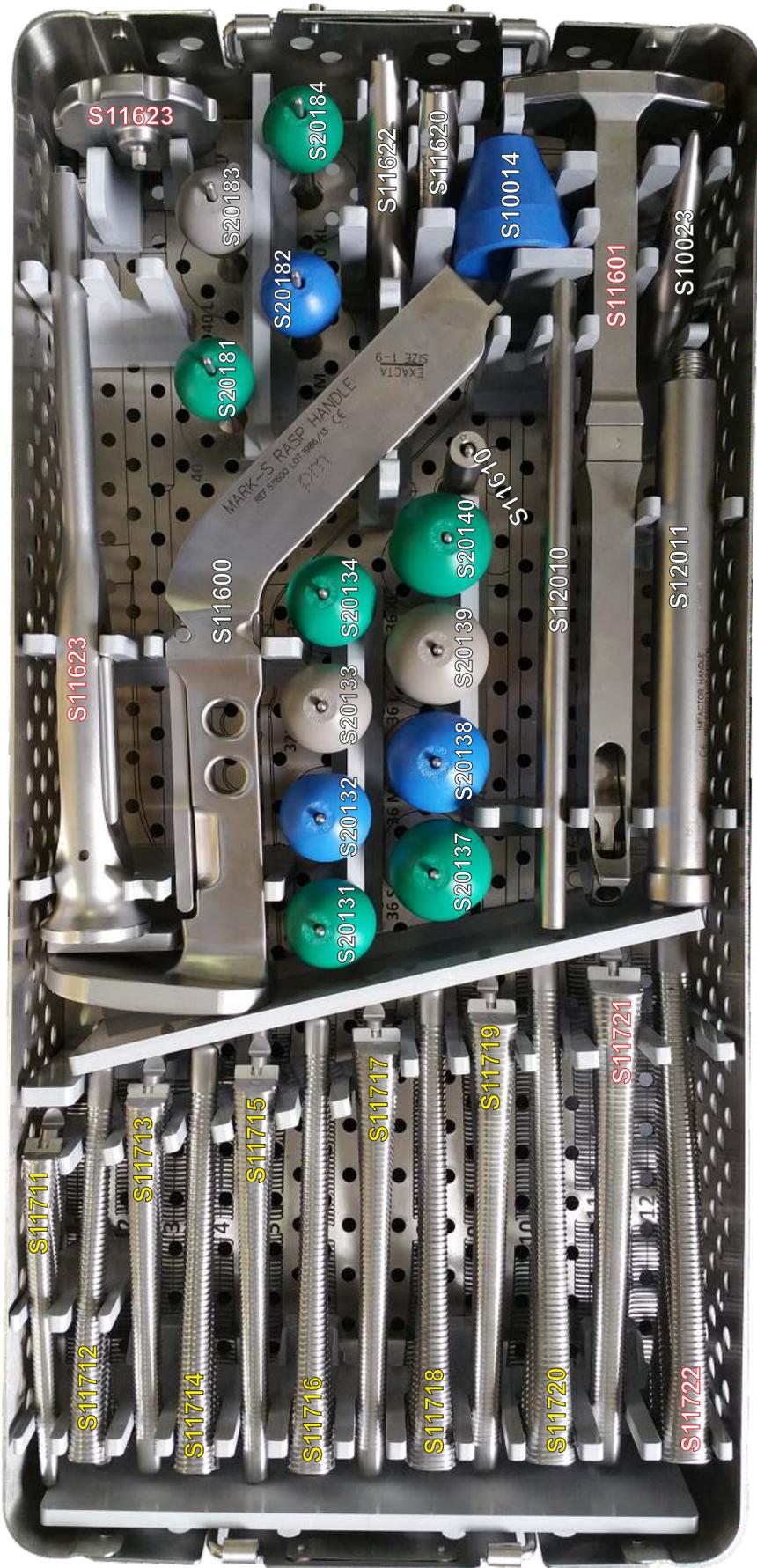
An **Extraction Threaded Adapter** to be used with the **Sliding Hammer** is also available upon request.

In this case, connect the quick coupling **Extraction Adapter (S11012)** to the **Sliding Hammer Impactor/Extractor (S10012)** and screw it into the threaded hole in the top of the stem.

Post-op care strategy is very important to allow the patient a correct recovery. The guidelines are established by the Surgeon and should consider several factors such as age, weight and bony structure of the patient.

In any case, it is necessary to avoid excessive load of the lower limb for a certain amount of time.

ATTENTION: the Surgeon is required to schedule regular check ups to verify the implant status.



S10014	HEAD IMPACTING END
S10023	IMPACTOR/EXTRACTOR - CONICAL TIP
S12010	STARTING CHISEL
S12011	UNIVERSAL IMPACTOR HANDLE
S11600	RASP HANDLE - Mark S Series - CURVED
S11601	RASP HANDLE - Mark S Series - STRAIGHT*
S11610	TRIAL NECK - Standard
S11620	TRIAL NECK - Lateralized
S11622	STEM IMPACTING END
S11623	STEM HOLDER w/threaded Rod *
S11711	EXACTA Mark S Rasp - Fine Pitch - size 1
S11712	EXACTA Mark S Rasp - Fine Pitch - size 2
S11713	EXACTA Mark S Rasp - Fine Pitch - size 3
S11714	EXACTA Mark S Rasp - Fine Pitch - size 4
S11715	EXACTA Mark S Rasp - Fine Pitch - size 5
S11716	EXACTA Mark S Rasp - Fine Pitch - size 6
S11717	EXACTA Mark S Rasp - Fine Pitch - size 7
S11718	EXACTA Mark S Rasp - Fine Pitch - size 8
S11719	EXACTA Mark S Rasp - Fine Pitch - size 9
S11720	EXACTA Mark S Rasp - Fine Pitch - size 10
S11721	EXACTA Mark S Rasp - Fine Pitch - size 11*
S11722	EXACTA Mark S Rasp - Fine Pitch - size 12*
S20181	TRIAL HEAD Ø 28mm - SHORT Neck
S20182	TRIAL HEAD Ø 28mm - MEDIUM Neck
S20183	TRIAL HEAD Ø 28mm - LONG Neck
S20184	TRIAL HEAD Ø 28mm - XL Neck
S20131	TRIAL HEAD Ø 32mm - SHORT Neck
S20132	TRIAL HEAD Ø 32mm - MEDIUM Neck
S20133	TRIAL HEAD Ø 32mm - LONG Neck
S20134	TRIAL HEAD Ø 32mm - XL Neck
S20137	TRIAL HEAD Ø 36mm - SHORT Neck
S20138	TRIAL HEAD Ø 36mm - MEDIUM Neck
S20139	TRIAL HEAD Ø 36mm - LONG Neck
S20140	TRIAL HEAD Ø 36mm - XL Neck

*** OPTIONAL INSTRUMENTS**

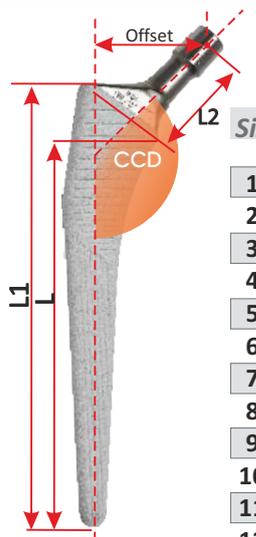
Large Pitch Rasps

S11711	EXACTA Mark S Rasp - size 1
S11712	EXACTA Mark S Rasp - size 2
S11713	EXACTA Mark S Rasp - size 3
S11714	EXACTA Mark S Rasp - size 4
S11715	EXACTA Mark S Rasp - size 5
S11716	EXACTA Mark S Rasp - size 6
S11717	EXACTA Mark S Rasp - size 7
S11718	EXACTA Mark S Rasp - size 8



EXACTA Femoral Stem - Cementless

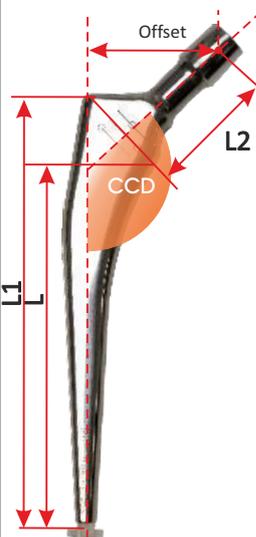
Class III



Size	Standard - CCD 135°		Lateral - CCD 127°					
	L1	L	Offset	L2	Titanium	HaX-Pore	X-Pore	HA
	mm	mm	mm	mm	Reference	Reference	Reference	Reference
1	130,5	110	40,0	41,0	11501	11901	11801	11601
2	140,5	120	40,5	41,0	11502	11902	11802	11602
3	145,5	125	41,0	42,0	11503	11903	11803	11603
4	150,5	130	42,0	43,0	11504	11904	11804	11604
5	155,5	135	43,3	44,0	11505	11905	11805	11605
6	160,5	140	43,5	44,5	11506	11906	11806	11606
7	165,5	145	44,5	45,0	11507	11907	11807	11607
8	170,5	150	45,0	45,0	11508	11908	11808	11608
9	175,4	154	45,0	45,2	11529	11929	11829	11609
10	180,4	158	45,5	45,2	11530	11930	11830	11610
11	185,4	162	45,5	45,8	11531	11931	11831	11611
12	190,4	166	46,0	46,5	11532	11932	11832	11612

EXACTA PLUS Femoral Stem - Cemented

Class III



* References with asterisk are available ON REQUEST

Size	Standard - CCD 135°		Lateral - CCD 127°							
	L1	L	Offset	L2	Polished	Matt	Offset	L2	Polished	Matt
	mm	mm	mm	mm	Reference	Reference	mm	mm	Reference	Reference
1	117	97	40,0	39,0	11701	11771*	46,0	43,0	11711	11786*
2	120	100	40,5	39,0	11702	11772*	46,5	43,0	11712	11787*
3	130	110	41,0	39,0	11703	11773*	48,0	43,5	11713	11788*
4	135	115	42,0	40,0	11704	11774*	49,0	45,5	11714	11789*
5	140	120	43,3	41,0	11705	11775*	50,0	46,5	11715	11790*
6	145	125	43,5	42,0	11706	11776*	51,0	47,0	11716	11791*
7	150	130	44,5	42,7	11707	11777*	52,0	47,8	11717	11792*
8	155	135	45,0	43,3	11708	11778*	52,5	48,4	11718	11793*
9	160	140	45,0	43,3	11729	11779*	52,5	48,4	11739	11794*
10	165	145	45,5	43,3	11730	11780*	53,0	48,4	11740	11795*
11	170	150	45,5	44,0	11731	11781*	53,0	49,0	11741	11796*
12	175	155	46,0	44,5	11732	11782*	53,5	49,5	11742	11797*

Information

INTENDED PURPOSE: EXACTA stems are intended for use in total or partial Hip Replacement procedures, combined with a femoral ball head (or a bi-articular head) and an acetabular cup. Indicated for primary hip arthroplasties in cases of serious joint degeneration, mainly due to arthrosis and post-traumatic degenerative factors. Device fixation is obtained by means of primary cementless press-fit stabilization or by using bone cement, depending on the version utilized.

MATERIALS:

Cementless stems: Titanium Aluminium Niobium forged alloy (Ti6Al7Nb) ISO5832/11
 Cemented stem: PM734 highly nitrogenized Stainless Steel forged alloy ISO5832/9

SURFACE FINISHING:

EXACTA Titanium: microstructured sandblasted surface roughness 4-6µm
 EXACTA HaX-Pore: double coating 300µm pure Titanium+50µm Hydroxyapatite Ca₁₀(OH)₂(PO₄)₆ plasma sprayed
 EXACTA X-Pore: coating 300µm pure Titanium plasma sprayed
 EXACTA HA: coating 80µm Hydroxyapatite Ca₁₀(OH)₂(PO₄)₆ plasma sprayed
 EXACTA Plus: mirror polished or matt (sandblasted, on request) finishing surface

STERILIZATION:

Method: accelerated electron beam irradiation (b rays - nominal dose 25 kGy), in vacuum.
 Validity: 5 years.

CLASSIFICATION:

Class III as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendements.

Warning

Before using a product introduced onto the market by permedica spa, the surgeon is encouraged to carefully study the following recommendations, warnings and instructions as well as the specific product information (surgical techniques and technical product description). **Negligence or lack of observance of this aspect exonerates the manufacturer from all responsibility.**

Definition

Joint Prosthesis: implantable medical device, including implantable components and materials that is in contact with the surrounding muscle and bones, and carries out functions similar to those of a natural articular joint.

General information

A joint prosthesis should only be considered if all other therapeutic possibilities have been carefully weighed and found unsuitable or inappropriate.

A joint prosthesis, even if successfully implanted will be inferior to a natural, healthy joint. Conversely for the patient, a joint prosthesis can be a beneficial replacement for a severely altered, pathological joint, eliminating pain and restoring good mobility and bearing capacity.

Every artificial joint is subject to unavoidable wear and ageing. Over the course of time, an artificial joint initially implanted in a stable manner can loosen therefore limiting or impairing perfect functionality. Wear, ageing and loosening of an implant can lead to reoperation.

Indications for Use

The following are the general guidelines for the use of prosthetic devices produced by permedica. For more detailed information refer to the Product Technical Sheet and Surgical Technique of the specific device:

- Advanced wear of the joint due to dysplasia, degenerative, post-traumatic, or rheumatic diseases.
- Fractures or avascular necrosis
- Negative outcome of previous surgeries such as joint reconstruction, osteotomies, arthrodesis, hemi-arthroplasty or total hip prosthesis, total knee prosthesis.

Use of this prosthetic device for reasons other than those prescribed is not permitted.

Contraindications

Infections or other specific conditions in the area surrounding the joint, as well as allergies to the implanted material, (cobalt, chromium, nickel, etc) represent absolute contraindications.

Relative factors that could compromise the success of the intervention are:

- Acute or chronic local or systemic infections, even far from the implant site, (risk of haematogenous diffusion of the infection towards the site);
- Insufficient bone structure at the proximal or distal level of the joint that does not guarantee good anchorage of the implant;
- Severe muscular, neural or vascular diseases that endanger the extremities involved;
- Overweight or obesity;
- Osteoporosis;
- Hypertrophy of the muscular tissue surrounding the joint;
- Metabolic disorders or lack of sufficient renal functions.

The patient must also be:

- Capable of understanding and following the doctor's instructions.
- Avoid excessive physical activity such as heavy work or competitive sports that involve intense vibration, jerking motions or heavy loading.
- Avoid excessive weight gain.
- Avoid drug abuse, including nicotine and alcohol.

General Information and precautions for the safe use of the implant

Products of permedica Spa may be implanted only by surgeons who are familiar with the general problems of joint replacement, with implant devices, the surgical instruments and who have mastered the product-specific surgical techniques.

Prostheses and prosthesis parts are always components of a system, and therefore must be combined with original parts belonging to the same system. Note must be taken of the system compatibility according to the 'Product Technical Sheet' and/or 'Surgical Techniques'. Prostheses and prosthesis parts from permedica Spa – in particular BIOLOX ceramic components - must never be combined with parts from other manufacturers. permedica excludes all liability for the negligent use of its implants with those of other manufacturers. Specific instruments are available for the implant devices of the various articular prostheses. Improper use of these instruments can cause poor positioning of the implant components. permedica Spa excludes all liability for the negligent use of its instrumentation or the use of that of third parties.

It is forbidden to re-utilize a prosthesis or a prosthesis part that was previously implanted in the body of a patient or another person, or to re-utilize, an implant that has come into contact with the body fluid or tissue of another person, or where the mechanical integrity (superficial, geometrical, or biological) cannot be guaranteed. They are mono-use devices.

Implants must be stored in their original packaging. Before implantation they must be checked for defects such as micro scratches or marks (can cause excessive wear or complications) on the articular surface. And therefore must be handled with extreme attention.

Prolonged contact - direct or indirect – of the electrocautery with implantable components, in particular in the vicinity of the femoral stems neck, can result in structural alterations which may modify the characteristics of resistance to fatigue of the material with consequent risk of breakage and must therefore be carefully avoided.

Coated prosthetic components, in particular those coated with Hydroxyapatite, should be handled with extreme care avoiding damage to the surface coating.

Contact of prosthetic components coated with Hydroxyapatite with anything other than the original package, clean surgical gloves and patient tissue should be avoided. Hydroxyapatite coated implants should never be cemented, instead should be implanted via 'press fit' method. Hydroxyapatite cannot be substituted with cement nor can it rectify insufficient primary stability.

TiNbN coating acts as an isolation barrier for the release of ions by the surrounding metallic materials. Since the long term duration of this barrier is not known, it cannot be guaranteed and therefore, it is up to the surgeon to determine if the use of TiNbN coated prosthetic components is indicated for patients with noted allergenic sensibility towards metal (nickel) and should carry out the requisite postoperative monitoring for inflammation or allergic development.

Literature reports possible adverse reactions caused by elevated blood levels of metal ions in patients with metal-on-metal prosthetic joint surfaces. Long-term systemic effects due to the accumulation of these ions are not known and therefore long term clinical consequences can not be guaranteed. It is therefore not recommended the use of this joint coupling in female patients of childbearing age and/or people with compromised kidney function.

Before sterile implants are removed from the packaging, the protective packaging must be examined for possible damage as this could impair the sterility. The expiration date for the sterility of the product must be observed and expired products must be returned to the manufacturer. Observation of sterility maintenance must be respected when opening the package. Before reduction or assembly, articulating or combined prostheses and prosthesis parts must be thoroughly cleaned; contamination, i.e. foreign particles, bone chips or residues of bone cement, can lead to third-body abrasion, incorrect functioning or fracture of the prosthesis or prosthesis parts.

Joint prosthesis must not be mechanically worked or changed in any way, unless this is expressly envisaged in the design and surgical technique. In case of doubt, recommendation must be obtained in writing from the manufacturer.

The surface of the prosthesis must not bear any writing nor be allowed to come into contact with metallic or other hard objects (especially in the case of ceramic implants), unless this is expressly envisaged by the of the 'Surgical Technique' description.

Prostheses or prosthesis parts that are contaminated, nonsterile, damaged, scratched or have been improperly handled or altered without authorization must not be implanted under any circumstances.

Reliable seating of femoral cone-ball head combinations is only possible with the completely intact surface of the ball head cone and intact surface of the femoral stem cone. It is absolutely essential that the outer cone of the femoral stem fits perfectly with the inner cone of the ball head. The cone size is indicated on the product label and on the implant itself.

Protective caps or other protective devices must be removed immediately before use.

The instruments are inevitably subject to a certain degree of wear and ageing, rarely there could be interoperative breakage, especially if over utilized or misused. permedica recommends verification for breakage, deformation, corrosion and correct functioning, before use. In the case of damage, the instruments must not be utilized but returned to the manufacturer for substitution.

Observe any additional information, i.e. those reported in the information label applied to the primary and/or the secondary packaging relating to possible limitations for use.

Complications or other factors that may occur for reasons such as incorrect indication or surgical technique, unsuitable choice of material or treatment, inappropriate use or handling of the instruments, and/or sepsis fall under the responsibility of the operating surgeon and cannot be blamed on the manufacturer.

Possible side effects

The following are among the most frequent possible side effects of implantable devices:

- pain;
- bone fractures due to overloading on one side or weakened bone substance;
- allergy to the implanted material, mainly to metal. This signifies the necessity of ulterior study. Implants made of extraneous material can provoke the formation of histiocytosis and consequently osteolysis;
- allergic reactions;
- metalysis and consequent osteolysis in particular for implants with metal/metal surfaces;
- prosthesis or prosthesis parts can fracture or loosen as a result of: overloading; excessive weight; non-physiological stresses; superficial damage; partial or total lost of fixation; incorrect manipulation or improper implantation (wrong choice of implant component or size, improper alignment, incorrect components connection, insufficient fixation);
- excess wear or loosening of the implant due to break down of the osseous bed;
- dislocation of the prosthesis due to changed conditions of load transfer (cement disintegration or breakage and/or tissue reactions) or to early or late infections;
- dislocation, subluxation, insufficient range of movement, undesirable shortening or lengthening of the extremity involved due to less than optimal positioning of the implant;
- Intra-operative or post-operative complications:
 - perforation or fracture of the bone segments;
 - vascular lesions;
 - temporary or permanent nerve lesions that can cause pain and numbness throughout the limb;
 - inter-operational Arterial Hypotension during the cementation;
 - varus or valgus deformity;
 - cardiovascular disturbance including vein thromboses, pulmonary embolism and myocardial heart attack;
 - haematoma;
 - late wound healing;
 - infection.

Pre-operative Planning

Failure to carry out proper preoperative planning can lead to errors (i.e. in regards to candidate selection, type of prosthesis, and correct implant size).

The operation should be precisely planned on the basis of the x-ray findings. Testing for eventual allergies to implant component materials should be established. X-rays provide important information on the suitable type of implant, its size and possible combinations. All types of implants and implant parts in the combination recommended by the manufacturer that may possibly be needed for the operation, as well as the instruments needed for their implantation, must be available in case another size or another implant is required. Most prosthesis components are supplied with test or trial parts for the measuring of the size to be implanted.

Patient Information

The doctor must explain the risks involved in the implantation of an endoprosthesis, possible side effects, and intrinsic limitations of the implant as well as the measures to undertake in order to reduce the possible side effects. In particular, the patient should be informed about the impact that the implant will have on his/her lifestyle, and that the prosthesis longevity could depend also on factors such as body weight and level of physical activity. Other factors regarding metal implant devices that should be communicated are:

- can affect the result of computer tomography (CT);
- can be detected by metal detectors
- in the case of cremation, removal could be required depending on local regulations.

The patient should be informed that, whenever the implanted device contains ferromagnetic materials (such as stainless steel or Cobalt Chrome alloys), it is not advised to undergo radiodiagnostic investigations based on magnetic fields (MR scan).

Sterility

General considerations

Implantable devices supplied by permedica spa in a sterile state must remain closed in the original protective packaging until the moment of implantation. Before utilizing the implant, certain controls should be carried out:

- verify sterility expiration date (month/year) on the label of the product;
- visually verify that the internal packaging and the label are intact;
- visually verify that the sterile primary packaging is integral and does not present breakage, tearing, holes or other types of damage.

If the sterile primary package is damaged or the implant or the implant supplied by permedica spa is in a non sterile state, refer to the paragraph "Resterilization".

Ceramic or metal implantable devices

Ceramic or metal implantable devices are supplied sterilized by irradiation of 25 kGy.

Plastic implantable devices

Plastic implantable devices are supplied sterilized by irradiation of 25 kGy or by ethylene oxide. The label of each implantable device specifies the method utilized for sterilization.

Resterilization

If a medical implant device supplied by permedica spa is sterilized or resterilized by the user, this is to be noted in the corresponding patient documentation (i.e. operation report), and must be conserved with the respective accompanying documents. Components can be resterilized provided that they have not come into contact with body fluid, bone and have not previously been implanted.

Validation of the cleaning and sterilization procedures, as well as the proper setting for the corresponding equipment must be checked regularly.

Ceramic or metal implantable devices

Metal implantable devices can be sterilized by the user, via gas (ethylene oxide) or utilizing superheat steam or vapour. In the case of resterilization with gas, sufficient time must be allowed for degassing.

BIOLOX ceramic components may be re-sterilized only in exceptional cases and exclusively by permedica spa.

"NON STERILE" metal or ceramic implants must not be sterilized in their original protective packages. Hydroxyapatite coated or pure Titanium metal implantable devices cannot be sterilized with gas (Ethylene Oxide), instead can be sterilized by superheat steam or vapour.

Plastic implantable devices

Implants made wholly or partly of polyethylene (UHMWPE) or Polymethylmethacrylate (PMMA) must not be resterilized utilizing superheat steam vapour, nor via irradiation nor via gas (ethylene oxide).

Instruments

All pertinent details regarding the cleaning and sterilization of instruments are supplied in the 'Instructions for the cleaning and sterilization of surgical instruments'. Instruments must be sterilized in the correct packaging via gas or vapour. Vapour sterilization should be carried out at a temperature of 121°C for 20 minutes. The sterilization of instruments made wholly or partly of plastic must not be heated above 140°C. In the case of resterilization with gas, sufficient time must be allowed for degassing.

Implant Materials

The label of each medical implant device carries the data relative to the type of material and surface coating utilized.

Endoprostheses by permedica spa are manufactured with the following materials:

- Stainless steel 316LVM (normative ISO 5832/1)
- Pure Titanium (normative ISO 5832/2)
- Titanium alloy Ti6Al4V (normative ISO 5832/3)
- CrCoMo casting alloy (normative ISO 5832/4)
- Highly nitrogenized Stainless steel – "PM 734" (normative ISO 5832/9)
- Titanium alloy Ti6Al7Nb (normative ISO 5832/11)
- CrCoMo casting alloy (normative ISO 5832/12)
- UHMWPE Polyethylene (normative ISO 5834/1 e 2)
- UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E (VITAL-E)
- UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E and cross-linked (VITAL-XE).
- Polymethylmethacrylate (PMMA)
- Alumina based BIOLOX FORTE sintered ceramic (normative ISO6474-1) and BIOLOX DELTA (normative ISO6474-2).

The combination of stainless steel and chrome-cobalt or Titanium implant components can cause corrosion. The label of the implant carries this warning.

