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

Réf. : ni_TTHREASY
Édition : 03
12-2019

Directive 93/42/CEE
Année marquage CE : 1997

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

TTHR & TTHR-EASY
STERILE FEMORAL STEMS FOR REVISON & RECONSTRUCTION
SINGLE USE STERILE IMPLANT

EN

1. DESCRIPTION

BIOTECHNI designs, manufactures and commercializes two types of revision and reconstruction femoral stems:
– Modular: the whole implant is made of two parts: a diaphyseal stem and metaphyseal component (or metaphysis). These two parts are fitted together with a morse taper.
– Monoblock: in this case, diaphysis and metaphysis constitute one monoblock stem.
These two types of stems have a collar, a cervico-diaphyseal angle of 135°, and a morse taper 5°42'30" (12/14 mini-taper) for the assembly with the femoral head. Distal end is equipped with a slot in order to reduce the risk of fracture during descent.
Locking screws (in titanium alloy TA6V ELI ISO 5832-3 & ASTM F136) are available from 20 to 55 mm (5 by 5 mm). Ref.: VC20 to VC55.

Stems are made out of titanium alloy (TA6V ELI ISO 5832-3 & ASTM F136) and coated with porous titanium (Ti) + hydroxyapatite (HA ISO 13779-2) or HA (ISO 13779-2). The type of coating is indicated on the product's label.

2. IMPLANTS IDENTIFICATION

Medical devices listed hereafter are CE 1639 marked according to the Directive 93/42/CEE.

MONOBLOCK STEMS

TTHR-EASY stems have a 5°42'30" (12/14) mini-taper and are Ti+HA coated.
TTHR-EASY stems are available in 32 references: **EASYxxyy-zzzD** & **EASYxxyy-zzzG** (xx= Ø metaphysis, yy= Ø diaphysis, zzz= stem length, D= right, G=left).

Conical taper	Metaphysis diameter (**xx** in mm)	Diaphysis diameter (**yy** in mm)	Stem length (**zzz** in mm)	Right side reference (**D**)	Left side reference (**G**)	Materials
12/14	10, 12 14, 16	10, 12	190, 240 290, 340	**EASYxxyy-190D** **EASYxxyy-240D** **EASYxxyy-290D** **EASYxxyy-340D**	**EASYxxyy-190G** **EASYxxyy-240G** **EASYxxyy-290G** **EASYxxyy-340G**	Titanium alloy TA6VELI + Ti+HA coating

MODULAR STEMS

Reconstruction modular stems are composed of a curved diaphyseal stem and a metaphyseal component. The assembling is done thanks to a morse taper and secured by an assembling screw in titanium alloy supplied with the metaphysis. Metaphyseal and epiphyseal parts are Ti+HA (pure titanium + hydroxyapatite) coated.

Component	Conical taper	Diameter (**xx** in mm)	Length (**yyy** en mm)	Reference	Materials
METAPHYSEAL	12/14	14, 16, 18, 20	85	**TTHR5xx**	Titanium alloy TA6VELI + Ti+HA coating
DIAPHYSEAL	/	10, 18 et 20	105, 130, 155, 180, 205, 255	**QHxx-yyy**	Titanium alloy TA6VELI + HA coating
		12, 14, 16	105, 130, 155, 180, 205, 255, 290		

3. COMPATIBILITY

TTHR and TTHR-EASY stems are compatible with all femoral heads and acetabular cups listed in the table below and supplied by BIOTECHNI.
If needed, a cerclage can be performed using the tunnels of the metaphyseal component. Use cerclage cables or wires with a diameter inferior to 2,3 mm.

Medical devices listed hereafter are CE 1639 marked according to the Directive 93/42/CEE.

References	Ceramic insert **ICERAM**xx-yy	Polyethylene insert and cup **MU-DB**xx-yyyy **IDM**xx-yy+ **C6DB**xx-yy	Stainless steel femoral head 5°43' **IN**xx.0yy	Bipolar Cup **CI60**xx **CI60**xx-22	BIOLOX® Delta ceramic femoral head 5°43' **CER**xxx-yy
TTHR5xx + **QH**xx	X	X	X	X	X
EASYxxyy-zzzD **EASY**xxyy-zzzG	X	X	X	X	X

The locking screws VCxx are compatible with the TTHR and TTHR-EASY stems.

4. INTENDED PURPOSE

TTHR and TTHR-EASY are revision and reconstruction femoral stems. They are intended for hip joint revision. The main goal of a joint prosthesis is to reduce the pain and improve mobility of patients.

5. INDICATIONS

TTHR and TTHR-EASY are intended in the following cases:
– Revision of a stem from total hip prosthesis,
– Revision of a stem from hemiarthroplasty.
– Grades II, III, IV SOFCOT or 3a, 3b and 4 of Paprosky.
The implants are intended to be used on adult 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.
– 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

– Do not use head with extra-long neck (+7 and above) in association with EASY1010, EASY1212.
– In order to determine the size of implants, the surgeon should use the X-ray preoperative templates made available. 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 packaging and labelling before use.
– 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 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 placement instruments 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 per-operative 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. Refer to § 10. Information provided by 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 not correctly handled.
– 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.
– Under no circumstances, the implant should be bent, curved, modified, adapted or refunded at the risk of compromising its resistance to fatigue and causing an immediate or delayed break.
– Incorrect placement of the implant can result in poor stability, dislocation and / or deformation, loosening, rupture of implanted components.
– BIOTECHNI advises expressly against use of implants manufactured by a third party in combination with the BIOTECHNI implants. 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 inadequate postoperative immobilization, an infection or a traumatism.
– Rupture at the base of the diaphyseal junction due to inadequacy between the volume of the metaphyseal implant and the loss of metaphyseal bone substance.
– 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.
– Wear of articular surfaces.
– Residual hip pain.
– 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 (allergy, hypersensitivity to materials), 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.

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 cans these complications be attributed to Biotechni.

11. PACKAGING AND STERILIZATION

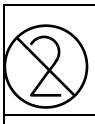
–The information mentioned on the product label allows to insure the traceability of its manufacturing. The implants are packaged per unit and are sterilized by gamma irradiation (R).
–Sterility is guaranteed as long as the packaging is intact and until the expiry date indicated on the packaging.
–Check 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.

	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