JUMP® System 3

Pressfit Cup

SURGICAL TECHNIQUE

CE 0426

permedica
ORTHOPAEDICS

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.

PRESS-FIT ACETABULAR CUPS

JUMP® System

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 Ø 6,5mm 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.

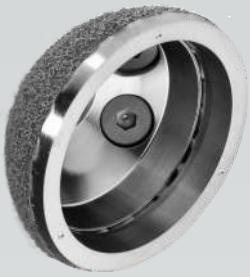
The instrumentation was designed to be simple and precise and to assist the surgeon in the correct implantation of the acetabular component.

WARNINGS:
Although the implantation of a press-fit cup has became 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.

INDICATION FOR USE

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.*

Use of the JUMP® System cup device 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;
- ✓ coxarthritis;
- ✓ Post-traumatic arthritis
- ✓ congenital hip dysplasia
- ✓ epiphysiolisis.

SURGICAL PROCEDURE

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:

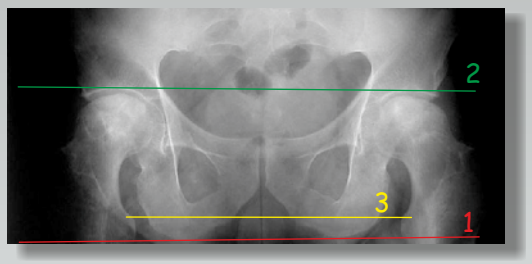


Fig. 1: pre-operative planning

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

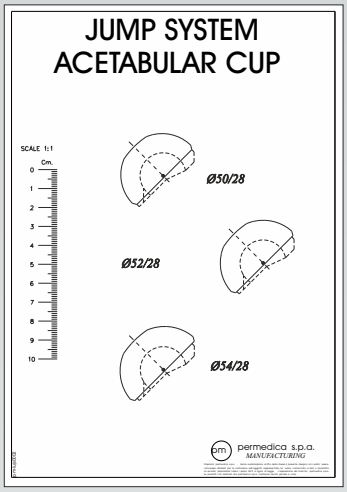
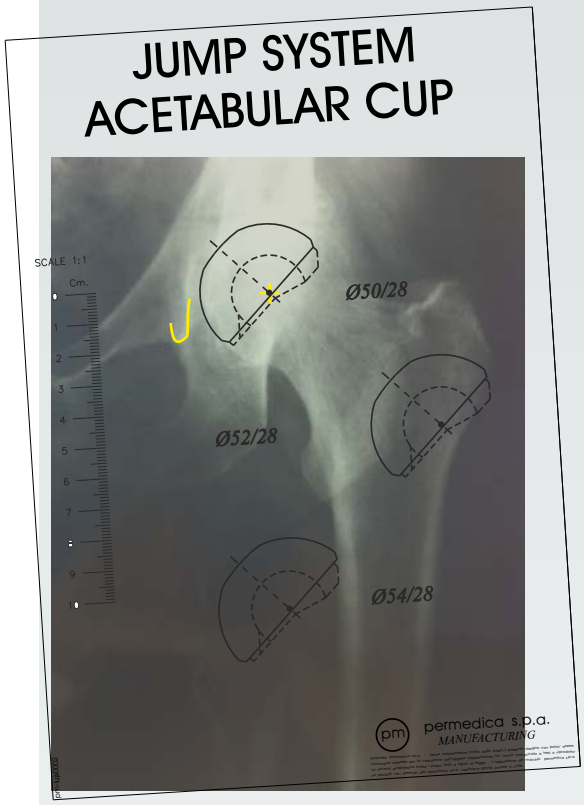


Fig. 1b: size evaluation

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.



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").

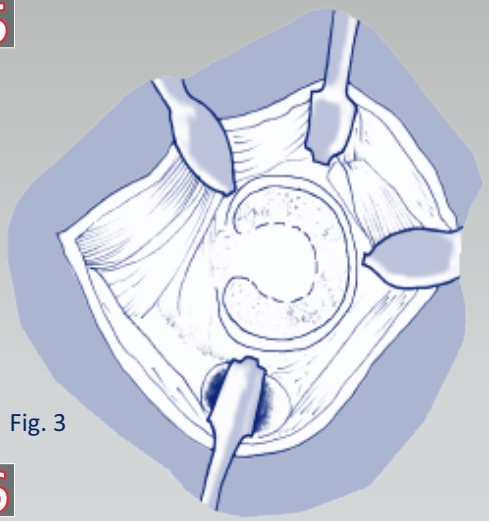


Fig. 3

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.

