



















 Implantology	 Packing unit	 Use-by date (only applies to sterile instruments)	 UDI Unique Device Identification
 Lot number	 For single use only	 Consult accompanying documents	 HIBC Health Industry Bar Code
 Manufacturer	 STERILE 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
 Medical Device	 Simple sterile barrier system with internal protective packaging	 Rx Only Sale to professional users only	 QTY Quantity
 Order number		 Follow the instructions for use	 Do not resterilize
			 CE-Marking  CE ₀₁₉₇

Manufacturer

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CE₀₁₉₇

0. revision: 2023-04-20

Current status and previous versions:
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 instruments:
++D986Isu3H, ++D986Iru3E, ++D986rot8P,
++D986INSWL, ++D986FTAVK

1.1 Intended use

FairImplant™ implants are designed for endosseous insertion into the upper or lower jaw. Depending on the specific indication, the implants are provided with different prosthetic suprastructures. To ensure successful prosthetic reconstruction, especially coordinated instruments are intended for the preparation of the implant site.

1.2 Condition when supplied

The FairImplant™ instruments and reconstructions are supplied in non-sterile condition. Prior to first use, they have to be cleaned and sterilised in compliance with EN ISO 17664 (see the manufacturer's information on the reprocessing of resterilisable instruments which are

supplied with the components).

1.3 Safety instructions and warnings

Cutting hard bones and reprocessing can lead to premature blunting of the blades. A prolonged use of the instruments is associated with thermal stress, which might have an impact on proper implant healing. Therefore, the drills need to be checked for damages or blunt blades after each use. Damaged instruments have to be replaced. It is up to the user to decide if and how often the instrument is reused. To prevent fracture of the instrument, please make sure to observe the recommended speeds and torques. Risk of injury caused by sharp blades of the bur! Risk of injury due to jamming and slipping of the bur! Be sure to observe the indicated maximum permissible speeds and torques to avoid injury or overstressing of the instruments.

2. System components, colour coding and length marking

Target size of implant	FI ø 2.8 mm	FI ø 3.5 mm	FI ø 4.2 mm	FI ø 5.0 mm	FI ø 6.0 mm	Length markings
Pilot drill ø 2.0	not suitable	limited suitability		suitable		4/6/8/10/13/16 mm
Pilot drill ø 1.5	suitable			limited suitability		4/6/8/10/13/16 mm
Predrill Triangular ø 2.0	suitable					4/6/8/10/13/16 mm
Drill probe ø 2.0		ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red	ø 6.0 mm black	-
Tissue punch support (Probe)	ø 2.8 mm white	ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red	ø 6.0 mm black	-
Depth probe	ø 1.4 mm / ø 1.9 mm					4/6/8/10/13/16 mm
Soft tissue punch	ø 2.8 mm white	ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red	ø 6.0 mm black	-
Implant drill*/ Dense drill (former extension drill)*	ø 2.8 mm white	ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red	ø 6.0 mm black	6/8/10/13/16 mm ¹ working length +1 mm ² working length +3 mm ³
Multi-lengths bur		ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red		8/10/13 mm ¹ working length +1.5 mm (FairTwo crestal)
Screw tap ⁴		ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red	ø 6.0 mm black	5.5/8.5/11.5/14.5 mm
Insertion tool friction ⁴		ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red	ø 6.0 mm black	-
Insertion tool ⁴	ø 2.8 mm white	ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red	ø 6.0 mm black	-
Insertion tool ⁴		S (short + long)		L (short + long)		-
Direction indicator ⁴		ø 3.5 mm yellow	ø 4.2 mm green	ø 5.0 mm red	ø 6.0 mm black	-
Direction indicator ⁴		S		L		-
Take-out tool insertion adapter FT		S and L				-
Counter insertion abutment		S and L				-
Take-out tool FT		S		L		-
Hex driver FT ⁴		different lengths				-
Drill extension		-				-
Torque ratchet ⁵		-				-

* The burs with length marking for the $\varnothing 4.2$ mm and 5.0 mm implants are available in lengths of 6 mm, 8 mm, 10 mm, 13 mm and 16 mm.

The burs for $\varnothing 3.5$ mm implants are available in lengths of 8 mm, 10 mm, 13 mm and 16 mm. The burs for $\varnothing 6.0$ mm implants are available in lengths of 6 mm, 8 mm, 10 mm and 13 mm.

The burs for $\varnothing 2.8$ mm implants are available in 13 mm length (with a marking at 10 mm).

¹ Marking of the desired working length/osseous drilling depth at the upper edge of the working part. Respectively the lower edge of the black laser marking.

² Marking of the desired working length + 1 mm at the top edge of the black laser marking.

