permedica
ORTHOPAEDICS

ACORN

Dual Mobility Acetabular Cup

SURGICAL TECHNIQUE

CE
0426

Both our Sales Representatives/Dealers and Product Specialists are at Your complete disposal for any further intormation 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 femaral 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 Hydroxyapayte 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 hypersensibility 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 became 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;
- ✓ revisons;
- ✓ recurrent dislocation after THA;
- ✓ displasy.

SURGICAL PROCEDURE

PRE-OPERATIVE PLANNING 1

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:

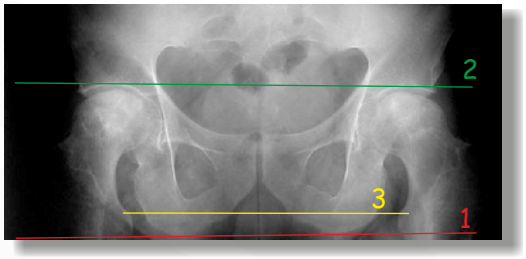


Fig. 1: Pre-operative planning

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 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 tronchanters.
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.

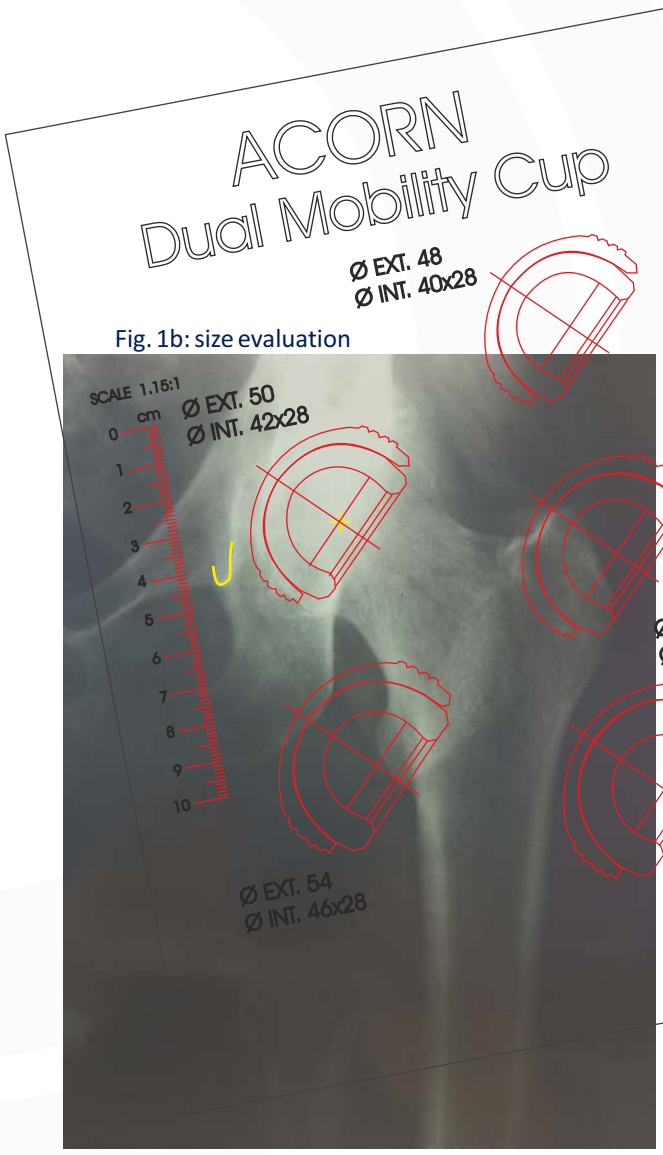


Fig. 1b: size evaluation

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 liklihood of any possible patient allergic reactions towards implantable device materials.

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.

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. 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 re-insertion. 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 doube 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”).

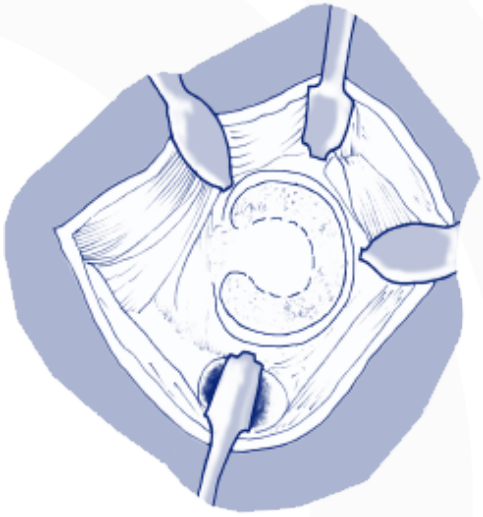


Fig. 3: Exposure of the acetabulum

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 bone walls with the risk of weakening them.

