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

GEO SHOULDER PROSTHESIS SYSTEM
SINGLE USE STERILE IMPLANT

EN

1. DESCRIPTION

GEO shoulder prosthesis system is modular and composed by the following components:

Designation	Reference	Material
GEO – Ti+HA coated glenoid base	A41-GGHxx	G2
GEO – Ti+HA coated revision glenoid base	A41-GGHR35x	G2
GEO – Geosphere for glenoid cavity	A41-GSxx	G
GEO – Screw for glenoid base	A41-VS45xx	A
GEO – Cortical screw	A41-VTC35xx	G
GEO – Humeral epiphysis to be cemented	A41-EPCxx	G
GEO – Ti+HA coated humeral epiphysis	A41-EPHxx	G2
GEO – Cup insert for epiphysis	A41-xxyy	A+F
GEO – Spacer +9mm for cup-insert	A41-20xx	A
GEO – Diaphyseal stem to be cemented – L100	A41-QCxx100	B
GEO – HA coated diaphyseal stem – L100	A41-QHxx100	B1
GEO – Revision diaphyseal stem to be cemented	A41-QRCxxyyy	B
GEO – HA coated revision diaphyseal stem	A41-QRHxxyyy	B1
GEO – Locking screw for GEO diaphyseal stem	A41-VCLxx	A

Note:
- « x » and « y » show dimensions or sizes.

Materials:
(A): Titanium alloy TA6V ISO 5832-3 or TA6V ELI ASTM F136
(B): Stainless steel ISO 5832-1
(B1): (B) + hydroxyapatite coating (HA)
(F): UHMWPE (ultra-high molecular weight polyethylene) ISO 5834-2
(G): Stainless steel ISO 5832-9
(G2): (G) + titanium and hydroxyapatite coating (Ti+HA)

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

2. COMPATIBILITY

All components from GEO shoulder prosthesis system are inter-compatible and form a full solution for the following indications. Use of other devices combined with GEO shoulder prosthesis system is strictly forbidden.

The components of GEO system in cemented version are 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.

3. INTENDED PURPOSE

GEO shoulder prosthesis system is indicated in total shoulder replacement or revision. The main goal of a joint prosthesis is to reduce the pain and improve mobility of patients.

4. INDICATIONS

GEO shoulder prosthesis system is intended to be used on adult patients with the following indications:
– Eccentric omarthrosis or gleno-humeral arthritis with rotators cuff tear, and sufficient glenoid bone stock;
– Persistent pseudo-paralyzed shoulder due to massive and irreparable rotator cuff tears;
– Acute fractures in the elderly with deficient cuff or risking of being;
– Severe fracture consequences, some tuberosity malunions after fracture;
– Prosthetic revision in a cuff-deficient shoulder.

5. CONTRAINDICATIONS / RISK FACTORS

Conditions which can severely affect the success of the implantation:
– Poor glenoid bone stock, osteopenia and/or severe osteoporosis.
– Deficient deltoid muscle.
– Any local, acute, or chronic infection. Any infectious illness. Fever or leucocytosis.
– Systemic and metabolic disorders. Any mental or neuromuscular disorder.
– Unresectable or residual tumor.
– Drug, tobacco and/or alcohol addiction and/or abuse.
– Proven or suspected sensitivity to materials.
– Intense physical activity.
– Pregnancy, obesity or overweight (BMI >25).
– Incomplete skeletal development.

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.

6. PRECAUTIONS

– A systematic preoperative arthroscanner (or MRI) must be performed in order to estimate glenoid bone stock which result can contraindicate the implementation of a reverse prosthesis.
– The parts to be assembled should be cleaned up before assembly to eliminate soft tissues or other materials.
– In order to determine the size of implants, the surgeon should use the 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 if there is any scratch, crack or 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 his 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), 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 § 9. 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.

7. 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.
– 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 breakage.
– 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.

8. SIDE EFFECTS

– Instability, dislocation of the prosthesis due to lack or excess of activity, a traumatism or biomechanical factors.
– Heterotopic ossifications that could limit rotation mobility.
– 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 bone perforation can occur due to numerous factors such as poor bone density, unsuitable implant and/or implantation technique, or traumatism.
– If bone screws are used, it is essential to choose appropriate lengths in order to avoid damage of the underlying soft tissues or organs and risk of internal bleeding.
– Infections, peripheral neuropathies, vascular damages, nerve damages.
– 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, sensitivity to materials.
– If infection occurs or if the patient reacts to the implantation of a foreign body, the treatment adapted to each case has to be instituted. If the infection or allergy cannot be treated with the prescribed methods, removal of the implant is recommended.

9. 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 subjected 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.

10. 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 damaged 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.

11. 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