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PATIENT-SPECIFIC SOLUTIONS

ATTENTION: OPERATING SURGEON PLEASE READ THE FOLLOWING INFORMATION PRIOR TO THE USE OF CRANIOTECH'S CUSTOM GLENOID IMPLANT.

TERMS & CONDITIONS:

Proper surgical procedures and techniques are the responsibility of the medical professional. The custom glenoid implant and surgical guides do not replace or reduce the responsibility of the surgeon to execute professional judgment during full course of executing the surgery. These guidelines are furnished for information purposes only. It remains the sole responsibility of the surgeon to make sure that he/she is satisfied, and deem it safe, to use the instrumentation and to ensure that the final implant placement is acceptable.

WARRANTY & LIMITATIONS OF LIABILITY:

Craniotech guarantees that each of its products is treated with utmost care in development, selection of material, manufacture and final inspection before release for distribution. Through inexpert storing, handling and other manipulation, the implant and guides can be damaged, and its operability can be restricted.

Craniotech accepts no liability or warranty for malfunctioning, breakdown and potential medical complications for patient and hospital staff, or for resulting damages arising from inexpert handling, operation, storing, from acts of God or from other external influences or manipulation.

Craniotech will replace any device, which, in its opinion, was defective at the time of shipment and if defects that were caused during manufacturing or packaging are immediately brought to the attention of Craniotech or its distributors. This warranty is exclusive and in lieu of all other warranties, whether expressed or implied, written or oral, including, but not limited to, any implied warranties of merchantability of fitness.

As a result of biological differences in individuals, no product is 100% effective under all circumstances. Craniotech has no control over the operation, inspection, maintenance, or use of its products after sale, and has no control over the selection of patients. Therefore, Craniotech and its distributors do not guarantee either for a good effect or against a poor result following use. Craniotech and its distributors shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of the device or from ineffective sterilisation processes or re-use of the product(s).

℞ Only MDR guidelines restrict this device to sale by or on the order of a qualified person (e.g. healthcare professional).

DESCRIPTION:

This document contains general instructions for use of the custom implants and guides. Refer to the Theatre Document for all case-specific instructions.

Craniotech's Custom Glenoid Implant and Surgical Guides are used to reconstruct a damaged or missing part of the patient's glenoid. The custom-made glenoid implant is manufactured according to the specifications of the healthcare professional. The dimensions of the implant are unique to the patient's anatomy. The fixation screw positions and trajectory are planned to achieve optimal bone purchase. Commercially available titanium fixation screws are used to fixate the custom implant to the bone. The custom surgical guides are designed to fit the patient's anatomy and help to position the implant correctly.

Custom Glenoid Implants are produced via additive manufacturing and CNC processes, from Ti64 ELI Titanium Alloy (ASTM F136, ASTM F3001 and ASTM F3302).

The custom surgical guides are produced through additive manufacturing from a durable polyamide, PA 2200 (ASTM F3091).

STORAGE:

The Craniotech Custom Glenoid Implant must be stored in a dry and clean place at ambient temperature protected from sunlight and heat sources.

INTENDED USE:

The Craniotech Custom Glenoid Implant is intended for use in primary or revision shoulder joint replacement procedures in skeletally mature individuals with a functional deltoid muscle.

INDICATIONS:

1. Intended in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implant and a functional deltoid muscle is necessary.
2. Intended for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.
3. Intended for cementless application with the addition of screw fixation in patients with unusual anatomy and/or

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extensive bone loss which precludes the use of a standard glenoid baseplate component.

CONTRAINDICATIONS:
Absolute contraindications include infection, sepsis, and osteomyelitis.

Relative contraindications include:

1. Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow directions.
2. Osteoporosis
3. Metabolic disorders which may impair bone formation.
4. Osteomalacia
5. Distant foci of infections which may spread to the implant site.

CLINICAL SAFETY, BENEFITS & PERFORMANCE:

- **Clinical safety:** The implant is safe for use for the patient and medical staff during surgery with low chance of loosening or implant failure.

- **Clinical performance:** The implant can be accurately positioned according to the pre-operative plan and its lattice surface that has the potential to support bone on-growth and secondary fixation.

