

Treatment and Surgery Guide

Cochlear™ Vistafix® 3 System

A BONE ANCHORED PROSTHETIC SOLUTION

Hear now. And always



This publication sets forth detailed recommended procedures for using Cochlear™ 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 when and as required.

Cochlear™ accepts no responsibility for any adverse outcomes if used with products not recommended by Cochlear. Close cooperation in an interdisciplinary team is essential for a successful outcome. Hands-on surgical workshops are available from Cochlear. Contact your local Cochlear office for details.

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Acknowledgements

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Note :

- Images in this guide are not to scale
 - Not all products are available in all markets. Product availability is subject to regulatory approval in the respective markets.
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Introduction

Since 1979, the Cochlear™ Vistafix® bone anchored facial prosthetic solution has proven successful for thousands of patients worldwide. The Cochlear Vistafix system* – which combines titanium implants, abutments, and retention components for prostheses – has yielded excellent results for patients with craniofacial defects due to congenital conditions, trauma or cancer surgery.¹

The Vistafix system builds on the technology of the Brånemark system providing a means of offering permanent and secure retention for facial prosthesis. The long-term predictability and success of such treatment is based on the creation of an active bond between the implant and the surrounding bone tissue -a process known as osseointegration.

The use of a precise implantation technique and attention to detail in soft tissue management is of utmost importance for a successful outcome and for a reaction-free implant site. This material offers guidance needed for performing the surgical procedure and fitting the prosthesis. In order to obtain optimal results, surgeons, prosthodontists, anaplastologists and technicians should work in close collaboration, which should continue during the follow-up period.

*The Vistafix 3 System consists of:

Cochlear Vistafix VXI300 Implant (Vistafix 3 Implant)

Cochlear Vistafix VXA300 Abutment (Vistafix 3 Abutment)



Preparations

Preliminary examination and consultation

A thorough examination of the defect tissue bed should be performed and aetiology of the defect should be determined: congenital, trauma or tumour surgery. Make sure that the patient has realistic expectations of the Vistafix treatment. 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. Multidisciplinary collaboration between for example maxillofacial surgeons, plastic surgeons and anaplastologists/prosthetists is always essential if optimal results are to be achieved.

External ear

Congenital and trauma patients

In order to achieve the best aesthetic result, auricular remnants are often removed. It is, however, important that the patient makes this decision and is aware that this removal is irreversible.

Tumour patients

For patients undergoing auriclectomy, a pre-surgical impression could facilitate future prosthetic procedures. In addition, specific surgical issues such as position of the tragus, lining the tissue bed with a hairless, split thickness skin graft etc., should be discussed.

For tumour surgery, Vistafix implants may be inserted at the time of surgery in order to shorten the rehabilitation time. The patient's age 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 that may adversely affect the aesthetic contours, or make it more difficult for the patient to attach or remove the prosthesis..

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.

Treatment planning

One-stage surgery vs. two-stage surgery

The surgeon will decide to follow either the one-stage or two-stage procedure. This decision is based on several factors including the type of defect, the thickness and quality of the cortical bone as well as the patient's age. Generally, one-stage surgery is recommended for auricular patients with good bone quality and thickness greater than 3mm and the two-stage surgery for patients with compromised or soft bone, irradiated bone, thin bone and special-needs patients (e.g., mentally or physically compromised) as well as orbital or nasal defects.

One-stage surgery	Two-stage surgery
Selection criteria	Selection criteria
Auricular defects Good bone quality and thickness > 3mm	Orbital and midface defects Compromised or soft bone Irradiated bone Bone thickness < 3 mm In conjunction with other surgery Special-needs patients (e.g., mentally or physically compromised)

The timing of the second stage of surgery depends on the thickness and quality of the bone encountered at stage one. The poorer the bone quality, the longer the time between stage one and two. As age and/or bone thickness increase, the time between the first and second stage surgeries may decrease.

Note :

- In the US and Canada, the Vistafix implant is indicated for children aged five years and older.

Irradiated tissue²⁻⁴

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 should 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 should receive 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 and a cover screw placed in the implant. However, the osseointegrated implants can be left in place under intact skin.

Placing sleeper implants

Since there is a slightly higher rate of implant loss in children, placing a sleeper implant is recommended in order to reduce the time between loss of an implant and restored possibility to wear the prosthesis. Sleepers are also recommended if the patient needs any special preparations for surgery, such as HBO or other anaesthetic-related considerations.

Treatment schedule

One-stage procedure	
Implant installation and abutment connection	
SURGICAL FOLLOW-UP	TIME AFTER SURGERY
Change dressing and remove sutures, if healed	1 week
Remove final dressing	2-3 weeks
Clean the implant area	Daily by patient
Check by treatment team	3 weeks
MAKING AND FITTING THE PROSTHESIS	
Make an impression of the defect area	3-6 weeks after surgery given that the soft tissue is sufficiently healed
Fabricate the prosthesis	3-4 days

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

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Two-stage procedure	
First stage: Implant installation	
SURGICAL FOLLOW-UP	TIME AFTER 1 ST SURGERY
Remove sutures, if healed	1 week
Osseointegration period	3-6 months
Second stage: Abutment connection	
SURGICAL FOLLOW-UP	TIME AFTER 2 ND SURGERY
Change dressing and remove sutures, if healed	1 week
Remove final dressing and healing cap	2-3 weeks
Clean the implant area	Daily by patient
Post-surgery check by treatment team	2-6 weeks depending on healing
MAKING AND FITTING THE PROSTHESIS	
Make an impression of the defect area	2-6 weeks after surgery
Fabricate the prosthesis	3-4 days

Measuring implant stability

Resonance frequency analysis (RFA) can supply clinically relevant information about the state of the implant-bone interface at any stage of the treatment or follow-up examinations. The measurement is performed with a small SmartPeg, which acts as a transducer attached to the implant or abutment. For more information about the Osstell device and SmartPeg, please visit www.osstell.com. Studies indicate that implants with high and increasing implant stability quotient (ISQ) values are successfully integrated. At the same time, low and decreasing ISQ values may be a sign of ongoing implant failure and/or marginal bone loss.⁵

Selecting the implant site

The position of the implants should be selected in collaboration with the anaplastologist and/or prosthetic team for the best aesthetic and functional outcome. The implant sites should be carefully marked, using a thin needle or surgical ink, down to the bone while the patient is sitting and the face can still be easily seen. The location of specific anatomical landmarks such as the linea temporalis, suprameatal spine, foramen mastoideum etc., is often helpful. Anatomical variations due to congenital malformation and prior surgery should be considered.

To obtain a good depth for the auricular prosthesis the retention bar should be located under the anti-helix part of the prosthesis; therefore the implants should also be located directly under the anti-helix (Fig. 1).

Two implants are normally sufficient for satisfactory retention. Three implants may however be needed for optimal retention while using magnets (Fig 2). A third implant can also be used as a sleeper implant in children or patients with irradiated bone.

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 patient's left side, the positions are at 4 o'clock and 1.30 (Fig. 3a). On the right side the corresponding positions are at 8 o'clock and 10.30 (Fig. 3b). The distance between the implants should be at least 15 mm to facilitate cleaning around the abutment.

Preparations for surgery

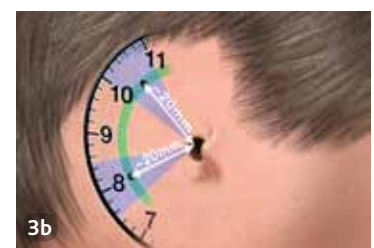
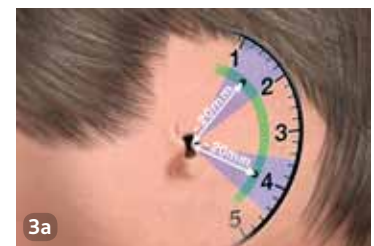
The operating room should be prepared as for any other implant surgical procedure, where all instruments are available, functional and sterile.

Prepare the patient as for any surgical procedure, i.e., shave if needed and sterilise the incision area.

Local or general anaesthesia can be used for adult patients. General anaesthesia is most commonly used when children undergo Vistafix surgery.

Note :

- Only sterile products designed for the VXI300 implant system should be used together.
- All sterile products are for single use only. Do not use products with damaged packaging or which are past their expiration date (Fig. 4).
- The peel-open pack inside the sterile product box acts as the sterile barrier. The plastic ampoule is only a container for the sterile product (Fig. 5). Inside the plastic ampoule, a titanium casing holds the product. The product should only be picked up by the relevant instrument.
- A set of all sterile products should always be available, as one-stage surgery may change to two-stage surgery. It is also recommended that for each component, an extra should be available in case it is dropped.



Component selection

Auricular prostheses

The most common abutment lengths for auricular prostheses are 3.5 and 4.5 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 abutments, longer abutments may be necessary. When a one-stage surgical procedure is planned, it is recommended to always have cover screws available during surgery in case bone quality is softer than anticipated and a two-stage procedure is required instead.

It is recommended that you always keep additional components for a 3 mm implant insertion available during surgery in case bone thickness is less than expected.

