Instructions for use
PG01 CMF System

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Content

MANUFACTURER

Digimed Medizintechnik
Kreutzerstraße 1
78573 Wurmlingen / Germany
Telephone: 07461 / 9101172
Fax: 07461 / 9101172
Enamel: info@digi-med.de
Internet: www.digi-med.de

CMF System

PLEASE READ IMPORTANT PRODUCT INFORMATION CAREFULLY BEFORE ANY CLINICAL APPLICATION!

CE 0483

SRN number: DE-MF-000007328

Dear customer!

With the purchase of this implant you will receive a high-quality product, the proper handling and use of which are described below. In order to keep hazards for patients and users as low as possible, we ask you to read and observe the instructions for use carefully.

Attention

Please read the information in these instructions carefully. Improper handling and care, as well as misuse can lead to premature wear and tear or risks for patients and users. Please also note the imprints on the packaging.

1 SCOPE

The scope of these instructions for use refers to the following products in our catalogues and brochures:

System:
System Ø 1.2 mm
System Ø 1.6 mm
System Ø 2.0 mm
System Ø 2.3 mm
System Ø 2.7 mm
IMF Fixation System
PIN Fixation System

2 INTENDED PURPOSE / INDICATION / MATERIAL

2.1 Purpose

Implants for the fixation of bone grafts and bone substitute materials in the reconstruction or osteosynthesis of jaw and facial bones, as well as for stabilization and rigid fixation in craniomaxillofacial fractures.

2.2 Indications

2.2.1 CMF System Plates, Screws, Meshes

2.2.1.1 System 1.2

Trauma

- Fractures of the cranial vault
- Orbital ligament fractures
- Frontal sinus fractures
- Naso-orbital-ethmoid fractures

Reconstruction of bony defects and deformities

- Cranial vault
- Fixation of bone grafts
- Orbital region
- Zygomatic region
- Dentoalveolar area

2.2.1.2 System 1.6 / 1.7

Trauma

- Cranial vault fractures
- Orbital ligament fractures
- Frontal sinus fractures
- Naso-orbital-ethmoid fractures
- Osteotomy fixation Le Fort I, II, III

Reconstruction of bony defects and deformities

- Skull vault
- Fixation of bone grafts
- Orbital region
- Zygomatic region
- Dentoalveolar area
- Genioplastic fixation

2.2.1.3 System 2.0

Trauma

- Craniofacial fractures
- Orthognathic midface/mandible
- Sagittal split osteotomy fixation
- Osteosynthesis of mandibular fractures
- Screw osteosynthesis

Reconstruction of bony defects and deformities

- Fixation of bone grafts
- Genioplastic fixation

2.2.1.4 System 2.3

- Fixation of sagittal split osteotomy
- Single, multiple comminuted fractures of the lower jaw

2.2.1.5 System 2.7

- Fixation of microvascular grafts in, reconstruction after resection
- Mandibular fracture fixation
- Bridging continuity defects after resection of a tumor, osteomyelitis or osteoradionecrosis and fixation of microvascular or non-vascularized grafts
- Bridging continuity defects for secondary reconstruction
- Fractures or associated defects with severe trauma

2.2.2 IMF Fixation System

Transient, perioperative stabilization of occlusion in adults.

- Simple, non-dissociated fractures of the lower or upper jaw
- Orthognathic interventions
- Temporary use during bone healing

2.2.3 PIN system

- Bone regeneration (bone augmentation, alveolar ridge)

2.3 Contraindications

2.3.1 CMF System Plates, Screws, Meshes

The implants of should not be used if the following provisions apply: Digimed Medizintechnik

- Fractures that cannot be repositioned or stabilized (except for reconstruction plates).
- Fractures of a severely atrophic lower jaw.
- Patients with manifest infection.
- Patients with metal allergies and foreign body sensitivity.
- Severely non-compliant patients with mental or neurological conditions who are unwilling or unable to follow post-operative care instructions.
- Patients with impaired blood supply or insufficient bone quality or quantity.
- Patients with unstable physical and/or mental health conditions.
- Mandibular reconstructions with systems 1.2 / 1.6-1.7 / 2.0