- **Clinical benefit:** The Craniotech Custom Glenoid Implant results in better functional outcome and high patient satisfaction.

MATERIALS:
The materials used to manufacture the custom-made implant and surgical guides are Ti64 ELI and polyamide, respectively.

POSSIBLE ADVERSE EFFECTS:
As with all surgeries, there are possible side effects including pain, swelling, bruising, bleeding, and infection.

Other risks to the patient include:

1. Insufficient bone reconstruction (osteolysis, osteomyelitis, osteoporosis), inhibited vascularization (the process of new blood vessels forming properly), or infection that may result in implant failure.
2. Material sensitivity reactions — when suspected, material sensitivity tests are made prior to implantation.
3. Hematoma (contusion or bruise)
4. Pain, discomfort, and abnormal sensation related to the implant. This usually resolves itself but can take weeks or months. Some people have a permanent change in sensation of the area surrounding the implant.
5. Loosening or migration of the implant due to trauma or loosened fixation devices that keep the implant in place.
6. Perforation or fracture of the scapula (shoulder blade) during or after surgery caused by trauma.
7. Reduction of mobility due to damage to the bone, calcification of joints, or incorrect placement of the implant or its components.
8. Total or partial dislocation of the joint due to improper placement of the implant's parts. Weak muscles and fibrous tissue can also play a role here.

⚠ WARNINGS:

1. To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the custom-made implant and surgical guides.
2. To avoid mix-ups and associated serious injury, patient identification on implants, models, and guides must be verified and confirmed against patient identification prior to use.
3. Device(s) are single-use only and designed for use with a specific patient only. To avoid risk of infection and serious injury, do not attempt to re-clean or re-sterilize or in any way re-use the products.
4. Surgical guides are designed for a specific patient. To avoid the potential for serious injury, surgical guides should not be modified in any way.
5. Do not place the implant without using the guides.
6. Be aware that these custom implants and guides have been manufactured based on CT scans of the patient. The surgery and implantation should take place as soon as possible after delivery of the custom-made implant. If the patient's anatomy has changed significantly since the time of the CT scan, the implants and guides should not be used.
7. Prior to use of any Craniotech custom-made solutions, the user must thoroughly review the instructions for use and all other labelling provided with the devices.

⚠ PRECAUTIONS:

1. Craniotech custom-made implants and surgical guides are shipped in a non-sterilised state. To avoid possibility of infection, sterilise per provided instructions for use.
2. To ensure that damage has not occurred during shipping and handling, inspect all implants and guides prior to use.

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Do not use if the implants and/or guides are broken, cracked or otherwise damaged.

3. Contact between the lattice surface of the implant and fabrics or other materials which may release fibres should be avoided.
4. Do not drop the implant. An implant that is dropped before or during surgery, should not be used anymore.
5. Use clean gloves when handling the implants during surgery.
6. To avoid material toxicity reactions, contact time for each material should be limited to the time shown below:

Material	Device	Contact Duration	Body Contact
Ti64 ELI	Implant	Indefinite	Tissue/Bone/ Mucosal Membrane
Polyamide	Guide	Limited (≤ 24 hours)	Tissue/Bone/ Mucosal Membrane

MATERIAL APPLICABILITY TABLE:

The following table defines the basic methods that must be used for cleaning and sterilization of the implants and guides:

Material	Sterilization
Ti64 ELI	Steam
Polyamide	Steam

CLEANING & STERILISATION:

Implants and guides are provided in NON-STERILE condition. Cleaning and sterilisation is required prior to use.

Cleaning:

The implant and guides should be handled with the greatest care to avoid damage. Always remove the implant and guides from the original packaging. The implant and guides can be cleaned using either manual cleaning or automated cleaning in a washer/disinfector (which fulfils the requirement of ISO 15883 series). It is the user responsibility to use the validated processing steps as given in the instructions below, according to ISO 17664-1.

