Fair Implant

Surgery Manual

Overview of the drilling protocol using a 13 mm drill as an example

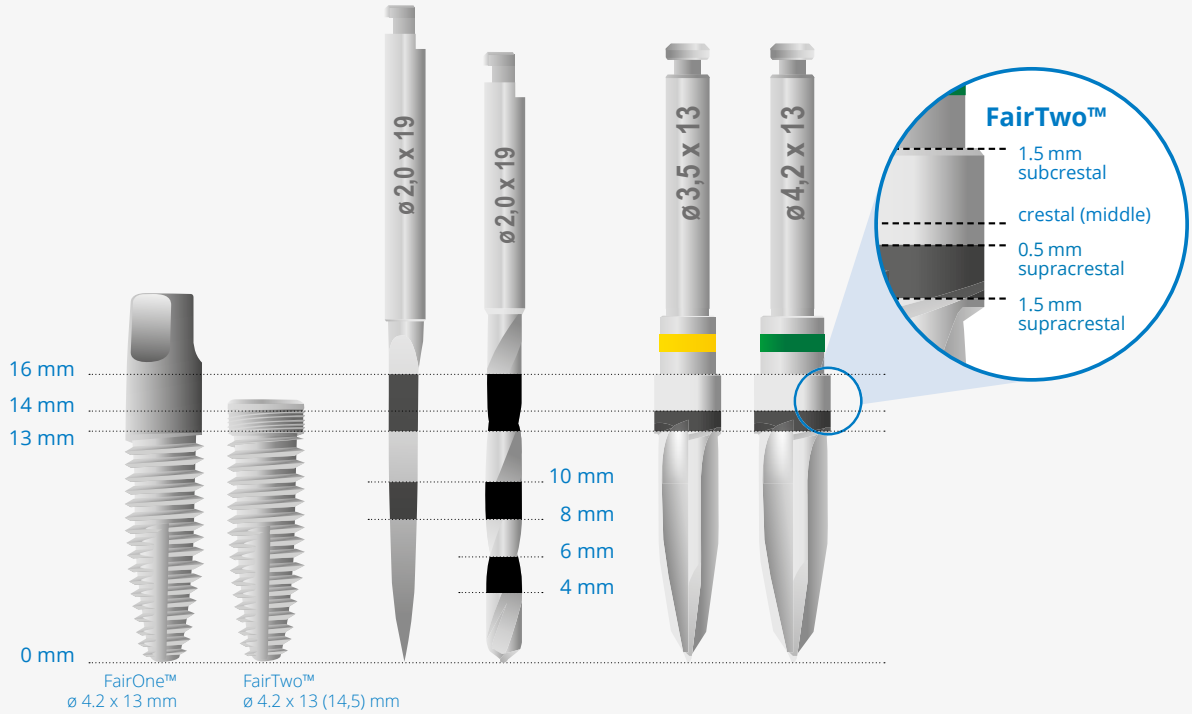


Fig. 1

Placement with different drilling depths

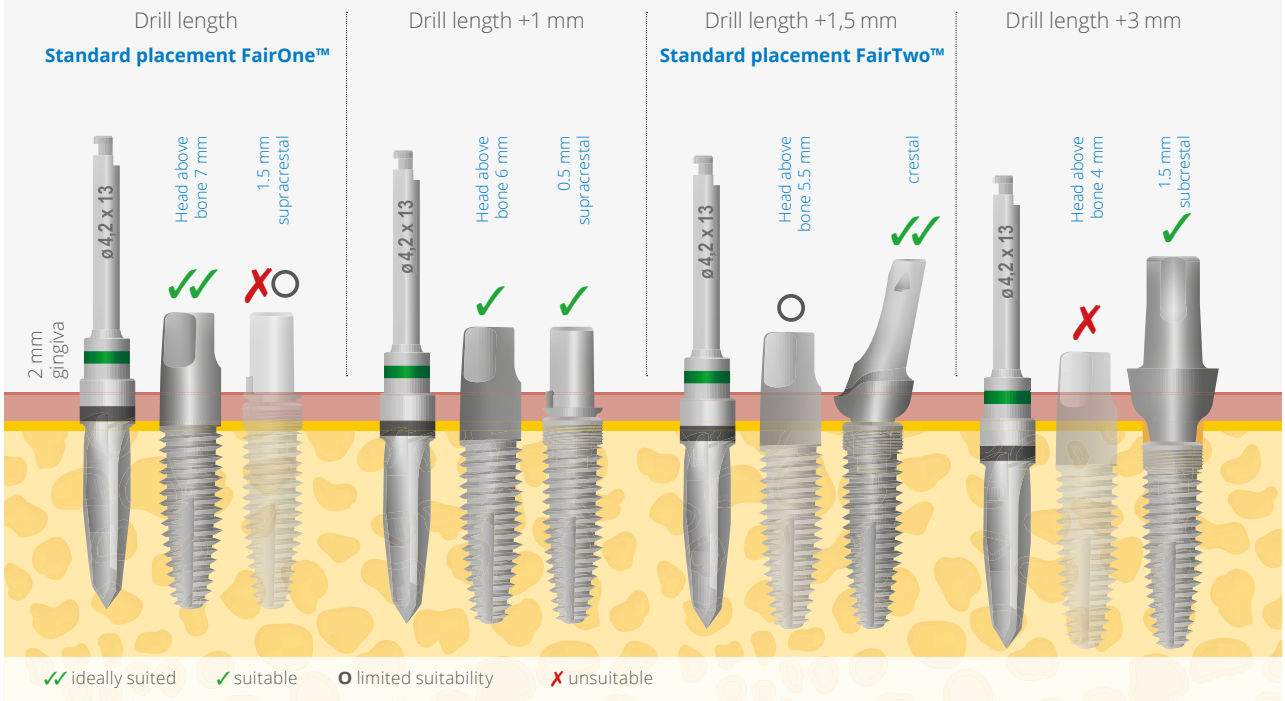


Fig. 2

Biological • Reliable • Economical • *Fair*

Biological

- IBIC (immediate bone-to-implant contact)
- FairOne™: taking the biological width into consideration
- FairTwo™: virtually one piece due to a conical internal connection
- Special surface roughness for mucosal apposition
- adsorbable CaP coating for accelerated osseointegration (BONIT®)
- Implant in the shape of a tooth root
- Implant and abutments made of medical grade 4 pure titanium
- Instruments for minimally invasive surgical procedures

Reliable

- Drills self-centring and extremely smooth running
- Implant shape supports borderline indications (low bone quality and height, narrow situation, sinus lift, bone spreading)
- Instrumentarium for hard and soft bone
- Abutment screws are safeguarded against falling out accidentally
- Impression posts can only be screwed into the correct final position
- Proven, excellent fabrication quality without residue
- Patented rotational security with FairTwo™

Economical

- Single-stage treatment with FairOne™ / FairTwo™ Plus significantly reduces the overall treatment costs in comparison to submerged healing with regard to chair times, material costs and laboratory work
- Reasonably priced treatment options are available in the case of submerged healing using LOCATOR® or One-Piece abutments
- The quiet-running drills have very high service lives and are excellent for collecting bone chips
- Only one system for virtually all indications

Fair

- Competent advice
- Highest fabrication quality
- Systematic, continuously developed system at a fair price

The FairImplant™ System

The FairImplant™ system supports the user with a comprehensive, coordinated instrumentarium. You are able to provide single-stage and two-stage treatment using only one system. You can provide standard or minimally invasive treatment and treat patients with any bone situation according to their requirements. This allows you to use only one system for virtually all indications.

On the one hand, this provides the operator with the assurance of being equipped for any situation and to change the protocol during treatment according to the situation without great effort. Coordination of the implant drills to the implants optimises primary stability and distance to the bone, ensuring the best possible IBIC and quick healing. These system characteristics provide additional reliability, in particular with borderline indications, and therefore enable responsible treatment.

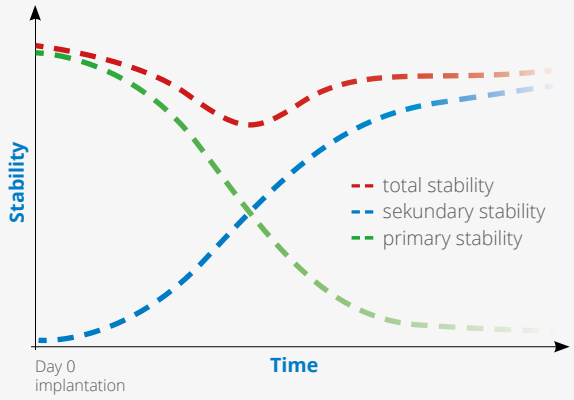
On the other hand, if the situation allows, with single-stage treatment you can provide implantations at a comparatively reasonable price and with minimal traumatic stress for the patient. This regularly expands the circle of interested patients.

System advantages

- Only one system for virtually all indications
- Same instrumentarium for both implants
- Optimised implant site preparation for maximum primary stability and quick healing
- Supports minimally invasive treatments
- Solutions for hard and soft bone
- Very quiet-running and self-centring drills
- Increased reliability with borderline indications

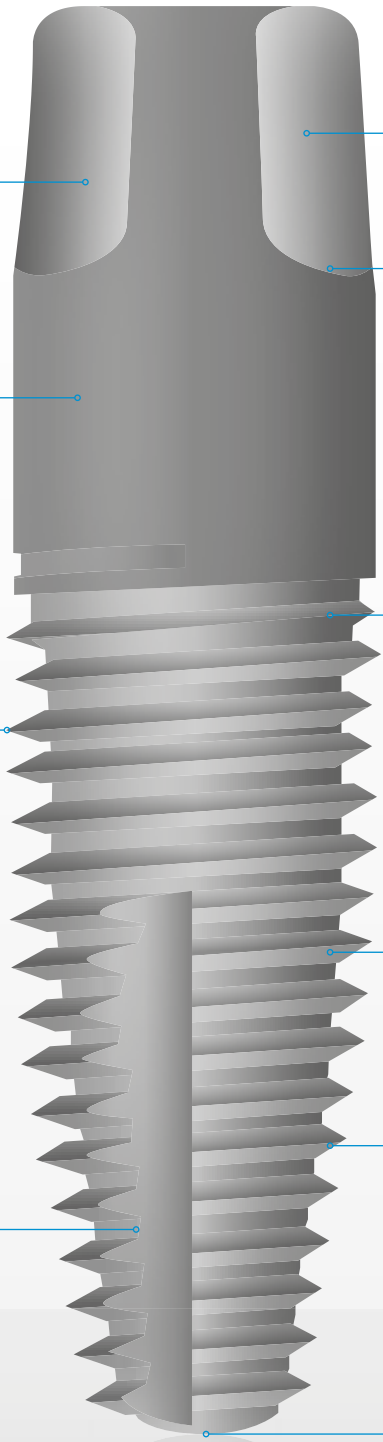
Primary stability and minimum distance to the bone due to matching shape

Very high primary stability, minimal distance to the bone and CaP coating optimise stability during the critical phase



Schematic diagram according to Raghavendra

FairOne™



Immediate impression head,
3 degrees with 3 sides

Solid – one-piece without microgap

Self-tapping thread

Precise, interlocking implant
site preparation for IBIC

Prosthetic treatment as
for a prepared tooth

Single-stage immediate
restorations possible

Implants are made of medical
grade 4* pure titanium

Coating with BONIT®, CaP,
is completely adsorbable

Conical for high primary
stability and bone spreading

Round apex for optimum
sinus floor elevation

* Exception: ø 2.8 mm medical grade 5 titanium alloy

Osseointegration and healing

The one-piece FairOne™ implant orientates consistently to the biological width, which adjusts to each tooth and implant. In order to maintain an ideal biological width, it has neither gaps nor microjoints.

It has two different degrees of surface roughness. One is optimally designed for osseointegration and the other for apposition of the mucosa.

The purpose of both is to keep the level of subsequent bone remodelling low. The single-stage procedure is particularly gentle on the tissue. The good initial apposition of the mucosa to the implant is permanently maintained, as the mucosa no longer has to be detached.

CaP coating for quicker healing

All titanium implants have a shear-resistant, completely resorbable calcium phosphate coating (BONIT®). The coating has been proven to accelerate the healing process, ensuring successful healing.

- 2-phase CaP coating on all implants
- Excellent biocompatibility
- Outstanding hydrophilic properties
- Layer thickness approx. 20 µm
- On the medical market since 1995

Advantages of FairOne™

- Excellent primary stability
- Gentle on the soft tissue
- No microgap
- Outstanding hydrophilic surface
- Single-stage treatment
- Easily prepared
- Easy prosthetic treatment
- Very economic

Fig. 3: FairOne™ placement, initial wetting of the hydrophilic surface (CaP coating)

Fig. 4: X-ray check four months postoperatively with complete preservation of the bone structure

Fig. 5: SEM examination in the DESY (German Electron Synchrotron)/Hamburg

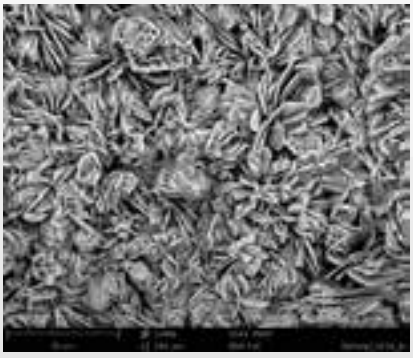
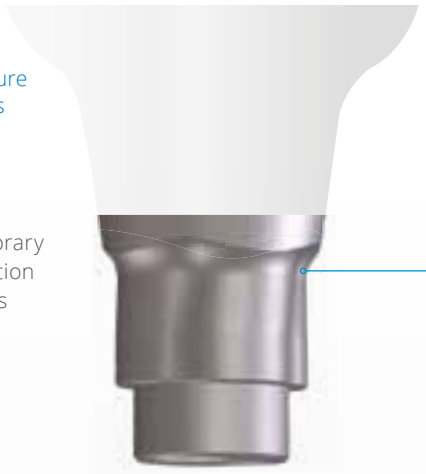


Fig. 6: SEM image of the CaP surface, 1,500 times magnification
Photo: University of Cologne, Germany, Implant Study 2014/15

FairTwo™

All implants with date of manufacture from 2015 onwards: FairTwo™ Plus with insertion abutment

Single-stage temporary immediate restoration using FairTwo™ Plus



Unique patented rotational security ensures easy placement and minimised circumferential backlash with four positions

Platform switching

Conical inner connection

Microthread, pitch as main thread

All implants and abutments are made of medical grade 4 pure titanium

Self-tapping thread

Coating with BONIT®, CaP, is completely adsorbable

Conical for high primary stability and bone spreading

Precise, interlocking implant site preparation for IBIC

Round apex for optimum sinus floor elevation

Osseointegration and healing

The material, surface and shape in the osseous region of FairTwo™ are the same as FairOne™.

The implant has a conical inner connection to the abutment to ensure that the influence of micromovement and microgaps is kept as low as possible. The biological width is taken into account by platform switching. All abutments are also made of medical grade 4 pure titanium.

Comparatively high primary stability can be achieved, whereby FairTwo™ can also be successfully used in borderline indications (such as low bone quality and height, narrow situation, sinus lift).

CaP coating for quicker healing

All titanium implants have a shear-resistant, completely resorbable calcium phosphate coating (BONIT®). The coating has been proven to accelerate the healing process, ensuring successful healing.

- 2-phase CaP coating on all implants
- Excellent biocompatibility
- Outstanding hydrophilic properties
- Layer thickness approx. 20 µm
- On the medical market since 1995

Fig. 7: FairTwo™ placement, initial coating of the hydrophilic surface (CaP coating)

Fig. 8: FairTwo™ with cover screw after placement

Advantages of FairTwo™

- Conical inner connection/ virtually one-piece
- Platform switching
- Microthread for mucosal apposition
- Hydrophilic coating
- Patented rotational security with minimum circumferential backlash
- Increased reliability with borderline indications

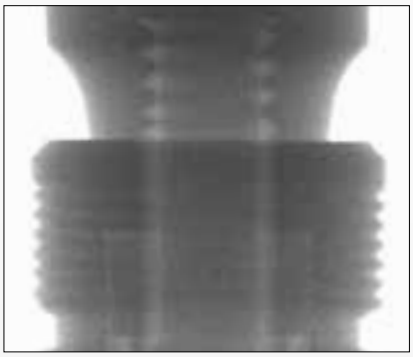


Fig. 9: Zipprich study by the University of Frankfurt, Germany: proves good implant/ abutment connection

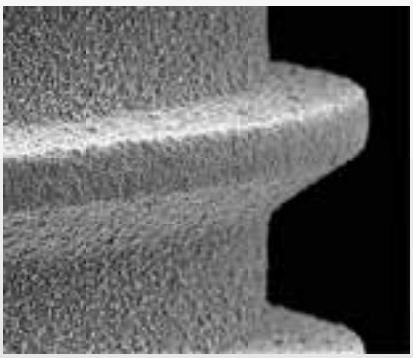


Fig. 10: SEM analyses prove perfect fabrication quality and no residue
Photo: University of Cologne, Germany, Implant Study 2011

Implant sizes at a glance

FairOne™ and FairTwo™ arranged according to diameter and length.
The figure in brackets indicates the total length for FairTwo™.