2.3.2 IMF Fixation System

Secondary reconstructions with the System 2.0 IMF-Fixation System

- Complex and/or dislocated fractures
- Unstable, segmented rows of teeth
- Combined mandibular and maxillary fractures

2.3.3 PIN system

Absolute contraindications

- Heavy smokers
- Inadequate vital recipient bed/bone quality. Attention is drawn to the need for careful consideration of the use by the surgeon.
- Incomplete dentoalveolar growth (exception: cases where dentoalveolar growth is not expected, e.g. ectodermal dysplasia)
- Acute infections in or near the area to be augmented as well as local pathological processes (e.g. symptoms such as fever, local inflammation, abscesses)

Relative contraindications

- Heavy smokers
- Material incompatibility
- Drugs / alcohol abuse
- Lack of cooperation on the part of the patient
- Mental condition that can lead to non-compliance with the doctor's order
- Highly atrophied jaw

2.4 Undesirable side effects / complications / risks

In many cases, complications are caused by the surgical procedure rather than the implant.

- Injury to nerves, vessels and organs
- Osteoporosis, limited or absent revascularization, bone resorption or poor new bone formation can lead to loosening, bending, cracking or fracture of the implant; in addition, premature loss of fixation with the bone is possible, so bone fragments cannot grow together.
- Mucous membrane or tissue reaction
- Rash
- Loosening of the implant due to insufficient, improper attachment
- possible nerve or blood vessel damage as a result of the surgical procedure
- Increased connective tissue response in the fracture area due to unstable comminuted fractures.
- Delayed, insufficient or missing bony construction of the fracture can lead to implant failure.
- Metal hypersensitivity reactions in patients after implant placement have been reported rarely.
- Malunion
- Pseudarthrosis
- Implant loses its function postoperatively
- Lack of healing
- Saliva fistula

The following side effects may occur after implantation:

- Exposure of meshes, pins, plates and/or screws
- immediate or delayed infection (deep and/or superficial)
- increased response of fibrous tissue around the fracture site due to unstable crushed fractures

The following side effects can occur after implantation for bone augmentation:

- Screw loosening
- prolonged postoperative pain
- Loss of grafts
- Screw breakage
- Dehiscence of soft tissue
- Bone loss
- Infections
- Nerve damage

In the course of market observation, further potential complications / side effects could be identified:

- Rupture of the implants
- Deformation of products
- Lack of healing
- Migration of products
- Infections, e.g. due to material incompatibilities
- Dehiscence of soft tissue
- Sharp edges on the device
- Formal defects (manufacturing defects)
- Packaging errors or labeling errors (incorrect information about the product)

2.5 Warnings

- The screws may only be used with the appropriate instruments:
- Implantation: Screwdriver see chapter Combination Digimed Medizintechnik
- Explantation: Screwdriver see chapter Combination Digimed Medizintechnik
- Make sure that the screws are firmly in place in the respective instrument. When implanting, make sure that there is sufficient axial pressure over the screws. Otherwise, there is a risk of mechanical damage.
- too much bending can lead to damage to the implants and/or premature failure of the plates and meshes.
- Bending in an anatomical position is allowed, bending back several times is prohibited.
- multiple bending can lead to damage to the implants and/or premature failure of the plates and meshes
- inadequate adaptation of the implants to the local situation can lead to delayed, inadequate support
- Reuse of implants is absolutely prohibited (single use).

Do not reuse

Failure to observe the restriction (single-use product) can have serious consequences for the patient, e.g.

1. Implant failure (e.g. fracture)
2. Lack of healing

2.6 Restrictions

The product group is not intended to be used on the central nervous/circulatory system.PG01 CMF System

2.7 Patient population

No specific patient populations. The products should be used taking into account the intended purpose, indications and contraindications, as well as taking into account the anatomy and state of health of the patient. The attending physician, surgeon decides depending on the circumstances.

2.8 User and field of application

The products are used by specialists in oral and maxillofacial surgery.
The treating surgeon is responsible for the correct selection of patients, for the necessary training, selection and placement of implants on the basis of sufficient experience, as well as the decision to leave or remove implants postoperatively.