Materials utilised for the surface coating of permedica spa implants are the following:

- Pure Titanium (normative ISO 5832/2)
- Hydroxyapatite (norma ISO 13779/2)
- TiNbN

Custom Made Implant Devices

A custom made implant is foreseen for patients that cannot be fitted with a regular or series implants. This implant is produced as a 'one of a kind' product following the indications of the surgeon and utilizing a regular implant design. The use of a custom made implant must be evaluated on a case by case basis.

The surgeon must be aware of the limitations inherent in a custom made implant and must take into account the construction and the materials chosen. The surgeon must also have the experience and capabilities necessary for the correct specifications and optimal application of the custom made product. Custom made implants do not have corresponding instrumentation.

Custom made implants are produced utilizing the technical expertise of permedica Spa acquired through series implant design. Because these implants are custom made, there is no clinical nor test data. Risks are higher with custom made products than with series implants. A custom made product must be utilized exclusively for the patient for whom it was designed.



CHALLENGING
EXCELLENCE
IN TECHNOLOGY





permedica
ORTHOPAEDICS

BI-POLAR HEAD



SURGICAL TECHNIQUE



Both our Sales Representatives/Dealers and Product Specialists are at Your complete disposal for any further information and/or explanation about the contents of this Surgical Technique.

Bi-Polar Head

The Bi-Polar Heads by permedica are composed of a metal outer shell and an Ultra High Molecular Weight PolyEthylene (UHMWPE) core with retentive ring.

The positive eccentricity allows for self valgus positioning of the Bi-Polar Head, reducing the risks of dislocation and improving the load stress distribution on the articular cartilage.

Two versions are available:

Monobloc version:

the outer shell and the insert are supplied pre-assembled. Are available in a range of sizes from \varnothing 42 to 60mm, with 1mm increments and inner socket fitting ball heads \varnothing 28mm.

The ball head fits into the Bi-Polar Head by snap-in insertion and the eventual removal is possible thanks to a special unlocking Ring provided with the instruments set.

Modular version:

the outer shell and the insert are supplied separately, to be assembled before implantation. The outer shell is available in a range of sizes from \varnothing 39 to 60mm, with 1mm increments. A colour coding on the main labeling allows identification of the correct coupling of the outer shell and the insert.

The ball head fits into the Bi-Polar Head by snap-in insertion and the eventual removal is possible thanks to a special unlocking Pince (cod. S26014) provided with the instruments set.

WARNINGS:

although the implantation of a Bi-Polar Head is a common procedure in the orthopaedic clinical practice, before to use a permedica's Bi-Polar Head it is necessary to get familiar with both the instruments set and the implants.

Good clinical results from a prosthetic intervention depends upon, other than the correct application of the surgical techniques, numerous factors of which good bone quality, wear values, and size optimization.

Before the operation is also necessary to investigate about any possible allergic reaction of the patient against the materials contained in the implantable devices.



INDICATIONS FOR USE

permedica's Bi-Polar Heads are intended to be used for primary prosthetic replacement of the femoral head in hemy-artroplasty applications due to the following diseases:

- ✓ rheumatoid arthritis;
- ✓ primary arthritis;
- ✓ post-traumatic arthritis;
- ✓ fractures involving the femoral head or neck

ATTENTION:

Further information is reported in the chapter of "Warnings, Indications and contraindication for implants", on the last page of this Surgical Techniques.

SURGICAL PROCEDURE

✓ Pre-operative planning	pg. 3
✓ Surgical access	pg. 3
✓ Exposure of the joint	pg. 3
✓ Preparation of the implant site	pg. 4
✓ Use of the Trial Bi-Polar Heads	pg. 4
✓ Implantation of the Bi-Polar Head - Monobloc	pg. 5
✓ Implantation of the Bi-Polar Head - Modular	pg. 5
✓ Removal of the Bi-Polar Head - Monobloc	pg. 6
✓ Removal of the Bi-Polar Head - Modular	pg. 6
✓ Post-Op care	pg. 6
✓ Instruments set	pg. 7

PRE-OPERATIVE PLANNING 1

A set of X-Ray templates, reproducing shape of the different sizes with 15% magnification, are available to allow the Surgeon in the choice of the proper size of the implant component to be used according to the anatomy of the patient.

The availability of trial components however allows the Surgeon to re-evaluate intraoperatively the choice made with the pre-operative plan.

WARNING:

*This Surgical Technique is to be intended as guide in assisting orthopaedic Surgeons already experienced in Hip Arthroplasty, with the objective of demonstrate the correct use of permedica's **Bi-Polar Head Instrumentation**.*

The Surgeon should in any case rely on his own knowledge and expertise in performing each single step of the intervention.

SURGICAL ACCESS 2

The joint exposure for the implantation of the Bi-Polar Head can be achieved by following any standard surgical approach, according to Surgeon's preferences and/or habits.

The following illustrated technique is given as an example and refers to an implantation realized via lateral access, with the patient in supine position.

JOINT EXPOSURE 3

A straight lateral incision is performed at the level of the *Greater Trochanter* on the side of the hip.

The subcutaneous tissues are retracted parallelly to the incision. The muscles of the *Gluteus Minimus* and *Medium*, as well as the *Lateral Vastum*, are released in their anterior third portion following the direction of its fibers..

The tendon-periosteal tissue between the *Medium Gluteus* and *Lateral Vastum* is accurately detached from the bone with an osteotome or a dissector.

With a diathermic technique small vessels are cauterized.

Then the joint capsule is exposed and ventral parts are prepared: the visible parts of the *Oblique Tendon*, *Rectum* and joint capsule are cut as well as the concrescence of the capsule with the tissues around the *Fascia Tesa*.

A pillow placed under the distal part can help access the coxa-femoral joint in case of tension of the soft tissues.

The retractors are positioned and the joint capsule is opened through a H-shaped incision (Fig. 1).

After opening the capsule, two *Homann blunt retractors* are introduced between the capsule and the femoral neck to protect posterior structures.

4

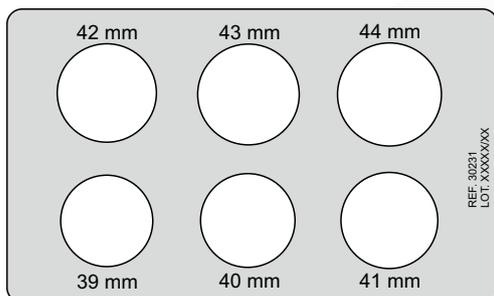
PREPARATION OF THE IMPLANT SITE

The Bi-Polar Head is used in the surgical treatment of the femoral neck/head fractures and the osteotomy should therefore not necessary. It might be however required to level the fracture line whenever it should be too high (involving the upper part of the neck or the head).

No preparation is required for the acetabular cavity as well, since the Bi-Polar head will fit the anatomical cavity.

Proceed then with removal of the femoral head utilizing a *Threaded Extractor*.

A *Sizing Plate* is available on request to measure the diameter of the femoral head removed.



5

USE OF THE TRIAL BI-POLAR HEADS

After removal of the femoral head, it will be possible to determine the size of the the acetabular cavity by means of the *Trial Bi-Polar Heads* (**Fig. 1**) mounted onto the *Positioning Handle* (S26010).

The correct size should correspond to the diameter of the femoral head removed (sized with the *Sizing Plate*) or anyway the size of the *Trial Bi-Polar Head* better fitting the cavity guaranteeing good mobility and stability.

Proceed then with the implantation of the femoral stem, following the procedure provided for it.

After the femoral stem has been implanted (or anyway with the Trial Stem in place) the selected *Trial Bi-Polar Head* can be used to carry out a trial reduction (**Fig. 2**) to check mobility and stability and to determine the correct neck length of the Ball Head to be used before proceeding with the definitive implantation of the components.



Fig. 1

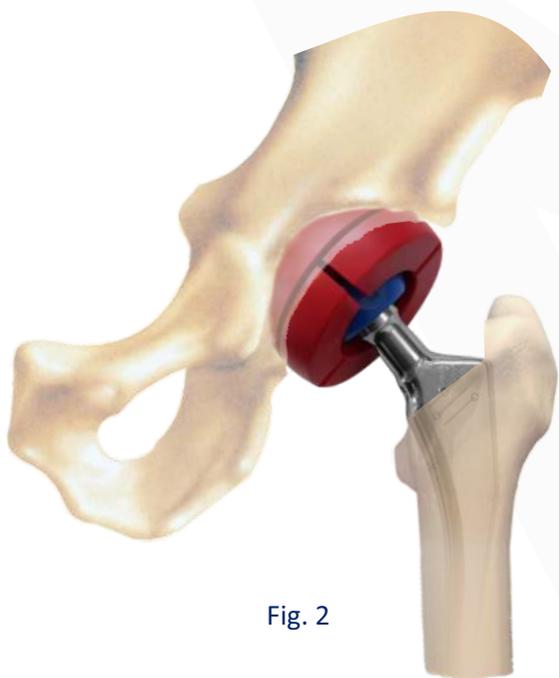


Fig. 2

IMPLANTATION OF THE DEVICE **6**

MODULAR version

After the correct size has been determined, unpack the definitive *Bi-Polar Head* and the corresponding *Insert* (refer to the color code) and assemble them together on the nurse table (**Fig. 3a-b**).

Insert the selected *Ball Head* into the assembled *Insert* (**Fig. 3c**): the locking ring will expand allowing engagement of the *Ball Head*.

The *Metal Shell* is extracted from its sterile package and the *Insert* assembled with the *Ball Head* is then inserted, pressing it until it is completely lodged (**Fig. 3d**).

The whole assembly can now be inserted onto the taper of the implanted femoral stem, then proceed with final reduction of the joint and wound closure (**Fig. 4**).

Fig. 3a



Fig. 3b



Fig. 3c



Fig. 3d



IMPLANTATION OF THE DEVICE **7**

MONOBLOC version

After implantation of the femoral stem, unpack the definitive *Bi-Polar Head* of the selected size and engage it onto the implanted *Ball Head*; a click of the inner retentive ring will indicate the correct engagement of the component.

Proceed with final reduction of the joint and wound closure (**Fig. 4**).

Fig. 4



8 REMOVAL OF THE DEVICE

MONOBLOC version

Whenever necessary, it is possible to disengage the *Monobloc Bi-Polar Head* from the *Ball Head* using the *Extraction Ring (S26011)* provided with the instruments set.

To allow disengagement the joint must be dislocated, place the *Extraction Ring* at the base of the *Ball Head* and push it inside the *Bi-polar Head*; this will expand the locking ring allowing removal of the device (**Fig. 5a**).

At this point it will be possible to remove the *Bi-Polar Head* by pulling it (**Fig. 5b**).

Fig. 5a



Fig. 5b



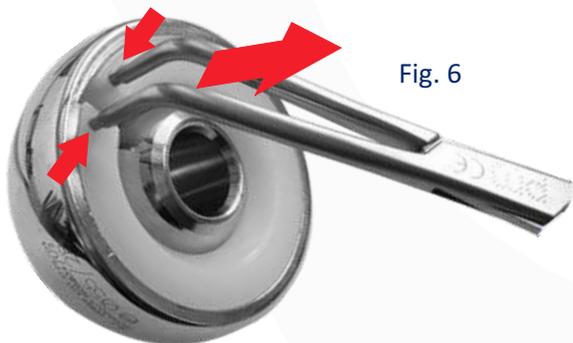
9 REMOVAL OF THE DEVICE

MODULAR version

Whenever it should be necessary to remove the *Modular Bi-Polar head* from the implanted stem, utilize the special *Extraction Forceps (S26014)* supplied with the instruments set.

Insert the tips of the *Forceps* into the holes to close the locking ring, then pull to remove the *Insert* from the *Metal Shell* (**Fig. 6**).

Fig. 6



POST-OP CARE

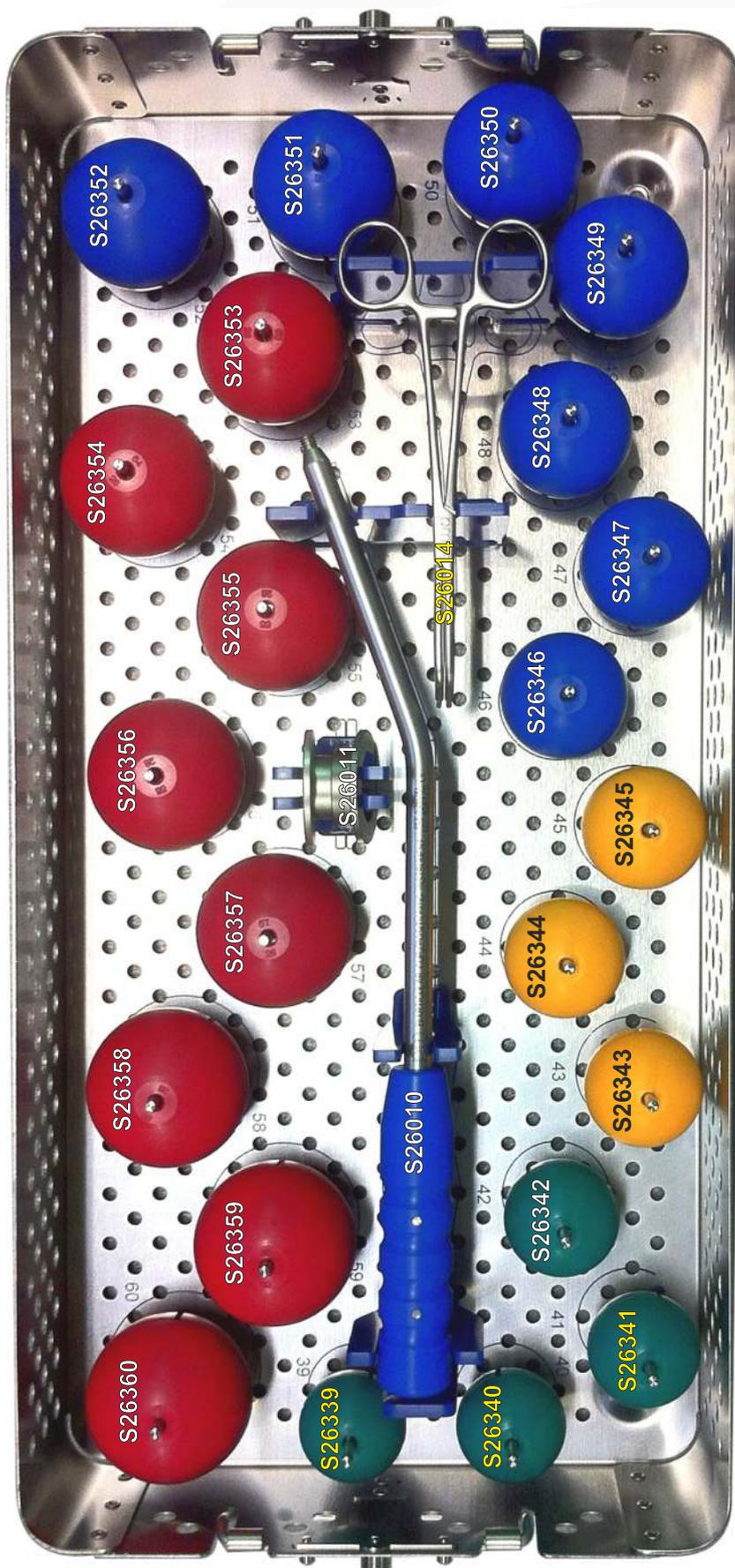
Post-op care strategy is very important to allow the patient a correct recovery. The guidelines are established by the Surgeon and should consider several factors such as age, weight and bony structure of the patient.

In any case, it is necessary to avoid excessive load of the lower limb for a certain amount of time.

ATTENTION: the Surgeon is required to program regular check ups to verify the implant status.

BI-POLAR HEAD INSTRUMENTS SET

S26100 MONOBLOC S26900 MODULAR



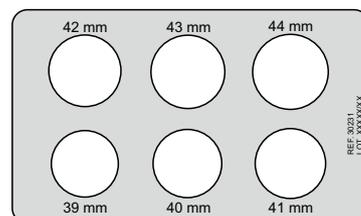
Instruments Tray - empty	S26002
Trials Positioning Handle	S26010
Extraction Ring Ø 28	S26011
Trial Bi-Polar Head Ø 28x42mm	S26342
Trial Bi-Polar Head Ø 28x43mm	S26343
Trial Bi-Polar Head Ø 28x44mm	S26344
Trial Bi-Polar Head Ø 28x45mm	S26345
Trial Bi-Polar Head Ø 28x46mm	S26346
Trial Bi-Polar Head Ø 28x47mm	S26347
Trial Bi-Polar Head Ø 28x48mm	S26348
Trial Bi-Polar Head Ø 28x49mm	S26349
Trial Bi-Polar Head Ø 28x50mm	S26350
Trial Bi-Polar Head Ø 28x51mm	S26351
Trial Bi-Polar Head Ø 28x52mm	S26352
Trial Bi-Polar Head Ø 28x53mm	S26353
Trial Bi-Polar Head Ø 28x54mm	S26354
Trial Bi-Polar Head Ø 28x55mm	S26355
Trial Bi-Polar Head Ø 28x56mm	S26356
Trial Bi-Polar Head Ø 28x57mm	S26357
Trial Bi-Polar Head Ø 28x58mm	S26358
Trial Bi-Polar Head Ø 28x59mm	S26359
Trial Bi-Polar Head Ø 28x60mm	S26360

Additional Instruments for Modular version

Extraction forceps	S26014
Trial Bi-Polar Head Ø 28x39	S26339
Trial Bi-Polar Head Ø 28x40	S26340
Trial Bi-Polar Head Ø 28x41	S26341

Optional Instruments

Femoral Head Sizing Plate Ø 39-44mm	S30231
Femoral Head Sizing Plate Ø 45-50mm	S30232
Femoral Head Sizing Plate Ø 51-55mm	S30233



Bi-Articular Cup - Monobloc



Socket Ø 28mm	
SIZE Ø	Reference
42mm	26742
43mm	26743
44mm	26744
45mm	26745
46mm	26746
47mm	26747
48mm	26748
49mm	26749
50mm	26750
51mm	26751
52mm	26752
53mm	26753
54mm	26754
55mm	26755
56mm	26756
57mm	26757
58mm	26758
59mm	26759
60mm	26760

Bi-Articular Cup - Modular

Colour coding refers to the coupling between Metal Shell and Insert.



SIZE Ø	Metal Shell		UHMWPE Insert Reference
	AISI 316 Reference	PM734 Reference	
39mm	26939*	25939	
40mm	26940*	25940	26971
41mm	26941*	25941	
42mm	26942*	25942	
43mm	26943*	25943	
44mm	26944*	25944	26972
45mm	26945*	25945	
46mm	26946*	25946	
47mm	26947*	25947	
48mm	26948*	25948	26973
49mm	26949*	25949	
50mm	26950*	25950	
51mm	26951*	25951	
52mm	26952*	25952	
53mm	26953*	25953	
54mm	26954*	25954	
55mm	26955*	25955	
56mm	26956*	25956	26974
57mm	26957*	25957	
58mm	26958*	25958	
59mm	26959*	25959	
60mm	26960*	25960	

Information

INTENDED PURPOSE:

Bi-Articular Headis intended to be used for the prosthetic replacement of the femoral head in hemi-arthroplasty applications, in combination with a femoral stem and an articular head. It is indicated in partial hip replacement procedures where the acetabular cartilage is not involved in arthrosic disease and therefore an hemi-arthroplasty has been chosen (usually in cases of femoral head fractures).

MATERIALS:

METAL SHELL- MONOBLOC: PM734 highly nitrogenized Stainless Steel forged alloy - ISO5832/9.

METAL SHELL- MODULAR: AISI316 stainless steel alloy - ISO5832/1.

PM734 highly nitrogenized Stainless Steel forged alloy - ISO5832/9.

INSERT: Ultra High Molecular Weight Polyethylene, without calcium stearate - ISO5834/1/2.

STERILIZATION:

Method: Ethylene Oxide (ETO) sterilization or accelerated electron beam irradiation (b rays nominal dose 25 kGy)

Validity: 5 years.

CLASSIFICATION:

Class III as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendments.

Warning

Before using a product introduced onto the market by permedica spa, the surgeon is encouraged to carefully study the following recommendations, warnings and instructions as well as the specific product information (surgical techniques and technical product description). It is also advisable to check the website for the availability of any updates to this Instructions for Use. **Negligence or lack of observance of this aspect exonerates the manufacturer from all responsibility.**

Definition

Joint Prosthesis: implantable medical device, including implantable components and materials that is in contact with the surrounding muscle and bones, and carries out functions similar to those of a natural articular joint.

General information

A joint prosthesis should only be considered if all other therapeutic possibilities have been carefully weighed and found unsuitable or inappropriate.

A joint prosthesis, even if successfully implanted will be inferior to a natural, healthy joint. Conversely for the patient, a joint prosthesis can be a beneficial replacement for a severely altered, pathological joint, eliminating pain and restoring good mobility and bearing capacity.

Every artificial joint is subject to unavoidable wear and ageing. Over the course of time, an artificial joint initially implanted in a stable manner can loosen therefore limiting or impairing perfect functionality. Wear, ageing and loosening of an implant can lead to reoperation.

Indications for Use

The following are the general guidelines for the use of prosthetic devices produced by permedica. For more detailed information refer to the **Product Technical Sheet and Surgical Technique of the specific device (check on the website for the availability):**

- Advanced wear of the joint due to dysplasia, degenerative, post-traumatic, or rheumatic diseases.
- Fractures or avascular necrosis
- Negative outcome of previous surgeries such as joint reconstruction, osteotomies, arthrodesis, hemi-arthroplasty or total hip prosthesis, total knee prosthesis.

Use of the prosthetic devices for purposes different than those intended is not permitted.

Contraindications

Infections or other septic conditions in the area surrounding the joint, as well as allergies to the implanted material, (cobalt, chrome, nickel, etc) represent absolute contraindications.

Relative factors that could compromise the success of the intervention are:

- Acute or chronic local or systemic infections, even far from the implant site, (risk of haematogenous diffusion of the infection towards the site);
- Insufficient bone structure at the proximal or distal level of the joint that does not guarantee good anchorage of the implant;
- Severe vascular, neurological or muscular diseases compromising the extremities involved;
- Overweight or obesity;
- Osteoporosis;
- Hypertrophy of the muscular tissue surrounding the joint;
- Metabolic disorders or lack of sufficient renal functions.

The patient must also be:

- Capable of understanding and following the doctor's instructions.
- Avoid excessive physical activity such as heavy work or competitive sports that involve intense vibration, jerking motions or heavy loading.
- Avoid excessive weight gain.
- Avoid drug abuse, including nicotine and alcohol.

General Information and precautions for the safe use of the implant

Products of permedica Spa may be implanted only by surgeons who are familiar with the general problems of joint replacement, with implant devices, the surgical instruments and who have mastered the product-specific surgical techniques.

Prostheses and prosthesis parts are always components of a system, and therefore must be combined with original parts belonging to the same system. Note must be taken of the system compatibility according to the "Product Technical sheet" and/or "Surgical Techniques". Prostheses and prosthesis parts from permedica Spa - in particular BIOLOX ceramic components - must never be combined with parts from other manufacturers. permedica excludes all liability for the negligent use of its implants with those of other manufacturers. Specific instruments are available for the implant devices of the various types of joint prostheses. Improper use of these instruments can cause poor positioning of the implant components. permedica Spa excludes all liability for the negligent use of its instrumentation or the use of third parties instruments.

It is forbidden to re-utilize a prosthesis or a prosthesis part that was previously implanted in the body of a patient or another person, or to re-utilize an implant that has come into contact with the body fluid or tissue of another person, or where the mechanical integrity (superficial, geometrical, or biological) cannot be guaranteed. They are single-use devices.

Implants must be stored in their original packaging. Before implantation they must be checked for defects such as micro scratches or marks (can cause excessive wear or complications) on the articular surface. And therefore must be handled with extreme attention.

Prolonged contact - direct or indirect - of the electrocautery with implantable components, in particular in the vicinity of the femoral stems neck, can result in structural alterations which may modify the characteristics of resistance to fatigue of the material with consequent risks of breakage and must therefore be carefully avoided.

Coated prosthetic components, in particular those coated with Hydroxyapatite, should be handled with extreme care avoiding damage to the surface coating.

Contact of prosthetic components coated with Hydroxyapatite with anything other than the original package, clean surgical gloves and patient tissue should be avoided. Hydroxyapatite coated implants should never be cemented, instead should be implanted via "press fit" method. Hydroxyapatite cannot be a substitute for bone cement, nor can it compensate for insufficient primary stability.

TiNBN coating acts as an isolation barrier for the release of ions by the underlying metallic materials. Since the long term duration of this barrier is not known, it cannot be guaranteed and therefore, it is up to the surgeon to determine if the use of TiNBN coated prosthetic components is indicated for patients with noted allergic sensibility towards metal (nickel) and should carry out the requisite postoperative monitoring for inflammation or allergic development.

Literature reports possible adverse reactions caused by elevated blood levels of metal ions in patients with metal-on-metal prosthetic joint surfaces. Long term systemic effects due to the accumulation of these ions are not known and therefore long term clinical consequences cannot be guaranteed. It is therefore not recommended the use of this joint coupling in female patients of childbearing age and/or people with compromised kidney function.

Before sterile implants are removed from the packaging, the protective packaging must be examined for possible damage as this could impair the sterility. The expiration date for the sterility of the product must be observed and expired products must be returned to the manufacturer. Observation of the common aseptic procedures must be respected when opening the package.

Prior to reduction or assembly, prostheses or articular prosthetic components must be thoroughly cleaned; contamination, i.e. foreign particles, bone chips or residues of bone cement, can lead to third-body abrasion, incorrect functioning or fracture of the prosthesis or prosthesis parts.

