



Vistafix™ Treatment Guide

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Acknowledgement

The protocols detailed in this manual originate from the clinical work carried out since 1978 by Prof. Anders Tjellström and Dr. Kerstin Bergström at the Implant Unit, Department of Otolaryngology, Sahlgrenska University Hospital, Gothenburg, Sweden.

Instrument and component preparation

This publication sets forth detailed recommended procedures for using Vistafix™ surgical components and instruments. It offers guidance needed for performing the procedure but as with any technical guide, the surgeon must consider the particular needs of each patient and make appropriate adjustments if and when required.

Note: The words fixture and implant are interchangeable and are used accordingly throughout this manual.

Introduction

The Vistafix™ system builds on the technology of the Brånemark system® providing a means of offering permanent and secure retention and secure support for facial prostheses. This system incorporates “osseointegration”, a term coined by Professor Per-Ingvar Brånemark, MD., PhD. when he discovered the ability of living bone to integrate with titanium.

Since 1977 osseointegrated implants have provided successful reconstructive treatments for more than a million patients (Vistafix patients/edentulous patients/partially edentulous patients/bone anchored sound processor patients).

The long-term predictability and success of such treatment is based on the fact that an active bond between bone and implant is created. The implant is not only accepted but also incorporated into the vital differentiated bone, which, through remodelling, gradually adapts to its new function.

For more information see references 1, 2 and 3 in the “References” section.

In order to create and maintain the appropriate structural and functional relationship between the biological and non-biological components, the various stages of treatment must be carried out with precision. The following points are vital for achieving successful results:

1. The anchoring components should be made of an inert material and with such geometrical shape and dimension that an appropriate mechanical system can be attached to them.
2. The implant surfaces should have an adequate microarchitecture and not be contaminated during surgical placement, ensuring that an optimum interface surface is established during implant installation.
3. The implant site should be prepared with care and the implant installed in such a way that the capacity of the osseous tissues to form new bone is maintained.
4. The skin-penetration of the abutment is accomplished in such a way that relative skin movements are reduced.
5. The preparation of the skin-penetrating area should be carried out in such a way as to allow the skin to adhere to the underlying periosteum.

Note: In order to obtain optimal results, surgeons, prosthodontists, anaplastologists and technicians should work in close collaboration. This collaboration should continue during the follow-up period.

For a successful result, it is necessary that the correct methodology, appropriate instrumentation and an interdisciplinary approach is used.

**General information and news is also available at:
www.vistafix.cochlear.com**

Patient selection – preliminary examination

External ear

A thorough examination of the defect tissue bed should be performed and aetiology of the defect should be determined; congenital, trauma or tumour surgery. However, the possibility of reconstructing an external ear using plastic surgical procedures should be discussed with the patient. If the patient wishes to pursue osseointegrated implants, the sequence of therapy and the possible morbidities should be carefully outlined. Sketches, photographs, models and computer-manipulated photos are useful in this respect.

In order to achieve the best result, auricular remnants are often removed. It is, however, important that the patient makes this decision and is aware that this removal is irreversible. For patients with auricular defects secondary to trauma, plastic surgical reconstruction is likewise considered. The method of choice (between osseointegrated implants and a prosthesis or surgical reconstruction) is again dependent upon the nature of the residual ear remnants and the patient's expectations. Furthermore, the patient can always opt to not have any treatment at all.

Multidisciplinary co-operation is always essential if optimal results are to be achieved, this is especially true for patients undergoing auriclectomy secondary to malignant tumours. For example, a presurgical impression of the ear to be removed could facilitate future prosthetic procedures. In addition, specific surgical issues such as retention of the tragus, lining the tissue bed with a hairless, split thickness skin graft etc, should be discussed. For tumour removal surgery, implants may be inserted and the skin-penetrating abutments connected at the time of tumour removal surgery in order to shorten the rehabilitation time. The expected life span of the patient and the psychosocial implications of rehabilitation also need to be considered during treatment planning.

Orbit and midface defects

The nature of the orbital defect and the morphology of the residual bone elements of the orbital rim need careful evaluation prior to implant placement. In addition, the prospective contours of the future orbital prosthesis should be anticipated so as to avoid the placement of implants in locations and directions which may adversely affect the aesthetic contours.

The same principles should guide clinicians regarding implant placement in patients with nasal defects—namely, the needs of stability, support and retention while avoiding implant placement which would adversely affect the aesthetic contours of the nasal prosthesis.

Note: In the orbit and midface area a two-stage procedure is recommended both in irradiated and non-irradiated patients.

Osseointegrated implants in irradiated tissue

For patients who have been irradiated, a two-stage procedure with a 4–6 month interval between implant placement and abutment connection is recommended. If possible, adjuvant therapy with hyperbaric oxygen, HBO, is used. Patients will be treated preoperatively with one 90 minute dive to 2.5 ATA per day for 20 days. On day 21 the implant operation is performed and, starting on day 22, the patient will have 10 more treatments in the hyperbaric chamber. This treatment is especially important for patients with orbit and midface defects. If a patient has already had an implant placed and is scheduled for irradiation around the implant area, the skin-penetrating abutments should be removed but the implants can be left in place under intact skin.

For more information see references 4, 5 and 6 and 7 in the “References” section.

Treatment planning

One-stage or two-stage procedure?

With the one-stage procedure, the implant, the abutment and the healing cap or the implant and the healing abutment are placed at the same time. After the osseointegration period (3–4 months) the making and fitting of the prosthesis can begin.

The two-stage procedure has a 4–6 months interval between implant placement and abutment connection. The longer time of six months for osseointegration should be used for paediatric patients, irradiated patients or other cases where the bone quality or clinical situation requires additional attention. One month after the abutment connection the work with the prosthesis can usually begin.

The one-stage procedure can replace the two-stage procedure for an auricular prosthesis in adult patients with non-irradiated tissue and when the patient agrees to be without the congenital remnants during the period of osseointegration. It should however be noted that, for any area other than the mastoid process, and in compromised tissue, a two-stage procedure is suggested.

Note: Regardless of a one or two-stage procedure the implant must not be loaded during the period of osseointegration.

One-stage procedure

- Auricular defects
- Adults
- Non-irradiated bone

Two-stage procedure

- Paediatrics
- Orbit and midface patients
- Auricular patients with poor bone quality
- Patients with irradiated bone
- Special Need Patients who may require covered implants during the osseointegration period (eg. Mental or physical compromised)

Treatment schedule

One-stage procedure

Implant and healing abutment/ abutment installation

Surgical follow-up	Time after surgery
Change dressing and remove stitches	1 week
Remove dressing	2–3 weeks
Osseointegration period	3 months
Cleaning of the implant area	Daily by patient
Check by treatment team	6 weeks

Making and fitting the prosthesis

Take impression of the defect area	3 months after surgery
Fabrication of the prosthesis	3–4 days

Note: As technology develops, new ways are being found to produce guides for surgery and planning for the prosthesis which can alter the timings of the making and fitting of the prosthesis.

Two-stage procedure

First stage: Implant installation

Surgical follow-up	Time after 1st surgery
Removal of stitches	1 week
Osseointegration period	4–6 months

Second stage: Abutment connection

Surgical follow-up	Time after 2nd surgery
Change dressing and remove stitches	1 week
Remove dressing and healing cap	2–3 weeks
Cleaning of the implant area	Daily by the patient
Post-surgery check by treatment team	6 weeks

Making and fitting the prosthesis

Take impression of the defect area	3–4 weeks after 2nd surgery
Fabrication of the prosthesis	3–4 days

Packaging and titanium components

Sterile packaging system

All titanium components, healing caps and disposable drills are supplied in sterile packaging to make the work at the clinic more simple and cost-effective.

The sterile packaging provides a better guarantee that the titanium components and disposable instruments are clean, sterile and free from contamination. The sensitive titanium surface structures are safeguarded and the instruments maintain their precision and sharpness.

Each peel-open package has the article name, article number, date and code of manufacture and expiry date printed on it. The batch numbers are for documentation and/or patient records.

Note: The peel-open package is sterile only if the package is intact.

The sterile packaging system consists of two types of packages, either a blister package or a plastic ampoule within a blister package (see fig. 1) A titanium pack sleeve is inside to hold the component.

Note: The blister package acts as the sterile barrier. The plastic ampoule is only a holder for the component.

If a blister package containing a titanium implant is damaged, the implant must not be used. In order to achieve successful osseointegration it is essential that the surface of the titanium implant is kept clean and free from contamination.

How to handle titanium components

The implant should **not** be in contact with anything (instrument, glove or patient tissue) in order to prevent the breakdown of the titanium oxide layer that is needed for osseointegration. Under normal circumstances, the plastic ampoule is placed in the hole in the Pick'n Place surgical organiser marked "Fixture", and then the pre-mounted implant is picked up from the plastic ampoule with the connection to handpiece. If the implant needs to be handled in any other way, this should be carried out in

the bowl for titanium components on the titanium tray, and with titanium forceps.

Other components such as drills, abutments and cover screws can be handled as any other sterile surgical component, i.e. by the gloved hand or with suitable instruments. It is important to make sure that sharp instruments do not scratch surfaces and threads, as this may reduce the performance of the component.

There is no need to keep titanium and stainless steel instruments apart as it is commonly known that there is no risk of contamination that could jeopardise the clinical result.

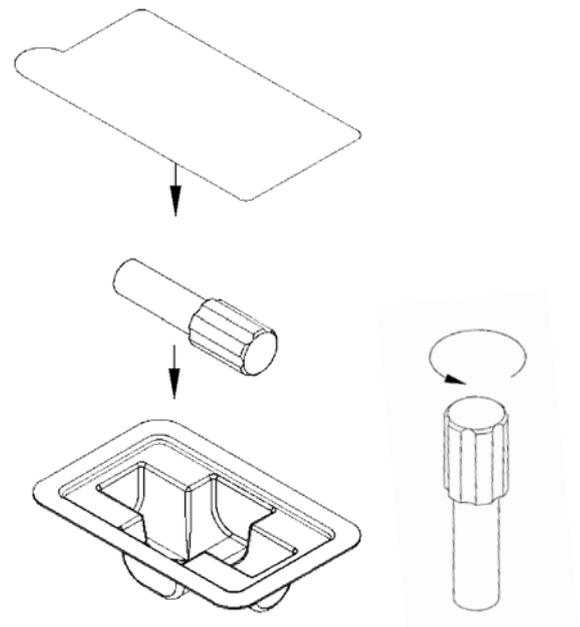


fig. 1

Component selection

Implant and abutment selection

Auricular prostheses

For an auricular prosthesis it is recommended to always keep components for a 3 mm implant insertion available during surgery in case bone thickness is less than expected.