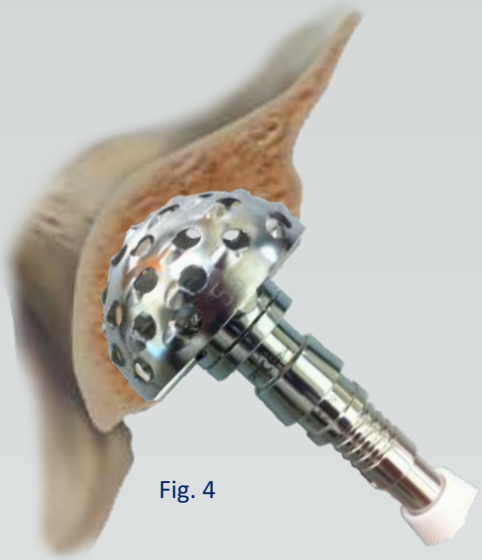


Fig. 4

** 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

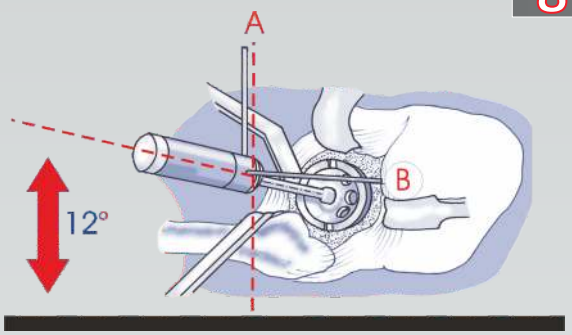


Fig. 6: Anteversion

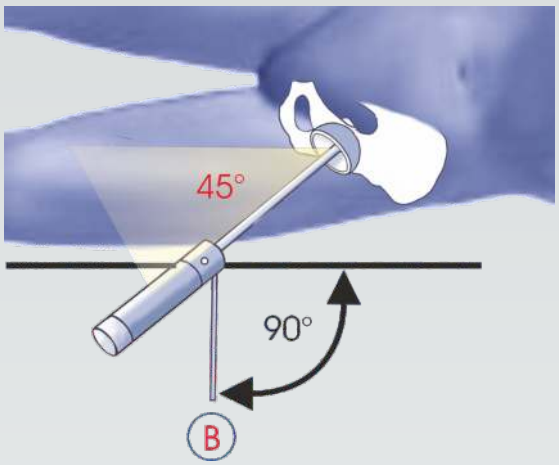


Fig. 7: Inclination

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 Ø 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 UNDESIRED BREAKAGE.

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 Ø 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 Ø3.5 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 onte 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, Ø 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.

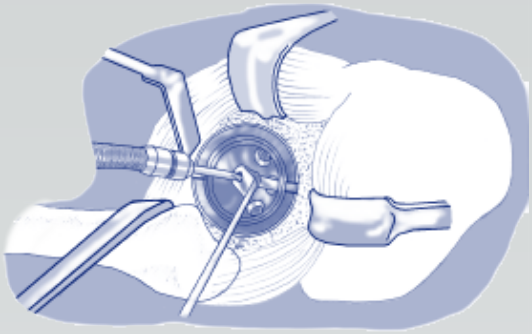


Fig. 8: Hole drilling

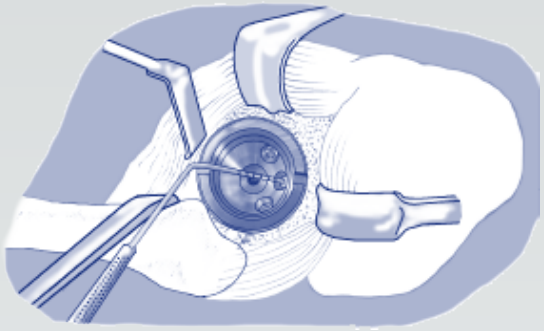


Fig. 9: Depth gauging

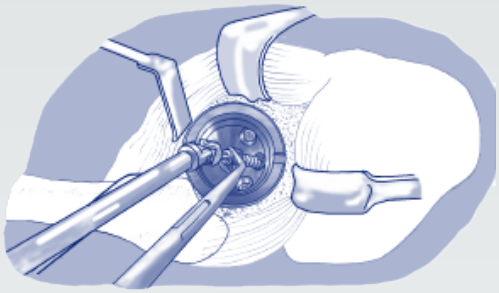


Fig. 10: Screw insertion

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

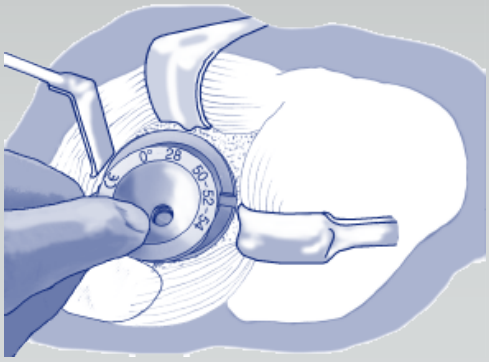


Fig. 11: Insertion of the Trial Insert

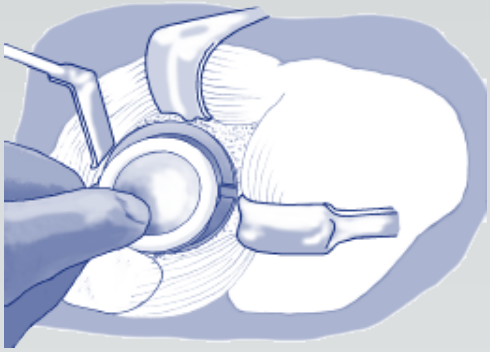


Fig. 12: Insertion of the definitive UHMWPE insert

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.

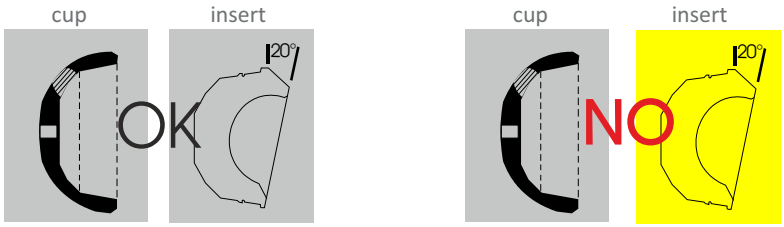
In case of dislocation, it is possible to use a hooded insert with 20° rim for better coverage of the area of concern. In case of serious ligament and/or muscolar deficit, a retentive insert can be used.