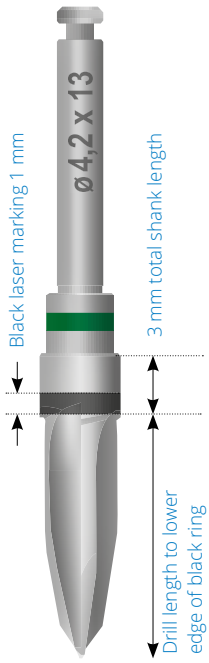
Implant drills at a glance

Implant drill identification: colour-coded ring
(dense drill identification: two colour-coded rings)

Drill length	ø 2.8 mm	ø 3.5 mm	ø 4.2 mm	ø 5.0 mm	ø 6.0 mm
6 mm			21 42 06	21 50 06	21 60 06
8 mm		21 35 08	21 42 08	21 50 08	21 60 08
10 mm	soon available 21 28 13*	21 35 10	21 42 10	21 50 10	21 60 10
13 mm	21 28 13	21 35 13	21 42 13	21 50 13	21 60 13
16 mm		21 35 16	21 42 16	21 50 16	

Implant drill dimensions

Example:
ø 4.2 x 13 mm



Drill placement see also Page 2

Indication

FairImplant™ implants can be used for single-tooth restorations, connecting multi-unit bridges and for restoring edentulous jaws also.

The root-shaped body in combination with form-congruent implant site preparation provide excellent primary stability and enable implant placement immediately after extraction.

The one-piece FairOne™ implant, in particular, enables a single-stage operation, which greatly reduces the time required for the entire treatment.

All criteria of the general implantation regulations must be taken into consideration. This applies especially for existing inflammatory processes and the quality and quantity of bone available.

Contraindications

General contraindications: General medical condition does not permit a surgical procedure.

Careful anamnestic and diagnostic evaluation of the patient is a prerequisite for determining all criteria, which could compromise the success of implantation and impair the health of the patient.

It is necessary to consider all local and systemic factors, which could influence the hard and soft tissue integration process. This allows assessment of the individual risks to implant placement (all relevant medication, nicotine and alcohol abuse, any drug misuse, connective tissue and bone diseases, parafunctions etc).

The generally valid anatomical requirements for implant placement should be checked using standard clinical and imaging methods.
This is an essential requirement for selection and individual placement of the implants.

Possible local contraindications:

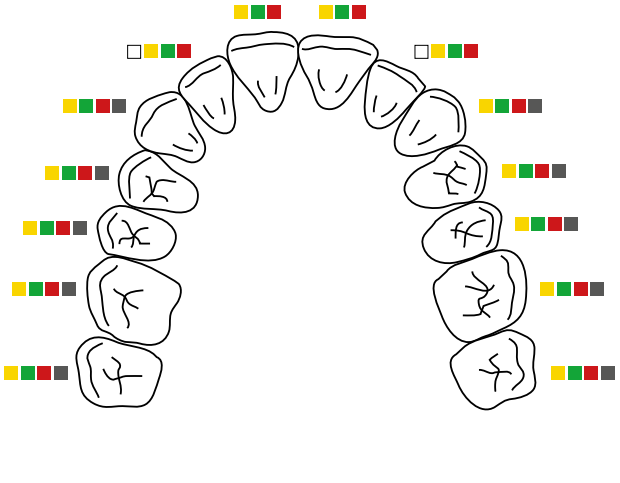
- Pathological changes in the jaw from a clinical and radiological point of view
- Relevant acute or chronic infectious diseases
- Subacute chronic osteitis in the maxilla and mandible
- Diseases, which cause microvascular disorders
- Systemic diseases
- Lack of bone structure or poor bone quality, which compromise the stable fit of the implant

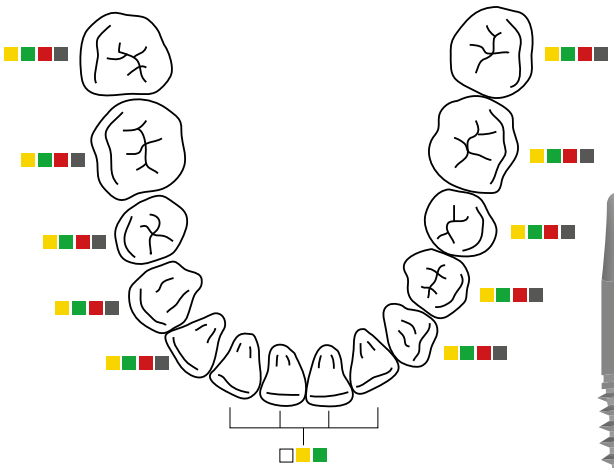
It is essential that the number and dimensions of the implants to be placed are in a sufficient ratio to the prospective loading.

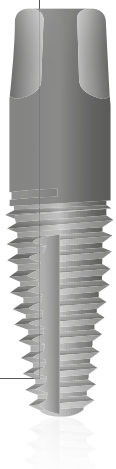
Generally: The usual contraindications which apply to implantology should be observed.

Indications of the different implant diameters

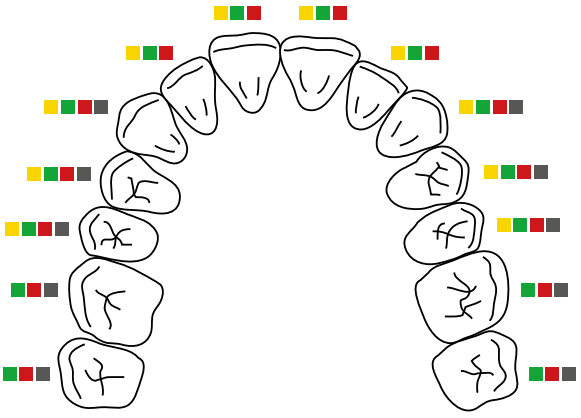
FairOne™

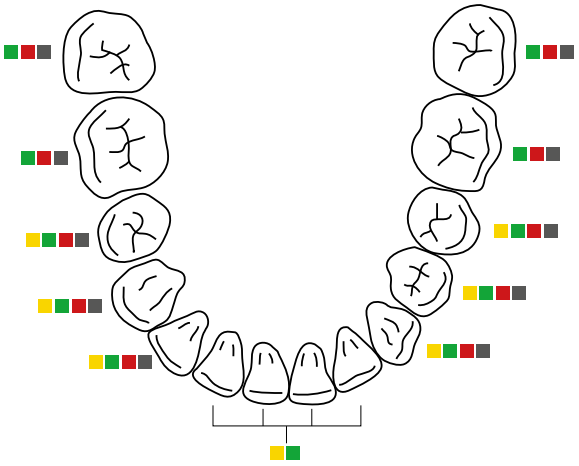


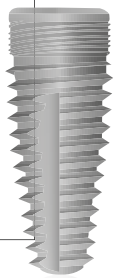




FairTwo™







Diameter	2.8 mm	3.5 mm	4.2 mm	5.0 mm	6.0 mm

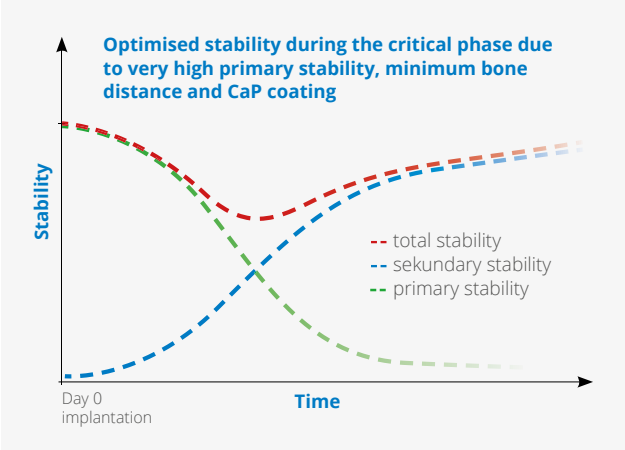


Fig. 11 Metamorphosis of the stability after implant placement according to Raghavendra

How to increase reliability during implant placement

The implant (prep) and implant (dense) drills ensure optimum stability thanks to the matching shape. The special design produces excellent bone chips and has the following advantages:

- Self-centring
- Extremely smooth running
- Exceptionally high service lives

There is a drill for every drill length and diameter to ensure minimally invasive procedures.

The system provides reliable initial positioning and solutions for every bone.

PLEASE NOTE: *It should be ensured that the chambers in the drill do not become clogged with bone chips. The bone chips collected in the drill must be removed from the chambers after every drilling procedure. It is advisable to collect the chips for filling any possible bone defects.*

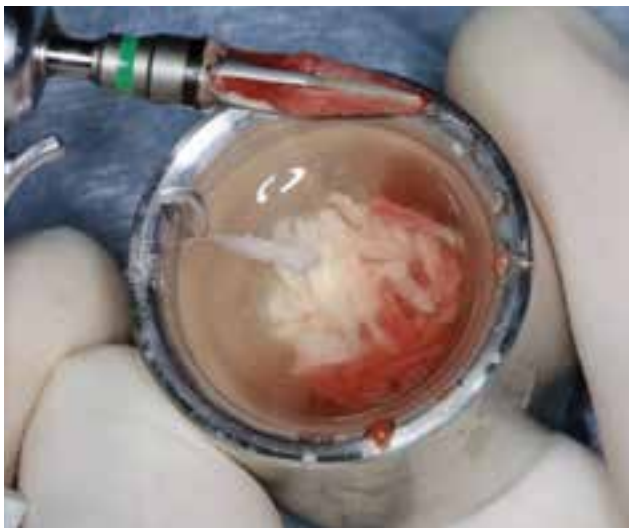
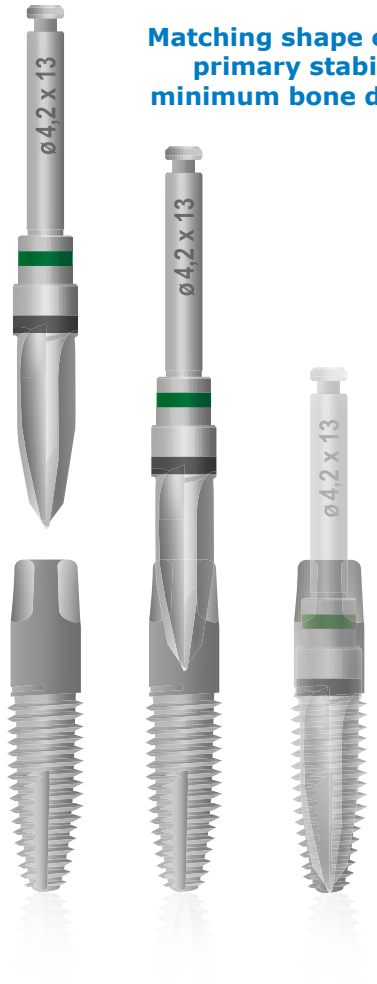


Fig. 12: bone harvesting by implant drill



Bone quality and preparation

The bone quality varies with each patient. Optimum results can only be achieved if suitable instruments are used for the respective situation.

FairImplant™ supplies:

- implant drill (prep)
- implant drill (dense)
- screw tap (helix)
- osteotome

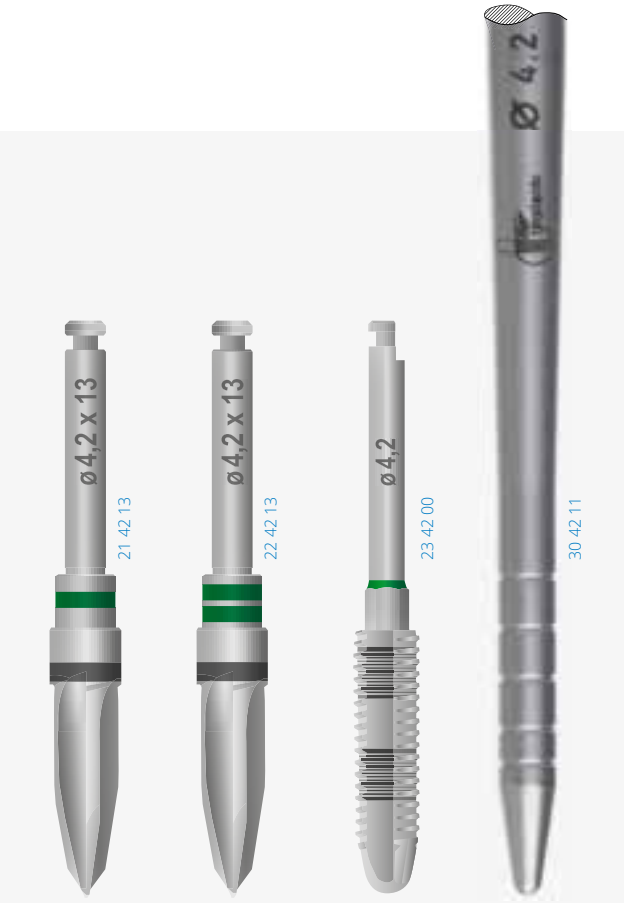


Fig. 13: Implant drill (prep), implant drill (dense), screw tap and osteotome, e.g. for size ø 4.2 mm x 13 mm

The appropriate instrument is available for final implant site preparation to suit every bone

Bone density	D1	D2	D3	D4
implant drill (prep)	O	✓	✓	O
implant drill (dense)	✓	✓	O	✗
screw tap (helix)	✓	✓	✗	✗
osteotome	O	O	O	✓

✓ suitable O limited suitability ✗ unsuitable

Preparation

The size and exact position should be determined and defined using suitable radiographic images.

Additional three-dimensional imaging procedures are recommended for determining the exact position and depth of the drilled site.

The adjacent structures must be checked before initial drilling (aids see Page 18). The surgical procedure should be defined.

Finally, implant placement should be defined. This determines the pilot drill size and drilling depth. The surrounding area of the operation site should be checked exactly to exclude any hazards to the adjacent structures.

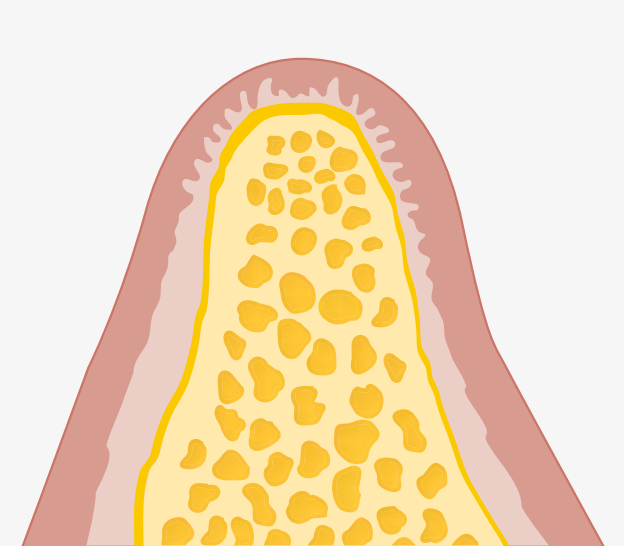


Fig. 14: Bone before implant site preparation

FairTwo™:

It should be determined whether the implant is to be placed supracrestally, crestally or subcrestally, depending on the mucosal situation or aesthetic requirements. This influences the drilling depth (see Fig. 15).

FairOne™:

The thread should be completely covered during placement of the FairOne™. The bone to mucosa junction should be in the parallel emergence zone. The drilling depth must be adapted accordingly.