The most common straight abutment lengths for auricular prostheses are 3 and 4 mm. A low profile on the anchoring system will always offer better possibilities for an aesthetic prosthesis, however it must still be possible to clean under the bar construction. For patients with special anatomy or very thick skin around the abutment (see section about tissue preparation on page 21) longer abutments may be necessary. When a one-stage surgical procedure is planned it is always recommended to have cover screws available during surgery in case bone quality is softer than anticipated and a two-stage procedure needs to be followed instead.

Orbital and mid-face prosthesis

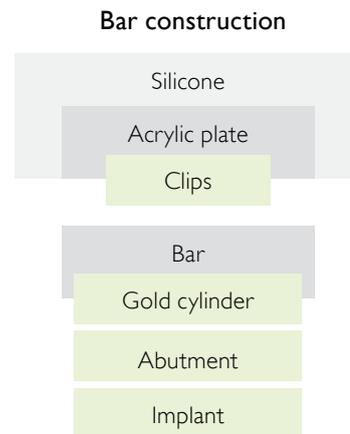
For orbital and mid-face prostheses a two-stage procedure is recommended. The selection of both implants and abutments is very dependent on the individual situation. The case should be carefully planned with anaplastologists and experienced clinicians. However, some general rules for component selection are highlighted below:

- Use a 4 mm implant when bone volume allows.
- Use flanged fixtures wherever possible.
- In irradiated or weak bone, place sleeper implants with cover screws.
- Avoid long cantilever forces.

Bar or Magnets?

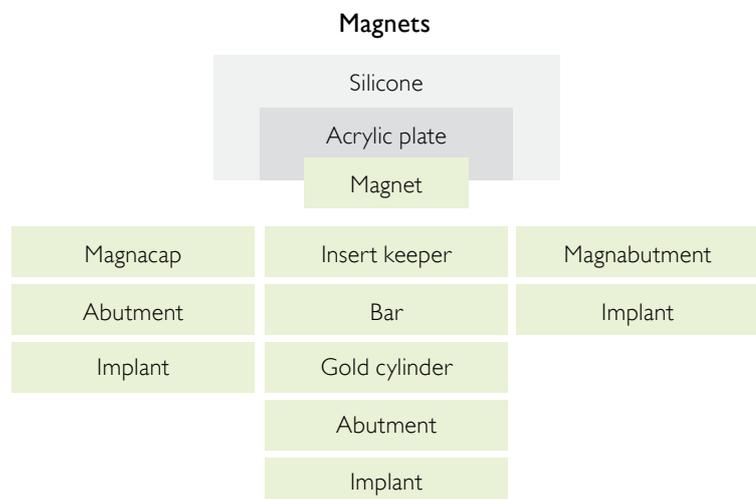
Bar construction

Where possible, a bar construction with clips is preferred due to the stronger retention force of the clips compared to the magnets. The bar construction does not include any ferromagnetic materials which makes it MRI compatible, whereas magnetic components need to be removed at MRI scanning. For most auricular prostheses it is possible to choose a bar construction.



Magnetic attachment

In some cases, where space is very limited, or where cleaning under the bar would be difficult, a magnetic attachment can be a better solution. If magnets are used a magnacap attached to an abutment is preferred compared to a magnabutment mounted directly on the implant. This is because it is not possible to apply a counter torque when attaching the magnabutment to the implant. A magnabutment involves interference with the skin penetration at MRI scanning and should only be used when space is extremely limited.

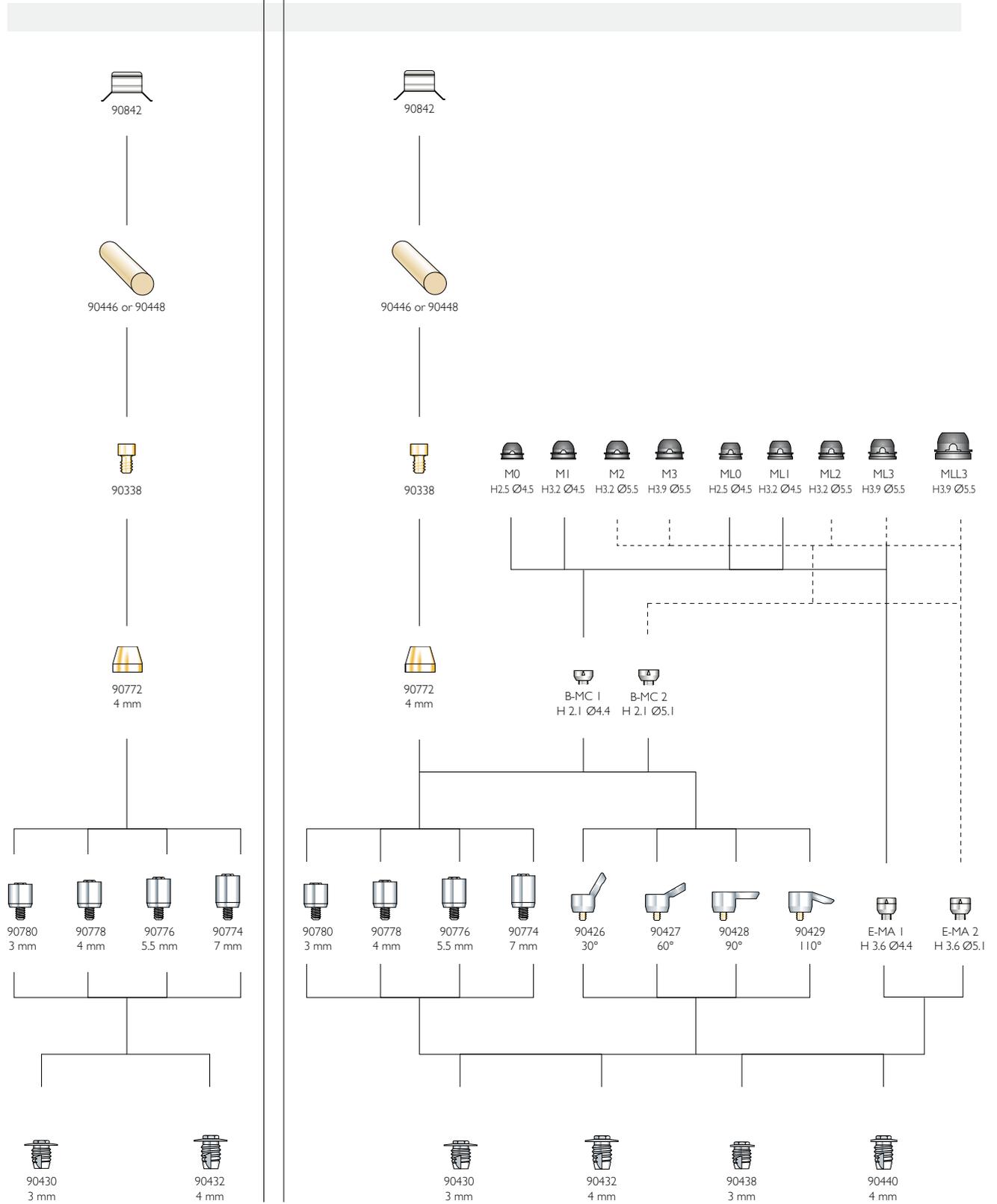


Patient component guide

EAR (bar retention)



MIDFACE (bar and / or magnet retention)



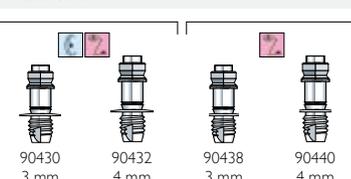
Surgical instrument guide

DRILLING

Fixture Length	Drills	
3 mm	 90415	+  90416
4 mm	 90415	+  90417

PATIENT COMPONENTS

Fixtures ST



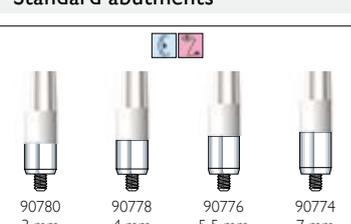
90430 3 mm 90432 4 mm 90438 3 mm 90440 4 mm

Cover screws



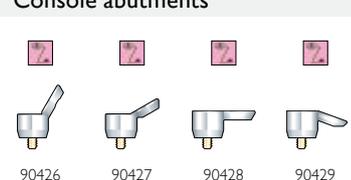
90360 Unigrip (Standard) 90620 Hex (Sleeper) 90362 Hex (Low profile)

Standard abutments



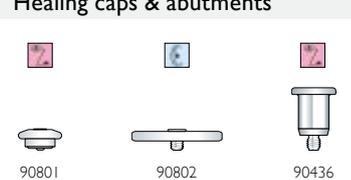
90780 3 mm 90778 4 mm 90776 5.5 mm 90774 7 mm