³ Marking of the desired working length + 3 mm at the top level of the non-cutting working part, between the colour coding and laser marking.

⁴ The marked instruments can be used manually by means of a ratchet adapter.

⁵ These articles have separate instructions for use.

3. Planning and preparation

Planning of the exact position and determination of the correct size of the implant and the implant bed must be done with great diligence to avoid damage to the structures surrounding the implant site. Careful assessment of the risks and benefits of the planned treatment is recommended. To ensure mechanical strength of the planned prosthetic supra-structures, suitable imaging investigations have to be made.

4. Indicators to be used during the treatment

During treatment, the indicators (drill sleeve, tissue punch support, depth probe and direction indicator) serve to determine the position, direction and depth of the implant and the implant site.

5. Implant bed preparation

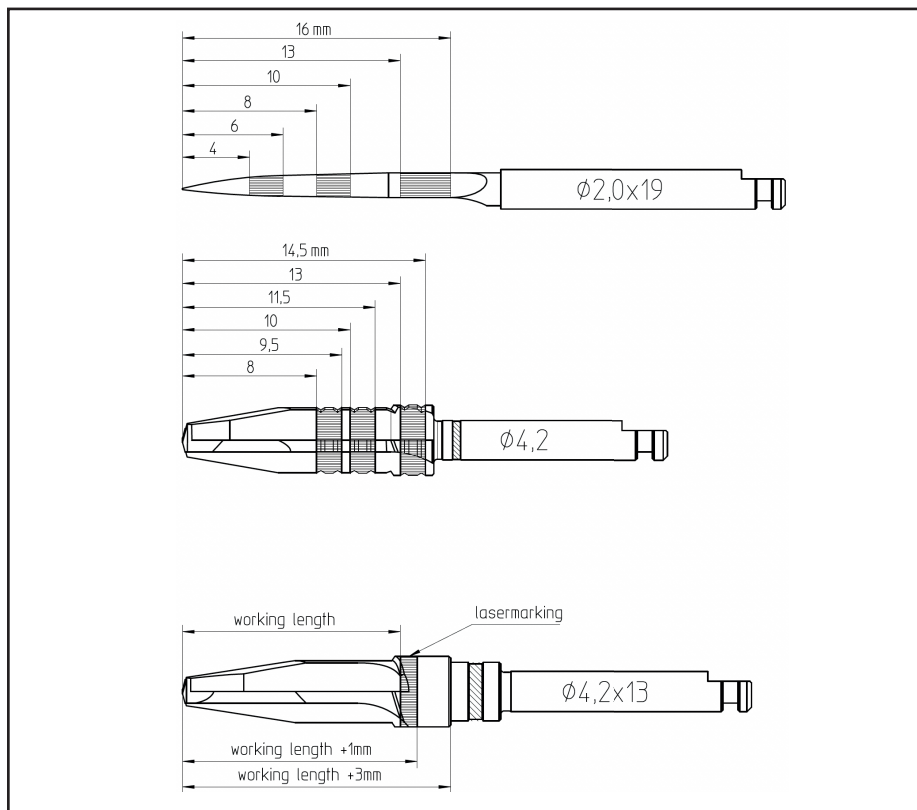
I. Basic principles

Constant external cooling with a suitable sterile rinsing solution should be provided during drilling. The external cooling prevents the bone tissue from overheating. Prepare the implant bed with drills and tissue punches up to the desired depth, applying little pressure, at a maximum speed of **800 rpm**. Implant and dense ceramic drills **max 500 rpm** with maximum cooling. Be sure to observe the indicated maximum speed to avoid fracture of the instrument and damage of the tissue. Do not exceed a torque of **30 Ncm** when using any of these implantology instruments. Make sure that the drill does not wedge and jam during use (increased risk of fracture). To guarantee this, it is essential to remove bone chips from the instrument in regular intervals.

II. Pilot hole

Apply a suitable triangular pre-drill, pilot drill $\varnothing 1.5$ mm and/or pilot drill $\varnothing 2.0$ mm at the intended site and drill to the desired depth. Attention! The use of the pilot drill $\varnothing 2.0$ mm for the implants in diameters 2.8 mm, 3.5 mm and 4.2 mm leads to a reduction of the primary stability at the bottom of the implant.

III. Tissue punching



If a minimally invasive operation technique is used, drill the pilot hole through the mucosa using the pilot drill $\varnothing 2.0$ mm. Insert a tissue punch support that matches the chosen diameter of the implant, punch out the mucosa by means of a soft tissue punch and remove residual tissue with suitable surgical instruments. Attention! A minimally invasive procedure is only permissible in healthy gingiva. Always make sure that the implant is completely surrounded by sufficiently firm sound gingiva.

