sintac
BIOMEDICAL ENGINEERING
a brand of GPI

INSTRUCTIONS FOR USE FOR THE TREATMENT OF CUSTOM MADE PROSTHESES

Cranial implant

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Custom-made devices manufactured by GPI SpA
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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	Non-sterile medical devices require an additional cleaning and sterilization process prior to implantation.
2	R ST01	Use only NEUTRAL AND ANTIBACTERIAL DETERGENTS for cleaning devices manufactured by GPI SPA.
3	R SP03	Do not use products from damaged or opened packages
4	R ST02	For non-sterile medical devices, carefully follow the sterilization procedure indicated for each material type.
5	R ST02	Take care not to steam sterilize polyethylene (UHMWPE) components
6	R ST01	Do not subject the medical device to re-sterilization.
7	R P12	To ensure the safety and effectiveness of the procedure, the prosthesis implantation must not be combined with prostheses from other sources unless this combination has been analyzed during the design phase.
8	R CH4	The medical device is designed to fit exclusively the patient's anatomy and the preoperative plans defined by the surgeon, based on an anatomical bone model obtained from the patient's CT scan. These plans include defining the desired positioning on the patient before the CT scan or on the bone model once produced. It is essential that the surgeon accurately reproduces the patient setup plan and any anatomical modeling during implantation to ensure correct placement of the prosthetic components.
9	R CH1	To ensure safety and effectiveness of the procedure, prosthesis placement does not require the use of bone cement or other filling agents
10	R CH1	The prosthesis components are intended to be implanted in mutually compatible sets. To ensure safety and effectiveness, the placement of the TC prosthesis does not require the use of components supplied by other manufacturers (except for fixation screws).
11	R CH2	The prosthesis components contain contact surfaces that may be damaged if handled improperly. Any damage to these surfaces can affect the long-term performance of the prosthesis. Avoid contact with the articular surfaces as much as possible. Prosthesis components must be handled only with smooth, blunt instruments to avoid damage. Do not use instruments with serrated or sharp edges.
12	R CH2	The bone model is fragile. Handle with care.
13	R CH2	The surgeon must be familiar with the application of the surgical medical device prior to use.
14	R CH2	The supplied instrumentation should never be used to perform tasks for which it was not specifically designed. Improper use of an instrument may 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 each other, as they may become damaged.
16	R CH2	Do not use damaged instruments. Damaged instruments must be replaced before use. Do not attempt to straighten or modify prosthetic device components or instruments, as this may compromise their strength and lead to subsequent failure or injury
17	R CH6	Before implanting the prosthesis, physically verify the prosthesis integrity, its conformity, and the serial number. The serial number is the reference number linked to the medical prescription and the declaration of conformity and is marked on the component where size allows, identifying the patient. Verify the exact correspondence of the serial number linking the patient on the declaration, label, and prosthesis before proceeding with implantation.
18	R-POST1	The physician is required to inform patients of the limitations of the TC prosthesis implantation. As these are custom prostheses, such limitations vary depending on the prosthesis and patient and are the responsibility of the requesting physician.

19	R-POST2 R-PP7	The physician is required to inform the patient about potential interactions arising from exposure to electromagnetic or radiofrequency fields.
20	R-CH7	The axial torque for tightening 2.7 mm screws must not exceed 576 N·mm.
21	R ST03	Check that the pouches are intact and the components are correctly packed and, where required, properly positioned within the sterilization devices to avoid pouch rupture.
22	R-CH9	Prostheses must not be manipulated or modified except as indicated in the design specifications. Any authorized modifications must be carried out exclusively outside the operating field.

2. INTENDED USE

2.1. CRANIAL IMPLANT

The prosthesis medical device (MD) for the reconstruction of a portion of the skull (TC) is a class III, implantable, custom-made medical device and is designed to be used for the reconstruction of a part of the skull, following demolitive surgery for tumor pathology or traumatic events suffered by the patient or for congenital malformations.

The MD is composed of a combination of one or more components packaged together in order to be used for the reconstruction of a portion of the skull and possibly of a surgical set composed of an anatomical bone model and cutting templates. These components have been customized exclusively for the patient identified on the device label, they are made via Additive Manufacturing (3D printing) or via CNC milling machine (Computer Numerical Control) based on a 3D project.
The project is developed on the basis of DICOM images and on the specific prescription written by any person authorized by national law by virtue of his personal qualification, which indicates, under the responsibility of that person, the specific characteristics of such design.

The prostheses are made with biocompatible material such as Ti64 titanium alloy, UHMWPE polyethylene, PEEK.

The cranial reconstruction surgery must be performed by medical and nursing personnel previously trained and specialized in surgical interventions for skull reconstruction surgeries in operating rooms equipped for this purpose.

2.2. WARNINGS OR EXCLUSIONS

The prostheses have specific design characteristics provided under the responsibility of the requesting physician who is authorized by national law by virtue of his professional qualifications.
Due to their personalized characteristics and the materials used, the prostheses are for single and exclusive use by the patient.

