permedica
ORTHOPAEDICS

BI-POLAR HEAD

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.

Bi-Polar Head

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

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

Two versions are available:

☑ **Monobloc** version:

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

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

☑ **Modular** version:

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

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

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

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

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

INDICATIONS FOR USE

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

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

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

SURGICAL PROCEDURE

PRE-OPERATIVE PLANNING 1

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

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

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WARNING:

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

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

SURGICAL ACCESS 2

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

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

JOINT EXPOSURE 3

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

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

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

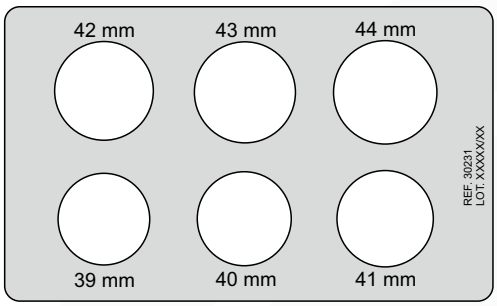
With a diathermic technique small vessels are cauterized.

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

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

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

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



4 PREPARATION OF THE IMPLANT SITE

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

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

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

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

5 USE OF THE TRIAL BI-POLAR HEADS

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

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

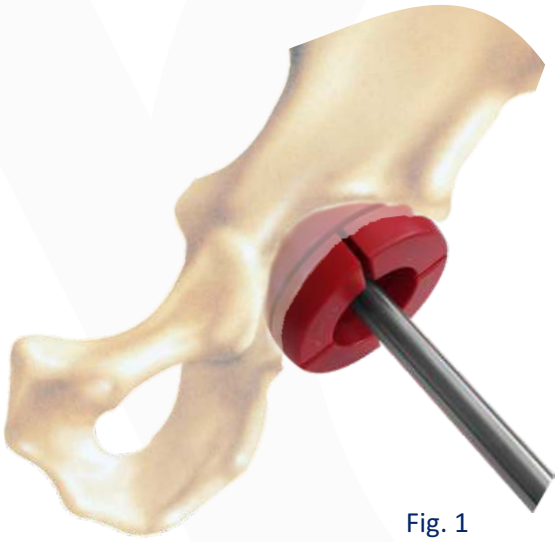


Fig. 1

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

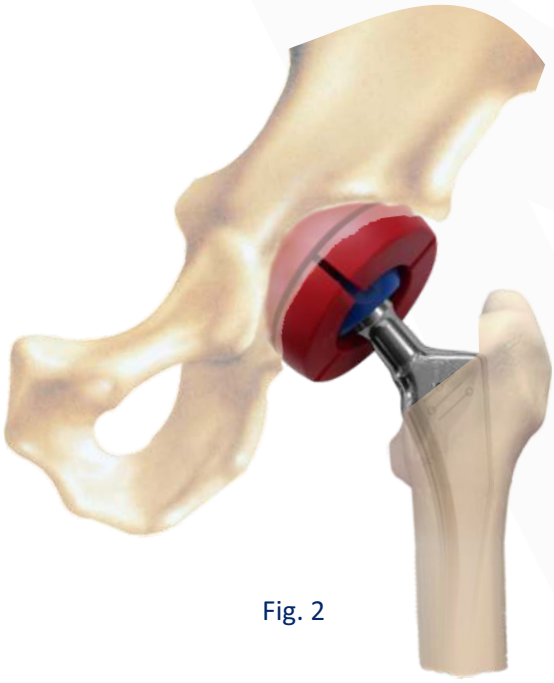


Fig. 2

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

IMPLANTATION OF THE DEVICE 6

MODULAR version