2.9 Clinical benefits

The clinical benefit of the product group PG02 CM System, when used in accordance with these instructions for use and recommended techniques, is the stabilization, reconstruction of bone segments, membranes in the craniofacial region. The product group facilitates healing and restores the anatomical relationships and functional properties.PG01 CMF System

2.10 Capability characteristics

Digimed Medizintechnik has proven the performance and safety of the products and that it is a state-of-the-art medical device for oral and maxillofacial surgery for stabilization, reconstruction of bone segments, when used in accordance with the instructions for use and labeling.PG01 CMF System

2.11 Material

Titanium implants according to:

- Titan Grade 5 - ELI (Ti6Al4V) gem. ASTM F136 oder ISO 5832-3
- Titanium Grade 2 according to ASTM F67 or 5832-2

The surface of these implants is chemically passive, not magnetic. These implants can be combined with the standardized material, the composition of which is specified within the standard, according to the table above and the required specifications. These titanium materials are biocompatible and prevent so-called chromium-nickel allergies in their properties!

2.12 Attention

Instruments, and in particular implants, may only be used by persons who have been specially trained or instructed to do so. Suitable instruments must be used for the application and explantation of the pins. (see "Instruments for introduction and explantation"). Explantation of the implants is recommended after the patient's recovery. A stay of the implants in the patient's body can be decided after evaluation of the doctor under the sole responsibility of the doctor,

3 MRI NOTES

The company is a manufacturer of orthopaedic implants made of titanium and titanium alloys. This type of non-ferromagnetic material does not pose a danger to the patient when examined with magnetic resonance imaging (MRI) if handled properly. Digimed Medizintechnik

Various studies and test reports have shown that this titanium alloy according to ISO ISO 5832-3 and ISO5832-2 can be safely used in an MRI environment and can be considered "MRI Conditional" according to ASTM F2503. MRI Conditional is defined as an item that has been shown to present no known hazards in a specific MRI environment with specified conditions of use (ASTM F2503, 3.1.9).

Precautions: The above statement is based on non-clinical testing. The actual temperature increase of the patient depends on a variety of factors beyond the SAR value and the time of radiofrequency application. Therefore, it is recommended to pay special attention to the following points:

- It is recommended that patients undergoing an MRI scan be thoroughly monitored for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MRI scanning.
- In general, it is recommended to use a low-field MRI system in the presence of conductive implants. The specific absorption rate (SAR) used should be reduced as much as possible.
- The use of the ventilation system can further help reduce the rise in temperature in the body.

The implants are made of a titanium that is not magnetic. For this reason, the systems have not been tested for heating, migration, or image artifacts in the magnetic resonance environment. The safety of these systems in the magnetic resonance environment is unknown.

Note that - MRI techniques in the form of special spin-echo sequences such as VAT, SEMAC (SEMAC-VAT - 2D), MSVAT-SPACE (3D) and MAVRIC should be used to optimize image quality and minimize artifacts.

4 POSTOPERATIVE CARE

Postoperative immobilization is not required. Initiate active mobilization as soon as possible.

5 LIFESPAN / EXPLANTATION

5.1 Lifetime

No indication of durability or functional restriction is given for implants delivered non-sterile after manufacture, if they are stored properly. The products are intended for single use, single use and long-term implantation.

5.2 Explantation

5.2.1 CMF System

After 6 to 12 months, the CMF systems can usually be removed, provided that complete bone formation is demonstrated around the fracture site. The duration of bone healing depends in particular on the age and bone quality of the patient. The material removal of the block augmentations must take place at the earliest 3 months and at the latest 6 months after a iliac crest augmentation. With the IMF Fixation System, explantation can take place after 5-7 days with trouble-free occlusion. In general, the attending physician/surgeon decides together with the patient when and if an explant must take place. The implants are designed for long-term implantation.

6 INSTRUCTIONS FOR USE AND SAFETY

The products must be inspected for defects, cracks, notches or other damage before use. Damaged products must be sorted out.
The products are delivered in a non-sterile condition and must be completely cleaned, disinfected and sterilized by the user before being used for the first time.

6.1 Surgical techniques

The respective recognized surgical techniques apply. The surgeon must undergo further training in accordance with the recognised surgical techniques. For surgical techniques in the CMF area, the technical literature Manual of Internal Fixation in the Cranio-Facial Skeleton AO Publishing [ISBN 978-3-642-63732-2] can be consulted.