IV. Implant bed preparation in dense bone conditions

The implant drills and dense drills are adapted to the different implant sizes. To ensure maximum primary stability of the implant, the use of an implant drill is recommended for the indicated combination of diameter and length. The use of the analogue dense drills and thread cutters leads to a reduction of the primary stability.

A. FairOne/FairWhite: It is always recommended to use the indicated implant drills for implant bed preparation. In case of failure to insert the implant to the required depth, the corresponding dense

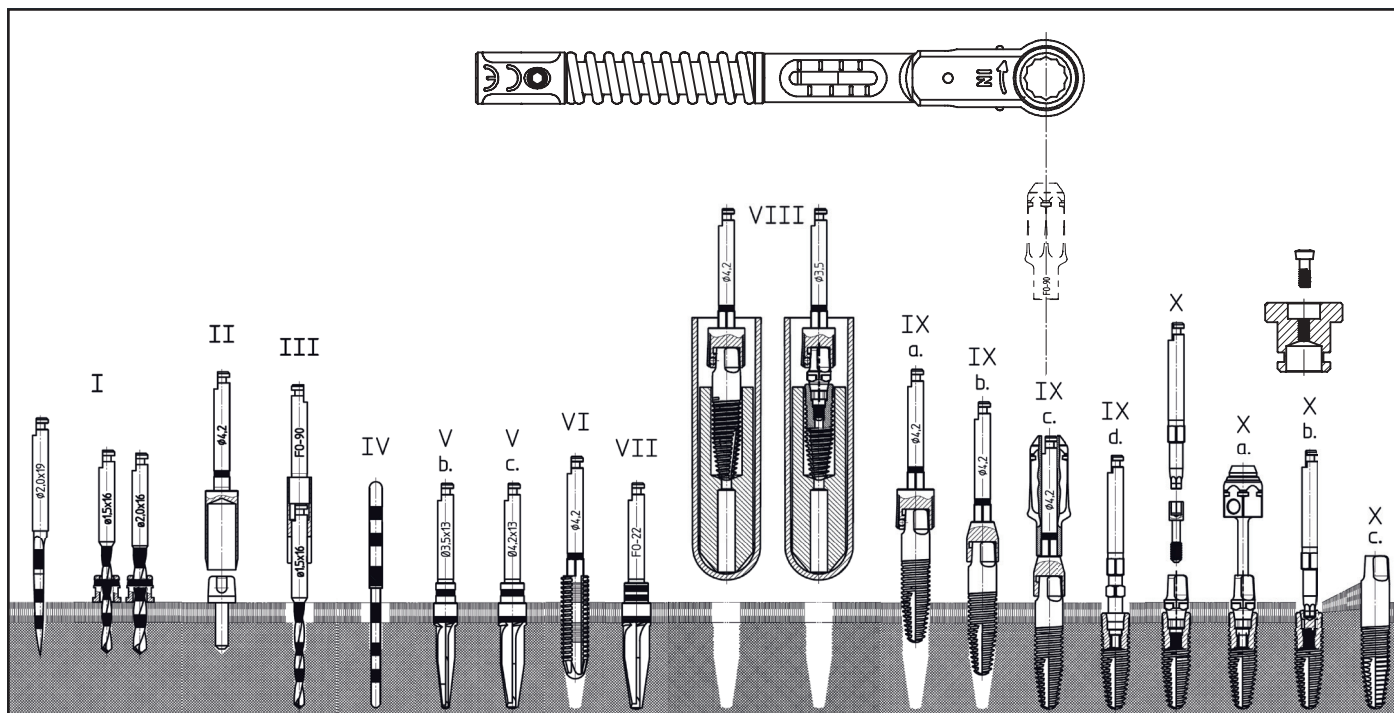
drills and/or thread cutters of the chosen implant size may be used in addition to complete preparation.

B. FairTwo: It is always recommended to use the indicated dense drills for implant site preparation. In case of failure to insert the implant to the required depth, the corresponding dense drills and/or thread cutters of the intended implant size may be used in addition to complete preparation. When using the multi length drill 8-10-13 with diameter, an implant drill or dense drill of corresponding diameter in 6 mm length may be used additionally to enlarge the bore hole and countersink the microthread. In case of soft bone structure and an expected lack of implant stability, the use of implant drills is recommended.

6. Drilling sequence FairImplant

Please refer to the below diagram of the procedure for preparation of the implant site and insertion of the implant.