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

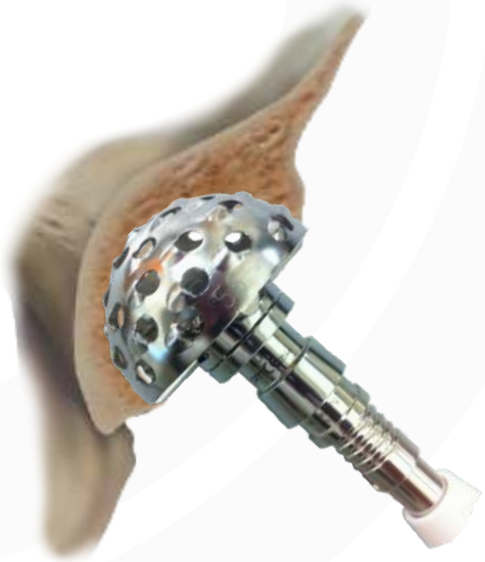


Fig. 4: acetabular reaming

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

7 SIZE EVALUATION

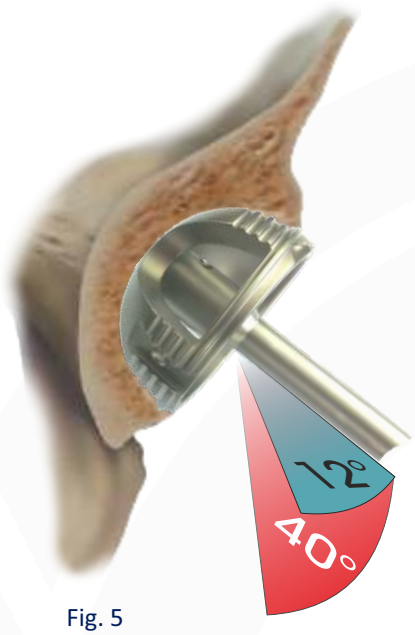


Fig. 5

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° 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.

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

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

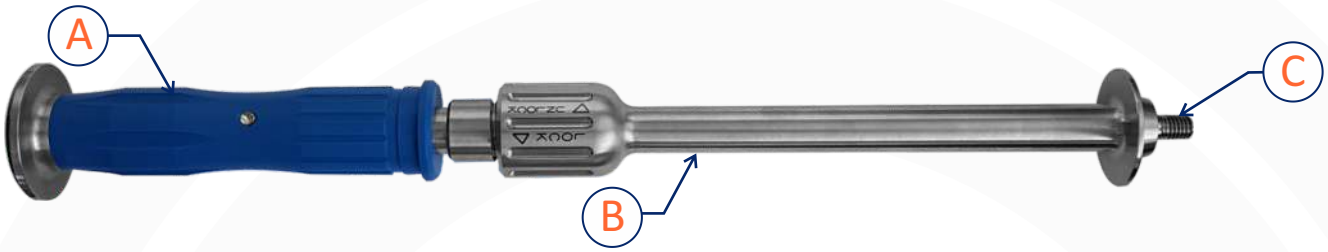
S38930

S38931

CUP IMPLANTATION
with STRAIGHT Handle

Ⓐ - Impugnatura
Ⓑ - Camicia
Ⓒ - Terminale filettato

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.