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

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

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

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

Fig. 3a

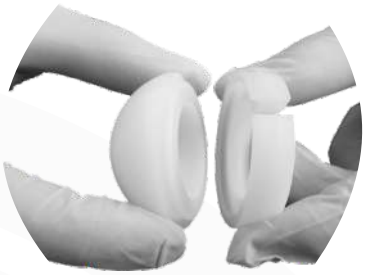


Fig. 3b

Fig. 3c

Fig. 3d

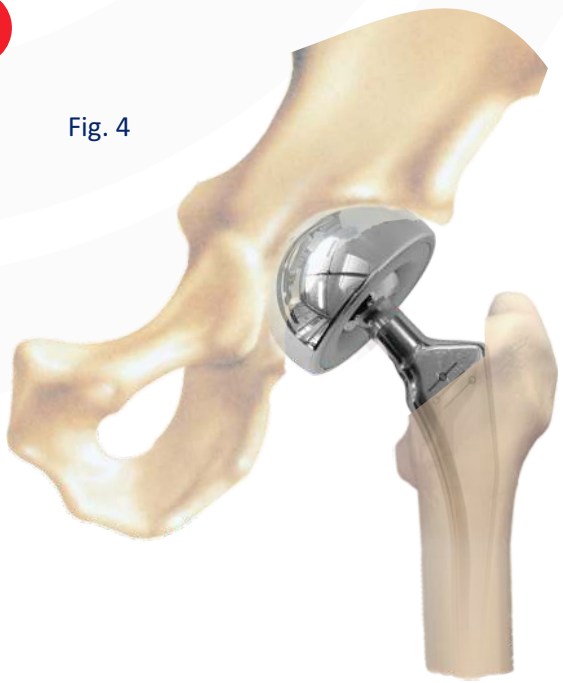
IMPLANTATION OF THE DEVICE 7

MONOBLOC version

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

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

Fig. 4



8 REMOVAL OF THE DEVICE

MONOBLOC version

Fig. 5a

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

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

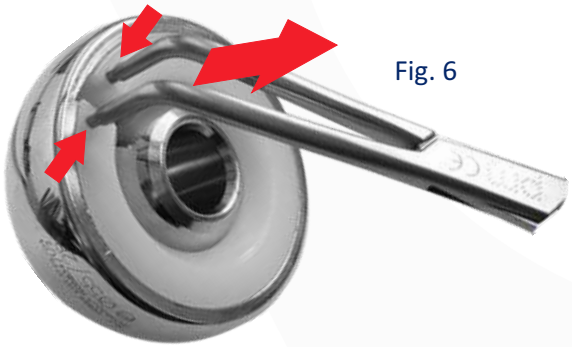
Fig. 5b

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

9 REMOVAL OF THE DEVICE

MODULAR version

Fig. 6



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

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

POST-OP CARE

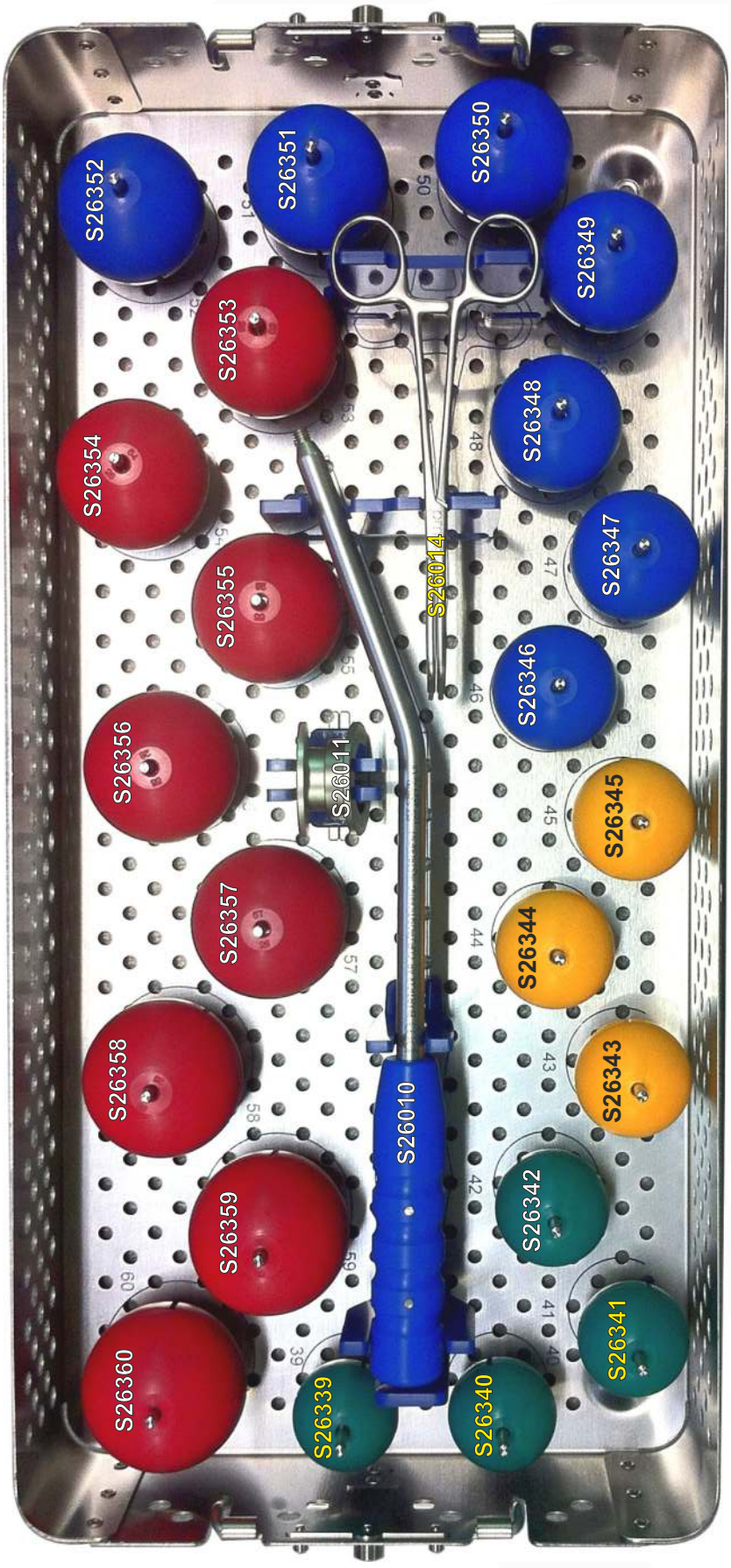
Post-op care strategy is very important to allow the patient a correct recovery. The guidelines are established by the Surgeon and should consider several factors such as age, weight and bony structure of the patient.

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

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

BI-POLAR HEAD INSTRUMENTS SET

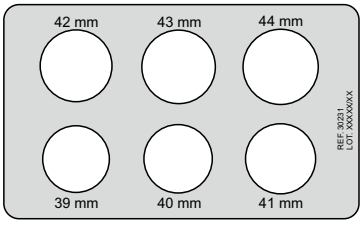
S26100 MONOBLOC
S26900 MODULAR



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

Additional Instruments for Modular version	
Extraction forceps	S26014
Trial Bi-Polar Head Ø 28x39	S26339
Trial Bi-Polar Head Ø 28x40	S26340
Trial Bi-Polar Head Ø 28x41	S26341

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



Reference Table * Codes with asterisk are available untill stock lasts

Bi-Articular Cup - Monobloc

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

Bi-Articular Cup - Modular

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

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

Information

INTENDED PURPOSE:

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

MATERIALS:

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

METAL SHELL- MODULAR: AISI316 stainless steel alloy - ISO5832/1.
PM734 highly nitrogenized Stainless Steel forged alloy - ISO5832/9.

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

STERILIZATION:

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

Validity: 5 years.

CLASSIFICATION:

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