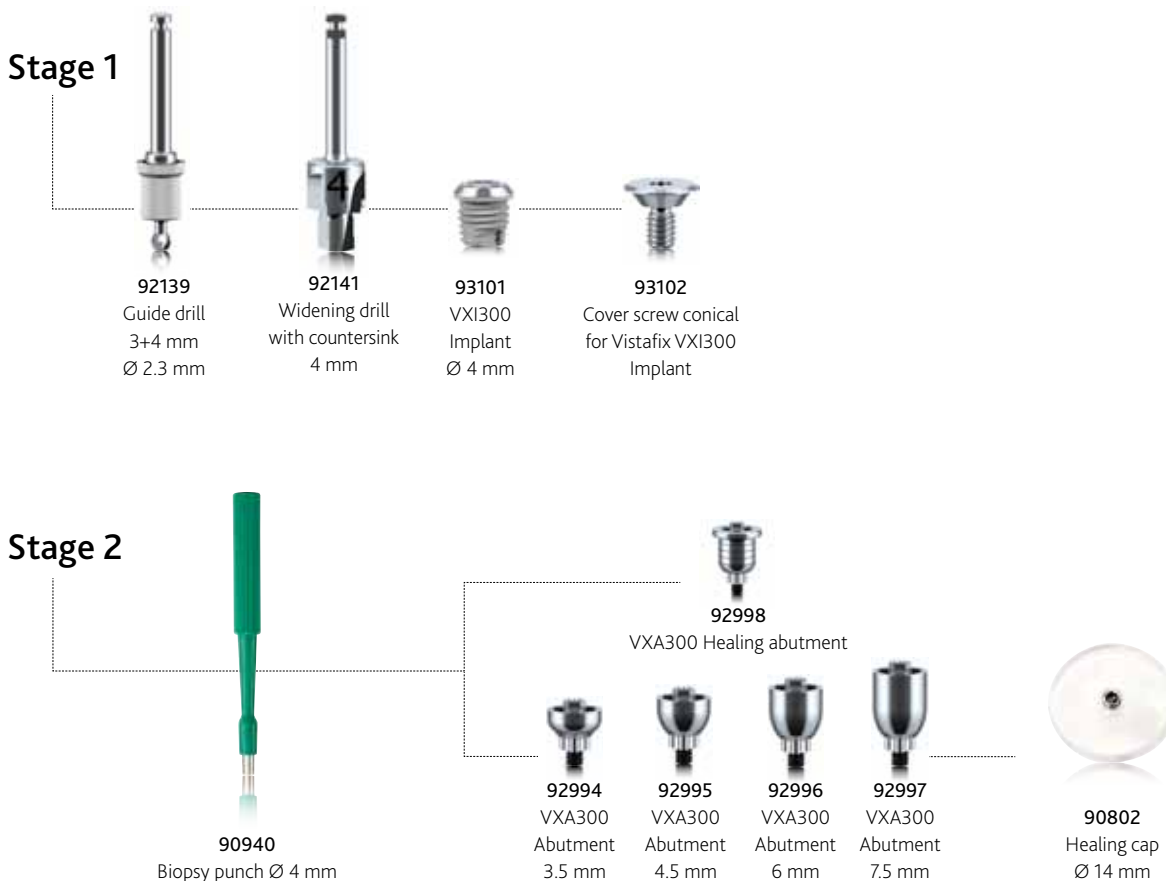
Orbital and midface prostheses

For orbital and midface prostheses a two-stage procedure is recommended. The unique situation will determine the selection of both implants and abutments. The case should be carefully planned with anaplastologists and experienced clinicians. It is in general recommended to use a 4 mm implant when bone volume allows and place sleeper implants with cover screws in irradiated or soft bone.

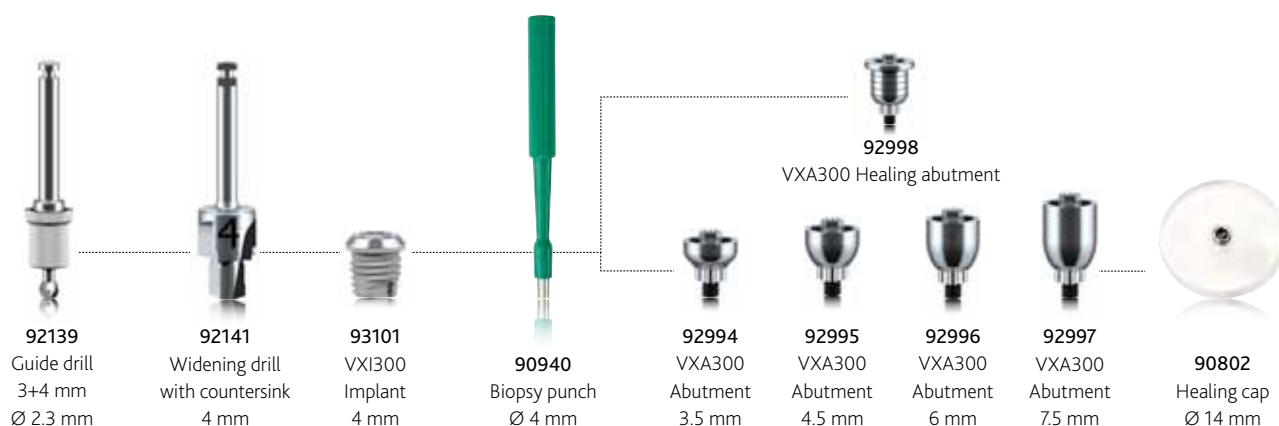
Note:

- Avoid long cantilever forces.
- Cochlear Vistafix VXA300 is contraindicated for patients with insufficient bone quality and quantity and in cases where flangeless implants are needed.

Typical set up for Vistafix two-stage surgery (4 mm)



Typical set-up for Vistafix one-stage surgery (4 mm)



Bar or Magnet retention

Bar construction

Where possible, a bar construction with clips is preferable due to the stronger retention force of the clips compared to the magnets. Magnetic components need to be removed during MRI scanning. For most auricular prostheses it is possible to choose a bar construction.

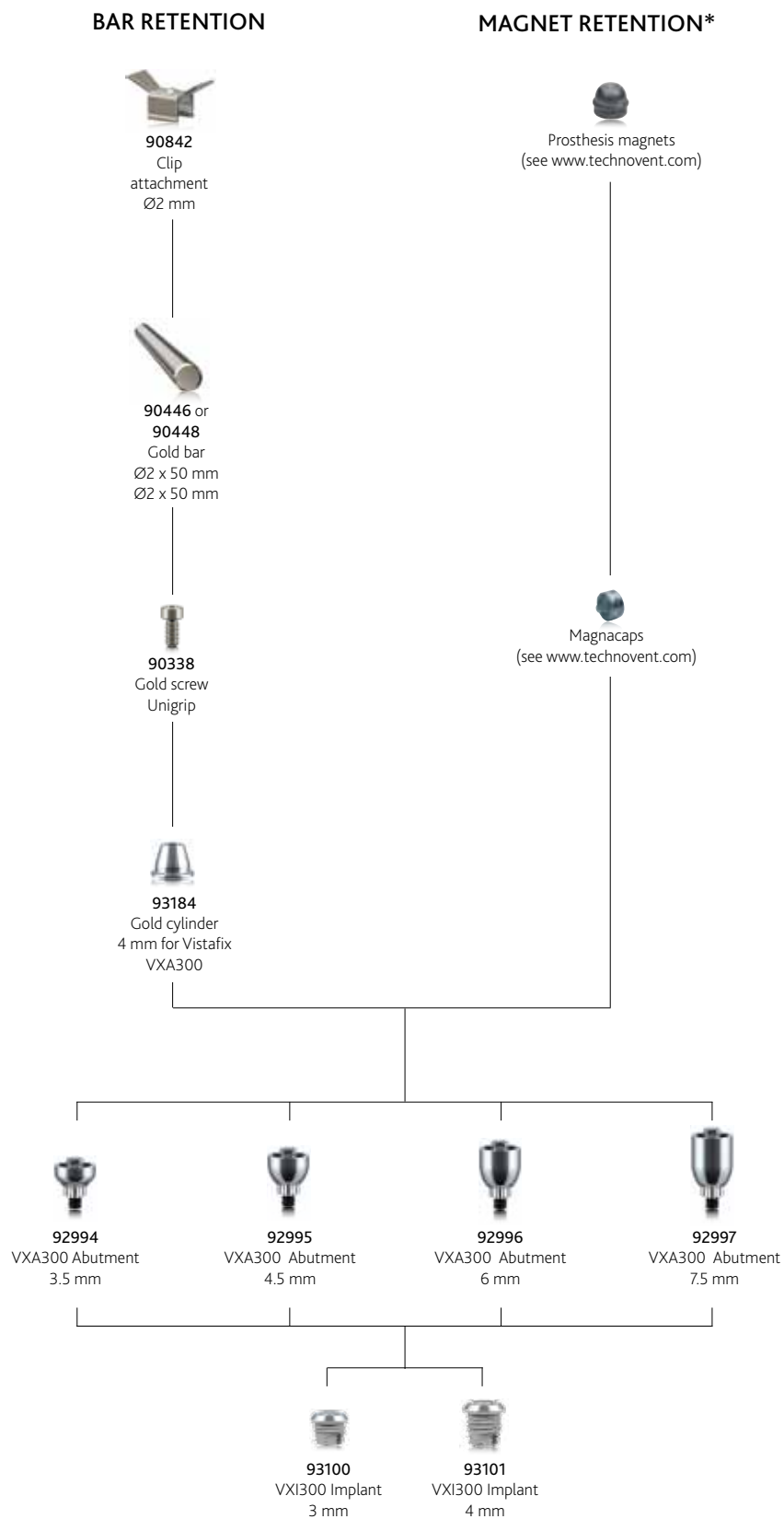
Magnetic attachment

In cases where space is very limited, where cleaning under the bar would be difficult, or where the patient has reduced motor skills, a magnetic attachment* can be a better solution. If magnets are used, a magnacap attached to an abutment is preferable, 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. Magnabutments are a contraindication to MRI. After removal of the magnabutments it is safe to perform MRI.

