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TECHNICAL **DOSSIER**

ÍNDICE

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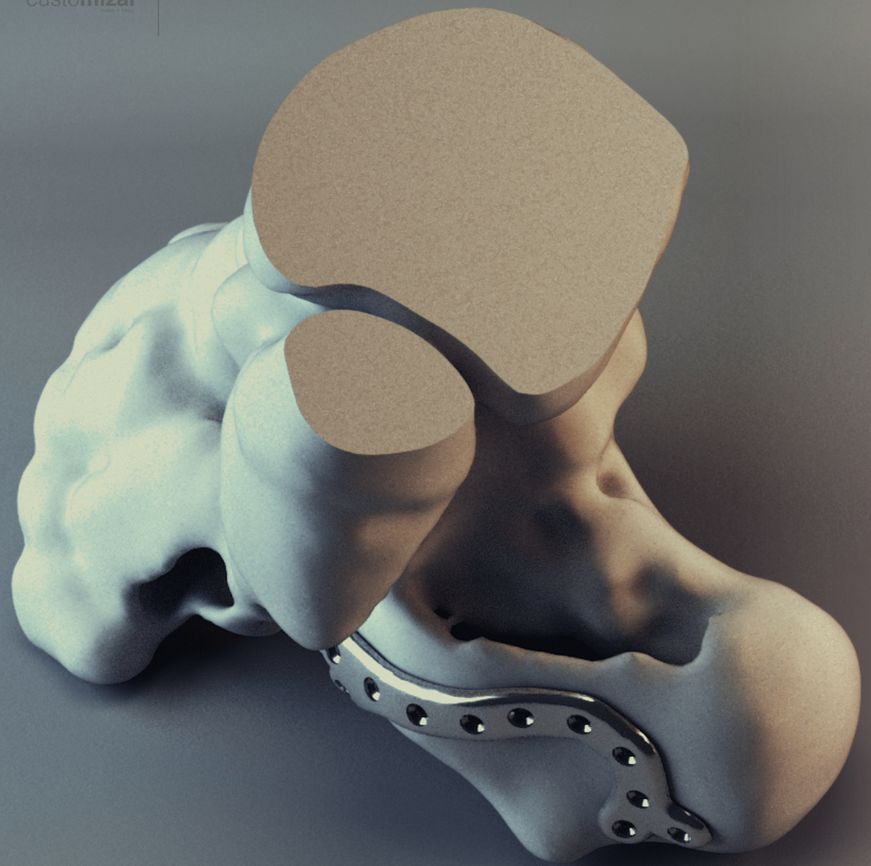


CUSTOMIZAR®
Introduction

At Customizar® we believe every patient is unique and requires personalized attention, especially when it comes to implants.

We provide implants and specific services for each surgery with the best treatment possible. Customizar® design and manufacture custom-made implants to improve the patient's life quality and recovery following the professional advice.

More than 10 years of experience working with additive and CAD CAM technologies allow us be flexible and provide the service and quality that identify Customizar®.

The essence of Customizar® is to facilitate the professional with all the means to provide personalized attention to their patients, meeting his/her particular treatment. The doctor guides his requests for every clinic case and conducts the most convenient design for the patient. At Customizar® we strive to perform our job through the doctor's eyes providing every patient the best solut

principles of the
osteosynthesis

In general terms, osteosynthesis principles can be summarized in 4 sections:

- **Fracture reduction and fixation** to restore anatomical relationships.
- **Stabilization: fracture fixation** providing absolute or relative stability as required by the type of fracture and injury.
- **Preservation of blood** supply to soft tissues and bone using the most careful handling and fracture reduction techniques.
- **Early and safe** mobilization of the injured part and the patient as a whole.

Complications of osteosynthesis surgical approaches using standard plates

The use of standard osteosynthesis plates show some inconveniences which the doctor has to face. The specialist in orthopedic surgery, neurosurgery or maxillofacial surgery has to adapt the material in the surgical field and manipulate the standard plate to adapt it to the injured area. This adaptation alters

the plate effort capacity with respect to its original state and, occasionally, causes some difficulties when implanting the screws, affecting the traction forces. All manipulation involves an increment of minor risks and also increases the time of the surgery.

