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

1 ADVERSE EVENTS

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.

2 EASY FAST DENTAL TITANIUM IMPLANT SYSTEM

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.

3 PRODUCT DESCRIPTION

Easy Fast implant screws have a microrough surface and are made of titanium, grade 4/ 3.7065, or titanium, grade 23 / Ti6Al4V-ELI. The thread type for Easy Fast D comprises a conical or tapered external thread with high primary stability, while Easy Fast S has a cylindrical external thread that is suitable for good bone density. The positive internal connection between the implant and abutment is achieved by means of a positive hexagon and tightening thread. The dimension of the internal connection is identical for diameters 3.5, 3.8, 4.0, 4.3 and 5.0, and diameter 3.0 has a reduced width across flats and thread (the shape is identical). Healing is performed subgingivally with a cover screw.

Table 1: Overview of available implant dimensions and materials

Trade name	Ø (mm)	Length (mm)	Titanium
Easy Fast S	3.0*, 3.8	8.5 / 10.0 / 11.5 / 13.0 / 16.0	Grade 4 / 23*
Easy Fast S	4.3 / 5.0	6.0 / 8.5 / 10.0 / 11.5 / 13.0 / 16.0	Grade 4
Easy Fast S MTF	3.8	8.5 / 10.0 / 11.5 / 13.0 / 16.0	Grade 4
Easy Fast S MTF	4.3 / 5.0	6.0 / 8.5 / 10.0 / 11.5 / 13.0 / 16.0	Grade 4
Easy Fast S MF	3.8	8.5 / 10.0 / 11.5 / 13.0 / 16.0	Grade 4
Easy Fast S MF	4.3 / 5.0	6.0 / 8.5 / 10.0 / 11.5 / 13.0 / 16.0	Grade 4
Easy Fast D	3.5, 4.0, 4.3, 5.0	8.5 / 10.0 / 11.5 / 13.0 / 16.0	Grade 4

Table 2: Overview of the available Easy Fast implant diameters with colour code

Ø (mm)	Colour code	Ø (mm)	Colour code
3.0	Violet	4.0	Brown
3.5	Green	4.3	Red
3.8	Yellow	5.0	Blue

4 INTENDED PURPOSE

4.1 INTENDED USE

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

4.2 INDICATIONS

The implant is intended for the immediate, delayed and late restoration of partial edentulism with single and multiple tooth gaps or complete edentulism.
A prerequisite for successful implantation is sufficient bone availability, in terms of bone quality and quantity. The implant system is suitable for immediate, delayed and late insertion.
Areas of application are complete dental prosthetics, partial denture prosthetics, implant prosthetics.

The implant is suitable for single tooth replacement, as well as for fixing bridges, partial and full dentures; if the total length of the implant is 6 mm, in conjunction with a bar restoration, each tooth position must be replaced with an implant. The implant is intended for permanent use.

4.3 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

4.3.1 SPECIFIC CONTRAINDICATIONS

Easy Fast S:

- Implants that are shorter than 8.5 mm and/or have a diameter of 3 mm should not be used in the anterior region with an axial masticatory load of more than 10°.

Easy Fast D:

- Implants that are shorter than 8.5 mm should not be used in the anterior region with an axial masticatory load of more than 10°.

4.4 EXPECTED CLINICAL BENEFIT

- Restoration of chewing function
- Restoration of aesthetics

4.5 Residual Risks, Complications and Known Side Effects

4.5.1 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

4.5.2 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

4.5.3 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

4.6 Intended user/operator

Qualified dentist, oral surgeon

4.7 Intended patient group

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

5 PRE-, INTRA- AND POST-OPERATIVE PRECAUTIONARY MEASURES

The following precautionary measures must be observed before, after and during insertion of the implant screws:
Before the insertion:

The implants are not labelled. Transfer product data, such as the item number and LOT number on the label, to the patient file immediately before opening the sterile packaging.

Implants may only be used within the shelf life period.

Implants must be stored dry and sealed. The sterile packaging should only be opened immediately before insertion. Any contact with foreign substances must be avoided before inserting the implant. The endosseous part of the implant must not be touched.

The clinical and radiological examination of the patient and a model analysis are essential prerequisites for successful implant treatment.

According to the relevant specialist literature, at least 4 implants are prescribed for the lower jaw and at least 6 implants for the upper jaw to stabilise a removable prosthetic restoration.
Always choose the implant with the appropriate length and diameter that can be supported by the available bone thickness, bone quality and space, as well as the expected chewing forces.

Sterile handling is mandatory. Potentially contaminated components must not be used under any circumstances, as contamination can lead to infection.

It is essential to read the instructions for use before using the implant system.
The implant system may only be used by dentists and doctors who are familiar with implantological surgery, including diagnosis, preoperative planning, implantation and aftercare. We therefore recommend that you be instructed in its use by an experienced user. If there are any uncertainties regarding the indication or the type of application, the product should not be used until all uncertainties have been clarified. Since the use of the product is beyond our control, any liability for damage caused by this is excluded. The responsibility lies exclusively with the practitioner.
Comprehensive, patient-specific, pre-operative planning is necessary before every insertion.

