Instructions for use Dental Implants FairOne and FairTwo

Implantology	Packing unit	Use-by date (only applies to sterile instruments)	Unique Device Identification
LOT Lot number	For single use only	Consult accompanying documents	HIBC Health Industry Bar Code
Manufacturer	STERILE R Sterilized using irradiation (Sterile instruments are marked as such on the label of the packaging)	Do not use in case of damaged packaging (only applies to sterile instruments)	Date of manufacture
MD Medical Device		Rx Only Sale to professional users only	QTY Quantity
REF Order number	Simple sterile barrier system with internal protective packaging	Follow the instructions for use	Do not resterilize
			CE CE-Marking CE 0197

Manufacturer
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EN

CE 0197

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Initial online instructions for use
Check current status at:
www.fairimplant.de/ifu-md/download

1. General information

Observe the instructions for use and retain for future reference. Make sure that the instructions kept in your practice are up-to-date. Exchange if necessary and pass the valid version on to all possible users in your practice for their perusal. You can also order the instructions for use printed within 5 working days after contacting us. Basic UDI for implants: „FairOne++D986FOD5 and FairTwo++D986FTDF".

1.1 FairImplant™ - Implants are intended for insertion into the bone of the maxilla or mandible. Based on the specific indication, the implants are provided with different prosthetic suprastructures. The purpose of the implants is to transmit the masticatory forces of the jaw to the prosthetic suprastructures.

1.2 Patient target group

The present implant system is aimed at patients with disorders of the masticatory function due to damaged or incomplete dentition. The benefit of this type of prosthetic reconstruction for the patient consists in partially or fully restoring the limited masticatory function of the sound natural teeth.

1.3 Qualification of the surgeon

The user must be a doctor or dentist authorised to insert dental implants and must have a profound knowledge of the surgical techniques used in implantology.

2. Product description

2.1 Implant shape

The implants feature a self-cutting thread with an anti-rotation notch which are gentle on the bone. The thread has a rough surface and is provided with a continuous calcium phosphate coating. With a thickness of 10 – 20 µm, the coating facilitates quick and safe osseointegration and will be reabsorbed completely after app. four to six weeks. In FairOne implants, the coating begins in the area of the first thread turn. FairTwo implants are equipped with a 2 mm long micro thread below the implant shoulder. Depending on the type of implant, the implants have different total lengths:
a) FairOne: The intraosseous implant length is reached at 0.5 mm above the last thread turn. This is the implant length specified on the packaging. Moreover, FairOne implants have a buildup of 7 mm length which consists of a 3 mm long passage zone with parallel walls and a 4 mm long prosthetic head (with a taper of 3). The prosthetic buildup of the long neck implant has a length of 10 mm because the passage zone has been lengthened by 3 mm.
b) FairTwo: The implant length refers to the nominal length plus 1.5 mm.

2.2 Packaging

The implants are supplied in single sterile packs and can be used straightaway. No prior preparation is required. Sterility of the implants is time-limited.

2.3 Materials

a) Implants: Pure titanium "Medical Grade" 4 acc. to DIN EN ISO 5832/II with calcium-phosphate coating BONIT®
b) Implants with diameter 2.8 mm: Titanium alloy "Medical Grade" 5 acc. to DIN EN ISO 5832/II with calcium-phosphate coating BONIT®
c) Abutment screw: Titanium alloy "Medical Grade" 5
Re. a. and b.: BONIT calcium phosphate coating. The coating serves to improve the osseointegration of the implant.
Attention: When directly applied onto the coating, medicaments and other chemicals might lower the pH value in that area, which could lead to flaking of the coating.