Engagement of the Cup on the Cup Holder

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

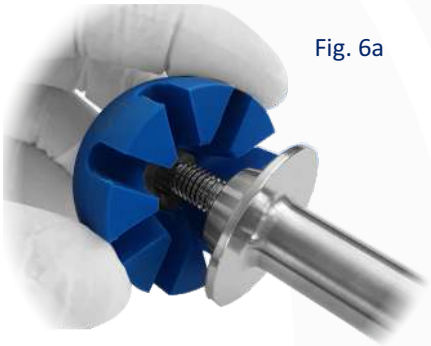


Fig. 6a

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

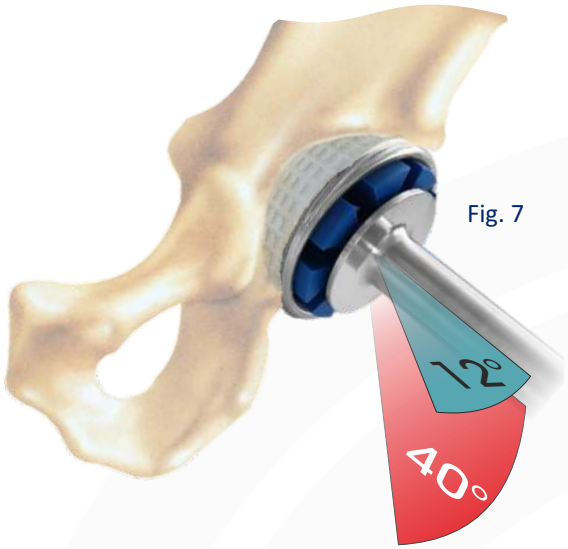


Fig. 7

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

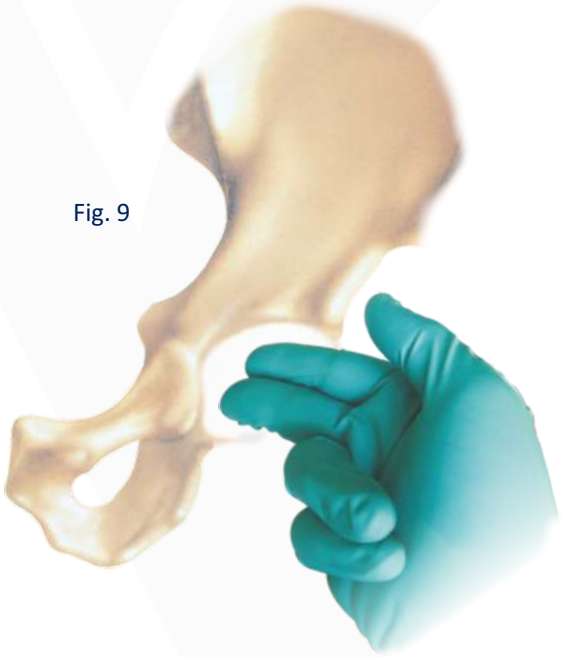


Fig. 9

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 (eveuntually slightly impacting with a hammer) and apply a continuous pressure untill 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

