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BIOMEDICAL ENGINEERING
a brand of GPI

INSTRUCTIONS FOR USE FOR THE TREATMENT OF CUSTOM MADE MEDICAL DEVICE Instrumentation

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Registration No. Database of manufacturers of custom-made medical devices of the Italian Ministry of Health: ITCA01050530

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1 WARNINGS

The warnings are identified with a progressive code **N and Rid is shown next to it** where Rid identifies the risk assessed in the risk analysis . Follow the warnings for safe use of the Customized Device.

GENERAL WARNINGS		For any complaint or report related to GPI products, please send an email to: segnalazionidm@pec.gpi.it
1	R-ST01	Medical devices, supplied NON-STERILE, require cleaning and sterilization prior to implantation.
2	R ST01	Only neutral, antibacterial detergents shall be used for cleaning GPI medical devices.
3	R SP03	Do not use products supplied in damaged or opened packaging.
4	R ST02	For medical devices supplied NON-STERILE, strictly follow the sterilization procedure specified for each material.
6	R ST01	The medical device shall not be re-sterilized.
8	R CH4	The components of the supplied medical devices are designed to adapt exclusively to the patient's anatomy and the pre-operative plans defined by the surgeon, based on an anatomical bone model obtained from the patient's CT scan. These plans include defining the desired setting on the patient before the CT scan or on the bone model once it is produced. It is essential that the surgeon accurately reproduce the patient's setting program and any anatomical modeling at the time of implantation to ensure the correct positioning of the prosthetic components.
10	R CH1	The components of the supplied medical devices are intended to be implanted in reciprocal coupling sets. To ensure the safety and effectiveness of the procedure, the placement of the prosthesis does not require the use of components supplied by other manufacturers (with the exception of the fixing screws).
11	R CH2	The components of the supplied medical devices contain surfaces that can be damaged if handled improperly. Any damage to these surfaces may affect the long-term performance of the prosthesis. Avoid contact with the articular surfaces whenever possible. Prosthesis components should be handled only with blunt, smooth-surfaced instruments to avoid damage. Instruments with serrations or sharp edges should not be used.
12	R CH2	The bone model is fragile. Handle with care.
13	R CH2	The surgeon must be familiar with the application of surgical DM prior to use.
14	R CH2	The supplied equipment should never be used to perform tasks for which it was not specifically designed. Improper use of an instrument can cause not only damage to the instrument but also injury to the patient/operator.
15	R CH2	Avoid storing or transporting instruments in contact with one another, as they may be damaged.
16	R CH2	Do not use damaged instruments. Damaged instruments must be replaced before use. Do not attempt to straighten or modify the components or instruments of the prosthetic device, as this may compromise their strength and lead to subsequent failure or injury.
17	R CH6	Before using the supplied medical devices, physically verify the integrity of each component, its conformity, and its serial number. The serial number is the reference number linked to the medical prescription and the declaration of conformity and is screen-printed on the component where size permits. This information identifies the patient. Verify that the serial number for connection to the patient on the declaration, label, and medical device corresponds precisely to the patient before proceeding with the prosthetic implant or using the equipment.
21	R ST03	Check that the bags used for sterilization are intact and that the components are correctly packaged and correctly positioned inside the sterilization systems to avoid the risk of bag breakage.
22	R-CH9	The supplied medical devices must not be manipulated or modified unless otherwise specified in the design specifications. Any authorized modifications must be performed exclusively outside the surgical field.

23	R-ST22	If the sterile packaging is damaged or opened, the device is NO LONGER STERILE and must be discarded. In this case, contact your authorized representative or the manufacturer.
24	R-ST21	For devices supplied sterile - Sterilization expiry date: do not use the device beyond the date indicated on the label (Annex I MDR 11.3).
25	R-ST09	For devices supplied sterile - EtO RESIDUES: The device is tested in accordance with ISO 10993-7 to ensure that Ethylene Oxide (EtO) and Ethylene Chlorohydrin (ECH) residues are within acceptable safety limits. In rare cases, hypersensitive patients may experience allergic reactions to EtO residues.
26	R-CH8	For devices supplied sterile - DO NOT RESTERILIZE: The device is sterilized only once using a validated EtO process. Any attempt at resterilization may compromise the structure, performance, and safety of the device, with the risk of releasing toxic residues or causing functional failure.

