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Instructions to the attention of the qualified surgeon and the operating room personal

FILLER-3ND cemented and cementless femoral stems
SINGLE USE STERILE IMPLANTS

EN

1. DESCRIPTION

BIOTECHNI supplies a range of hip prostheses including femoral stems, femoral heads.
The FILLER-3ND stem is available in cemented (uncoated) and cementless (coated) versions; the kind of coating is mentioned on the product label: Ti for porous titanium, HA for hydroxyapatite (ISO 13779-2). Coated stems are made in titanium alloy (TA6V ISO 5832-3) and uncoated stems are made in stainless steel (ISO 5832-9). Femoral heads are available in stainless steel (ISO 5832-9) or Biolox®Delta alumina ceramic (BIOLOX®delta is a high-purity alumina matrix with zirconia reinforcement in accordance with ISO 6474-2.).
Materials are mentioned on each product label.

2. IMPLANTS IDENTIFICATION

Medical devices listed hereafter are CE 1639 marked according to the Directive 93/42/CEE.
Note: « x » and « y » represent various dimensions:

Reference	Description
FI040xx	FILLER-3ND 135° cementless femoral stem Ti+HA coated
FIC040xx	FILLER-3ND 135° cementless femoral stem collared Ti+HA coated
FI043xx	FILLER-3ND 130° varized femoral stem Ti+HA coated
FI044xx	FILLER-3ND 130° lateralized femoral stem Ti+HA coated
FI050xx	FILLER-3ND 135° femoral stem Ti coated
FI041xx	FILLER-3ND 135° cemented stainless steel smooth femoral stem
FI020xx	Long FILLER femoral stem HA coated
INxx.0yy	5°43’ Stainless steel femoral head
CERxxx-yy	BIOLOX® Delta femoral head 5°43’

3. COMPATIBILITY

FILLER-3ND femoral stems are compatible with all acetabular cups and inserts supplied by BIOTECHNI. Metallic femoral heads are fully compatible with all the acetabular inserts supplied by BIOTECHNI (except the ceramic inserts). Ceramic heads are fully compatible with all the acetabular inserts supplied by BIOTECHNI. The 5°43’ stainless steel and ceramic femoral heads are compatible with femoral stems supplied by BIOTECHNI, with the following exception**: Do not use femoral heads with extra-long neck (+7 or more) with lateralized stems all sizes, or with EASY1010, EASY1212 stems of the BIOTECHNI’s range.**
A femoral head must be used in association with a femoral stem and an acetabular cup (metallic and ceramic heads) or bipolar cup (metallic heads only). Medical devices listed hereafter are CE 1639 marked according to the Directive 93/42/CEE.

See appendix A1:

- ICERAMxx-yy : Ceramic insert
- MU-DBxx-yyyy : Polyethylene insert
- IDMxx-yy+ : Dual mobility polyethylene insert APOGEE
- CI60xx / CI60xx-22 : Bipolar cup SNAPFIT
- CAPxx ; CAPCxx : APOGEE acetabular cup
- C6DBxx-yy : GYPTIS acetabular cup
- MU-Txx : Coated MULTI acetabular cup
- CIG-xxTH : Coated IGLOO 18° acetabular cup
- TTHR5xx ; QHxx-yyy ; VCxx : Ti+HA coated reconstruction modular femoral stem & locking screw
- EASYxxyy-zzzD ; EASYxxyy-zzzG : Ti+HA coated reconstruction monobloc femoral stem

The FILLER-3ND stem in cemented version is intended to be used in association with a PMMA-based bone cement (with or without antibiotics) for the fixation of joint prostheses, compliant with ISO 5833 standard. Refer to the instructions of bone cement manufacturer.

4. INDENTED PURPOSE

FILLER-3ND femoral stems and femoral heads are intended for use in hip hemiarthroplasty (except for Biolox® Delta femoral heads) and total hip joint arthroplasty. The main goal of a joint prosthesis is to reproduce the articular anatomy, reduce pain, and improve mobility to the patient. An artificial joint should only be indicated for patients who failed to respond to non-surgical management options.