Bar construction	Magnets
Silicone	Silicone
Acrylic plate	Acrylic plate
Clips	Magnet*
Bar	Magnacap*
Gold cylinder	Magnabutment*
Abutment	Abutment
Implant	Implant



























*See www.technovent.com

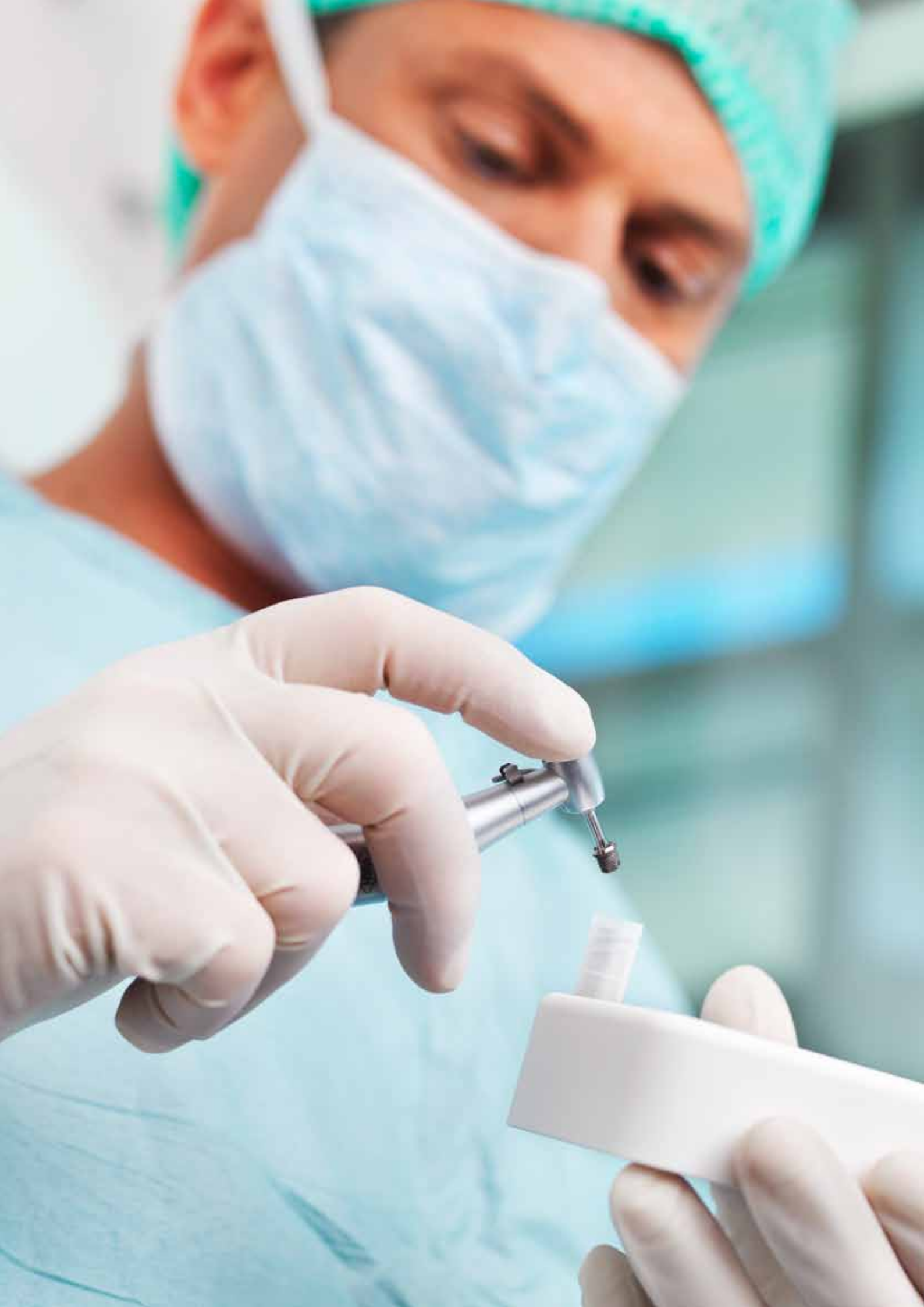
Retention component guide



*See www.technovent.com

Instrument & component guide

	PATIENT COMPONENTS	ASSOCIATED INSTRUMENTS
VXI300 Implants	 <p>93100 3 mm</p>  <p>93101 4 mm</p>	<p>Insertion</p>  <p>92142 Implant inserter</p> <p>Manual insertion</p>  <p>92143 Multi wrench with ISO adapter</p>
Cover screw	 <p>93102 Cover screw conical for Vistafix VXI300 Implant</p>	 <p>90469 Screwdriver Unigrip 95 mm</p>  <p>90459 Screwdriver Unigrip 20 mm</p>
VXA300 Abutments	 <p>92994 3.5 mm</p>  <p>92995 4.5 mm</p>  <p>92996 6 mm</p>  <p>92997 7.5 mm</p>	<p>Tightening</p>  <p>92143 Multi wrench with ISO adapter</p>  <p>90397 Machine screwdriver abutment</p> <p>Counter torque</p>  <p>93183 Counter torque wrench for Vistafix VXA300</p>
Healing cap / abutment	 <p>90802 Healing cap Ø 14 mm</p>  <p>92998 VXA300 Healing abutment</p>	<p>Healing cap</p>  <p>90469 Screwdriver Unigrip 95 mm</p> <p>Healing abutment</p>  <p>90459 Screwdriver Unigrip 20 mm</p>  <p>92143 Multi wrench with ISO adapter</p>  <p>90397 Machine screwdriver abutment</p>  <p>93183 Counter torque wrench for Vistafix VXA300</p>
Additional instruments	 <p>91116 Drill indicator for WS-75 and Osscora</p>  <p>90381 Machine screw-driver Unigrip 25 mm</p>  <p>90944 Raspatorium</p>  <p>90943 Dissector</p>	 <p>Osscora surgical set</p> <p>The unit has dedicated programs for each step of Vistafix surgery. Program two (high speed, 2000 rpm) is for drilling and the third and final program (low speed, 15 rpm) is for implant placement.</p>



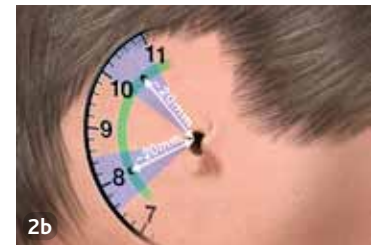
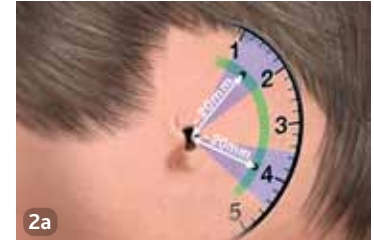
Vistafix one-stage surgery

This section describes a typical Vistafix one-stage surgical procedure.

In the one-stage procedure, implant, abutment and healing cap, or alternatively implant and healing abutment, are placed at the same time.

1. Prepare the site

- The position of the implants should be selected in collaboration with the anaplastologist and/or prosthetic team for the best aesthetic and functional outcome.
- The implant sites should be carefully marked, using a thin needle or surgical ink, down to the bone. The surgeon should use a template, prepared by the anaplastologist, to mark the implant sites prior to the surgical procedure.
- To obtain a good depth for the auricular prosthesis the retention bar should be located under the anti-helix part of the prosthesis; therefore the implants should also be located directly under the anti-helix (Fig. 1).
- 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 patient's left side, the positions are at 4 o'clock and 1.30 (Fig. 2a). On the right side the corresponding positions are at 8 o'clock and 10.30 (Fig. 2b). The distance between the implants should be at least 15 mm to facilitate cleaning around the abutment.



2. Make the incision

- Make an incision approximately 10 mm behind the implant site. Perform a sharp dissection down to the periosteum. When the periosteum is exposed, a cruciate incision is made (Fig. 3) in the periosteum at each implant site. Raise the edges with skin hooks.

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Note: Electrocoagulation should be used with care in order to minimise tissue trauma.
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3. Drill with the guide drill

Note:

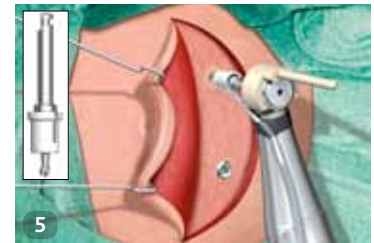
Drilling and placing the implant are generally done in one sequence. It is recommended to start with the inferior implant due to the higher likelihood of air cells in the area. Section 3-5 in this guide illustrate the drilling and placement of the superior implant.

Be certain to drill at an angle perpendicular to the bone surface. The drill indicator facilitates correct drill orientation and should be used during drilling and implant placement.

- Set the drill unit to the high-speed setting: 2000 rpm with coolant (program 2 for the Osscora surgical set) (Fig. 4).
- Begin drilling with the guide drill and 3 mm spacer (Fig. 5).
- While drilling, move the burr up and down and slightly enlarge the hole to ensure visual inspection, and that the coolant reaches the tip of the drill. Cooling is critical, as an osteocyte will die after 1 minute at 42°C.
- Check the bottom of the hole repeatedly for bone, both visually and with the dissector (Fig. 6).
- If the bone has adequate thickness, remove the white spacer on the guide drill and continue drilling to a depth of 4 mm (Fig. 7). If, however, soft tissue is encountered when drilling with the white spacer, drilling should be terminated and the procedure completed with the 3 mm components.

Note :

- Observe the quality and quantity of the cortical bone and spongiosa air cells during initial penetration. Proceed with care to avoid penetrating the wall of the sigmoid sinus or damaging the dura mater.



4. Drill with the widening drill

The next step is to widen the hole to the correct diameter.

- Keep the drill unit on the high-speed setting: 2000 rpm with coolant (program 2 for the Osscora surgical set) (Fig. 4).
- Use either a 3 or 4 mm widening drill, depending on the depth reached with the guide drill (Fig. 8).
- Move the widening drill up and down during drilling to ensure that the coolant reaches the tip of the drill. Only use up and down movements, do not make the hole larger than the actual drill size.
- Use the dissector to remove bone chips frequently from the drill flutes.
- When reaching the bone surface, use the widening drill to create a small countersink in the bone (maximum 0.5 mm) (Fig. 9, 10). The widening drill has been designed with a hard stop to allow early recognition of when countersinking is complete. However, take care not to press too hard, especially in soft bone to avoid excessive countersinking.

