Ponto – The bone anchored hearing system from Oticon Medical

Surgical Manual

The Ponto System
Contents

Introduction ........................................... 3
Patient selection ................................... 4
Pre-operative evaluation and counseling. ... 8
Procedure schedule ................................. 11
Surgical components and instruments ... 12
Cleaning of non-disposable instruments . 15

Patient preparation ............................... 16
Single-stage surgical procedure ............. 17
Healing and aftercare ............................. 25

Two-stage surgical procedure ............... 26
Troubleshooting. ................................ 30
Complications ..................................... 32

Pediatric surgery ................................. 33
Introduction

The Ponto bone anchored hearing system is designed to give patients improved hearing through direct bone conduction. The Ponto sound processor converts sound into vibrations that are transmitted via the abutment and implant through the skull bone directly to the cochlea. In this way the Ponto System works independently of the function of the ear canal and middle ear, which means that any conductive element of the hearing impairment is overcome.

The Ponto system implant components are based on the Brånemark principles for osseointegration. Long term experience from bone anchored hearing implants has been combined with advanced Oticon sound processor technology to create the best possible hearing solution from a surgical as well as audiological point of view.

Before performing implant surgery for a bone anchored sound processor, it is vital that the surgeon and the nursing team have undergone proper training for the procedure. A close collaboration between the surgery and audiology teams throughout the evaluation, treatment and follow-up phase is also necessary. In case of malformations, the reconstructive surgeon may also have valuable input for the best site selection and timing of surgery.

A successful patient outcome is based on thorough planning and carefully performed surgery, focusing on achieving a successful anchorage of the implant in the bone and a problem-free skin penetration. Bone and soft tissues should be handled with great care at all stages of surgery to avoid tissue trauma, and an appropriate period should be left for osseointegration before loading the implant. Reduction of subcutaneous tissue around the skin penetration is probably the most important surgical aspect and should be generous, while being performed with great patience and care.

Note: This manual describes the standard single-stage and two-stage surgical procedures for placing an Oticon Medical bone anchored implant. All patients must be given individual assessment, and the procedure should be adapted to the individual situation where necessary.
Patient selection

Audiological indications for Ponto Pro and Ponto sound processors

Conductive or mixed hearing loss

Patients with conductive or mixed hearing loss, who can still benefit from amplification of the sound, may be candidates for the bone anchored sound processor.

The pure tone average bone conduction threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Studies indicate that patients with an air-bone gap of more than 30 dB (PTA) will benefit significantly from a bone anchored sound processor as compared to an air conduction hearing aid.¹

Treatment benefits

Advantages compared to conventional air conduction hearing aids:

- The sound signals will bypass the conductive loss. This means that less amplification is needed, which has a positive effect on the sound quality.
- The ear canal remains completely open, which means that the situation for patients with ear infections and draining ears can be improved.

Advantages compared to middle ear surgery:

- The bone anchored sound processor can be evaluated by the patient and audiologist before surgery.
- The implantation involves a surgical procedure that is simple, reversible and does not expose the patient to any risk of additional hearing impairment.

Advantages compared to conventional bone conductors:

- Patient comfort is improved as there is no constant pressure against the skull.
- Sound quality is better as there is no attenuation of the signal passing through the skin.
- More discreet

Typical audiogram, mixed hearing loss

Typical audiogram, conductive hearing loss
Single sided deafness
(Unilateral sensorineural deafness)
Patients with a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, and who for some reason do not wish to, or cannot, use an AC CROS, may be suitable candidates for a bone anchored hearing system. In this application the sound processor is placed on the deaf side, picking up sound and transferring it to the patient’s functioning cochlea.

The pure tone average air conduction threshold of the hearing ear should be better than 20 dB HL AC (measured at 0.5, 1, 2 and 3 kHz).

Treatment benefits
Single sided deafness patients may benefit from a bone anchored sound processor in terms of reduced head shadow effect and improved speech intelligibility in noise.²

Advantages compared to a CROS aid:
- The ear canal remains completely open.
- No cables are needed for transmitting the sound to the hearing cochlea.
Pure sensorineural hearing loss in combination with an external otitis that contraindicates the use of an air conduction hearing aid

The pure tone average bone conduction threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Bilateral implants

Bilateral fitting is applicable for most patients with a symmetrical bone conduction threshold. The difference between the left and right sides’ bone conduction thresholds should be less than 10 dB on average (measured at 0.5, 1, 2 and 4 kHz), or less than 15 dB at individual frequencies. Bilateral sound processors produce binaural hearing with improved sound localization and speech recognition in noise.