The implant system may only be used in accordance with the indication and in accordance with the general rules for dental/surgical procedures, as well as in compliance with occupational safety and accident prevention regulations. The instructions for use are not sufficient for practitioners inexperienced in implantological procedures to ensure professional and safe use.
Before each procedure, ensure that all required parts, instruments and auxiliary equipment are complete, functional and available in the required quantity.
The implant system may only be used if it is in perfect condition.

Only original General Implants products may be used. This applies to the entire product portfolio (implants, abutments, drills, tools, instruments, etc.). If products are used that have been placed on the market by third-party manufacturers, the warranties are void. In cases of disregard, no responsibility is accepted for errors arising from this.
For dense and very dense bone (D1 and D2 bone), a full-length hole must be drilled with appropriate drills before inserting the implant. For the softer bone types (D3 and D4), drilling is limited to bone marking or minimal drilling.

For the insertion:

The insertion torque for the implants must not exceed 45 Ncm. A higher insertion torque harbours the risk of fracturing the implant or tearing out the bone tissue.

When preparing the implant site and inserting the implant, it is important to avoid approaching the mandibular canal. Nerve injuries can lead to anaesthesia, paraesthesia or dysaesthesia.

Care must be taken to ensure that the implant is correctly aligned, especially if high loads are expected. Always ensure that a minimum distance of 1.5 mm is maintained between the natural tooth and the outer edge of the top of the multi-unit implant. In the case of adjacent implants, there must be a minimum distance of 3 mm between the multi-unit edges.

The threaded neck of the implant should be fully embedded in the bone and be at least 2 mm or more subcrestal

Avoid correcting the vertical position by turning it backwards (anti-clockwise). This could cause bolted transmission elements to loosen, which can lead to a reduction in primary stability.

All parts used in the patient's mouth must be secured against aspiration and swallowing.

After the insertion:

- After implantation, the type of implant used and the LOT number must be recorded in writing in the documentation (additional label).

6 COMPATIBILITY INFORMATION

Only original products from General Implants GmbH may be used. This applies to the entire product portfolio: Implants, abutments (locators, ball anchors, etc.), anchoring aids (O-ring (matrix)), gingiva formers, drills, tools and instruments.
Crowns, bridges and prosthetics are excluded from this.

In order to fix the crown or bridge to the customised abutment in the case of fixed dentures, they are bonded using a special cement. Any cement suitable for titanium implants can be used.
Locator dentures (removable dentures) are connected to the female part of the denture by the male part of the locator and fixed in this way.
Anchoring elements for combined dentures are bar connections, telescopes and attachments, which can block several teeth together as a retaining and supporting function.

7 SHELF LIFE AND STERILISATION

The implants are supplied sterile and have a shelf life of 5 years after gamma sterilisation. They are no longer to be used after the expiry date.

The medical device is to be stored dry in the outer carton  and  protected from direct sunlight.

Only intact sterile packaging protects the implant from external influences and, if stored correctly, guarantees sterility until the expiry date printed on the packaging. Implants with damaged sterile packaging or seals must not be used at any time.

The sterile packaging may only be opened immediately before insertion. It is recommended that you always have a replacement product to hand.

The implants are intended for single use only. Reprocessing, e.g. after the maximum storage period has expired, is not permitted. Expired implants must be disposed of.

The abutment components are supplied non-sterile. These must always be prepared and sterilised by the practitioner before use. Please consult the instructions for use for abutments and prosthetic components available online at: https://g-imp.de/IFU

8 INFORMATION ON MRI SAFETY

The implant system has not been tested for safety and compatibility in the MR environment. It was not tested for heating, migration or image artefacts. The safety of the product in the MR environment is therefore unknown. Scanning a patient with this product may result in injury to the patient. According to currently available scientific literature, it can be assumed that titanium as a material reflects the state of the art. Furthermore, current findings suggest that only minor effects are to be expected from titanium. However, the individual decision on the use of magnetic resonance examinations is the responsibility of the radiologist in each individual case.

9 SERVICE / COMPLAINTS / DISPOSAL

Unused implants cannot be returned to General Implants GmbH.
To protect your and our employees, products that are part of a complaint or require repair must be thoroughly cleaned and sterilised before being sent to General Implants GmbH.

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

10 VALIDITY

The publication of these instructions for use renders all previous editions invalid.

11 EXPLANATION OF THE PICTOGRAMS

	Caution: Warning of injury!		Caution: Warning of damage
	Use-by date		Do not use if the packaging is damaged.
	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.		Sterilized using irradiation
	Keep dry		Do not re-sterilise
	Keep away from sunlight		Do not reuse
	Humidity limitation		Temperature limit
	Medical Device		Sterile barrier system with internal protective packaging
	Catalogue number		Batch code
	Manufacturer		Unique device Identifier
	Date of manufacture		CE mark with identification number of the notified body
	MR-Unsafe		

12 LEGAL MANUFACTURER

General Implants GmbH Deutschland
Eisenbahnstraße 100
78573 Wurmlingen
Germany

NOTIFIED BODY

mdc medical device certification GmbH
Kriegerstrasse 6
70191 Stuttgart
Germany

Version: A02 Easy Fast; valid starting from 02/2026