Console abutments



90426 30° 90427 60° 90428 90° 90429 110°

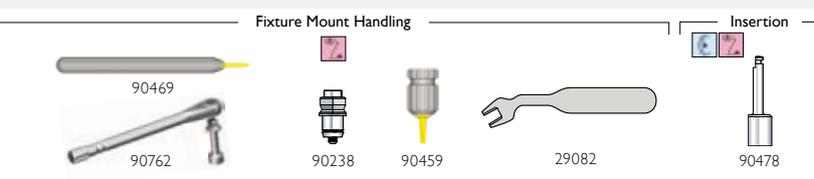
Healing caps & abutments



90801 Ø6.5 mm 90802 Ø14 mm 90436

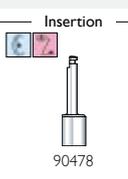
ASSOCIATED INSTRUMENTS

Fixture Mount Handling



90469 90762 90238 90459 29082

Insertion

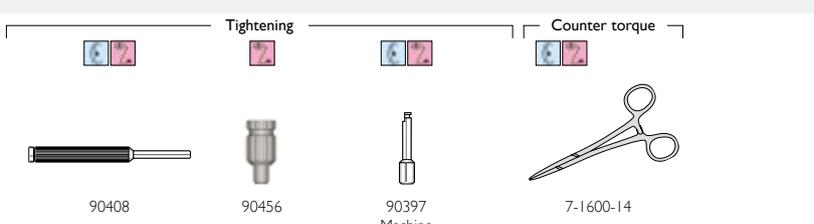


90478



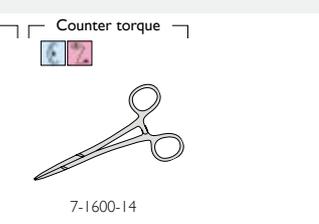
90469 Unigrip 90459 Unigrip 90453 Hex

Tightening



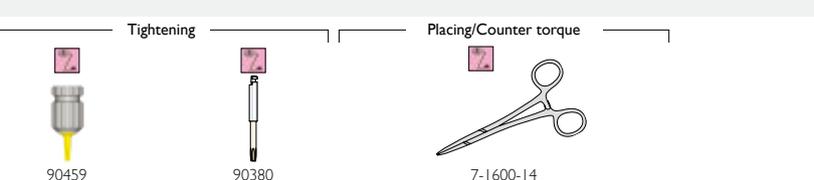
90408 90456 90397 Machine

Counter torque



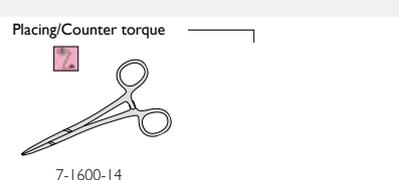
7-1600-14

Tightening

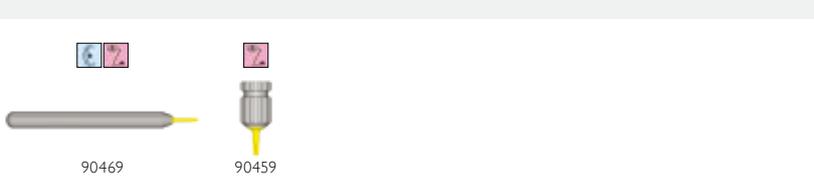


90459 90380 Machine

Placing/Counter torque



7-1600-14



90469 90459

Surgical instrument sets

Vistafix™ Basic Surgical Instrument Set (for auricular prosthesis)

1. Surgical organiser; titanium
2. Screwdriver Unigrip 95 mm
3. Surgical wrench set
4. Abutment clamp
5. Screwdriver for internal hexagon long
6. Forceps, titanium
7. Dissector
8. Raspatorium
9. Machine screwdriver abutment
10. Connection to handpiece
11. Drill indicator
12. Screwdriver for internal hexagon 20mm



Vistafix™ Complementary Surgical Instrument Set (for small spaces and shallow defects, for mid-face and orbital prosthesis)

Note: this instrument set is a complement to the Vistafix™ basic surgical instrument set.

1. Open-end wrench
2. Fixture mount Unigrip short
3. Machine screwdriver Unigrip 20 mm
4. Screwdriver Unigrip 20 mm
5. Screwdriver for internal hexagon 17 mm



Drilling equipment

W&H drilling equipment – Implantmed

The W&H Implantmed drilling equipment consists of one control unit, one motor and one foot control (see fig. 2).

The Implantmed unit features several programs covering the various stages in the surgical procedure. The drilling sequence during bone preparation, fixture/abutment insertion and the secure tightening of abutment screws at second stage can be set automatically. The programs can be adjusted to the optimum speed and torque for each stage of the procedure.

Programs 3 and 4 can both be used for the drilling procedure. The speed can be easily adjusted by choosing the required program and then pressing the plus (+) or minus (–) buttons. The selected maximum speed (rpm) is then shown on the display. The available speed range is 15–2000 rpm for the handpiece 20:1 WS-75 E/KM.

Note: The handpiece 20:1 WS-75 E/KM (with gear ratio 20:1) should always be used for Vistafix surgery to give the correct speed and torque.

Program 5 is used for implant installation and screw tightening. This program uses a fixed speed and the display shows the torque limitation value. The speed is fixed at 15 rpm in forward mode and 30 rpm in reverse mode. The torque control can be adjusted from 5 to 50 Ncm. The maximum torque is adjusted by pressing the plus (+) or minus (–) buttons and the selected torque is shown on the display.

The Implantmed unit has a built-in roller pump that can be used for cooling with saline solution instead of a manual syringe. The pump can be switched on from the console or by using the foot control.

Note: The setting on the drilling unit is specially adjusted for contra-angle handpiece WS-75 E/KM, i.e. changing the handpiece will result in an incorrect speed or torque, which may severely jeopardise the clinical result.

For further information see the relevant manual.

Previous Drilling Equipment – Controller Set

The previous drilling equipment, the Controller Set, consists of one high speed drill controller unit and one low speed torque controller unit. When using a connected drill and torque controller, only the foot control included in the drill controller is used.

The shank, with the blue ring, and the head with a green dot should always be used with the torque controller unit. With the drill controller unit, the shank with a black ring and the head with a green dot should be used.

Note: The motors for the Controller Set are not autoclavable.

For further information see the relevant manual.



fig. 2

Component set up for surgery

Typical component set up for a one-stage auricular prosthesis in an adult patient

Implant and healing abutment insertion

- 1 Guide drill 3+4 mm
- 1 Drill countersink 3 mm
- 1 Drill countersink 4 mm
- 2 or 3 Flange fixture ST 3 mm (Self-tapping)
- 2 or 3 Flange fixture ST 4 mm (Self-tapping)
- 1 Biopsy punch Ø4 mm
- 2 or 3 Healing abutments

The number of components required will depend on the number of implants intended to be placed. A set of both one-stage and two-stage components should always be available (see across), as a one-stage procedure may have to be changed to a two-stage procedure. It is also recommended that one extra of each component is available, in case a component is dropped.

Many auricular prostheses are being made with three implants instead of two, since surgeons, prosthodontists, and anaplastologists feel this gives more stability and allows better distribution of weight on the prosthesis.

Typical component setup for a two-stage procedure

First stage - Implant insertion

- 1 Guide drill 3+4 mm
- 1 Drill countersink 3 mm
- 1 Drill countersink 4 mm
- 2 or 3 Flange fixture ST 3 mm (Self-tapping)
- 2 or 3 Flange fixture ST 4 mm (Self-tapping)
- 2 or 3 Cover screws

Second stage - Healing abutment installation

- 1 Biopsy punch Ø4 mm
- 2 or 3 Healing abutments or abutments

Preparation for surgery

Operating theatre

The operating theatre is prepared for surgery in the same fashion as for ordinary ear surgery.

Suggested preparation for implant installation

Supplies necessary in operating theatre

- Implantmed drilling equipment
- Selection of components; drills, fixtures and cover screws (see page 14).
- Antiseptic solution for patient preparation (alcohol base)
- Xylocain-adrenalin solution for local anaesthesia (10–15 ml)
- 0.5% Xylocain – adrenalin is used for haemostasis if the operation is performed under general anaesthesia
- Suture material 4/0 Dexon and 4/0 Polyamid
- Marker pen/needle and dye
- Dressing of choice, gauze and bandage
- Sterile drapes in various sizes for patients

Equipment and instruments

Vistafix™ instruments:

- Vistafix™ basic surgical instrument set
- Vistafix™ complementary surgical instrument set

Irrigation:

- The Implantmed has a built-in irrigation system. A bag of saline is attached to the unit and the disposable irrigation tubing is attached to the handpiece. If the irrigation tubing is unavailable then a syringe can be used, although the tubing is the preferred.

Handpieces:

- The handpiece and motor are sterile and packed in a cassette. These should be mounted and, in order to dispose of excess oil, the motor run for a short period in a vertical position with the tip down. The handpiece is then dried with a damp gauze dressing.

Suction:

- 1 suction tube
- 2 plastic suction tips

Prepping:

- Sponge holders
- Gauze
- Stainless steel bowl

Surgical instruments (basic requirements):

- 1–2 scalpels
- 2–5 scalpel blades No. 15
- 1–2 Dissectors
- Self-retaining retractor
- Elevators
- Retractors
- Syringe (L.A.)
- Tissue forceps
- Dissecting scissors
- Suture scissors
- Needle holder
- Artery forceps
- Towel clips
- Gauze

Preparation for surgery

Suggested preparation for abutment connection

Supplies necessary in operating theatre

- Healing abutments or selection of abutments and healing caps
- Disposable 4 mm biopsy punch
- Antiseptic solution for patient preparation
- Sterile saline pour bottle, syringe and needle
- Suture material 4/0 Polyamid and 6/0 non- absorbable Monofilament (if a skin graft is performed)
- Dressing of choice, gauze and bandage

Equipment and instruments

Vistafix™ instruments:

- Vistafix™ basic surgical instrument set
- Vistafix™ complementary surgical instrument set

Suction:

- 1 suction tube
- 1 plastic suction tip

Prepping:

- Sponge holders
- Gauze
- Stainless steel bowl

Surgical instruments (basic requirements):

- 1 probe
- 1–2 scalpel
- 1–5 scalpel blades No. 15
- Dissectors
- Retractors
- Elevators
- Skin hooks
- Tissue forceps
- Dissecting scissors
- Suture scissors
- Needle holder
- Towel clips
- Syringe (L.A.)
- Gauze

Patient preparation

In the operating theatre, the patient should be prepared as for any surgical procedure, i.e. the incision area should be shaved and sterile.

Pre-medication and anaesthetics

In adults the procedure can be performed under general or local anaesthesia. In children general anaesthesia is preferred.

Local anaesthesia

As pre-medication, Valium 10–20 mg i.v. is recommended in adults. 10 mg/ml Xylocain with 5 µg/ml adrenalin s.c. solution is recommended as local anaesthesia. 10–15 ml is generally enough, but this may vary depending on the number of implants to be installed. The anaesthetic should infiltrate the periosteum at the implant site.

General anaesthesia

When the surgery is performed under general anaesthesia, the use of 5–10 ml 5 mg/ml Xylocain with 5 µg/ml adrenalin s.c. for haemostasis is recommended.

Skin preparation

The position of the implants should be selected in collaboration with the anaplastologist for the best aesthetic outcome. Before the surgical field is prepared, and while the patient's face can still be fully and easily seen, the implant sites are carefully marked, using a thin needle and surgical ink, down to the bone. It is recommended that the surgeon use a template, prepared by the anaplastologist, to mark the implant sites prior to the surgical procedure.

Auricular prosthesis

To obtain a good depth for the auricular prosthesis the retention bar should be located under the anti-helix part of the prosthesis, with the implants also being directly under the anti-helix (see fig.3).