Joint prosthesis must not be mechanically adapted or modified in any way, unless this is expressly envisaged in the design and surgical technique. In case of doubt, recommendation must be obtained in writing from the manufacturer.

The surface of the prosthesis must not bear any writing nor be allowed to come into contact with metallic or other hard objects (especially in the case of ceramic implants), unless this is expressly envisaged by the of the "Surgical Technique" description.

Prostheses or prosthesis parts that are contaminated, nonsterile, damaged, scratched or have been improperly handled or altered without authorization must not be implanted under any circumstances.

Reliable connection of femoral ball-heads with conical coupling is only possible with the completely intact surface of both the ball head cone and the femoral stem cone. It is absolutely essential that the outer cone of the femoral stem fits perfectly with the inner cone of the ball head. The cone size is indicated on the product label and on the implant itself.

Protective caps or other protective devices must be removed immediately before use.

The instruments are inevitably subject to a certain degree of wear and ageing, rarely there could be interoperative breakage, especially if over utilized or misused. permedica recommends verification for breakage, deformation, corrosion and correct functioning, before use. In the case of damage, the instruments must not be utilized but returned to the manufacturer for substitution.

Observe any additional information, i.e. those reported in the information label applied to the primary and/or the secondary packaging relating to possible limitations for use.

Complications or other factors that may occur for reasons such as incorrect indication or surgical technique, unsuitable choice of material or treatment, inappropriate use or handling of the instruments, and/or sepsis fall under the responsibility of the operating surgeon and cannot be blamed on the manufacturer.

Possible side effects

The following are among the most frequent possible side effects of implantable devices:

- pain;
- bone fractures due to overloading on one side or weakened bone substance;
- allergy to the implanted material, mainly to metal. This signifies the necessity of ulterior study. Implants made of extraneous material can provoke the formation of histiocytosis and consequently osteolysis;
- allergic reactions;
- metalysis and consequent osteolysis in particular for implants with metal/metal surfaces;
- prosthesis or prosthesis parts can become loose or loosen as a result of: overloading; excessive weight; non-physiological stresses; superficial damage; partial or total lost of fixation; incorrect manipulation or improper implantation (wrong choice of implant component or size, improper alignment, incorrect components connection, insufficient fixation);
- excess wear or loosening of the implant due to breakdown of the osseous bed;
- dislocation of the prosthesis due to changed conditions of load transfer (cement disintegration or breakage and/or tissue reactions) or to early or late infections;
- dislocation, subsequent insufficient range of movement, undesirable shortening or lengthening of the extremity involved due to less than optimal positioning of the implant;
- Intra-operative or post-operative complications:
 - perforation or fracture of the bone segments;
 - vascular lesions;
 - temporary or permanent nerve lesions that can cause pain and numbness throughout the limb;
 - inter-operational/Arterial Hypotension during the cementation;
 - varus or valgus deformity;
 - cardiovascular disturbance including vein thromboses, pulmonary embolism and myocardial heart attack;
 - haematoma;
 - late wound healing;
 - infection.

Pre-operative Planning

Failure to carry out proper preoperative planning can lead to errors (i.e. in regards to candidate selection, type of prosthesis, and correct implant size).

The operation should be precisely planned on the basis of the x-ray findings. Testing for eventual allergies to implant component materials should be established. X-rays provide important information on the suitable type of implant, its size and possible combinations. All types of implants and implant parts in the combination recommended by the manufacturer that may possibly be needed for the operation, as well as the instruments needed for their implantation, must be available in case another size or another implant is required. Most of the prosthesis components are supplied with trial parts or measuring instruments that should be accurately used to determine the correct size to be implanted.

Patient Information

The doctor must explain the risks involved in the implantation of an endoprosthesis, possible side effects, and intrinsic limitations of the implant as well as the measures to undertake in order to reduce the possible side effects. In particular, the patient should be informed about the impact that the implant will have on his/her lifestyle, and that the prosthesis longevity could depend also on factors such as body weight and level of physical activity. The patient must also be informed that the devices implanted, due to the presence of metal components:

- can affect the result of computer tomography (CT);
- can be detected by metal detectors
- in the case of cremation, removal could be required depending on local regulations.

Implantable prosthetic devices containing metal and / or magnetic and / or electro conductive elements have not been evaluated for safety and compatibility in an electromagnetic environment. Related risks, including heating, migration and imaging artifacts next to the implants are known, but have not been evaluated for these components. For this reason, the patient should be informed that, whenever the implanted devices contain such materials, it is not advised to undergo radio diagnostic investigations based on magnetic fields (MR scan).

Components made only in UHMWPE or VITAL-E or VITAL-XE are made of non-metallic, non-conductive and non-magnetic materials. Therefore, according to the ASTM F-2503 standard, the devices are defined as "MR Safe".

Sterility

General considerations

Implantable devices supplied by permedica spa in a sterile state must remain closed in the original protective packaging until the moment of implantation. Before utilizing the implant, certain controls should be carried out:

- verify sterility expiration date (month/year) on the label of the product;
- visually verify that the internal packaging and the label are intact;
- visually verify that the sterile primary packaging is integral and does not present breakage, tearing, holes or other types of damage.

If the sterile primary package is damaged or the implant supplied by permedica spa is in a non sterile state, refer to the paragraph "Resterilization".

Ceramic or metal implantable devices

Ceramic or metal implantable devices are supplied sterilized by irradiation of 25 kGy.

Plastic implantable devices

Plastic implantable devices are supplied sterilized by irradiation of 25 kGy or by ethylene oxide. The label of each implantable device specifies the method utilized for sterilization.

Resterilization

If a medical implant device supplied by permedica spa is sterilized or resterilized by the user, this is to be noted in the corresponding patient documentation (i.e. operation report), and must be conserved with the respective accompanying documents. Components can be resterilized provided that they have not come into contact with body fluid, bone and have not previously been implanted.

Validation of the cleaning and sterilization procedures, as well as the proper setting for the corresponding equipment must be checked regularly.

Ceramic or metal implantable devices

Metal implantable devices can be sterilized by the user, via gas (ethylene oxide) or utilizing superheat steam or vapour. In the case of resterilization with gas, sufficient time must be allowed for degassing.

BIOLOX ceramic components may be re-sterilized only in exceptional cases and exclusively by permedica spa.

"NON STERILE" metal or ceramic implants must not be sterilized in their original protective packages.

Hydroxyapatite coated or pure Titanium metal implantable devices cannot be sterilized with gas (Ethylene Oxide), instead can be sterilized by superheat steam or vapour.

Plastic implantable devices

Implants made wholly or partly of polyethylene (UHMWPE) or Polymethylmethacrylate (PMMA) must not be resterilized utilizing superheat steam vapour, nor via irradiation nor via gas (ethylene oxide).

Instruments

All pertinent details regarding the cleaning and sterilization of instruments are supplied in the "Instructions for the cleaning and sterilization of surgical instruments". Instruments must be sterilized in the correct packaging via gas or vapour. Vapour sterilization should be carried out at a temperature of 121°C for 20 minutes. The sterilization of instruments made wholly or partly of plastic must not be heated above 140°C. In the case of resterilization with gas, sufficient time must be allowed for degassing.

Implant Materials

The label of each medical implant device carries the data relative to the type of material and surface coating utilized.

Endoprotheses by permedica spa are manufactured with the following materials:

- Stainless steel 316LVM (normative ISO5832/1)
- Pure Titanium (normative ISO 5832/2)
- Titanium alloy Ti6Al4V (normative ISO 5832/3)
- CrCoMo casting alloy (normative ISO 5832/4)
- Highly nitrogenized Stainless steel – "PM 734" (normative ISO 5832/9)
- Titanium alloy Ti6Al7Nb (normative ISO 5832/11)
- CrCoMo casting alloy (normative ISO 5832/12)
- UHMWPE Polyethylene (normative ISO 5834/1 e 2)
- UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E (VITAL-E)
- UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E and cross-linked (VITAL-XE).
- Polymethylmethacrylate (PMMA)
- Alumina based BIOLOX FORTE sintered ceramic (normative ISO6474-1) and BIOLOX DELTA (normative ISO6474-2).

The combination of stainless steel and chrome-cobalt or Titanium implant components can cause corrosion. The label of the implant carries this warning.

Materials utilized for the surface coating of permedica spa implants are the following:

- Pure Titanium (normative ISO 5832/2)
- Hydroxyapatite (norma ISO 13779/2)
- TiNBN

Custom Made Implant Devices

A custom made implant is foreseen for patients that cannot be fitted with a regular or series implants. This implant is produced as a "one of a kind" product following the indications of the surgeon and utilizing a regular implant design. The use of a custom made implant must be evaluated on a case by case basis.

The surgeon must be aware of the limitations inherent in a custom made implant and must take into account the construction and the materials chosen. The surgeon must also have the experience and capabilities necessary for the correct specifications and optimal application of the custom made product. Custom made implants do not have corresponding instrumentation.

Custom made implants are produced utilizing the technical expertise of permedica Spa acquired through series implant design. Because these implants are custom made, there is no clinical nor test data. Risks are higher with custom made products than with series implants. A custom made product must be utilized exclusively for the patient for whom it was designed.



permedica s.p.a.

via Como 38/39 - 23807 Merate (Lc)

Italy

tel.: +39 039 95 14 811

permedica switzerland s.a.

via al Molino 31 - CH-6926 Scairolo di Collina d'Oro

Switzerland

tel.: +41 91 960 90 80

permedica deutschland GmbH

Blumenthalsrtasse 22 - 12103 Berlin

Germany

tel.: +49 (0) 30 75 44 74 64



www.permedica.com



permedica
ORTHOPAEDICS

ACORN

Dual Mobility
Acetabular Cup



SURGICAL TECHNIQUE



Both our Sales Representatives/Dealers and Product Specialists are at Your complete disposal for any further information and/or explanation about the contents of this Surgical Technique.



ACORN DUAL MOBILITY ACETABULAR CUP

The concept of dual mobility involves the use of a metal shell within which articulates a mobile insert, of a perfectly compatible diameter, wherein the femoral ball head articulates as well. This system allows the use of large diameter heads, thereby permitting a wide Range Of Movement and increasing joint stability.

First introduced in the '70s by Prof. Bousquet, this type of implant has demonstrated high joint stability even in critical cases during clinical use

ACORN Dual Mobility by permedica is an acetabular component particularly indicated in those cases with high risk of dislocation (patients with low muscles tone, bad neuromotor control, or recurrent dislocations after THA).

The cup presents a hemispherical geometry with polar deflection and circumferential radial grooves guaranteeing optimal press-fit in the equatorial region.

The material utilized for its realization is the highly nitrogenized Stainless Steel alloy.

The cementless version presents a **HaX-pore** double coating (500 microns pure titanium and 40 microns Hydroxyapatite applied in a controlled atmosphere with vacuum plasma-spray technique) aiming to achieve optimal primary fixation and to promote osseointegration for secondary biological stabilization.

The cemented version has circumferential and radial grooves to enhance cement anchoring.

The articular inserts are designed to perfectly fit with the inner of each cup size, thus guaranteeing high joint stability. Realized with the latest generation Ultra High Molecular Weight PolyEthylene (GUR1020) without calcium stearate, and are also available in **VITAL-E** version with Vitamin-E.

The instruments set was designed for simplicity and precision thus helping the surgeon in the correct implantation of the acetabular component.

ACORN Dual Mobility cup is also available with a **BIOLOY®** coating, that acts as an insulating barrier and permits cup use for patients with hypersensitivity to the metallic ions contained in the Stainless Steel alloy.

**PRIMARY
HaX-Pore**



**PRIMARY
HaX-Pore BIOLOY®**



CEMENTED

**CEMENTED
BIOLOY®**

WARNINGS:

Even though the implantation of a press-fit cup has become a routine procedure in clinical orthopaedic practices, before using the device, it is necessary to become familiar with both the instruments and the implants.

Other than the implementation of a correct Surgical Technique, a good clinical outcome for a THA is also dependent upon several factors such as; bone stock quality, wear values and correct implant sizing.

INDICATION FOR USE

Use of the ACORN Dual Mobility cup is indicated in primary surgeries, cemented or cementless (where bone structure is suitable to guarantee a correct and enduring mechanical fixation by means of press-fit insertion technique) or revision surgeries.

ATTENTION:

Further information is reported in the chapter “Warnings, Indications and Contraindications for implants” of the Instructions for Use at the end of this Surgical Technique or anyway included in the package of each single implantable product.

Some of the possible indications for use are:

- ✓ Rheumatoid arthritis;
- ✓ primary arthritis;
- ✓ post-traumatic arthritis;
- ✓ revisions;
- ✓ recurrent dislocation after THA;
- ✓ displasy.

SURGICAL PROCEDURE

✓ Pre-operative planning	page	3
✓ Surgical access	page	4
✓ Joint exposure	page	4
✓ Femoral neck osteotomy	page	5
✓ Acetabular preparation	page	5
✓ Acetabular reaming	page	5
✓ Trial evaluation	page	6
✓ Cup implantation	page	6
✓ Functional evaluation	page	7
✓ Assembly of the UHMWPE insert	page	12
✓ Final reduction	page	12
✓ Post-operative care	page	12
✓ Instruments Set	page	13

The objective of preoperative planning is to select the most suitable prosthesis for implantation, determine the ideal anchorage position, establish correct positioning for good biomechanical reconstruction, correct eventual dysmetria and verify size.

With these objectives in mind it is necessary to carry out a radiographical exam of the coxo-femoral joint (pelvis and proximal third of the femur) with projected Anterior-Posterior and Latero-Lateral images, with enough focal distance to obtain an enlargement of at least 15%.

In summary, correct preoperative planning is advisable in order to carry out the following general characteristic evaluation:

CENTER OF ROTATION REPRODUCTION

From the A/P pelvis radiograph the contralateral femoral head center of rotation can be determined, when it is healthy, and the distance from the radiographic U is quantified.

EVALUATION OF EVENTUAL DYSMETRIA

Three horizontal lines are traced (Fig. 1): a Bi-ischiatic line (1), between the inferior margins of the ischium; an above acetabular line (2), between the upper margins of the acetabular cavity, and a bi-tronchanteric line (3), between the two lesser trochanters.

If these three lines are parallel amongst themselves, there is no dysmetria.

If lines (1) and (2) are parallel but line (3) is divergent, there is dysmetria due to a deformation of the femur.

If lines (2) and (3) are parallel but (1) is divergent, there is a dysmetria due to a cotyloid deformation.

In the case where all three lines are divergent amongst themselves, there is a combined dysmetria, determined by a cotyloid deformation as well as a femur deformation.

EVALUATION OF THE IMPLANT SIZE

After having studied and evaluated the above sited information via radiographic templates (with 15% magnification), choose the optimal size combination for the femoral component as well as the acetabular component (Fig. 1b).

With pre-operative planning it is necessary to verify if a satisfactory press-fit insertion can be achieved, avoiding protrusion of the cup in the upper part as much as possible. Whenever the cavity is not be deep enough to guarantee correct housing, the surgeon should evaluate the opportunity to use a different type of implant.

On the other hand, in the case of a deep cavity the surgeon should consider filing the bottom with bone grafts to avoid excessive sinking of the cup, thereby achieving better reproduction of the rotation center.

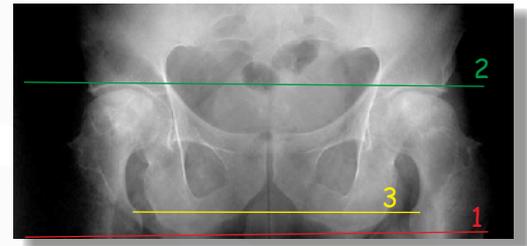


Fig. 1: Pre-operative planning

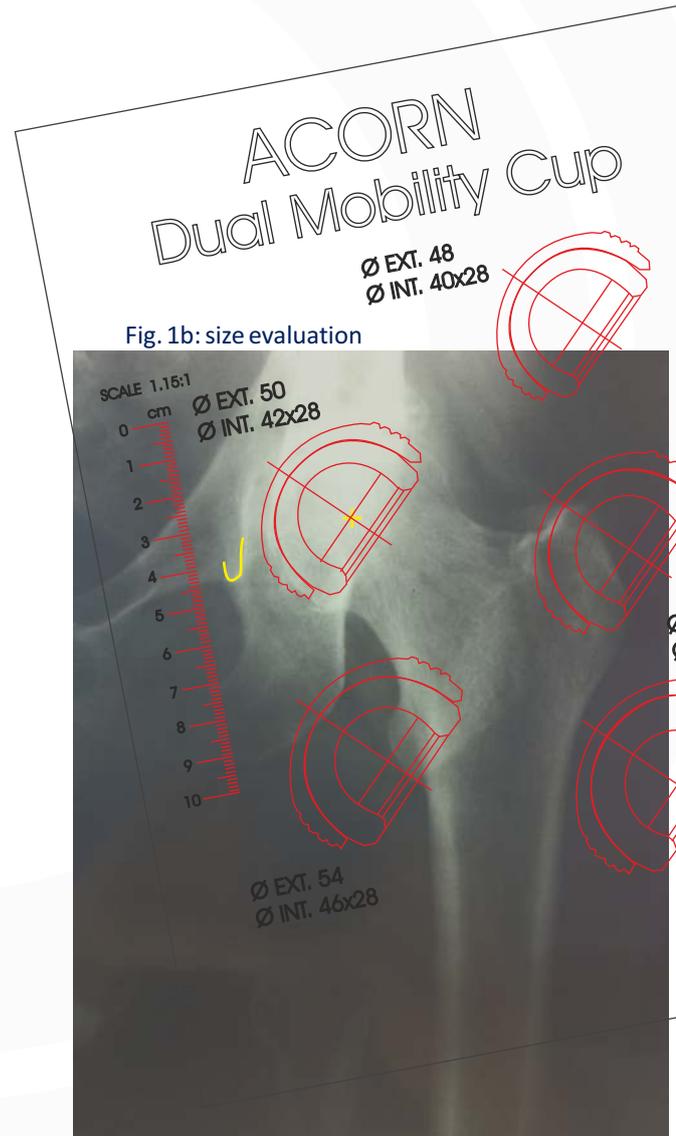


Fig. 1b: size evaluation

Failing to execute accurate pre-operative planning could lead to poor results. The intervention should be carefully planned, based upon X-Ray screening.

Before the operation it is also necessary to investigate the likelihood of any possible patient allergic reactions towards implantable device materials.

2 SURGICAL ACCESS

WARNING:

This Surgical Technique is to be intended as guide in assisting orthopaedic Surgeons already experienced in Hip Arthroplasty, with the objective of demonstrating the correct use of permedica's ACORN Double Mobility cup Instrumentation.

The Surgeon should in any case rely on his own knowledge and expertise in performing each single step of the intervention.

The initial exposure of the joint can be achieved by following any standard surgical approach, according to Surgeon's preferences and/or habits.

The following illustrated technique refers to an implant realized via a Postero-Lateral Access.

3 JOINT EXPOSURE

The incision is centered on the posterior half of the *Greater Trochanter* and extended distally along the femoral diaphysis for 10 cm. and proximally following the direction of the *gluteus maximus* fibers.

The *Fascia Lata* is divided in line with the cutaneous incision. The *Gluteus Maximus* is divided longitudinally via a blunt dissection. Cauterize the bleeding points.

Expose the *Short External Rotators muscles* positioning a blunt retractor between the *Capsule* and the *Gluteus Medius*, putting them in tension via internal rotation of the joint. Pass a suturing thread into the *Piriformis Tendon* in order to evidence the position for successive reinsertion. Detach entirely or separately the *External Rotators muscles* by carrying out an incision as close as possible to the bone.

Cut the *Joint Capsule* starting from the Acetabular Cavity margin and going till the base of the *Femoral Neck*.

Dislocate the *Femoral Head* turning the joint internally with the knee flexed. In some cases it is necessary to section the *Round ligament* first.

Utilize a double pointed retractor in order to lift the femoral head thus providing optimal exposure.

4 FEMORAL NECK OSTEOTOMY

The osteotomy is executed by means of an oscillating saw, in accordance with the surgical technique of the selected femoral implant (Fig. 2).

The femoral head is removed and conserved to obtain eventual bone grafts.

N.B.: Femoral neck osteotomy can be also effected according to Surgeon's preferences, leaving the femoral head in the acetabular cavity.

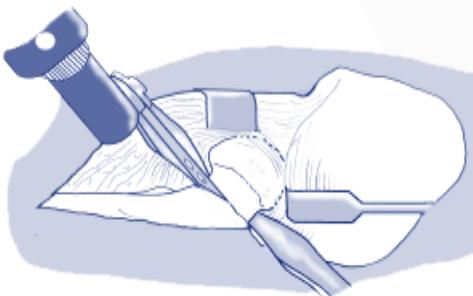


Fig. 2: femoral neck osteotomy

ACETABULAR PREPARATION 5

The exposure of the acetabulum is improved by positioning 3 or 4 spiked Hohmann retractors (Fig. 3) one of which, inserted at the base of the ischium, pushes the upper end of the femur on the back toward the distal direction.

The capsule is totally removed from the entire circumference of the acetabular cavity. The ligament of the femoral head and possible cartilage residue must be cut and removed.

Any traces of hard, sclerotic bone must be removed by means of a hooked chisel (particularly for dysplastic acetabula with "double bottom").

ACETABULAR REAMING 6

Objective of the acetabular reaming is to expose the subchondral bone among the peripheral equatorial region to allow a good primary stabilization of the implant.

Reaming is carried out by using **hemispherical grater reamers** (Fig. 4) powered by a surgical power tool. It is advisable to begin with a small sized reamer, removing cartilage and bone until reaching the subchondral layer, in this way establishing a reamer immersion limit for successive reaming. Gradually increase the reamer size until the reamer tends to seize (an index of optimal press-fit). At the end of the reaming action the subchondral bone should be bleeding in order to optimize cementless fixation.

Reaming should be carried out following the orientation that will be given to the definitive Cup:

- ☑ in the frontal plane the cup should have 40° abduction angle to allow adequate coverage of the head and polyethylene insert especially in the area where mechanical stresses are more pronounced;
- ☑ In the Anterior-Posterior plane it is mostly important to pursuit an optimal cup lodging. Considering the excellent intrinsic stability characteristics of the system, it is not necessary to look for a "systematic" anteversion but rather an adaptation to the morphology of the acetabulum, leveling to the posterior and lower rims.

ATTENTION: the eventual presence of particularly sclerotic bone could influence the correct machining of the reamer, pushing it in the direction of the less resistant bone walls with the risk of weakening them.

It is therefore advisable to weaken the consistence by starting it with a gauge.

* An Off-set Reamer Handle is also available for minimally invasive or anterior approach.

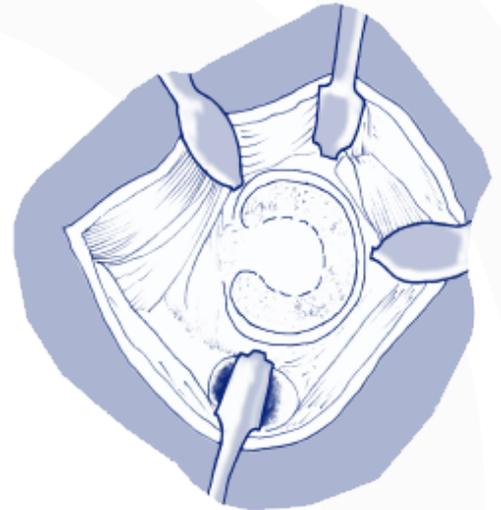


Fig. 3: Exposure of the acetabulum



Fig. 4: acetabular reaming



7 SIZE EVALUATION

ATTENTION: use of the **Trial Cup** allows to evaluate the shape congruence of the prepared site, as well as the effectiveness of the press-fit insertion. At this purpose utilize a trial cup of the same size as the last **Acetabular Reamer** used (line-to-line).

Mount the **Trial Cup** of the desired diameter onto the **Monobloc Cup Introducer** (S30088).

Position the trial cup into the prepared acetabular cavity by correctly orienting ($40/45^\circ$ in abduction and $10/15^\circ$ of anteversion) and lightly impact until reaching the bottom of the acetabular site (Fig. 5). Verify through the slots on the trial cup, that the cup is inserted onto the bottom of the acetabular site.

The trial cup must be inserted in such a way as to provide resistance to traction and have good stability. It should be considered that the final cup, having a wider surface contact area and higher roughness values, will have a netly superior grip.

Once the stability of the trial cup (corresponding to the last reamer used), proves to be satisfactory, proceed to the implantation of the cup of that size.

Whenever satisfactory stability of the trial cup is not achieved :

- ☑ Reaming could be poor, the area of elastic bone was not exceeded: a light retouch with the last reamer utilized should be enough to reach the stability area.
- ☑ The Trial Cup could be “floating” on the acetabular rim, forcing at the entrance: in this case, verify that the labrum has been effectively removed and ream the entry of the acetabulum using a larger reamer (2 sizes larger).