The fixing systems used for anchoring the prostheses are not supplied with the prostheses, unless there is a request for a customized production, in which case they are an integral part of the MD, but are defined in the design phase by the medical staff according to the most appropriate standard for the specific surgery.

3. CONTROINDICATIONS AND PRECAUTIONS

The use of the custom-made cranial implant prosthesis shall be carefully evaluated in patients presenting with:

- active or chronic infections
- insufficient bone quantity or quality
- systemic conditions increasing susceptibility to infection
- known allergy to device materials
- poor patient compliance or harmful habits

4. NORMATIVE REFERENCES

MDR 745/2017	Reg EU medical device
UNI EN ISO 9001:2015+A1:2024	Quality management systems - Requirements
UNI CEI EN ISO 13485:2021	Medical Devices Quality management systems Requirements for regulatory purposes
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
UNI EN 62366-1:2015/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-Joint replacement implants - Particular requirements
UNI EN ISO 16061:2021	Instruments for use in association with non-active surgical implants - General requirements
UNI EN ISO 10993-1:2021	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
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 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 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
ISO 19227:2018	Implants for surgery — Cleanliness of orthopedic implants — General requirements
UNI EN ISO 5832-3:2022	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
ISO 5834-2:2025	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms
ASTM F136-13(2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM F2026 – 23	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
ASTM F648 -21	Standard specification for ultra-high-molecular-weight polyethylene powder and fabricated form for surgical implants

5. MATERIALS

All prosthetic 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%

- **Ultra-high molecular weight polyethylene UHMWPE GUR 1050 type 2, ISO 5834 -2 / ASTM F648 standard**

  Chemical Composition

  - Ethylene homopolymer according to ASTM D4020: Balance
  - Ash: max 125 mg/kg max
  - Titanium (Ti): max 40 mg/kg
  - Chlorine (Cl): max 30 mg/kg
  - Aluminium (Al): max 20 mg/kg
  - Calcium (Ca): max 5mg/kg

- **polyetheretherketone (PEEK), ASTM F2026 standard, material certified at origin ISO 10993-1 Invibio OptimaTM**

  Chemical composition:

  - Total heavy metals (Ag, As, Bi, Cd, Cu, Hg, Mo, Pb, Sb, and Sn): maximum 100 ppm

NOTE: Standard prosthesis fixation systems, identified by the surgeon in the initial design phase, are not supplied with the prosthetic MD.

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

Details of the materials of composition of the prosthetic MD are given in the declaration of conformity.

5.1. STORAGE CONDITIONS OF THE MATERIALS

The prosthetic 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.

5.3. DISPOSAL OF PACKAGING

To help protect the environment, please dispose of the packaging properly by following the instructions below.

TYPE OF MATERIAL	URBAN WASTE	SPECIAL WASTE
Sealing paper— PAP 20	PAPER	EER 15.01.01
Corrugated cardboard — PAP 20	PAPER	EER 15.01.01
Document folder — PAP 20	PAPER	EER 15.01.01
Adhesive seal — PVC 3	PLASTIC	EER 15.01.02
Adhesive tape — PP 5	PLASTIC	EER 15.01.02
Sleeve — LDPE 4	PLASTIC	EER 15.01.02

Before disposal, reduce the volume of packaging; place each item of packaging in the designated recycling bin; always check your municipality's regulations.

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 following the placement of this prosthesis, which may require further treatment. The occurrence of a complication may be related to or influenced by the patient's previous surgical history or pre-existing medical conditions.

8. STERILIZATION

The devices are supplied non-sterile and must be cleaned and sterilized by the user prior to clinical use, following the instructions provided in this chapter and in accordance with UNI EN ISO 17665 standards.

The user must:

- perform a careful 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) PROSTHESES AND COMPONENTS

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

FOR POLYETHER ETHER KETONE (PEEK) PROSTHESES AND COMPONENTS

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

FOR HIGH-DENSITY POLYETHYLENE (UHMWPE) PROSTHESES AND COMPONENTS

Hydrogen peroxide sterilization: with operating temperature range of 50-55°C, with a minimum residence cycle of 37 minutes + 3 minutes of initialization.

FOR HIGH-DENSITY POLYETHYLENE COUPLED WITH TITANIUM ALLOY (UHMWPE+TI6AL4V) PROSTHESES AND COMPONENTS

Hydrogen peroxide sterilization: with operating temperature range of 50-55°C, with a minimum residence cycle of 37 minutes + 3 minutes of initialization.

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 labeling of the medical device indicates “NON-STERILE” along with the 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 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)
- REF Catalogue code identifying the MD
- SN 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
- NON STERILE 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

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 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 non-sterile:

11.2.1 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.