Two implants are normally sufficient for satisfactory retention. The ideal position is approximately 20 mm from the centre of the external ear canal opening or, in the case of the atretic ear, the anticipated opening. On the right side the positions are at 8 o'clock and 10.30 (see fig. 4). On the left side the corresponding positions are at 4 o'clock and 1.30. The distance between the implants should be at least 15 mm, depending on the anatomical situation. In the mastoid area flange fixtures should be used.

When using the two-stage procedure, tags and remnants are often left in place at the first stage and not removed until the second operation.

The location of specific anatomical landmarks i.e. linea temporalis, suprameatal spine, foramen mastoideum etc. is often helpful. Anatomical variations due to congenital malformation and prior surgery should be considered.

Mid-face and orbital prosthesis

When placing implants in the orbit and in the midface it is extremely important that the surgeon works with the anaplastologist in detail regarding the positions and directions of the implants. A template may be used in order to achieve a successful result. If not, the final aesthetic result could be jeopardized. In a narrow orbital rim the flangeless fixture should be the implant of choice. It is also important to consider the position and orientation of the implant in order to facilitate cleaning around the abutment.

For more information see reference 8 in the "References" section.



fig. 3



fig. 4

Surgical technique

This chapter describes the two different types of Vistafix™ FAST® system surgical procedures, one-stage FAST® surgery and two-stage FAST® surgery. The decision on which surgical procedure should be followed is based on the criteria below.

One-stage surgery is carried out on:

- Auricular defects
- Adults
- Non-irradiated tissue

Two-stage surgery is carried out on:

- Paediatrics
- Orbit and midface patients
- Auricular patients with poor bone quality
- Patients with irradiated bone
- Special Need Patients who may require covered implants during the osseointegration period (eg. mentally or physically compromised)

The surgical procedures are described using step by step instructions. Each step in the different procedures is marked according to the explanation below.

OS = One-stage FAST® surgery

TS = Two-stage FAST® surgery

Surgical procedure for one-stage FAST® surgery and first part of the two-stage FAST® surgery

The following describes a one-stage FAST system surgical procedure that is carried out for an auricular prosthesis in good quality bone. It also describes the first part of a two-stage FAST system surgical procedure that is carried out for an auricular prosthesis.

Note: If you are following the protocol for second part of the two-stage surgery, start at “TS8 Tissue preparation” on page 28.

The surgical procedure may be facilitated by the use of magnifying glasses. A conventional suction device should be used. Electro coagulation should be used with care in order to minimise tissue trauma.

OS1 TS1 Incision

An incision is made 10 mm behind the anticipated implant site. Sharp dissection is performed down to the periosteum. The periosteum is exposed and a cruciate incision should be made in the periosteum at each implant site. The edges are then raised with the raspatorium (see fig. 5).

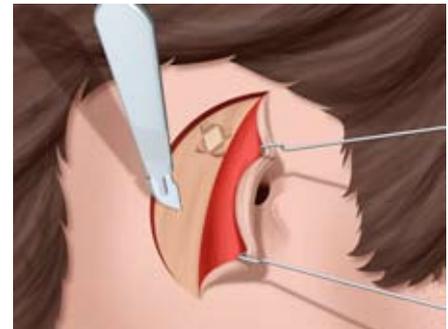


fig. 5

OS2 TS2 Irrigation

When rotating instruments are used abundant irrigation must be applied. This can be with room temperature saline solution or sterile water. The irrigation is directed at the point where the drill penetrates the bone surface. Bone chips should be removed frequently from the drill flutes allowing for clean, sharp cutting. During all drilling procedures the burr is moved up and down in the preparation hole, allowing the irrigation to reach the cutting edge, thus facilitating the removal of cut bone tissue. The quality and quantity of the cortical bone and the spongiosa air cells are noted during initial penetration.

Surgical technique

OS3 TS3 3mm Guide drill

Note: During all drilling the drill indicator should be attached to the drill handpiece.

Drilling begins with the guide drill with the spacer kept on 3 mm (see fig. 6), and the drill indicator attached. Whilst drilling with the guide drill, the burr is moved up and down and around in the hole to ensure that the cooling solution reaches the tip of the drill. While gradually deepening and widening the hole with the guide drill it is important not to over widen the section that will contain the implant threads as this may cause loss of initial stability. The bottom of the hole is repeatedly checked for bone at the base of the site, both visually and with the blunt dissector.

Note: It should be noted that it is possible to penetrate the wall of the sigmoid sinus and expose the dura mater, and therefore the surgeon should proceed with care.

OS4 TS4 4mm Guide drill

If there is adequate bone thickness, the spacer on the drill is removed, allowing drilling to continue to a depth of 4 mm. Drilling continues in the same manner using the whole length of the drill to allow space for the countersink (see fig. 7). If, however, soft tissue is encountered, drilling should be terminated and the procedure completed with the 3mm components. In most adults there is sufficient bone volume for a 4 mm implant.

OS5 TS5 Countersink

After preparation of the primary hole for the implant, the next step is to widen the hole to the exact diameter. This procedure is performed with either a 3 or 4 mm drill countersink, depending on the depth reached with the guide drill (see fig. 8).

The countersink should be moved up and down during drilling ensuring that the irrigation reaches the tip of the drill. Bone chips should be removed frequently from the drill flutes. The countersunk area on the bone surface should be even all around the implant site. It is also very important to be careful not to over-countersink, as this will mean that the final connection between the implant and abutment is below the surface of the bone (see fig. 9).

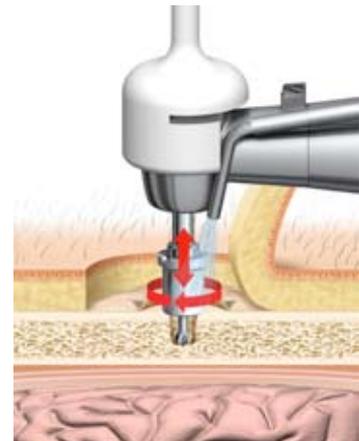


fig. 6

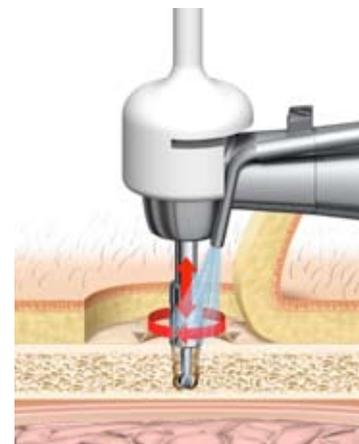


fig. 7

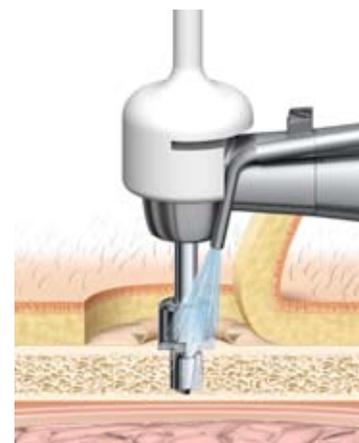


fig. 8

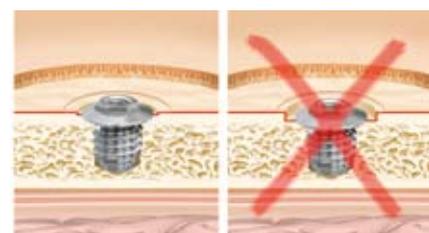


fig. 9

Surgical technique

OS5 TS5 Countersink continued

When the surface of the bone is uneven, the countersink allows the flange of the titanium implant to have maximum contact with the bone surface. The tip of the countersink is blunt in order to minimize the risk of damaging any tissue at the bottom of the hole.

Note: Cooling is very important for all drilling procedures. Heat can damage the bone tissue and jeopardise osseointegration.

It is important that drilling is carried out perpendicular to the bone surface, as the angle of the implant site will affect the orientation of the implant and the abutment.

The drill indicator will facilitate correct drill orientation, and should be used with the guide drills, drill countersink and implant.

Two-stage surgery (TS)

If you are following the protocol for the first part of the two-stage surgery, move on to “TS6 Implant installation” on page 26.

OS6 Tissue preparation

Subcutaneous tissue reduction is preferably carried out prior to implant placement. There are three prerequisites for establishing and maintaining a reaction-free skin-penetration.

Firstly, the skin surrounding the implants should be hairless to help keep the implant site clean. Secondly, all subcutaneous tissue must be removed in order to minimize skin mobility in relation to the implant. Thirdly, the periosteum should be carefully trimmed to its innermost layer, and the flap then sutured down to the periosteum.

It is vital that the skin is prepared properly to avoid tissue and hair re-growth, which will cause irritation or wound healing problems around the abutments. If any subcutaneous tissue is left, the tissue is likely to grow up around and over the abutment(s) and cause irritation. This may mean that additional skin reduction has to be carried out at a later date.

Hair follicles should be scraped from the flap. It is useful to use skin hooks to raise the edges of the flap when removing the subcutaneous tissue. (see fig. 10).

To avoid steep steps around the implant sites, a subcutaneous tissue reduction is performed at the periphery of the flap (see fig. 10). The thicker the subcutaneous tissue is, the larger the reduction should be. Sufficient skin reduction is of decisive importance in order to obtain a reaction free skin-penetration. It is advised that when the depth of tissue is about 6mm then you should remove soft tissue approximately 20 mm outwards from the flap edges. It is essential that the skin flap is thin, has smooth edges and is generous in size in order to achieve a gradual, tension-free sloping edge down to the implants.

When reducing the subcutaneous tissue in a patient who has a thick skin flap, or who has thick subcutaneous tissue, it is important to remember that the risk of post-operative numbness around the site area could be greater. The numbness may remain for a period of time or be permanent.

Keeping the periosteum intact is extremely important to maintain the blood supply required for the skin flap to heal. But it is extremely important that it is trimmed back to leave only the innermost layer, removing everything that is easily raised and ensuring the edges are laid back down.