2 INTENDED USE

2.1 INSTRUMENTATION

The instrumentation medical device (MD) developed and produced individually or in association with implants for joint reconstruction or osteosynthesis can be composed of cutting and/or drilling templates, orthognathic splints and anatomical replicas.

Cutting and drilling templates like orthognathic splints are custom-made, invasive, single-use, surgical-type medical devices intended for temporary use.

Cutting and drilling templates are intended to be used for bone resection and drilling required for joint reconstruction or osteosynthesis surgery or orthopaedic surgery in general.

Orthognathic splints are used to align the dental arches and define correct occlusion during surgery, at the end of which they are removed.

Anatomical replicas are custom-made, single-use medical devices used for surgical planning.

Drilling templates can be made of Ti64 titanium or polyamide or another recognised state-of-the-art biocompatible material by means of Additive Manufacturing (3D printing) technology or CNC milling.

Orthognathic splints are made of Polyamide or other biocompatible material recognized as state of the art through Additive Manufacturing technology (3D printing).

The anatomical replicas are made of Polyamide using Additive Manufacturing technology (3D printing).

Such instruments are made exclusively for the patient, and according to the specific written prescription of any person authorized by national law by virtue of his personal qualification, which indicates, under the responsibility of that person, the specific characteristics of the design.

The surgical procedure that requires the use of these instruments must be performed by medical and nursing personnel previously trained and specialized in orthopedic surgical procedures for the reconstruction of the joint in question in operating rooms equipped for this purpose.

2.2 WARNINGS OR EXCLUSIONS

The instruments described above have specific design characteristics provided under the responsibility of the requesting Doctor who is authorized by national law by virtue of his professional qualifications.

The instruments described above, due to their personalized characteristics and the materials used, are for single and exclusive use by the patient.

3 CONTROINDICATIONS AND PRECAUTIONS

The use of the patient-specific instrumentation must be carefully evaluated if the patient has one or more of the following conditions:

- Patients with conditions or diseases that affect bony landmark recognition.
- Any active infection of the surgical area where the surgery will be performed is a contraindication for cutting-drilling guides.

4 NORMATIVE REFERENCES

MDR 745/2017	Reg EU medical device
UNI EN ISO 9001:2015/A1:2024	Quality management systems — Requirements
UNI EN ISO 13485:2016 /A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes
UNI CEI EN ISO 14971:2022	Medical devices - Application of risk management to medical devices
UNI EN 62366-1:2015/A1:2020	Medical devices - Application of usability engineering to medical devices
UNI EN ISO 14155:2025	Clinical investigation of medical devices for human subjects - Good clinical practice
UNI EN ISO 10993-1: 2021	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
UNI EN ISO 16061:2021	Instruments for use in association with non-active surgical implants - General requirements
UNI EN ISO 5832-3:2022	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ASTM F136-13(2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
UNI CEI EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements
UNI EN ISO 17665:2024	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
UNI EN ISO 14937:2009	Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
UNI EN ISO 17664-1:2021	Processing of health care products manufacturer for the processing of medical devices —Information to be provided by the medical device- Part 1: Critical and semi-critical medical devices
UNI EN ISO 11135-1:2020	Sterilization of health-care products validation and routine control of a sterilization process for medical devices - Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process form medical devices

5 MATERIALS

All instrumentation materials comply with the UNI ISO/ASTM surgical prosthesis standards indicated*.

- **Titanium alloy Ti-6Al-4V ELI,** conforming to ISO 5832-3/ASTM F136 standards*

  Chemical Composition

  - Titanium (Ti): Balance
  - Aluminum (Al): 5.5-6.5%
  - Vanadium (V): 3.5-4.5%
  - Oxygen (O): max 0.13%
  - Nitrogen (N): max 0.05%
  - Carbon (C): max 0.08%
  - Hydrogen (H): max 0.012%
  - Iron (Fe): max 0.25%

- **polyamide PA12, material certified at origin ISO 10993-1**

**For 3D printed components, compliance with the indicated standards refers to chemical and mechanical properties.*

Details of the materials of composition of the medical device are given in the declaration of conformity.

5.1 Storage conditions of the materials

The MD should be stored in a clean, dry environment and should be protected from sunlight and extreme temperatures.

5.2 Disposal of materials

The disposal of removed materials, including instruments, must be carried out in accordance with the standard for special surgical waste, in use in operating theatres.