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).

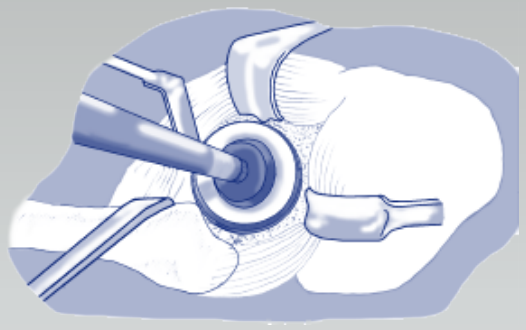


Fig. 13: Impaction of the UHMWPE insert

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 CERAMI 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 proceding 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. 14a Fig. 14b Fig. 14c

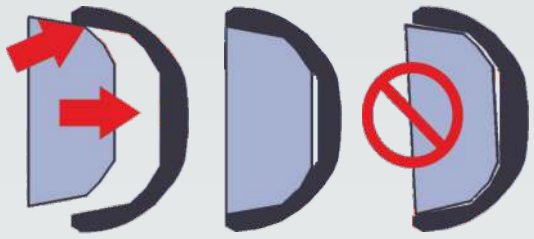


Fig. 14: correct insertion of the ceramic insert

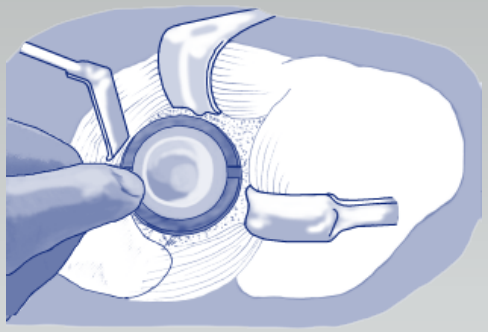


Fig. 15: placement of the ceramic insert

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).

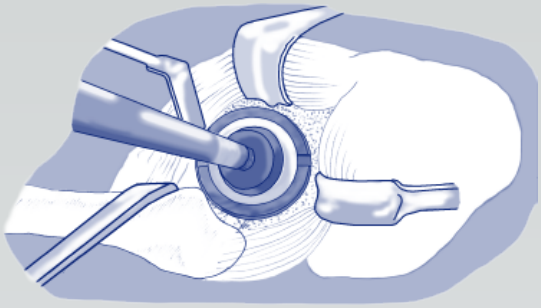


Fig. 16: Impaction of the ceramic insert

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 Balll Impacting Head (S30026, S30092, S35015) mounted on the Insert Impactor Handle (S30012) (Fig. 16).

13 REMOVAL OF THE CERAMIC LINER

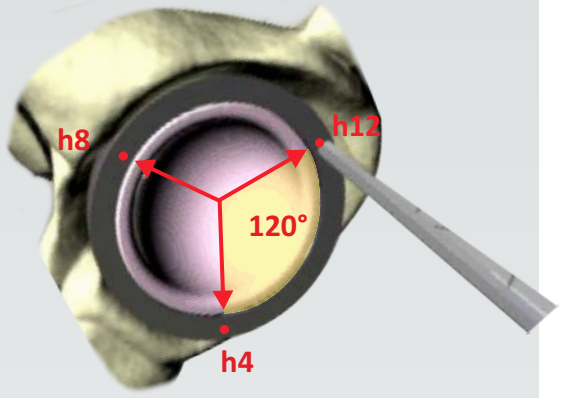


Fig. 17

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.