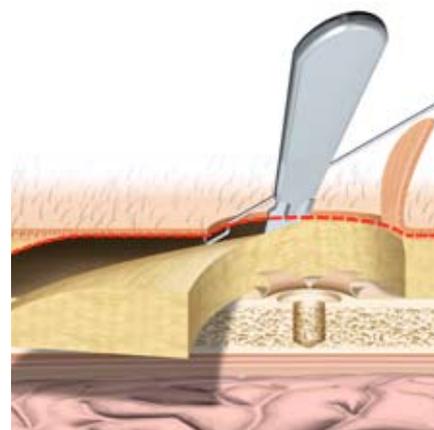


fig. 10

Surgical technique

OS7 Implant installation

For implant insertion the low speed setting on the Implantmed, which is marked with a picture of an implant, should be used. The torque limit setting on the drill panel should be adjusted to suit the quality of the bone. In compact cortical bone a torque setting of 40 Ncm is recommended. In soft bone a lower torque setting of 20 Ncm should be used. The torque can then be increased if it is needed.

Torque Table

Implant Level	
Compact cortical bone	40 – 50 Ncm
Irradiated or soft bone	20 – 30 Ncm
Paediatric implant	20 Ncm
Abutment Level	
Abutment	20 Ncm
Gold Cylinder	10 Ncm
Gold Screw	10 Ncm

The self-tapping fixture with pre-mounted fixture mount is seated inside the plastic ampoule in a titanium cylinder and is delivered sterile. The plastic ampoule is opened by unscrewing the lid so that the bottom section can be placed in the holder on the titanium tray (see fig. 11).

The self-tapping fixture with pre-mounted fixture mount is picked up with the connection to handpiece, which is placed into the drill handpiece. The square inside the connection to handpiece is matched with the square on top of the fixture mount. It is recommended that the drill indicator is used during implant insertion (see fig. 12).

The implant is installed without cooling until the small grooves in the distal end of the implant are well within the canal. (Irrigation at this time results in cooling solution being compressed into marrow spaces in the bone by the implant.) After this, the implant placement continues under abundant irrigation (see fig. 13). If the implant enters the hole incorrectly, the drill motor is put in reverse and the implant is unscrewed. The correct angle is then found and the implant re-inserted.

The surgical wrench can be used for the final insertion of the implant if the implant has not seated correctly or if there is a problem with the drill unit. It should be used with great care in order to not damage the bone.



fig. 11



fig. 12

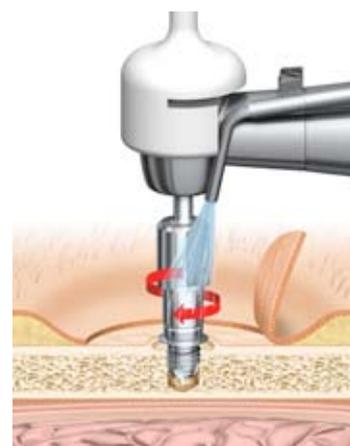


fig.13

Surgical technique

OS7 Implant installation continued

When the flange of the implant has seated in the countersunk area, the handpiece will stop and is then lifted off the fixture mount. The mount is removed using the Unigrip screwdriver and the surgical wrench (see fig. 14). Caution should be observed in order to avoid loosening the implant through a lever arm effect or counter torque. This is especially important if the bone is of poor quality.

Note: It is very important to use the surgical wrench with the “in” (which is printed on the top of the wrench) facing upwards.



fig. 14

OS8 Healing abutments and abutments

When using the one-stage FAST system, healing abutments can be used during the period of osseointegration and the permanent abutments can be placed at a later date at the clinic. This enables the tissue to heal properly before the length of the final abutment is chosen.

The edges around the flap are sutured down to the periosteum, holding the tissue in place. The flap is laid back, stretched out and sutured down.

Holes are punched through the skin exactly over the sites of the implants with a 4 mm biopsy punch (see fig. 15).

The healing abutments are placed using a Unigrip screwdriver and a dressing is placed around the healing abutments (see fig. 16).

Permanent abutments can also be placed at this stage; see section on abutment connection in Two-stage surgery.



fig. 15

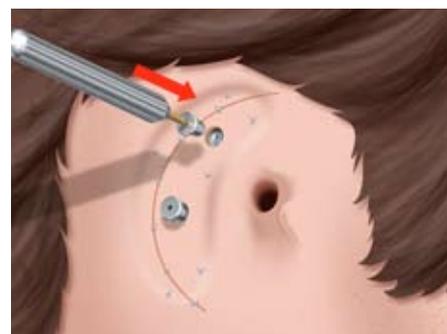


fig. 16

Surgical technique

OS9 Dressings

Care is taken in the choice of dressing and aftercare of the wound. Traditionally the graft has been dressed with ointment soaked ribbon gauze wrapped around the abutment to avoid the formation of a haematoma (see fig. 17).

The ribbon gauze must be applied evenly in order to avoid obstructing the blood supply as this may cause tissue necrosis and may disturb the graft. Tissue damage can occur as the gauze dries and adheres to the wound. It is also difficult to remove and uncomfortable for the patient.

New wound care techniques can reduce complications, increase comfort for the patient and decrease the time spent on aftercare by the clinician. There are now many dressings available, but for a graft site it is generally accepted that a non or low adherent wound contact layer and light pressure dressing is adequate. Many types of dressings are suitable, but a few suggestions follow.

Foam dressing

A foam such as Alleyvn* Hydrocellular which is a hydrophylic, polyurethane dressing with a trilaminar structure. This dressing has a three-dimensional polyurethane net, which is low adherent to the wound interface. It is made from hydrophilic foam that absorbs and retains fluid and has an outside layer of opposite film. It can be used for low to medium exuding wounds and can be cut to shape for fitting around the abutment and healing cap. The dressing can be left in place for up to seven days.

Soft silicone wound contact layer

A soft silicone mesh such as Mepitel** which is a non-adherent dressing made of a medical grade silicone gel bound to a soft and pliable polyimide netting which allows the passage of exudate. This is an ideal wound contact layer as it does not adhere to the wound at all, can be left in place for seven days and can be cut to size. In some hospitals this dressing is quite widely used and is available in most ward areas or Accident & Emergency.

Antiseptic dressing

An antiseptic such as Inadine*** is a low-adherent knitted viscose dressing impregnated with 10% povidone-iodine in a water soluble polyethylene glycol base. It is generally used for the prophylaxis and treatment of a wide range of bacterial, protozoal and fungal organisms. Inadine needs to be used in conjunction with gauze as it does not have any absorption properties. It can be cut to shape and left in place for 5–7 days or until colour is lost.



fig. 17

* Alleyvn is a trademark of Smith and Nephew

** Mepitel is a registered trademark of Mölnlycke Health Care

*** Inadine is a trademark of Johnson & Johnson

Dressing protocol using foam

Operating theatre dressing:

- Cut or biopsy punch $\varnothing 4$ mm holes in foam dressing
- Apply over abutments directly on to the wound
- Healing caps to hold in place
- Cover with gauze and mastoid pressure bandage (see fig. 18 and 19).

One day post op:

- Remove outer bandage
- Leave foam dressing and healing caps in place
- Keep dry

5–6 days post op:

- Remove healing caps
- Carefully remove foam dressing
- Gently clean wound with normal saline and gauze
- Remove any dried blood
- Re-apply foam dressing and healing caps
- Patient can wash hair if dressing is protected

10–14 days post op:

- Remove foam dressing
- Remove sutures
- Gently clean any dried blood or scabs
- Patient can wash hair
- If healed, no further dressing required



fig. 18



fig. 19

Dressing protocol using silicone or antiseptic wound contact layer

Operating theatre dressing:

- Cut or biopsy punch $\varnothing 4$ mm holes in the dressing
- Place over abutments directly on to the wound
- Apply at least two layers of gauze to exert pressure to graft
- Healing caps
- Cover with gauze and mastoid bandage

One day post op:

- Remove outer bandage
- Leave the dressing, gauze dressing and healing caps in place
- Keep dry

5–6 days post op:

- Remove healing caps
- Carefully remove dressing and gauze dressing
- Gently clean wound with normal saline, gauze or tips
- Remove any dried blood
- Re-apply dressing and gauze dressing and healing caps
- Patient can wash hair if dressing is protected

10–14 days post op:

- Remove the dressing
- Remove sutures
- Gently clean any dried blood or scabs
- Patient can wash hair
- If healed, no further dressing required

Surgical technique

First part of the two-stage FAST[®] surgery continued

TS6 Implant installation

For implant insertion the low speed setting on the Implantmed, which is marked with a picture of an implant, should be used. The torque limit setting on the drill panel should be adjusted to suit the quality of the bone. In compact cortical bone a torque setting of 40 Ncm is recommended. In soft bone a lower torque setting of 20 Ncm should be used. The torque can then be increased if it is needed

Torque Table

Implant Level

Compact cortical bone	40 – 50 Ncm
Irradiated or soft bone	20 – 30 Ncm
Paediatric implant	20 Ncm

Abutment Level

Abutment	20 Ncm
Gold Cylinder	10 Ncm
Gold Screw	10 Ncm

The self-tapping fixture with pre-mounted fixture mount is seated inside the plastic ampoule in a titanium cylinder and is delivered sterile. The plastic ampoule is opened by unscrewing the lid so that the bottom section can be placed in the holder on the titanium tray (see fig. 20).

The self-tapping fixture with pre-mounted fixture mount is picked up with the connection to handpiece, which is placed into the drill handpiece. (see fig. 21). The square inside the connection to handpiece is matched with the square on top of the fixture mount.

Note: It is recommended that the drill indicator is used during implant insertion.

The implant is installed without cooling until the small grooves in the distal end of the implant are well within the canal. (Irrigation at this time results in cooling solution being compressed into marrow spaces in the bone by the implant.) After this, the implant placement continues under abundant irrigation (see fig. 22). If the implant enters the hole incorrectly, the drill motor is put in reverse and the implant is unscrewed. The correct angle is then found and the implant re-inserted.



fig. 20



fig. 21

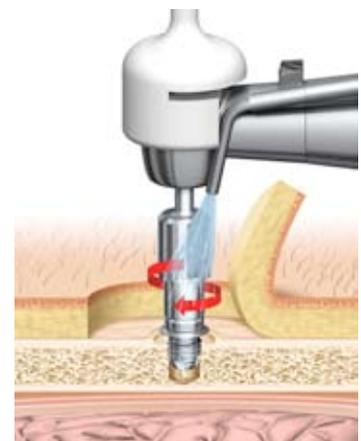


fig. 22

Surgical technique

The surgical wrench can be used for the final insertion of the implant if the implant has not seated correctly or if there is a problem with the drill unit. It should be used with great care in order not to damage the bone.