6 PRECAUTIONS

It is the responsibility of the surgeon using this product to assess the clinical and medical status of the patient and to be aware of all aspects of implantation procedures and potential complications that may occur for each specific case. The results of the surgical procedure may worsen over time and no longer meet the patient's or surgeon's expectations. Therefore, any additional or alternative procedures to be carried out must be weighed. Revision implant surgery is not uncommon, so the surgeon should perform a careful risk-benefit clinical analysis to achieve the best long-term outcome for the patient.

The patient should be informed of the limitations of the reconstruction and the need to avoid loading the implant with excessive loads until an adequate level of fixation and healing has been achieved.

It is the surgeon's responsibility to become familiar with the surgical techniques for implanting these devices through the study of relevant publications, consultation with experienced collaborators, and training on the procedures applicable to this particular prosthesis.

Accepted surgical practice must be followed in post-operative care.

DO NOT USE COMPONENTS IN OPEN OR DAMAGED PACKAGING.

6.1 Magnetic Resonance and Radiofrequency Safety Information

The metal material used for the prostheses is not considered hazardous or incompatible for MRI and radiofrequency.

However, there are inherent risks associated with the use of metal implants in an MRI and radio frequency environment, including component migration, heat induction, and signal interference or distortion in the vicinity of the components.

Thermal induction of metal systems is a risk that depends on the geometry and material of the components, as well as on MRI and radio frequency aspects such as the power, duration and sequence of the pulses.

Because MRI or radiofrequency equipment is not standardized, the severity of these problems and the likelihood of them occurring with these implants are not known.

The safety and compatibility of these implants in MRI and radio frequency environments have not been evaluated. No tests have been conducted regarding the heating or migration of these systems to these environments.

Because these devices have not been tested, GPI cannot make recommendations regarding the use of magnetic resonance imaging with such implants, or radiofrequency, either regarding safety issues or image accuracy.

Some components are passive metal devices, and there is generally the possibility of mutual interference with certain imaging modalities, including image distortion in MRI and X-ray scattering in CT scans.

7 ADVERSE HEALTH EFFECTS OF THE DEVICE

Adverse events may occur after placement of this prosthesis requiring further treatment.

The occurrence of a complication may be related to or influenced by the patient's previous surgical history or previous medical condition.

Generally, adverse events reported in the literature in the clinical practice of this type of medical device include the following:

- Damage to surrounding soft tissue or bone, pain, swelling, or bruising;
- Muscle spasms or localized stiffness;
- Migration, deformation, or breakage of instrument components;
- Local or allergic reactions to the materials used;
- Indirect effects on adjacent or contralateral anatomical structures.

The occurrence and severity of these events depend on the surgical technique, the operator's experience and the patient's condition.

8 STERILIZATION

GPI SPA medical devices can be supplied **sterile** or **non-sterile**, depending on the supply specifications required by the customer or the user clinical center.

The devices supplied **sterile** are sterilized using Ethylene Oxide (EtO), according to a validated process in accordance with ISO 11135, which guarantees a Sterility Assurance Level (SAL) of 10^{-6}.

Devices supplied **non-sterile** must be cleaned and sterilized by the user before clinical use, following the instructions in this chapter and in accordance with UNI EN ISO 17665 and UNI EN ISO 14937 standards.

8.1 Devices supplied Sterile

The devices supplied **STERILE** are intended **for single use only (Disposable).** Sterilization is carried out using **Ethylene Oxide (EtO),** in accordance with **ISO 11135**.
Before opening the sterile package, the user is required to visually inspect the sterile barrier for integrity.

Integrity of the package: Do not use the device if the pouch, blister pack, or seal is open, punctured, moistened, or damaged. A compromised barrier does not guarantee sterility.

Expiration date: Do not use the device beyond the date indicated on the label

If the sterile package is damaged or opened, the device is NO LONGER STERILE and should be discarded. If this occurs, contact your authorized representative or manufacturer.

DO NOT RESTERILIZE: The device is sterilized only once using a validated EtO process.

Any attempt at resterilization may compromise the structure, performance and safety of the device, with the risk of toxic residue release or functional failure.

EtO RESIDUES: The device is checked in accordance with ISO 10993-7, to ensure that Ethylene Oxide (EtO) and Ethylene Hydrochloride (ECH) residues are within acceptable safe limits.

In rare cases, hypersensitive patients may experience allergic reactions to EtO residues.

8.2 Devices supplied NOT Sterile

If the device is supplied **NON-STERILE**, the label clearly states "NOT STERILE".
In this case, the user must:

- perform a cleaning and sterilization before clinical use,
- follow the validated procedures in this chapter,
- use sterilization methods appropriate to the construction material (Ti6Al4V, UHMWPE, PEEK, etc.).