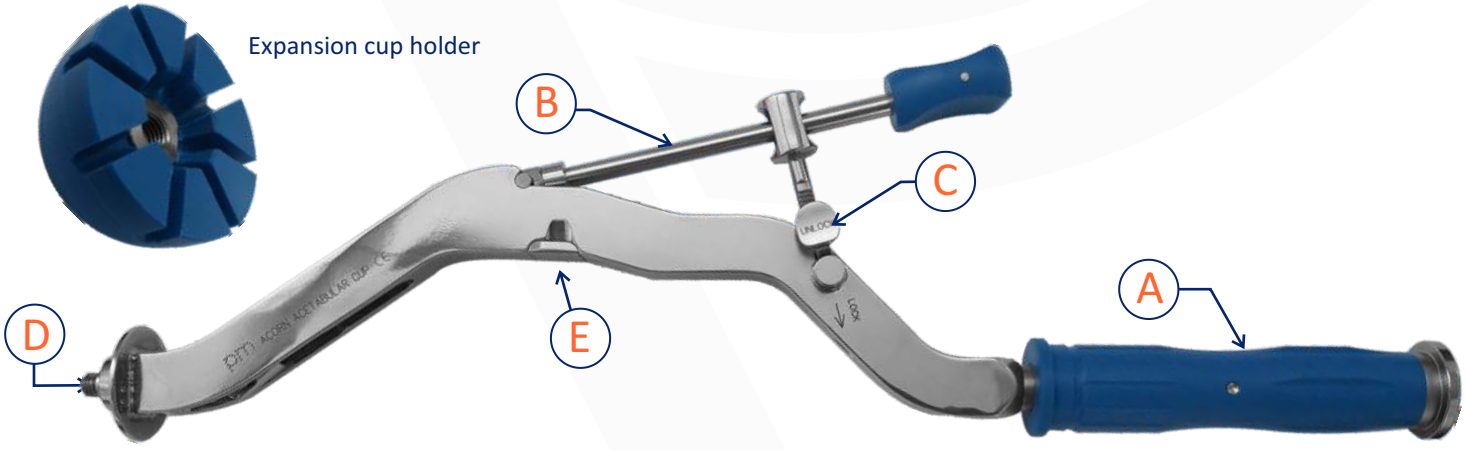
CURVED Handle

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



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

Fig. 10a

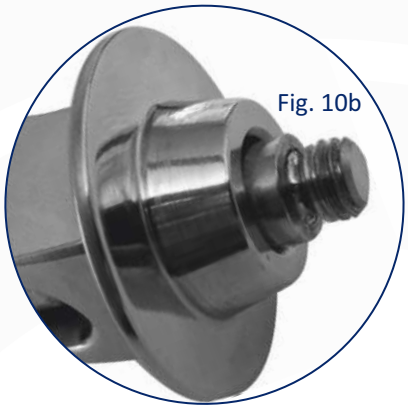


Fig. 10b

Fig. 11

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

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

Fig. 12a

Cup locked

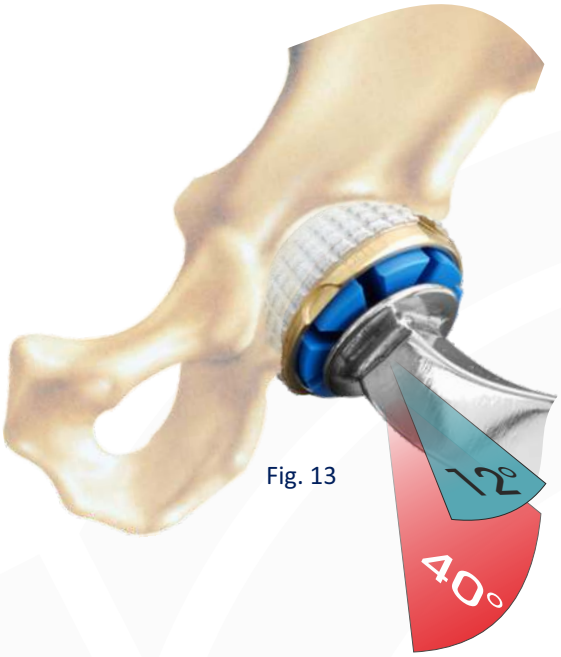


Fig. 13

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. 14

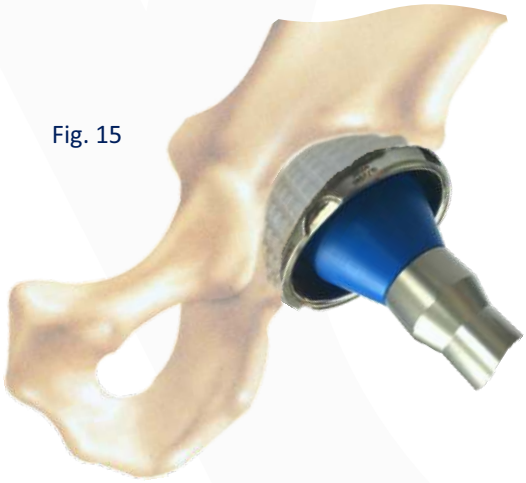


Fig. 15

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 ostophytes or protuberances that can be found along the rim, which may limit joint function and mobility.

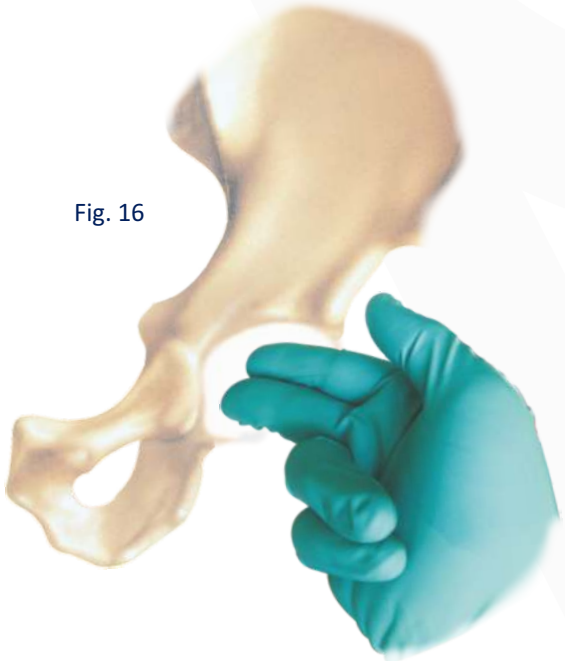


Fig. 16

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 (eveuntually slightly impacting with a hammer) and apply a continuous pressure untill complete hardening of the bone cement occurs, removing the exceeding bone cement all around the whole perimeter of the cup.