When the flange of the implant has seated in the countersunk area, the handpiece will stop and is then lifted off the fixture mount. The fixture mount is removed using the Unigrip screwdriver and the surgical wrench (see fig. 23). Caution should be observed in order to avoid loosening the implant through a lever arm effect or counter torque. This is especially important if the bone is of poor quality.

Note: It is very important to use the surgical wrench with the “in” (which is printed on the top of the wrench) facing upwards.

TS7 Cover screw

A cover screw is inserted into the implant with the Unigrip screwdriver to protect the internal threads (see fig. 24). The periosteum is folded back around the flange of the implant and the incision is closed (see fig. 25 and 26).

A standard mastoid dressing is left in place for 1–2 days (see fig. 27). After this the dressing is removed and a small bandage is all that is necessary. After a day or two most patients can return to normal activities.

The implants are left for a period of 4–6 months during which time osseointegration takes place.

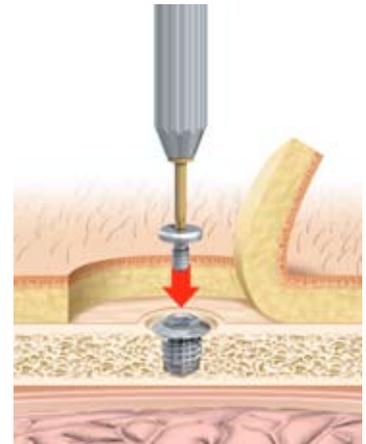


fig. 24

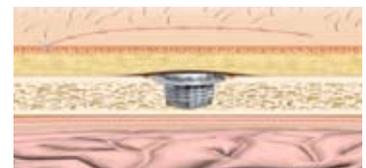


fig. 25



fig. 26



fig. 23



fig. 27

Surgical technique

Second part of the two-stage FAST® surgery

TS8 Tissue preparation

The patient is prepared for surgery. There are three prerequisites for establishing and maintaining a reaction-free skin-penetration.

Firstly, the skin surrounding the implants should be hairless to help keep the implant site clean. Secondly, all subcutaneous tissue must be removed in order to minimize skin mobility in relation to the implant. Thirdly, the periosteum should be carefully trimmed to its innermost layer; and the flap then sutured down to the periosteum.

It is vital that the skin is prepared properly to avoid tissue and hair re-growth, which will cause irritation or wound healing problems around the abutments. If any subcutaneous tissue is left, the tissue is likely to grow up around and over the abutment(s) and cause irritation. This may mean that additional skin reduction has to be carried out at a later date.

Hair follicles should be scraped from the flap. It is useful to use skin hooks to raise the edges of the flap when removing the subcutaneous tissue. (see fig. 28). To avoid steep steps around the implant sites, a subcutaneous tissue reduction is performed at the periphery of the flap (see fig. 29). The thicker the subcutaneous tissue is, the larger the reduction should be. Sufficient skin reduction is of decisive importance in order to obtain a reaction free skin-penetration. It is advised that when the depth of tissue is about 6mm then you should remove soft tissue approximately 20 mm outwards from the flap edges. It is essential that the skin flap is thin, has smooth edges and is generous in size in order to achieve a gradual, tension-free sloping edge down to the implants.

When reducing the subcutaneous tissue in a patient who has a thick skin flap, or who has thick subcutaneous tissue, it is important to remember that the risk of post-operative numbness around the site area could be greater. The numbness may remain for a period of time or be permanent.

Keeping the periosteum intact is extremely important to maintain the blood supply required for the skin flap to heal. But it is extremely important that it is trimmed back to leave only the innermost layer; removing everything that is easily raised and ensuring the edges are laid back down.



fig. 28

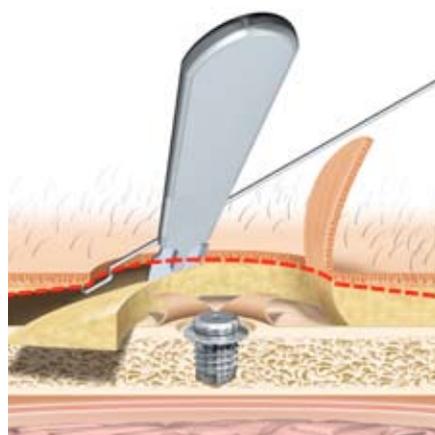


fig. 29

Surgical technique

TS9 Cover screw removal

The head of the cover screws are exposed. The edges of the flap are then sutured down to the periosteum.

The flap is laid back down and sutured. Holes are punched exactly over the cover screws with a 4 mm biopsy punch (see fig. 30).

The cover screws are removed through the flap using the Unigrip screwdriver (see fig. 31).



fig. 30

TS10 Abutment connection

Healing abutments

A healing abutment is used so that the permanent abutments can be placed at a later date under local anaesthetic at the clinic. This enables the tissue to heal properly before the most appropriate abutment length is chosen.

The healing abutment is placed using a Unigrip screwdriver (see fig. 32).

A dressing is placed around the healing abutments (see fig. 33).

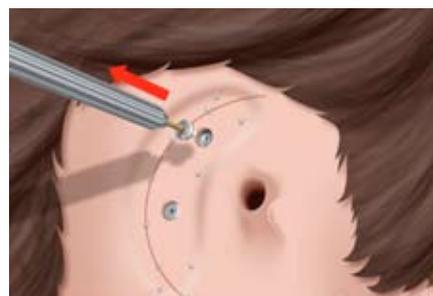


fig. 31

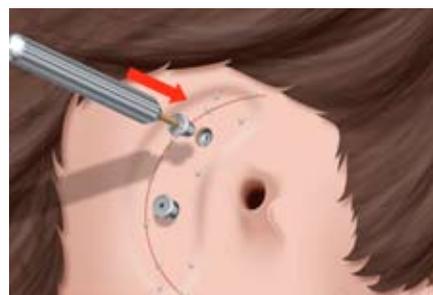


fig. 32

For more information on Dressings, see relevant section on page 24.

Abutments

Permanent abutments may be placed at this stage, although the tissue does alter and this may mean that a different length abutment may be needed before making the final prosthesis.

Note: If healing abutments are used they need to be removed for the permanent abutments to be placed.

The abutment cylinders used for the auricular prosthesis have an internal screw for attachment to the implants. The abutments are available in four lengths: 3, 4, 5.5 and 7 mm and come with an abutment holder connected to make placement easier (see fig. 34). The most common lengths used are the 3 and 4 mm abutment, other alternatives are only used in special situations relating to the surrounding tissue where greater space needs to be created.



fig. 33



fig. 34

Surgical technique

The abutments are picked up and placed onto the head of the implant and screwed partially down to secure it (see fig. 35). The abutment holder is then removed by snapping it off of the abutment

Note: The abutment should be correctly fitted on to the hexagon head of the fixture (not resting on top of the hexagon) in order to avoid the abutments becoming loose.

The abutment should be held in position with the abutment clamp (see fig. 36) as a counter torque, to avoid any movement of the abutment, which could introduce a force on the implant. The internal screw is then tightened into the implant using the internal hexagon screwdriver (see fig. 37).

Abutments should be tightened down to the correct torque (20Ncm) using the machine screwdriver on the handpiece or the manual torque wrench (see fig. 38 and 39).

Note: The abutment clamp should be used to avoid counter torque (see fig. 37, 38 and 39).



fig. 35



fig. 36



fig. 37



fig. 38



fig. 39

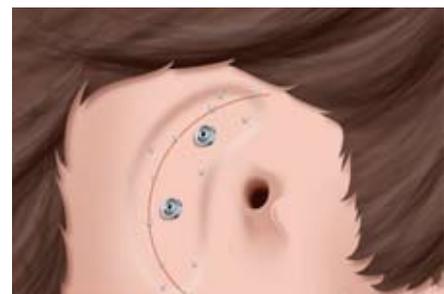


fig. 40

Surgical technique

TS11 Healing caps

Plastic healing caps are attached to each abutment. These are designed to hold down the dressing during the initial healing period in order to prevent post-operative haematoma.

There are two widths of healing caps; Ø14 mm and Ø6.5 mm. The choice of healing cap depends on the space between the abutments. The Ø14 mm cap should preferably be used for an auricular prosthesis.

The healing caps are placed using the Unigrip screwdriver (see fig. 41).

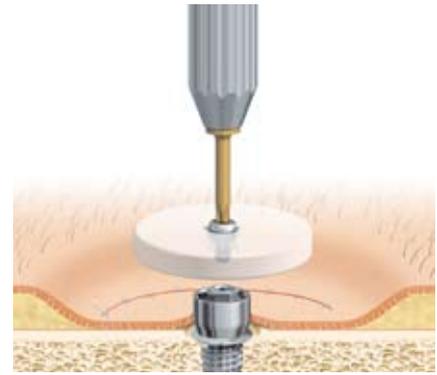


fig. 41

TS12 Dressings

The dressings are placed (see fig. 42 and 43).

Please see section “Dressings” on page 24.



fig. 42

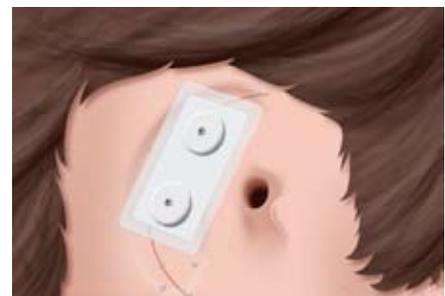


fig. 43

Complications & troubleshooting

The incidence of complications is very low. However, a few complications may occur:

Safety, effectiveness and complications

Listed below are some of the potential complications, relating to safety and effectiveness, that patients should be made aware of and consider before surgery:

- Paresthesia
- Perforation of the dura
- Infection of the bone leading to Osseo necrosis
- Subdural haematoma
- Meningitis
- Inadequate temporal bone depth
- Skin graft loss
- Local or systemic infection
- Implant mobility
- Failure of the prosthesis and abutment dislodging if trauma occurs, causing displacement of the implant
- Participation in sporting activities is seldom a problem. In heavy contact sports some precautions may be indicated
- It is important to instruct patients regarding potential complications

Troubleshooting

Tissue and flap

- If the flap is damaged and cannot be put back in place, an alternative option is to take a hairless skin graft from, for example, the retro auricular fold. The ideal situation is a split thickness skin graft placed directly on the bone or periosteum.
- A patient who has very thick skin or constant re-growth of the subcutaneous tissue may need a longer abutment.
- When reducing the subcutaneous tissue in a patient who has a thick skin flap or is clinically obese, it is important to remember that the risk of post-operative numbness around the site area could be greater; the numbness may remain like this for a period of time or be permanent.
- Inflammation and infection around the skin-penetrating abutment may be due to movement of the skin in relation to the implant. This can be caused by excessive thickness of the subcutaneous tissue layer, a loose abutment or the fact that the implant has not osseointegrated with the bone. These phenomena may result in pain.
- If hyper mobility of the skin is the reason for irritation around the implant, a further subcutaneous tissue reduction should be performed. In such cases it is recommended that the patient is closely followed post-operatively and that a light pressure dressing is applied for 2–3 weeks. During the first weeks after surgery, partial, or even on rare occasions, sub-total graft and flap necrosis has been seen. However, conservative treatment has been successful in these situations, although the healing period may be extended.
- Poor personal hygiene or inappropriate vigorous cleaning may also cause irritation. Alcohol or chlorhexidin solutions should not be used.
- Long standing infection around the implant should be cultured and the relevant antibiotic be given orally.
- If the implant does not fully osseointegrate with the bone, it should be removed. The implant site in the bone is carefully curetted and the defect filled with blood coagulates. New bone formation will take place and one year later it should be possible to put a new implant in the same place. However, in most cases, adjacent bone is available and suitable for the placement of another implant at the same time the loose implant is removed.
- Irritation may also arise when two abutments are too close to each other. There should be at least 15 mm between the abutments. Skin diseases such as seborrhoic eczema may give rise to irritation.