Medical devices, supplied in a "NON-STERILE" condition, require an additional cleaning and sterilization process prior to implantation.

All devices produced by GPI SPA can be damaged if subjected to the use of acid-based detergents. It is therefore recommended to use only NEUTRAL AND ANTIBACTERIAL DETERGENTS.

For GPI SPA medical devices that are supplied under NON-STERILE conditions, to make their clinical use safe, it is recommended to follow the sequence specified below.

A. INITIAL TREATMENT AT THE POINT OF USE

- Remove the outer cardboard packaging box used for shipping
- Take out the inner box with the GPI logo

B. Preparation before cleaning

- Remove products from inner packaging
- Disassemble the medical device into its components
- Examine the good condition of the product
- Check that there are no processing residues/dust and if there is any cleaning/unblocking/washing of the holes before sterilization.

C. Cleaning and disinfection

Wash manually or mechanically with mild neutral detergent (absolutely non-acidic) and warm water, following the detergent manufacturer's instructions for use; Avoid using the detergent at an extreme concentration. PH-neutral enzymatic cleaners and warm water can be used to facilitate cleaning. Submit to a validated process in accordance with the ISO 15883 series standards.

The use of highly alkaline detergents (pH ≥ 12) is not recommended. Avoid prolonged exposure to acidic or alkaline solutions and solutions containing chlorides, bromides, or iodine.

After washing, rinse thoroughly with clean, deionized or distilled water.

D. DRYING

Dry completely before sterilization with a low-particle absorbent tissue, or with an industrial dryer or in a drying booth.

E. Inspection and maintenance

Inspect for cleanliness for the absence of any visible residue, especially in the least accessible areas. Thoroughly check the prosthesis components and/or associated instruments for damage, with particular attention to the areas of the devices in the moving parts or joints. Do not use prosthetic components or instruments that have been damaged. In this case, inform the manufacturer immediately, the user must not carry out any maintenance and/or restoration activities.

F. Packaging

Prosthesis components and/or associated instrumentation should be repackaged appropriately at the hospital. They are intended for sterilization in double bags according to the sterilization method for the different products. This SBS must have been validated to demonstrate the ability to oppose an adequate microbial barrier.

G. Sterilization

It has been demonstrated that the following process parameters produce a product with a SAL level of 10-6 log in accordance with UNI EN ISO 17665 and UNI EN ISO 14937. Other similar cycles may be used but have not been evaluated. It is the responsibility of the user to demonstrate the adequacy of the sterilization cycle used should it vary from the following indications:

For Titanium alloy (Ti6Al4V) Instrumentation

Steam sterilization: pre-vacuum steam autoclave sterilization at a temperature of 134 °C for a minimum of 5 minutes.

For Polyamide (PA) Instrumentation

Steam sterilization: pre-vacuum steam autoclave sterilization at a temperature of 134 °C for a minimum of 5 minutes.

At the end of the sterilization cycle, check the change of the SBS (sterile barrier system) indicators, the integrity of both the packaging system and the product. In case of anomalies or doubts, consider the product non-compliant and consequently do not make it available to the user, as safety for the patient cannot be guaranteed.

H. Storage

Store in a clean, cool, dry place away from heat sources.

I. Transport

To prevent damage to medical devices during transport, we recommend the use of appropriate racks, trays or rigid containers. Avoid storing or transporting tools that are in contact with each other as they may be damaged.

9 RESTERILIZATION

Do not subject the medical device to the re-sterilization process

The re-sterilization of the device is not allowed, as it has not undergone specific checks and validation.

10 LIMITED WARRANTY

GPI warrants that this product meets the manufacturer's specifications and is free from manufacturing defects upon delivery.

These provisions have been validated by the MD manufacturer as being able to achieve the required cleaning and sterilization.

The user must ensure that the preparation and sterilization of the MD, as actually performed using the equipment, materials and personnel achieves the desired result. This requires verification and/or validation and systematic monitoring of the process.

This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product after receipt by the user.

11 LABEL

The labels applied to the packaging of the medical device have been defined and drafted in accordance with the applicable requirements of Regulation (EU) 2017/745 (MDR), in particular the provisions of Annex I, point 23.2.