7 PATIENT BEHAVIOUR

The patient should be advised that the safety and lifespan of the implant depend on his behavior and activity. Therefore, any form of competitive and competitive sports in which the implants are affected is contraindicated.

8 CORRECT SELECTION OF IMPLANTS

The choice of implants is made taking into account the patient-specific characteristics, such as the type of fracture / injury or the need for bone augmentation and the condition of the patient's bone material. The implantation method should be chosen in accordance with the state of the art in this field. Errors in the selection of the implant can lead to premature clinical implant failure. The use of the right components allows for a sufficient blood supply and results in a stable fixation, whereas a

wrong decision can lead to loosening, bending or fracture of the implant and/or bone, among other things. In general, the implants are designed for temporary use. However, due to the use of pure titanium and titanium alloys, it is also possible to leave them in the operated area. However, this evaluation is the sole responsibility of the doctor.

9 COMBINATION PRODUCTS & ACCESSORIES

9.1 Tools

Plate cutting instruments are used to divide or shorten plates in the area of the webs. When cutting, care must be taken to ensure that the cut parts do not throw away, so do not point them at people when cutting and possibly cover them during the cutting process. The panel part to be used must be deburred after cutting to avoid friction conditions on the fabric.

Drills: Always use the shortest possible drill bit to ensure the best possible concentricity. It should be checked whether the drill connection and the drill rig are compatible. Basically only work with a drill bush or similar and at speeds of <= 1000 rpm. When drilling, provide sufficient cooling with NaCl to minimize the heat load on the bone. This is the only way to minimize the risk of bone demineralization. The manufacturer recommends one-time application of drill bits. Depth gauge: Measurement of the screw length with the implant plate. The value displayed on the depth gauge corresponds to the screw length as indicated on the packaging.

9.2 Color coding of screws and drills

The identification of the screws and drills is done by means of a color coding that the system displays. The following color codes correspond to the same diameter:

	Blue	System Ø 1.2 mm
	Green	System Ø 1.6 mm
	Gold	System Ø 2.0 mm
	Violet	System Ø 2.3 mm
	Gold	System Ø 2.7 mm

9.3 Instruments for introduction and explantation

# Twist drill Ø 1.0 mm for system Ø 1.2 mm	# Screwdriver 95-120-72
# Twist drill Ø 1.3 mm for system Ø 1.7 mm	# Screwdriver 95-120-81
# Twist drill Ø 1.5 mm for system Ø 2.0 mm	# Screwdriver 95-120-13
# Twist drill Ø 1.8 mm for system Ø 2.3 mm	# Screwdriver 95-120-25
# Twist drill Ø 2.0 mm for system Ø 2.7 mm	# Screwdriver 95-120-25

Under no circumstances may the implants be combined with products, components and instruments from other manufacturers. Combinations with products from other manufacturers can have a negative impact on the result of the procedure and are not permitted, as the components used may not be coordinated. It is recommended to use only instruments and accessories from the company. to be used. Digimed Medizintechnik Digimed Medizintechnik

9.4 Bone substitute material

State-of-the-art autogenous material must be used for bone block technology. Autogenous bone augmentation material (autologous bone), is made from the patient's own bone, which is taken from somewhere else in the body. The bone typically comes from the chin, jaw, lower leg bone, hip, or

skull. Autogenous bone grafting material is advantageous in that the material is living bone, which means that it contains living cellular elements that enhance bone growth, and the risk of rejection reactions is very low.

9.5 IMF Fixation System

The IMF screws can be combined with commercially available binding wires / cerclage wires with implant quality and suitable CE marking with other manufacturers. The manufacturer offers different sizes of binding wires / cerclage wires, which are sold as commercial goods.

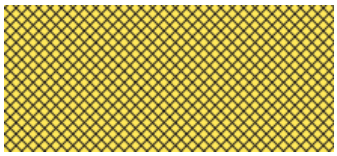
Combination:

The screws are used with binding wire / cerclage wire in combination:

Diameter wire: Ø 0.4, 0.5, 0.6 mm wire
Material: 1.4441 wire

9.6 Pins Fixation System

The PIN system can be applied with a titanium mesh.