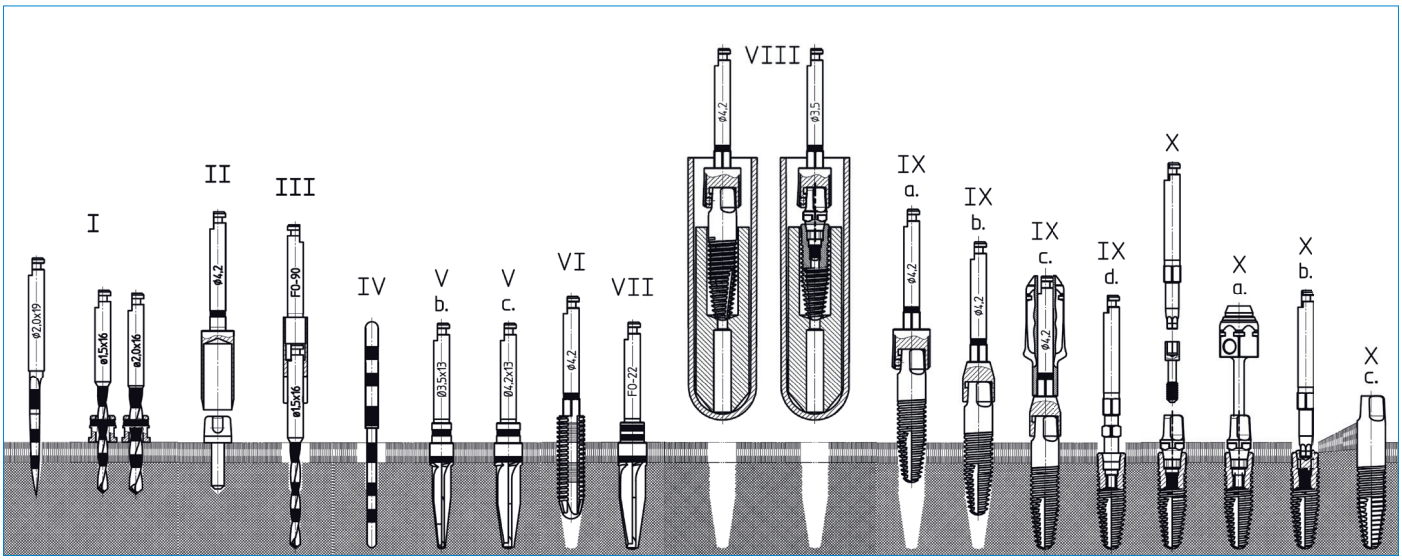
3. Indications and contraindications

3.1 Indications

The implants are intended for the prosthetic reconstruction of single teeth, bridges, or partial or full dentures. In addition, the current indications as described by the Consensus Conference of the Implantological Associations (for example DGZI, DGI, DGZMK, etc.) apply for the present implants.

3.2 Contraindications

All current contraindications as described by the Consensus Conference of the Implantological Associations (for example DGZI, DGI, DGZMK, ect.) apply for the present implants.
General contra-indications: The general medical condition of the patient does not allow a surgical intervention. A comprehensive anamnesis and evaluation of the patient are essential preconditions in order to define all criteria that might jeopardize the success of the implant insertion and impair the health of the patient. Contra-indications include incomplete alveolar growth, allergies or an immunological reaction to one or several of thematerials used, patients undergoing bisphosphonate therapy, chemotherapy or radiotherapy as well as pregnant women. Any local and systemic factors that might affect the hard and soft tissue integration have to be carefully considered. This allows an individual assessment of the risks involved with the insertion of an implant (all relevant medications, nicotine, alcohol or drug abuse, tissue and bone diseases, parafunctions etc.). The established clinical and imaging tests have to be performed to make sure that the generally required anatomical conditions applicable to the insertion of an implant are met. This is an essential condition for the correct choice and the individually adapted placement of an implant. Possible local contra-indications include pathological changes in the jaw from a clinical and radiological aspect, relevant acute and chronic infectious diseases, subacute chronic ostitis of the maxilla and mandibular that leads to microvascular changes, systemic diseases and lack of bone substance or poor bone quality that impede the firm fit of the



implant.