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

CLEANING OF THE HANDLE

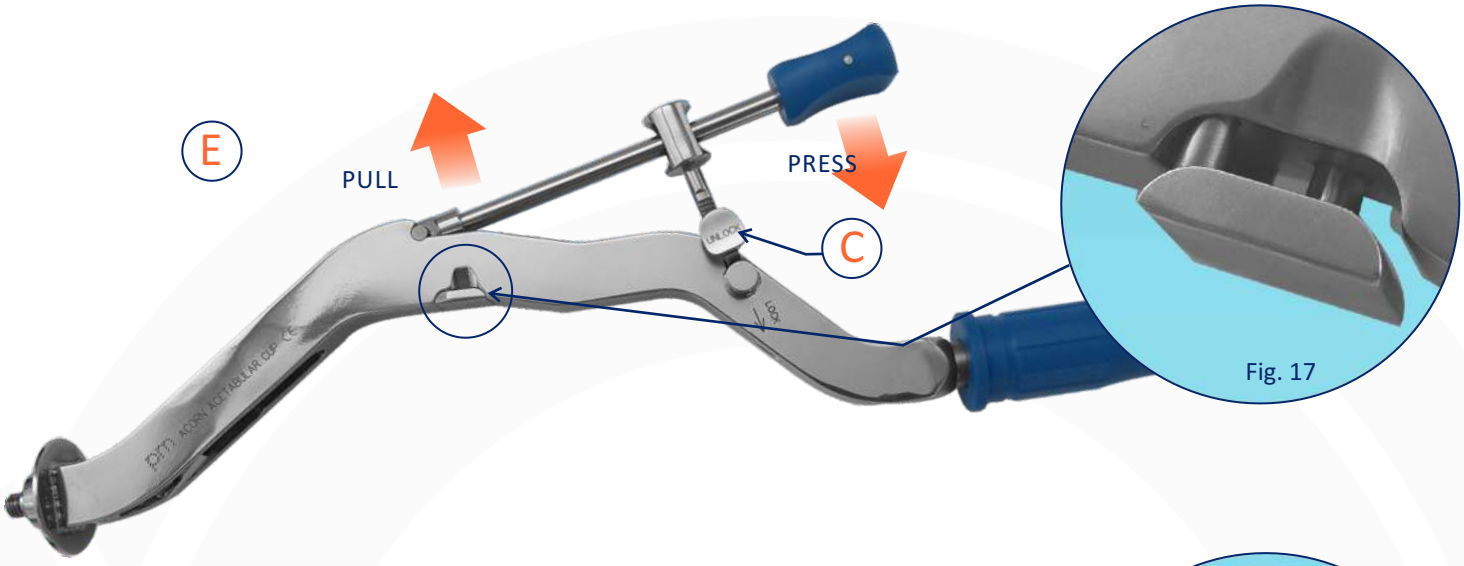


Fig. 17

The instrument can be disassembled to allow washing and sanification 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.


Fig. 18a

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

Fig. 18


Fig. 18b

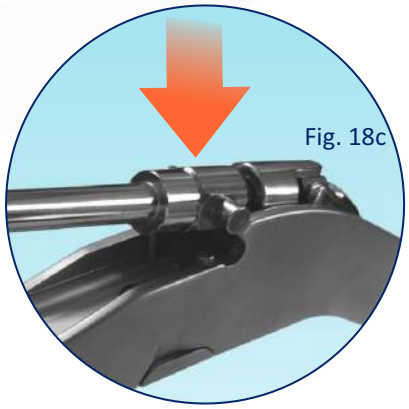


Fig. 18c

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).

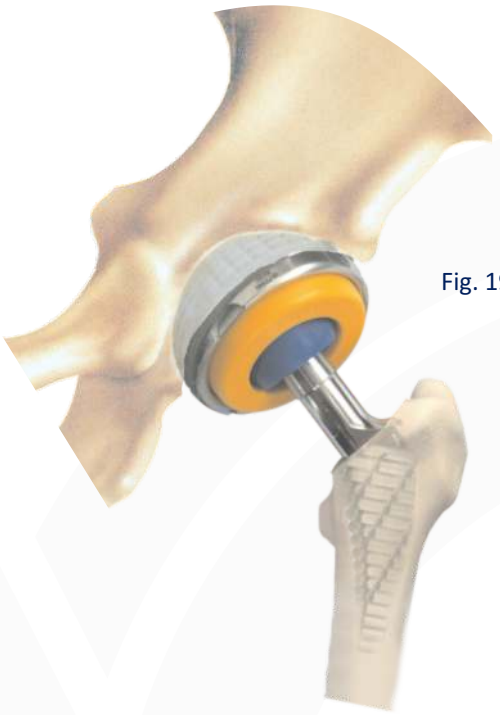


Fig. 19

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 definate 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 untill 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.*