First 3D solutions

In recent years, the demand of advanced solutions to perform reconstruction processes due to fracture, oncology or congenital disease as well as some aesthetic surgery where an orthopedic surgeon or a maxillofacial surgeon is required, has increased considerably.

First 3D printing developments to manufacture implants require the previous fabrication of moulds which meant an increase in cost and also require longer waiting time and longer hospital stay, consequently, increasing the risk of nosocomial infection and delaying the beginning of mobility.

our solutions

Customizar® patient-specific implants are designed to adapt to the anatomy of the patient and to ensure a precise fit that facilitate their placement and significantly reduce the time of surgery, the risk of associated infection and minimize rejection allowing a quality recovery in less time.

Once the doctor diagnoses and assesses the solution for the patient, the Customizar® team of professionals integrates it into a design programme that will allow the custom-made manufacture of the osteosynthesis material for that particular patient. By means of this integration, it is not necessary to manufacture previous moulds for subsequent 3D printing. **From the CT images and the professional's comments, the requested pieces are made and will be ready for surgery in a maximum time of 72-96 hours**, except in very specific cases

Customizar® uses Titanium TI6AI4V with a degree of purity of 99.7% for the manufacture of parts which, thanks to its minimal porosity, make it the most prepared to support mechanical stress. The specificity of manufacturing plates of lower thickness in microns facilitates the fusion during the manufacture of the pieces unlike the techniques Electrom-beam additive manufacturing (electro bus metal) that, when making the fusion in a single process, require thicker layers in the manufacturing process, translating into a lower purity and ease of breakage.

Customizar® allows:

- A precise fit: it adapts perfectly to the patient's anatomy.
- Reduced fitting time: there is no need for prior adaptation.
- Less time in the surgical field: no adaptation of the osteosynthesis pieces is required.
- Minimization of infection risks due to manipulation.
- Reduction of manufacturing time through CADCAM technologies controlled directly by the professional.
- Maximum manufacturing and delivery time: 96 hours, except few cases.
- Total adaptability subject to the osteosynthesis capacity of the piece, the speed and compactness required by the professional.
- Design of bone fragment replicas or complete bone replicas for replacement operations in oncology or orthopaedic surgery (dysplasia, congenital problems, atrophy,...)
- Adaptation of the plate surfaces to the doctor's needs. The surfaces can be polished or porous with different hexagonal or octagonal frameworks.... depending on the osteosynthesis capacity of the piece, its speed and compactness as required by the professional subject to the area where it is to be used.
- Versatility. Customizar® plates and implants can be adjusted to any screw and instrument available on the market. Inform us about the set of screws you use in the operating room and we will make sure they fit perfectly into your custom-made implant.

CT Protocols

Data and images required by the team of doctors who will perform the surgery need to follow specific parameters to guarantee the quality of the implant.

We provides radiology professionals with a series of protocols by area -foot, shoulder, etc. - with the recommended parameters based on the nature of the injury.

This documentation may vary and is reviewed and extended according to the new updates and/or new techniques and specifications of the radiology equipment.

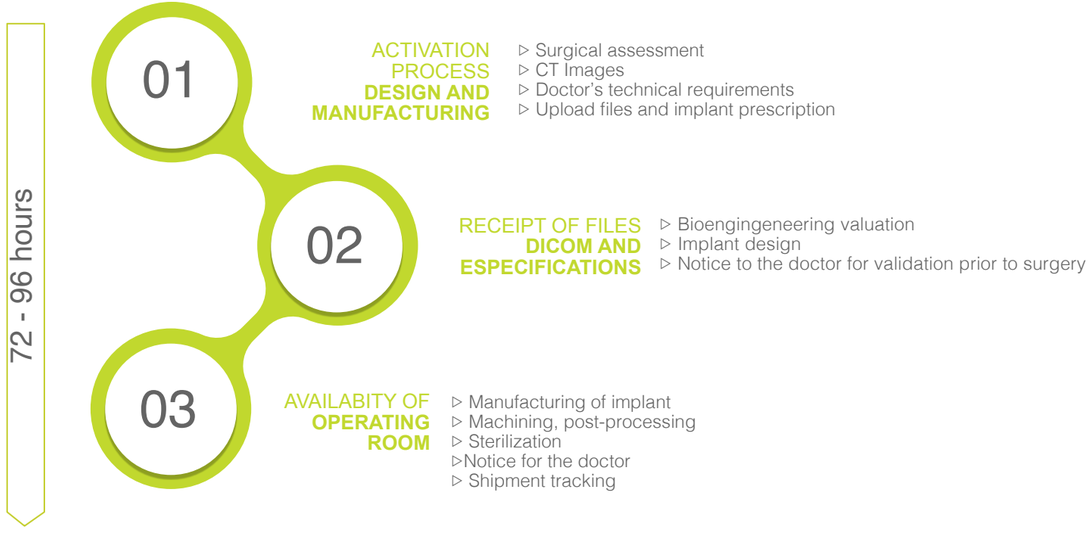
Link to download the protocols:

https://www.customizar.es/dosier/guias.html

MiTE® make it easy

Our engineering team collaborates with the doctor in the design of the implant. It is possible to order customized implants in a simple and safe way through the Customizar® platform and with the support of our engineering team.

Our online platform is protected with the latest online security protocols and patient data is anonymized when dumping the medical image, ensuring the privacy of the patient's information and offering greater safety within the framework of the quality and health product system according to **UNE-EN ISO 9001:2015 and UNE-EN ISO 13485:2016, the European Union's General Data Protection Regulation 2016/679, and Organic Law 3/2018 of 5 December** on the protection of personal data and guarantee of digital rights.



Biomodels

At Customizar® we produce 3D biomodels from medical images that help reveal often masked facts and plan surgery.

If you would like a biomodel, please contact your authorized distributor.

Surgical guides

We can help you prepare the surgery. Surgical planning allows to decide in advance the direction and depth of the cut, the implant and the screw. Surgical guides are a solution that allows the precise transfer of surgical planning to the operating room. These customized tools are designed to perfectly match the bone structures of your patient. They fit in a single location and allow a precise execution of the surgery.

If you require a surgical guide, please contact your authorized distributor.

Orthoses

Customizar® orthoses and fixations facilitate the recovery of the neuromusculoeskeletal system allowing a greater quality of life. The new 3D printing technologies and the use of new materials allow the manufacture of patient-specific orthoses or prostheses.

The materials used in the 3D printing are certified for use in contact with the skin and allow fabrication of lighter, more breathable and permeable orthoses which facilitate the doctors' follow-up and supervision of the patient and above all, reduce recovery times.

Implants

Once the implant has been designed and validated by the doctor, Customizar® manufactures the implant in Titanium Ti6Al4V within the committed time. All the material is sterilized before delivery.

our products

1.- ACETABULUM PLATE
Dynamic mesh
Acetabulum plate

2.- ANKLE PLATE
Fixation plate
Atrodesis plate
Hook plate
Malleolus plate

3.- BREASTBONE/STERNUM PLATE
Box plate
X plate
Straight plate

4.- CALCANEUS PLATE
Locking plate
Anterior process calcaneal plate
Calcaneal osteotomy plate
Posterior tuberosity calcaneal plate
Lateral wall calcaneal plate

5.- CLAVICLE PLATE
Acromioclavicular plate
Superior clavicle plate
Midshaft clavicle plate
Anterior clavicle plate
Lateral clavicle plate
Medial clavicleplate
Variable angle clavicle plate
Hook clavicle plate

6.- CMF PLATE
Plate for ortognatic surgery
Plate for facial fracture
Orbital floor plate
MTJ plate
Craniofacial mesh/plate
Preprosthetic surgery plate
Esthetic plates (chin, mandibular angle, malar prothesis)
Reconstruction plate

7.- CONDYLAR PLATE
Condylar miniplate
Subcondylar locking plate
Condylar plate
Subcondylar plate
Supracondylar plate

8.- FEMUR PLATE
Pediatric implant
Femoral screw
Compression plate
Correction plate
Locking plate
Variable angle plate
Proximal plate
Lateral plate
Medial plate
Distal plate
Periprosthetic plate
Osteotomy plate

9.- FIBULA PLATE
Posterolateral fibula plate
Lateral fibula plate
Distal fibula plate
Compression fibula plate
Postdistal fibula plate
Hook fibula plate
Anterior fibula plate

