BIOTECHNI
Z.I. Athélia II
178, avenue du Serpolet
13600 LA CIOTAT - France
Tél. : +33 (0)4 42 98 14 30
Fax : +33 (0)4 42 98 14 39
www.biotechni.com

CE 1639

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

GYPTIS acetabular cup to be cemented
SINGLE USE STERILE IMPLANTS

EN

1. DESCRIPTION

BIOTECHNI designs, manufactures and commercializes GYPTIS cemented acetabular cup.
GYPTIS (C6DBxx-yy) acetabular cup to be cemented is made of UHMWPE (ISO 5834-2) with stainless steel radiographic marker (ISO 5832-1).
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*
C6DBxx-yy	GYPTIS cemented rim acetabular cup

3. COMPATIBILITY

GYPTIS acetabular cup to be cemented is fully compatible with the femoral heads and stems listed in the table below and supplied by BIOTECHNI. Medical devices listed hereafter are CE 1639 marked according to the Directive 93/42/CEE.

<u>See appendix 1 (A1):</u>
- ICERAMxx-yy: Ceramic insert
- MU-DBxx-yyyy: Polyethylene insert
- INxx.0yy: Stainless steel femoral head 5°43'
- IDMxx-yyy+: Polyethylene insert
- C6DBxx-yy : GYPTIS polyethylene acetabular cup
- CI60xx ; CI60xx-22 : Bipolar cup
- 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
- CAPxx ; CAPCxx : APOGEE acetabular cup

– **MU-T**xx : Coated MULTI acetabular cup
– **CIG**-xxTH : Coated IGLOO 18° acetabular cup
– **TTHR5**xx ; **QH**xx-yyy ; **VC**xx : Ti+HA coated reconstruction modular femoral stem & locking screw TTHR
– **EASY**xxyy-zzzD; **EASY**xxyy-zzzG : Ti+HA coated reconstruction monobloc femoral stem TTHR-EASY

The table below addresses the compatibility between acetabular cups and screws, plug and inserts components:

Inserts/Screws/Plug	*MULTI cup* MU-Txx	*IGLOO cup* CIG-xxTH	*GYPTIS cup* C6DBxx-yy
ICERAMxx-yy	X	X	/
MU-DBxx-yyyy	X	X	/
MU-VISxx	X	/	/
CIG-B1	/	X	/

GYPTIS acetabular cup to be cemented 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.
GYPTIS acetabular cup to be cemented is placed directly into the acetabular cavity and is not associated to any metallic shell.

4. INTENDED PURPOSE

GYPTIS acetabular cup are intended to be used with femoral head and stem for total hip joint replacement. The main 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

GYPTIS acetabular cup are intended in total hip joint replacement for:
– Total Hip arthroplasty
– Primary Osteoarthritis

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.
– Non terminated skeletal development.
– Intense physical activity.
– Proved or suspected sensitivity to materials.
– Tumor 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 case a ceramic component breaks, a pairing of metal (ball head) with polyethylene (insert) and of metal with metal is contraindicated in a revision.
– 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 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 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 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	IICER AMxx-yy	MU-DBxx-yyyy IDMxx	INxx.0yy	CI60x x CI60x x-22	CERxx x-yy
FI040xx	X	X	X	X	X
FIC040xx	X	X	X	X	X
FI043xx	X	X	X	X	X
FI044xx	X	X	X	X	X
FI050xx	X	X	X	X	X
FI041xx	X	X	X	X	X
FI020xx	X	X	X	X	X
TTHR5xx ; QHxx-yyy ; VCxx	X	X	X	X	X
EASYxxyy-zzzD ; EASYxxyy-zzzG	X	X	X	X	X
INxx.0yy	/	X	/	X	/
CERxxx-yy	X	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