Note :

- Do not use the guide drill after the widening drill since the guide drill stop diameter is smaller than the site.
- The blunt tip of the widening drill minimises the risk of damage to tissue at the bottom of the hole.
- Be very careful not to over-widen the section that will contain the implant threads or you risk losing initial implant stability.
- 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.

5. Place the implant

- Set the drill to the torque setting (program Implant installation for the Osscora surgical set) (Fig. 11).
- Set the torque limit to suit the quality of the bone.

BONE QUALITY	SUGGESTED TORQUE
Compact bone	40-50 Ncm
Compromised or soft bone	20-30 Ncm

- Open the ampoule upright by unscrewing the lid so the bottom section can be placed in the holder on the component tray (Fig. 12).
- Pick up the implant using the implant inserter (Fig. 13). It is easier to fit the implant inserter in the implant if the drill motor is running.
- Place the implant without irrigation until the first threads of the implant are well within the bone. Irrigation at this time would result in cooling solution being compressed into the marrow spaces in the bone by the implant (Fig. 14).
- Once in the bone, continue implant placement with irrigation.
- The Osscora surgical set stops automatically and beeps when the preset torque is reached.
- Carefully lift up on the handpiece to remove the implant inserter from the implant.

Note :

- The implant must not come into contact with anything other than the ampoule and implant inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.
- If the implant enters the hole incorrectly, press reverse on the drill unit and unscrew the implant. Then find the correct angle and re-insert the implant. This should be attempted only once.
- If the drill stops early - before the flange of the implant is seated in the countersunk bone - reverse one thread and increase the torque with the +/- on the control panel of the drill system.
- Be very careful not to loosen the implant through a lever arm effect. The risk of this occurring is quite high if the implant site consists of a thin layer of bone combined with loose marrow and cancellous bone tissue.
- When placing the implant in hard bone, slight pressure may need to be applied during the initial insertion.
- The implant can be inserted manually with the multi wrench and the implant inserter. Rotate the whole multi wrench shaft clockwise ("IN" facing upwards) (Fig. 15).



6. Reduce subcutaneous tissue

There are three prerequisites for establishing and maintaining a reaction-free skin-penetration. First, the skin surrounding the implants should be hairless to help keep the implant site clean. Second, all subcutaneous tissue must be removed in order to minimise skin mobility in relation to the implant. Third, the periosteum should be carefully trimmed to its innermost layer, and the flap then sutured down to the periosteum.

Attention to detail during skin preparation is vital to avoid tissue and hair regrowth, which can increase the risk of irritation or wound healing problems around the abutment.

- Scrape hair from the flap (Fig. 16).
- It is useful to use skin hooks to raise the edges of the flap when removing the subcutaneous tissue. Remove all subcutaneous tissue with hair follicles under the skin flap to minimise skin mobility in relation to the implant (Fig. 17).
- Remove subcutaneous tissue at the periphery of the flap holding the blade parallel to the skin (Fig. 18). When the depth of the tissue is about 6 mm it is advisable to remove soft tissue approximately 20 mm outwards from the flap edges. The thicker the subcutaneous tissue is, the larger the reduction should be.
- Trim any remaining periosteum that can be raised down to the innermost layer to avoid regrowth of tissue and to avoid mobility. However, the periosteum must remain intact to maintain the blood supply required for healing (Fig. 19).
- Suture the flap down to the periosteum at the base of the skin flap (Fig. 20).

7. Close and suture

- Suture the edges around the flap down to the periosteum in order to hold the tissue in place.
- Lay the flap back, stretch it out and suture it down (Fig. 21).



8. Connect healing abutments or abutments

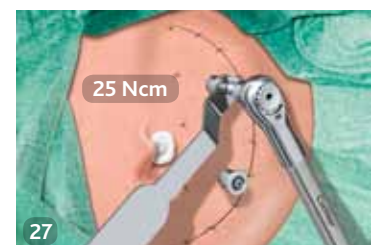
Healing abutments can be used during the initial healing stage and the permanent abutments can be placed at a later date at the clinic. This enables the tissue to heal properly before the length of the final abutment is chosen.

Permanent abutments may be placed at this stage as an alternative to healing abutments. The tissue will alter during healing, and this could mean that a different height abutment may be needed before making the final prosthesis.

The healing abutments and abutments come with an abutment holder (white plastic) to make placement easier (Fig. 22).

- Punch holes through the skin exactly over the positions of the implants with a 4 mm biopsy punch (Fig. 23).
- Pick up the healing abutment or abutment from the sterile packaging and place it into the implant. Make sure the abutment is correctly fitted in the tri-lobe connection of the implant otherwise the abutment screw cannot be tightened.
- Hand-tighten the screw partially to secure it (Fig. 24). The abutment holder is then removed by snapping it off of the abutment.
- Set the drill to the torque setting (program Implant installation for the Osscora surgical set) and set the torque limit to 25 Ncm (Fig. 25).
- Finalise the tightening of the abutment screw to 25 Ncm with the machine screwdriver abutment and the counter torque wrench (Fig. 26).
- For manual tightening, tighten the abutment screw to 25 Ncm using the multi wrench ("IN" facing upwards) with the machine screwdriver abutment (Fig. 27, 28). Use the counter torque wrench as counter torque.

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Note: The counter torque wrench should always be used to avoid counter torque forces on the implant.
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9. Place the dressing and healing caps

Always place the dressing on the skin to ensure skin-bone contact and to prevent a haematoma formation.

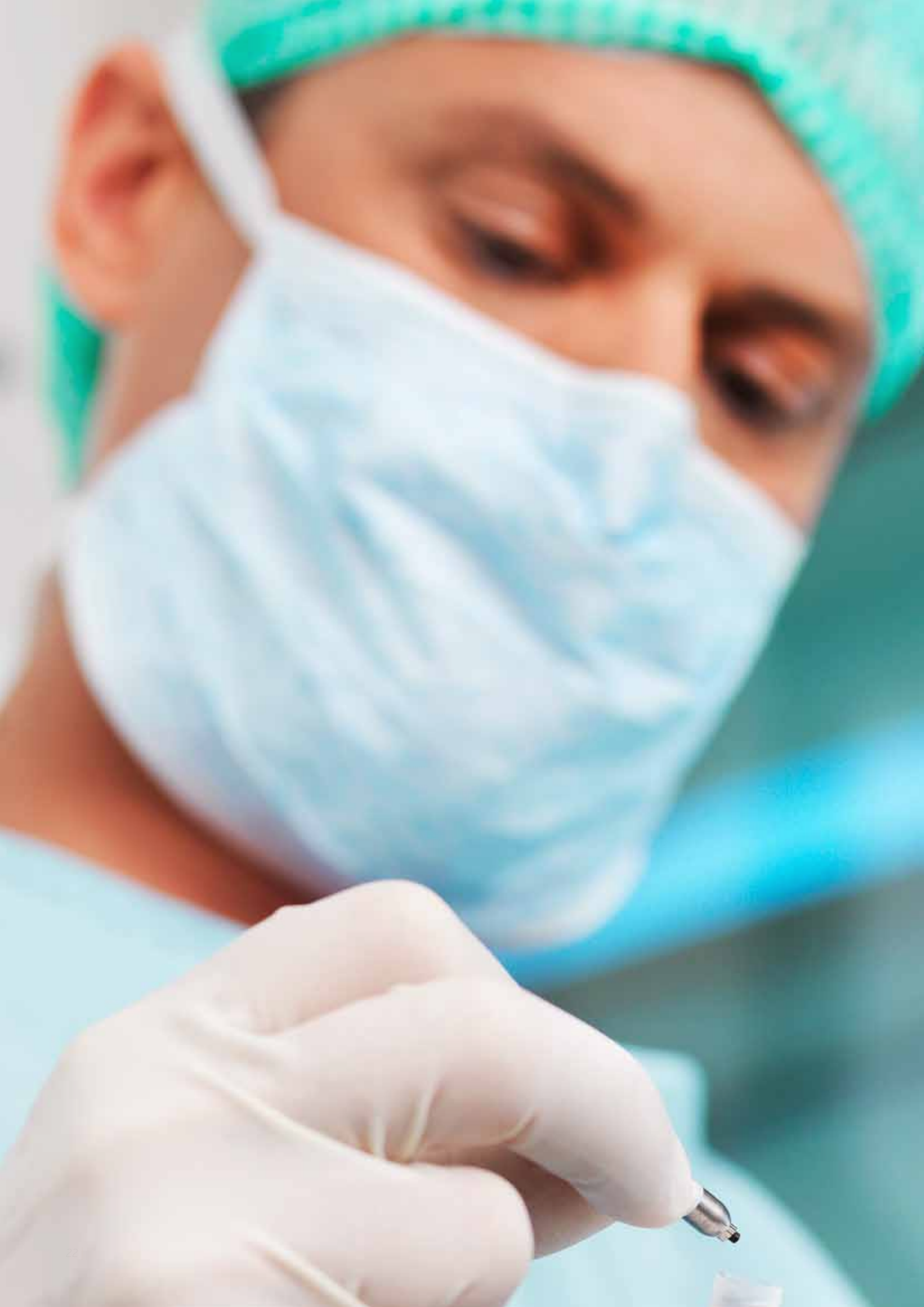
9a. Healing abutments

- If healing abutments are used, place a dressing around the healing abutments (Fig. 29).
- Place a mastoid dressing (Fig. 33).

9b. Abutments

- Place the healing cap on the abutment and hand-tighten the screw using the Unigrip screwdriver (Fig. 30).
- The healing cap can be placed either before or after the dressing depending on the dressing type (Fig. 31, 32).
- Place a mastoid dressing (Fig. 33).