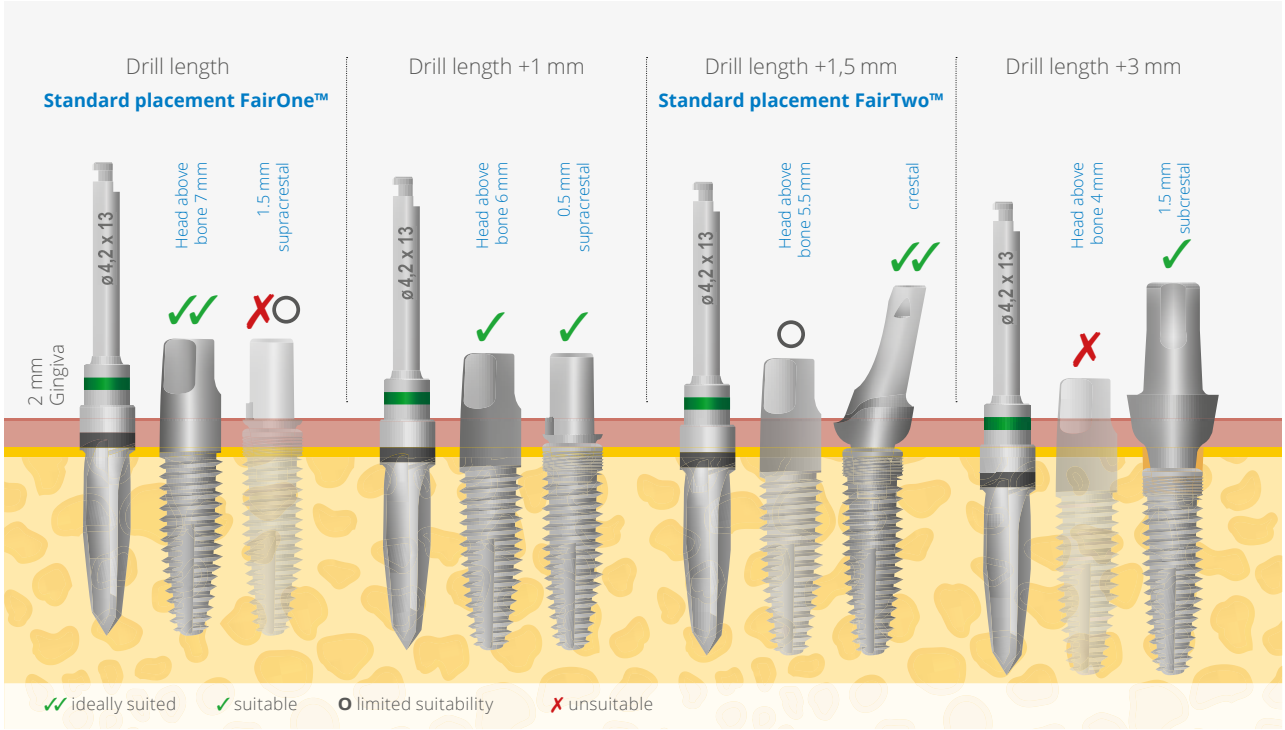


Fig. 15: Placement according to drill length

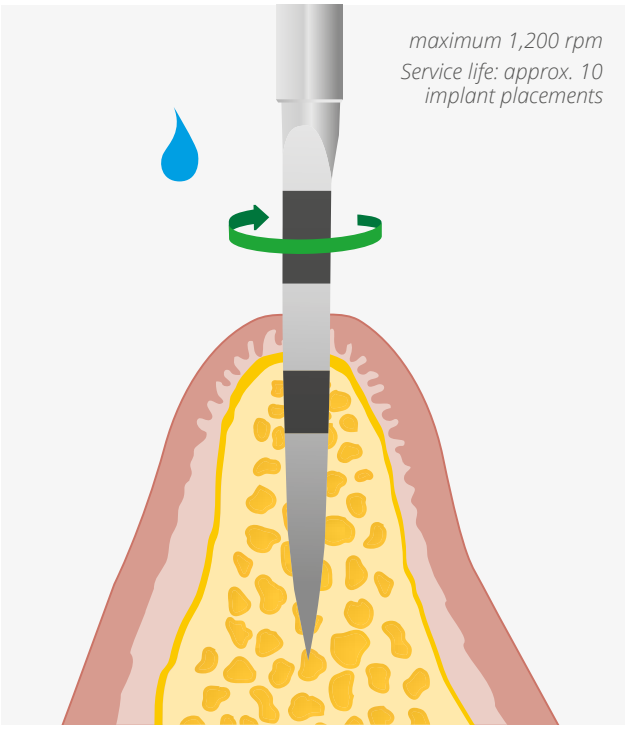


Fig. 16: Initial positioning using the triangular pilot drill

Pilot drilling

Drilling should be performed under continuous external cooling with a suitable, sterile rinsing solution.

The triangular pre-drill can be used optionally for initial drilling for defining the drilling axis prior to use of the pilot drill. It enables precise drill guidance, even in restricted anatomical conditions.

Place the appropriate pilot drill (ø 1.5 mm or ø 2.0 mm) on the planned position and use the appropriate drill probe (see Page 18) or a surgical stent as a positioning aid for the selected implant size.

The intended drilling depth for implants ø 2.8 mm and ø 3.5 mm can only be achieved using the ø 1.5 mm pilot drill. The ø 2.0 mm pilot drill required for the punch hole should be used with the drilling depth reduced by approx. 2 mm. The depth of the drilled pilot site can be measured using a depth probe.

The mucosa must be punched out before pilot drilling is performed (see Page 20).

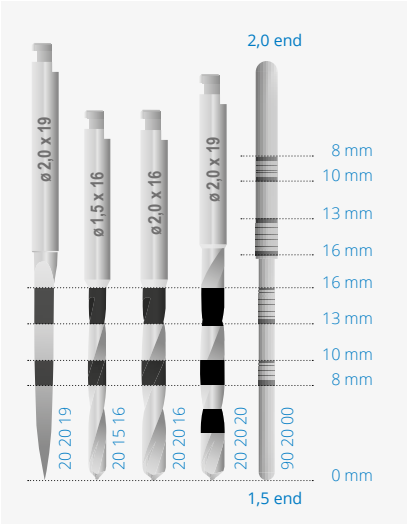


Fig. 17: Pilot drill and depth probe

	ø 2,8 mm	ø 3,5 mm	ø 4,2 mm	ø 5,0 mm	ø 6,0 mm
Triangular drill ø 2,0 mm	✓	✓	✓	✓	✓
Pilot drill ø 1,5 mm	✓	✓	✓	✓	✓
Pilot drill ø 2,0 mm	✗	o*	✓	✓	✓

✓ suitable o limited suitability ✗ unsuitable

** Brief drilling required for guidance (see Page 18)*

Surgical options

The instrumentarium supports the following techniques:

- Determining the distance to the adjacent tooth
- Full flaps
- Partial flaps
- Minimally invasive punch holes

Determining the distance to the adjacent tooth

The drill probe simulates the position of the implant. This allows the distance to the adjacent teeth to be clearly visualised during pilot drilling. The drill probe with the diameter of the planned implant is used together with ø 2.0 mm pilot drill.

The drill probes simulate the diameter of the FairOne™ heads, insertion abutments and one-piece abutments. The positioning to the adjacent teeth can be accurately checked.

The implant position can be corrected at any time during the pilot drilling phase. The alignment of the drill should be checked by the team.

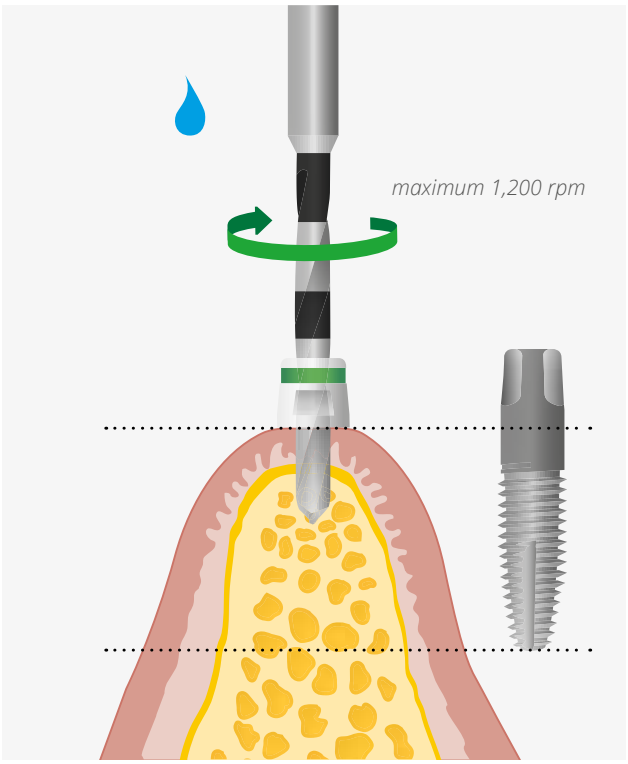


Fig. 18: Pilot drilling with drill probe for determining the distance

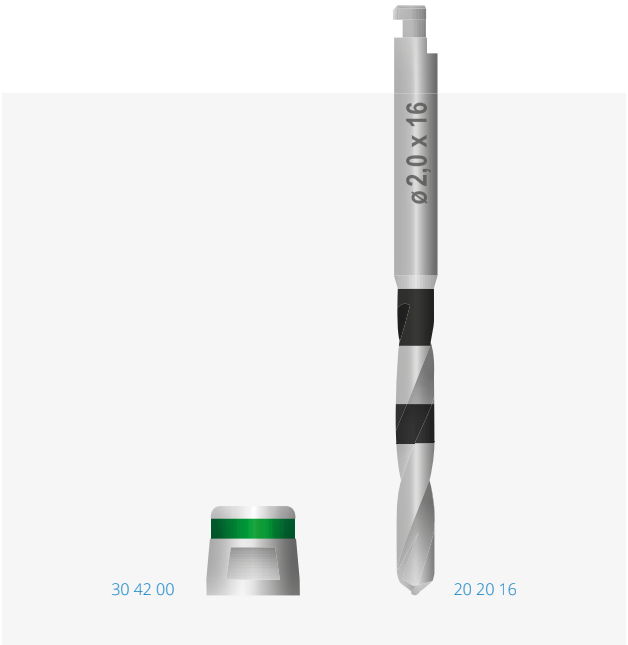


Fig. 19: Pilot drill with drill probe

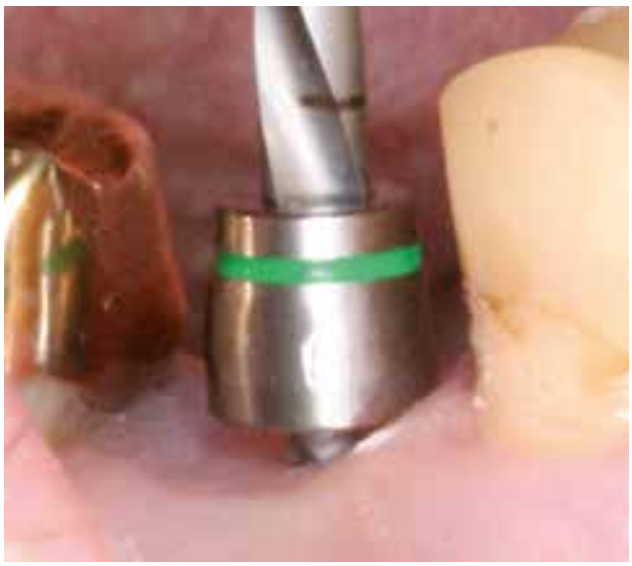


Fig. 20: Simulation of the distance of the implant to the adjacent teeth

Implant placement involving raising a flap

Minimally invasive implant placement is not always possible.
In case of minimal width of fixed gingiva or reduced bone availability it is practical to prepare a flap in order to allow visual control when placing the implant. The incision should be positioned to ensure that sufficient fixed gingiva can surround both sides of the implant after suturing.

The same drill sequence is used after raising a flap as with the minimally invasive technique. The only major difference is in observing the length marking of the implant drill. Here it is essential to pay attention to the marking of the bone height on the implant drill (see Page 2).

The implant can be placed using a contra angle or ratchet. With FairOne™ the mucosa should be sutured closely around the implant to achieve optimum connective tissue and epithelial attachment (see Fig. 46). If in doubt, a flap should always be raised to ensure dependable implantation.

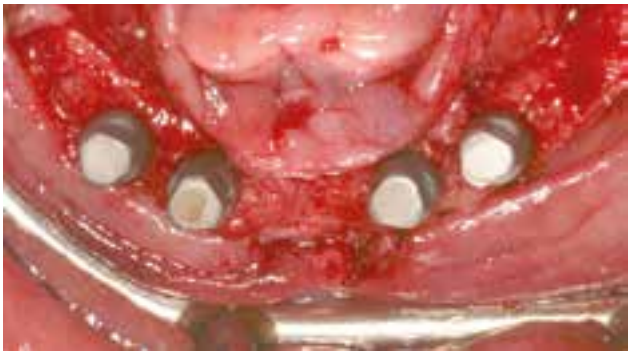


Fig. 21: Raising a flap

USER TIP:
Implant placement in the aesthetic zone

Dental floss can be placed around the adjacent teeth for determining the implant position. The implant should be positioned to ensure that the buccal tangent is approx. 1.5 - 2.0 mm from the implant.

Placing the implant in the centre of the alveolus does not always lead to an optimum result with immediate implant placement in the aesthetic zone.

The triangular pre-drill is recommended for initial pilot drilling that deviates from the centre of the alveolus (see Page. 17).

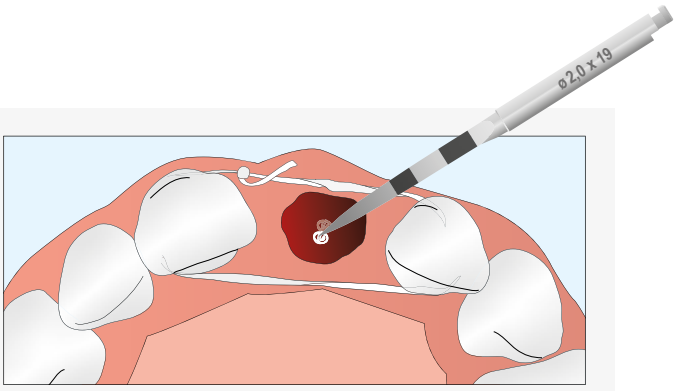


Fig. 22: Extraction alveolus – placing dental floss for determining the implant position

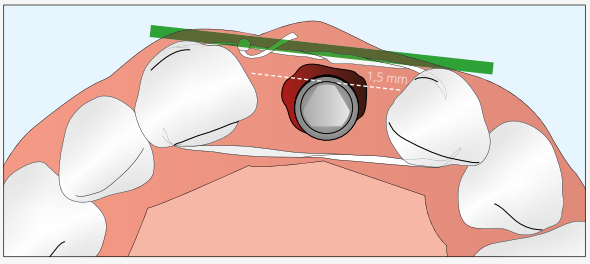


Fig. 23: Position approx. 1.5 - 2.0 mm palatally of the tangent of the adjacent teeth

Fig. 24: Tissue punch probe in the drilled pilot site

Punching soft tissue minimally invasively

The anatomical conditions should be carefully evaluated for a minimally invasive procedure. Particular consideration should be given to both the osseous structures and width of the attached gingiva. FairImplant™ provides a coordinated instrumentarium for this purpose, which enables the soft tissue to be punched out to a matching shape. This allows immediate connective tissue apposition to the implant surface. The soft tissue punch should be used as standard with minimally invasive procedures.

The initial drilled pilot site should be extended to ø 2.0 mm to enable placement of the tissue punch probe; the depth is determined according to the implant to be placed.

The tissue punch probe, which corresponds to the implant diameter, should be placed in the drilled pilot site. The distances to the adjacent teeth can now be checked again.

The soft tissue punch should be inserted in the contra-angle (maximum 800 rpm), placed over the tissue punch probe and the tissue punched quickly until bone contact is achieved.