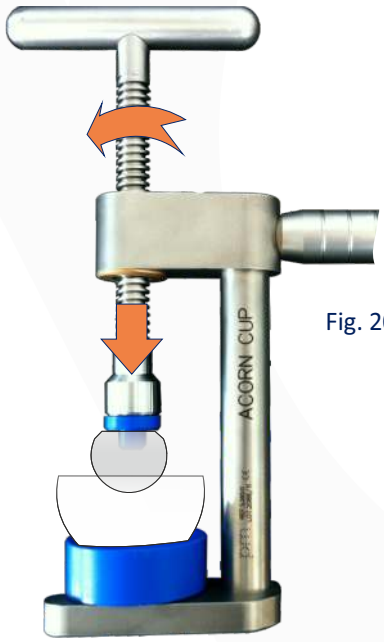


Fig. 20a

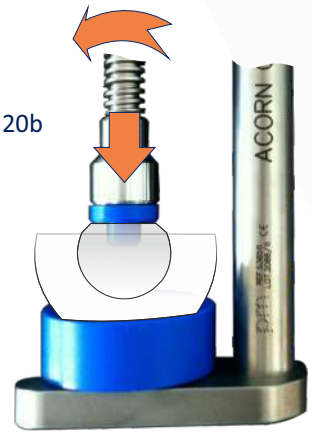


Fig. 20b

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).

POST-OPERATIVE CARE

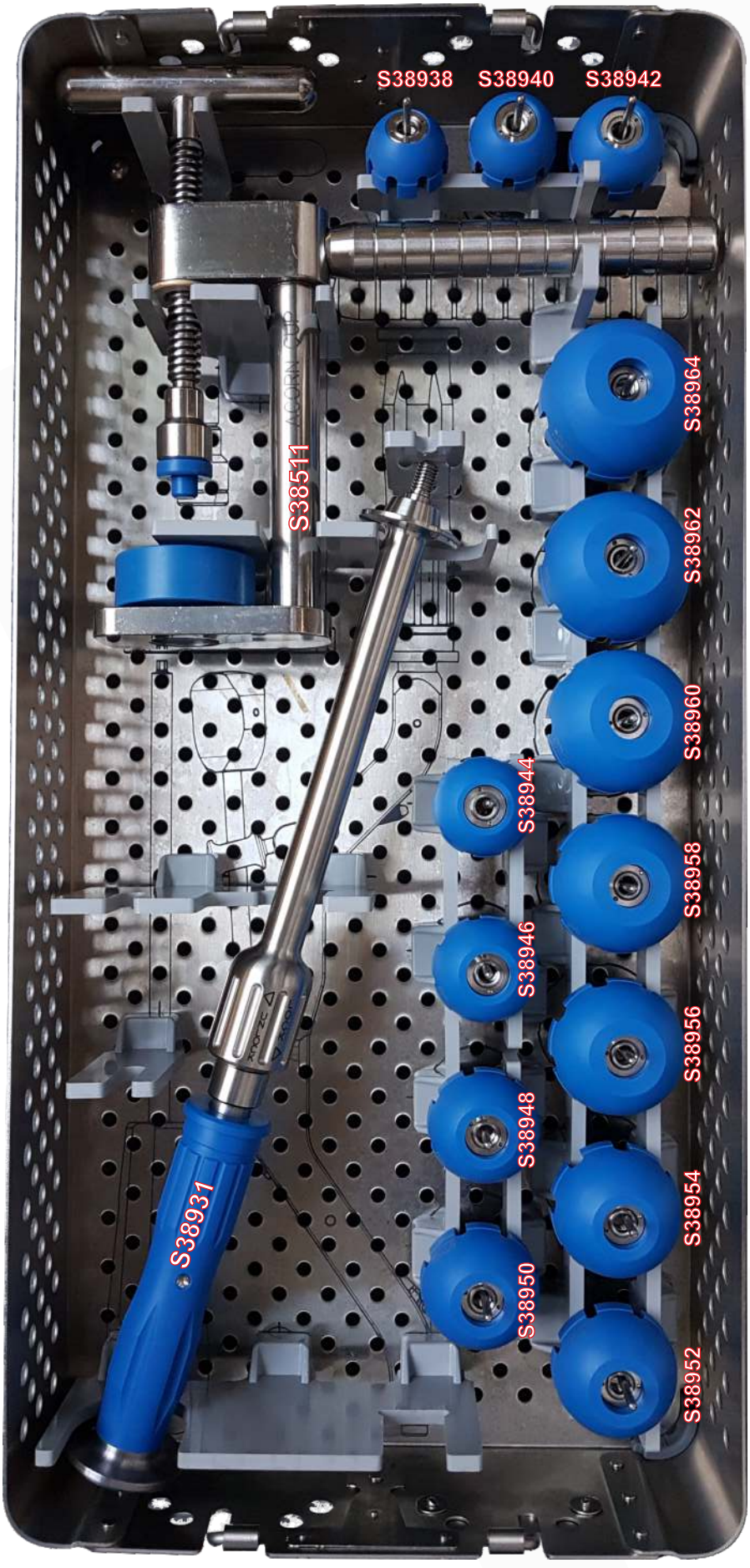
Post-op care strategy is very important to permit correct patient recovery. Guidelines are established by the Surgeon and should consider several factors such as age, weight and bony structure of the patient.