Option 1: Manual Cleaning

1. Rinse the device under cold running tap water for a minimum of 2 minutes. While rinsing, use a soft-bristled brush to clean the device.
2. Prepare a detergent solution intended for cleaning medical devices (e.g. enzymatic solution – Enzol) per manufacturer's recommendation for correct exposure time, temperature, water quality and concentration.
3. Fully immerse the device into the detergent solution and allow it to soak for 1 minute.
4. Remove the device from the detergent solution and rinse it under cold running tap water for a minimum of 2 minutes. While rinsing, use a syringe to flush the lumens of the device.
5. Prepare a newly made, clean detergent solution per manufacturer's recommendation for correct exposure time, temperature, water quality and concentration.
6. Fully immerse the device into the detergent solution and allow it to soak for 1 minute. While soaking, use a soft-bristled brush to clean it.
7. Remove the device from the detergent solution and rinse it under running reverse osmosis/deionized (RO/DI) water for a minimum of 2 minutes. While rinsing, use a syringe to flush the lumens of the device.
8. Visually inspect the device for visible soil.
9. Perform a final rinse on the device under running RO/DI water.
10. Dry the device using a clean, lint-free cloth and/or filtered pressurized air.
11. Carefully examine the device to see if it is clean and undamaged.

Option 2: Automated Cleaning in a Washer

1. Rinse the device under cold running tap water for a minimum of 1 minute.
2. Rinse the device under running reverse osmosis/deionized (RO/DI) water for a minimum of 2 minutes. While rinsing, use a syringe to flush the lumens of the device.
3. Prepare a detergent solution intended for cleaning medical devices (e.g. enzymatic solution – Enzol) per manufacturer's recommendation for correct exposure time, temperature, water quality and concentration.
4. Fully immerse the device into the detergent solution and allow it to soak for 1 minute. While rinsing, use a soft-bristled brush to clean the device.
5. Remove the device from the detergent solution and rinse it under cold running tap water for a minimum of 1 minute. While rinsing, use a syringe to flush the lumens of the device.
6. Visually inspect the device for visible soil.
7. Transfer the device to the automated washer for processing.
8. Select the cycle in the table below and ensure the set of cycle parameters are properly programmed.
9. Carefully examine the device to see if it is clean and undamaged.

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Phase	Minimum Duration (minutes)	Minimum Temperature	Detergent Type
Pre-wash	2	Cold tap water	N/A
Wash	2	43°C	Enzymatic Cleaner (e.g. Enzol)
Rinse	2	43°C	N/A
Thermal Disinfect	1	90°C	N/A
Drying	30	90°C	N/A

Sterilisation:
Remove the device from the original packaging. Sterilise the device using pre-vacuum steam sterilisation in a steriliser fulfilling the requirements of ISO 17665-2024 before use. Do not use a flash auto-clave cycle.

It is the user's responsibility to use the validated processing steps as given in the instructions below. During sterilisation of single devices, sterilisation pouches (fulfilling the requirements of ISO 11607) may be used.

Steam Sterilisation:

The steam sterilization settings used must fall within the following parameters to achieve a 10^{-6} sterility assurance level (SAL):

Temperature		Exposure Time		Dry Time
Min.	Max.	Min.	Max.	
134°C	137°C	3 min.	18 min.	≥ 30 min.

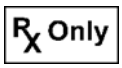
DISPOSAL:
Any Craniotech custom implant and guide that has been contaminated with blood, tissue or other bodily fluids/matter is considered infectious medical device waste and should be handled and disposed in accordance with hospital procedures.

CONTACT DETAILS:
For any questions or concerns, please contact Craniotech. In case you encounter any problem when using this system or want to provide any feedback, please contact:

Craniotech (Pty) Ltd
Office A2, Block A, Carpe Diem, Quantum Street
Techno Park, Stellenbosch
South Africa, 7600
Tel: +27 (0) 21 490 5161
Email: info@craniotech.com

For a patient or user in the European Union if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to Craniotech.

Symbol Legend:

	**Warning** Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Non-sterile
	**Caution** Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Manufacturer
	Date of Manufacture
	Do Not Re-Use
	Use-by date
	Prescription Only
	Case Number
	Consult Instruction for Use
	Keep dry
	Keep away from sunlight
	Do not use if package is damaged and consult the instructions for use.
	Full name of the patient

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	The date the implant was placed
	The name and address of the healthcare centre or doctor who performed the implantation.
	Website where a patient can obtain additional information on the implant.
	Name of the implant (MD = Medical Device)
	Importer
	Distributor
	Authorised Representative in the European Union.