

## BIOTECHNI



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

#### SNAPFIT HIP BIPOLAR CUP SINGLE USE STERILE IMPLANTS

EN

#### 1. DESCRIPTION

BIOTECHNI designs, manufactures and commercializes bipolar hip cups. SNAPFIT bipolar cups (CI60xx / CI60xx-22 are made out of stainless steel (ISO 5832-1) and high density polyethylene (UHMWPE ISO 5834-2). The external surface of the cup, in mirror polished stainless steel, is intended to be in contact with the internal surface of the healthy cotyloid cavity, the internal surface in UHMWPE with retention ring and rim is intended to be in contact with a prosthetic femoral head. The SNAPFIT bipolar hip cups are available in multiple external sizes and are compatible with different prosthetic femoral heads diameters (22.22mm for CI60xx-22 and 28mm for CI60xx). 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 » represents various dimensions:

References	Description
CI60xx	SNAPFIT bipolar cup internal diameter of 28mm
CI60xx-22	SNAPFIT bipolar cup internal diameter of 22.22mm

#### 3. COMPATIBILITY

The SNAPFIT bipolar cups are fully compatible with the femoral heads and stems listed in the table below (see appendix A1) and supplied by BIOTECHNI. Medical devices listed hereafter are CE 1639 marked according to the Directive 93/42/CEE.

- INxx.0yy : Stainless steel femoral head 5°43'
- CERxxx-yy: BioloX® Delta ceramic femoral head 5°43'
- FI040xx: FILLER-3ND cementless femoral stem Ti+HA coated
- FIC040xx: FILLER-3ND collared cementless femoral stem Ti + HA coated
- FI043xx: FILLER-3ND cementless varised femoral stem Ti+HA coated
- FI044xx : FILLER-3ND cementless lateralized femoral stem Ti+HA coated
- FI050xx : FILLER-3ND cementless femoral stem Ti coated
- FI041xx : FILLER-3ND cemented femoral stem
- FI020xx: Long FILLER femoral stem HA coated
- TTHR5xx ; QHxx-yyy ; VCxx : Ti+HA coated reconstruction modular femoral stem & locking screw
- EASYxxyy-zzzD ; EASYxxyy-zzzG : Ti+HA coated reconstruction monoblock femoral stem

SNAPFIT hip bipolar cups are intended to be used in contact with a healthy and native cotyloid cavity of the articulation of the hip.

#### **4. INTENDED PURPOSE**

SNAPFIT hip bipolar cups are intended to be used with femoral head and stem for partial hip joint replacement (hemiarthroplasty). The goal of a joint prosthesis is to reproduce the articular anatomy and to 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**

SNAPFIT hip bipolar cups are intended in partial hip joint replacement (hemiarthroplasty) for:

- Intracapsular femoral head or neck fractures;
- Pertrochanteric fracture
- Revision of partial hip prosthesis;

The bipolar cups are intended to be used on adult (skeletally mature) patients.

#### **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.
- Morphological alterations of the affected acetabulum, severe hip dysplasia or other remodelling acetabular alterations (coxarthrosis)
- Drug, tobacco and/or alcohol addiction and/or abuse.
- Non terminated skeletal development.
- Intense physical activity.
- Proved or suspected sensitivity to materials.
- Tumour unresectable or residual.
- 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 made available.
- 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 for the patient to 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 occur with the use of metallic implants. In order to reduce artefacts, MRI images correction techniques can be used.

## **8. WARNINGS**

- Do not use an implant damaged, contaminated or handled not correctly.
- Implant already implanted must never be reused, even if it doesn't show any visible damage, because it could induce 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.
- 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.
- 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 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, 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.
- Allergy, hypersensitivity to materials.

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.

## **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 behaviour, mainly regarding 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 these complications can 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 is 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 of 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.

Compatibilité avec Cupule mobile (CI60xx / CI60xx-22) Compatibility with Bipolar cup (CI60xx / CI60xx-22)	
Têtes fémorales	
INxx.0yy	X
CERxxx-yy	/
Tiges fémorales	
FI040xx FI040xx FI043xx FI044xx FI050xx FI041xx FI020xx	X
TTHR5xx QHxx-yyy VCxx EASYxxyy-zzzD EASYxxyy-zzzG	X

	Do not reuse - Single use
	Manufacturer
	Expiry date
	Fragile; handle with care
	Date of manufacture
	Reference
	Sterilized using irradiation

	Do not use if package is damaged
	Keep away from rain
	Keep away from sunlight
	Batch number
	Do not resterilize