10.- FOOT PLATE
Compresiion plate
Locking plate
Dorsal plate
Mtp plate
Osteotomy plate
T plate
H plate
L plate
Straight plate
Variable angle plate
Artrodesis plate
Forefoot plate
Wedge block flat foot plate
Osteotomy foot plate
Lisfranc foot plate
Hallux plate
Atrodesis lapidus foot plate

11. HAND PLATE
T plate
Y plate
Z plate
Straight plate
Curved plate
Fusion plate
Variable angle plate
Phalanx plate
Artrodesis plate
Metacarpal plate
Dorsal plate
Mtf plate

12. HIP PLATE
Hook plate
Lateral plate
Locking plate
Variable angle plate
Pediatric hip plate

13.- HUMERUS PLATE
Distal humerus plate
Medial plate
Posterolateral plate
Posteromedial plate
Dorsolateral plate
Locking plate with support
Compresion plate
Lateral plate
Inverse glenoid plate

14.- PELVIS PLATE
Infrapectineal plate
Suprapectineal plate
Straight plate
Curved plate

15.- RADIUS PLATE
Distal palte
Proximal plate
Palmar plate
Volar plate
Variable angle plate
Dorsal plate
Dorsolateral plate
Diaphysary plate
Poliaxial plate

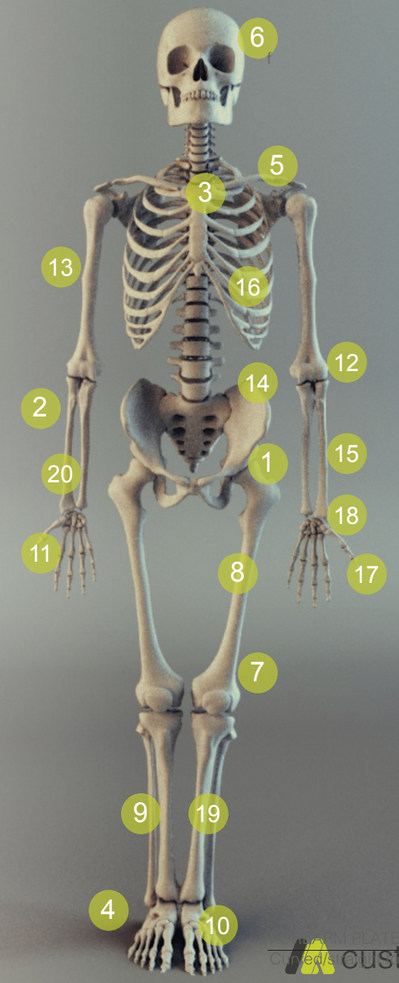
16.- RIB PLATE
Precontoured rib plate
Straight rib plate

17.- SMALL FRAGMENT PLATE
Locking plate

18. WRIST PLATE
Artrodesis plate

19.- TIBIAL PLATE
Component tibia base plate
Tibia implant for pediatric reconstruction
Partial tibia plate
Pilon tibia plate
Tibia compresion plate
Distal tibia plate
Anterolateral tibil plate
Medial plate
Proximal plate
Lateral tibia plate
Variable angle tibia plate
Oteotomy tibia plate
Cemented tibia plate

20.- ULNA PLATE
Variable angle plate
Proximal plate
Diaphysary plate
Distal plate
Lateral plate
Hook plate
Dorsal plate
Olecranon plate
Osteotomy plate



benefits fo the
patient

Customizar® contributes to an improvement in the patient's quality of life, allowing for a better recovery, reducing risks and shortening treatment time.

Less pre-surgical waiting time.

a. Risk reduction of nosocomial infections.
b. Earlier start of physiotherapy.
c. Shorter time from admission to hospital discharge.

Less possibility of rejection.

a. The prostheses are personalized to the injury and the patient.
b. Less possibility of reoperations.

Technical integration of the surgical process, allowing the design of the patient's prostheses or plates and the orthoses to be integrated for subsequent immobilization

benefits fo the
doctor

Customizar® collaborates with the professionals by bringing together the patient's needs and the doctor's requirements and knowledge.