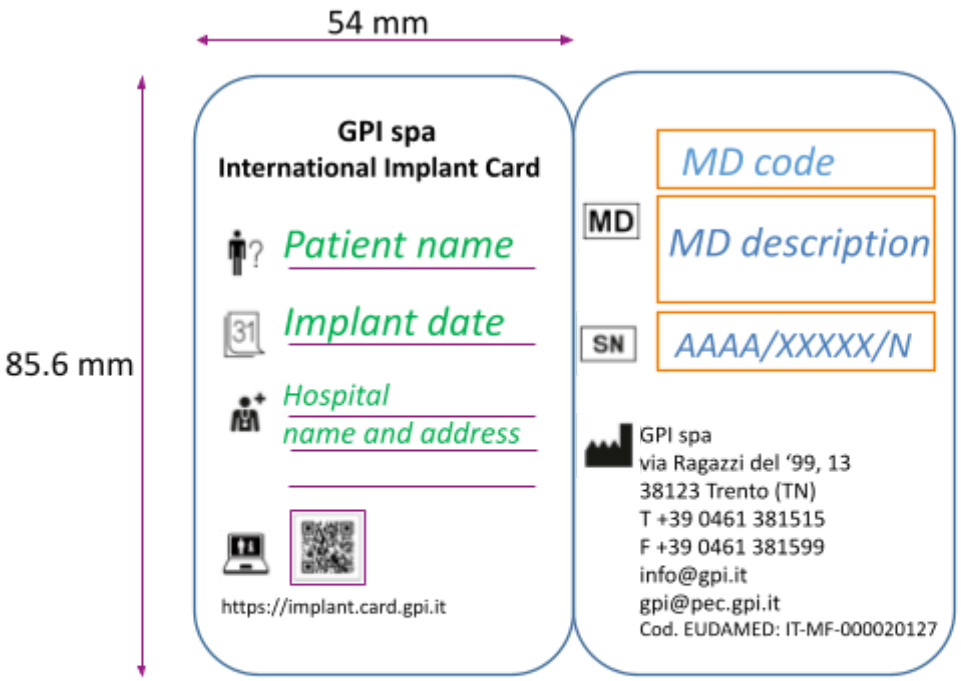
The following is an example of a label for the instrumentation provided non-sterile:

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

12. IMPLANT CARD

The implant card is provided by GPI to Healthcare Facilities and packaged together with the medical devices produced. In it there are fields that must be completed by the competent healthcare personnel, in particular it is necessary to:

- Complete the card (green parts in the image) with all the information requested by referring to the symbol legend below;
- Give the patient the implant card.



Text printed during the manufacturing process

Text handwritten by healthcare personnel

Text pre-printed by the manufacturer

Symbol Legend

- Patient's name
- Date of implantation
- Name and address of the healthcare facility
- Website address/QRcode with patient information
- MD — Medical Device Code and Description
- SN — Medical Device Serial Number
- Manufacturer

Information to be provided to the Patient by the Healthcare Facility

- Any warnings, precautions or measures to be taken by the Patient or a healthcare professional in relation to mutual interference with reasonably foreseeable external influences, medical examinations or environmental conditions.
- Every information on the expected useful life of the devices and on any necessary follow-up.

- Any other information to ensure safe use of the device by the patient, including information on materials and substances to which the patient may be exposed.

13. 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.

14. CLINICAL FOLLOW-UP

Periodic follow-up visits are recommended to monitor the position and status of prosthetic components, as well as to check the condition of the bone. Periodically take post-operative x-rays to get an accurate picture of the condition immediately after the operation and highlight any long-term signs of displacement, loosening, bending or cracking of the components.

In order to be able to implement the surveillance and surveillance plan required by EU Reg 2017/745 and ensure the safety of the performance of its products, GPI spa requires the commitment of its customers to provide for the collection of preoperative data and post-operative follow-up data, using a standardized data collection form.

In particular, the following data must be reported:

Subjective data

- Post-implant aesthetic satisfaction
- Reported quality of life compared to before the prosthesis implantation

Objective data

- Prosthesis stability and osseointegration
- Detected neurological complications

Results should be collected at each follow-up interval indicatively for the following time sampling:

- post-operative-immediate
- 7/10 days
- 1 month
- 3 months
- 6 months
- 1 year
- 1 time per year for subsequent years

The collection of clinical data is necessary to evaluate the performance of the prosthesis and the effects on the patient such as: reduction of pain, improvement of functions and quality of life of the patient.

15. IMPLANT LIFESPAN

The estimated lifespan of custom made implantable devices manufactured by GPI is 15 years or higher.

This is based on:

- technical data of wear tests and fatigue simulation (FEM surveys),
- established clinical literature,
- clinical and post-market experience of GPI with implantable devices already placed on the market.

The device is designed to replace the affected anatomical structure, permanently, consistent with the individual clinical factors of the patient and with compliance with surgical and post-operative instructions.

16. 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.

17. DISTRIBUTORS

ITALY

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