Instructions for use

Please print out these instructions for use and keep them in a safe place for future reference. Ensure that you always have the latest version of these instructions for use. You can find the latest versions on our website at https://g-imp.de/IFU

Report adverse events, such as malfunctions/patient injuries, immediately to your competent authority and to General Implants GmbH in accordance with the country-specific requirements. To report to General Implants GmbH, Germany, please use our website at: https://general-implants.com/ccn/ Please also use this link if you have a complaint about one of our products.

Knowledge of the relevant surgical methods is a prerequisite for carrying out implantological treatments. Surgical experience and experience in assessing the normal and pathological course of treatment are essential. Prosthetic planning must be carried out before implant placement - even if the surgical situation may necessitate a change in planning later on.

1 PRODUCT DESCRIPTION

Gingiva formers and abutments have a polished surface and are made of grade 23 titanium / Ti6Al4V-ELI.
The outer geometry of the abutments is approximately rotationally symmetrical, straight, or angled. The form-fitting internal connection between the implant and the abutment is achieved by a hexagon and thread.
The implant system includes a cover screw and a locking screw. Both have different functions. They are made of Grade 23 titanium / Ti6Al4V-ELI or Grade Ti-6Al-7Nb titanium and have a polished surface.

2 INTENDED PURPOSE

2.1 INTENDED USE

Implant system for oral endosseous implantation in the upper and lower jaw.

2.2 INDICATIONS

The gingiva former is used to prepare the gingiva after implantation for the subsequent insertion of the dental prosthesis and crown. The gingiva former is screwed into the implant and shapes the gingiva for the subsequent crown construction.

The abutment serves as a connecting piece to bring a dental implant into function with the dental prosthesis (crown, denture).

The retention screw is used to fix the abutment in place. The cover screw, on the other hand, is inserted together with the implant and is used for subgingival healing. The sinus lift is a kind of “umbrella” that is designed to prevent the implant from disappearing into the jaw.

2.3 CONTRAINDICATIONS

Absolute contraindications:

- General inoperability
- Lack of consent from the patient
- Patients are known to be allergic to one of the ingredients
- Infections and inflammations in the oral cavity, especially in the area to be operated on
- Blood clotting disorders
- Immunosuppression
- Oncological diseases and treatments

- Poor oral hygiene
- Uncompensated diabetes
- Infected extraction sockets, major apical ostitis (bone inflammation) and bone defects

Relative contraindications:

- Diabetes
- Alcohol and nicotine abuse with impaired wound healing
- Imminent, immediate proximity of endangered structures (nerve, maxillary sinus, etc.)
- Insufficient bone volume and soft tissue coverage
- Bruxism

2.4 EXPECTED CLINICAL BENEFIT

- Restoration of chewing function
- Restoration of aesthetics

2.5 RESIDUAL RISKS, COMPLICATIONS AND KNOWN SIDE EFFECTS

2.5.1 RESIDUAL RISKS

Table 3: Overview of residual risks

Residual risk	Root cause
movement of implant	insufficient postoperative care, premature loading of implant
implant-superstructure loosening / failure	
failure to osseointegrate	insufficient postoperative care, premature loading of implant
	Migration of bacteria/biofilm at the interface between tissue/bone and implant/prosthetic structure
peri-implantitis	Migration of bacteria/biofilm at the interface between tissue/bone and implant/prosthetic structure
peri-implant mucositis; Tissue reaction/inflammatory reactions in surrounding tissue	
Bone degeneration / resorption. Late implant failure	Altered distribution of the mechanical (mastication) load in the treated area
Migration, heating or formation of artefacts Soft or hard tissue injury, wrong diagnosis due to insufficient MRI imaging; visceral burns	 Device have not been tested for MRI compatibility
Use of contaminated / non-sterile products, cross-contamination, Possible acute or delayed infection of the patient, local irritations and infections	Non-compliance with the principles of asepsis during implantation

2.5.2 PATIENT SPECIFIC RISK FACTORS

- Diabetes
- Alcohol and nicotine abuse with impaired wound healing
- Imminent, immediate proximity of endangered structures (nerve, maxillary sinus, etc.)
- Insufficient bone volume and soft tissue coverage
- Bruxism

2.5.3 KNOWN COMPLICATIONS AND SIDE-EFFECTS

- Postoperative, acute pain and / or inflammation
- degeneration / resorption or periimplant bone due to altered distribution of the mechanical (mastication) load in the treated area

2.6 INTENDED USER/OPERATOR

Qualified dentist, oral surgeon

2.7 INTENDED PATIENT GROUP

Patients whose jaw growth is complete. For patients whose jaw growth is not yet complete, other orthodontic systems should be used.

3 OPERATIVE INSTRUCTIONS

The gingiva former and screws are inserted using a screwdriver. This screwdriver is available in three different versions – manual, for a ratchet, or for a contra-angle handpiece. The user can decide which version they prefer and want to use.
The abutment is secured with a screw (retention screw), which means that it is only indirectly secured with a screwdriver.
The cover screw is inserted manually. After healing, the cover screw is removed and the gingiva former is screwed into the implant by hand.
After removal of the gingiva former, the abutment is inserted. For the Easy Fast D implant system, the retention screw must be tightened with a torque of 25 Ncm. For the Easy Fast S implant system, however, a torque of 30 Ncm is required.

For reasons of hygiene and health protection, all medical devices distributed by General Implants Deutschland GmbH that are delivered in a non-sterile condition must be sterilized before first use.

The hygiene regulations of the individual national and international legal provisions for dental/medical practices, hospitals, and dental laboratories must be observed.

Only devices that have undergone a validated procedure may be used for sterilization. The following parameters for sterilization must be strictly adhered to, as they have undergone a validated process. If sterilization is carried out using different parameters, the sterility of the product cannot be guaranteed.

4 STERILIZATION INSTRUCTIONS

⚠ Sterilization must be performed by trained personnel in a room equipped for this purpose (with a clean and unclean zone).

4.1 Preparation for sterilization

The products must be removed from the blister pack in a clean environment using sterile tweezers and immediately double-packed in a sterilization bag (e.g., from Stericlin).

4.2 Sterilization

The products are sterilized by steam sterilization in a Type B autoclave.

Temperature	Vacuum phases	Holding time	Pressure	Drying time
134°C	3	5 min	3 Bar	20 min

5 DISPOSAL

The products must be disposed of in accordance with local regulations and environmental regulations, taking into account the respective degree of contamination.

6 VALIDITY

With the publication of these instructions for use, all previous information becomes invalid.

7 REPORTING OBLIGATION

All serious incidents occurring in connection with the products must be reported to the manufacturer and the competent authority (BfArM).

8 EXPLANATION OF THE PICTOGRAMS

	Caution: Warning of injury!		Consult instructions for use. Download the instructions for use from our Website https://g-imp.de/IFU) before using the product and keep them in a safe place.
	Keep away from sunlight		Do not reuse
	Medical Device		Non-sterile
	Catalogue number		Batch code
	Manufacturer		Unique device Identifier
	MR-Unsafe		CE mark with identification number of the notified body

9 LEGAL MANUFACTURER

General Implants GmbH Deutschland
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NOTIFIED BODY

mdc medical device certification GmbH
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