Vistafix two-stage surgery

This section describes a typical Vistafix two-stage surgical procedure.

When using the two-stage procedure, auricular tags and remnants are often left in place at the first stage and not removed until the second operation. Subcutaneous tissue reduction is often carried out at stage two of the procedure to ensure successful implantation prior to the tissue reduction.

First stage of the two-stage surgery

1. Prepare the site

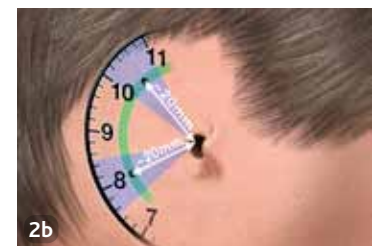
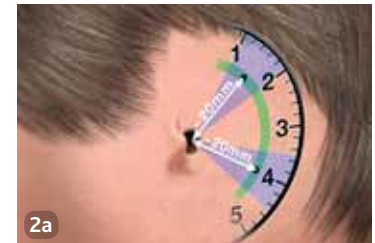
- The position of the implants should be selected in collaboration with the anaplastologist and/or prosthetic team for the best aesthetic and functional outcome.
- The implant sites should be carefully marked, using a thin needle or surgical ink, down to the bone. The surgeon should use a template, prepared 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; therefore the implants should also be located directly under the anti-helix (Fig. 1).
- 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 patient's left side, the positions are at 4 o'clock and 1.30 (Fig. 2a). On the right side the corresponding positions are at 8 o'clock and 10.30 (Fig. 2b). The distance between the implants should be at least 15 mm to facilitate cleaning around the abutment.

Midface and orbital prosthesis

- When placing implants in the orbit and in the midface it is very 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 jeopardised. It is also important to consider the position and orientation of the implant in order to get a good retention and to facilitate cleaning around the abutment.⁶



2. Make the incision

- Make an incision approximately 10 mm behind the implant site. Perform a sharp dissection down to the periosteum. When the periosteum is exposed, a cruciate incision is made (Fig. 3) in the periosteum at each implant site. Raise the edges with skin hooks.

.....
Note: Electrocoagulation should be used with care in order to minimise tissue trauma.
.....

3. Drill with the guide drill

Note:

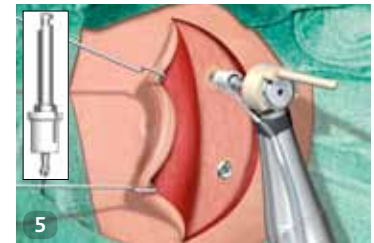
Drilling and placing the implant are generally done in one sequence. It is recommended to start with the inferior implant due to the higher likelihood of air cells in the area. Section 3-5 in this guide illustrate the drilling and placement of the superior implant.

Be certain to drill at an angle perpendicular to the patient and bone surface. The drill indicator facilitates correct drill orientation and should be used during drilling and implant placement.

- Set the drill unit to the high-speed setting, 2000 rpm with coolant (program 2 for the Osscora surgical set) (Fig. 4).
- Begin drilling with the guide drill and 3 mm spacer (Fig. 5).
- While drilling, move the burr up and down and slightly enlarge the hole to ensure visual inspection, and that the coolant reaches the tip of the drill. Cooling is critical, as an osteocyte will die after 1 minute at 42°C.
- Check the bottom of the hole repeatedly for bone, both visually and with the dissector (Fig. 6).
- If the bone has adequate thickness, remove the white spacer on the guide drill and continue drilling to a depth of 4 mm (Fig. 7). If, however, soft tissue is encountered when drilling with the white spacer, drilling should be terminated and the procedure completed with the 3 mm components.

Note :

- Observe the quality and quantity of the cortical bone and spongiosa air cells during initial penetration. Proceed with care to avoid penetrating the wall of the sigmoid sinus or damaging the dura mater.



4. Drill with the widening drill

The next step is to widen the hole to the right diameter.

- Keep the drill unit on the high-speed setting, 2000 rpm with coolant (program 2 for the Osscora surgical set) (Fig. 4).
- Use either a 3 or 4 mm widening drill, depending on the depth reached with the guide drill (Fig. 8).
- Move the widening drill up and down during drilling to ensure that the coolant reaches the tip of the drill. Only use up and down movements, do not make the hole larger than the actual drill size.
- Use the dissector to remove bone chips frequently from the drill flutes.
- When reaching the bone surface, use the widening drill to create a small countersink in the bone (maximum 0.5 mm) (Fig. 9, 10). The widening drill has been designed with a hard stop to allow early recognition of when countersinking is complete. However, take care not to press too hard, especially in soft bone to avoid excessive countersinking.

Note :

- Do not use the guide drill after the widening drill since the guide drill stop diameter is smaller than the drilled hole.
- The blunt tip of the widening drill minimises the risk of damage to tissue at the bottom of the hole.
- Be very careful not to over-widen the section that will contain the implant threads or you risk losing initial implant stability.
- 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.

5. Place the implant

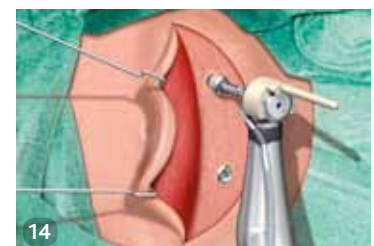
- Set the drill to the torque setting (program Implant installation for the Osscora surgical set) (Fig. 11).
- Set the torque limit to suit the quality of the bone.

BONE QUALITY	SUGGESTED TORQUE
Compact bone	40-50 Ncm
Compromised or soft bone	20-30 Ncm

- Open the ampoule upright by unscrewing the lid so the bottom section can be placed in the holder on the component tray (Fig. 12).
- Pick up the implant using the implant inserter (Fig. 13). It is easier to fit the implant inserter in the implant if the drill motor is running.
- Place the implant without irrigation until the first threads of the implant are well within the bone. Irrigation at this time would result in cooling solution being compressed into the marrow spaces in the bone by the implant (Fig. 14).
- Once in the bone, continue implant placement with irrigation.
- The Osscora surgical set stops automatically and beeps when the preset torque is reached.
- Carefully lift up the handpiece to remove the implant inserter from the implant.

Note :

- The implant must not come into contact with anything other than the ampoule and implant inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.
- If the implant enters the hole incorrectly, press reverse on the drill unit and unscrew the implant. Then find the correct angle and re-insert the implant. This should be attempted only once.
- If the drill stops early - before the flange of the implant is seated in the countersunk bone - reverse one thread and increase the torque with the +/- on the control panel of the drill system.
- Be very careful not to loosen the implant through a lever arm effect. The risk of this occurring is quite high if the implant site consists of a thin layer of bone combined with loose marrow and cancellous bone tissue.
- When placing the implant in hard bone, slight pressure may need to be applied during the initial insertion.
- The implant can be inserted manually with the multi wrench and the implant inserter. Rotate the whole multi wrench shaft clockwise ("IN" facing upwards) (Fig. 15).



6. Place the cover screw

Inserting a cover screw protects the internal threads of the implant from tissue and bone overgrowth during the healing phase.

- Place and hand tighten the cover screw using the screwdriver Unigrip 95 mm (Fig. 16).
- Suture down the periosteum with resorbable sutures over the implant.
- Suture the flap into position (Fig. 17).
- Place a mastoid dressing.

Second stage of the two-stage surgery

1. Reduce subcutaneous tissue

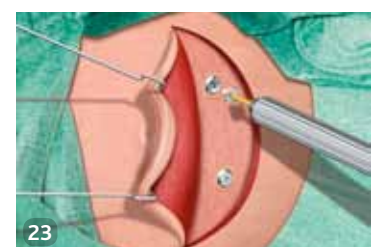
There are three prerequisites for establishing and maintaining a reaction-free skin-penetration. First, the skin surrounding the implants should be hairless to help keep the implant site clean. Second, all subcutaneous tissue must be removed in order to minimise skin mobility in relation to the implant. Third, the periosteum should be carefully trimmed to its innermost layer, and the flap then sutured down to the periosteum.

Attention to detail during skin preparation is vital to avoid tissue and hair regrowth, which can increase the risk of irritation or wound healing problems around the abutment.

- Scrape hair from the flap (Fig. 18).
- It is useful to use skin hooks to raise the edges of the flap when removing the subcutaneous tissue. Remove all subcutaneous tissue with hair follicles under the skin flap to minimise skin mobility in relation to the implant (Fig. 19).
- Remove subcutaneous tissue at the periphery of the flap holding the blade parallel to the skin (Fig. 20). When the depth of the tissue is about 6 mm it is advisable to remove soft tissue approximately 20 mm outwards from the flap edges. The thicker the subcutaneous tissue is, the larger the reduction should be.
- Trim any remaining periosteum that can be raised down to the innermost layer to avoid regrowth of tissue and to avoid mobility. However, the periosteum must remain intact to maintain the blood supply required for healing (Fig. 21).
- Suture the flap down to the periosteum at the base of the skin flap.

2. Remove the cover screw

- Punch holes exactly over the cover screws with a biopsy punch Ø4 mm (Fig. 22).
- Lift up the flap and remove the cover screws using the screwdriver Unigrip 95 mm (Fig. 23).
- Suture the edges around the flap down to the periosteum, to hold the tissue in place.
- Lay the flap back, stretch it out and suture it down (Fig 24).



3. Connect healing abutments or abutments

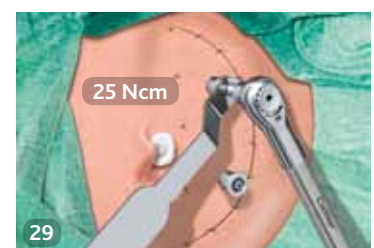
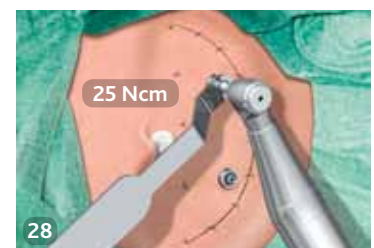
Healing abutments can be used during the initial healing stage and the permanent abutments can be placed at a later date at the clinic. This enables the tissue to heal properly before the length of the final abutment is chosen.