Each medical device is supplied with the following labels:

- n.1 general identification label of the MD, applied to the external transport packaging
- n.1 general identification label of the MD, applied to the prosthesis packaging
- n.2 general identification labels of the MD, included inside the prosthesis package
- n.1 specific label identifying each individual component (prosthetic or instrumental)

The labelling of the medical device varies according to the condition of supply:

- For devices supplied sterile, the label clearly states the sterilization method used (e.g. "STERILE EO" for Ethylene Oxide sterilization) and its symbols in accordance with ISO 15223-1, together with the expiration date and the indication "Disposable / Non-reusable".

- For devices supplied **non-sterile,** the label reads "NON-STERILE" along with product identification information and instructions requiring sterilization prior to clinical use.

All labels are designed to ensure clarity, traceability and compliance with applicable regulatory requirements, ensuring that the user can immediately identify the sterility status of the device and the correct mode of use.

11.1 Examples of General Label

11.1.1 Example of General Label for MD supplied Sterile

11.1.2 Example of General Label for MD supplied NON-Sterile

THE FOLLOWING SYMBOLS AND WORDING APPEAR ON THE LABEL:

- CUSTOM-MADE DEVICE: indicates the type of medical device
- DESCRIPTION of the type of custom-made device in the catalogue (e.g. SURGICAL RECONSTRUCTION OF THE TEMPOROMANDIBULAR JOINT)
- 

Catalogue code identifying the MD
- 

Serial number: identification number of the prosthesis: YEAR/JOB CODE/N PROSTHESIS: YYYY/XXXXX/N
- 
Date of manufacture expressed in year/month
- 
Term of use or expiration date expressed in year/month. If not specified, a term of 1 year from the date of manufacture is considered
- 
The medical device can be used only once or on a single patient during a single operation
- 
Need to consult the instructions for use for important cautionary warnings, such as warnings and precautions, which, for various reasons, cannot be reported on the device itself
- 

The medical device has not undergone a sterilization procedure
- 
Consult the instructions for use
- 
QR links to digital documents (instructions for use)
- 
Do not use the medical device if the packaging is damaged or opened
- 
Keep away from sources of moisture
- 
Keep away from heat and light sources
- UNCEMENTED USE: informs that the MD must be implanted without the use of bone cement
- 

Sterilized with Ethylene Oxide

NOTE: the unique patient identifier is not shown on the label as it is uniquely linked to the Serial Number and shown on the declaration of conformity.

11.2 Examples of Single Component Label

The MD is provided with a set of labels to be applied to the casing of each of its components.

Each label shows the serial number of the reference MD (AAAA/CODCOMMESSA/N coding), the code and description of the specific component and the material that composes it to avoid errors during sterilization.

The following are examples of labels for each component of implantable prosthesis supplied in sterile and non-sterile options:

11.2.1 Example of Label for Component of MD supplied Sterile

11.2.2 Example of Label for Component of MD supplied NON-Sterile

Where Y is the marking of the orientation of the prosthesis component in relation to the body part and can be optionally:

- D if Right component
- S if Left component
- ANT if front component
- POST if rear component
- Not indicated if it has no ambiguity.

11.3 Examples of Instrumentation Label associated with the MD

The instrumentation for use in association with the MD (e.g. cutting templates and anatomical replicas) is the set of components that assist the implant that cannot be identified as implantable parts of the prosthesis.

The following is an example of a label for the instrumentation provided in sterile or non-sterile options:

11.3.1 Example of Label for Instrumentation Component of the MD supplied Sterile

11.3.2 Example of Label for Instrumentation Component of the MD supplied NON-Sterile

12 OPERATING INSTRUCTIONS

Since it is a custom-made device whose design is defined on the basis of a medical prescription, the implant must be positioned following the surgical operating instructions defined by the requesting doctor, based on the preoperative planning and the specific needs of the patient.

13 WARRANTY CLAUSE AGAINST POSSIBLE LIABILITY

The instructions described above have been validated by GPI SPA as a precise description of the preparation of a medical device for use on a single patient.

It is the responsibility of the operator in charge of the treatment to verify that the treatment itself, carried out using the equipment, materials and personnel available at the appropriate facility, achieves the desired result.

This usually requires validation and cyclical control of the operating procedure.

The cleaning, disinfection and sterilization procedures must be carried out and recorded according to the protocols in force at the facility responsible for the aforementioned operations.

Any deviation by the operator in charge of the treatment with respect to the instructions provided must be evaluated and recorded with regard to effectiveness and potential negative and adverse consequences.

14 DISTRIBUTORS

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