3.2.1 Primary stability/placement of FairOne implants

Given that the prosthetic head of the FairOne implant is uncovered, the implant will be subjected to high loads during the healing phase. The limits of the application of FairOne implants is therefore not only determined by the condition of the bone quality/structure and the possibility of achieving a sufficient primary stability of the implant, but also by the possibility of achieving a three-dimensional, definite placement of a one-piece implant. In case of failure to ensure anatomical placement of the FairOne implant with a sufficient primary stability, the use of this implant is contraindicated. The general restrictions for immediate implants as described by the Implantological Associations apply.

3.2.2 Mechanical loads and implants with ø 2.8 mm and 3.5 mm

Implants with smaller diameters can only withstand to limited mechanical loads. This has to be taken into consideration when choosing the proper implants based on the indications. The general restrictions for implants with reduced diameters (ø 2.7 mm to 3.5 mm) as described by the Implantological Associations apply. Implants with a diameter of ø 2.8 mm are only authorized for single-tooth gaps of teeth 12, 22, 31, 32, 41 and 42. FairTwo implants with a diameter of 3.5 mm are authorized for teeth 1, 2, 4, 5 and 6. In principle, when planning prosthetic abutments and reconstructions with these or other implants, the expected mechanical stress based on the respective prosthetic solution has to be estimated, and a sufficient number of implants must be placed.

4. Adverse effects and interactionsg

The insertion of a dental implant is a surgical intervention that requires at least a local anesthetic. Apart from reactions to the materials used (for ex. materials or anesthetics), further complications may occur. This applies to any type of surgery and cannot be ruled out. These complications include injury to important local structures such as the nerves in the lower jaw (nervus alveolaris inferior), the lingual nerve (nervus lingualis), neighboring teeth, soft tissues, the maxillary sinus or blood vessels (hemorrhages). Complications that might occur after the operation include secondary hemorrhages, bruising, swelling, infections, wound healing disorders, periimplantitis and loss of the implant.

5. Surgical procedure

The general instructions for different surgical procedures are described in the specialised literature related to implantology.

6. Implant bed preparation

Please refer to the below diagram of the procedure for preparation of the implant site and insertion of the implant. Please also refer to the instructions for use supplied with the corresponding instruments.

I. Drilling of the pilot hole with drill probe as an orientation guide for the subsequent positioning of the implant, without reaching the full working length. To place the tissue punch support (probe), the bore hole must be 7 mm deep with a diameter of 2 mm. This depth is achieved when the laser marking - applied at a depth of 11 mm - at the upper edge of the drilling sleeve is reached.

II. Positioning of the tissue punch support (probe) and soft tissue punch of the mucosa. optional: following a minimally invasive surgical technique

III. Drilling the pilot hole to the full working length (for example with drill extension)

a) Triangular pre-drill for all implant diameters; can be omitted if using a pilot drill

b) 1.5 mm (implant ø 3.5 mm and 4.2 mm); can be omitted if using the triangular pre-drill

c) 2.0 mm (implant ø 5.0 mm and 6.0 mm); can be omitted if using the triangular pre-drill

IV. Checking the drilling depth and direction by means of a depth probe

V. Drilling the shape to the required working length is carried out with up to four diameter sizes, in ascending order:

a. Implant ø 2.8 mm -> 2.8 mm

b. Implant ø 3.5 mm -> 3.5 mm

c. Implant ø 4.2 mm -> 3.5 – 4.2 mm

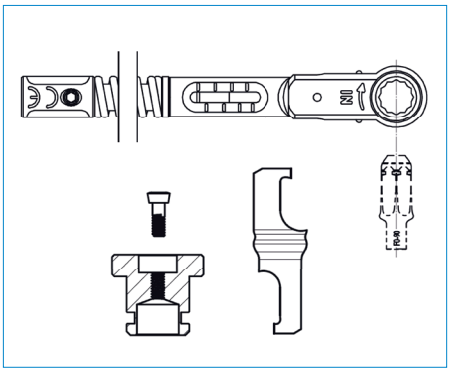
d. Implant ø 5.0 mm -> 3.5 – 4.2 – 5.0 mm