Complications & troubleshooting

Drills and implants

- The guide drill must be used to its full length so that sufficient depth is reached for the drill countersink.
- The countersinking should be even so that the flange on the implant seats correctly and keeps the implant perpendicular to the skin. This will facilitate the correct positioning of the sound processor.
- Sometimes an air pocket may occur while drilling, taking the drill into the wrong direction. In this case a new site should be chosen.
- When placing the implant in hard bone, pressure may be needed during insertion. This applies only at the initial insertion – once the implant has entered the bone no further pressure should be applied. If the implant stops it should be reversed out a few threads and then re-inserted.
- The torque can be adjusted depending on the quality and hardness of the bone. This should be done gradually, but can be raised to a torque of 50 Ncm.
- If the abutment is insufficiently tightened, either initially, or at abutment change, it may become loose and a skin infection could develop.

Note: Any implant losses should be reported to your Cochlear representative for monitoring.

Mechanical complications

- There must always be sterile-packed duplicates of all instruments and components.
- The implant can be inserted manually if needed with the aid of the surgical wrench. The surgical wrench is placed on top of the connection to handpiece on the square. The surgical wrench is then rotated until the implant flange has reached the bone surface (ensure that "IN" is facing upwards on the wrench).
- If the flange does not reach the bone surface then the surgical wrench may be used to check the final tightening of the implant. This should however be carried out with great care in order not to damage the bone. This manual procedure is also performed under abundant irrigation. Note that the implant does not need to be tightened any further into the bone after the flange has reached the bone surface.

MRI (Magnetic resonance imaging).

The implant and the abutment can be left in place if the patient has to undergo MRI. Scientific studies have shown that the effects are negligible.

Note: The magnabutments and magnacaps have to be removed prior to the patient undergoing MRI.

For more information see reference 7 in the "References" section.

Irradiation

If a patient already has implants placed, and is scheduled for irradiation around the implant area, the skin-penetrating abutments should be removed and the implants left in place under the skin.

Aftercare

One-stage procedure

The dressing and healing routine follows that of the two-stage procedure. However, it is very important to avoid loading the implant until osseointegration has taken place and the soft tissues have healed. Therefore it is essential to wait for 3 months before beginning work on attaching the prosthesis. Loading the implant too soon may result in implant loss. In addition, the fit of the prosthesis may be jeopardized if the area is not fully healed.

Two-stage procedure

One week after abutment surgery the healing caps and the dressing are removed. The area is then cleaned with great care and the wound is aerated for one hour. The healing caps are then repositioned and a new dressing is put in place to maintain slight pressure on the skin flap/graft for another week (see fig. 44 and 45). At this stage the healing caps and the dressing are removed and the area left open.

During the following 2–3 weeks the patient should clean the skin once a day with ointment. After this the patient may switch to soap and water and only use the ointment occasionally.

Epithelial debris around the abutment will continue to accumulate and, in some patients, this may require removal by the surgeon. Most patients, however, are able to accomplish this task by themselves.

Cleaning of the implant area should be performed carefully to avoid damage to the fixture-tissue interface. Vigorous cleaning and the use of strong detergents should be avoided.

Follow-up

A daily cleaning routine is of utmost importance to maintain a reaction-free skin-penetration. This should be stressed, as there is seldom any discomfort even if the skin becomes irritated and/or infected (see fig. 46).

Cleaning under the bar construction is important. If the soft tissue grows up against the bar, this may indicate that soft tissue reduction was insufficient at original surgery. Surgical revision and further soft tissue reduction may then be necessary.

It is also important that the patient takes part in a follow-up program. Usually once or twice a year is enough, but some patients need more frequent “check-ups”.

At these visits the stability of the implants/abutments is checked. Both the hexagon fitting of the implant as well as the tightness of the gold screw should be checked. If necessary the abutment screws should be tightened.

One of the most common reasons for skin irritation is mobility at the skin-penetrating site.

Good daily hygiene and regular follow-up visits are important for a reliable long-term result.



fig. 44



fig. 45



fig. 46

Prosthetic Instrument Guide

PATIENT COMPONENTS

Gold cylinder and screw



90772
4 mm



90338

Magnacaps



B-MC 1
Ø4.4 mm



B-MC 2
Ø5.1 mm

Magnabutments (direct on fixture)



E-MA 1
Ø4.4 mm



E-MA 2
Ø5.1 mm

ASSOCIATED INSTRUMENTS



90469



90459



90381
Machine



90380
Machine

Placing and Tightening



CF 1
Ø4.4 mm



CF 2
Ø5.1 mm



CF 3
Ø4.4 mm Machine



CF 4
Ø5.1 mm Machine

Counter Torque



7-1600-14

LABORATORY COMPONENTS

Impression copings & guide pins



90379
Squared



90794
10 mm



90796
20 mm



90377
Tapered

ASSOCIATED INSTRUMENTS



90469
Unigrip



90459
Unigrip

Prosthetic instruments

Vistafix™ Prosthetic and lab instrument set
(includes instruments necessary for prosthetic and lab procedures)

1. Screwdriver Unigrip 95 mm
2. Screwdriver Unigrip 20 mm
3. Abutment clamp
4. Torque wrench set
5. Machine screwdriver Unigrip 20 mm
6. Machine screwdriver abutment



Prosthetic management after abutment connection

If a one-stage procedure has been performed, work on the prosthesis can start 3 months after the surgery to allow the implants to osseointegrate.

If a two-stage procedure has been performed, work on the prosthesis can usually begin 3–4 weeks after the abutment operation.

The first step is to produce a working model in high quality model stone. This model is a copy of the defect area with the abutments transferred by the impression to the cast.

Impression

The skin around the abutments is carefully cleaned (see fig. 47). The abutment screw should be checked, and tightened if needed, using the torque wrench. The external ear canal opening is packed with gauze to prevent penetration by the impression material. A soft, flexible silicone material is used to make the impression

Impression copings with guide pins are attached to the percutaneous abutments (see fig. 48).

A thin layer of flexible, light body silicone is applied around the copings and over the entire area required for making the prosthesis (see fig. 49).

A second layer of solid or heavy body impression silicone is applied to secure the impression copings in position and to stabilize the impression (see fig. 50).

Note: It is important not to cover the impression copings with silicone.

In order to facilitate the sculpturing of the prosthesis, an impression of the opposite ear is taken. This impression is poured in dental stone and will be used as a comparison during sculpturing of the prosthetic ear (see fig. 51).



fig. 47



fig. 48



fig. 49

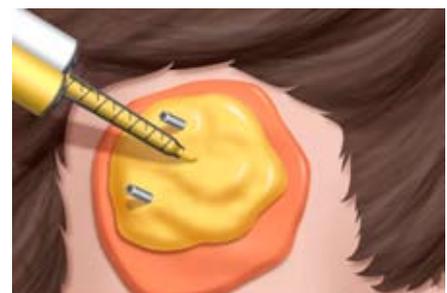


fig. 50



fig. 51

Prosthetic management after abutment connection

When the silicone material has set, the guide pins are unscrewed and the impression is carefully removed. Abutment replicas are then attached to the impression copings by tightening the guide pins. The impression with the copings and replicas is cast in dental stone (see fig. 52).

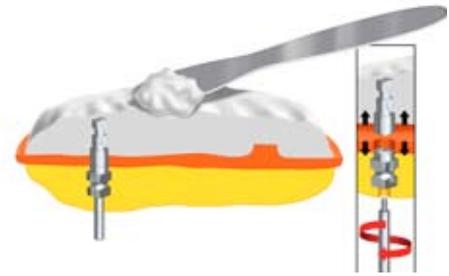


fig. 52

When the impression is separated from the cast an exact working model of the patient's defect area is achieved, with the abutment replicas in exactly the same position, direction and height as the skin-penetrating abutments.

Framework

At this stage the design of the framework is determined and a drawing of the shape of the bar construction is made.

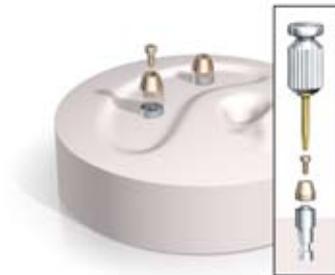


fig. 53

The gold cylinders are placed on the abutment replicas of the working model (see fig. 53). A Ø2 mm gold alloy bar is placed that stretches between and beyond the abutments with an appropriate shape. It is desirable to place the bar under the anti-helix part of the ear (see fig. 54 and 55). In order to minimise torque on the implants the bar should not extend more than 8–10 mm beyond the abutments (see fig. 56).



fig. 54

The bar is attached to the gold cylinders with sticky wax or acrylic. The bar construction is removed from the working model and embedded in investment in preparation for soldering. Following soldering, the bar construction is carefully checked on the working cast and on the patient for a perfect fit. A welding technique can also be used.

