The Healthcare Partner

INSTRUCTIONS FOR USE FOR THE TREATMENT OF CUSTOM PROSTHESES

Instrumentation

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The custom-made device is manufactured by:

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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

⚠ WARNINGS GENERAL		For any type of report regarding GP I products , please send an email to the following email address: segnalazionidm@pec.gpi.it
1	**R-ST01**	Prosthetic components and instrument sets are supplied **NON-STERILE** and require an additional cleaning and sterilization process prior to implantation.
2	**R ST01**	Use only NEUTRAL AND ANTIBACTERIAL DETERGENTS for cleaning operations on the devices produced by GPI SPA
3	**R SP03**	Do not use products from damaged or opened packages.
4	**R ST02**	Carefully follow the sterilization procedure indicated for each type of material
5	**R ST02**	Be careful not to steam sterilize polyethylene (UHMWPE) components
6	**R ST01**	For a further process of re-sterilization of a component of the prosthesis, refer to the *RESTERILIZATION paragraph* of this information leaflet.
7	**R P12**	To guarantee safety and effectiveness of the intervention, the implantation of the prosthesis must not be combined with prostheses of other origins unless this combination has been analyzed in the design phase.
8	**R CH4**	The components of the IA prosthesis are designed to uniquely fit the patient's anatomy and the pre-operative plans of the implanting surgeon, using an anatomical bone model produced from a CT scan of the patient. These preoperative plans include establishing the desired setting on the patient before the CT scan or on the bone model after it has been produced. It is very important that the surgeon accurately reproduce the patient setting plan and any anatomical contouring at the time of implantation in order to achieve the intended placement of the prosthesis components.
9	**R CH1**	To ensure the safety and effectiveness of the operation, the positioning of the IA prosthesis does not require the use of bone cement or other filling agents
10	**R CH1**	The components of the joint prosthesis are intended to be implanted in mutually mating sets. To guarantee safety and effectiveness of the intervention, the positioning of the IA prosthesis does not require the use of components supplied by other manufacturers (with the exception of fixing screws)
11	**R CH2**	Prosthesis components contain joint surfaces that can be damaged if mishandled. ○ Any damage to these surfaces can affect the long-term performance of the prosthesis. ○ Avoid contact with the joint surfaces as much as possible. ○ Denture components should only be handled with blunt, smooth-surfaced instruments to avoid damage. ○ Tools with teeth, serrations or sharp edges should not be used.
12	**R CH2**	The bone model presents characteristics of fragility. Handle with Care.
13	**R CH2**	The surgeon must be familiar with the application of the surgical MD before use.

14	**R CH2**	The equipment provided 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 trauma to the patient/operator
15	**R CH2**	Avoid storing or transporting tools in contact with each other as damage may occur.
16	**R CH2**	Do not use damaged tools. Damaged instruments must be replaced before using them . Do not attempt to straighten or modify prosthetic MD components or instruments as this may compromise strength of the same and lead to subsequent failures or injuries
17	**R CH6**	Before implanting the prosthesis, physically check the integrity of the prosthesis conformity and serial number. The serial number is the reference number linked to the medical prescription and the declaration of conformity and is silk-screened on the component where the dimensions allow it, data that identifies the patient. Check the exact correspondence of the serial number connecting to the patient on the declaration, label and prosthesis, before proceeding with the prosthetic implant.
18	**R-POST1**	The doctor is responsible for informing patients of the limitations of implanting the IA prosthesis. Since these are custom prostheses, these limits differ depending on the prosthesis and the patient and are the responsibility of the requesting doctor.
19	**R-POST2** **R-PP7**	The doctor is required to inform the patient about the potential interaction resulting from exposure to electromagnetic fields or radio frequencies
20	**R-CH7**	The axial torque for tightening the 2.7 mm screws must not exceed 576 N*mm
21	**R ST03**	Check that the bags are intact and the components are correctly packaged and correctly positioned inside the sterilization systems to avoid the risk of breaking the bag.

2. INTENDED USE

2.1 Instrumentation

The instrumentation DM 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. CONTRAINDICATIONS

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 REQUIREMENTS

MDR 745/2017	Reg EU medical device
EN ISO 9001:2015	Quality management systems — Fundamentals and vocabulary
EN ISO 13485:2016 /A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2 019	Medical Devices - Applying risk management to medical devices
EN ISO 14155:2020	Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice
UNI EN ISO 16061:2021	Instrumentation for use in association with non-active surgical implants - general requirements
EN 62366-1:2015+AC:2015+AC:2016+A1: 2020	Medical devices - Application of usability engineering to medical devices
UNI EN ISO 14630:2025	Non-active surgical implants - general requirements
UNI EN ISO 21534:2009	Non-active surgical implants - special requirements
UNI EN ISO 10993-1:2021	Biological evaluation of medical devices
UNI EN ISO 5832-3:2022	Surgical implants - metallic materials - part 3: Titanium6-aluminum 4-vanadium alloy
ISO 5834-2:2019	Surgery implants: part 2 Ultra high molecular weight polyethylene
ISO 5832-4:2014	Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy
UNI CEI EN ISO 15223-1:2021	Medical devices - Symbols to be used in medical device labels, labeling and information to be provided - Part 1: General requirements
ASTM F2026 − 17	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
UNI EN ISO 17665-1:2007	Sterilization of healthcare products - Moist heat - Part 1: Requirements for development, validation and routine control
UNI EN ISO 14937:2009	Sterilization of healthcare products - General requirements for the characterization of a sterilizing agent and for the development, validation and systematic control of a sterilization process for medical devices
UNI EN ISO 17664-1:2021	Packaging of health care products - Information to be provided by the medical device manufacturer for the packaging of medical devices - Part 1: Critical and semi-critical devices