Permanent abutments may be placed at this stage as an alternative to healing abutments. The tissue will alter during healing, and this could mean that a different height abutment may be needed before making the final prosthesis.

The healing abutments and abutments come with an abutment holder (white plastic) to make placement easier (Fig. 25).

- Pick up the healing abutment or abutment from the sterile packaging and place it into the implant. Make sure the abutment is correctly fitted in the tri-lobe connection of the implant otherwise the abutment screw cannot be tightened.
- Hand-tighten the screw partially to secure it (Fig. 26). The abutment holder is then removed by snapping it off of the abutment.
- Set the drill to the torque setting (program Implant installation for the Osscora surgical set) and set the torque limit to 25 Ncm (Fig. 27).
- Finalise the tightening of the abutment screw to 25 Ncm with the machine screwdriver abutment and the counter torque wrench (Fig. 28).
- For manual tightening, tighten the abutment screw to 25 Ncm using the multi wrench ("IN" facing upwards) with the machine screwdriver abutment (Fig. 29, 30). Use the counter torque wrench as counter torque.

Note: The counter torque wrench should always be used to avoid counter torque forces on the implant.



4. Place the dressing and healing caps

Always place the dressing on the skin to ensure skin-bone contact and to prevent a haematoma formation.

4a. Healing abutments

- If healing abutments are used, place a dressing around the healing abutments (Fig. 31).
- Place a mastoid dressing (Fig. 35).

4b. Abutments

- Place the healing cap on the abutment and hand-tighten the screw using the Unigrip screwdriver (Fig. 32).
- The healing cap can be placed either before or after the dressing depending on dressing type (Fig. 33, 34).
- Place a mastoid dressing (Fig. 35).



Aftercare

Dressing guidelines

1 day post-op	5-7 days post-op	10-14 days post-op
<ul style="list-style-type: none">• Remove the mastoid dressing.• Leave the dressing and healing cap in situ.• Ensure that the patient does not allow any water to come in contact with the wound for 5–7 days after surgery.	<ul style="list-style-type: none">• Remove the healing cap.• Carefully remove the dressing.• Remove the sutures (if applicable).• Gently clean the wound with water and gauze.• Gently remove any dried blood or debris.• Assess the wound site and treat accordingly.• If healed, no further dressing is required.• Apply a topical antibiotic to the incision and abutment area.• Provide the patient with aftercare instructions and emphasise the importance of daily cleaning.	<ul style="list-style-type: none">• If necessary, repeat relevant steps as in the previous visit.• If the wound site has not healed, consult a wound care specialist.

Patient aftercare instructions

The prosthesis can be worn for all normal activities including swimming and sports. It may be advisable to remove it and wear some protection, for example a headband, over the bar if you take part in contact sports. The prosthesis should be removed when sleeping.

The average lifetime of prostheses is about 18 months but if the patient takes good care of the prosthesis, it can last two years or longer.

Good hygiene is critical to maintaining normal usage of the Vistafix prosthesis. Patients who are unable to clean the skin around the abutment need help from their family or caregivers.

In case of infection, cleaning routines should be checked. If infection persists, it may be controlled by applying a course of topical antimicrobial cream to the skin surrounding the abutment. Topical antimicrobial cream may be administered by wrapping ointment-soaked ribbon gauze around the abutment when positioning the healing cap.



Daily care – the abutment area

The area around the abutment should be cleaned on a daily basis to avoid debris build up. A soft cleaning brush (Fig. 1), or non-alcohol wipes (such as baby wipes) can be used around the base of abutment. The soft cleaning brush (obtained from the clinic) should be changed every 3 months. Cleaning this area is most easily done when the patient takes a bath or takes a shower as plenty of warm water and soap on the area will help to soften any crust that may have developed around the base of the abutment. Any mild soap or shampoo will do, but some users have found anti-dandruff shampoo particularly effective.

Care of the prosthesis

The prosthesis should be cleaned regularly by gently brushing with soap and water. Abrasive powders and bleaches should be avoided. The edges of this type prosthesis are very thin so care must be taken when handling it. In the early stages following the fitting of the prosthesis there should be regular visits to the outpatient clinic to make sure that all is well. The patient should be instructed to contact a Vistafix health professional if experiencing any persistent irritation, soreness or inflammation around the abutment.

Hair Care

Patients who wish to have their hair permed or coloured should remove the prosthesis and protect the abutments with a small amount of cotton wool and cling film secured with a small elastic band. This will prevent the solution or dye irritating the tissue around the abutment. The hair should not be permed or coloured until the surgical site is fully healed.

Adjustment of the abutment

Occasionally the abutment may become slightly loose and need tightening. In case of persistent soft tissue complications the abutment may need to be replaced. The procedure takes a few minutes and local anaesthetic is seldom required.

For abutments that need adjusting, the multi wrench with ISO adapter, machine screwdriver abutment and counter torque wrench are required. (Fig 1). Insert the ISO adapter in the multi wrench and then insert the machine screwdriver abutment in the ISO adapter (Fig. 2).

When adjusting the abutment, always use the counter torque wrench with the multi wrench to minimise the load on the implant.

Tighten the abutment

- Tighten the abutment screw to 25 Ncm using the multi wrench ("IN" facing upwards) with the machine screwdriver abutment (Fig. 3). Use the counter torque wrench as counter torque.

Replace the abutment

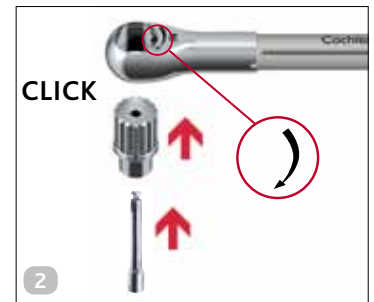
- Loosen the abutment screw using the multi wrench ("OUT" facing upwards) with the machine screwdriver abutment and the counter torque wrench. The ISO adapter can be used as a small handheld screwdriver.
- Clean the skin thoroughly. If needed, let the area heal 1–2 weeks. A cover screw can be used to cover the implant during healing. If needed, punch a new hole with a biopsy punch Ø4 mm.
- Pick up the abutment from the sterile packaging and place it into the implant. Make sure the abutment is correctly fitted in the tri-lobe connection of the implant; otherwise the abutment screw cannot be tightened.
- Hand-tighten the screw partially to secure it (Fig. 4). The abutment holder is then removed by snapping it off the abutment.
- Tighten the abutment screw to 25 Ncm using the multi wrench ("IN" facing upwards) with the machine screwdriver abutment and the counter torque wrench (Fig. 3).

Note :

- The VXA300 Abutments are only compatible with VXI300 Implants (Fig. 4).
- The previous series abutments with hexagonal couplings should be tightened to 20 Ncm (see torque table below).
- The previous series abutments with hexagonal couplings are compatible with the previous Vistafix implants with hexagonal connections. Be sure to fit the abutment onto the hexagon head of the implant (Fig. 5).

Torque table

PRODUCTS	TIGHTENING TORQUE
VXA300 Abutments	25 Ncm
Previous series abutments with hexagonal coupling	20 Ncm



Complications & troubleshooting

The success rate for Vistafix® surgery is very high, however, unexpected situations, both intra-operatively and postoperatively, may occur. Below is a list of potential complications and recommendations for handling them. Importantly, the patient must be informed of all complications related to safety and effectiveness prior to surgery.

The regulation of medical devices requires the manufacturer to report adverse events to the appropriate authority. Should such an incident occur, notify your local Cochlear™ office or its official distributor as soon as possible.

Complications during surgery

The implant becomes stuck during insertion

This can occur if the implant alignment is incorrect. Set the drill unit to reverse mode before unscrewing the implant. Find the correct alignment and re-insert the implant. If the same happens again, select a new implant site nearby.

The implant continues to rotate when the flange is down

This happens most often when dealing with compromised and soft bone, and when the torque is set too high in relation to the quality of the bone. Prepare a new implant site at least 5 mm from the first site and then place the implant with lower torque.

Exposure of dura mater and perforation of the sigmoid sinus

Although rare, a mild CSF or blood leak can occur during guide hole drilling. If this occurs, it is a low pressure system that can be sealed easily. For a patient with good bone volume, place the implant to seal the leak. If the bone is too thin, choose a new implant site at least 5 mm from the original site (as close as possible as long as the two sites don't intersect), after sealing the leak with soft tissue or bone wax.

Subdural haematoma

This condition, caused by venous bleeding under the dura, is rare and typically slow developing. It is not often identified during surgery, but is more likely caused by direct trauma and will develop gradually over time and give general neurological symptoms. Should this occur, a CT or MRI can be used to verify the diagnosis. Treat this condition according to general practice.

Postoperative soft tissue complications

Inflammation and infection around the abutment

Poor or excessive personal hygiene is a common reason for skin irritation, but irritation could also be due to movement of the skin caused by a too thick soft tissue layer, a loose abutment, or insufficient osseointegration.

If the skin around the abutment becomes inflamed, thoroughly clean the entire implant site and, if appropriate, apply antimicrobial ointment/cream. Provide the patient with the appropriate aftercare instructions.

Persistent soft tissue complications

When patients have a persistent problem around the abutment, remove the abutment and clean the skin thoroughly. Perform a culture before providing the appropriate antimicrobial and anti-inflammatory treatment. A steroid ointment can also be used. Allow the area to heal for 1–2 weeks before placing a new abutment.