e. Implant ø 6.0 mm -> 3.5 – 4.2 – 5.0 – 6.0 mm

VI. Screw tap optional (optimum speed: (20 - 25 rpm) in case of hard bones

VII. Dense drill optional: in case of hard bones or in case of FairTwo for normal or hard bones

VIII. Removal of implant from primary packaging by means of insertion tool with friction (FairOne). For removal of FairTwo implants Platfor S or L, please use the insertion tools (FairOne) ø 3.5 mm or ø 5.0 mm. When using an abutment to insert the implant: Once an



insertion torque of 20 Ncm is achieved, remove the abutment and continue to insert the implant with the inserting tool FT (see IX.d), to assure easy and safe removal of the abutment.

IX. Insertion of the implant

a) Mechanically, with insertion tool with friction (FairOne).
b) With insertion tool without friction (FairOne)
c) Insertion tool without friction (FairOne) with ratchet adapter
d) Insertion tool FT (FairTwo) as an alternative to the insertion tool FairOne with insertion abutment

X.) With a FairTwo implant being inserted to the full working length 1.5 mm of the micro thread are above the bone level an 0.5 mm are below the bone level. Depending on the clinical situation and the experience of the surgeon, the micro thread of the implant may be positioned in the hard or soft tissue. When positioning the implant in the crestal bone, the insertion depth of the implant working length needs to be increased by 1.5 mm (This depth is achieved in the middle of the 3 mm long shank of the bur, or at the upper edge of the multi-lengths burs). After insertion of the FairTwo implant, the insertion abutment can either remain in place or be removed by unscrewing the abutment screw. Picture X on the diagram shows removal of the abutment screw. With the help of the hex driver with friction, the screw is removed from the implant. Then, the screw can be unscrewed from the inner thread of the abutment.
X a) In the event that the FairTwo implant is inserted with an insertion abutment, this can either remain in place or be removed by unscrewing the abutment screw. A jamming abutment may be removed with the Take Out Tool for insertion adapters or the abutment Take Out Tool.
X b) With FairTwo implants the cover screw is inside the lid of the primary packaging. The implant is sealed by screwing the cover screw onto the implant (max. 5 Ncm) by using the hex driver. On the drawing, the FairTwo implant ø 4.2 x 13 (14.5) mm is positioned in such a way that the bone level is reached at 13 mm on the left hand side and at 14.5 mm at the right hand side.
X c) Long neck - A special implant for use in areas with garland-shaped anatomy of the soft and hard tissue or in case of considerable mesio-distal height differences. In comparison to the standard version, the supra-osseous part of the implant has been lengthened by 3 mm. Due to the longer supra-osseous part, excellent primary stability is of essential importance.

7. General handling

The implants are to be stored in their properly sealed, undamaged secondary package. The secondary package is to be removed just before the intervention. Before inserting the implant, the secondary packaging has to be inspected for damages. A damaged package might impair sterility of the implant. Never use an unsterile implant or reuse an implant that has been implanted before. The implant is part of an implant system and may only be used in combination with the original FairImplant components and instruments. Make sure that the implants are not contaminated. Important: In case of suspected damage of the sealed seam of the sterile packaging, the implant may not be used and cannot be returned to the manufacturer.

7.1 Packaging and sterility

The packaging of FairImplant implants is composed of:
- The outer protective box
- The secondary packaging (deep-drawn blister)
- The primary packaging (plastic tube with titanium protective cover and lid with cover screw)

An intact packaging makes sure that the implant is protected against environmental influences and ensures sterile storage. In case of opened or damaged packaging, sterility of the implant is no longer guaranteed, and the implant may not be used.

7.2 Handling of the sterile packaging

When removing the implant from its packaging, make sure to observe all general rules of asepsis. The outer protective box is opened by an unsterile person (e.g. a stand-by employee). This person is responsible for removing the deep-drawn blister and opening it without contaminating the inner primary package (plastic tube). After this, the primary packaging is either removed by a sterile person, or the unsterile person lets the primary package glide onto a sterile surface (for example a tray). With the help of the insertion wrench (with friction ball), the surgeon then removes the implant from the tube. The same insertion wrench is used to insert the implant in the prepared implant bed. Make sure that the implant does not come in contact with unsterile surfaces during this manoeuvre. Make sure that the implant is not contaminated with saliva. Insert the implant in the implant bed to the required depth.