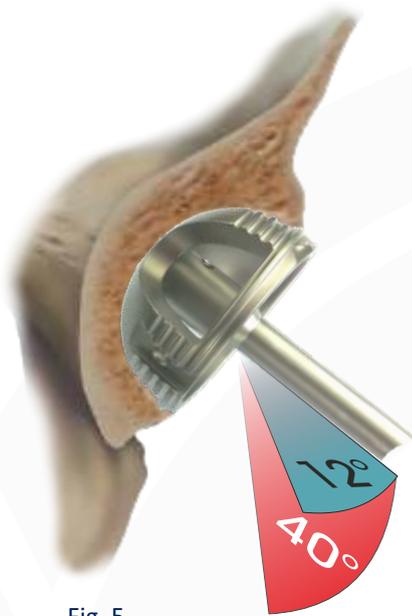


Fig. 5

8 CUP IMPLANTATION

For the implantation of the ACORN cup, suitable Expansion Cup Holders are used, one for each cup size, fitting with two types of Positioning Handles:

S38930 Handle for Expansion Cup Holder - CURVED

S38931 Handle for Expansion Cup Holder - STRAIGHT



Expansion Cup Holder



S38930



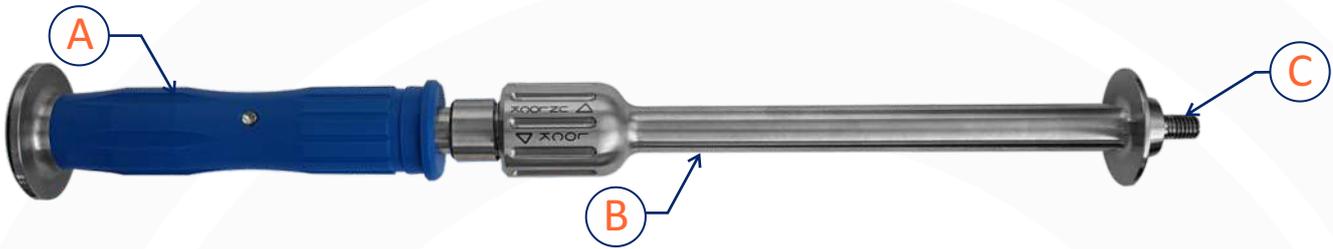
S38931

CUP IMPLANTATION with STRAIGHT Handle

The **STRAIGHT Positioning Handle (S38931)** is normally supplied as standard instrument for the implantation.

It consists of a handle with a threaded end over which is inserted a sleeve with a tapered end that expands the **Cup Holder**.

- Ⓐ - Impugnatura
- Ⓑ - Camicia
- Ⓒ - Terminale filettato



Engagement of the Cup on the Cup Holder

Screw the **Expansion Cup-Holder** of the selected size onto the Threaded End until reaching the tapered end of the sleeve (Fig. 6a/b).

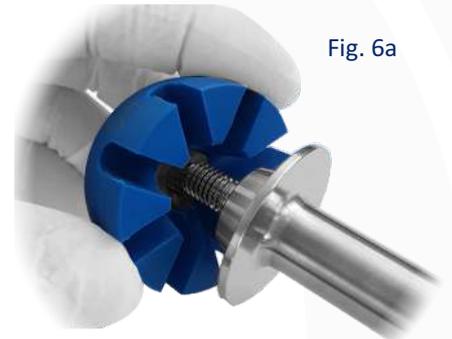


Fig. 6a

Engage the Cup onto the **Expansion Cup-Holder** (fig. 6c) then turn clockwise (LOCK) the knob of the sleeve Ⓑ to lock the Cup by expanding the **Cup-Holder** (fig. 6d).

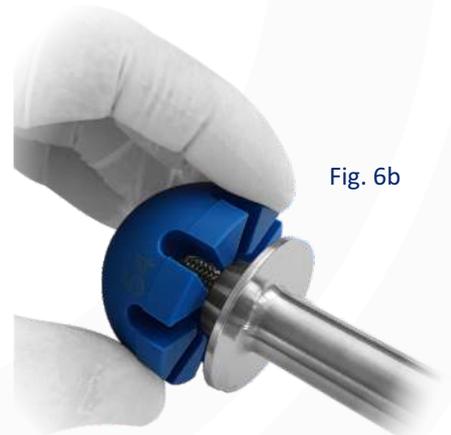


Fig. 6b



Fig. 6d



Fig. 6c

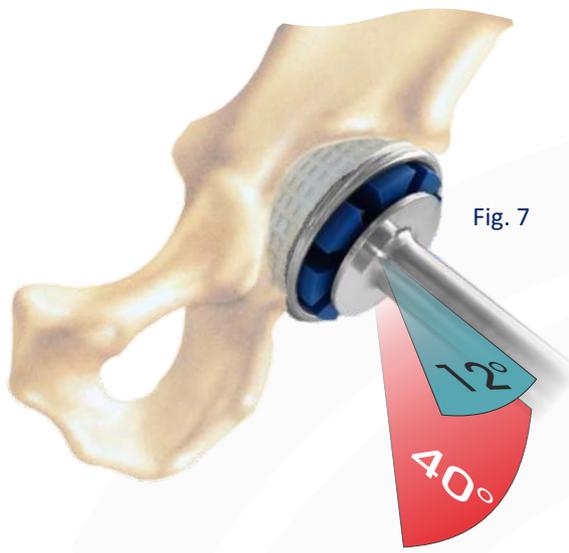


Fig. 7

PRESS-FIT insertion

ATTENTION: use an ACORN Cup of the same size of the last reamer used (line-to-line).

Engage the Cup assembled onto the **Positioning Handle** into the acetabular cavity taking care to give the correct orientation, then impact with firm strokes until complete housing (Fig. 7).

Once impacted the Cup, turn the knob **C** counterclockwise to release the Cup, then remove the instrument (fig. 8).



Fig. 8



Fig. 9

Cemented Cup implantation.

ATTENTION: use an ACORN Cemented cup at least 1 size smaller than the last reamer used to allow a sufficient layer of bone cement all around the prosthesis.

Follow the same procedure as for the press-fit insertion but with the acetabular cavity filled with bone cement (Fig. 9).

Once established the correct positioning, push the cup into the prepared site (eventually slightly impacting with a hammer) and apply a continuous pressure until complete hardening of the bone cement occurs, removing the exceeding bone cement all around the whole perimeter of the cup.

As soon as the bone cement has hardened, turn the knob **C** counterclockwise to release the Cup (fig. 8) then remove the instrument

CUP IMPLANTATION

CURVED Handle

Locking the Cup on the Cup Holder

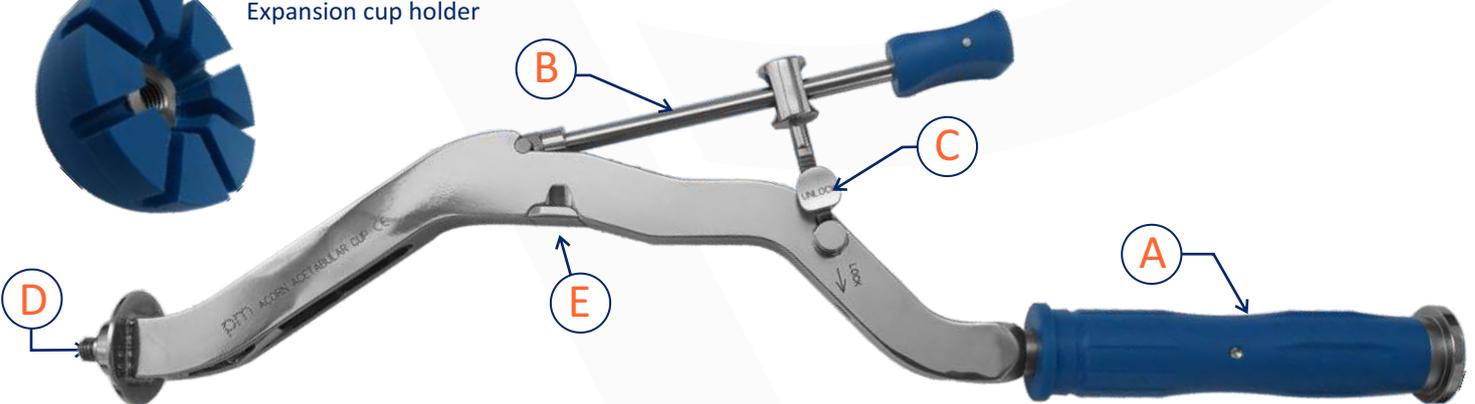
The **Curved Cup Impactor** (S38930) is designed to facilitate the cup implantation when minimally invasive or anterior surgical access are used.

The device is provided with a set of **Expansion Cup Holders**, one for each cup size.

- A** - Handle
- B** - Articulated rod
- C** - Unlock button
- D** - Threaded end
- E** - Release tie for disassembling



Expansion cup holder



Pull the Articulated Rod (B) in order to fully expose the Threaded End (D) (Fig. 10 a/b).



Fig. 10a

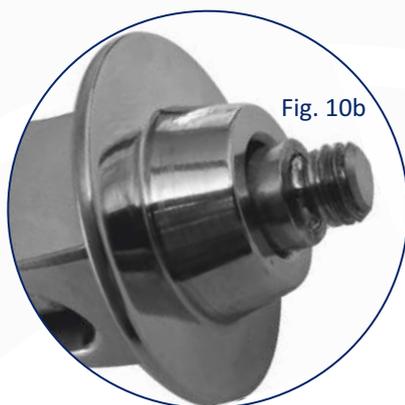


Fig. 10b

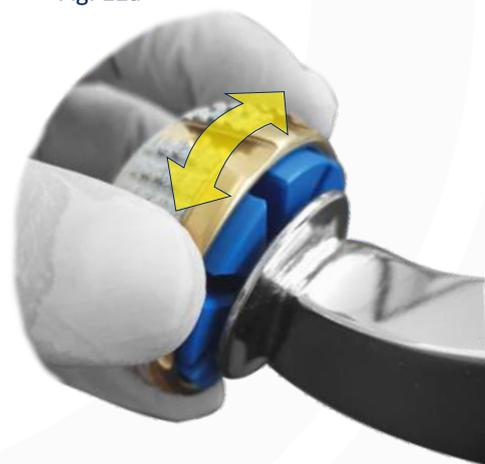
Screw the Expansion Cup-Holder of the selected size onto the Threaded End (Fig. 11).



Fig. 11

Engage the Cup onto the Expansion Cup-Holder making sure to orientate it in the most convenient position for the introduction (fig. 12a) then push the knob of the Articulated Rod (Fig. 12b) to lock the Cup by expanding the Cup-Holder.

Fig. 12a



ATTENTION: it is important that the inner of the cup and the Cup-Holder are both perfectly clean and dry.

PRESS-FIT Cup implantation

ATTENTION: use an ACORN Cup of the same size of the last reamer used (line-to-line).

Insert the cup assembled onto the **Curved Cup Impactor** taking care to give the correct orientation (Fig. 13).

Once impacted the Cup, press the Unlock Button **C** (Fig. 14) to release the Cup, then remove the instrument.

NOTE: depending on the pressure applied in the previous step to lock the Cup, the Unlock Button could result more or less hard to be released.

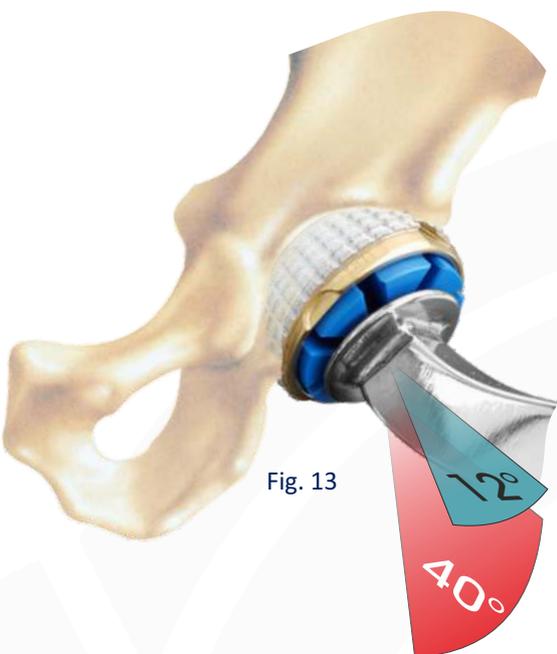


Fig. 13



Fig. 14

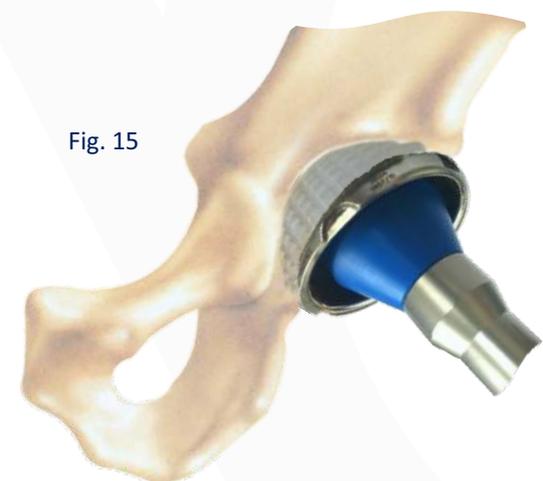


Fig. 15

Whenever necessary it is possible to proceed with further impaction (Fig. 15) by means of the **Impacting End (S38514)** assembled onto the **Threaded Handle (S38513)**.

After definitive assesment of the Cup, it is possible to remove any osteophytes or protuberances that can be found along the rim, which may limit joint function and mobility.



Fig. 16

Cemented Cup implantation.

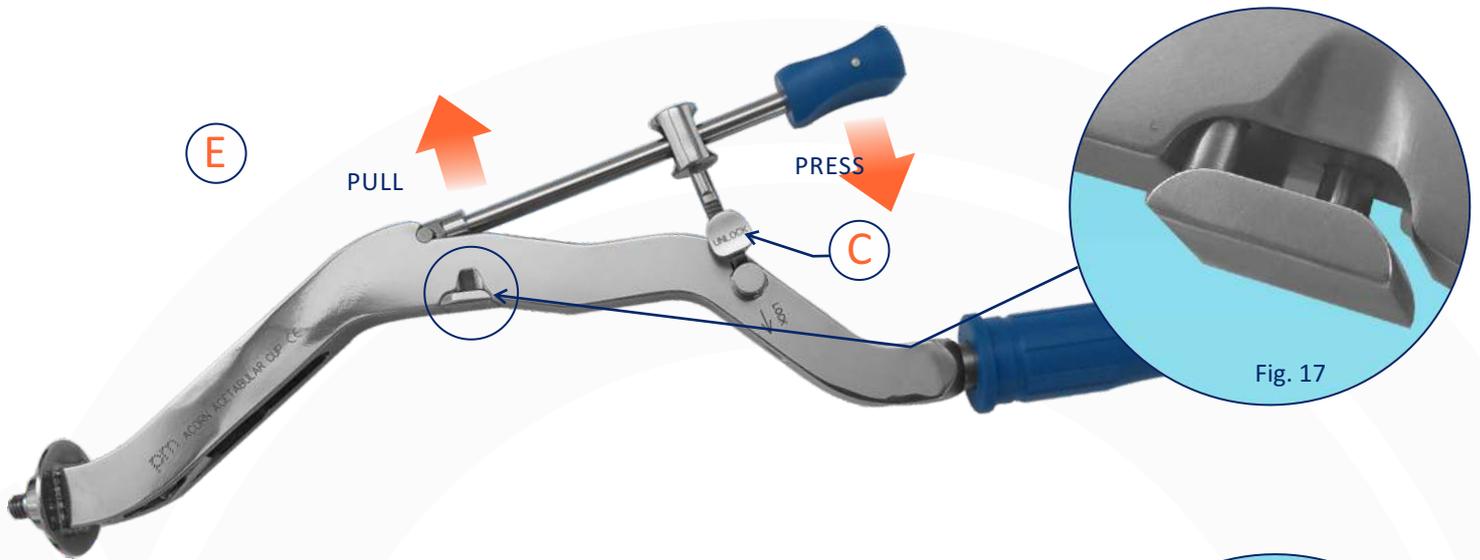
ATTENTION: use an ACORN Cemented cup at least 1 size smaller than the last reamer used to allow a sufficient layer of bone cement all around the prosthesis.

Follow the same procedure as for the press-fit insertion but with the acetabular cavity filled with bone cement (Fig. 16).

Once established the correct positioning, push the cup into the prepared site (eventually slightly impacting with a hammer) and apply a continuous pressure until complete hardening of the bone cement occurs, removing the exceeding bone cement all around the whole perimeter of the cup.

As soon as the bone cement has hardened, press the Unlock Button **C** (Fig. 14) to release the Cup, then remove the instrument.

CLEANING OF THE HANDLE



The instrument can be disassembled to allow washing and sanitification procedure. For disassembly of the instrument proceed as follows:

- ① Pull the Release Tie **E** (fig. 17)
- ② Extract the Articulated Rod by pulling it up in the central part and pushing down at the same time the knob.
- ③ Once the Articulated Rod is released, push the Unlock Button **C** for complete extraction.

The Articulated Rod can be extracted to facilitate cleaning, it cannot be completely removed from the instrument (Fig. 18).

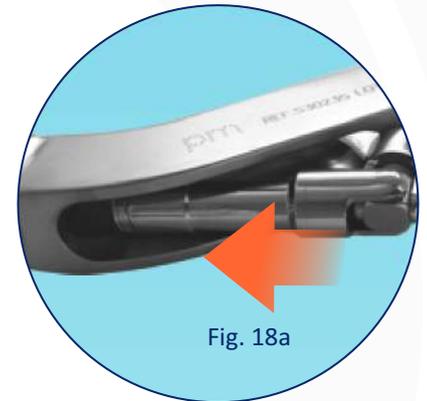
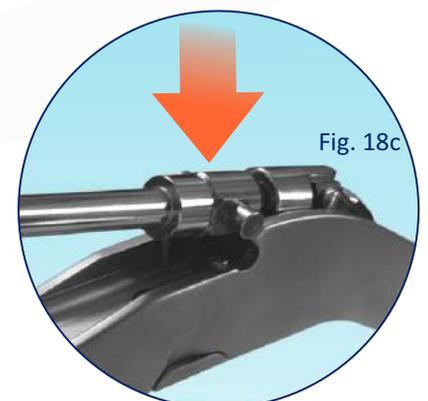
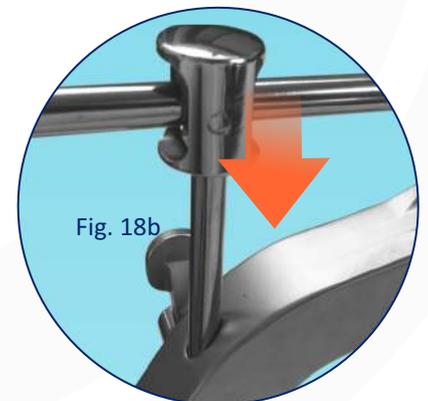
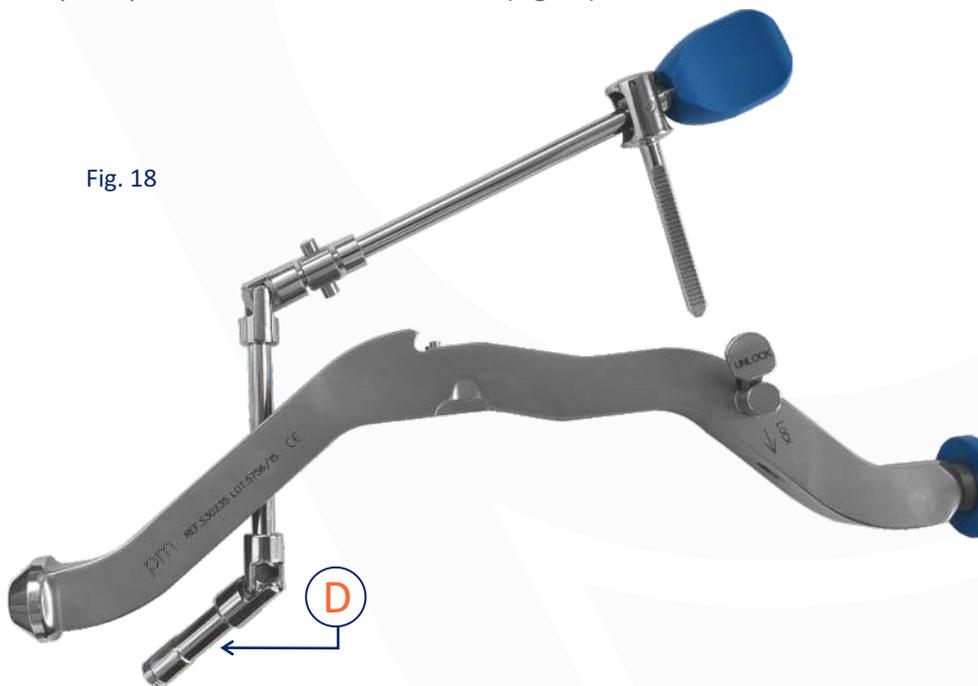


Fig. 18



To re-assemble the instrument proceed as follows:

- ① Re-insert the Threaded End **D** into its housing (fig. 18a)
- ② Re-insert the knurled rod of the Articulated Rod into its housing (Fig. 18b).
- ③ Push in the center to lodge the Articulated Rod, taking care to properly align the teeth (Fig. 18c).

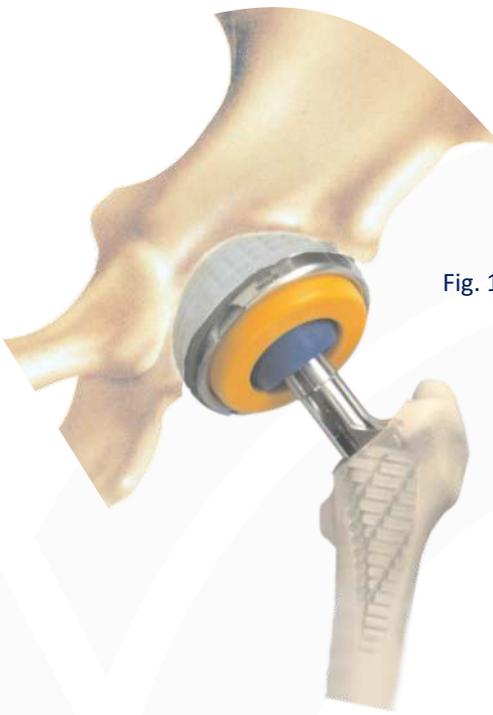


Fig. 19

9 TRIAL EVALUATION

Before proceeding with implantation of the definitive dual mobility insert it is possible to carry out a trial reduction to test the joint and define the optimal neck length of the femoral ball head to be used.

After positioning of the femoral component (trial rasp or definite stem), insert a trial ball head size Ø 28mm Medium neck on the taper and then the trial size corresponding to the implanted cup (Fig. 19).

Reduce the joint to check mobility and stability. Stability is considered optimal if no dislocation is identified when movements of flexion and extra-rotation with adduction are performed.

The length of the ball head to be used is then also verified: this is considered optimal when, by pulling the limb, an excursion of less than 10mm is detectable. Otherwise, the use of a shorter or longer neck should be evaluated, also taking into account the total length of the limb compared to the contralateral to avoid leg lengthening.

10 INSERT/BALL-HEAD ASSEMBLING

Once the definitive components to be used have been selected, it is possible to proceed with their assembling:

the *Articular Head* fits into the retentive *Dual Mobility Insert* by snap-in insertion, easy to achieve using the special **Press (S38511)**.

the *Dual Mobility Insert* is placed onto the base of the **Press** and the ball head is engaged at the entrance of the socket with the cone facing up (Fig.20a).

Turn the **Press** by turning the T-Handle clockwise thus pressing on the ball head until snap-in is achieved (Fig. 20b).

the *Articular Head* assembled with the *Dual Mobility Insert* is then inserted onto the stem's taper and impacted using the *Femoral Head Impactor*.

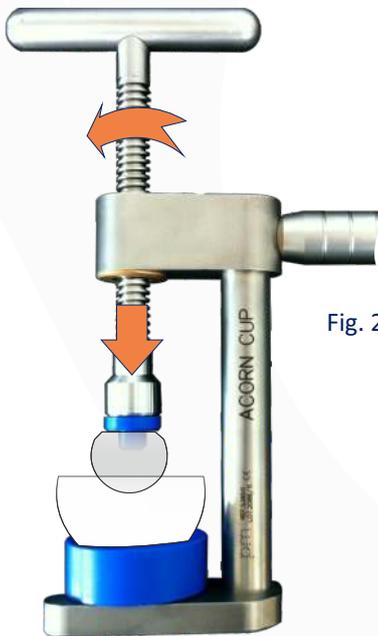


Fig. 20a

11 FINAL REDUCTION

At this point it is possible to definitively reduce the joint by pushing the Insert, assembled onto the stem, into the Cup.

WARNING: before proceeding with the reduction it is necessary to carefully verify that the inner of the Cup is perfectly clean and free of any bone debris, soft tissues and especially any bone cement particles (whenever bone cement has been used for stem fixation).



Fig. 20b

POST-OPERATIVE CARE

Post-op care strategy is very important to permit correct patient recovery. Guidelines are established by the Surgeon and should consider several factors such as age, weight and bony structure of the patient.