Skin overgrowth

If the skin grows back to its original thickness, skin reduction surgery is indicated. In some patients (predominantly male teenagers) an inflammatory reaction may occur and result in complete overgrowth of the abutment by soft tissue. Treatment with topical steroid cream or a steroid injection may be considered.^{7,8}

Persistent skin overgrowth

Use a longer abutment if a patient has persistent regrowth of the subcutaneous tissue, which is common in patients with very thick skin.

Keloids

In the case of keloids that do not subside over time, place a silicone disc over the keloid and keep pressure on the silicone disc for 7–10 days.

Skin flap necrosis

Skin flap necrosis can occur within the immediate postoperative period. Simply remove any necrotic tissue and apply a mild antibiotic ointment. Systemic antibiotic treatment is an alternative. Major or even total flap necrosis will often heal, but this could take several months. A skin graft is seldom required.

Postoperative numbness - parasthesia

Postoperative numbness after tissue reduction may occur. Usually this will disappear after a few months. For those who have had significant amounts of subcutaneous tissue removed this may be permanent.

Postoperative bone tissue complications

Implant loss

Potential causes of the failure of osseointegration include lack of adequate bone quantity/quality, trauma, infection, generalised diseases and surgical complications.

Bony overgrowth

The potential for a bony overgrowth around the implant increases in implanted children. Removal of some bone at the time of soft tissue revision surgery will allow maximum clearance between the skin and the lateral surface of the abutment.

Pain when touching the abutment

If the patient experiences pain when touching the abutment, there may be an increased risk of implant loss. In most cases, the loose implant can be removed and another one placed in adjacent bone. In others, the implant must be removed and the defect then carefully curetted and filled with blood coagulates. In most cases adjacent bone is available and suitable for the placement of another implant.

Bone infection leading to osteonecrosis

This is seen almost exclusively in patients with previously irradiated implant sites. It is most easily avoided by administering hyperbaric oxygen (HBO) before and after surgery and by striving for minimal tissue damage during surgery.³

Special Considerations

MRI and magnetic fields

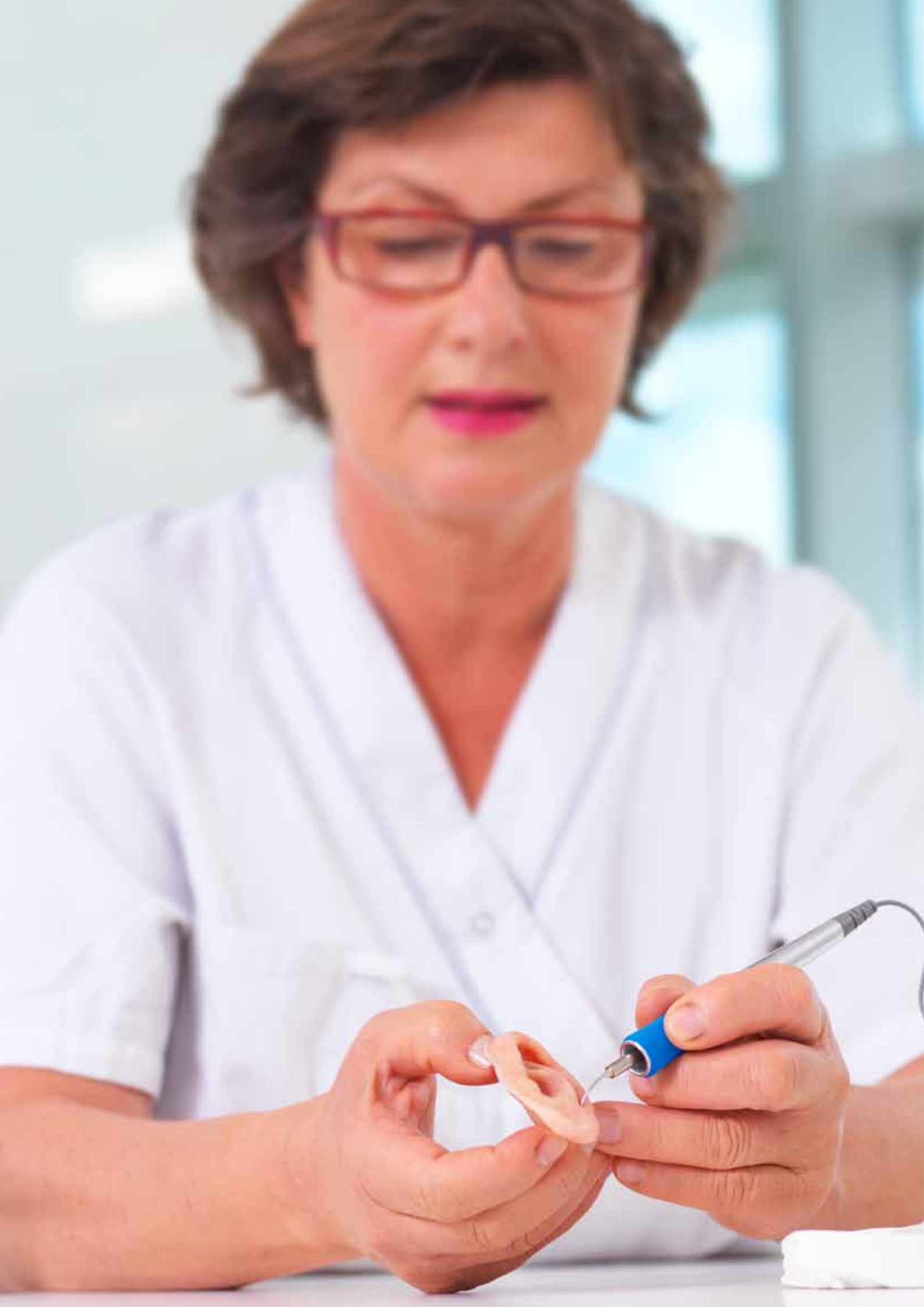
Be certain to caution patients about procedures such as MRI and any others involving magnetic fields. Patients fitted with facial or auricular prostheses can undergo an MRI, as long as the prosthesis and the bar construction, any fixation magnets, magnabutments or magnacaps attached to the implants are removed prior to the procedure. This will eliminate the risk of implant loss and minimise the artifacts. The implant itself and the abutment are not ferromagnetic and will not cause any problems for the patient during an MRI ⁹⁻¹¹ (up to 3T).

Radiation therapy

If a patient already has implants placed, and is scheduled for radiation therapy around the implant areas, the abutments should be removed but implants could be left in place to allow healing of the site before radiation is performed. A cover screw can be used to cover the implant until the abutment is replaced.

Sporting activities

It is important to educate the parents and caregivers about the need for helmets and other safety precautions during sporting activities to minimise traumatic events. Traumatic implant loss can still occur across all age groups.





Making and fitting the prosthesis

Prosthetic instruments

The instruments shown below are needed for prosthetic and lab procedures



92143 Multi wrench with ISO adapter



93183 Counter torque wrench for Vistafix VXA300



90397 Machine screwdriver abutment



90469 Screwdriver Unigrip 95 mm AND/OR 90459 Screwdriver Unigrip 20mm



90381 Machine screwdriver Unigrip 25 mm AND/OR 90380 Machine screwdriver Unigrip 20 mm

Prosthetic instrument guide

PATIENT COMPONENTS		ASSOCIATED INSTRUMENTS		
Gold cylinder and gold screw				
	93184 Gold cylinder 4 mm for Vistafix VXA300 Abutment			
				
	90338 Gold screw Unigrip for gold cylinder			90380 Machine screwdriver Unigrip 20 mm
LABORATORY COMPONENTS		ASSOCIATED INSTRUMENTS		
Impression copings & guide pins				
	93192 Impression coping squared for Vistafix VXA300			
				
	90469 Screwdriver Unigrip 95 mm			90459 Screwdriver Unigrip 20 mm

1. Make an impression of the implant site

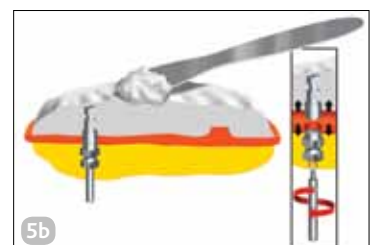
- Clean the skin around the abutments carefully.
- Check the abutment screw and tighten if needed (Page 32.)
- Pack the external ear canal opening with gauze to prevent penetration by the impression material.
- Attach impression copings with guide pins to the abutments (Fig. 1).
- Apply a thin layer of flexible, light body silicone around the copings and over the entire area required for making the prosthesis (Fig. 2).
- Apply a second layer of solid or heavy body impression silicone to secure the impression copings in position and to stabilise the impression (Fig. 3).



2. Prepare a working model

- When the silicone material has set in the impression of the implant site, remove the impression carefully.
- Unscrew the guide pins from the abutments and carefully remove the impression (Fig 4).
- Attach abutment replicas to the impression copings by using the guide pins (Fig 5a).
- Cast the impression with the copings and replicas in dental stone (Fig. 5b).
- Let the dental stone dry, and separate the impression from the cast by loosening the guide pins.

An exact working model of the patient's defect area has now been fabricated, with the abutment replicas in exactly the same position, direction and height as the skin-penetrating abutments.



3. Make an impression of the opposite ear (when possible)

In order to facilitate the sculpturing of the prosthesis, an impression of the opposite ear can be taken. This is then used as a comparison during sculpturing of the prosthetic ear (Fig. 6).

- Apply impression silicone around the opposite ear and let it cure.
- Remove the impression and pour dental stone in the impression.

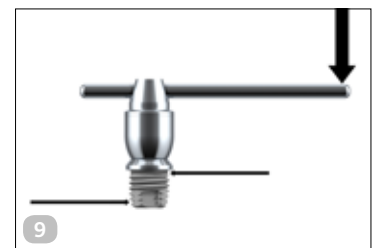
4. Design the framework

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

- Place the gold cylinders on the abutment replicas of the working model (Fig. 7). Tighten the gold screws to 10 Ncm using the multi wrench with ISO adapter and the machine screwdriver Unigrip.
- Cut and grind a Ø2 mm gold alloy bar so that it stretches between and beyond the abutments with an appropriate shape (Fig. 8).