7.3 Sterilisation

FairImplant implants are subjected to gamma sterilization in their protective packages. Gamma sterilization: EN 11137. When subjecting the implant packaging to gamma radiation, the colour of the sterilization indicator on the left of the label on the secondary packaging will change from yellow to red.

7.4 Re-sterilisation

When the use-by date is reached, or in case of damaged packaging: Do not use or re-sterilise the implant! When using unsterile implants or implants that are contaminated with foreign particles, the risk of implant failure due to foreign body reactions or infections is considerably increased. If sterilization of the implant is carried out on one's own responsibility, impairment of the sterilization quality and damage of the implant coating are to be expected, which can have a negative influence on implant healing.

7.5 Prosthetic components FairTwo

Please find below a list of the prosthetic components required for the creation of temporary and permanent prosthetic reconstructions. In order to guarantee a solid bond between the implant and the supra-osseous parts and to avoid excessive loads being applied to the implant/abutment connection, the abutment screw is permanently fixed with a torque of 25 Ncm. To ensure gentle insertion of the screw, we recommend tightening the screw to the definitive torque after app. 5 minutes. To facilitate handling and testing in the dental laboratory, the screw

must be hand-screwed (max. torque of 10 Ncm). The system components are designed and manufactured according to the state of art. The general rules of dentistry have to be observed.
a) Long-term: Abutment Standard, metal basis, one-piece, can be ground/ PreForm, angled abutment 16° and 21°, LOCATOR classic/RTx in S + L, definite torque 25 Ncm
b) Long-term: Abutment rescue ø 3.5 mm, 4.2 mm, 5.0 mm and 6.0 mm (Attention! No taper but butt joint), definite torque 25 Ncm
c) Long-term: Insertion abutment S ø 3.5 mm and L ø 5.0 mm (CAVE! not firmly premounted – if to be used as abutment, make sure to fix is with 25 Ncm; insertion torque with insertion instruments max. 20 Ncm, to assure easy and safe removal of the abutment)
d) Long-term: Cone magnet in S, definite torque of 25 Ncm
d) Short-term: Healing cape in S + L and Rescue ø 3.5 mm, 4.2 mm, 5.0 mm and 6.0 mm, temporarily with a torque of 10 Ncm
e) Temporarily: Direction indicator, impression copings, open and close and Scanbosdy in L + L, temporarily with a max. torque of 10 Ncm

8. Transport and storage

Be sure to use suitable containers for transport to avoid shaking of the instruments inside the packaging. The instruments are to be stored at room temperature in a dry environment. Protect from light. Do not use the implants after expiry of the use-by date.

9. Safety instructions and warnings

Preparation of the implant bed requires instruments in perfect condition and with sharp blades. To prevent overheating of the tissue surrounding the implant site, make sure to use sufficient cooling throughout the preparation. Protection of the tissues surrounding the implant site – especially the bone tissue - must be ensured to avoid surgical trauma, contamination or infections. The drills and tissue punches are used at a maximum speed of 800 rpm. Implant and dense ceramic drills max 500 rpm with maximum cooling.

The implants and screw taps are inserted at a speed of 20 – 25 rpm. The max. insertion torque when using FairOne is 70 Ncm and 50 Ncm with FairTwo or FairWhite. A higher torque might lead to failure of the osseointegration (for example due to tissue necrosis) or to damage of the instruments and the implant or the structures surrounding the implant site. Avoid immediate loading of the implants.

10. Safety and liability

The user is responsible for checking the product prior to use to ensure that it is suitable for the intended purpose. The user is responsible for the application of the instruments. In case of contributory negligence by the user, FairImplant™ partially or totally declines liability for all resulting damages. Serious adverse events associated with the use of the instruments or implants need to be reported to the competent authorities in your country and to FairImplant™.