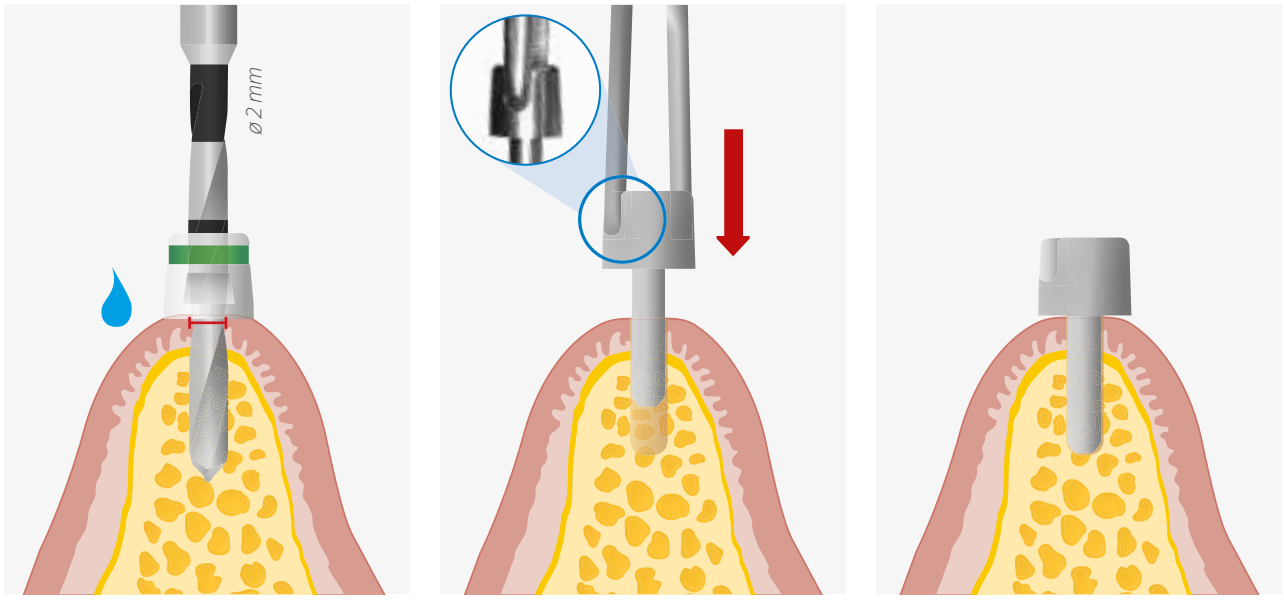


Fig. 25: The pilot drill must drill to a depth of 7 mm for placing the tissue punch probe.

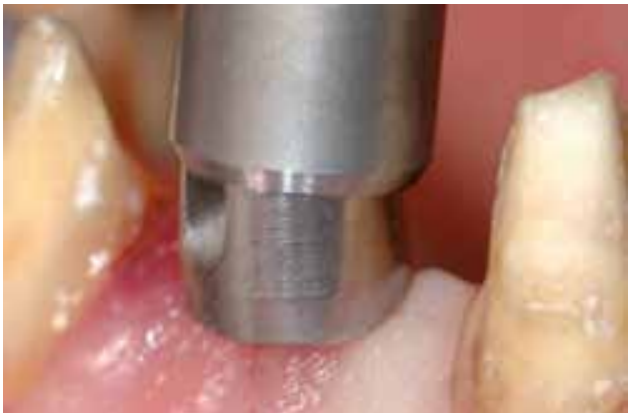


Fig. 26: The soft tissue punch is placed over the tissue punch probe

Fig. 27: Excision of the gingiva

The punched out mucosa should be removed using a suitable instrument. A sharp curette or Wedelstaedt chisel, for example is recommended for this. The entire connective tissue must be removed without residue.

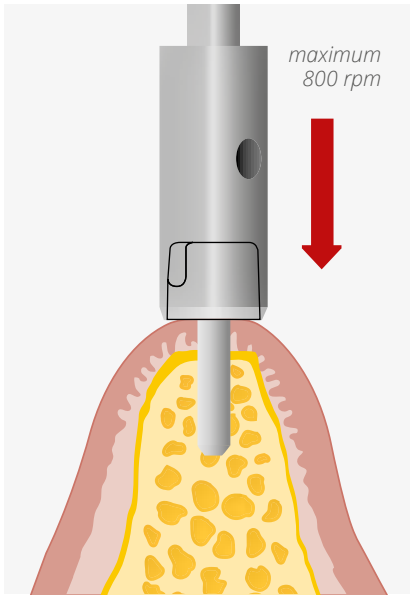


Fig. 28: Punching out the attached gingiva

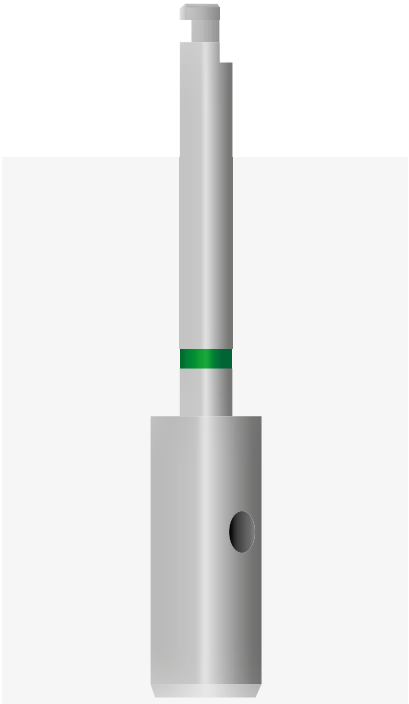


Fig. 29: Soft tissue punch

PLEASE NOTE: *A minimally invasive technique is only permitted within the attached gingiva! It should always be ensured that the implant is surrounded by adequate attached gingiva after placement.*

Raising a partial flap

In case of facial bone retraction or very thin facial mucosa, a flap of buccal mucosa can be raised.

First the implant position should be determined and then the mucosa drilled through into the bone using the pilot drill. An incision should now be placed crestally through the drilled site and the buccal flap raised as far as necessary.

The oral segment should be punched as in the minimally invasive technique. The implant site should be prepared in accordance with the protocol.

After placement of the FairOne™, the flap should be sutured to position it closely against the implant.

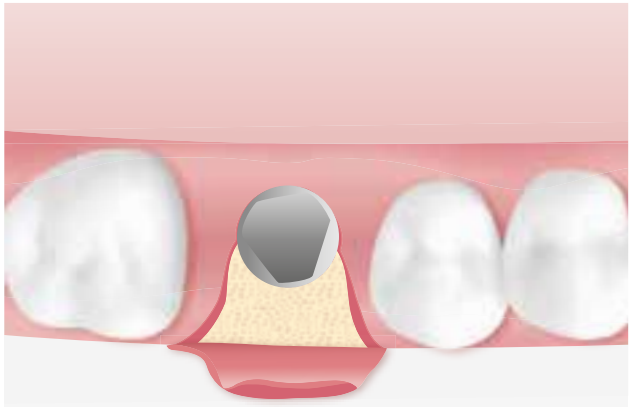


Fig. 30: Partial flap with FairOne™

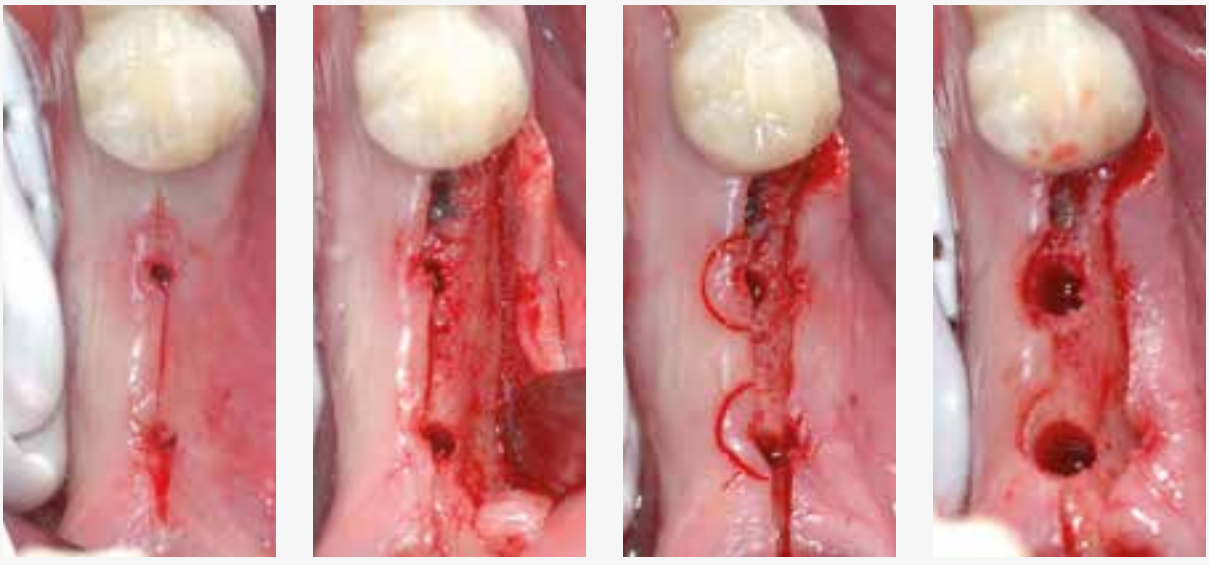


Fig. 31: Partial flap; gingival retraction buccally, punched crescents

Implant (prep) drilling

Drilling should be performed under continuous external cooling with a suitable sterile rinsing solution. External cooling prevents excessive heating of the bone tissue. Bone chips can also be removed or rinsed off.

To prepare the implant site gently and safely, ensure that the drills do not bend or seize during use.

The site should be prepared applying minimal pressure at a maximum speed of 800 rpm until the required depth is reached. The drill should be constantly in motion in the implant site. A maximum torque of 30 Ncm should not be exceeded for any drill.

Assuming bone conditions permit, it is recommended to perform final form drilling using the dense drill for submerged healing with FairTwo™. This enables implant placement using adequate torque.

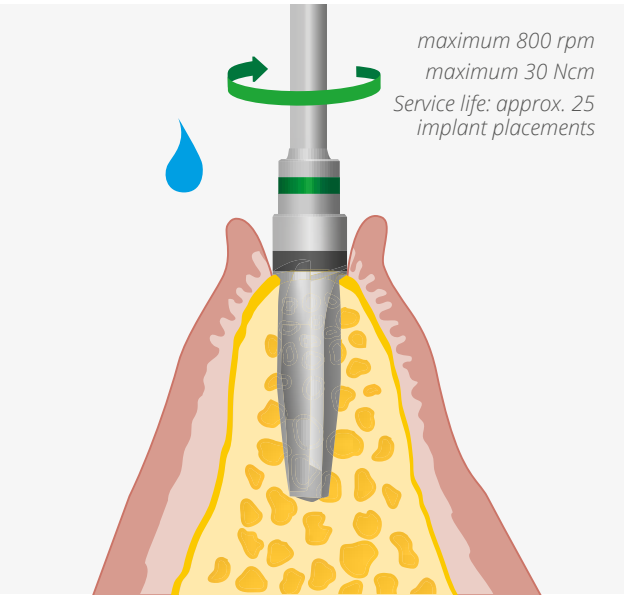


Fig. 32: Implant drill example ø 4.2 mm

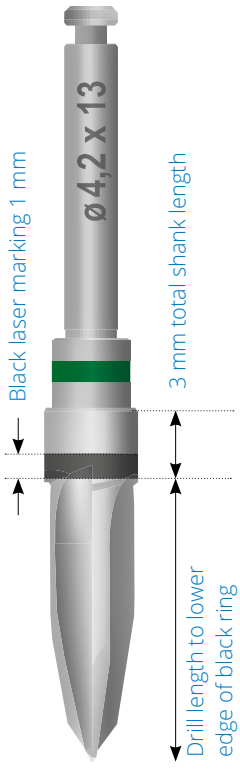
Drilling sequence for the dense drills

After pilot drilling, the dense drills should be used in the required length, always starting with the smallest and proceeding to the final diameter and using all intermediate sizes according to the table on page 26.

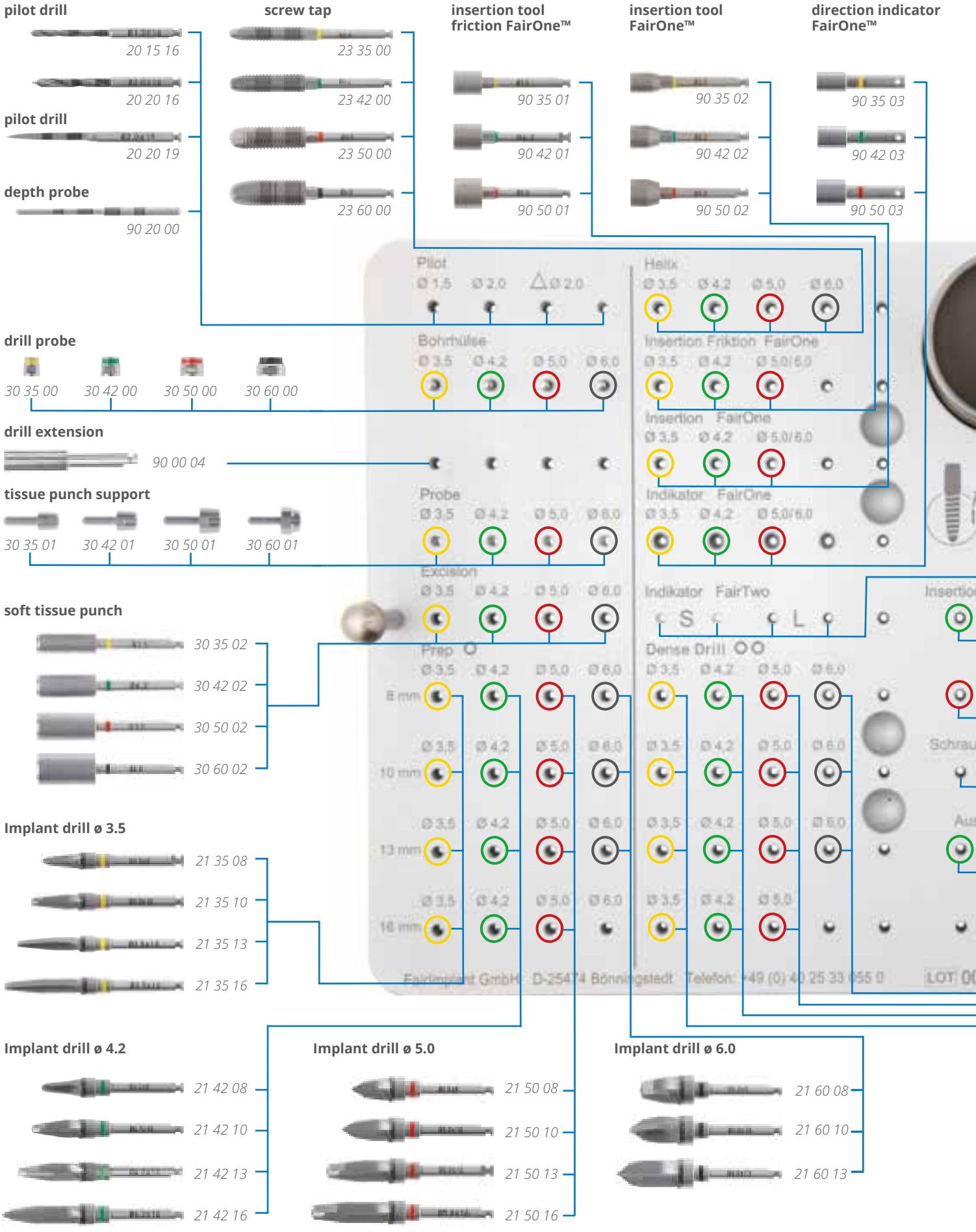
The diameters are marked with a colour-coded ring to allow easier differentiation. Every prep or dense implant drill has four blades along the entire length of the drill to the lower edge of the black ring.

Depending on the placement, it is necessary to prepare the implant site beyond the length of the drill (see Fig. 2 on Page 2).