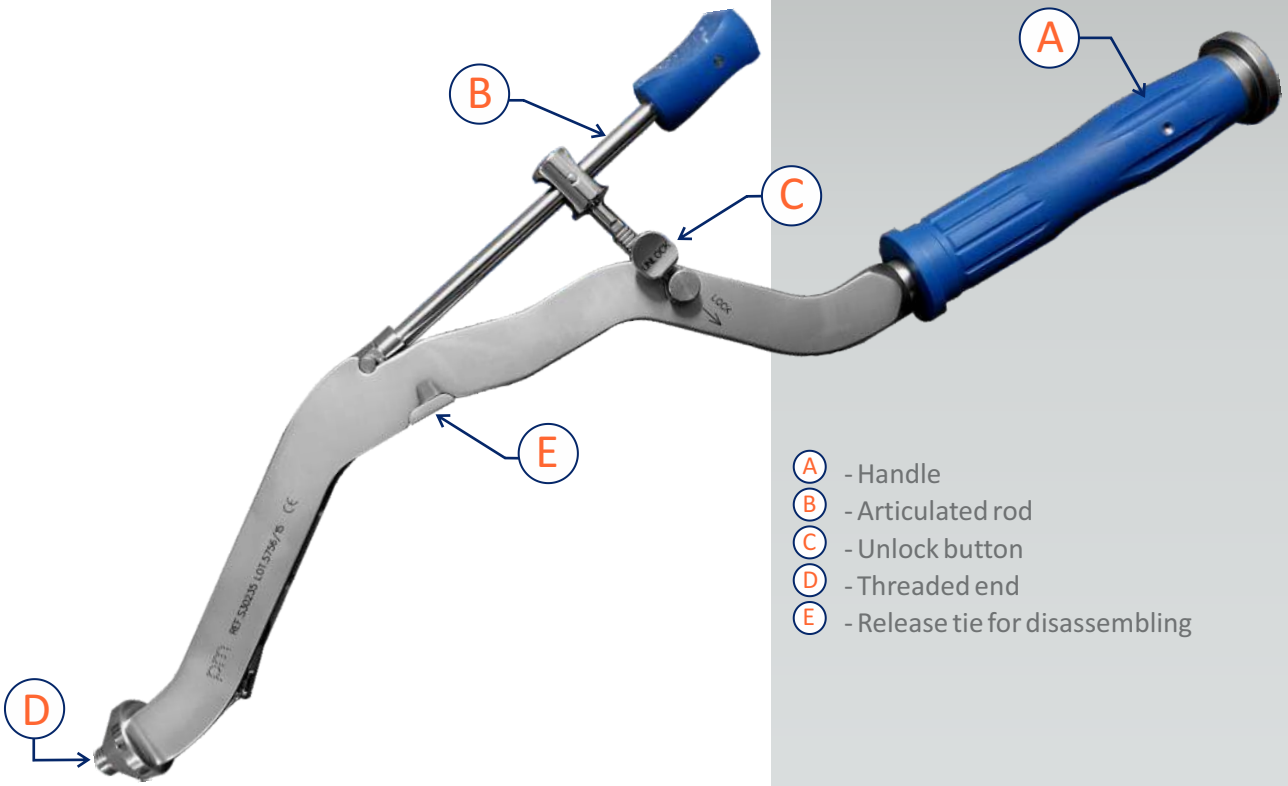
POST-OP CARE

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

APPENDIX 1

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).

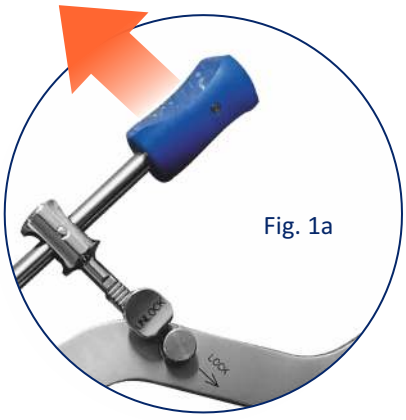


Fig. 1a

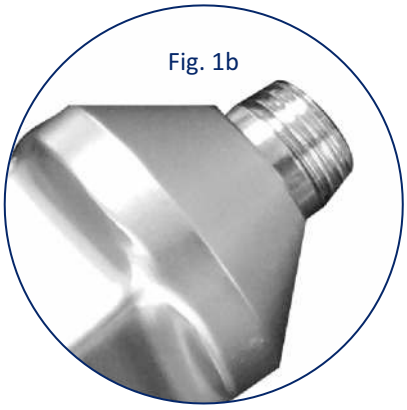


Fig. 1b

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).