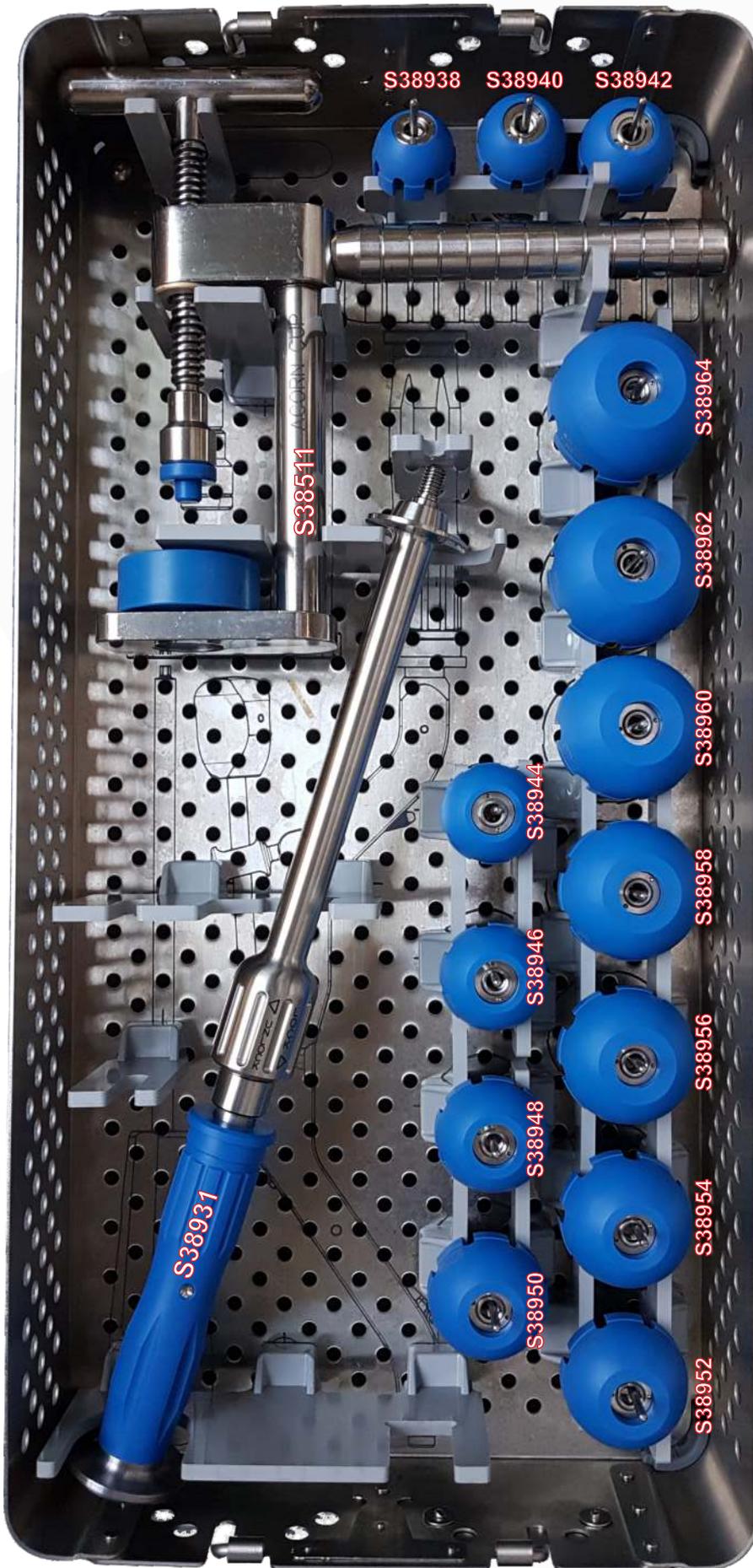
In any case, it is necessary to avoid excessive load of the lower limb for a certain amount of time.

ATTENTION: the Surgeon is required to program regular check ups to verify the implant status.

ACORN DUAL MOBILITY INSTRUMENTS SET

S38500

Tray # 1



S38501	INSTRUMENTS TRAY 1/2 - Empty
S38511	ACORN: Clamp for Head-Insert Assembly
S38931	ACORN: Handle for Expansion Cup Holder STRAIGHT
S38938	ACORN: Expansion Cup Holder Ø 38mm
S38940	ACORN: Expansion Cup Holder Ø 40mm
S38942	ACORN: Expansion Cup Holder Ø 42mm
S38944	ACORN: Expansion Cup Holder Ø 44mm
S38946	ACORN: Expansion Cup Holder Ø 46mm
S38948	ACORN: Expansion Cup Holder Ø 48mm
S38950	ACORN: Expansion Cup Holder Ø 50mm
S38952	ACORN: Expansion Cup Holder Ø 52mm
S38954	ACORN: Expansion Cup Holder Ø 54mm
S38956	ACORN: Expansion Cup Holder Ø 56mm
S38958	ACORN: Expansion Cup Holder Ø 58mm
S38960	ACORN: Expansion Cup Holder Ø 60mm
S38962	ACORN: Expansion Cup Holder Ø 62mm
S38964	ACORN: Expansion Cup Holder Ø 64mm

Optional Instruments

S38930 Handle for Expansion Cup Holder - CURVED



*References with asterisk are available on special request

ACORN Dual Mobility Cups



size Ø	PRIMARY		CEMENTED	
	HaX-Pore	HaX-Pore BIOLOY®	Cemented	Cemented BIOLOY®
	reference	reference	reference	reference
38mm	38338	38438	38638	39238*
40mm	38340	38440	38640	39240*
42mm	38342	38442	38642	39242*
44mm	38344	38444	38644	39244*
46mm	38346	38446	38646	39246*
48mm	38348	38448	38648	39248*
50mm	38350	38450	38650	39250*
52mm	38352	38452	38652	39252*
54mm	38354	38454	38654	39254*
56mm	38356	38456	38656	39256*
58mm	38358	38458	38658	39258*
60mm	38360	38460	38660	39260*
62mm	38362	38462	38662	39262*
64mm	38364	38464	38664	39264*

ACORN Dual Mobility Inserts



Ø inner	size Ø	UHMWPE	VITAL-E®	VITAL-XE®	Ø inner	size Ø	UHMWPE	VITAL-E®	VITAL-XE®
		reference	reference	reference			reference	reference	reference
22 mm	38mm	38838	38838E	38838XE*	28 mm	46mm	38846	38846E	38846XE*
	40mm	38840	38840E	38840XE*		48mm	38848	38848E	38848XE*
	42mm	38842	38842E	38842XE*		50mm	38850	38850E	38850XE*
	44mm	38844	38844E	38844XE*		52mm	38852	38852E	38852XE*
	46mm	38946*	38946E*	38946XE*		54mm	38854	38854E	38854XE*
	48mm	38948*	38948E*	38948XE*		56mm	38856	38856E	38856XE*
	50mm	38950*	38950E*	38950XE*		58mm	38858	38858E	38858XE*
	52mm	38952*	38952E*	38952XE*		60mm	38860	38860E	38860XE*
	54mm	38954*	38954E*	38954XE*		62mm	38862	38862E	38862XE*
	56mm	38956*	38956E*	38956XE*		64mm	38864	38864E	38864XE*
	58mm	38958*	38958E*	38958XE*					
	60mm	38960*	38960E*	38960XE*					
	62mm	38962*	38962E*	38962XE*					
	64mm	38964*	38964E*	38964XE*					

Information

INTENDED PURPOSE:

ACORN dual mobility cup is an acetabular component utilized in Total Hip Replacement procedures in combination with its dedicate articular liner, a femoral ball-head and a femoral stem. It is indicated in cases of coxarthrosis, both for primary and/or revisions. Due to its characteristics, the dual mobility cup is particularly indicated in those cases with low muscle tone where, by using traditional cups, dislocation phenomena could occur. Anchoring of the device is achieved by primary press-fit insertion or by means of bone cement, depending on the model used.

MATERIALS:

CUP: highly nitrogenized stainless steel forged alloy - ISO5832/9.

INSERT: Ultra High Molecular Weight Polyethylene without Calcium Stearate - ISO5834/1/2. Also available in VITAL-E® version, UHMWPE added with Vitamin-E (Alpha Tocopherol) anti-oxydant and VITAL-XE® (cross-linked)

COATINGS:

HaX-Pore: 300µm pure Titanium + 60µm Hydroxyapatite Ca₁₀(OH)₂(PO₄)₆

BIOLOY®: Titanium Niobium Nitride (TiNbN) PVD

STERILIZATION:

Method: Ethylene Oxyde (ETO) or accelerated electron beam irradiation (b rays - nominal dose 25 kGy), in vacuum.

Validity: 5 years.

CLASSIFICATION:

Class III as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendments.

Warning

Before using a product introduced onto the market by permedica spa, the surgeon is encouraged to carefully study the following recommendations, warnings and instructions as well as the specific product information (surgical techniques and technical product description). It is also advisable to check the website for the availability of any updates to this Instructions for Use. **Negligence or lack of observance of this aspect exonerates the manufacturer from all responsibility.**

Definition

Joint Prosthesis: implantable medical device, including implantable components and materials that is in contact with the surrounding muscle and bones, and carries out functions similar to those of a natural articular joint.

General information

A joint prosthesis should only be considered if all other therapeutic possibilities have been carefully weighed and found unsuitable or inappropriate.

A joint prosthesis, even if successfully implanted will be inferior to a natural, healthy joint. Conversely for the patient, a joint prosthesis can be a beneficial replacement for a severely altered, pathological joint, eliminating pain and restoring good mobility and bearing capacity.

Every artificial joint is subject to unavoidable wear and ageing. Over the course of time, an artificial joint initially implanted in a stable manner can loosen therefore limiting or impairing perfect functionality. Wear, ageing and loosening of an implant can lead to reoperation.

Indications for Use

The following are the general guidelines for the use of prosthetic devices produced by permedica. For more detailed information refer to the **Product Technical Sheet and Surgical Technique of the specific device (check on the website for the availability):**

- Advanced wear of the joint due to dysplasia, degenerative, post-traumatic, or rheumatic diseases.
- Fractures or avascular necrosis
- Negative outcome of previous surgeries such as joint reconstruction, osteotomies, arthrodesis, hemi-arthroplasty or total hip prosthesis, total knee prosthesis.

Use of the prosthetic devices for purposes different than those intended is not permitted.

Contraindications

Infections or other septic conditions in the area surrounding the joint, as well as allergies to the implanted material, (cobalt, chrome, nickel, etc) represent absolute contraindications.

Relative factors that could compromise the success of the intervention are:

- Acute or chronic local or systemic infections, even far from the implant site, (risk of haematogenous diffusion of the infection towards the site);
- Insufficient bone structure at the proximal or distal level of the joint that does not guarantee good anchorage of the implant;
- Severe vascular, neurological or muscular diseases compromising the extremities involved;
- Overweight or obesity;
- Osteoporosis;
- Hypertrophy of the muscular tissue surrounding the joint;
- Metabolic disorders or lack of sufficient renal functions.

The patient must also be:

- Capable of understanding and following the doctor's instructions.
- Avoid excessive physical activity such as heavy work or competitive sports that involve intense vibration, jerking motions or heavy loading.
- Avoid excessive weight gain.
- Avoid drug abuse, including nicotine and alcohol.

General Information and precautions for the safe use of the implant

Products of permedica Spa may be implanted only by surgeons who are familiar with the general problems of joint replacement, with implant devices, the surgical instruments and who have mastered the product-specific surgical techniques.

Prostheses and prosthesis parts are always components of a system, and therefore must be combined with original parts belonging to the same system. Note must be taken of the system compatibility according to the "Product Technical sheet" and/or "Surgical Techniques". Prostheses and prosthesis parts from permedica Spa - in particular BIOLOX ceramic components - must never be combined with parts from other manufacturers. permedica excludes all liability for the negligent use of its implants with those of other manufacturers. Specific instruments are available for the implant devices of the various types of joint prostheses. Improper use of these instruments can cause poor positioning of the implant components. permedica Spa excludes all liability for the negligent use of its instrumentation or the use of third parties instruments.

It is forbidden to re-utilize a prosthesis or a prosthesis part that was previously implanted in the body of a patient or another person, or to re-utilize an implant that has come into contact with the body fluid or tissue of another person, or where the mechanical integrity (superficial, geometrical, or biological) cannot be guaranteed. They are single-use devices.

Implants must be stored in their original packaging. Before implantation they must be checked for defects such as micro scratches or marks (can cause excessive wear or complications) on the articular surface. And therefore must be handled with extreme attention.

Prolonged contact - direct or indirect - of the electrocautery with implantable components, in particular in the vicinity of the femoral stems neck, can result in structural alterations which may modify the characteristics of resistance to fatigue of the material with consequent risks of breakage and must therefore be carefully avoided.

Coated prosthetic components, in particular those coated with Hydroxyapatite, should be handled with extreme care avoiding damage to the surface coating.

Contact of prosthetic components coated with Hydroxyapatite with anything other than the original package, clean surgical gloves and patient tissue should be avoided. Hydroxyapatite coated implants should never be cemented, instead should be implanted via "press fit" method. Hydroxyapatite cannot be a substitute for bone cement, nor can it compensate for insufficient primary stability.

TiNBN coating acts as an isolation barrier for the release of ions by the underlying metallic materials. Since the long term duration of this barrier is not known, it cannot be guaranteed and therefore, it is up to the surgeon to determine if the use of TiNBN coated prosthetic components is indicated for patients with noted allergic sensibility towards metal (nickel) and should carry out the requisite postoperative monitoring for inflammation or allergic development.

Literature reports possible adverse reactions caused by elevated blood levels of metal ions in patients with metal-on-metal prosthetic joint surfaces. Long term systemic effects due to the accumulation of these ions are not known and therefore long term clinical consequences cannot be guaranteed. It is therefore not recommended the use of this joint coupling in female patients of childbearing age and/or people with compromised kidney function.

Before sterile implants are removed from the packaging, the protective packaging must be examined for possible damage as this could impair the sterility. The expiration date for the sterility of the product must be observed and expired products must be returned to the manufacturer. Observation of the common aseptic procedures must be respected when opening the package.

Prior to reduction or assembly, prostheses or articular prosthetic components must be thoroughly cleaned; contamination, i.e. foreign particles, bone chips or residues of bone cement, can lead to third-body abrasion, incorrect functioning or fracture of the prosthesis or prosthesis parts.

Joint prosthesis must not be mechanically adapted or modified in any way, unless this is expressly envisaged in the design and surgical technique. In case of doubt, recommendation must be obtained in writing from the manufacturer.

The surface of the prosthesis must not bear any writing nor be allowed to come into contact with metallic or other hard objects (especially in the case of ceramic implants), unless this is expressly envisaged by the of the "Surgical Technique" description.

Prostheses or prosthesis parts that are contaminated, nonsterile, damaged, scratched or have been improperly handled or altered without authorization must not be implanted under any circumstances.

Reliable connection of femoral ball-heads with conical coupling is only possible with the completely intact surface of both the ball head cone and the femoral stem cone. It is absolutely essential that the outer cone of the femoral stem fits perfectly with the inner cone of the ball head. The cone size is indicated on the product label and on the implant itself.

Protective caps or other protective devices must be removed immediately before use.

The instruments are inevitably subject to a certain degree of wear and ageing, rarely there could be interoperative breakage, especially if over utilized or misused. permedica recommends verification for breakage, deformation, corrosion and correct functioning, before use. In the case of damage, the instruments must not be utilized but returned to the manufacturer for substitution.

Observe any additional information, i.e. those reported in the information label applied to the primary and/or the secondary packaging relating to possible limitations for use.

Complications or other factors that may occur for reasons such as incorrect indication or surgical technique, unsuitable choice of material or treatment, inappropriate use or handling of the instruments, and/or sepsis fall under the responsibility of the operating surgeon and cannot be blamed on the manufacturer.

Possible side effects

The following are among the most frequent possible side effects of implantable devices:

- pain;
- bone fractures due to overloading on one side or weakened bone substance;
- allergy to the implanted material, mainly to metal. This signifies the necessity of ulterior study. Implants made of extraneous material can provoke the formation of histiocytosis and consequently osteolysis;
- allergic reactions;
- metalysis and consequent osteolysis in particular for implants with metal/metal surfaces;
- prosthesis or prosthesis parts can loosen or loosen as a result of: overloading; excessive weight; non-physiological stresses; superficial damage; partial or total lost of fixation; incorrect manipulation or improper implantation (wrong choice of implant component or size, improper alignment, incorrect components connection, insufficient fixation);
- excess wear or loosening of the implant due to breakdown of the osseous bed;
- dislocation of the prosthesis due to changed conditions of load transfer (cement disintegration or breakage and/or tissue reactions) or to early or late infections;
- dislocation, subsequent insufficient range of movement, undesirable shortening or lengthening of the extremity involved due to less than optimal positioning of the implant;
- Intra-operative or post-operative complications:
 - perforation or fracture of the bone segments;
 - vascular lesions;
 - temporary or permanent nerve lesions that can cause pain and numbness throughout the limb;
 - inter-operational/Arterial Hypotension during the cementation;
 - varus or valgus deformity;
 - cardiovascular disturbance including vein thromboses, pulmonary embolism and myocardial heart attack;
 - haematoma;
 - late wound healing;
 - infection.

Pre-operative Planning

Failure to carry out proper preoperative planning can lead to errors (i.e. in regards to candidate selection, type of prosthesis, and correct implant size).

The operation should be precisely planned on the basis of the x-ray findings. Testing for eventual allergies to implant component materials should be established. X-rays provide important information on the suitable type of implant, its size and possible combinations. All types of implants and implant parts in the combination recommended by the manufacturer that may possibly be needed for the operation, as well as the instruments needed for their implantation, must be available in case another size or another implant is required. Most of the prosthesis components are supplied with trial parts or measuring instruments that should be accurately used to determine the correct size to be implanted.

Patient Information

The doctor must explain the risks involved in the implantation of an endoprosthesis, possible side effects, and intrinsic limitations of the implant as well as the measures to undertake in order to reduce the possible side effects. In particular, the patient should be informed about the impact that the implant will have on his/her lifestyle, and that the prosthesis longevity could depend also on factors such as body weight and level of physical activity. The patient must also be informed that the devices implanted, due to the presence of metal components:

- can affect the result of computer tomography (CT);
- can be detected by metal detectors
- in the case of cremation, removal could be required depending on local regulations.

Implantable prosthetic devices containing metal and / or magnetic and / or electro conductive elements have not been evaluated for safety and compatibility in an electromagnetic environment. Related risks, including heating, migration and imaging artifacts next to the implants are known, but have not been evaluated for these components. For this reason, the patient should be informed that, whenever the implanted devices contain such materials, it is not advised to undergo radio diagnostic investigations based on magnetic fields (MR scan).

Components made only in UHMWPE or VITAL-E or VITAL-XE are made of non-metallic, non-conductive and non-magnetic materials. Therefore, according to the ASTM F-2503 standard, the devices are defined as "MR Safe".

Sterility

General considerations

Implantable devices supplied by permedica spa in a sterile state must remain closed in the original protective packaging until the moment of implantation. Before utilizing the implant, certain controls should be carried out:

- verify sterility expiration date (month/year) on the label of the product;
- visually verify that the internal packaging and the label are intact;
- visually verify that the sterile primary packaging is integral and does not present breakage, tearing, holes or other types of damage.

If the sterile primary package is damaged or the implant supplied by permedica spa is in a non sterile state, refer to the paragraph "Resterilization".

Ceramic or metal implantable devices

Ceramic or metal implantable devices are supplied sterilized by irradiation of 25 kGy.

Plastic implantable devices

Plastic implantable devices are supplied sterilized by irradiation of 25 kGy or by ethylene oxide. The label of each implantable device specifies the method utilized for sterilization.

Resterilization

If a medical implant device supplied by permedica spa is sterilized or resterilized by the user, this is to be noted in the corresponding patient documentation (i.e. operation report), and must be conserved with the respective accompanying documents. Components can be resterilized provided that they have not come into contact with body fluid, bone and have not previously been implanted.

Validation of the cleaning and sterilization procedures, as well as the proper setting for the corresponding equipment must be checked regularly.

Ceramic or metal implantable devices

Metal implantable devices can be sterilized by the user, via gas (ethylene oxide) or utilizing superheat steam or vapour. In the case of resterilization with gas, sufficient time must be allowed for degassing.

BIOLOX ceramic components may be re-sterilized only in exceptional cases and exclusively by permedica spa.

"NON STERILE" metal or ceramic implants must not be sterilized in their original protective packages.

Hydroxyapatite coated or pure Titanium metal implantable devices cannot be sterilized with gas (Ethylene Oxide), instead can be sterilized by superheat steam or vapour.

Plastic implantable devices

Implants made wholly or partly of polyethylene (UHMWPE) or Polymethylmethacrylate (PMMA) must not be resterilized utilizing superheat steam vapour, nor via irradiation nor via gas (ethylene oxide).

Instruments

All pertinent details regarding the cleaning and sterilization of instruments are supplied in the "Instructions for the cleaning and sterilization of surgical instruments". Instruments must be sterilized in the correct packaging via gas or vapour. Vapour sterilization should be carried out at a temperature of 121°C for 20 minutes. The sterilization of instruments made wholly or partly of plastic must not be heated above 140°C. In the case of resterilization with gas, sufficient time must be allowed for degassing.

Implant Materials

The label of each medical implant device carries the data relative to the type of material and surface coating utilized.

Endoprotheses by permedica spa are manufactured with the following materials:

- Stainless steel 316LVM (normative ISO5832/1)
- Pure Titanium (normative ISO 5832/2)
- Titanium alloy Ti6Al4V (normative ISO 5832/3)
- CrCoMo casting alloy (normative ISO 5832/4)
- Highly nitrogenized Stainless steel – "PM 734" (normative ISO 5832/9)
- Titanium alloy Ti6Al7Nb (normative ISO 5832/11)
- CrCoMo casting alloy (normative ISO 5832/12)
- UHMWPE Polyethylene (normative ISO 5834/1 e 2)
- UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E (VITAL-E)
- UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E and cross-linked (VITAL-XE).
- Polymethylmethacrylate (PMMA)
- Alumina based BIOLOX FORTE sintered ceramic (normative ISO6474-1) and BIOLOX DELTA (normative ISO6474-2).

The combination of stainless steel and chrome-cobalt or Titanium implant components can cause corrosion. The label of the implant carries this warning.

Materials utilized for the surface coating of permedica spa implants are the following:

- Pure Titanium (normative ISO 5832/2)
- Hydroxyapatite (norma ISO 13779/2)
- TiNBN

Custom Made Implant Devices

A custom made implant is foreseen for patients that cannot be fitted with a regular or series implants. This implant is produced as a "one of a kind" product following the indications of the surgeon and utilizing a regular implant design. The use of a custom made implant must be evaluated on a case by case basis.

The surgeon must be aware of the limitations inherent in a custom made implant and must take into account the construction and the materials chosen. The surgeon must also have the experience and capabilities necessary for the correct specifications and optimal application of the custom made product. Custom made implants do not have corresponding instrumentation.

Custom made implants are produced utilizing the technical expertise of permedica Spa acquired through series implant design. Because these implants are custom made, there is no clinical nor test data. Risks are higher with custom made products than with series implants. A custom made product must be utilized exclusively for the patient for whom it was designed.



permedica s.p.a.

via Como 38/39 - 23807 Merate (Lc)
Italy
tel.: +39 039 95 14 811

permedica switzerland s.a.

via al Molino 31 - CH-6926 Scairolo di Collina d'Oro
Switzerland
tel.: +41 91 960 90 80

permedica deutschland GmbH

Blumenthalsrtasse 22 - 12103 Berlin
Germany
tel.: +49 (0) 30 75 44 74 64



www.permedica.com



permedica
ORTHOPAEDICS

JUMP[®] System₃

Press-fit Cup



SURGICAL TECHNIQUE



Both our Sales Representatives/Dealers and Product Specialists are at Your complete disposal for any further information and/or explanation about the contents of this Surgical Technique.



JUMP[®] System

PRESS-FIT ACETABULAR CUPS

The JUMP[®] System acetabular components by permedica are consists of a range of hemispherical shaped cups with polar deflection and external porous coated surface, and related joint liners in UHMWPE, ceramic and metal (dual mobility).

The range includes the following options:

- ✓ JUMP[®] System;
- ✓ JUMP[®] System PE (accepting only PE inserts);
- ✓ JUMP[®] System PEG.
- ✓ JUMP[®] System **TRASER[®]** and **TRASER[®] Revision**.

The external surface presents bioactive coatings such as the HaX-Pore with pure Titanium and Hydroxyapatite to improve primary stability and promote biological integration.

The **TRASER[®]** Cup has a trabecular surface with open pores whose randomized size and geometry gives the implant an excellent primary stability and provides an ideal structure for bone in-growth thus favouring biological integration.

The UHMWPE inserts range provides different versions: near standard and 20° antiluxation, retentive models are available as well as new protuded models allowing displacement of the femoral head's center of rotation. The range is also available in the VITAL-XE[®] option, moderated cross-linked polyethylene added with VITAMIN-E.

BIOLOX[®] Delta ceramic inserts allows low friction and low wear ceramic-on-ceramic couplings.

The JUMP[®] System Dual Mobility insert represents an effective solution for those cases where a high possibility of dislocation can be expected (patients with poor muscle tone or neuromotor control). A metal insert fits into the cup and makes it compatible with ACORN Dual Mobility UHMWPE or VITAL-XE[®] articular inserts.

The JUMP[®] System range of acetabular cups are endowed with holes (3 or 4 depending on the version) for the eventual additional fixation by means of Ø6,5mm cancellous screws.

TRASER[®] Revision Cup version has a multi-hole configuration to allow fixation screws placement in a wider area and a range of sizes suitable for revision cases.

NOTE:

- ☑ The JUMP[®] System cups are supplied with screw holes plugged with caps (to be removed in case of additional screws fixation rimuovere in caso di fissazione addizionale mediante viti) with the exception of JUMP[®] SYSTEM PE where the screw holes CANNOT BE SEALED with caps.