5. INDICATIONS

FILLER-3ND stems and femoral heads are intended for the following cases:
- Femoral head or neck fractures (cemented and cementless versions).
- Aseptic osteonecrosis of the femoral head (cementless version).
- Arthrosis (cemented and cementless versions).
- Rheumatoid arthritis and post-traumatic arthritis (cementless version).
- Total replacement of articular hip prosthesis; (cementless version).
- Partial replacement of articular hip prosthesis (cementless version, except for Biolox® Delta femoral head);
- The implants are intended to be used on adult patients (skeletally mature);

6. CONTRAINDICATIONS / RISK FACTORS

Conditions which can severely affect the success of the implantation:
- Any local, acute, or chronic infection. Any infectious illness. Fever or leucocytosis.
- Systemic and metabolic disorders. Any mental or neuromuscular disorder.
- Deficient bone stock, osteopenia and/or severe osteoporosis.
- Drug, tobacco and/or alcohol addiction and/or abuse.
- Intense physical activity.
- Proved or suspected sensitivity to materials.
- Tumor unresectable or residual.
- Non terminated skeletal development.
- Pregnancy, obesity or overweight (BMI >25).

These contraindications are of general order and not exhaustive, and the surgeon will have to evaluate each patient, in order to determine the risks specific to the surgery and the benefit for the patient.

7. PRECAUTIONS

- In order to determine the size of implants, the surgeon should use the X-ray preoperative templates put at his disposal. Check very carefully the association between bone loosening and the size of implants. It is under the responsibility of the surgeon to evaluate these parameters and to decide the date and intensity of progressive reload for the treated limb, according to its bone reconstruction.

– Check the integrity of the packaging and the labelling before opening the packaging.
– The implants must be handled and/or implanted by well-trained, qualified surgeons aware of these instructions for use and having detailed knowledge and experience of orthopaedic preoperative and surgical techniques, and of the potential risks associated to the operation to be performed.
– When handling the implants, avoid any contact or shock with other material or tools which may alter or damage the implant surface.
– The appropriate choices of type and dimensions of the implant, its positioning and its fixation are of prime importance to ensure the clinical success of the operation.
– The surgeon must use the instrumentation recommended in accordance with the operative technique available from the manufacturer.
– Check the absence of scratches or cracks, or any dirt on the implant before implantation.
– In situ and preoperative use of any drug product in conjunction with the implant is under the surgeon's responsibility.
– The correct functionality of the instruments should be checked before use.
– Do not put in contact with implants made of incompatible metals according to EN ISO 21534.
– The implant life within the body depends of several factors which do not allow guaranteeing that the implant withstands indefinitely to the stresses which are normally supported by the normal healthy bone. It is the surgeon's responsibility to provide to its patient before and after surgery all useful information relative to the conditions affecting the implantation success and the limits provided by the implants, mainly concerning any physical excess of activity (like heavy physical labour, violent motions, sports) and/or of ponderal load, in order that the patient adopt a behaviour and rules of life proper to limit the risks of adverse effects and implant failure. Refer to § 10. Information provided to the patient
– It is recommended to ensure a regular clinical and radiological follow-up to identify any complication, migration, and/or excessive wear of the implant.
– The apparition of artefacts in MRI images can occurred in the case of metallic implants. In order to reduce artefacts, MRI images correction techniques can be used.