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

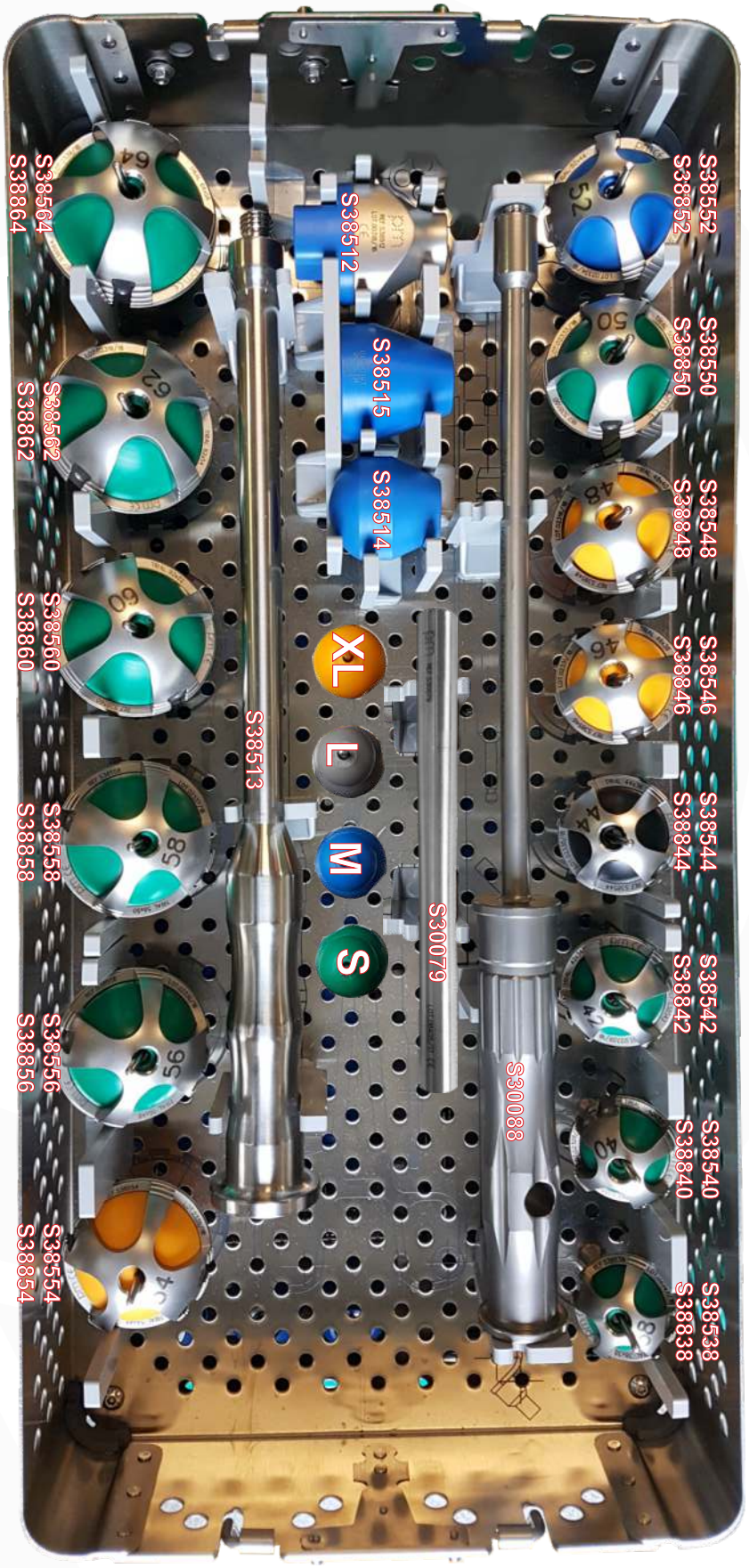
Optional Instruments

S38930	Handle for Expansion Cup Holder - CURVED

S38500 ACORN DUAL MOBILITY INSTRUMENTS SET

Tray # 2

S38502	INSTRUMENTS TRAY 2/2 - Empty
S20121	TRIAL HEAD Ø 22mm - SHORT NECK
S20122	TRIAL HEAD Ø 22mm - MEDIUM NECK
S20123	TRIAL HEAD Ø 22mm - LONG NECK
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
S30079	TOMMY BAR
S38512	ACORN: Cup Re-positioning End
S38513	ACORN: Handle
S38514	ACORN: Cup Impacting End
S38515	ACORN: Head Pushing End
S38538	ACORN: TRIAL CUP Ø 38 mm
S38540	ACORN: TRIAL CUP Ø 40 mm
S38542	ACORN: TRIAL CUP Ø 42 mm
S38544	ACORN: TRIAL CUP Ø 44 mm
S38546	ACORN: TRIAL CUP Ø 46 mm
S38548	ACORN: TRIAL CUP Ø 48 mm
S38550	ACORN: TRIAL CUP Ø 50 mm
S38552	ACORN: TRIAL CUP Ø 52 mm
S38554	ACORN: TRIAL CUP Ø 54 mm
S38556	ACORN: TRIAL CUP Ø 56 mm
S38558	ACORN: TRIAL CUP Ø 58 mm
S38560	ACORN: TRIAL CUP Ø 60 mm
S38562	ACORN: TRIAL CUP Ø 62 mm
S38564	ACORN: TRIAL CUP Ø 64 mm
S38838	ACORN: TRIAL INSERT Ø 38 mm
S38840	ACORN: TRIAL INSERT Ø 40 mm
S38842	ACORN: TRIAL INSERT Ø 42 mm
S38844	ACORN: TRIAL INSERT Ø 44 mm
S38846	ACORN: TRIAL INSERT Ø 46 mm
S38848	ACORN: TRIAL INSERT Ø 48 mm
S38850	ACORN: TRIAL INSERT Ø 50 mm
S38852	ACORN: TRIAL INSERT Ø 52 mm
S38854	ACORN: TRIAL INSERT Ø 54 mm
S38856	ACORN: TRIAL INSERT Ø 56 mm
S38858	ACORN: TRIAL INSERT Ø 58 mm
S38860	ACORN: TRIAL INSERT Ø 60 mm
S38862	ACORN: TRIAL INSERT Ø 62 mm
S38864	ACORN: TRIAL INSERT Ø 64 mm



**References with asterisk are available on special request*

ACORN Dual Mobility Cups

	PRIMARY		CEMENTED	
	HaX-Pore	HaX-Pore BIOLOY®	Cemented	Cemented BIOLOY®
size Ø	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 reference	VITAL-E® reference	VITAL-XE® reference
22 mm	38mm	38838	38838E	38838XE*
	40mm	38840	38840E	38840XE*
	42mm	38842	38842E	38842XE*
	44mm	38844	38844E	38844XE*
	46mm	38946*	38946E*	38946XE*