5. MATERIALS

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

- Ti-6Al-4V ELI titanium alloy, compliant with 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

Note: Standard prosthesis fixing systems, identified by the surgeon in the initial design phase, are not supplied with the prosthetic DM.

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

The detail of the composition materials of the prosthetic DM is reported in the declaration of conformity.

5.1. Storage conditions of materials

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

5.2. Disposal of materials

The disposal of removed materials, including instruments, must take place according to the standard for special surgical waste, in use in operating rooms .

6. PRECAUTIONS

It is the responsibility of the surgeon using this product to evaluate the patient's clinical and medical status and be aware of all aspects of implant 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 performed should be considered. Revision implant surgery is not uncommon, so the surgeon should perform a careful clinical risk-benefit analysis to achieve the best long-term outcome for the patient.

The patient must be informed about 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 study of relevant publications, consultation with experienced collaborators, and training in the procedures applicable to this particular prosthesis.
Accepted surgical practice should be followed in postoperative care.

DO NOT USE COMPONENTS IN OPEN OR DAMAGED PACKAGES.

6.1. Magnetic resonance and radio frequency safety information

The metallic material used for prostheses is not one of the materials considered dangerous or incompatible for magnetic resonance imaging and radiofrequency.

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

Thermal induction of metallic implants is a risk that depends on the geometry and material of the components, as well as on MRI and radiofrequency aspects such as power, duration and sequence of pulses. Because MRI or radiofrequency equipment is not standardized, the severity of these problems and the likelihood of them occurring with these implants are unknown.

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 in these environments. Because these devices have not been tested, GPI cannot make recommendations regarding the use of magnetic resonance imaging with these implants, or radio frequency either regarding safety issues or the accuracy of the images. Some components are passive metallic devices and generally there is the potential for mutual interference with certain imaging modalities, including image distortion in MRI and X-ray scattering in CT.

7. ADVERSE HEALTH EFFECTS OF THE DEVICE

may occur after placement of this prosthesis that require further treatment.
The occurrence of a complication may be related to or influenced by the patient's previous surgical history or previous medical conditions.
The adverse events reported in the literature in the clinical practice of mandibular prostheses are generally the following:

- Infection
- Chronic or recurrent pain and/or swelling
- Loss of joint mobility due to the development of adhesions (scar tissue), heterotopic bone, or ankylosis
- Dislocation of the prosthesis components
- Wear, movement, breakage or loosening of prosthesis components
- Perforation or dehiscence of surrounding tissues
- Foreign body reaction or allergic reaction to prosthesis components

Other complications may occur such as:

- Post-operative pain, swelling, bruising, jaw muscle spasm or hematoma formation
- Peripheral neuropathies
- Negative effects on the contralateral joint when the prosthesis is positioned unilaterally

8. STERILIZATION PROCEDURE

 **All medical devices supplied by GPI SPA are packaged in "NON-STERILE" packaging.**

The devices produced by GPI SPA, through the selective laser fusion process of Titanium, Cobalt Chrome and Polyamide powders and the devices produced by GPI SPA through the milling process of high density polyethylene and PEEK will be damaged with the use of high-density detergents. acid based, therefore only use NEUTRAL AND ANTIBACTERIAL DETERGENTS.

 **GPI SPA medical devices are supplied in NON-STERILE conditions, therefore, to ensure safe clinical use, it is recommended to follow the specified sequence:**

a) initial treatment at the point of use;

- remove the outer cardboard packaging used for shipping
- take out the inner box with the GPI logo

b) preparation before cleaning;

- remove the products from the internal 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 are, clean/unblock/wash 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 extreme concentrations. Neutral pH enzymatic cleaners and warm water can be used to facilitate cleaning. Subject to a validated process compliant 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 an absorbent fabric with low particle release, or with an industrial dryer or in a drying cabinet.

e) inspection and maintenance;

During cleaning, inspect the absence of any visible residue, especially in the less accessible areas. Carefully check the components of the prosthesis and/or associated instruments to verify that they are not damaged, paying particular attention to the areas of the devices in the moving or interlocking parts. 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;

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

g) sterilization;

The following process parameters have been demonstrated to 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 user's responsibility to demonstrate the adequacy of the sterilization cycle used should it vary from the following indications:

For anatomical replicas and surgical guides in Titanium alloy (Ti6Al4V):

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

For anatomical replicas and surgical guides in polyamide (PA):

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

At the end of the sterilization cycle, check the change in the SBS (sterile barrier system) indicators and 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 and dry place and away from heat sources.

i) transport

To avoid damage to medical devices during transport, we recommend the use of appropriate racks, trays or rigid containers. Avoid storing or transporting tools in contact with each other as damage may occur.