Fig. 2b

Fig. 2a

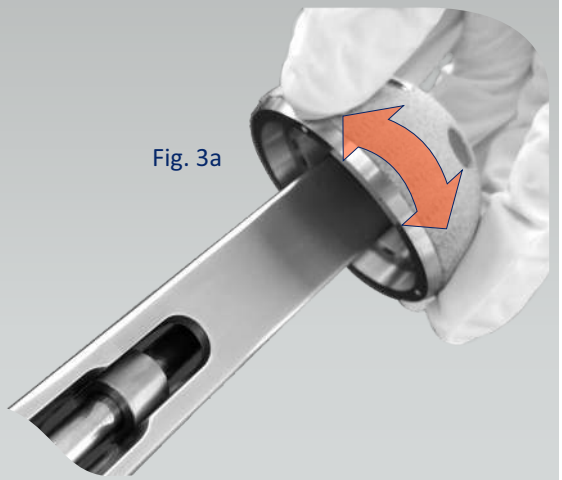


Fig. 3a

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. 3b

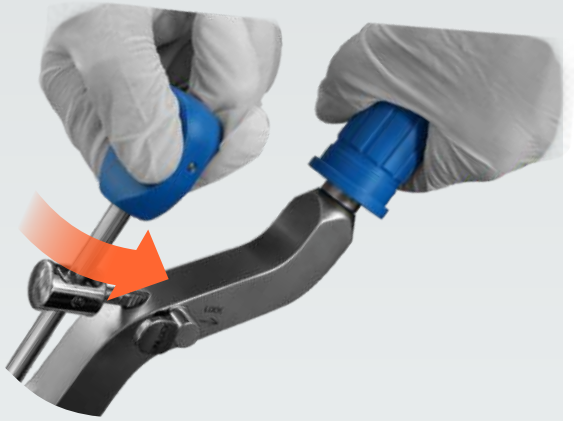
CUP IMPLANTATION

Fig. 4a

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. 4b



CLEANING OF THE HANDLE

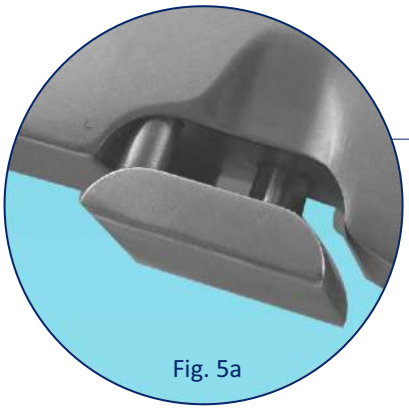
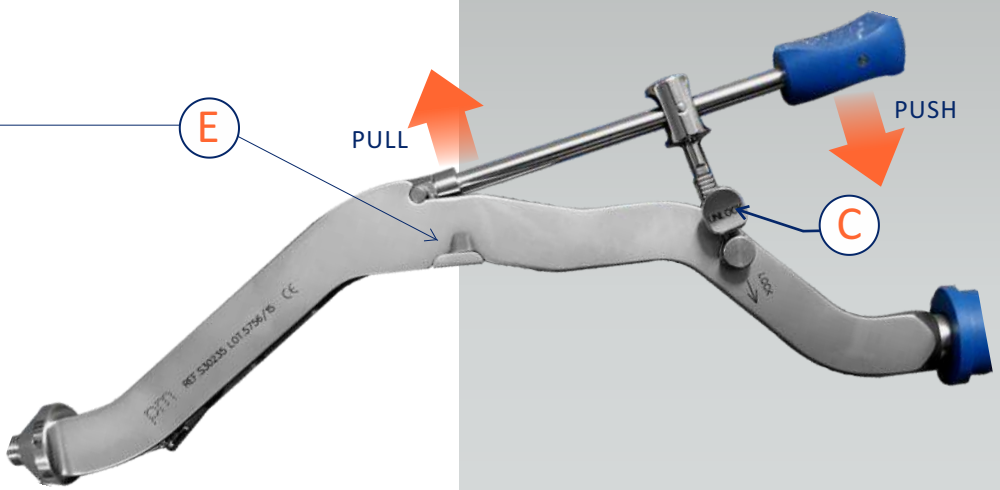


Fig. 5a



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. 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).

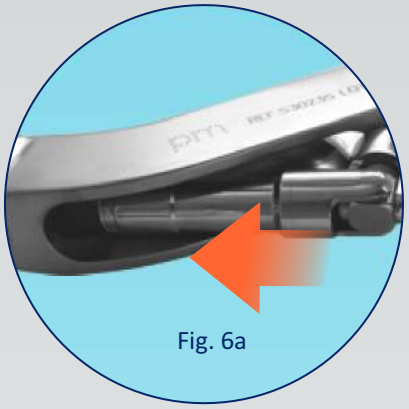


Fig. 6a

Fig. 6

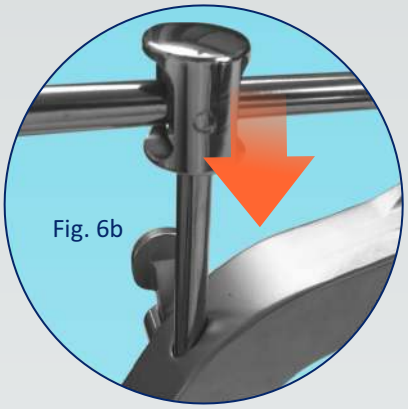


Fig. 6b

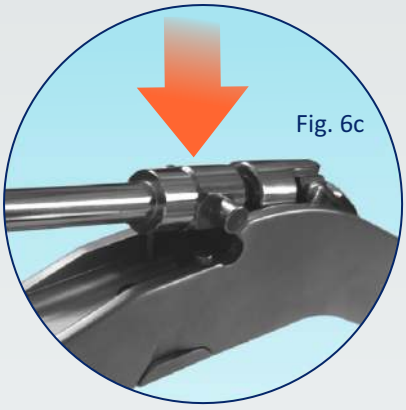


Fig. 6c

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

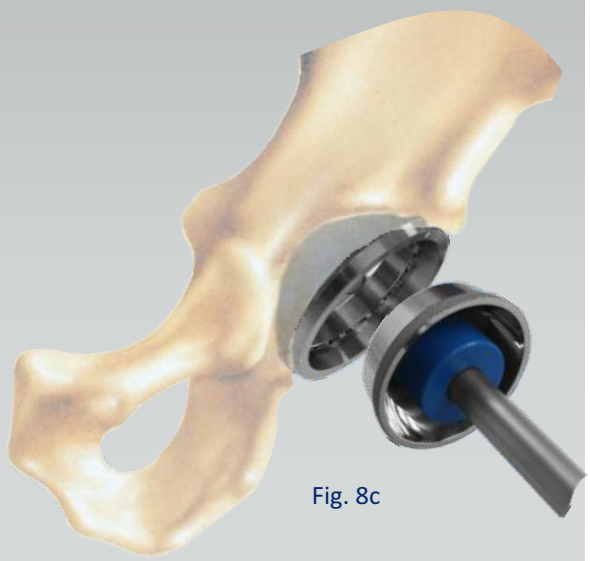


Fig. 8c

The Trial components for the Dual Mobility option are marked with the JUMP SYSTEM color coding. Marking is reported on the Metal Trial Adater 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. 7