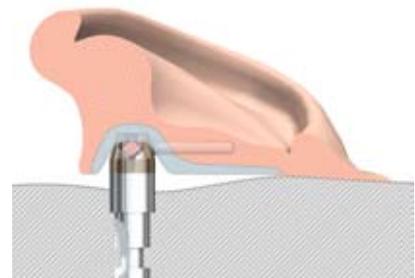


fig. 55

The bar construction is placed on the working model and the retention clips are positioned on the bar. Undercuts are blocked out with wax and auto-polymerizing acrylic resin is poured over the bar and clip construction (see fig. 57). Care is taken to make sure that the sides of the clips are free from the acrylic resin. This will facilitate their activation and adjustment. The acrylic resin plate is tried on the patient to verify fit and contours.



fig. 56



fig. 57

Prosthetic management after abutment connection

Sculpturing

A 2 mm space is left between the skin and acrylic plate at the back of the prosthesis. The skin must have access to air in order to prevent irritation due to moisture accumulation.

The wax ear is then softened and positioned onto the acrylic plate on the patient in order to identify the correct orientation (see fig. 58). The anterior margin of the wax ear should be made very thin.



fig. 58

Mould-making

When the wax ear model has an optimal fit, abutment replicas are placed onto the gold cylinders of the bar construction (see fig. 59).

The bar with the replicas is positioned into the clips on the fitting side of the prosthesis.

The ear and bar are embedded in a mould of plaster stone consisting of three parts (see fig. 60).

The wax is then removed from the mould by using boiling water (see fig. 61).



fig. 59

Bonding procedure

Before silicone is placed into the mould, the acrylic plate must be prepared in the following way to achieve a strong bond between acrylic/silicone (see fig. 62):

1. The surface is roughened with a stone.
2. The roughened surface is cleaned with acetone.
3. A primer is applied in two thin layers and allowed to dry.
4. The prepared acrylic plate is placed onto the bar.

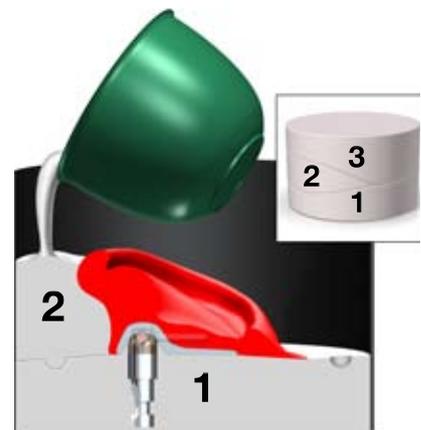


fig. 60

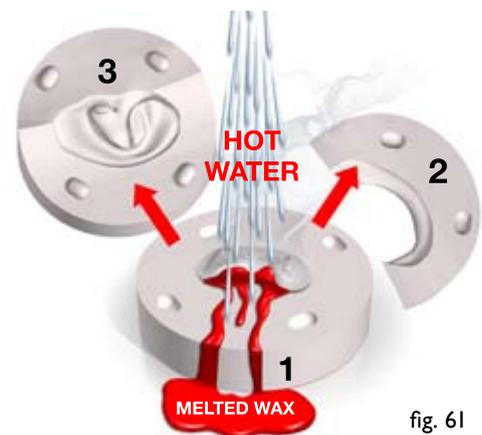


fig. 61

Prosthetic management after abutment connection

Silicone making

The silicone is mixed with colour pigments to match the skin tones of the patient. A catalyst is added according to the manufacturers' recommendation. As much internal coloration as possible is made to achieve a lifelike prosthesis (see fig. 62).

When the silicone has polymerized, the prosthesis is carefully removed from the mould and trimmed (see fig. 63). The prosthesis is tried on the patient to evaluate retention, fit, and colour (see fig. 64).

Extrinsic tinting is applied if necessary (see fig. 65).

The prosthesis is delivered to the patient with instructions for care of the prosthesis and skin.



fig. 62



fig. 63

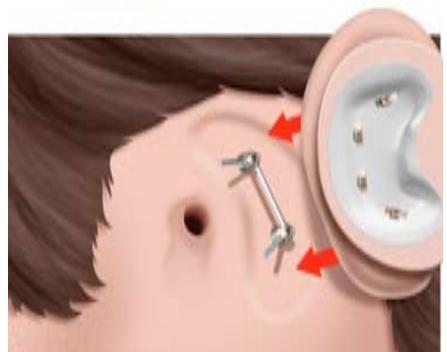


fig. 64



fig. 65

Cleaning and sterilization guidelines

The devices shall be reprocessed in accordance with established local routines for surgical instruments at the hospital clinic. Cochlear gives the following recommendations:

WARNINGS	Do not exceed 137°C (278,6°F)
Limitations on reprocessing	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage.
INSTRUCTIONS	
Containment and transportation:	It is recommended that the instruments are reprocessed as soon as is reasonably practical following use. If the reprocessing is delayed the instruments should be submerged into disinfectant solution to prevent drying. It is not recommended to use aldehydes, such as glutaraldehyde and formaldehyde, as disinfectors for instruments that are not properly cleaned.
Preparations for cleaning:	<p>Before cleaning the following instruments should be disassembled. Small parts/screws can remain in the small box in the cassette during washing and be assembled afterwards.</p> <ul style="list-style-type: none"> • Fixture Mount short Unigrip • Dermatome • Torque wrench • Surgical wrench <p>The Torque wrench and the Surgical wrench should be disassembled according to the instructions in their "Instructions for Use". The wrenches should be completely dismantled and all inner and outer surfaces should be visibly cleaned.</p>
Cleaning: Automated	<p>All reusable surgical instruments, including instruments with plastic parts, can be automatically cleaned combined with thermal disinfection:</p> <p>Equipment: Automatic standard approved washer-disinfector.</p> <p>Detergent: Low alkaline detergent recommended from the manufacturer of the washer-disinfector.</p> <p>Final rinsing phase/disinfection stage: 85-93°C (185-199.4°F) for 1-3 minutes.</p> <p>Water quality: Processed water or according to the hospitals procedure.</p> <p>When unloading the washer-disinfector, check the narrow parts on the instruments for complete removal of visible soil. If necessary repeat cycle or use manual cleaning.</p>

Cleaning and sterilization guidelines

<p>Cleaning: Manual</p>	<p>All other surgical instruments, including instruments with plastic parts, can be manually cleaned:</p> <p>Equipment: Interdental brush soaked with detergent solution. Items that can be submersed under water should be cleaned and brushed under water in order to avoid aerolisation spray. If additional cleaning is necessary, put the instrument in a manual ultrasonic bath.</p> <p>Detergent: All commonly used low alkaline detergents for surgical instruments.</p> <p>Initial pre-rinsing phase: Rinse in cold water: The temperature should not exceed 35°C (95 °F) in order to prevent the blood from coagulating.</p> <p>Final rinsing phase: Rinse carefully in hot water until the instruments are free from all detergent solution.</p> <p>Water quality: Processed water or according to the hospitals procedure.</p>
<p>Chemical Disinfection:</p>	<p>Before the manual cleaning if risk for infection, otherwise after the manual cleaning. It is not recommended to use aldehydes, such as glutaraldehyde and formaldehyde, as disinfectors for instruments that are not properly cleaned.</p> <p>Disinfectants: All commonly used disinfectants for surgical instrument or alcohol (ethanol: 70 %, or isopropanol: 45 %) with additive of surfactants.</p> <p>Let the instruments soak in the disinfectant solution for at least 10 minutes.</p>
<p>Drying:</p>	<p>Automatic: Let the instruments dry in the washer-disinfector if drying is included as a part of the washer-disinfector cycle. Do not exceed 137°C (278.6 °F).</p> <p>Manual: Dry each item with a clean lint free towel or let it air dry under controlled conditions.</p> <p>Place the instruments into the appropriate instrument organizer or the instrument cassette before sterilization.</p>
<p>Maintenance, Inspection and Testing:</p>	<p>All instruments: Visually inspect for damage and wear.</p> <p>Where instruments form part of a larger assembly, check assembly with mating components.</p> <p>For the Torque wrench and the Surgical wrench: apply a small quantity instrument lubricant to joints.</p>

Cleaning and sterilization guidelines

<p>Packaging:</p>	<p>Packaging materials, which fulfil the requirements in accordance with EN 868, should be used.</p> <p>Singly: Individual items can be packaged in heat sealable pouches. The choice of sterilization temperature should follow the packaging material manufacturers' recommendation. Ensure that the pack is large enough to contain the instruments without stressing the seals.</p> <p>In sets: The instrument cassette, loaded with the instruments, shall be packaged in a double layer of sterilization wrap using the appropriate method.</p>							
<p>Sterilization:</p>	<p>Steam sterilization with saturated steam under pressure is recommended for all surgical instruments, the surgical organizer and the instrument cassette. The sterilization parameters should be validated in accordance with EN 554.</p> <p>Equipment: Steam steriliser, which fulfils the requirements in accordance with EN 285 (large sterilizers) or EN 13060 (small sterilizers). The process intended for use should be validated in accordance with EN 554.</p> <p>Sterilant: Saturated steam. Do not exceed 137°C (278.6 °F) with restriction to the product materials.</p> <p>Drying: According to the performance of the autoclave, carefully check that the instruments are dry before storing.</p> <table border="1" data-bbox="579 1245 1428 1346"> <tr> <td data-bbox="579 1245 887 1294">Temperature:</td> <td data-bbox="887 1245 1139 1294">134 °C (273.2 °F)</td> <td data-bbox="1139 1245 1428 1294">121 °C (249.8 °F)</td> </tr> <tr> <td data-bbox="579 1294 887 1346">Holding time, minimum:</td> <td data-bbox="887 1294 1139 1346">3 minutes</td> <td data-bbox="1139 1294 1428 1346">15 minutes</td> </tr> </table>		Temperature:	134 °C (273.2 °F)	121 °C (249.8 °F)	Holding time, minimum:	3 minutes	15 minutes
Temperature:	134 °C (273.2 °F)	121 °C (249.8 °F)						
Holding time, minimum:	3 minutes	15 minutes						
<p>Storage:</p>	<p>Sterilized and packed articles should be stored in a controlled area where they are protected from dust, moisture and large temperature changes.</p>							

The instructions provided above have been validated by the medical device manufacturer as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed, using the equipment, materials and personnel available at the processing facility, achieves the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Implantmed Sterilisation guidelines

Sterilisation guidelines for the W&H Implantmed drill unit can be found in the Instructions For Use that came with the drill unit.

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