General dimensions implant drill



System overview FairImplant™



direction indicator FairTwo™

90 16 03

90 20 03

insertion tool FairTwo™

90 23 03

90 32 03

90 23 04

90 32 04

screwdriver FairTwo™

90 00 05

90 00 06

LOCATOR®-**screwdriver**

90 00 09

miniscrewdriver, short

90 00 07

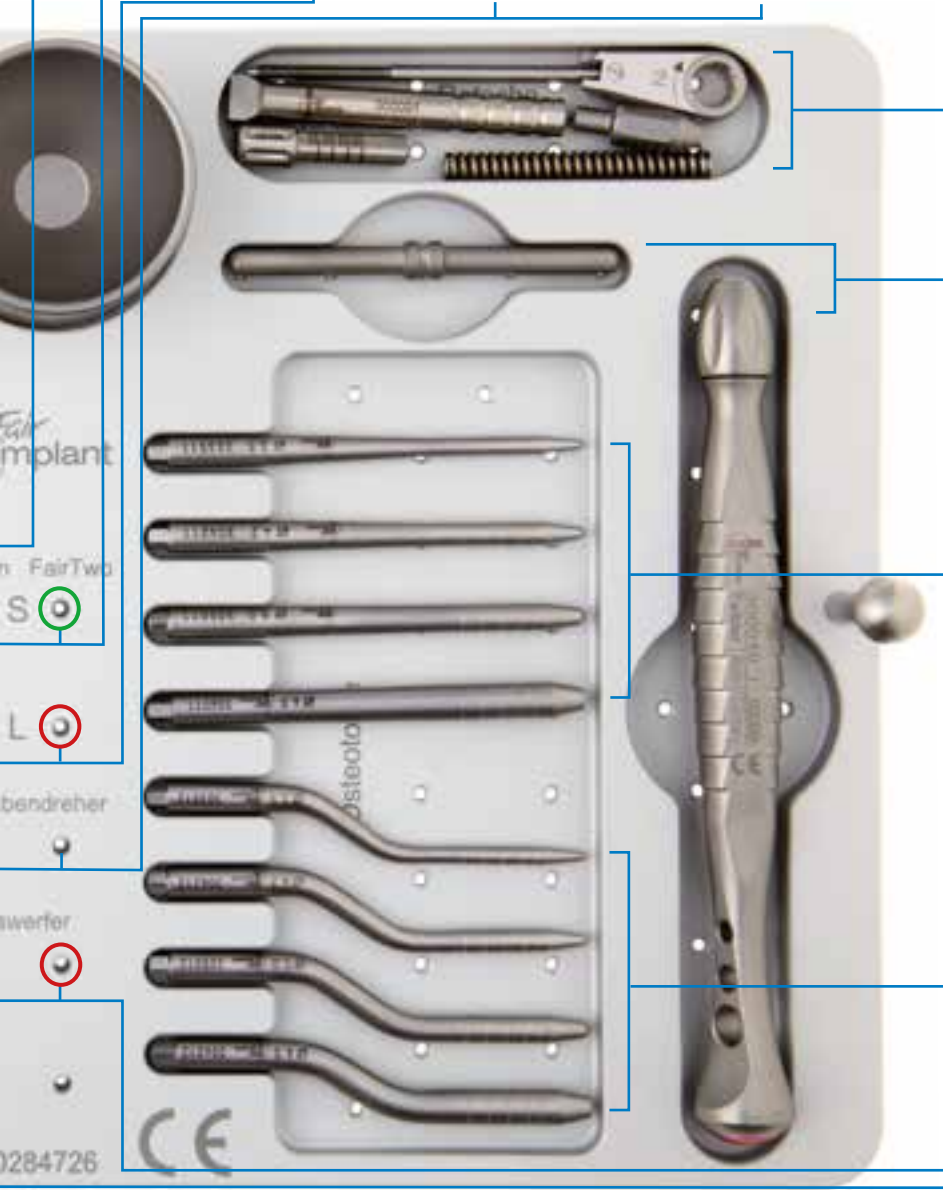
miniscrewdriver, long

90 00 08

ratchet 90 00 01

ratchet adapter 90 00 03

Always dismantle and **oil** the tool before every sterilization; otherwise there will be immediate wear!



osteotome

twister handle 30 00 10

straight

ø 3.5 (8-10-13-16-19) 30 35 11

ø 4.2 (8-10-13-16-19) 30 42 11

ø 5.0 (8-10-13-16-19) 30 50 11

ø 6.0 (8-10-13-16-19) 30 60 11

angulated

ø 3.5 (8-10-13-16-19) 30 35 12

ø 4.2 (8-10-13-16-19) 30 42 12

ø 5.0 (8-10-13-16-19) 30 50 12

ø 6.0 (8-10-13-16-19) 30 60 12

take-out tool

91 16 00

91 20 00

dense drill ø 6.0

22 60 08

22 60 10

22 60 13

dense drill ø 3.5

22 35 08

22 35 10

22 35 13

22 35 16

dense drill ø 4.2

22 42 08

22 42 10

22 42 13

22 42 16

dense drill ø 5.0

22 50 08

22 50 10

22 50 13

22 50 16

Sequence and number of implant drills according to implant size

Implant drills in implant length	implant diameter ☐ ø 2.8 mm	■ ø 3.5 mm	■ ø 4.2 mm	■ ø 5.0 mm	■ ø 6.0 mm
ø 2,8 mm	✓✓✓	–	–	–	–
ø 3,5 mm	–	✓✓✓	–	–	–
ø 4,2 mm	–	✓*	✓✓✓	–	–
ø 5,0 mm	–	✓*	✓	✓✓✓	–
ø 6,0 mm	–	✓*	✓	✓	✓✓✓

** Length 6 mm: ø 3.5 mm omitted*

✓✓✓ Drilled final site ✓ Drilled pilot site – No drilled site

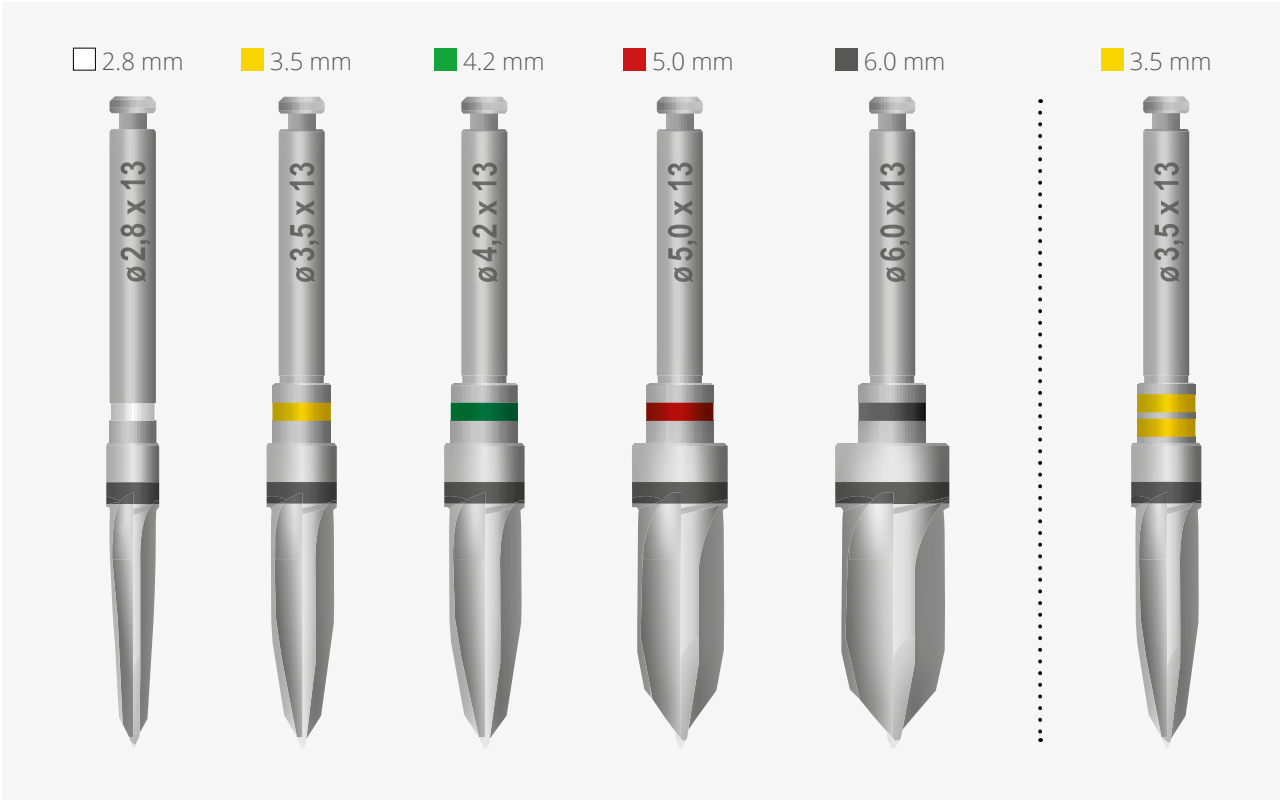
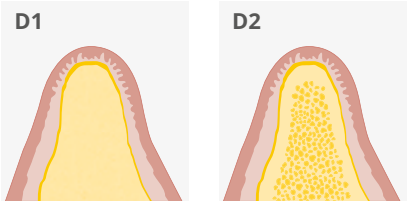


Fig. 33: Prep drills have one colour-coded ring – dense drills have two colour-coded rings



Hard bone (D1/D2)

In case of hard bone (D1 and, if applicable, D2), it is recommend to prepare the implant site accordingly. The system includes the dense drill (two colour-coded rings) and screw tap for this purpose. The implant site should always be prepared, so that the implant can be placed to the required placement depth using the desired torque of 45 Ncm.

Note: The stability of the FairOne™ implant allows for higher torque. The FairImplant™ ratchet is scaled to 70 Ncm.

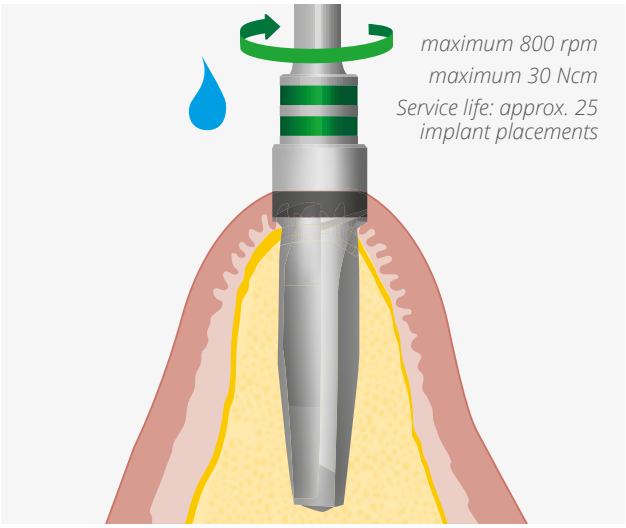


Fig. 34: Implant dense drill with two colour-coded rings

Dense drill

The dense drill is marked with a double colour-coded ring. It extends the drilled site by approx. half the thread depth of the implant.
Use of the dense drill is especially indicated with FairTwo™ to achieve the required placement depth.

The preparation instruments are coordinated in combination with use of the screw tap and this should be decided intraoperatively according to the available bone quality.

Note: In case of very hard bone, the dense drill and screw tap can be combined.

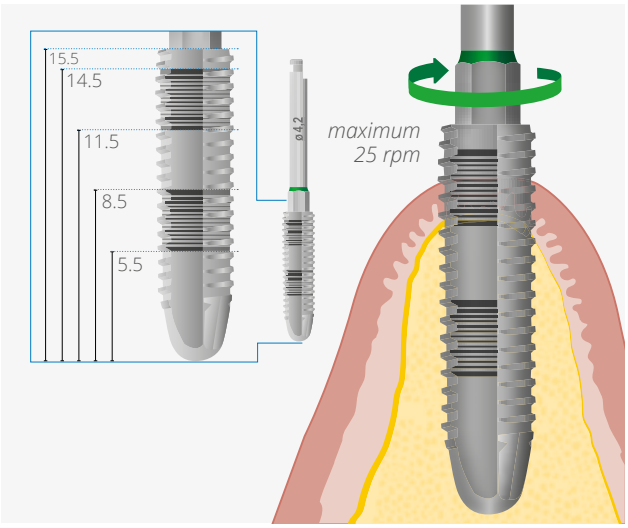


Fig. 35: Screw tap with dimensions

Screw tap (helix)

The implants have a self-tapping thread.

In case of hard bone, the thread is fully or partially pre-tapped using the screw tap. The conical area of the implant site can be extended using the cylindrical screw tap.

The screw tap is used with the ratchet adapter and ratchet. This allows a torque of 45 to 70 Ncm to be used. This should be carefully coordinated to ensure that the implant site is not prepared too wide.

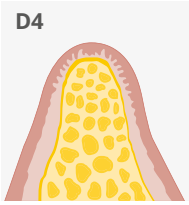
Soft bone (D4)

In case of soft bone, the operator can prepare the implant site undersized. The implant site is condensed during implant placement. Osteotomes can also be used for bone condensing and extension.

Similar to the dense drills, the osteotomes match the shape of the implant core diameter (see Page 5). Osteotomes should be used to condense the soft bone laterally after appropriate undersized preparation.

Adequate primary stability of up to 45 Ncm can generally also be achieved in D3 and D4 quality bone thanks to the conical implant shape.

The osteotomes are tailored to the implant sizes and are available in straight and angled shapes. The tip is convex.



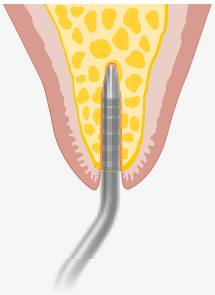


Abb. 36: Bone Spreading

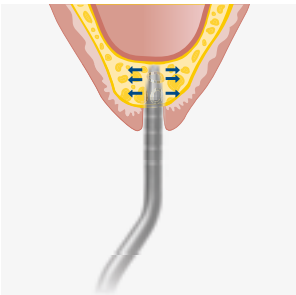
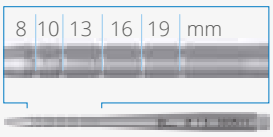


Abb. 37: Bone Condensing

Fig. 38: Twister osteotome handle for interchangeable inserts



Osteotome insert, straight, ø 3.5 mm, convex

Osteotome insert, straight, ø 4.2 mm, convex

Osteotome insert, straight, ø 5.0 mm, convex

Osteotome insert, straight, ø 6.0 mm, convex

Osteotome insert, angulated, ø 3.5 mm, convex

Osteotome insert, angulated, ø 4.2 mm, convex

Osteotome insert, angulated, ø 5.0 mm, convex

Osteotome insert, angulated, ø 6.0 mm, convex

Abb. 39: Osteotome overview

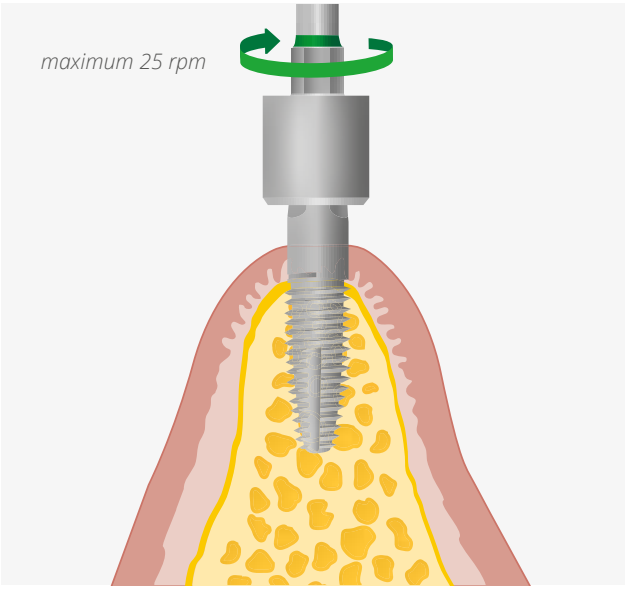


Fig. 40: Placement of FairOne™ using the insertion tool friction

Placement

The insertion tools have a contra-angle coupling. Implants can be inserted using a contra angle with a torque of up to 40 Ncm and FairImplants™ special hex with a maximum speed of 25 rpm. The ratchet adapter with FairImplants™ hex should be used for transmitting higher torques.

Here the torque is transmitted via a hex (Fig. 40). Contra angle transmission at a higher torque can result in damage to the instrument or contra-angle (bending, twisting, distortion).

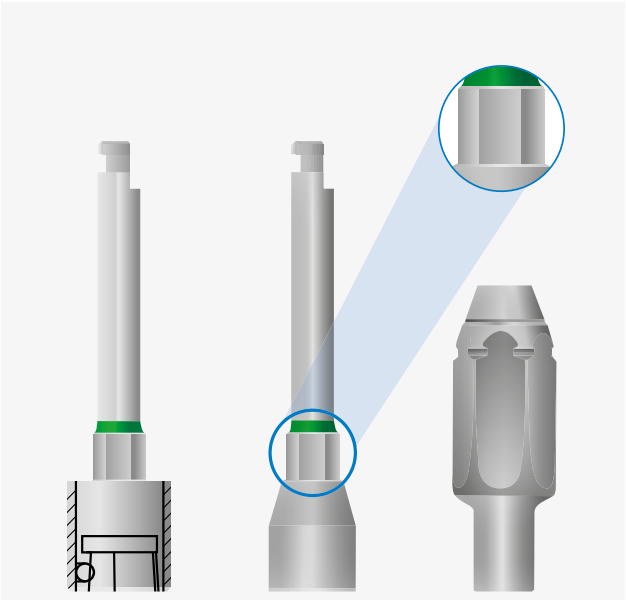


Fig. 41: From left to right insertion tool friction, insertion tool and ratchet adapter

Placement FairOne™

Two insertion tools are available for placement of the implant.

The insertion tool friction should be used as a standard instrument.

The friction-free, narrower insertion tool should be used as an alternative where only limited space is available. Alternatively, placement can be performed using the ratchet adapter and ratchet.