The instrumentation was designed to be simple and precise and to assist the surgeon in the correct implantation of the acetabular component.

WARNINGS:

Although the implantation of a press-fit cup has become a routine procedure in the clinical orthopaedics practice, before using the device it is necessary to know and get familiar with both the instruments and the implants.

Other than the implementation of a correct Surgical Technique, a good clinical outcome of a THA also depends upon several factors such as bone stock quality, wear values and correct implant sizing.



JUMP[®] System JUMP[®] System PE



JUMP[®] System **TRASER[®]** JUMP[®] System **TRASER[®] Revision**



UHMWPE **VITAL-XE[®]** **BIOLOX[®] Delta**



DUAL MOBILITY Option

The 14 sizes of cups are related to the correct trial and definitive inserts by means of an apposite COLOR CODE.

NOTE:

- ☒ *This Surgical Technique is to be intended as guide in assisting orthopaedic Surgeons already experienced in Hip Arthroplasty, with the objective of demonstrate the correct use of permedica's JUMP® System cup Instrumentation. The Surgeon should in any case rely on his own knowledge and expertise in performing each single step of the intervention.*
- ☒ *Further information is reported in the chapter "Warnings, Indications and Contraindications for implants" at the end of this Surgical Technique.*

INDICATION FOR USE

Use of the JUMP® System cup is indicated in primary or revision surgeries, where bone structure is suitable to guarantee a correct and enduring mechanical fixation by means of press-fit insertion technique.

Some possible indication for use are the following:

- ✓ rheumatoid arthritis;
- ✓ coxarthrosis;
- ✓ Post-traumatic arthritis
- ✓ congenital hip dysplasia
- ✓ epiphysiolisis.

SURGICAL PROCEDURE

✓ Pre-Operative planning	pag. 3
✓ Surgical Approach	pag. 4
✓ Joint exposure	pag. 4
✓ Femoral neck osteotomy	pag. 4
✓ Exposure of the acetabular cavity	pag. 5
✓ Acetabular reaming	pag. 5
✓ Size evaluation	pag. 5
✓ Cup implantation	pag. 6
✓ Additional screw fixation	pag. 7
✓ Trial reduction	pag. 8
✓ Insertion of UHMWPE/VITAL-XE insert	pag. 9
✓ Insertion of Ceramic insert	pag. 9
✓ Removal of Ceramic insert	pag. 10
✓ Post-Op care	pag. 10

APPENDIX:

① Use of the Curved M.I.S. Cup Impactor	pag. 11
② DUAL MOBILITY Option	pag. 14

PRE-OPERATIVE PLANNING 1

The objective of preoperative planning is to choose the most suitable prosthesis to implant, determine the ideal anchorage position, establish the correct positioning for good biomechanical reconstruction, correct eventual dysmetria and verify the size. With these objectives in mind it is necessary to carry out a radiographical exam of the coxo-femoral joint (pelvis and proximal third of the femur) with projected Anterior-Posterior and Latero-Lateral images, with enough focal distance to obtain an enlargement of at least 15%.

In summary, a correct preoperative planning is advisable in order to carry out the following general characteristic evaluation:

CENTER OF ROTATION REPRODUCTION

From the A/P pelvis radiograph the controlateral femoral head center of rotation can be determined, when it is healthy, and the distance from the radiographic U is quantified.

EVALUATION OF EVENTUAL DYSMETRIA

Three horizontal lines are traced (Fig. 1): a Bi-ischiatic line (1), between the lower margins of the ischium; an above acetabular line (2), between the upper margins of the acetabular cavity, and a bi-tronchanteric line (3), between the two lesser trochanters.

If these three lines are parallel amongst themselves, there is no dysmetria.

If lines (1) and (2) are parallel but line (3) is divergent, there is dysmetria due to a deformation of the femur. If lines (2) and (3) are parallel but (1) is divergent, there is a dysmetria due to a cotyloid deformation.

In the case that all three lines are divergent amongst themselves, there is a combined dysmetria, determined by a cotyloid deformation as well as a femur deformation.

IMPLANT SIZE EVALUATION

After having studied and evaluated the above sited information via radiographic templates (with 15% magnification), choose the optimal size combination for the femoral component as well as the acetabular component (Fig. 1b).

It is possible to prepare a traced radiographic lucent of the hip by placing the lucent over the prosthesis to be implanted.

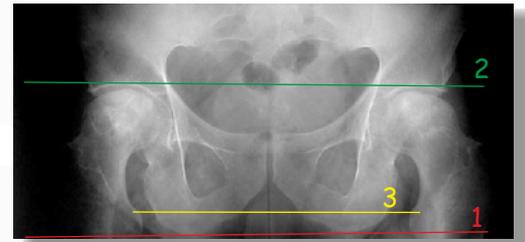


Fig. 1: pre-operative planning

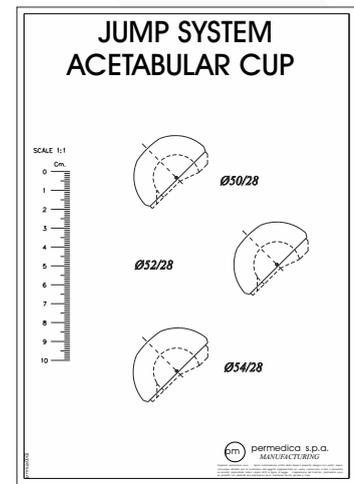
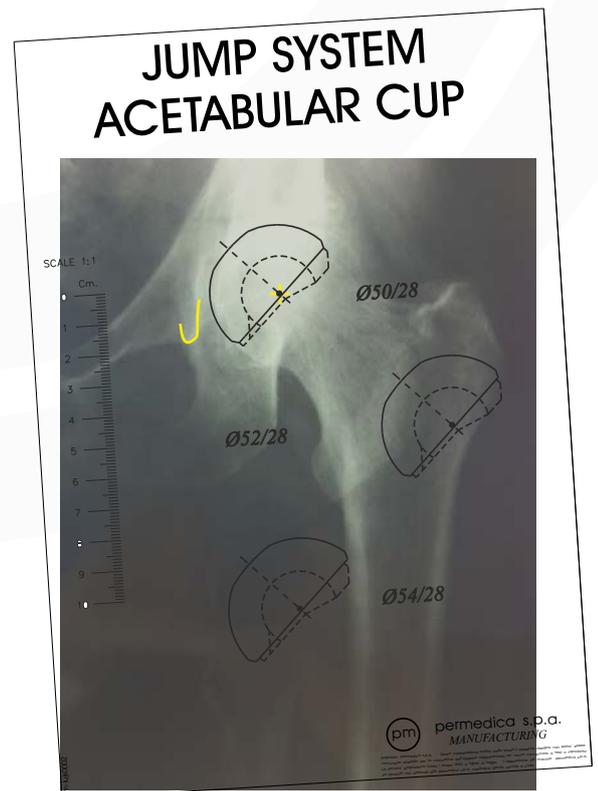


Fig. 1b: size evaluation



Failing to execute accurate pre-operative planning could lead to poor results. The intervention should be carefully planned, based upon X-Ray screening.

Before the operation it is furthermore necessary to investigate the possibility of any possible allergic reactions of the patient towards implantable device materials.

2 SURGICAL ACCESS

The initial exposure of the joint can be achieved by following any standard surgical approach, according to Surgeon's preferences and/or habits.

The following illustrated technique refers to an implant realized via a Postero-Lateral Access.

3 JOINT EXPOSURE

The incision is centered on the posterior half of the *Greater Trochanter* and extended distally along the *Femoral Diaphysis* for 10 cm, curving posteriorly and proximally following the direction of the *gluteus maximus* fibers.

The fascia lata is divided in line with the cutaneous incision. The *gluteus maximus* is divided longitudinally via a blunt dissection. Cauterize the bleeding points.

Expose the short external rotators muscles positioning a blunted retractor between the capsule and the *gluteus medius* tendon, placing tension via the internal rotation of the joint. Pass a suturing thread into the *piriform* tendon in order to evidence the position for successive suturing. Detach entirely or separately the external rotatory muscle by carrying out an incision as close as possible to the bone.

Cut the joint capsule beginning at the acetabular cup margin and going to the base of the femoral neck.

Dislocate the femoral head turning the joint internally with the knee flexed. In some cases it is necessary to section the *Round Ligament* first.

Utilize a bi-forked retractor in order to lift up the femoral head thus providing optimal exposure.

4 FEMORAL NECK OSTEOTOMY

The osteotomy is executed by means of an oscillating saw, in accordance with the surgical technique of the selected femoral implant (Fig. 2).

The femur head is removed and conserved to obtain eventual bone grafts.

N.B.: Femoral neck osteotomy can be also effected according to Surgeon's preferences, leaving the femoral head in the acetabular cavity.

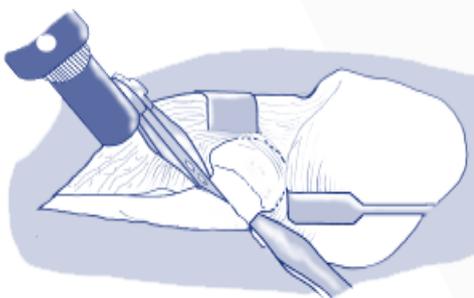


Fig. 2: Femoral neck osteotomy

EXPOSURE OF THE ACETABULUM 5

The exposure of the acetabulum is improved by positioning 3 or 4 spiked Hohmann retractors (Fig. 3) one of which, inserted at the base of the ischium, pushes the upper end of the femur on the back toward the distal direction.

The capsule is totally removed from the entire circumference of the acetabular cavity. The ligament of the femoral head and possible cartilage residue must be cut and removed.

Possible traces of hard, sclerotic bone must be removed by means of a hooked chisel (particularly for dysplastic acetabula with “double bottom”).

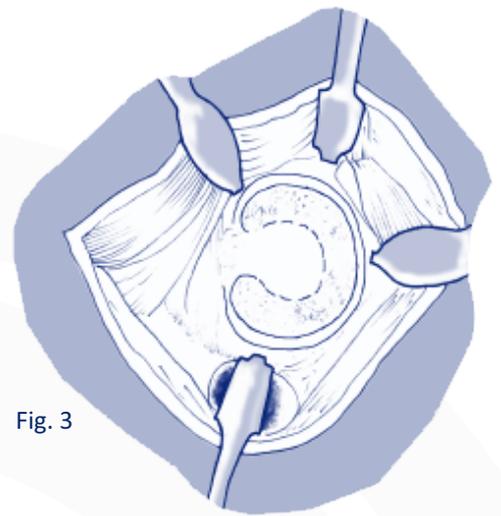


Fig. 3

ACETABULAR REAMING 6

Reaming of the acetabulum is carried out by using **hemispherical grater reamers** powered by a surgical power tool.

It is advisable to begin with a small sized reamer, removing cartilage and bone until reaching the subchondral layer, in this way establishing a reamer immersion limit for successive reaming.

Gradually increase the reamer size, proceeding with a 45° abduction angle and 10°-15° anteversion angle, until reaching healthy bone and obtaining a hemispheric and symmetrical cavity (Fig. 4).

ATTENTION: the eventual presence of particularly sclerotic bone could influence the correct machining of the reamer, pushing it in the direction of the less resistant bone walls with the risk of weakening them. It is therefore advisable to weaken the consistence by starting it with a gauge.

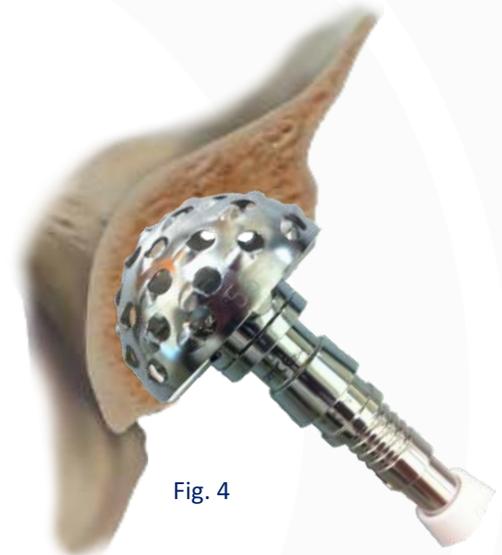


Fig. 4

* An Off-set Reamer Handle is also available for minimally invasive or anterior approach refer to chapter Instruments on page 18).



SIZE EVALUATION 7

ATTENTION: use of the **Trial Cup** allows to evaluate the congruence shape of the prepared site, as well as the effectiveness of the press-fit insertion. At this purpose utilize a trial cup of the same size as the last **Acetabular Reamer** used.

Mount the **Trial Cup** (from S32144 to S32170) of the desired diameter onto the **Monobloc Cup Introducer** (S30088).

Position the trial cup into the prepared acetabular cavity by correctly orienting (40/45° in abduction and 10/15° of anteversion) and lightly impact until reaching the bottom of the acetabular site (Fig. 5). Verify through the slots on the trial cup, that the cup is inserted onto the bottom of the acetabular site.

The trial cup must be inserted in such a way as to provide resistance to traction and have good stability. It should be considered that the final cup, having a wider surface contact area and higher roughness values, will have a netly superior grip.

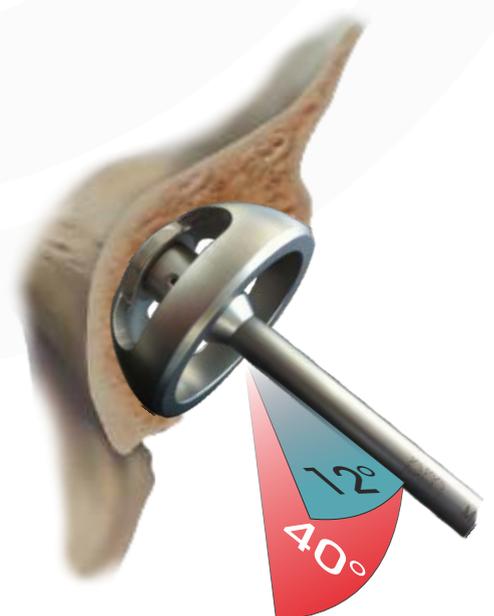


Fig. 5: Trial cup

Once the stability of the trial cup (corresponding to the last reamer used), proves to be satisfactory, proceed to the implantation of the cup of that size.

Whenever satisfactory stability of the trial cup is not achieved:

- ☑ Reaming could be poor, the area of elastic bone was not exceeded: a light retouch with the last reamer utilized should be enough to reach the stability area.
- ☑ The Trial Cup could be “floating” on the acetabular rim, forcing at the entrance: in this case, verify that the labrum has been effectively removed and ream the entry of the acetabulum using a larger reamer (2 sizes larger).

8 CUP IMPLANTATION

Fixate the acetabular component of the same diameter as the trial cup to the special **Monobloc Cup Introducer (S30088)**.

In case that the Curved Impactor is used, please refer to instructions at page 10.

Position the cup into the prepared acetabular site with an abduction angle of 45° and an anteversion angle of 10° - 15° and impact the posterior plate of the introducer with an adequately weighted hammer.

Verification of good implant/bone contact and correct insertion of the cup into the acetabular site can be controlled through the screw holes.

Verify the stability of the cup and then unscrew the introducer. The hole of the introducer can be plugged by a special polar plug utilizing the **Hexagonal Screwdrivers \varnothing 3.5mm (S30020 o S30022)**.

In the case of the JUMP[®] System PEG acetabular cup, this plug is supplied in the same package together with the implant.

ORIENTATION

The Instruments Set is provided with a **Cup Orientation Device (S30028)** providing two **Rods (S30029)**, A and B, which allow the orientation of the implant with the correct rotation, inclination, and ant version.

With the patient in a supine position, an anteversion of 12° is obtained by aligning Rod 'A' perpendicularly in respect to the ground (Fig. 6).

Aligning Rod 'B' perpendicularly in respect to the side of the operating bed, an inclination of 45° is obtained (Fig. 7).

IMPORTANT!!

WHENEVER IT SHOULD BE NECESSARY TO CHANGE THE ORIENTATION AFTER THE CUP HAS BEEN IMPACTED, ALWAYS REMOVE THE COMPONENT (USING THE CUP IMPACTOR WITH THE AID OF THE TOMMY BAR) AND RE-POSITION IT WITH THE DESIRED ORIENTATION.

DO NEVER TRY IN ANY CASE TO CHANGE THE ORIENTATION BY HITTING THE RIM OF THE CUP WITH ANY METAL TOOL: THIS COULD CREATE A DEFORMATION OF THE PROFILE THAT - IN CASE OF A CERAMIC LINER SHOULD BE USED - COULD LEAD TO UNDESIRE BREAKAGE.

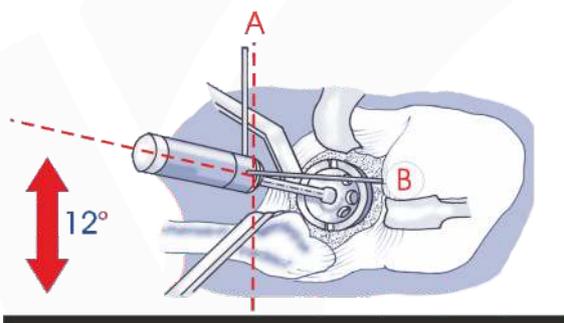


Fig. 6: Anteversion

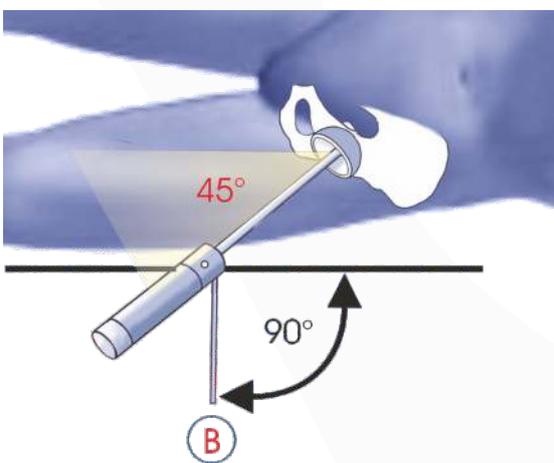


Fig. 7: Inclination

ADDITIONAL FIXATION BY SCREWS 9

The use of titanium cancellous bone screws, with a 6.5 mm diameter, is required when the primary stabilization of the press-fit implant is not considered optimal. Moreover, upon Surgeon's discretion, one or two screws inserted into the superior quadrant of the cup can be useful to the rotational stability of the implant.

ATTENTION:

In the case of the JUMP® System, JUMP® System PEG and TRASER® acetabular cup, before implanting the screws, the plugs (provided preassembled in the holes) must be removed utilizing one of the Hexagonal Screwdrivers \varnothing 3.5mm (S30020 or S30022).

WARNING: in JUMP® System cup size 44mm the sealing plugs are not threaded but "bayonet lock": for removal it's enough to unscrew turning the plug less than 1/4 turn.

The \varnothing 3.5 mm Drill Bit (S30015 or S30016), mounted by means of a Flexible Drill Shaft (S30014) on a surgical drill, is inserted into the Double Drill Sleeve (S30017) and positioned toward the first hole to drill (Fig.8).

The Double Drill Sleeve is equipped with two bushes: a long one allows drilling up to 25 mm long holes and a short one allows drilling up to 35 mm long holes. Switch the motor on to drill the bone by pushing the drill bit thoroughly.

WARNING: It is recommended to always use the Double Drill Sleeve to obtain a more precise hole and to operate correctly with the drill bit.

The length of the screws to use is determined through a Depth gauge for screws (S30018) inserted in the new hole (Fig.9).

As screws are self-threading, hole tapping is usually not required. However, it can be performed if difficulties arise in penetrating a sclerotic bone, which is particularly hard, using a standard tapper for cancellous screws, \varnothing 6.5mm.

The screw of appropriate length is mounted on one of the Screw-drivers (S30020 or S30022) holding it with the Screw-holding forceps (S30024), and is screwed in (Fig. 10) until the flat head of the screw is completely sunk into the titanium shell.

WARNING: Make sure that the head of the screw is completely sunk into its hole. Head protrusion could make the liner insertion difficult.

JUMP® System, JUMP® System PE and TRASER® cups are provided with three holes for screws insertion.

JUMP® System PEG cup is provided with four holes for screws insertion.

JUMP® System TRASER® Revision is provided with 8 holes (3+5) for screw insertion.

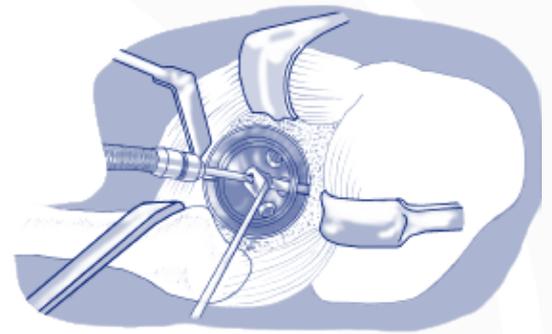


Fig. 8: Hole drilling

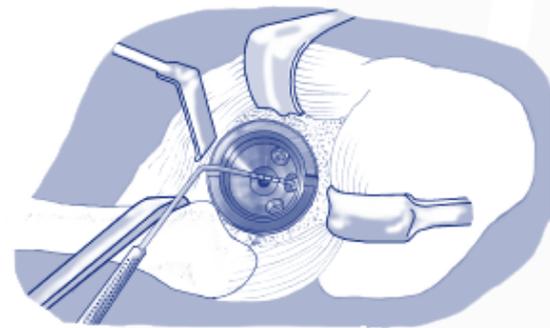


Fig. 9: Depth gauging

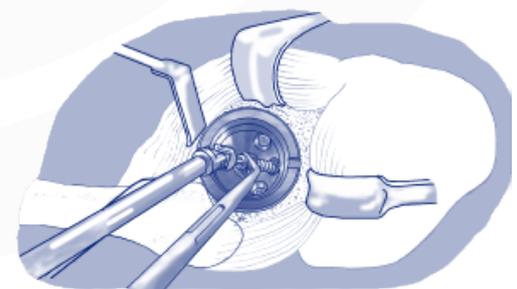


Fig. 10: Screw insertion

10 TRIAL REDUCTION

N.B.: Use only JUMP® System insert provided by permedica.

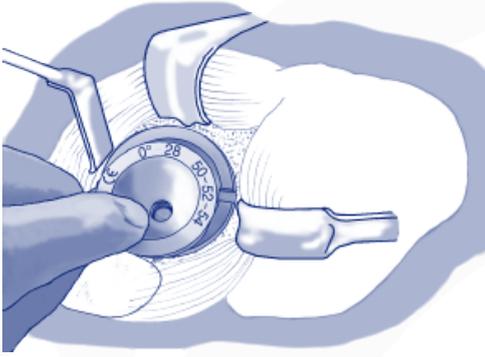


Fig. 11: Insertion of the Trial Insert

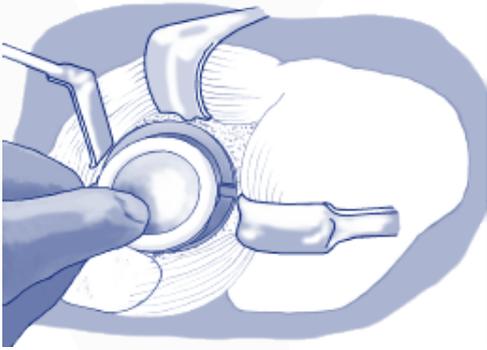


Fig. 12: Insertion of the definitive UHMWPE insert

Before inserting the definitive liner, a trial reduction can be run to assess the effectiveness of the implant.

The trial insert sized as the implanted cup, is manually inserted, or by means of the **Insert Impactor Handle (S30012)**, into the titanium shell (Fig.11).

WARNING: The JUMP® System acetabular shells use a **COLOR CODE** for the immediate identification of components and cup/insert combination. Check carefully that the insert has the same **COLOR CODE** as the implanted cup.

The trial insert is designed to be easily removed, using the **Insert Impactor Handle**.

Proceed with the femoral stem broaching procedure.

Once the trial (or the definitive) femoral stem has been placed, use a trial head matching the trial insert placed into the cup to perform joint reduction and check out its mobility and stability. Stability is considered optimal if no dislocation occurs undergoing the joint to flexion and external rotation with adduction movements.

In case of dislocation, it is possible to use a hooded insert with 20° rim for better coverage of the area of concern. In case of serious ligament and/or muscular deficit, a retentive insert can be used.

In presence of severe muscular or capsulo-ligamentous deficit it is possible to use Retentive Inserts or **DUAL MOBILITY inserts** (refer to page 13).

After checking out the joint effectiveness and finding the adequate position of the joint, trial components are removed to implant the definitive ones.

INSERTION OF UHMWPE/VITAL-XE LINERS **11**

WARNING: prior to open the sterile packaging verify the correspondence of the Color Code (refer to table at page 10).



Before inserting the liner, the inner of the titanium shell must be thoroughly cleaned.

The proper **Insert Impacting End** is mounted in the **Insert Impactor Handle (S30012)**.

Polyethylene joint insert, of the correct size, is manually positioned seated into the titanium cup (Fig. 12). If a hooded insert is used, it will be positioned to ensure a better coverage of the area of concern.

WARNING: After the insert impactation, the orientation of the hood will not be possible.

The insert is definitely seated by impacting it with the appropriate **Ball Impacting Head (S30026, S30092, S35015)** until the edge of the insert is line-to-line with the edge of the titanium shell (Fig. 13).