8. WARNINGS

– The wear couple consists of two articulating joint surfaces of precisely defined geometry and of precisely defined material. A femoral head can only be combined with an insert of suitable diameter. Do not put a femoral head directly in an untreated cotyloid cavity.
– The bearing surface in contact with Biolox®Delta heads must exclusively be made of UHMWPE or of the same Biolox® Delta alumina ceramic
– The bearing surface in contact with metallic heads must exclusively be made of UHMWPE.
– Femoral heads with extra-long neck (+7 or more) must not be used with all the lateralised stems, or with EASY1010, EASY1212 stems of the BIOTECHNI's range.
– In no case, the implant has to be contoured, modified or machined to avoid compromising its fatigue strength and causing its immediate or premature failure under load.
– An incorrect implant positioning can lead to a bad stability, dislocation and/or bending, loosening, breakage of the implanted components.
– Do not use an implant damaged, contaminated or handled not correctly.
– Do not use a femoral head with a stem taper presenting visible damages.
– Using a metallic or BIOLOX® ball head in combination with a prosthesis stem left in situ in a revision surgery is contraindicated. A metallic or BIOLOX® ball head must only be used with a brand-new, unused and undamaged stem taper.
– Implants already implanted must never be re-implanted, even if it doesn't show any visible damage, because of infection, pain or reintervention risk. BIOTECHNI declines any responsibility for such a use.
– The only valid sterility method is the one performed by the manufacturer. BIOTECHNI declines any responsibility in case of resterilization by the user.
– Do not use a ceramic head that have received a shock. A used Biolox® ball head poses risk of damage potentially invisible to the naked eye. Since any kind of damage can adversely affect the ceramic's

functionality and/or stability, safe use cannot be ensured. Any damage (e.g. points of impact or metal deposition) can cause excessive wear or fracture and may lead to complications. Therefore, only an unused and undamaged Biolox® ball head taken from the original packaging immediately prior to placement must be used. A Biolox® ball head which has been already placed must not be re-used. Due to the necessary exact fit between the Biolox® ball head and the prosthesis stem, only new and undamaged prosthesis components must be combined. This also means, for example, that a Biolox® ball head which has already been placed on a prosthesis stem and then removed must not be placed on the stem again. Likewise, a Biolox® ball head with any kind of damage must not be used but has to be discarded instead. This also applies, for example, to a Biolox® ball head which has been dropped.

- In case a ceramic component breaks, a synovectomy has to be performed whenever appropriate. In addition, pairing of metal (ball head) with polyethylene (insert) and of metal with metal is contraindicated in this case of revision.
- In the specific case of the revision surgery, after a ceramic head fracture:
  1- Replace the ceramic insert or the polyethylene part of the acetabular cup;
  2- Imperatively use a ceramic (not metallic) head on a brand new stem.
- BIOTECHNI advises expressly against use of implants manufactured by a third party in combination with the BIOTECHNI implant. BIOTECHNI declines any responsibility for the performance of such a combination and possible consequences for the patient's health.

9. SIDE EFFECTS

- Dislocation of the hip prosthesis due to lack or excess of activity, a traumatism or biomechanical factors.
- Loosening of the implant may be induced by a healing delay, premature loading, an inadequate initial implant fixation and/or postoperative immobilization, an infection or a traumatism.
- Fissuring or fracture or perforation of the bone can occur due to numerous factors such as poor bone density, unsuitable implant and/or implantation technique, or traumatism.
- Peripheral neuropathies, vascular damage, nerve damage, infections.
- Each patient scheduled to undergo a surgical operation may be subject to unforeseen per or postoperative complications. The tolerance of surgery, drugs and a foreign body may be different from one patient to another. The reactions and the complications that may arise during surgery and use of the implant must be discussed with the patient and the latter must have full understanding thereof.
- If infection occurs or if the patient reacts to the implantation of a foreign body the treatment suited to each case is to be instituted. If the infection or allergy cannot be treated with the prescribed methods, withdrawal of the implant is recommended.
- Mechanical sound may be heard when walking. Noise generated during movement after a BIOLOX® ball head has been implanted is not sufficient to indicate a malfunction or change in the performance of the endoprosthesis system. However, it is recommended to check the integrity of the endoprosthesis system.
- Residual hip pain.
- Allergy, hypersensitivity to materials.