.....
Note: It is desirable to place the bar under the anti-helix part of the ear (Fig. 8). In order to minimise torque on the implants the bar should not extend more than 8–10 mm beyond the abutments (Fig. 9).
.....

- Attach the bar to the gold cylinders with sticky wax or acrylic (Fig. 10).
- Remove the bar construction from the working model and embed it in the investment in preparation for soldering (Fig. 10).
- Solder the bar to the gold cylinders. A welding technique can also be used.
- Check the bar construction carefully on the working cast and on the patient for a perfect fit.



5. Make the acrylic plate

- Place the bar construction on the working model and position the retention clips on the bar.
- Make an undercut block with wax to prevent the finished acrylic plate from touching the skin. Make sure that the sides of the clips are protected by wax from the acrylic resin. This will facilitate their activation and adjustment (Fig. 11).
- Pour auto-polymerizing acrylic resin over the bar and clip construction (Fig. 12). Make the acrylic plate as flat as possible so as not to compromise the shape of the prosthesis.

.....
TIP: Reinforce the plate with fibres to minimise the risk of breakage.
.....

- Try the acrylic resin plate on the patient to verify fit and contours.



6. Sculpt and fit the wax model

- Sculpt a wax model of the prosthesis (Fig. 13).

.....
TIP: If available, use the impression of the opposite ear as a guide when sculpting the wax model or scan the opposite plaster ear and reverse.
.....

- Soften the wax model and position the wax ear onto the acrylic plate on the patient (Fig. 14).
- Make sure that there is a 2 mm space between the skin and the back of the plate/prosthesis. The skin must have access to air in order to prevent irritation due to moisture accumulation.
- Check the model's fit from all angles with the patient's mouth open and closed, moving their face and standing up/sitting down.
- The anterior margin of the wax ear should be made very thin.



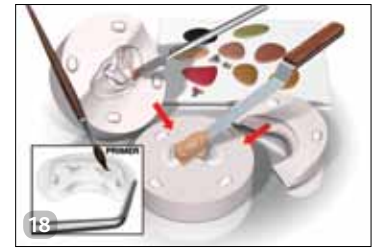
7. Make the plaster mould

- Place abutment replicas onto the gold cylinders of the bar construction and position the bar and abutment replicas into the clips of the acrylic plate (Fig. 15).
- Fabricate a three-piece plaster mould (Fig. 16). Embed the fitting side of the wax ear and bar into plaster. Separate the plaster with a separating agent. Make key holes in the mould to ensure correct fit between the parts. Pour the second part of the mould up to the middle of the helix. Use the separation agent and make key holes and pour the third part of the mould with plaster.
- Once the mould is set, separate the mould pieces by using hot/boiling water (Fig. 17).

8. Prime the acrylic plate

Before silicone is placed into the mould, the acrylic plate must be prepared to achieve a strong bond between acrylic and silicone:

- Roughen the surface with a stone.
- Clean the roughened surface with acetone.
- Apply a primer in two thin layers and allow it to dry.
- Place the prepared acrylic plate onto the bar.



9. Mix the silicone and pack the mould

- Mix silicone with colour pigments to match the skin tone of the patient (Fig 18). A catalyst must be added according to the manufacturer's recommendation.
- "Paint" the outer layers of the silicone using as much internal coloration as possible to achieve a life-like prosthesis (Fig 18).

.....
TIP: Add fibres to mimic superficial blood vessels.
.....

- Let the silicone polymerize.
- Carefully open the mould and remove the prosthesis. Perform any final trimming that may be necessary (Fig. 19).



10. Final patient fitting

- Try the prosthesis on the patient to evaluate retention, fit, and colour (Fig. 20).

.....
Note: For full retention force, the clip attachment should be activated by carefully compressing the two lamellae.
.....



- Apply extrinsic colouring/tinting if necessary (Fig. 21).
- Deliver the prosthesis to the patient with instructions for taking care of the prosthesis and the surrounding skin.



Cleaning and Sterilisation Guidelines

Reusable instruments

Reprocess all reusable instruments in accordance with the established local routines at the hospital clinic.
Cochlear provides the following recommendations:

 Warnings	Do not exceed 137.0°C (278.6°F)	
Limitations on reprocessing	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear or damage.	
Instructions		
CONTAINMENT & TRANSPORTATION	Reprocess the instruments as soon as possible following use. If reprocessing is delayed, submerge the instruments in a disinfectant solution.	
PREPARATIONS FOR CLEANING	Disassemble the following instruments: Multi wrench.  Caution: The instruments are not validated for cleaning and disinfection in the Baha instrument organiser and must be cleaned and disinfected separately.	
CLEANING: AUTOMATIC	Equipment: Automatic standard approved washer-disinfector. Detergent: Low alkaline detergent as recommended by the manufacturer of the washer-disinfector. Final rinsing phase/disinfection stage: 85.0-93.0°C (185.0-199.4°F) for 1-3 minutes. After washer-disinfection ensure that even narrow parts of instruments are completely free from visible soil. If necessary repeat cycle or use manual cleaning.	
CLEANING: MANUAL	Equipment: Interdental brush soaked with detergent solution. Items that can be submerged in water should be cleaned under water, in order to avoid aerosolisation spray. If additional cleaning is necessary, all instruments can be placed in a manual ultrasonic bath. Detergent: All low alkaline detergents commonly used for surgical instruments. Initial pre-rinsing phase: Rinse in cold water. The temperature should not exceed 35.0°C (95.0°F). Final rinsing phase: Rinse in hot water.	
CHEMICAL DISINFECTION	Before manual cleaning if risk for infection, otherwise after manual cleaning. Disinfectants: All disinfectants commonly used for surgical instruments or alcohol (ethanol: 70%, or isopropanol: 45%) with added surfactants.	
DRYING	Automatic: Dry instruments in the washer-disinfector. Do not exceed 137.0°C (278.6°F). Manual: Dry each item with a clean lint free towel or let it air dry in controlled conditions.	
MAINTENANCE, INSPECTION AND TESTING	Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Where instruments form part of a larger assembly, check assembly with mating components.	
PACKAGING	Use packaging materials that comply with applicable standards such as ISO 11607 and/or EN 868. Individually: In heat sealable pouches. Ensure that the pack is large enough to contain the instruments without stressing the seals. In sets: Place the cleaned instruments in the Baha instrument organiser and pack in a doubler layer of sterilisation wrap.	
STERILISATION	Sterilisation parameters must conform to ISO 17665 or be set by a validation study. Equipment: Steam sterilisers which fulfil the requirements of EN 285 (large sterilisers) or EN 13060 (small sterilisers). The process intended for use should be validated in accordance with ISO 17665. Sterilant: Saturated steam. Do not exceed 137.0°C (278,6°F.)	
TEMPERATURE MINIMUM HOLDING TIME	134.0°C (273.2°F) 3 minutes	121.0°C (249.8°F) 15 minutes
STORAGE	Store sterilised and packed instruments in a controlled environment free from dust, moisture and large temperature changes.	

Hear now. And always

As the global leader in hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. With our hearing solutions, Cochlear has reconnected over 250,000 people to their families, friends and communities in more than 100 countries.

Cochlear is also a leading provider of facial prosthetic solutions, helping people around the world build confidence and active social lives.

Along with the industry's largest investment in research and development, we continue to partner with leading international researchers and hearing professionals, ensuring that we are at the forefront in the science of hearing.

For the hearing impaired receiving any one of Cochlear's hearing solutions, our commitment is that for the rest of their life they will Hear now. And always

REFERENCES

1. Westin T, Tjellström A, Hammerlid E, Bergström K, Rangert B. Long-term study of quality and safety of osseointegration for the retention of auricular prostheses. *Otolaryngology; Head and Neck Surgery*. 1999; 121(1): 133-43.
2. Granström G, Tjellström A. Effects of irradiation on osseointegration before and after implant placement: a report of three cases. 1997; 12(4):547-51.
3. Granström G, Tjellström A, Brånemark PI. Osseointegrated implants in irradiated bone: a case controlled study using adjunctive hyperbaric oxygen therapy. *Journal of Oral and Maxillofacial Surgery*. 1999; 57(5):493-9.
4. Tjellström A, Granström G, Bergström K. Osseointegrated implants for craniofacial prosthesis. In: Weber RS, editor. *Basal and Squamous Cell Skin Cancers of the Head and Neck*. Philadelphia: Williams & Wilkins; 1996.
5. Sennerby L, Meredith N. Implant stability measurements using resonance frequency analysis: biological and biomechanical aspects and clinical implications. *Periodontology*. 2000; 47:51-66.
6. Reisberg D, Habakuk S. Use of a surgical positioner for bone-anchored facial prosthesis. 1997; 12:376-379.
7. Falcone MT, Kaylie DM, Labadie RF, Haynes DS. Bone-anchored hearing aid abutment skin overgrowth reduction with clobetasol. *Otolaryngology; Head and Neck Surgery*. 2008; 139(6):829-32.
8. Ghossaini SN, Spitzer JB. Local steroid injections in the management of skin growth over the abutment in Baha patients. *Otolaryngology; Head and Neck Surgery*. 2009; 141(4):530-2.
9. Devge C, Tjellström A, Nellström H. Magnetic resonance imaging in patients with dental implants: a clinical report. 1997; 12(3):354-9.
10. Fritsch MH, Naumann IC, Mosier, KM. Baha devices and magnetic resonance imaging scanners. *Otology & Neurotology*. 2008; 29(8):1095-9.
11. Arndt S, Kromeier J, Berlís A, Maier W, Laszlj R, Aschendorff, A. Imaging procedures after bone anchored hearing aid implantation. *Laryngoscope*. 2007; 117(10):1815-8.

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