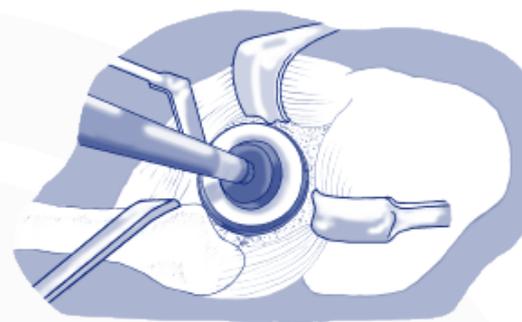


Fig. 13: Impactation of the UHMWPE insert

NOTES for RETENTIVE INSERT:

- ✓ Do not execute a trial reduction with a retentive insert in the titanium cup.
- ✓ Do not use the 28mm Ball Impacting Head for the definitive insertion. Use only 22mm Ball Impacting Head. It can be suitable, before impactation, to place a gauze on the bottom of the insert.

INSERTION OF CERAMIC LINERS **12**

WARNING:

- ✓ Do not use with JUMP® System PE
- ✓ BIOLOX® ceramic inserts must be exclusively used in coupling with BIOLOX® ceramic ball heads by Ceramtec AG;
- ✓ Before proceeding to the implantation of a BIOLOX® ceramic joint insert, it is necessary to ascertain the correct positioning of the acetabular cup, carrying out a trial reduction. In case of a tendency to dislocate, the choice of an hooded antiluxation UHMWPE insert should be evaluated.
- ✓ If the femoral stem is already implanted, pay careful attention that no components are damaged.
- ✓ Do not use metal impactors on ceramic inserts.

Before proceeding to the placement of the joint inserts, the inside of the JUMP® System acetabular cup must be accurately cleaned.

Manually place the insert into the acetabular cup and push it in the conical site utilizing the cup walls as a guide (Fig. 14a) until achieving complete insertion (Fig. 14b).

Incorrect positioning (Fig. 14c), even by one degree, is absolutely necessary to avoid as it could cause inevitable breakage or mobilization of the insert.

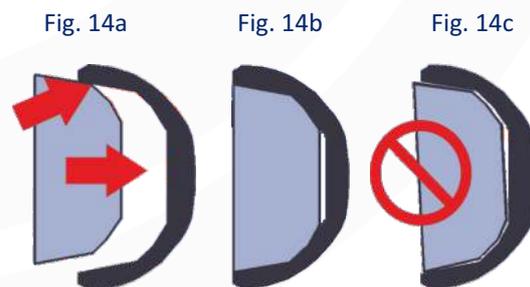


Fig. 14: correct insertion of the ceramic insert

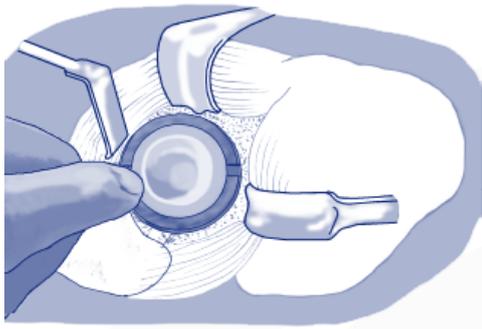


Fig. 15: placement of the ceramic insert

Passing over with a finger, verify that the insert is perfectly leveled with the rim of the titanium cup, an indication of correct seating (fig. 15).

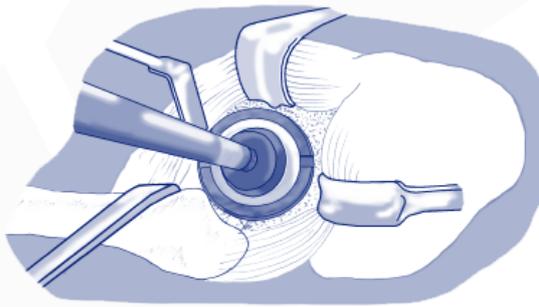


Fig. 16: Impaction of the ceramic insert

Once the correct positioning of the insert is assured, one moves on to the definite embedding, by simply pushing the insert with force and lightly impacting it with the appropriate **Ball Impacting Head (S30026, S30092, S35015)** mounted on the **Insert Impactor Handle (S30012)** (Fig. 16).

13 REMOVAL OF THE CERAMIC LINER

In case it should be necessary to remove a ceramic insert, apply light vibrating taps to the acetabular cup in such a way as to loosen the insert and allow removal.

At this purpose, an **Extractor for ceramic inserts (S35013)** is supplied with the instrumentation.

Tap on the cup rim in 3 points at 120° (imagining a clock, tap at h 4, h 8 and h 12) (Fig. 17).

WARNING: In case of removal of a ceramic liner, check carefully the microstructured surface in the inner taper of the cup: if any visible damage should be detected (grooves, scratches) **AVOID** to use a new ceramic liner. Switch to a PolyEthylene one.

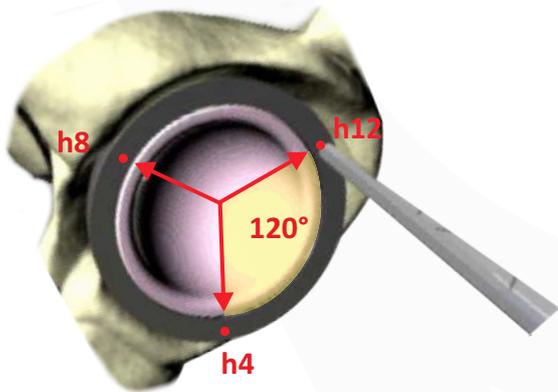


Fig. 17

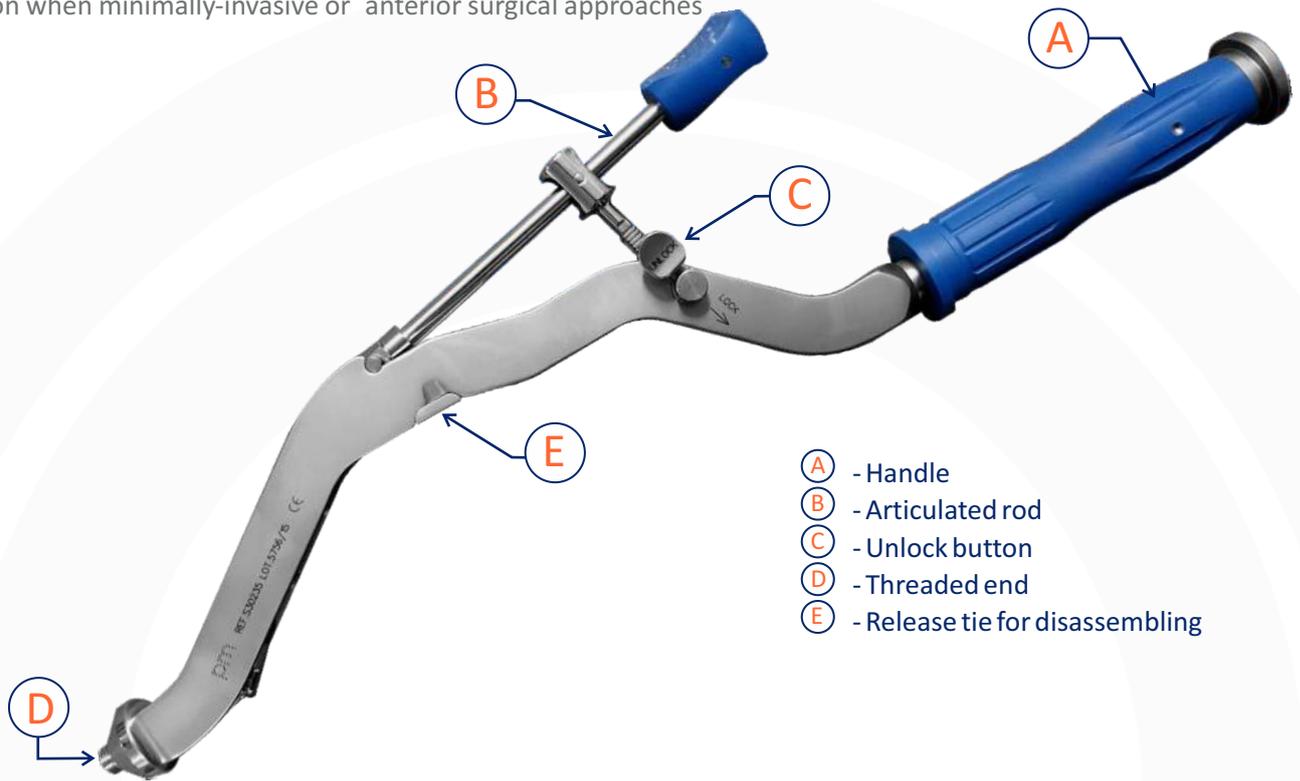
POST-OP CARE

Post-op care strategy is very important to allow the patient a correct recovery. The guidelines are established by the Surgeon and should consider several factors such as age, weight and bony structure of the patient.

In any case, it is necessary to avoid excessive load of the lower limb for a certain amount of time.

USE OF THE CURVED CUP IMPACTOR 1 APPENDIX

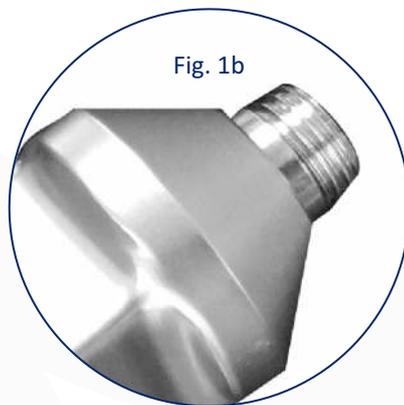
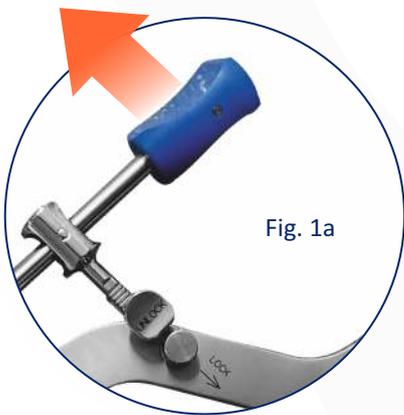
The **Curved Cup Impactor S30235** is designed to facilitate cup implantation when minimally-invasive or anterior surgical approaches are used.



- (A) - Handle
- (B) - Articulated rod
- (C) - Unlock button
- (D) - Threaded end
- (E) - Release tie for disassembling

ENGAGEMENT OF THE CUP

Pull the Articulated Rod (B) in order to fully expose the Threaded End (D) (Fig. 1 a/b).



Place the Cup on the sterile serving trolley with the inner facing upwards, engage the Threaded End into the central hole (Fig. 2) and screw by turning the knob of the Articulated Rod clockwise (Fig. 2b).



Once screwed the Cup is still free to rotate. By turning the Cup, rotate the cup to set the holes in the most convenient location for the introduction (fig. 3a) then lock the Cup by pressing the knob of the Articulated Rod (Fig. 3b).

Fig. 3a

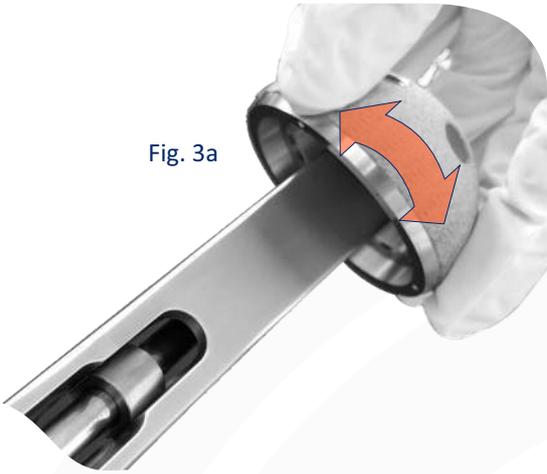


Fig. 3b



CUP IMPLANTATION

Proceed with Cup implantation by following the procedure described at page 6 for the correct orientation.

Once seated the Cup, press the Unlock Button **C** (Fig. 4a) then turn the knob of the Articulated Rod counterclockwise (Fig. 4b) to release the Cup and remove the instrument.

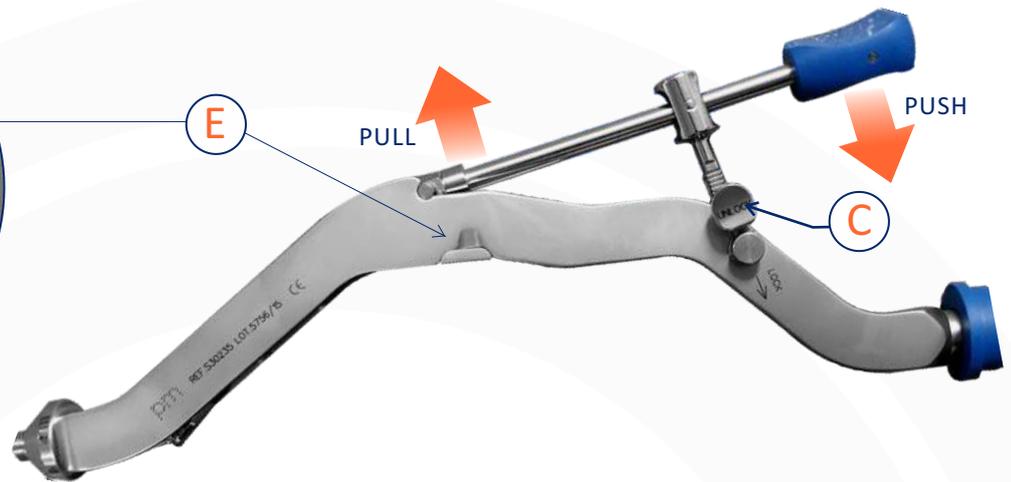
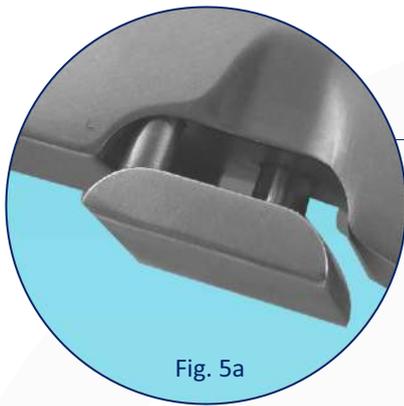
Fig. 4a



Fig. 4b



CLEANING OF THE HANDLE



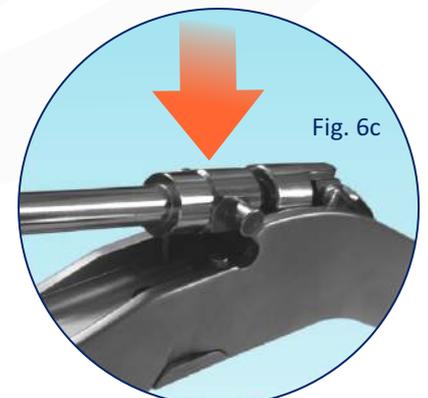
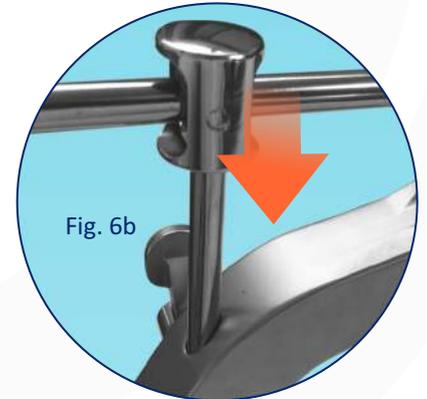
The instrument can be disassembled to allow washing and sanitification procedure. For disassembly of the instrument proceed as follows:

- ① Pull the Release Tie **E** (fig. 5a)
- ② Extract the Articulated Rod by pulling it up in the central part and pushing down at the same time the knob.
- ③ Once the Articulated Rod is released, push the Unlock Button **C** for complete extraction (Fig. 6).

Although the Articulated Rod can be extracted to facilitate cleaning, it cannot be removed from the instrument (Fig. 6).



Fig. 6



To re-assemble the instrument proceed as follows:

- ① Re-insert the Threaded End **D** into its housing (fig. 6a)
- ② Re-insert the knurled rod of the Articulated Rod into its housing (Fig. 6b).
- ③ Push in the center to lodge the Articulated Rod, taking care to properly align the teeth (Fig. 6c).

APPENDIX 2 DUAL MOBILITY OPTION - TRIAL INSERT

The Trial components for the Dual Mobility option are marked with the JUMP SYSTEM color coding. Marking is reported on the **Metal Trial Adapter** and the corresponding **Dual Mobility Trial Insert** (Fig. 7). Refer to the reference table at the end of this Surgical Technique for more information.



Fig. 8c



Fig. 7

ATTENTION:

refer to the color code marking (BLACK/YELLOW/GREY/BLUE/RED) without minding the color of the components.

Screw the **Metal Trial Adapter** onto the **Positioning Handle S30019** (Fig. 8a/b) and then proceed with placement into the implanted Cup (Fig. 8c).

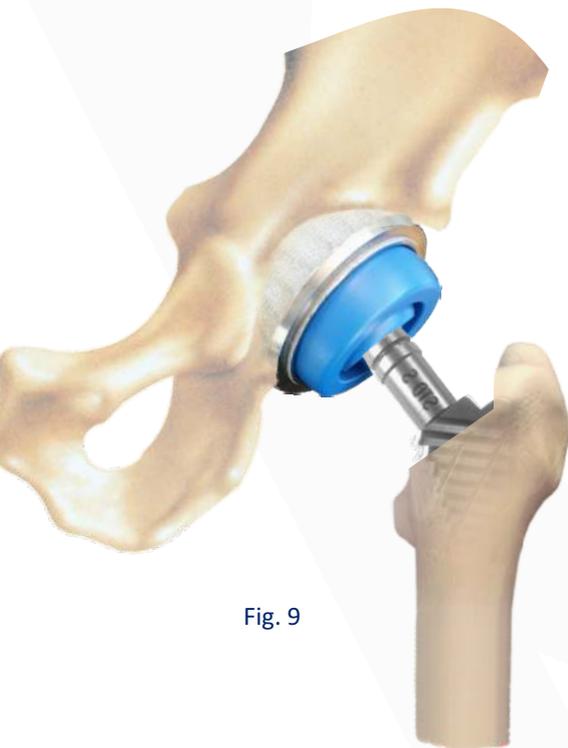


Fig. 9



Fig. 8a



Fig. 8b

Proceed with femoral broaching.

Once reached the proper stem size the **Broach** is left into the femur and equipped with the proper **Trial Cone**, a **Trial Head Ø 28mm** and the **Dual Mobility Trial Insert** corresponding to the implanted cup. After joint reduction proceed with stability and mobility controls (Fig. 9).

Stability is considered optimal if no dislocation occurs undergoing the joint to flexion and external rotation with adduction movements..

After checking out the joint effectiveness and finding the adequate position of the joint, trial components are removed to implant the definitive ones.

Use the **Positioning Handle** to remove the **Metal Trial Adapter**.

INSERTING the DUAL MOBILITY ADAPTER

A special **Positioner with suck (S30078)** is available for the positioning of the implantable Dual Mobility Insert into the metal shell.

Place the suction end of the **Positioner** inside the Insert adapter: a slight pressure will be sufficient to hook it (Fig. 10a).

Place the Insert adapter inside the implanted cup (Fig. 10b) taking care to place it perfectly leveled to the outer rim.



Push the button on the **Positioner** (Fig. 10c) to release suction and thus leaving the insert lodged inside the cup.

Make sure of the correct positioning and hit the insert for final seating.



HEAD/INSERT ASSEMBLY

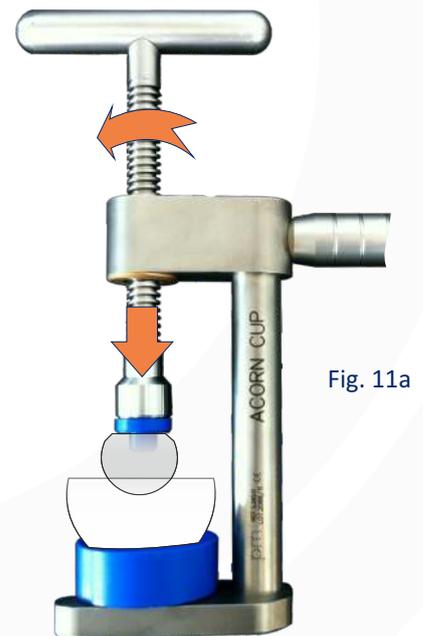
Once the definitive components to be used have been decided, it is possible to proceed with their assembling:

the *Articular Head* fits into the retentive double mobility *Insert* by snap-in insertion, easy to achieve using the special **Press (S38511)**.

the *articular insert* is placed onto the base of the **Press** and the ball head is engaged at the entrance of the socket with the cone facing up (Fig.11a).

Turn the **Press** by turning the T-Handle clockwise thus pressing on the ball head until snap-in is achieved (Fig. 11b).

the *Articular Head* assembled with the double mobility *Insert* is then inserted onto the stem's taper and impacted using the *Femoral Head Impactor*.



FINAL REDUCTION

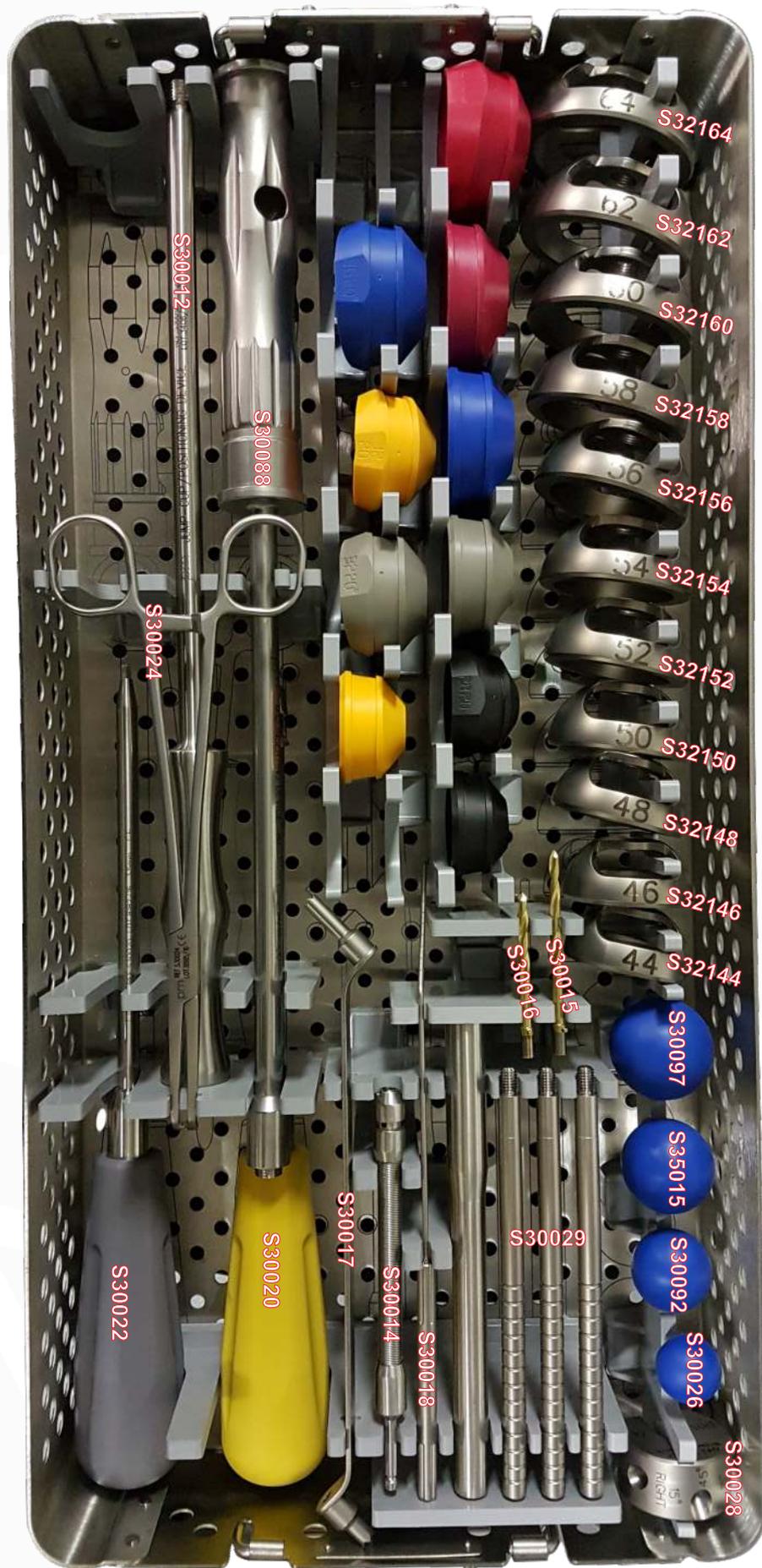
At this point it is possible to definitively reduce the joint by pushing the *Insert*, assembled onto the stem, into the *Cup*.

WARNING: before proceeding with the reduction it is necessary to carefully verify that the inner of the Cup is perfectly clean and free of any bone debris, soft tissues and especially any bone cement particles (whenever bone cement has been used for stem fixation).