10. INFORMATION PROVIDED TO THE PATIENT

- The surgeon must inform the patient of the potential risks and undesirable effects of having an artificial joint fitted and have his agreement to the proposed operation. The surgeon must inform the patient about the potential post-operative complications.
- The surgeon must inform the patient that an artificial joint should not be submitted to the same mechanical stress as the natural joint.
- The surgeon must inform the patient receiving the device that the safety and durability of the implant depend on his behavior, mainly concerning any excessive loading through patient weight and/or activity (like heavy physical labour, violent motions, violent sports).
- An extreme quick overload, such as traumatism, accident, can lead to a fracture, sometimes long after

the incident.
– The patient must inform his surgeon of any event that could compromise the successful integration of the implant and must submit to periodic post-operative checks.
– Interference risks during physiotherapy: Ask the patient to systematically mention that he/she is carrier of an implant.
– Interference risks during MRI: BIOTECHNI's implants can be considered as MRI compatible up to 3 T. However, BIOTECHNI always recommends consulting the MRI equipment manufacturer to confirm the compatibility before use.

Note: Please note that any artificial joint is subject to wear and a surgeon may have to operate again. The debris from wear may cause metallosis and osteolysis. The surgeon is responsible for complications caused by incorrect prescription, non-respected operating technique or a lack of asepsis. Under no circumstances can these complications be attributed to Biotechni.

11. PACKAGING AND STERILIZATION

– The information mentioned on the product label allows to insure the traceability of its manufacturing. The implants are packaged per unit and are sterilized by gamma irradiation (R).
– Sterility is guaranteed as long as the packaging is intact and until the expiry date indicated on the packaging.
– Check for perfect sealing of packaging items (peel pouches or shells and seals) and overall integrity before using the implants.
– Do not use a product with a damage package or a broken tamper-proof label. In this case, the product must be returned.
– Do not use an implant if its packaging has been opened outside the operating theatre.
– When handling the sterile barrier unit (last protection), wear sterile gloves and use sterile instruments.
– The sterilization indicator on the outer package confirming the gamma sterilization must be red; this colour may be faded by bad storage conditions: heat, humidity, light, etc. In all cases, a stick-on dot that is orange may indicate an unsterile product, and in this case, the product must not be used. The expiry date in indicated on the product label.

12. WASTE MANAGEMENT

Explanted implants and packaging waste from operation must be handed over to a specialized service for environmentally safe disposal in compliance with strict hygiene rules under the responsibility of the medical center, and according to the local applicable regulations.
A product explanted because a defect must be returned to the manufacturer after decontamination.

Note: Any serious incident occurred in relation to the device and relative instrumentation should be reported to the manufacturer and competent authority of the pertinent Member State.
For any additional information, please contact your representative or the manufacturer.

The reference text is the French text.

A.1	ICERA Mxx-vv	MU-DBxx-vvvv	INxx.0yy	IDMxx-yyy+	CI60xx / CI60xx	CERxx x-yy
FI040xx	X	X	X	X	X	X
FIC040xx	X	X	X	X	X	X
FI043xx	X	X	X	X	X	X
TFV50xx	X	X	X	X	X	X

FI044xx	X	X	X	X	X	X
TFL60xx	X	X	X	X	X	X
FI050xx	X	X	X	X	X	X
FI041xx	X	X	X	X	X	X
FI020xx	X	X	X	X	X	X
INxx.0yy	/	X	/	X	X	/
CERxxx-yy	X	X	/	X	/	/
CAPxx; CAPCxx	/	/	X	X	/	X
C6DBxx-yy	/	/	X	/	/	X
MU-Txx	X	X	X	/	/	X
CIG-xxTH	X	X	X	/	/	X
TTHR5xx ; QHxx-yyy ; VCxx	X	X	X	X	X	X
EASYxxyy-zzzD ; EASYxxyy-zzzG	X	X	X	X	X	X

	Do not reuse - Single use
	Manufacturer
	Expiry date
	Fragile; handle with care
	Date of manufacture
REF	Reference
STERILE R	Sterilized using irradiation
	Do not use if package is damaged
	Keep away from rain
	Keep away from sunlight
LOT	Batch number

	Do not resterilize