- Pieces are manufactured following the professional's requirements there is no need to adjust the piece during the surgery.
- Less chance of rejection due to an inadequate mobility or breakage of the material,thus reducing the number of re-interventions.
- In certain cases it allows to make smaller incisions, favoring minimally invasive surgery.
- It enhances the possibility of developing new designs linked to the doctor's experience.

quality
customizar®

Quality and service is the key of Customizar® success and our best guarantee.

The confidence and loyalty that more and more professionals and organisations are placing on us, are the driving force which promote our continuous improvement. For this reason, Customizar® has implemented a management system with the aim of systematizing processes and clearly identifying the company's strong points and areas for improvement.

▷ Customizar® complies with **UNE - EN ISO 9001 Y UNE-ENE ISO 13485, with the Regulation (EU)) 2017/745,** as well as with its own protocol for the manufacture of tailor-made implants.

▷The **Regulation (EU) 2017/745 of the European Parliament and Council dated 5th April on medical devices**, amending **Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) N°. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC**, provides that custom-made implants are classified as: "custom-made device" means "any device specially manufactured in accordance with a medical prescription of any person authorized by national law on the basis of his professional qualification, which includes, under the responsibility of that person, specific design features, and which is intended to be used only by a particular patient for the sole purpose of meeting his particular condition and needs". "Products as they are placed on the market, if they comply with **Article 52(8) and Annex XII**I. As it is not a serial product but a customized one, CE marking is not required by the legislation in force.

Research and development

At Customizar® we do research to develop new ways to improve our products and personalized services. Our goal is constant improvement and business excellence in the field of trauma, orthopaedic and maxillofacial surgery. As an innovative company we are always open to participate in the development of R+D+i projects.

Tecnología

At Customizar® we use state-of-the-art manufacturing techniques such as high-precision milling and 3D printing to achieve the perfect end result. The combined application of different production methods creates new synergies. The right combination of the main market references in each of the technological disciplines allows Customizar® to offer innovative solutions.

Materials

Ti6Al4V is a high strength titanium alloy successfully used in orthopaedic applications characterized by high corrosion resistance, high mechanical strength and biocompatibility. Grade 23 Ti6Al4V is characterized by low oxygen content and is suitable for medical applications as well as other applications allowing higher oxygen concentrations. Titanium promotes osteointegration and can be sterilized by all common methods.

The main properties of Titanium are:

- ▷ Light weight, tensile strength
- ▷ Steady material
- ▷ Biocompatible
- ▷Excellent corrosion resistance

Ti6Al4V

CHEMICAL COMPOSITION

Elements	CONCENTRATION elements (WT%) ASTM F136/B348
Ti	Balance
Al	5.5 - 6.5
V	3.5 - 4.5
Fe	Max 0.25
O	Max 0.13
N	Max 0.05
C	Max 0.08
H	Max 0.0125

PHYSICAL PROPIETIES

Propieties	Value
Densidad (g/cm³)	4.4
Fuerza de tensión UTS (MPa)	>900
Fuerza de producción (MPa)	>850
Módulo de Young (GPa)	>105
Alargamiento (%)	<12

additional information

General terms of use

CUSTOMIMPLANTS® fixation systems are intended for the fixation of bone fractures, bone reconstructions and osteotomies. We offer multiple fixation characteristics and different sizes.

The implants are made of medical grade titanium. As it is a custom-made product, pre-planning is needed to obtain definition of the best fit.

Surgery contraindications

- Active or latent infection, sepsis, osteoporosis or in patients with immune deficiencies
- Physiologically or psychologically unfit patient.
- Inadequate neuro-vascular, skin or bone condition.
- Irreparable tendon system.
- Possibility of conservative treatment.
- Growing patients with open epiphyses.
- Patients with a high level of activity.
- Patients with previous sensitisation to stainless steel.
- Patients with certain metabolic diseases.
- Patients who exhibit disorders that could cause the patient to ignore the limitations of fixation, not following the indications for post-operative care.
- Patients who are skeletally immature and that the implant should not alter growth.