S35200 JUMP SYSTEM INSTRUMENTS SET

S30012	INSERT IMPACTOR: HANDLE
S30014	FLEXIBLE DRILL SHAFT
S30015	TWIST DRILL Ø 3,5x56mm.
S30016	TWIST DRILL Ø 3,5x70mm.
S30017	DOUBLE DRILL GUDE SLEEVE
S30018	DEPTH GAUGE
S30020	HEX. SCREWDRIVER Ø 3,5mm STRAIGHT
S30022	HEX. SCREWDRIVER Ø 3,5mm CARDAN
S30024	SCREW HOLDING FORCEPS
S30026	INSERTS Impaction End Ø 28mm
S30028	ORIENTING DEVICE
S30029	ROD FOR CUP ORIENTING DEVICE
S30088	UNIVERSAL CUP IMPACTOR - (thread M10)
S30092	INSERTS Impaction End Ø 32mm
S32244	TRIAL CUP - INOX Ø 44 mm
S32246	TRIAL CUP - INOX Ø 46 mm
S32248	TRIAL CUP - INOX Ø 48 mm
S32250	TRIAL CUP - INOX Ø 50 mm
S32252	TRIAL CUP - INOX Ø 52 mm
S32254	TRIAL CUP - INOX Ø 54 mm
S32256	TRIAL CUP - INOX Ø 56 mm
S32258	TRIAL CUP - INOX Ø 58 mm
S32260	TRIAL CUP - INOX Ø 60 mm
S32262	TRIAL CUP - INOX Ø 62 mm
S32264	TRIAL CUP - INOX Ø 64 mm
S35015	INSERTS Impaction End Ø 36mm



OPTIONAL INSTRUMENTS SET
DUAL MOBILITY OPTION

S35102



S30078	INSERTS POSITIONER with Sucking End
S35019	POSITIONER for DUAL MOBILITY Trial Inserts
S36205	DUAL MOBILITY Trial Insert - BLACK
S36201	DUAL MOBILITY Trial Insert - YELLOW
S36202	DUAL MOBILITY Trial Insert - GRAY
S36203	DUAL MOBILITY Trial Insert - BLUE
S36204	DUAL MOBILITY Trial Insert - RED
S38844	ACORN: TRIAL INSERT Ø 44mm (BLACK)
S38846	ACORN: TRIAL INSERT Ø 46mm (YELLOW)
S38848	ACORN: TRIAL INSERT Ø 48mm (GREY)
S38852	ACORN: TRIAL INSERT Ø 52mm (BLUE)
S38854	ACORN: TRIAL INSERT Ø 54mm (RED)
S38511	ACORN: Clamp for Head-Insert Assembly

S30101 ACETABULAR REAMERS SET

Standard Set

S30042	Acetabular Reamer Ø 42mm
S30044	Acetabular Reamer Ø 44mm
S30046	Acetabular Reamer Ø 46mm
S30048	Acetabular Reamer Ø 48mm
S30050	Acetabular Reamer Ø 50mm
S30052	Acetabular Reamer Ø 52mm
S30054	Acetabular Reamer Ø 54mm
S30056	Acetabular Reamer Ø 56mm
S30058	Acetabular Reamer Ø 58mm
S30060	Acetabular Reamer Ø 60mm
S30062	Acetabular Reamer Ø 62mm
S30064	Acetabular Reamer Ø 64mm
S30073	Acetabular Reamer SHAFT - HUDSON conn.

SYNTHES/AO



HUDSON



STRYKER/ZIMMER-HALL



Optional Instruments (on request)

S30071	Acetabular Reamer SHAFT - SYNTHES/AO
S30072	Acetabular Reamer SHAFT - STRYKER/ZIMMER
S30041	Acetabular Reamer Ø 41mm
S30043	Acetabular Reamer Ø 43mm
S30045	Acetabular Reamer Ø 45mm
S30047	Acetabular Reamer Ø 47mm
S30049	Acetabular Reamer Ø 49mm
S30051	Acetabular Reamer Ø 51mm
S30053	Acetabular Reamer Ø 53mm
S30055	Acetabular Reamer Ø 55mm
S30057	Acetabular Reamer Ø 57mm
S30059	Acetabular Reamer Ø 59mm
S30061	Acetabular Reamer Ø 61mm
S30063	Acetabular Reamer Ø 63mm
S30065	Acetabular Reamer Ø 65mm
S30066	Acetabular Reamer Ø 66mm
S30068	Acetabular Reamer Ø 68mm
S30070	Acetabular Reamer Ø 70mm

Off-Set Reamer Handle

S30270	OFF-SET Reamer Handle - Main Body
S30271	SYNTHES/AO Adapter
S30272	STRYKER/ZIMMER-HALL Adapter
S30273	HUDSON Adapter



JUMP SYSTEM Cementless Press-Fit Cups

Class III

Accepting all types of inserts



	Standard	X-Pore	HA	HaX-Pore
SIZE	Reference	Reference	Reference	Reference
42	35142*	35242*	35442*	35342*
44	35145	35244	35444	35345
46	35147	35246	35446	35347
48	35149	35248	35448	35349
50	35150	35250	35450	35350
52	35153	35252	35452	35353
54	35155	35254	35454	35355
56	35156	35256	35456	35356
58	35158	35258	35458	35358
60	35160	35260	35460	35360
62	35162	35262	35462	35362
64	35164	35264	35464	35364
66	35166*	35266*	35466*	35366*
68	35168*	35268*	35468*	35368*
70	35170*	35270*	35470*	35370*

JUMP SYSTEM PE Cementless Press-Fit Cups

Class III

Accepting PE and VITAL-XE inserts only



	Standard	X-Pore	HA	HaX-Pore
Size	Reference	Reference	Reference	Reference
48	35791*	35991*	35491*	35881
50	35792*	35992*	35492*	35883
52	35793*	35993*	35493*	35882*
54	35794*	35994*	35494*	35884*

JUMP® System TRASER® Press-Fit Cup

Class III

Accepting all types of inserts

TRASER®



TRASER® REVISION

Accepting PE and VITAL-XE inserts only



TRASER®		TRASER® REVISION	
SIZE	Reference	SIZE	Reference
44	39344	-	-
46	39346	-	-
48	39348	48	39448
50	39350	50	39450
52	39352	52	39452
54	39354	54	39454
56	39356	56	39456
58	39358	58	39458
60	39360	60	39460
62	39362	62	39462
64	39364	64	39464
66	39366*	66	39466*
68	39368*	68	39468*
70	39370*	70	39470*
Special sizes on request		72	39472*
		74	39474*
		76	39476*
		78	39478*
		80	39480*

Accessories

Class IIb

Sealing Plug



codice
Polar Plug M10 **35103**

Fixation Screws Ø 6,5 mm



Length	Reference
20mm	36720
25mm	36725
30mm	36730
35mm	36735
40mm	36740
45mm	36745
50mm	36750
60mm	36760

JUMP® SYSTEM Dual Mobility option

Class III



CUP SIZE	BIOLOY® PM734	BIOLOY® CrCo	UHMWPE	VITAL-XE®	Color Coding	inner Ø
	reference	reference	reference	reference		
44-46	36215	36205	38844	38844XE	BLACK	22mm
48-50	36211	36201	38846	38846XE	YELLOW	28 mm
52-54	36212	36202	38848	38848XE	GREY	
56-60	36213	36203	38852	38852XE	BLUE	
62+	36214	36204	38854	38854XE	RED	

JUMP SYSTEM Articular Inserts

Class III

ATTENTION:
The COLOUR CODING refers to CUP / INSERT coupling.



Ø Socket	UHMWPE			VITAL-XE®			BIOLOX® Delta
	Reference						
22mm							
28mm	36303*		36304*				
	36301	36363	36302	36301XE	36363XE	36302XE	36007*
	36305	36364	36306	36305XE	36364XE	36306XE	
	36311	36365	36312	36311XE	36365XE	36312XE	
	36321	36374	36323	36321XE	36374XE	36323XE	
32mm	36307	36366	36308	36307XE	36366XE	36308XE	
	36309	36367	36310	36309XE	36367XE	36310XE	
	36313	36368	36314	36313XE	36368XE	36314XE	36011
	36319	36369	36320	36319XE	36369XE	36320XE	36016
	36340	36376	36342	36340XE	36376XE	36342XE	36015
36mm	36315	36370	36316	36315XE	36370XE	36316XE	36017
	36317	36371	36318	36317XE	36371XE	36318XE	36018
	36343	36378	36345	36380XE	36382XE	36381XE	36022
	36325	36329	36326	36343XE	36378XE	36345XE	36025
40mm	36327	36330	36328	36325XE	36329XE	36326XE	36026
	36346		36347	36327XE	36330XE	36328XE	
	36348		36349	36346XE		36347XE	36041
			36348XE		36349XE	36042	

Information

INTENDED PURPOSE: JUMP® System is an acetabular component for cementless applications to be used in Total Hip Replacement procedures in combination with an articular liner, a femoral ball-head and a femoral stem. Indicated in primary and revision hip arthroplasties, all cases of coxarthrosis where the bony tissue is suitable enough to guarantee a correct and stable primary mechanical press-fit fixation.

Anchorage of the device to the bone is achieved by press-fit insertion. Whenever necessary, fixation can be improved by using cancellous bone screws inserted into the dedicated holes.

STERILIZATION:

Method: Ethylene Oxide (ETO) or accelerated electron beam irradiation (β rays - nominal dose 25 kGy), in vacuum.

Validity: 5 years.

CLASSIFICATION:

Class III or IIb as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendments.

Materials

CUPS, SCREWS, PLUGS:

Titanium Aluminium Vanadium Ti₆Al₄V Alloy - ISO5832/3.

INSERTS:

UHMWPE: Ultra High Molecular Weight Polyethylene without Calcium Stearate - ISO5834/1/2.

VITAL-XE: cross-linked UHMWPE added with Vitamin E - ISO5834/1/2.

CERAMIC: BIOLOX® Delta mix of Alumina and Zirconia Oxide (Al₂O₃ + ZrO₂) - ISO6474.

Metal Dual Mobility:

- PM734 highly nitrogenized Stainless Steel forged alloy ISO5832/9

- CrCoMo forged alloy ISO5832/12

SURFACE FINISHING:

HaX-Pore: 500µm pure Titanium + 40µm Hydroxyapatite Ca₁₀(OH)₂(PO₄)₆ applied with plasma spray technique.

X-Pore: 500µm pure Titanium applied with plasma spray technique.

HA: 80µm Hydroxyapatite Ca₁₀(OH)₂(PO₄)₆ applied with plasma spray technique.

Standard: microstructured sandblasted surface roughness 4-6µm.

BIOLOY®: TiNbN coating (Dual Mobility inserts)

Warning

Before using a product introduced onto the market by permedica spa, the surgeon is encouraged to carefully study the following recommendations, warnings and instructions as well as the specific product information (surgical techniques and technical product description). It is also advisable to check the website for the availability of any updates to this Instructions for Use. **Negligence or lack of observance of this aspect exonerates the manufacturer from all responsibility.**

Definition

Joint Prosthesis: implantable medical device, including implantable components and materials that is in contact with the surrounding muscle and bones, and carries out functions similar to those of a natural articular joint.

General information

A joint prosthesis should only be considered if all other therapeutic possibilities have been carefully weighed and found unsuitable or inappropriate.

A joint prosthesis, even if successfully implanted will be inferior to a natural, healthy joint. Conversely for the patient, a joint prosthesis can be a beneficial replacement for a severely altered, pathological joint, eliminating pain and restoring good mobility and bearing capacity.

Every artificial joint is subject to unavoidable wear and ageing. Over the course of time, an artificial joint initially implanted in a stable manner can loosen therefore limiting or impairing perfect functionality. Wear, ageing and loosening of an implant can lead to reoperation.

Indications for Use

The following are the general guidelines for the use of prosthetic devices produced by permedica. For more detailed information refer to the **Product Technical Sheet and Surgical Technique of the specific device (check on the website for the availability):**

- Advanced wear of the joint due to dysplasia, degenerative, post-traumatic, or rheumatic diseases.
- Fractures or avascular necrosis
- Negative outcome of previous surgeries such as joint reconstruction, osteotomies, arthrodesis, hemi-arthroplasty or total hip prosthesis, total knee prosthesis.

Use of the prosthetic devices for purposes different than those intended is not permitted.

Contraindications

Infections or other septic conditions in the area surrounding the joint, as well as allergies to the implanted material, (cobalt, chrome, nickel, etc) represent absolute contraindications

Relative factors that could compromise the success of the intervention are:

- Acute or chronic local or systemic infections, even far from the implant site, (risk of haematogenous diffusion of the infection towards the site);
- Insufficient bone structure at the proximal or distal level of the joint that does not guarantee good anchorage of the implant;
- Severe vascular, neurological or muscular diseases compromising the extremities involved;
- Overweight or obesity;
- Osteoporosis;
- Hypertrophy of the muscular tissue surrounding the joint;
- Metabolic disorders or lack of sufficient renal functions.

The patient must also be:

- Capable of understanding and following the doctor's instructions.
- Avoid excessive physical activity such as heavy work or competitive sports that involve intense vibration, jerking motions or heavy loading.
- Avoid excessive weight gain.
- Avoid drug abuse, including nicotine and alcohol.

General Information and precautions for the safe use of the implant

Products of permedica Spa may be implanted only by surgeons who are familiar with the general problems of joint replacement, with implant devices, the surgical instruments and who have mastered the product-specific surgical techniques.

Prostheses and prosthesis parts are always components of a system, and therefore must be combined with original parts belonging to the same system. Note must be taken of the system compatibility according to the "Product Technical sheet" and/or "Surgical Techniques". Prostheses and prosthesis parts from permedica Spa - in particular BIOLOX ceramic components - must never be combined with parts from other manufacturers. permedica excludes all liability for the negligent use of its implants with those of other manufacturers. Specific instruments are available for the implant devices of the various types of joint prostheses. Improper use of these instruments can cause poor positioning of the implant components. permedica Spa excludes all liability for the negligent use of its instrumentation or the use of third parties instruments.

It is forbidden to re-utilize a prosthesis or a prosthesis part that was previously implanted in the body of a patient or another person, or to re-utilize an implant that has come into contact with the body fluid or tissue of another person, or where the mechanical integrity (superficial, geometrical, or biological) cannot be guaranteed. They are single-use devices.

Implants must be stored in their original packaging. Before implantation they must be checked for defects such as micro scratches or marks (can cause excessive wear or complications) on the articular surface. And therefore must be handled with extreme attention.

Prolonged contact - direct or indirect - of the electrocautery with implantable components, in particular in the vicinity of the femoral stems neck, can result in structural alterations which may modify the characteristics of resistance to fatigue of the material with consequent risks of breakage and must therefore be carefully avoided.

Coated prosthetic components, in particular those coated with Hydroxyapatite, should be handled with extreme care avoiding damage to the surface coating.

Contact of prosthetic components coated with Hydroxyapatite with anything other than the original package, clean surgical gloves and patient tissue should be avoided. Hydroxyapatite coated implants should never be cemented, instead should be implanted via "press fit" method. Hydroxyapatite cannot be a substitute for bone cement, nor can it compensate for insufficient primary stability.

TiNBN coating acts as an isolation barrier for the release of ions by the underlying metallic materials. Since the long term duration of this barrier is not known, it cannot be guaranteed and therefore, it is up to the surgeon to determine if the use of TiNBN coated prosthetic components is indicated for patients with noted allergic sensibility towards metal (nickel) and should carry out the requisite postoperative monitoring for inflammation or allergic development.

Literature reports possible adverse reactions caused by elevated blood levels of metal ions in patients with metal-on-metal prosthetic joint surfaces. Long term systemic effects due to the accumulation of these ions are not known and therefore long term clinical consequences cannot be guaranteed. It is therefore not recommended the use of this joint coupling in female patients of childbearing age and/or people with compromised kidney function.

Before sterile implants are removed from the packaging, the protective packaging must be examined for possible damage as this could impair the sterility. The expiration date for the sterility of the product must be observed and expired products must be returned to the manufacturer. Observation of the common aseptic procedures must be respected when opening the package.

Prior to reduction or assembly, prostheses or articular prosthetic components must be thoroughly cleaned; contamination, i.e. foreign particles, bone chips or residues of bone cement, can lead to third-body abrasion, incorrect functioning or fracture of the prosthesis or prosthesis parts.

Joint prosthesis must not be mechanically adapted or modified in any way, unless this is expressly envisaged in the design and surgical technique. In case of doubt, recommendation must be obtained in writing from the manufacturer.

The surface of the prosthesis must not bear any writing nor be allowed to come into contact with metallic or other hard objects (especially in the case of ceramic implants), unless this is expressly envisaged by the of the "Surgical Technique" description.

Prostheses or prosthesis parts that are contaminated, nonsterile, damaged, scratched or have been improperly handled or altered without authorization must not be implanted under any circumstances.

Reliable connection of femoral ball-heads with conical coupling is only possible with the completely intact surface of both the ball head cone and the femoral stem cone. It is absolutely essential that the outer cone of the femoral stem fits perfectly with the inner cone of the ball head. The cone size is indicated on the product label and on the implant itself.

Protective caps or other protective devices must be removed immediately before use.

The instruments are inevitably subject to a certain degree of wear and ageing, rarely there could be interoperative breakage, especially if over utilized or misused. permedica recommends verification for breakage, deformation, corrosion and correct functioning, before use. In the case of damage, the instruments must not be utilized but returned to the manufacturer for substitution.

Observe any additional information, i.e. those reported in the information label applied to the primary and/or the secondary packaging relating to possible limitations for use.

Complications or other factors that may occur for reasons such as incorrect indication or surgical technique, unsuitable choice of material or treatment, inappropriate use or handling of the instruments, and/or sepsis fall under the responsibility of the operating surgeon and cannot be blamed on the manufacturer.

Possible side effects

The following are among the most frequent possible side effects of implantable devices:

- pain;
- bone fractures due to overloading on one side or weakened bone substance;
- allergy to the implanted material, mainly to metal. This signifies the necessity of ulterior study. Implants made of extraneous material can provoke the formation of histiocytosis and consequently osteolysis;
- allergic reactions;
- metalysis and consequent osteolysis in particular for implants with metal/metal surfaces;
- prosthesis or prosthesis parts can loosen as a result of: overloading; excessive weight; non-physiological stresses; superficial damage; partial or total lost of fixation; incorrect manipulation or improper implantation (wrong choice of implant component or size, improper alignment, incorrect components connection, insufficient fixation);
- excess wear or loosening of the implant due to breakdown of the osseous bed;
- dislocation of the prosthesis due to changed conditions of load transfer (cement disintegration or breakage and/or tissue reactions) or to early or late infections;
- dislocation, subsequent insufficient range of movement, undesirable shortening or lengthening of the extremity involved due to less than optimal positioning of the implant;
- Intra-operative or post-operative complications:
 - perforation or fracture of the bone segments;
 - vascular lesions;
 - temporary or permanent nerve lesions that can cause pain and numbness throughout the limb;
 - inter-operational/Arterial Hypotension during the cementation;
 - varus or valgus deformity;
 - cardiovascular disturbance including vein thromboses, pulmonary embolism and myocardial heart attack;
 - haematoma;
 - late wound healing;
 - infection.

Pre-operative Planning

Failure to carry out proper preoperative planning can lead to errors (i.e. in regards to candidate selection, type of prosthesis, and correct implant size).

The operation should be precisely planned on the basis of the x-ray findings. Testing for eventual allergies to implant component materials should be established. X-rays provide important information on the suitable type of implant, its size and possible combinations. All types of implants and implant parts in the combination recommended by the manufacturer that may possibly be needed for the operation, as well as the instruments needed for their implantation, must be available in case another size or another implant is required. Most of the prosthesis components are supplied with trial parts or measuring instruments that should be accurately used to determine the correct size to be implanted.

Patient Information

The doctor must explain the risks involved in the implantation of an endoprosthesis, possible side effects, and intrinsic limitations of the implant as well as the measures to undertake in order to reduce the possible side effects. In particular, the patient should be informed about the impact that the implant will have on his/her lifestyle, and that the prosthesis longevity could depend also on factors such as body weight and level of physical activity. The patient must also be informed that the devices implanted, due to the presence of metal components:

- can affect the result of computer tomography (CT);
- can be detected by metal detectors
- in the case of cremation, removal could be required depending on local regulations.

Implantable prosthetic devices containing metal and / or magnetic and / or electro conductive elements have not been evaluated for safety and compatibility in an electromagnetic environment. Related risks, including heating, migration and imaging artifacts next to the implants are known, but have not been evaluated for these components. For this reason, the patient should be informed that, whenever the implanted devices contain such materials, it is not advised to undergo radio diagnostic investigations based on magnetic fields (MR scan).

Components made only in UHMWPE or VITAL-E or VITAL-XE are made of non-metallic, non-conductive and non-magnetic materials. Therefore, according to the ASTM F-2503 standard, the devices are defined as "MR Safe".

Sterility

General considerations

Implantable devices supplied by permedica spa in a sterile state must remain closed in the original protective packaging until the moment of implantation. Before utilizing the implant, certain controls should be carried out:

- verify sterility expiration date (month/year) on the label of the product;
- visually verify that the internal packaging and the label are intact;
- visually verify that the sterile primary packaging is integral and does not present breakage, tearing, holes or other types of damage.

If the sterile primary package is damaged or the implant supplied by permedica spa is in a non sterile state, refer to the paragraph "Resterilization".

Ceramic or metal implantable devices

Ceramic or metal implantable devices are supplied sterilized by irradiation of 25 kGy.

Plastic implantable devices

Plastic implantable devices are supplied sterilized by irradiation of 25 kGy or by ethylene oxide. The label of each implantable device specifies the method utilized for sterilization.

Resterilization

If a medical implant device supplied by permedica spa is sterilized or resterilized by the user, this is to be noted in the corresponding patient documentation (i.e. operation report), and must be conserved with the respective accompanying documents. Components can be resterilized provided that they have not come into contact with body fluid, bone and have not previously been implanted.

Validation of the cleaning and sterilization procedures, as well as the proper setting for the corresponding equipment must be checked regularly.

Ceramic or metal implantable devices

Metal implantable devices can be sterilized by the user, via gas (ethylene oxide) or utilizing superheat steam or vapour. In the case of resterilization with gas, sufficient time must be allowed for degassing.

BIOLOX ceramic components may be re-sterilized only in exceptional cases and exclusively by permedica spa.

"NON STERILE" metal or ceramic implants must not be sterilized in their original protective packages.

Hydroxyapatite coated or pure Titanium metal implantable devices cannot be sterilized with gas (Ethylene Oxide), instead can be sterilized by superheat steam or vapour.

Plastic implantable devices

Implants made wholly or partly of polyethylene (UHMWPE) or Polymethylmethacrylate (PMMA) must not be resterilized utilizing superheat steam vapour, nor via irradiation nor via gas (ethylene oxide).

Instruments

All pertinent details regarding the cleaning and sterilization of instruments are supplied in the "Instructions for the cleaning and sterilization of surgical instruments". Instruments must be sterilized in the correct packaging via gas or vapour. Vapour sterilization should be carried out at a temperature of 121°C for 20 minutes. The sterilization of instruments made wholly or partly of plastic must not be heated above 140°C. In the case of resterilization with gas, sufficient time must be allowed for degassing.

Implant Materials

The label of each medical implant device carries the data relative to the type of material and surface coating utilized.

Endoprotheses by permedica spa are manufactured with the following materials:

- Stainless steel 316LVM (normative ISO5832/1)
- Pure Titanium (normative ISO 5832/2)
- Titanium alloy Ti6Al4V (normative ISO 5832/3)
- CrCoMo casting alloy (normative ISO 5832/4)
- Highly nitrogenized Stainless steel – "PM 734" (normative ISO 5832/9)
- Titanium alloy Ti6Al7Nb (normative ISO 5832/11)
- CrCoMo casting alloy (normative ISO 5832/12)
- UHMWPE Polyethylene (normative ISO 5834/1 e 2)
- UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E (VITAL-E)
- UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E and cross-linked (VITAL-XE).
- Polymethylmethacrylate (PMMA)
- Alumina based BIOLOX FORTE sintered ceramic (normative ISO6474-1) and BIOLOX DELTA (normative ISO6474-2).

The combination of stainless steel and chrome-cobalt or Titanium implant components can cause corrosion. The label of the implant carries this warning.

Materials utilized for the surface coating of permedica spa implants are the following:

- Pure Titanium (normative ISO 5832/2)
- Hydroxyapatite (norma ISO 13779/2)
- TiNBN

Custom Made Implant Devices

A custom made implant is foreseen for patients that cannot be fitted with a regular or series implants. This implant is produced as a "one of a kind" product following the indications of the surgeon and utilizing a regular implant design. The use of a custom made implant must be evaluated on a case by case basis.

The surgeon must be aware of the limitations inherent in a custom made implant and must take into account the construction and the materials chosen. The surgeon must also have the experience and capabilities necessary for the correct specifications and optimal application of the custom made product. Custom made implants do not have corresponding instrumentation.

Custom made implants are produced utilizing the technical expertise of permedica Spa acquired through series implant design. Because these implants are custom made, there is no clinical nor test data. Risks are higher with custom made products than with series implants. A custom made product must be utilized exclusively for the patient for whom it was designed.



permedica s.p.a.

via Como 38/39 - 23807 Merate (Lc)
Italy
tel.: +39 039 95 14 811

permedica switzerland s.a.

via al Molino 31 - CH-6926 Scairolo di Collina d'Oro
Switzerland
tel.: +41 91 960 90 80

permedica deutschland GmbH

Blumenthalsrtasse 22 - 12103 Berlin
Germany
tel.: +49 (0) 30 75 44 74 64



www.permedica.com