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

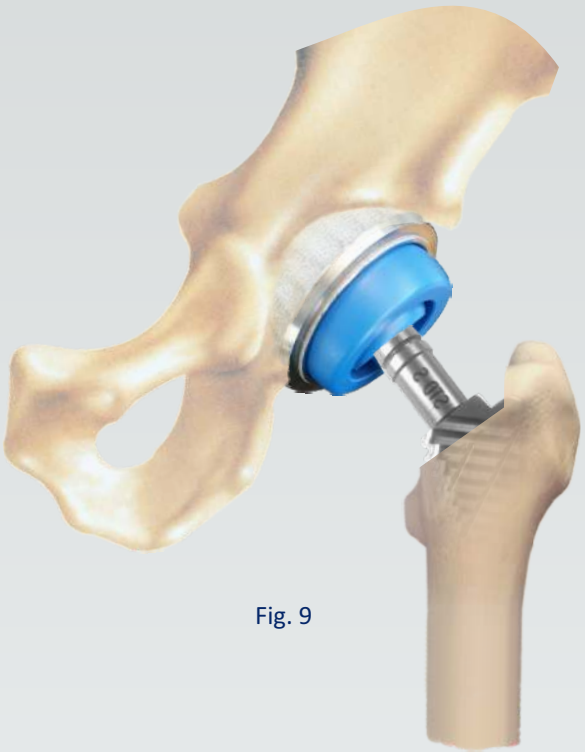
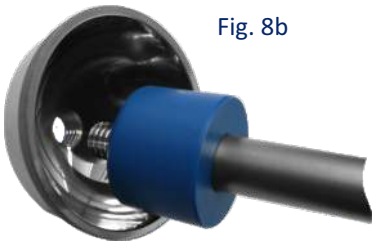


Fig. 9

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. 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 Adater.

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.

Fig. 10a

Fig. 10c

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.

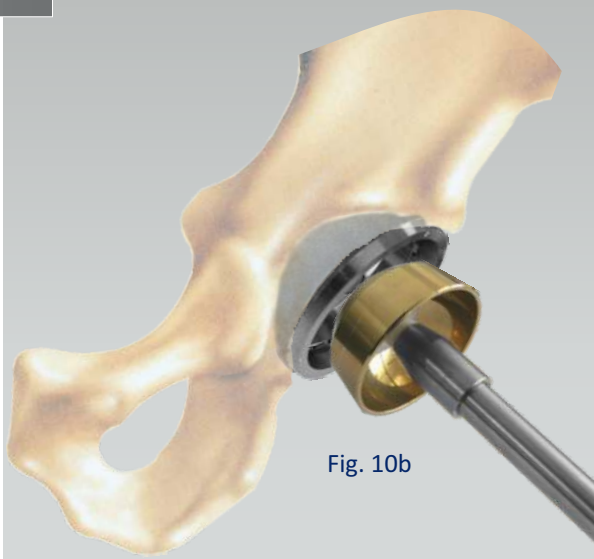


Fig. 10b

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 untill 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.*

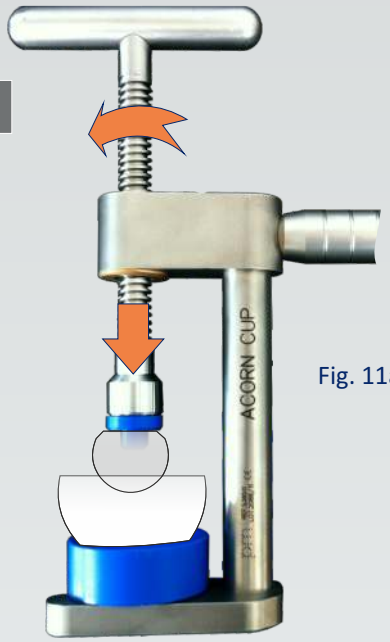


Fig. 11a

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).

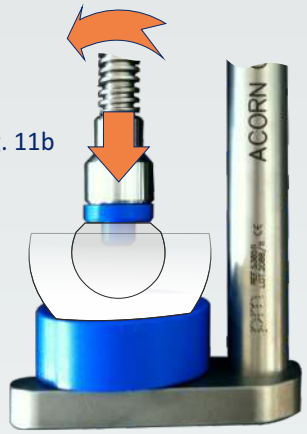
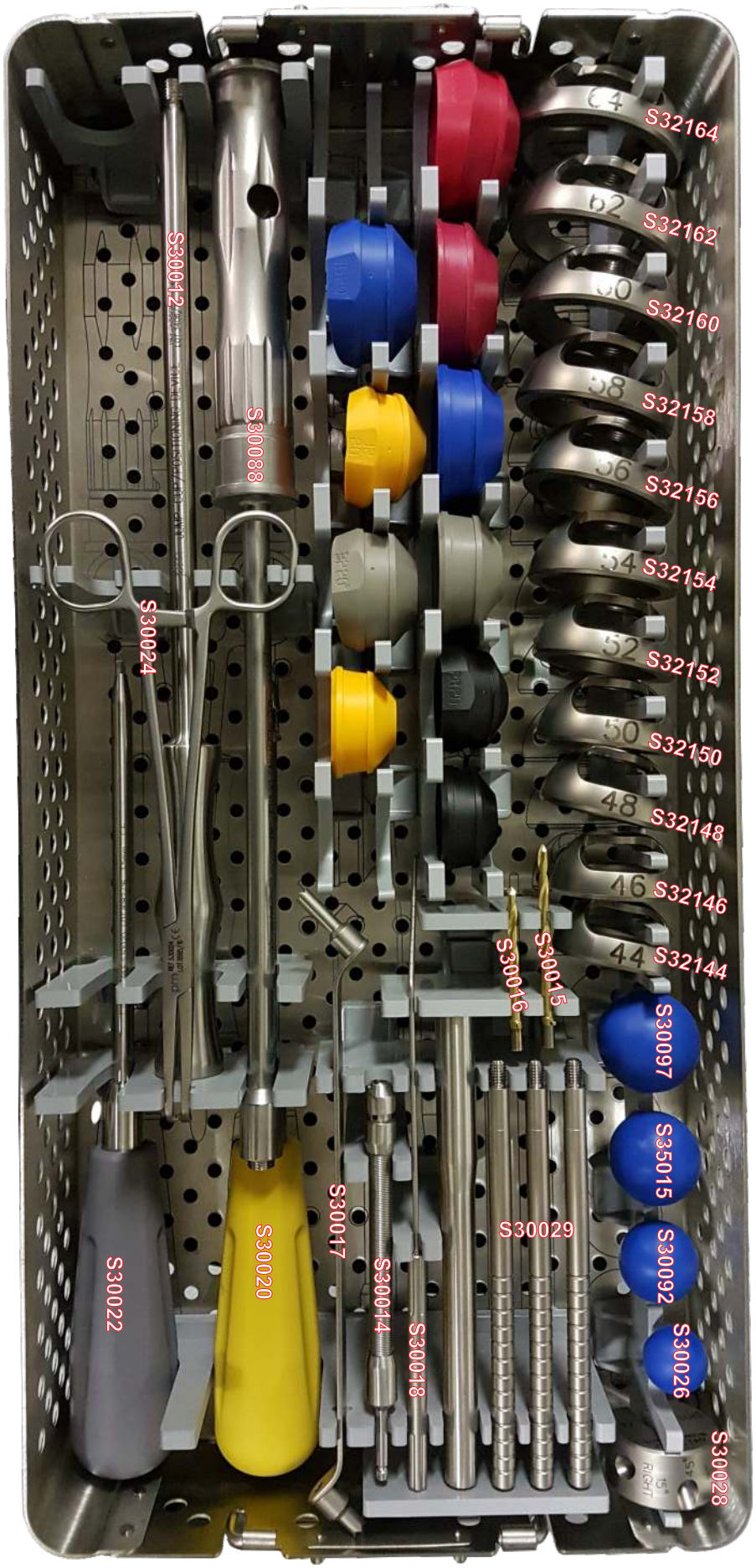