	48mm	38948*	38948E*	38948XE*
	50mm	38950*	38950E*	38950XE*
	52mm	38952*	38952E*	38952XE*
	54mm	38954*	38954E*	38954XE*
	56mm	38956*	38956E*	38956XE*
	58mm	38958*	38958E*	38958XE*
	60mm	38960*	38960E*	38960XE*
	62mm	38962*	38962E*	38962XE*
	64mm	38964*	38964E*	38964XE*

Ø inner	size Ø	UHMWPE reference	VITAL-E® reference	VITAL-XE® reference
28 mm	46mm	38846	38846E	38846XE*
	48mm	38848	38848E	38848XE*
	50mm	38850	38850E	38850XE*
	52mm	38852	38852E	38852XE*
	54mm	38854	38854E	38854XE*
	56mm	38856	38856E	38856XE*
	58mm	38858	38858E	38858XE*
	60mm	38860	38860E	38860XE*
	62mm	38862	38862E	38862XE*
	64mm	38864	38864E	38864XE*

Information

INTENDED PURPOSE:

ACORN dual mobility cup is an acetabular component utilized in Total Hip Replacement procedures in combination with it's 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 it's characteristics, the dual mobility cup is pasrticularly 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 $Ca_{10}(OH)_2(PO_4)_6$

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 amendements.

WARNINGS, INDICATIONS AND CONTRAINDICATIONS

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.

Controindications

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 ioint 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 allergenic sensibility towards metal (nickel) and should carry out the requisite postoperative monitoring for inflammation or allergenic 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 of use 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 alterated 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 histocitosy 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 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, 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 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.

Endoprostheses 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.

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