9. RESTERILIZATION

Re-sterilization of the device is not permitted, as it has not been subjected to specific checks and validations.

10. WARRANTY LIMITED

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

These provisions have been validated by the manufacturer of the DM as capable of achieving the required cleaning and sterilization.

The user must ensure that the preparation and sterilization of the DM, 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 device MD, once produced, is placed in non-sterile packaging, as the sterilization of the product takes place shortly before the surgical operation as reported in this document.
The label relating to the MD is placed on the box.
The content of the label complies with what is indicated in point 23.2 of Annex I of RDM 745/2017 and is illustrated below.
The symbols and phrases indicated on the label were taken from the reference standard UNI CEI EN ISO 15223-1:2021

Each MD will be supplied with 1 label shown on the prosthetic packaging, one on the box and 2 inside the box available to the doctor and the patient, 1 specific label for each individual component of the prosthetic MD.

11.1. Example of prosthesis label

The labeling of the prosthesis consists of:

- **MD LABEL** : main label that identifies the prosthetic MD
- **COMPONENT LABEL** : label for each individual component that makes up the MD (implantable components of the prosthesis)
- **INSTRUMENTATION LABEL** : label for each individual instrumentation for use in association with the prosthesis (non-implantable components: e.g. cutting templates and anatomical models)

Below is an example of a TMJ prosthesis MD present in the price list:

REF AND MD DESCRIPTION

REF AND DESCRIPTION of the COMPONENTS

Es. CUSTOM MD					
KIT	Operation	n.	art.	Description	
TMJ1	Temporomandibular Articulation	1	man	replica mandibola in poliammide	Instrumentation of the MD
		1	tgmt - 1	dima di taglio e foratura in titanio	
		1	rc4	replica cranio 1/3 in poliammide	
		1	pt7	placca mandibolare con condilo in titanio Ti64	Components of the MD
		1	mg1	protesi glena condilare in PE-UHMW	
		1	pt3	placca fissaggio in Ti64	

MD LABEL EXAMPLE

The following symbols and wording appear on the label:

- CUSTOM DEVICE: indicates the type of medical device
- DESCRIPTION of the type of customized device in the catalog (SURGICAL MD FOR RECONSTRUCTION OF THE TEMPOROMANDIBULAR JOINT in the example)
- REF Catalog code identifying the MD
- SN Serial number: identification number of the prosthesis: YEAR/ORDER CODE/N PROSTHESIS: AAAA/XXXXX/N

-  Manufacturing date expressed in year/month
-  Term of use or expiry date expressed in year/month. If not specified, a term of 1 year from the date of production 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 information, such as warnings and precautions, which, for various reasons, cannot be reported on the device itself
- 

The medical device has not been subjected to a sterilization process
-  Consult the instructions for use
-  QR link to digital documents (instructions for use)
-  Do not use the medical device if the packaging is damaged or opened
-  Keep away from sources of humidity
-  Keep away from heat and light sources

- UNCEMENTED USE: Informs that the MD must be implanted without the use of bone cement

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

Label of the single component of the prosthesis MD

The MD is supplied with a set of labels to be applied to the casing of each component.
Each label shows the serial number of the reference MD (code AAAA/CODCOMMESSA/N), the code and description of the specific component and the material that composes it to avoid errors during the sterilization phase.

Below is an example of a label for a single component of an implantable prosthesis:

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

- D if Right component
- S if Left component,
- ANT if frontal component
- POST if posterior component,
- Not indicated if unambiguous.

Instrumentation labeling for use in association with the MD

The instrumentation for use in association with the MD (e.g. cutting templates and anatomical replicas) is the set of components to assist the implant which are not identifiable as implantable parts of the prosthesis.

Below is an example of a label for instrumentation:

: GPI SPA – Via Ragazzi del '99, n.13 -30123 Trento (TN) – ITALY

REF : XXX (code component)

Descrizione descrizione e REF DM padre
Description: REF description and MD root
Materiale - Material: ex: lega di Titanio Ti6Al4V - Ti6Al4V Alloy

: AAAA/MM production

SN : AAAA/XXXXX/N

: Dr. XXXXXX – Hospital: XXXXX

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 physician, 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 falls under the sphere of responsibility of the operator in charge of the treatment to verify that the treatment itself, performed using the equipment, materials and personnel available at the appropriate facility, achieves the desired result.
This normally requires validation and cyclic 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 structure responsible for the aforementioned operations.
Any deviation by the treatment operator from the instructions provided must be assessed and recorded with regard to effectiveness and potential negative and adverse consequences.

14. DISTRIBUTORS

ITALY:

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EUDAMED code: IT-MF-000020127
Registration number Database of manufacturers of customized medical devices of the Ministry of Health: ITCA01050530