Fig. 11b

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 S35102

DUAL MOBILITY OPTION

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

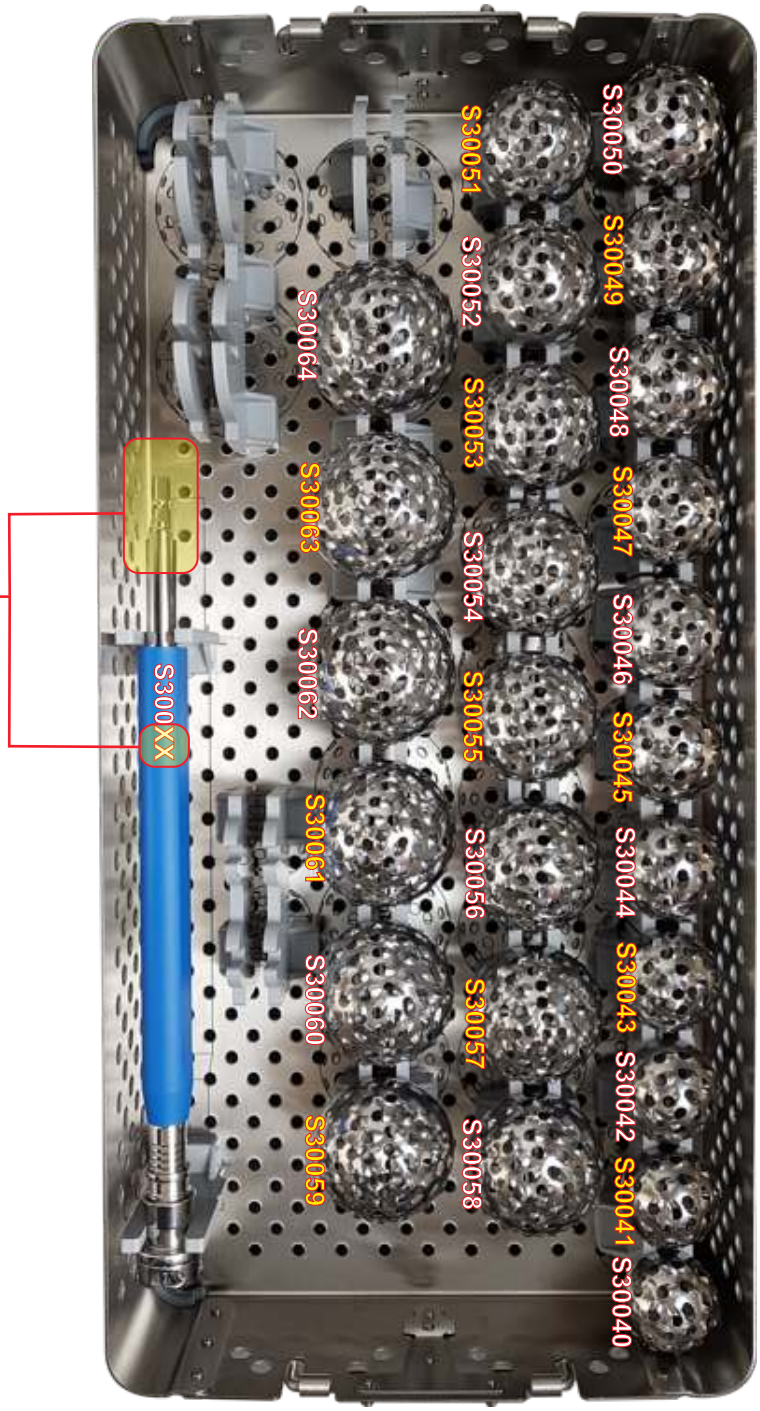
S30101 ACETABULAR REAMERS SET

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.