I. Drilling of the pilot hole with triangular predrill and pilot drill with drilling sleeve 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 and pilot drill \varnothing 1.5mm) Use pilot drill \varnothing 1.5 mm (for implants - \varnothing 3.5 mm and 4.2 mm) and pilot drill \varnothing 2,0 mm (for implants - \varnothing 5.0 mm and 6.0 mm)

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

b. \varnothing 1.5 mm (Implant diameters \varnothing 3.5 mm and 4.2 mm); can be omitted if using the triangular pre-drill

c. \varnothing 2.0 mm (Implant diameter \varnothing 5.0 mm and 6.0 mm); can be omitted if using a 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, in ascending order:

a. For implants \varnothing 2.8 mm -> 2.8 mm

b. For implants \varnothing 3.5 mm -> 3.5 mm

c. For implants \varnothing 4.2 mm -> 3.5 - 4.2 mm (Except length 6 mm - 3.5 mm is omitted)

d. For implants \varnothing 5.0 mm -> 3.5 mm - 4.2 mm - 5.0 mm

e. For implants \varnothing 6.0 mm -> 3.5 mm - 4.2 mm - 5.0 mm - 6.0 mm

VI. Screw tap, optional in case of hard bones (opt. speed: **20 - 25 rpm**, max. speed 25 rpm)

VII. Dense drill Optional: in case of hard bones

VIII. Removal of implant from primary packaging by means of

a. Insertion tool with friction (FairOne)

b. Insertion abutment FairTwo. For removal of FairTwo implants Platform S or L insertion tools (FairOne) \varnothing 3.5 mm or \varnothing 5.0 mm have to be used. 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). Please make sure that a torque of 40 Ncm is not exceeded, to prevent damage to the shank connection

b. With insertion tool without friction

c. Insertion tool without friction with ratchet adapter; A torque of up to 70 Ncm can be transmitted with the adapter

d. Insertion tool FT (FairTwo) as an alternative to the insertion tool FairOne with screw-in adapter or insertion abutment

IX c. FairOne implant inserted to full working length.

IX d. With a FairTwo implant being inserted to the full working length 1.5 mm of the micro thread (total length 2 mm)

are above 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 tissues.

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. The implant is sealed by screwing the cover screw (screwed in the lid of the packaging) onto the implant with the Hex Driver (**max. 5 Ncm**). On the drawing, the FairTwo implant \varnothing 4.2 x 13 (14.5) 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 implant - 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 FairOne, 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. FairTwo prosthetic restoration components

The prosthetic restoration components may be used by properly trained dentists, doctors and dental technicians only. The general rules of dentistry, in particular regarding prosthetic restorations, apply. Two different screw sizes are available:

Platform S for implants with a diameter of 3.5 and 4.2 mm

Platform L for implants with a diameter of 5.0 and 6.0 mm

I. Healing caps, impression copings, temporary fixation and fixation in the Please make sure to observe the maximum permissible torque of **10 Ncm** for temporary intraoral and extraoral fixation, removal of the impression coping screws and the healing caps.

II. Definite fixation of abutments

Definite fixation of the abutment is to be carried out with a torque of **25 Ncm**. To ensure gentle insertion of the screw, the screw has to be retightened to the definitive torque of 25 Ncm after approx. 5 minutes. In case of using higher fixation torques, there is an increased risk of causing damage to the screw. In a worst-case scenario, the screw might even fracture. In case of using lower torques, there is an increased risk of

the screw loosening. Loose abutment connections need to be retightened to the definite torque immediately by using undamaged screws to prevent damage of the prosthetic reconstruction.

III. Loosening of the abutment connection

If, after loosening of the abutment screw, the abutment cannot be manually removed, use the Take-Out Tool. This is screwed into the inner thread of the abutment until the bottom of the implant is reached, whereupon the abutment can be removed in axial direction. A higher torque might be necessary to remove the abutment. To this end, Take-Out Tool is provided with a ratchet connection.

8. Recommendations for maintenance

All the components of the system are supplied in a non-sterile condition. Prior to the first use, the burs must therefore be cleaned, disinfected and sterilized according to the method normally used at your practice. Inappropriate or inadequate care can easily cause damage to the instruments. Be sure to observe the legal provisions regarding the reprocessing of medical devices valid in your country and

follow the manufacturer's instructions on the reprocessing of re-sterilisable instruments supplied with the instruments.

9. Transport and storage

Be sure to use suitable containers for transport. Notably, the cutting instruments need to be protected. Packed instruments have to be protected against UV radiation and high temperatures. Cleaned instruments need to be stored in a dry place. Do not store in the same room as solvents or chemical products. When observing these conditions of storage, the indicated shelf life of the instruments will not be affected.

10. Safety and responsibility

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™.