Mesh size: min. Ø 1 mm
Mesh plate thickness: 0.1mm to 0.3mm

- 95-291-51
- 95-291-52
- 95-291-53
- 95-291-54
- 95-291-55
- 95-291-56

10 EXCLUSION OF REUSABILITY

Once implants have been inserted, they must not be reused under any circumstances. The products are intended for single use only. Failure to observe the restriction (single-use product) can have serious consequences for the patient

- Failure of the implant (e.g. fracture)
- Lack of healing

11 REPROCESSING

In principle, implants themselves may only be inserted once. Once an insert is complete, the implant must not be used again.

If implants are prepared for application and not used clinically, i.e. not implanted and not contaminated in the operating room with, for example, blood, tissue (contact with patients), they may generally continue to be used after reprocessing and sterilization. However, this does not apply,

- ✓ if the color anodizing (color coding) of the implants has changed in such a way that a correct assignment to the corresponding drills is no longer guaranteed.

All right

Not okay

After treatment of a patient infected with Creutzfeldt-Jakob disease, the accessories as well as the instruments for insertion / use must not be reused and must not be reprocessed. The products must be disposed of.

12 PREPARATION AND TRANSPORT

All system components are delivered non-sterile. It is therefore imperative that they be cleaned and sterilized before being used on the patient. In the case of reusable instruments, this applies to any reuse.

Transport of the implants / instruments in a closed container to the reprocessing site in order to avoid damage to the implants / instruments and contamination of the environment.

13 CLEANING & DISINFECTION

13.1 Basics

If possible, a mechanical process (RDG (washer-disinfector)) should be used for cleaning and disinfection. Due to the significantly lower effectiveness and reproducibility, a manual process – also using an ultrasonic bath – should only be used if a mechanical process is not available or in accordance with country-specific requirements (e.g. in Germany for critical B products, a mechanical process is mandatory). Pre-treatment must be carried out in both cases.

13.2 Pretreatment

The implants can be brushed under the surface of the water (tap water) until they are optically clean.

13.3 General information on machine cleaning/disinfection with a (RDG)

When choosing the RDG, it is important to pay attention to:

- that the RDG has been tested in principle (e.g. DGHM or FDA approval/clearance/registration or CE marking in accordance with DIN EN ISO 15883),
- that, if possible, a tested program for thermal disinfection (A0 value > 3000 or – for older devices – at least 5 min at 90 °C/194 °F) is used (in the case of chemical disinfection, risk of disinfectant residues on the products),
- that the program used is suitable for the products and contains sufficient rinsing cycles (at least three depleting steps after cleaning (or neutralization, if applied) or conductivity control recommended to effectively prevent detergent residues)),
- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used for rinsing,
- that the air used for drying is filtered (oil-free, low in germs and particles) and
- that the RDG is regularly maintained, checked and calibrated.

When selecting the cleaning agent system used, care must be taken to:

- that this is basically suitable for the cleaning of invasive medical devices made of metals and plastics,
- that – if no thermal disinfection is used – a suitable disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that this is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the products

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant, as well as specifications for rinsing, must be strictly adhered to.

Expiration:

1. Insert the products into the RDG. Make sure that the products do not touch each other.
2. Launch the program.
3. Remove the products from the RDG after the end of the program.
4. Check and pack the products as soon as possible after removal.

13.4 Cleaning & disinfection

Proof of the basic suitability of the products for effective mechanical cleaning and disinfection was provided by an independent, officially accredited and recognized testing laboratory using the cleaning agent Neodisher Mediclean Forte 0.4% (v/v). The procedure described below has been taken into account.

Cleaning

Step	Parameter	
Pre-rinse	Rinsing temperature	Cold water
	Exposure time	60 s
Clean	Cleaning temperature	154
	Exposure time	600 s
	Detergent	Neodischer Medclean Forte
	Concentration	0,70 %
Nachspülen	Rinsing temperature	Cold deionized water
	Exposure time	120 s

Disinfection

Step	Parameter	
Thermal disinfection	Desinfektionstemperatur	93° C (Ao 3000)
	Exposure time	300 s
Dry	Drying temperature	100° C
	Drying	20 min

14 FUNCTIONAL TESTING AND PACKAGING

The products must be tested for cleanliness and functionality after reprocessing and before sterilization. If necessary, the reprocessing process must be repeated until the product is optically clean.
Please pack the products or sterilization trays in sterilization containers or very large products in single-use sterilization packaging (single or double packaging) that meet the following requirements (material/process):