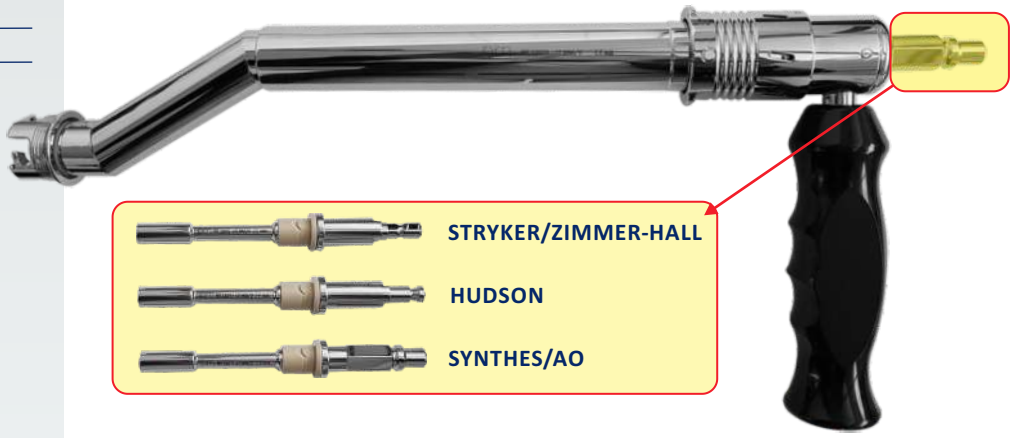
Optional Instruments (on request)

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



Reference Table * References with asterisk are available on request

JUMP SYSTEM Cementless Press-Fit Cups

Class III

Accepting all types of inserts

* References with asterisk are available ON REQUEST

SIZE	Standard Reference	X-Pore Reference	HA Reference	HaX-Pore 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

WITH HOLES

Size	Standard Reference	X-Pore Reference	HA Reference	HaX-Pore 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

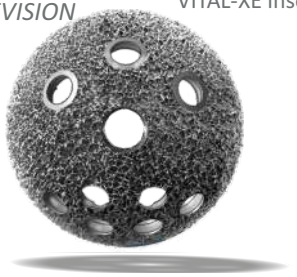
Class III

TRASER®

Accepting all types of inserts

TRASER® REVISION

Accepting PE and VITAL-XE inserts only



SIZE	TRASER® Reference	SIZE	TRASER® REVISION 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*
		72	39472*
		74	39474*
Special sizes on request		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

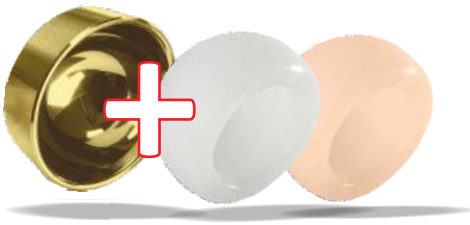
Reference Table

** References with asterisk are available on request*

JUMP® SYSTEM Dual Mobility option

Class III

BIOLOY®



CUP SIZE	BIOLOY® PM734 reference	BIOLOY® CrCo reference	UHMWPE reference	VITAL-XE® reference	Color Coding	inner Ø
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 0° Reference	UHMWPE 10° Reference	UHMWPE 20° Reference	VITAL-XE® 0° Reference	VITAL-XE® 10° Reference	VITAL-XE® 20° Reference	BIOLOX® Delta 0° Reference
22mm	36303*		36304*				
28mm Neutral 0°	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	
	36307	36366	36308	36307XE	36366XE	36308XE	
	36309	36367	36310	36309XE	36367XE	36310XE	
32mm Hooded 10°	36313	36368	36314	36313XE	36368XE	36314XE	36011
	36319	36369	36320	36319XE	36369XE	36320XE	36016
	36340	36376	36342	36340XE	36376XE	36342XE	36015
	36315	36370	36316	36315XE	36370XE	36316XE	36017
	36317	36371	36318	36317XE	36371XE	36318XE	36018
36mm Hooded 20°				36380XE	36382XE	36381XE	36022
	36343	36378	36345	36343XE	36378XE	36345XE	36025
	36325	36329	36326	36325XE	36329XE	36326XE	36026
	36327	36330	36328	36327XE	36330XE	36328XE	
40mm	36346		36347	36346XE		36347XE	36041
	36348		36349	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 Oxyde (ETO) or accelerated electron beam irradiation (þ 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 amendements.

Materials

CUPS, SCREWS, PLUGS:

Titanium Aluminium Vanadium Ti_6Al_4V 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 ($Al_2O_3 + ZrO_2$) - ISO6474.

Metal Dual Mobility:

- PM734 higly nitrogenized Stainless Steel forged alloy ISO5832/9
- CrCoMo forged alloy ISO5832/12

SURFACE FINISHING:

HaX-Pore: 500µm pure Titanium + 40µm Hydroxyapatite $Ca_{10}(OH)_2(PO_4)_6$ applied with plasma spray technique.

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

HA: 80µm Hydroxyapatite $Ca_{10}(OH)_2(PO_4)_6$ applied with plasma spray technique.

Standard: microstrudtured sandblasted surface roughness 4-6µm.

BIOLOY®: TiNbN coating (Dual Mobility inserts)

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). **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 dieases.
- 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.

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 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 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 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 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 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 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 can not 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 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 alterated 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 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 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 utilyzing 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 utilyzing 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 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 utilyzing 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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