Adverse effects

- Allergic reactions to materials; sensitivity to metal, which can cause histological reactions, pseudotumours and lesions associated with aseptic lymphocytic vasculitis (LAVLA).
- Delayed wound healing; deep wound infection (early or late) that may require removal of the implant Rarely, it may be necessary to amputate the limb.
- Sudden drop in blood pressure during surgery due to use of bone cement.
- Damage to blood vessels or bruising.
- Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as a possible result of surgical trauma, causing pain or swelling of the affected limb.
- Cardiovascular disorders such as venous thrombosis, pulmonary embolism or myocardial infarction, among others.
- Fatigue fracture of prosthetic components can occur as a result of trauma, strenuous activity, improper alignment, incomplete seating of the implant, duration of service, loss of fixation, lack of union or overweight.
- Dislocation, migration or subluxation of prosthetic components due to incorrect placement, trauma, loss of fixation, or laxity of muscle and fibrous tissue.
- Residual pain.
- Swelling

PRECAUTIONS

Precautions before surgery

The surgeon must evaluate each situation individually, based on the clinical presentation of the patient, to make any decision regarding the selection of the implant.

The surgeon should be thoroughly familiar with the implant, the instruments and the surgical procedure before performing the operation.

The surgeon should contact CUSTOMIMPLANTS® or its authorized distributor to obtain specific surgical techniques for the product.

The surgeon should also use the medical devices according to the indications on their labels and the manufacturer's instructions for use, especially during insertion and removal.

The following factors, which may increase the risk of failure and may be critical to the final success of the procedure, should be taken into account in the selection of the patient: the patient's weight, activity level and profession.

All these factors can influence the duration and stability of the implant. An overweight patient can produce high loads on the implant, which can lead to implant failure.

The surgeon should consider the ability and the willingness of the patient to follow the instructions, and to control his or her weight and activity level.

No implant, including the implant/bone interface, can be expected to withstand the activity levels and loads that normal healthy bone would, and no implant can be expected to be as strong, reliable or durable as natural human bone.

The patient should not have unrealistic functional

expectations for occupations or activities that include walking, running, heavy lifting or intensive muscular strain.

Other situations that carry a higher risk of failure are as follows:

- ▷ Uncooperative patient or patient with neurological disorders, unable to follow instructions.
- ▷ Major bone loss, severe osteoporosis, or procedures for which an appropriate implant fit cannot be obtained.
- ▷ Metabolic disorders that may prevent bone formation.
- ▷ Osteomalacia.
- ▷ Poor prognosis for adequate wound healing (e.g. pressure ulcer, end-stage diabetes, severe protein deficiency or malnutrition).
- ▷ Pre-existing processes, usually considered for any surgery, such as bleeding disorders, prolonged treatment with steroids, immunosuppressive treatment or high-dose radiotherapy

The patient should be warned of the risks involved in surgery and made to understand the possible adverse effects.

The patient should be warned that the implant does not replace normal healthy bone and that it may break or be damaged as a result of certain activities or trauma.

The patient should also be warned of other risks that the surgeon may wish to disclose. The patient should also be warned to report to the surgeon any unusual noises or sensations, which could indicate a malfunction of the implant

Precautions during the surgery

There are specialized instruments that must be used to guarantee the precise implantation of the implant. Although it is not common, the instruments can break, especially after prolonged use or the application of excessive force. For this reason, the instruments should be examined before surgery for damage or wear.

Inspect the devices before use for damage during transport or storage, or for any obvious defect when unpacking that increases the possibility of fragmentation during an operation.

Implants require careful seating and adequate bone support.

For the correct selection of the implant, the following should be taken into account: the design, the fixation, the weight and age of the patient, the quality of the bone, the size, the degree of activity, the state of health before the operation, as well as the experience of the surgeon and his familiarity with the device. All these parameters can influence the duration and stability of the implant. Surgeons should inform patients about these factors.

Post-operative precautions

The patient should be warned of the limitations of reconstruction and the need to prevent the implant from bearing all the weight until proper fixation and complete healing has been achieved. Regular follow-up is recommended in order to monitor the position and condition of the implant components, as well as the condition of the bone.

Regular post-operative radiographs are recommended for careful comparison with early post-operative conditions to detect signs of long-term changes in position or loosening, bending or cracking of components.

There are inherent risks associated with the use of metal implants in an MRI environment, including component migration, thermal induction and signal distortion or interference in areas near the component(s). Thermal induction of metallic implants is a risk related to the geometry and material of the components, as well as to the power, duration and sequence of the MRI pulses. Since MRI equipment is not standardized, the intensity and probability of these manifestations with these implants are unknown.

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