The prosthetic head of the ø 6.0 mm implant corresponds to the head of the ø 5.0 mm implant. Accordingly, the ø 5.0 mm implant insertion tools are used.

The aim should be to apply a minimum torque of 40 Ncm to ensure the necessary primary stability.

FairOne™ can be inserted with the ratchet using a torque of up to 70 Ncm.

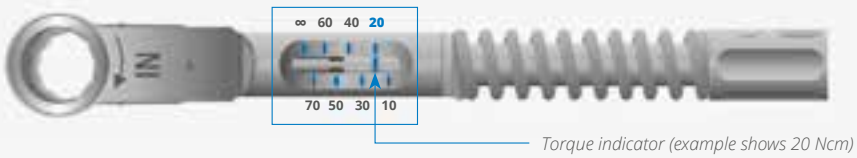


Fig. 42: Torque ratchet

PLEASE NOTE: *The implant should be inserted into the prepared bone site using an insertion tool. If the distances to the adjacent teeth allow, the insertion tool friction should be used. Non-friction instruments risk that the implant is not held securely in position and falls out. This type of instrument also wears out faster.*

The implant must not come into contact with unsterile surfaces during this procedure.

Contamination with saliva must be avoided.

Blood should be left in the implant site before implantation. A surgical ejector should not be used around the implant site during this phase.

The implant is then inserted into the drilled site and rotated until it reaches the required length. When placed to the drilling length, the thread starts 0.5 mm beneath the bony edge.

This can vary depending on the anatomical structure and planned placement (see Fig. Page 2).

Following placement of a FairOne™ implant, it can be splinted temporarily to protect it against loading during the healing phase. Contact with the opposing dentition must be avoided.

Fig. 43: FairOne™ placement, initial wetting of the hydrophilic surface

If the final depth is not reached with the maximum torque, the implant should be unwound.

The implant should be replaced in the sterile primary packaging during the intervening period. The implant site must then be extended.

With minimally invasive procedures the gingiva should tightly surround the implant after successful implantation. If this is not the case, the mucosa should be adapted to the implant using a suture.

Fig. 44: Placement using the insertion tool

Fig. 45: Implant following placement

Fig. 46: Finally, a vertical mattress suture

Alignment of FairTwo™

After placement, ensure that every implant is aligned correctly. The guide edge (marked green in the illustrations) of the insertion instruments indicates the direction, which is relevant for angled abutments. Generally, the guide edge should be aligned buccally, to compensate optimally for any adjustment of the axis.

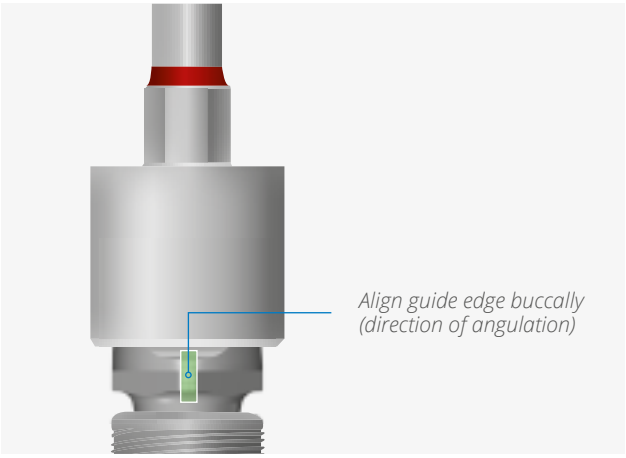


*Fig. 47: Insertion tool friction and FairTwo™ Plus with **insertion abutment** and guide edge*

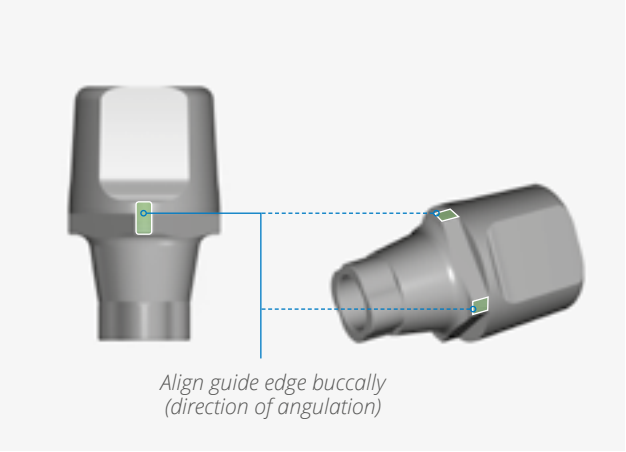


*Fig. 48: Alignment of **insertion abutment***

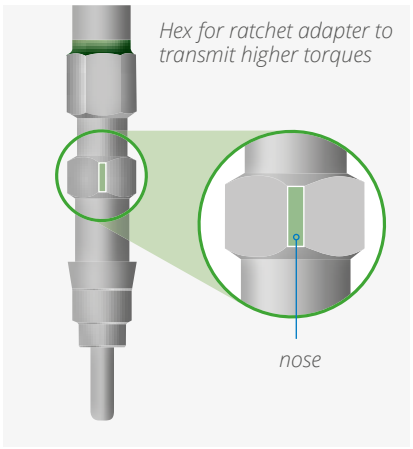


Fig. 49: Alignment with the FairTwo™ insertion tool buccally on the square

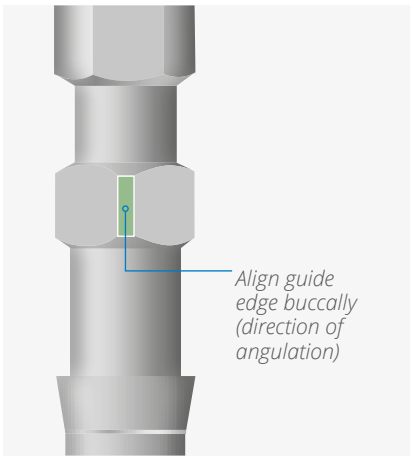


Fig. 50: Alignment of insertion FT

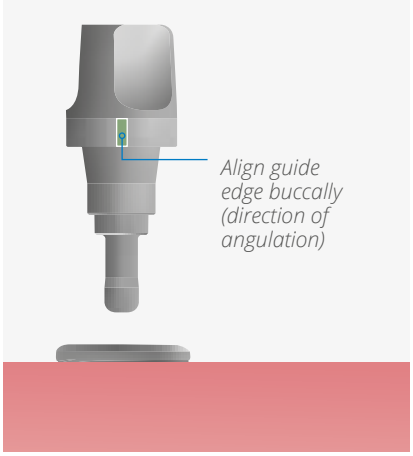


*Fig. 51: Alignment of **insertion adapter***

Placement FairTwo™

I. Insertion tool

FairTwo™ implants can always be removed and inserted using the insertion FT (S or L). Neither an insertion abutment nor an adapter is included with implants with a date of manufacture prior to 10/2012.

If present, the insertion aid should be removed when taking the implant from the primary packaging. The insertion FT should be fully inserted in the longitudinal direction of the implant. **The insertion tool FT is fully inserted if the exposed edge of the insertion FT is flush with the implant shoulder.** a.

If the insertion FT is not fully (flush) inserted, a) the implant may fall out or, b) the implant and insertion FT may be damaged during placement b.

The implant can be placed using a contra angle or manually. After reaching the planned placement length, the implant should be aligned. The guide edges of the square indicate the direction of the angled abutment. It is recommended to align the guide edges buccally (Fig. 52a and Fig. 58). The insertion FT should then be removed by pulling in the longitudinal direction of the implant.

After removal of the adapter, the cover screw should be inserted into the implant with a maximum of 5 Ncm using a screwdriver. Finish by placing the sutures.

Damaged instruments must be immediately replaced by new ones.

PLEASE NOTE: *The instrument and/or implant may be damaged with high torques exceeding approx. 45 Ncm and insertion outside the axis slot to the implant.*

Visual check

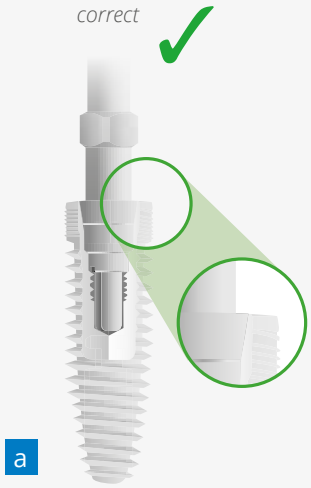


Fig. 52a: The insertion FT is correctly positioned if the exposed edge is flush with the implant shoulder.

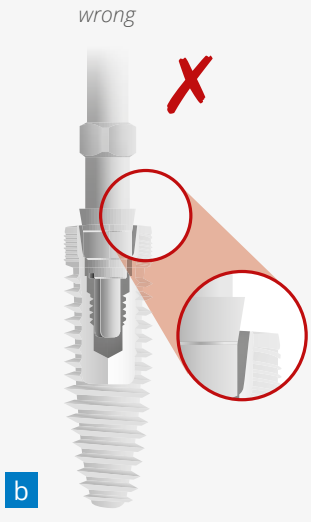


Fig. 52b: If the insertion FT is not fully (flush) inserted, a) the implant may fall out or, b) the implant and insertion FT may be damaged during placement.

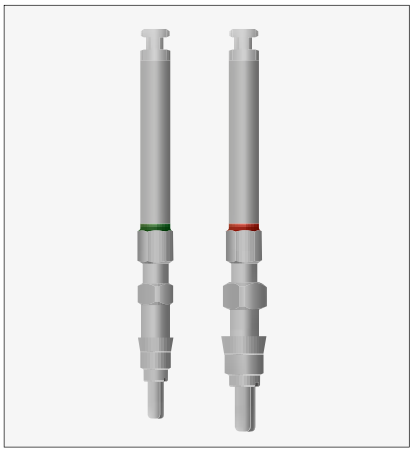


Fig. 53: FairTwo™ insertion FT S+L

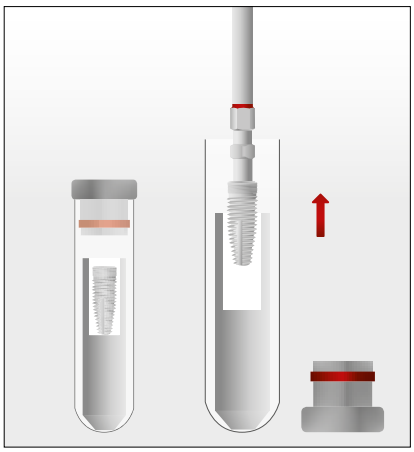


Fig. 54: Removal from the primary packaging

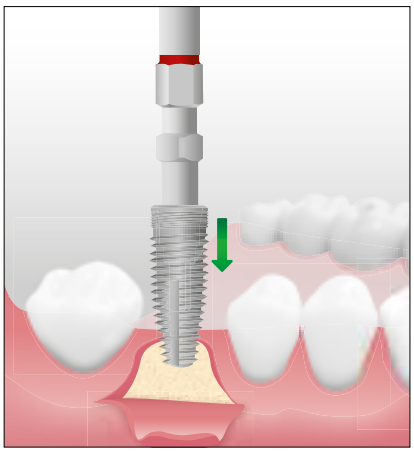


Fig. 55: Placing the implant

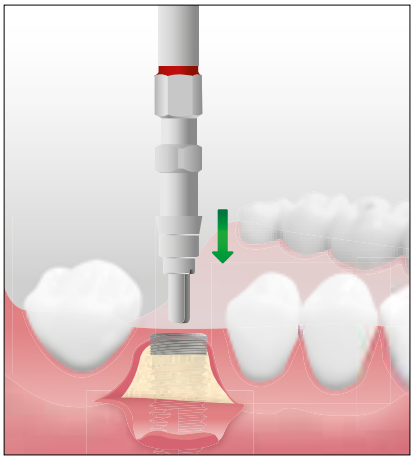


Fig. 56: Inserting the insertion tool

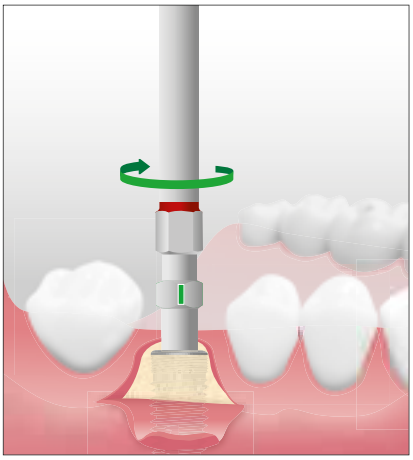


Fig. 57: Placement to the planned length

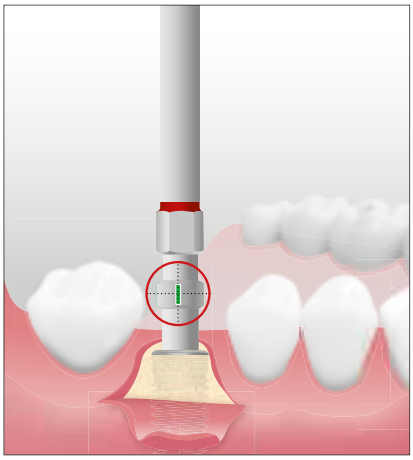


Fig. 58: Buccal alignment of the guide edge

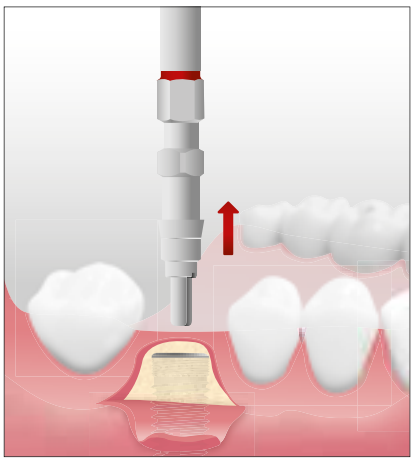


Fig. 59: Removing the insertion tool

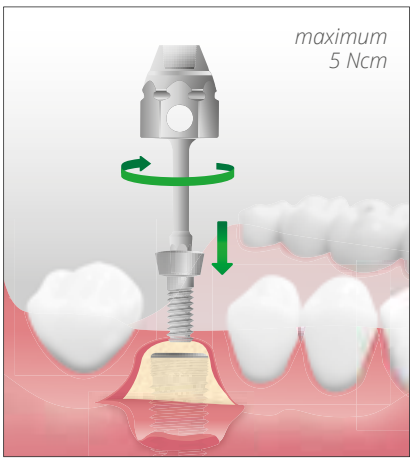


Fig. 60: Fitting the cover screw

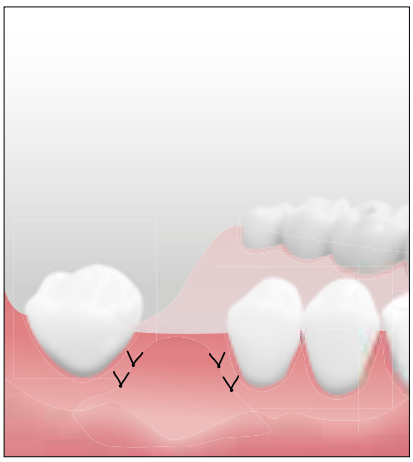


Fig. 61: Suturing

II. Insertion abutment

FairTwo™ Plus contains a pre-assembled insertion abutment.

The implant should be removed in the same way as with FairOne™ using the insertion tool friction (Fig. 71). The implant should be inserted using a contra angle or manually using the ratchet and ratchet adapter.

The implant should be aligned after reaching the planned placement length (Fig. 65). The insertion tool is removed after placement. For a temporary restoration the insertion abutment can remain in position.

Submerged healing is an alternative method. The abutment screw is unscrewed using the FairTwo™ screwdriver and the abutment removed (Fig. 66).

Should the insertion abutment seize, it can be removed using the take out insertion adapter (Fig. 66; see Page 37). Removal using the Take Out Tool is safest with regard to stress on the bone. To do this, first the abutment screw should be unscrewed from the inner locking thread by turning it anti-clockwise using a Fair Two™ screwdriver. A counter nut is available for secure fixation of the implant.

The abutment should then be removed using the take out tool.

The cover screw should be screwed into the implant with a maximum of 5 Ncm using a FairTwo™ screwdriver. Finish by placing the sutures.