- ✓ DIN EN ISO/ANSI AAMI ISO 11607 (für USA: FDA-Clearance)

- ✓ suitable for steam sterilization (temperature resistance up to at least 137 °C (280 °F), sufficient vapor permeability)
- ✓ Adequate protection of the products or sterilization packaging against mechanical damage
- ✓ Regular maintenance according to the manufacturer's specifications (sterilization container)
- ✓ A maximum weight of 10 kg per package/contents of the sterilization container must not be exceeded

15 STERILIZATION

Only the following sterilization methods shall be used for sterilization; other sterilization methods are not permitted.

15.1 Steam sterilization:

Sterilization of the products by means of a fractionated pre-vacuum process (according to DIN EN ISO 17665-1), taking into account the respective national requirements. 3 pre-vacuum phases with at least 60 millibar pressure Heating to a sterilization temperature of at least 134°C; max. 137°C Shortest holding time: 5 min Drying time: at least 10 min.
It is the duty of the user to ensure that the reprocessing process, including resources, materials and personnel, is suitable to achieve the required results. The state of the art and national laws require the following of validated processes.

16 STORAGE

Storage of the implants in a dry, clean and dust-free environment. No indication of durability or functional restriction is given for implants delivered non-sterile after manufacture, if they are stored properly.

17 REPAIRS & SERVICE

Do not carry out repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and intended for this. If you have any complaints, complaints or information regarding our products, please contact us.

18 HANDLING

The system components must be carefully handled and stored. Damage or scratches on the implant can significantly impair the strength and fatigue resistance of the product.

19 DISPOSAL

The disposal of the products, packaging material and accessories must be carried out in accordance with the nationally applicable regulations and laws. Specific instructions for this are not given by the manufacturer.

20 DISCLAIMERS & WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service. However, we cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. We cannot accept any liability for any incidental or consequential damages.

Any product liability expires,

- in case of damage due to improper storage, handling, cleaning and / or sterilization
- in case of incorrect cleaning and sterilization
- in case of non-observance of these instructions for use

THE COMPANY ASSUMES NO LIABILITY IF IT CAN BE PROVEN THAT THESE INSTRUCTIONS FOR USE HAVE BEEN VIOLATED. Digimed Medizintechnik

21 INFORMATION

21.1 Batch traceability

In order to ensure the traceability of implants, EN ISO 13485 requires batch traceability from all parties involved in distribution:
Chapter 7.5.3.2. Specific requirements for active implantable medical devices and implantable medical devices
When establishing records for traceability, the organization must include all components and materials used, as well as working environment conditions, if these could cause the medical device to fail to meet its specified requirements.
The organization shall require that its agents or sales representatives maintain records of the shipment of medical devices with regard to traceability and that such records be available for inspection.
Records must be kept of the name and address of the recipient of the shipping packaging.

Due to the small diameter of the implants, there is no direct marking on the product. For the purpose of traceability, the user must ensure that the product label is stored in the patient file.

21.2 LINK to the Summary of Safety and Clinical Performance Article 32

At the time of writing these instructions, the EUDAMED database was not yet active. Therefore, no link to the safety and clinical performance brief can be provided here. The Safety and Clinical Performance Brief is up-to-date and will be kept up to date. Digimed Medizintechnik

21.3 Serious incidents

Serious incidents involving the device must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established. This notification must be made immediately after the occurrence so that important reporting deadlines can be met if necessary. The affected products must be discarded, reprocessed and sent to the manufacturer for examination. Your specialist dealer will be happy to help you with this.
Upon receipt of your report, we will inform you of the further necessary measures within a reasonable period of time.

21.4 Article 18 of MDR 207/745

According to the definition of Article 18 paragraph (3), the devices are exempt from the obligation to have an implantation card. Nevertheless, we recommend that the labeling of the products be kept in the patient's file.

22 SYMBOL EXPLANATIONS

The CE marking with the identification number of the notified body applies exclusively to the implantable devices.

	Manufacturer		Observe the instructions for use
	Non-sterile		CE marking with number of the notified body
	Do not reuse		Batch designation
	Attention		Order number
	Medical		Only for professionals USA