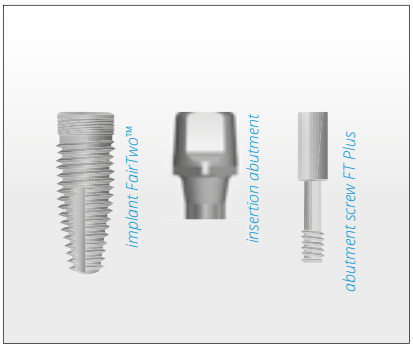


Fig. 62: FairTwo™ Plus dismantled

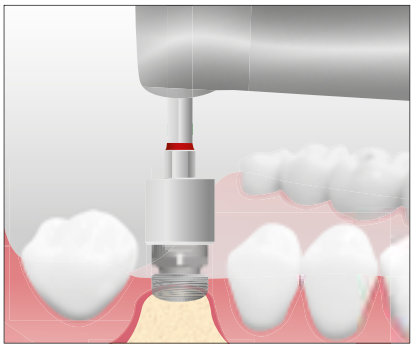


Fig. 63: Contra angle placement

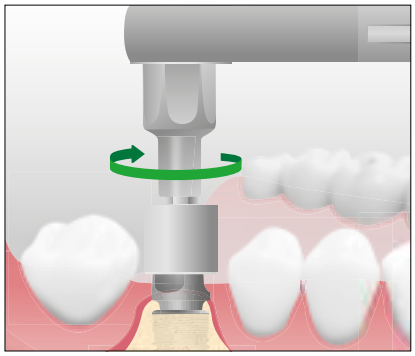


Fig. 64: Placement using the ratchet

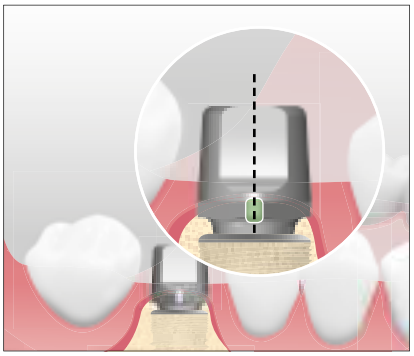


Fig. 65: Aligning the implant

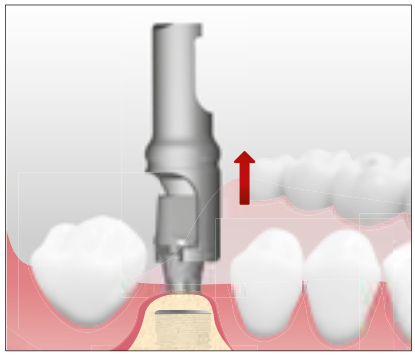


Fig. 66: Removing the abutment

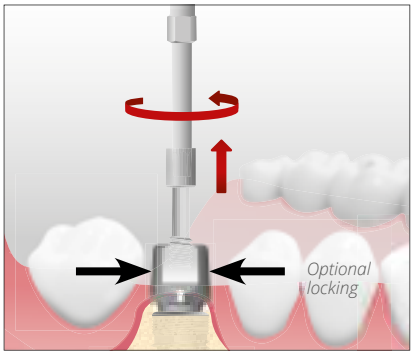


Fig. 67: Taking out the insertion adapter

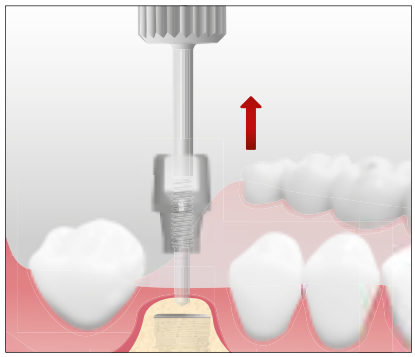


Fig. 68: Removing the insertion abutment

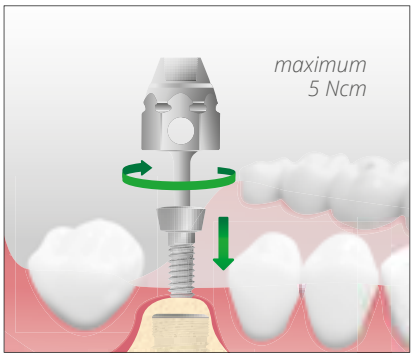


Fig. 69: Fitting the cover screw

Take out tool

1 The abutment screw must first be unscrewed from the abutment to use the take out tool.

2 The screw should then be removed from the inner thread of the abutment (Fig. 70). To remove the screw the screwdriver should be gripped in the socket of the screw using light pressure. The screw should be unscrewed anti-clockwise from the thread while using a slight pulling motion.

3 The take out tool can now be
4 screwed into the abutment until the take out tool comes into contact with the base and the abutment loosens automatically from the conical section.

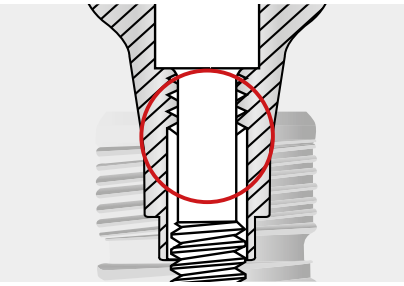


Fig. 70: Inner thread in the abutment, screw and screw channel

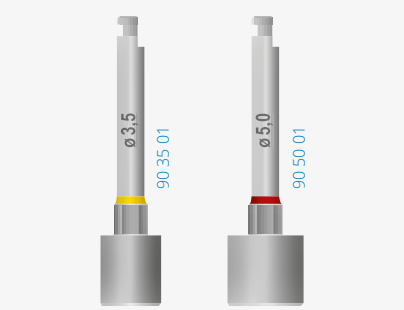


Fig. 71: Insertion tool friction
ø 3.5 mm for platform S (left) and ø 5.0 mm for platform L (right)

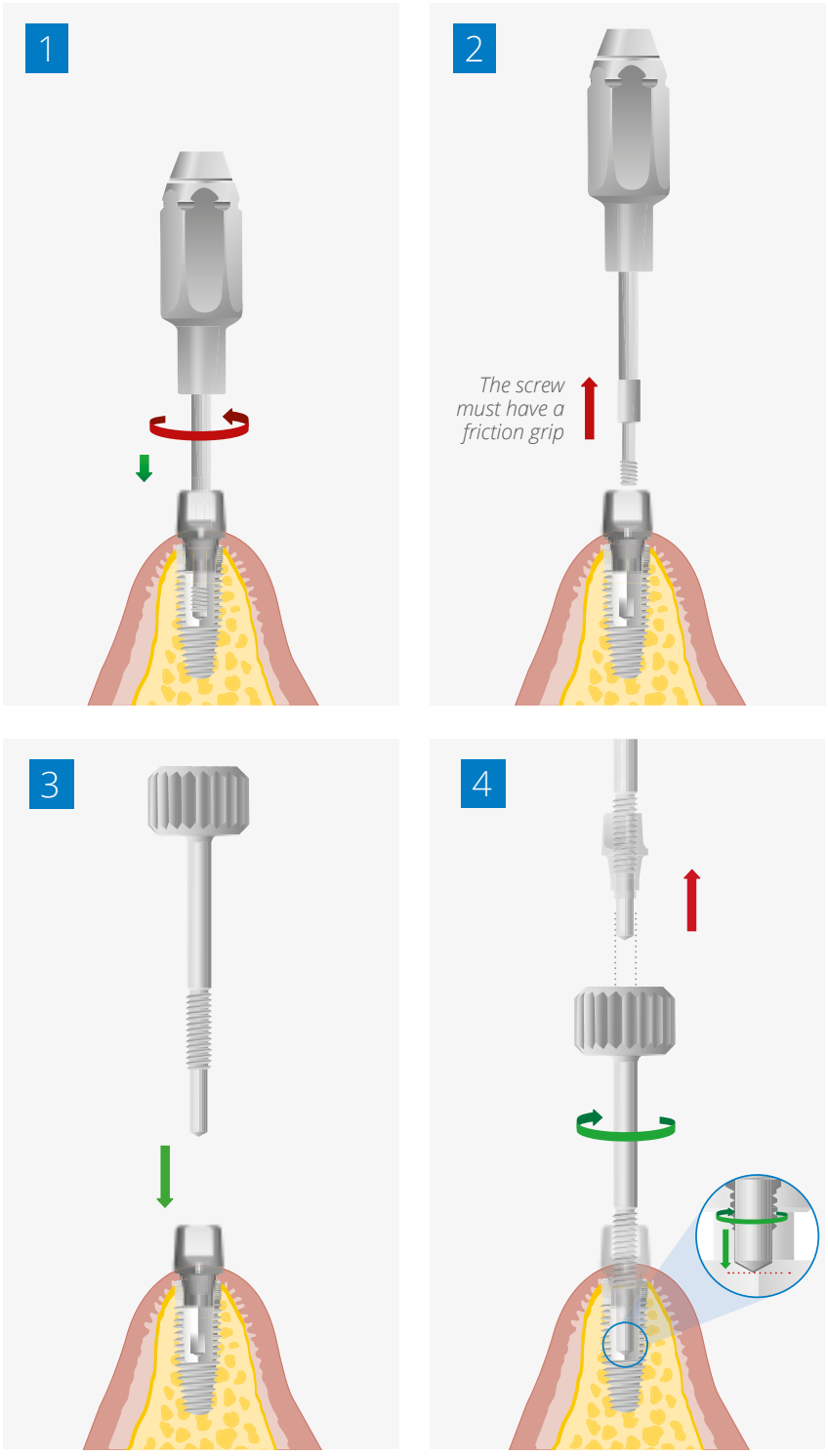


Fig. 72: Sequence for loosening a fixed abutment;
1. Loosen the screw;
2. Grip the screw using friction and unwind it from the inner thread of the abutment;
3. and 4. Wind in the take out tool

Fig. 73: FairTwo™ with insertion adapter

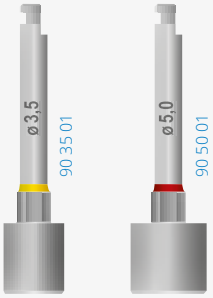


Fig. 74: Insertion tool friction ø 3.5 mm for platform S (left) and ø 5.0 mm for platform L (right)

III. Insertion adapter

(Date of manufacture: 10/2012 to 12/2014)

Removing the implant using the insertion adapter is completed in the same way as when removing FairOne™ using the insertion tool FairOne™ ø 3.5 mm for S and ø 5.0 mm for L.

The adapter has a square, which sits directly on the implant shoulder. The edge/lug indicates the direction of the angled abutment in case angulation is necessary. Generally, the edge/lug is aligned buccally.

Contra angle or manual placement up to a maximum of 25 Ncm is recommended. The adapter seizes relatively tightly when higher torques are applied. With border-line indications or when 25 Ncm is exceeded it is recommended to remove the adapter and continue placement using the insertion tool FairTwo™ with contra-angle adapter (see Page 32).

If the adapter seizes, it must be unscrewed anti-clockwise to release it. The adapter can then be easily removed using the take out tool (see right). Alternatively, the adapter can be removed axially using a pair of pliers, e.g. Luer pliers.

After removal of the adapter, the cover screw should be inserted in the implant with a maximum of 5 Ncm using a FairTwo™ screwdriver. Finish by placing the sutures.

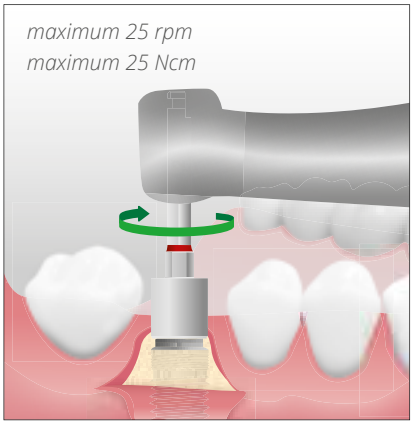


Fig. 75: Contra angle placement

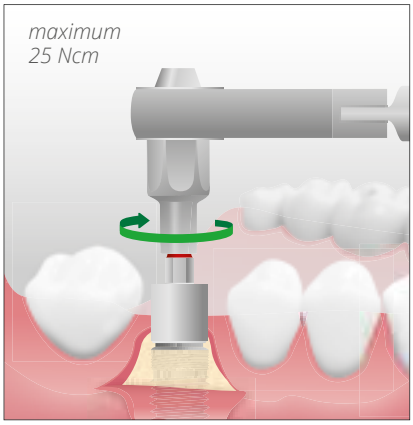


Fig. 76: Placement using the ratchet

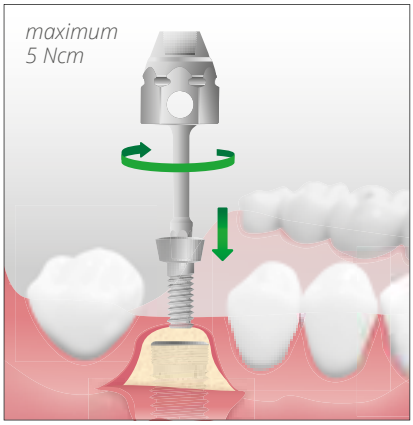


Fig. 77: Fitting the cover screw

Take out insertion adapter

The lever ends of the take out insertion adapter fit exactly on the implant shoulder between the lugs of the adapter/insertion abutment, which indicate the direction of angulation. The take out tool should then be tipped. The take out insertion adapter should be blocked with the thumb at implant shoulder level and tipped at the other end. The end pushes away on the implant shoulder, without transferring any force to the bone. Once the adapter has loosened, it can be easily removed axially.

The take out insertion adapter cannot function with subcrestal or very tightly placed adapters. In this case the adapter must be removed in time to allow implant placement using the insertion FT.

In the case of unfavourable bone conditions with little stability it is recommended to remove the adapter before placement and use the FairTwo™ insertion tool.

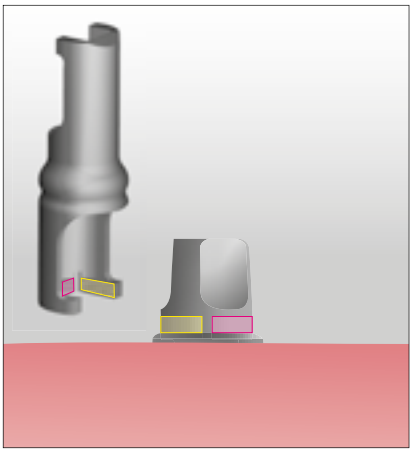


Fig. 78: Alignment of the take out insertion adapter

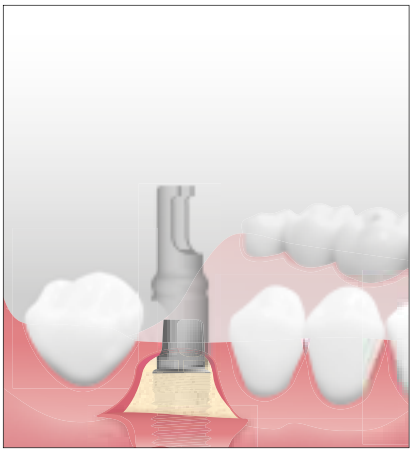


Fig. 79: Fit the take out insertion adapter

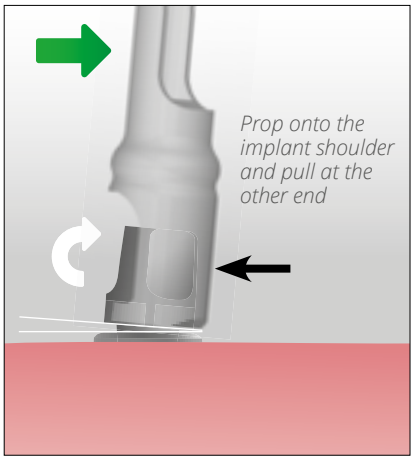


Fig. 80: Tipping the take out insertion adapter

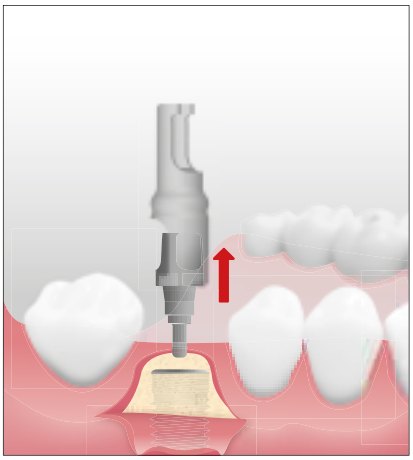


Fig. 81: Removing axially

Fig. 82: Alternative removal technique using Luer pliers

Fig. 83: Insertion adapter in use

Fig. 84: Insertion adapter after removal

Example of FairOne™ temporary restoration

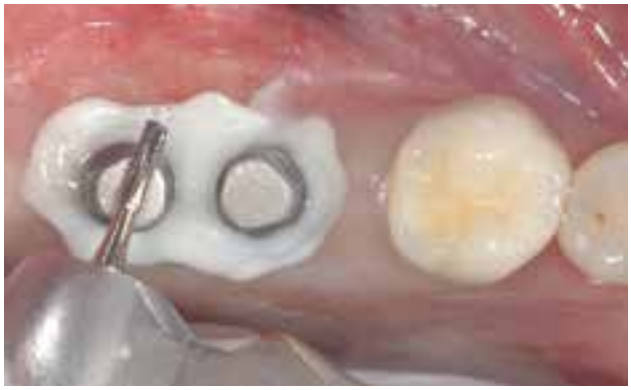


Fig. 85: Preparation immediately postoperatively for temporary restoration/height reduction with gingival protection using a liquid rubber dam

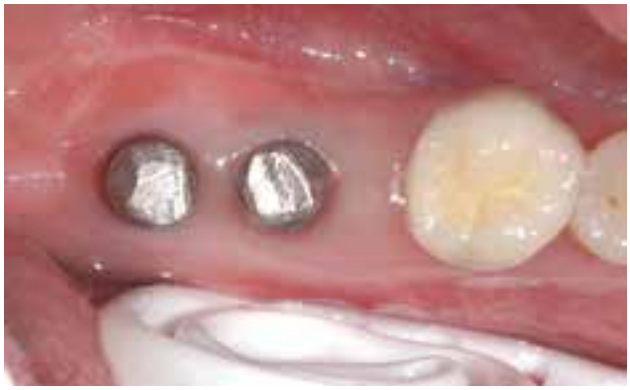


Fig. 86: Final preparation for the temporary restoration

Fig. 87: Fitting the temporary restoration

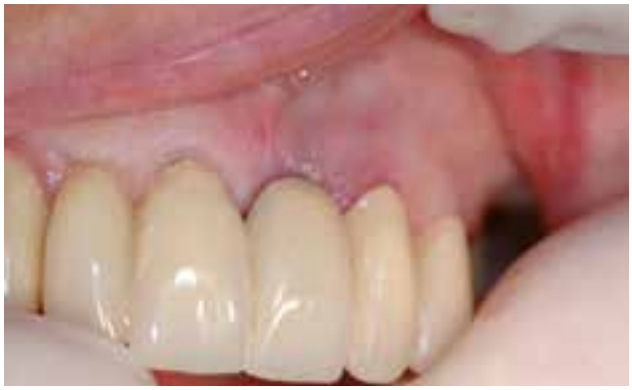


Fig. 88: Fitting the temporary restoration

Immediate restoration and immediate loading

The FairOne™ implant is a one-piece implant and therefore suitable for immediate restoration. In principle, the following explanations also apply for FairTwo™ Plus with insertion abutment and restoration with the one-piece abutment.

Immediate restoration is defined as meaning immediate prosthetic restoration of the implant. The temporary restoration should be designed so that the implant remains non-loaded in occlusion and articulation.

Immediate loading is defined as the immediate intraoperative or early occlusal, articulated and functional loading of a placed implant. This can be achieved by a temporary or definitive restoration.

PLEASE NOTE: *Important! Immediate loading should be avoided for FairOne™, if possible. Prerequisite for immediate loading is an adequate relationship of number, dimension and primary stability of the placed implants to the anticipated functional loading.*

The temporary restoration should be completed according to the principles of an immediate restoration. The contacts should therefore be reduced accordingly, so that 40 micrometer thick articulation foils remain out of contact. An immediate restoration is primarily used for temporary aesthetic rehabilitation.

Immediate preparation

If preparation of the implant head is required immediately after implant placement, it is essential to protect the operating site against metal chips entering.

This can either be achieved using the rubber dam technique or composites used, for example, in the bleaching technique for gingival protection. When using a rubber dam it is recommended to use clasp No. 212. This can be supported and secured in the region of the adjacent teeth using registration silicone, if required.

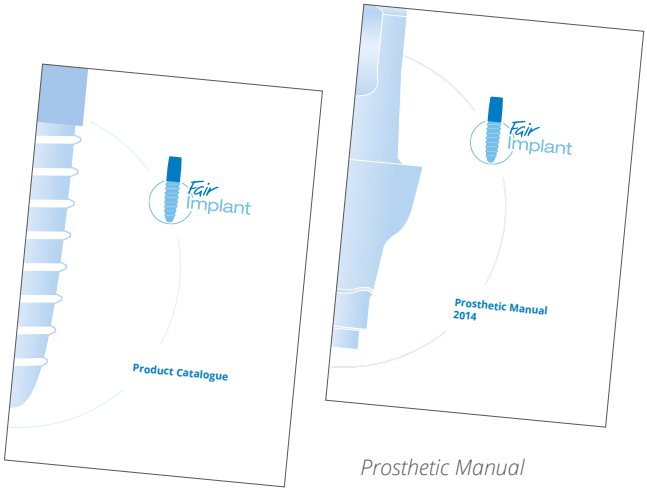
The use of composites for gingival protection is mainly recommended with minimally invasive procedures, as bonding with existing sutures can be avoided.

Intraoperative preparation should be reduced to the extent required for a temporary restoration.

The final shape of the preparation, particularly in the margin region, should only be determined after the healing phase is complete.

The temporary restoration should also be left out of contact in the marginal area.

Further information regarding prosthetic restoration can be found in the prosthetic manual.



Product catalogue *Prosthetic Manual*

Instrument preparation

The drills are supplied non-sterile. The drills must therefore be cleaned, disinfected and sterilised before initial use.

The drills should be placed in disinfectant solutions immediately after surgery. Do not allow surgical residue (blood, secretions, tissue residue) to dry.

The drills should be disinfected and cleaned with disinfecting and cleaning agents for rotary instruments (e. g. Alpro BIB forte). The instructions for use (e. g. reaction time, concentration, suitability) can be found in the manufacturer's instructions for these agents. Cleaning brushes with metal-free bristles should be used for pre-cleaning to ensure that the instruments are not damaged.

Rinse off the disinfecting and cleaning agent very thoroughly with water and carefully dry the instruments (e.g. using a jet of air). Never leave or store the instruments moist / wet.

The instruments may not come into contact when cleaning in an ultrasonic cleaner!

The cleaned instruments should be visually checked. Damaged or blunt instruments should be sorted out and no longer used. The same applies for instruments that have been overloaded. These instruments must be no longer used, as there is an increased risk of fracture!

The ratchet should be dismantled, cleaned, sterilised and lubricated according to instructions.

Instruments should be sterilised in an autoclave (134°C) in accordance with the usual procedures (www.rki.de). The instructions of the respective manufacturer must be followed.

The instruments should be checked for superficial damage (cracking) after sterilisation. Damaged instruments must no longer be used, as there is an increased risk of fracture!

Disclaimer

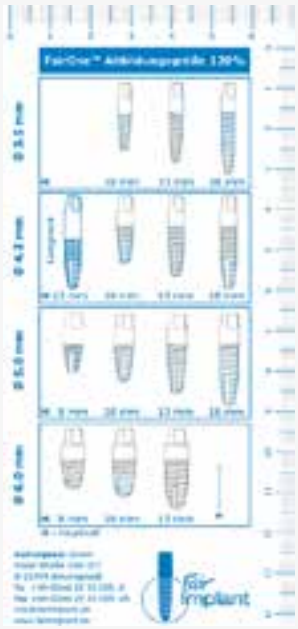
The respective valid package leaflets for using FairImplant™ products such as instructions for use, manuals and individual information apply.

The operating dentist is solely responsible for ensuring the correct indication when using FairImplant™ products. The manual provides a description of the handling of the product. Assessment of the individual case by the dentist is, however, essential and is not replaced by this manual.

For this reason FairImplant™ expressly disclaims any liability for any defects and damages, which are caused by errors in application, incorrect placement or improper handling of FairImplant™ products.

FairImplant™ system radiographic stent

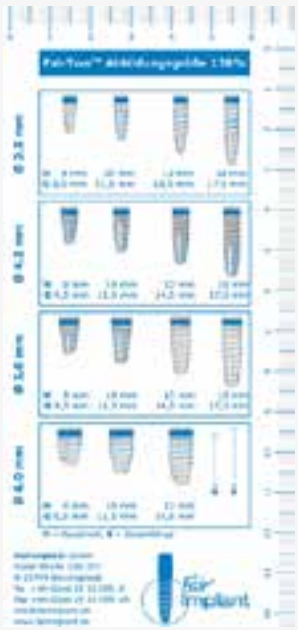
100 %



130 %

Fig. 89: Radiographic stent for FairOne™

100 %



130 %

Fig. 90: Radiographic stent for FairTwo™

Explanation of blister / implant packaging

The implants are packaged in the outer protective box. This contains the sterile secondary packaging (blister), patient labels and instructions for use.

The sealed secondary packaging should not be damaged and must only be opened shortly before implant placement. It contains the primary packaging with the implant in a protective titanium sleeve.

Any contamination of the implant must be avoided.

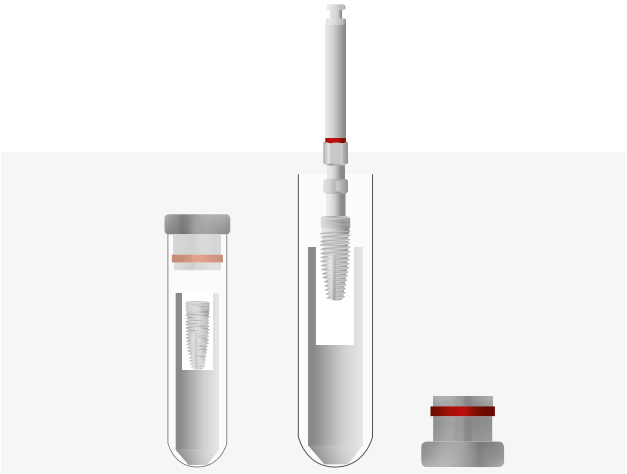


Fig. 91: Primary packaging implant with protective titanium sleeve, plastic tube and plug.

Fig. 92: Front of the outer protective box

Fig. 93: Outer protective box from 01/2015 with inspection window

Fig. 94: Front of the implant blister packaging with indicator

Fig. 95: Back of the implant blister packaging

Special features FairTwo™

till 10/2012

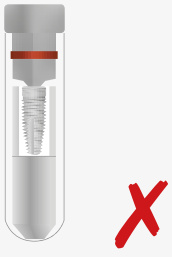


Fig. 96: FairTwo™ without insertion aid

from 11/2012

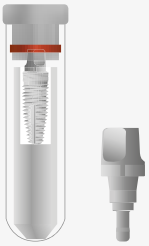


Fig. 97: FairTwo™ with insertion adapter

from 01/2015

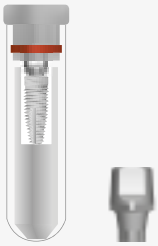


Fig. 98: FT-Plus with insertion abutment

Explanation of pictograms

Implantology

Date of Exp.

Attention! Included note documents

Attention: Federal law (USA) restricts this product to sale by or on order of a physician .

Date of manufacture

Sterilization by irradiation

Article number

Do not use if package is damaged

packaging unit

LOT-number

not for reuse (only for single use)

max. rounds per minute

Packaging and sterility

The intact packaging protects the implant against exterior influences and guarantees sterility during storage. Sterility is no longer guaranteed if the packaging has been opened or damaged beforehand and, in this case, the implants may no longer be used.

PLEASE NOTE: *Damaged packaging cannot be returned.*

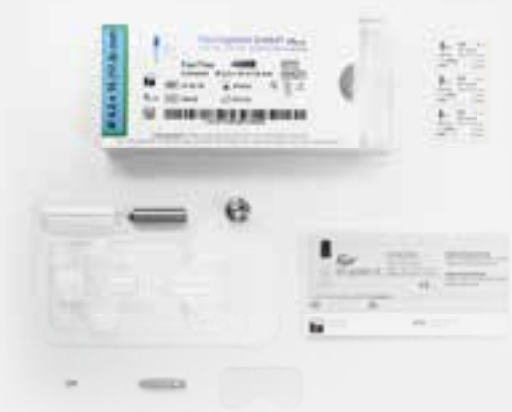


Fig. 99: Contents of a FairTwo™ implant

Handling of the sterile packaging

The relevant rules of asepsis should be observed when removing the implant from the packaging.

Non-sterile = Illustrations with green gloves

Sterile = Illustrations with yellow gloves

1. Non-sterile assistant checks the size of the implant and packaging.

2. Non-sterile assistant opens the box at the perforation.

*3. Non-sterile assistant removes the blister pack. The coloured point is the sterilisation indicator, which must be **red**.*

4. Non-sterile assistant opens the outer protective box and removes the blister pack (sterile secondary packaging).

5. Non-sterile assistant opens the vacuum-formed blister pack without contaminating the secondary packaging (plastic tube) inside.

6. Non-sterile assistant passes the implant to the operator. The implant is removed from the plastic tube.

7. The plastic tube is opened and the plug removed (sterile primary packaging).

8a. The implant is removed using the contra-angle and FairOne™ insertion tool.

8b. The implant can now be placed.

9a. The ratchet adapter is fitted to the insertion tool.

9b. The implant is removed using the ratchet adapter and insertion tool.

10. The implant is removed using the ratchet, ratchet adapter and FairTwo™ insertion tool.

11a. The plastic cover is removed. Non-sterile assistant slides the FairTwo™ cover screw onto a sterile surface.

11b. The cover screw is picked up using the FairTwo™ screwdriver.

11c. Cover screw integrated into the plug in preparation for the next packaging validation (replaces Figure 11a and 11b).

General patient instructions

Placing an implant, particularly using single-stage operating procedures such as FairOne™, places special demands on the cooperation and compliance of the patient. This is because the implant protrudes into the oral cavity directly after implantation and an immediate restoration is necessary or desired, especially in the aesthetic zone, but also for reasons of masticatory function. It is, therefore, important to ensure that patients are provided with an explanation and instructions.

Preoperative codes of conduct

Professional tooth cleaning is recommended a few days prior to implant placement. Disinfectant mouth-washes should be used for reducing bacterial exposure. Any further premedication required is the responsibility of the operator.

In order to prepare themselves accordingly, patients should be informed of the important aspects mentioned on the next page.

Postoperative codes of conduct

It is essential that the patient is informed of the following postoperative codes of conduct during the healing phase and after healing. These should be strictly adhered to.

During the healing phase

- The patient must abstain from nicotine and alcohol on the day of the operation and two days thereafter.
- Physical exertions should be avoided.
- The patient should only eat or drink after the local anaesthetic wears off.
- Only liquids and soft food should be eaten in the first days after implant placement.
- The patient should not chew near the implant.
- Scrupulous oral hygiene must be ensured in all other areas of the oral cavity.
- The special significance of the first 4-8 weeks postoperatively for osseointegration should be explained to the patient and he should be asked to adapt his eating and lifestyle habits accordingly.
- External cooling in cycles of 20 minutes cooling and non-cooling is recommended to avoid postoperative swelling.

After healing

The same general aftercare criteria as with a natural tooth apply after healing and definitive prosthetic restoration of the one-piece FairOne™ implant. This also applies for oral hygiene instructions.

Particular reference should be made to the importance of regular professional tooth cleaning.

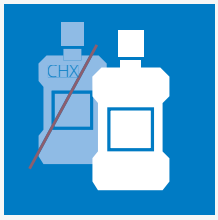
Fig. 100: Patient pass – implant ID card

Fig. 101: Three stickers with the LOT No. are included in every implant package

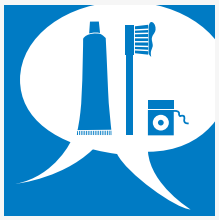
In general, aftercare depends on the invasiveness and outcome of surgery.

1. 

Patient instructions: See Page 46

2. 

Germ-reducing mouthwashes are a practical measure; preparations containing chlorhexidine should be avoided in the first 24 hours postoperatively.

3. 

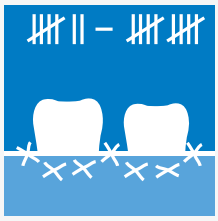
Hygiene instructions in the implant region should be individually adapted depending on the invasiveness of surgery.

4. 

Check-ups should be individually agreed. These are recommended after one, four, six, eight weeks and monthly thereafter.

5. 

Postoperative medication (analgetics, antibiotic treatment, anti-inflammatories) should be individually determined by the operator.

6. 

De-suturing is recommended seven to ten days postoperatively.

The type, length, diameter and LOT number of the implants in relation to the patient should be recorded stating the region in which the implants were placed.

This is best achieved with the stickers supplied in the packaging.

A total of three stickers are available. Use these for documentation in the patient's implant ID card (see Fig. 101).

Acknowledgement:

At this point we would like to thank our clients for the many constructive suggestions for further development of our system. We can only improve with your contributions.

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Quality made in Germany

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