Head band / Soft band – when implantation is contraindicated

For children who are too young to have an implant placed and for other patients who are not suited for implantation, the sound processor can be used on a soft band or head band. (The soft band is an elastic band with a connection plate.) The sound processor is connected to the head band or soft band and works in a similar way to a conventional bone conductor. Due to the attenuation of the signal through the skin, patients with conductive or mixed hearing loss should then have a pure tone average bone conduction threshold of the indicated ear that is better than or equal to 25 dB HL (measured at 0.5, 1, 2, 3 kHz).

Note: Patient candidates should always be tested with the sound processor on a test band or test rod preoperatively to evaluate the benefit.

Other criteria

A maximum speech discrimination score better than 60% when using a phonetic balanced word list is recommended, but an individual evaluation must always be made based on the patient’s speech discrimination and his or her specific needs.

Common medical background

• Chronically draining ears (external otitis, draining otitis media and radically operated ears) where conventional hearing aids aggravate infection or cause feedback problems, poor wearing comfort or poor sound quality.

• Skin allergies where an ear mold aggravates problems.

• Congenital malformations where ear canals are absent and cannot be restored through conventional surgery.

• Ear canal stenosis or previous ear surgery which makes an ear mold unsuitable.

• Conductive hearing loss due to ossicular disease that cannot be rectified, at all or to a sufficient extent, by surgical correction or conventional hearing aids.

• Sensorineural deafness in one ear and conductive hearing loss in the other, where surgery in the ear with conductive hearing loss is considered too risky.

• Unilateral sensorineural deafness caused by acoustic neuroma surgery, sudden deafness or other factors, and where an AC CROS is not feasible or desired.

⚠️ Warning!

The test band, head band or soft band must not be placed on top of an abutment or bone anchored implant.
Cautions

- It is vital to be able to maintain proper hygiene around the abutment. Factors that affect this ability should be considered, as well as the possibilities of obtaining help to maintain sufficient hygiene, if necessary. In children the responsibility falls on the parents or caregiver.

- Patients with psychiatric disease, immature personality, drug or alcohol abuse, or who are unable to follow instructions or participate in continued follow-ups are unsuitable for treatment with a bone anchored hearing implant. Poor hygiene significantly increases the risk of adverse skin reactions.

- It is important that the patient develops realistic expectations through clear information about the treatment and about what a bone anchored hearing system may do for that individual patient. The patient must be provided with clear information about possible complications, aftercare requirements and precautions for the surgical procedure.

- Sufficient bone depth and bone quality must be present for a successful anchoring of the implant in the bone. The two-stage surgical procedure may be applied for patients with a bone depth of less than 3 mm, by using a modified surgical technique with for example a PTFE membrane. However, the individual assessment of each patient candidate must be carefully done and the surgical procedure performed with great care. Disease, history of irradiation or other factors that may affect the bone quality should always be considered in the individual assessment of the patient. Bone quality should be further examined by the surgeon when preparing the implant site.

- The skin area around the implant site should be prepared to a thin, hairless graft without any subcutaneous tissue, and with gentle slopes from the surrounding thick skin down to this area. The hairless thin skin area should be at least 20 mm in diameter. This is very important since thick skin around the implant makes it difficult for the patient to maintain good hygiene around the skin penetration, and because movement of the skin in relation to the abutment may cause skin irritation.

- The skin condition should always be considered. Patients with psoriasis or diabetic patients have not been reported to have an increased risk of implant loss or skin problems.

Contraindications

- Inability to maintain, or lack of help with maintaining, sufficient hygiene around the abutment.

- Insufficient bone quality or bone thickness that will jeopardize the implant stability in the short or long term. This is for example the case with small children.

- The placement of a bone anchored implant is contraindicated in children below the age of five in the US.

- Patients with poor bone quality or with a bone depth of 3 mm or below are contraindicated for the single stage surgical procedure.

Note: Patients who are not suited or who are too young to receive a bone anchored implant may instead use the sound processor connected to a head band or soft band.
Pre-operative evaluation and counseling

Throughout the evaluation and counseling process it is vital that surgeons and audiologists cooperate closely in order to achieve an optimal patient outcome from both a surgical and audiological perspective.

Evaluation equipment
To demonstrate the sound processor and to evaluate the benefit for the patients, Ponto can be connected to any of the following test accessories:

- Test band – a firm head spring with a connector plate. The test band is used when testing the sound processor for shorter periods, mainly inside the clinic or hospital. The sound processor is clicked onto the connector plate of the test band and the test band is placed around the patient’s head. Make sure that the sound processor does not touch the pinna or hand as this will cause feedback.

- Head band – a softer head spring than the test band. The head band can be used when testing the sound processor during longer periods, for example when the patient is sent home with the sound processor to evaluate the benefits for several days or weeks. It is also suitable for daily use by patients who are unsuitable for implantation but who can gain from using Ponto as a traditional bone conductor. The sound processor and head band are connected in the same way as with the test band (see above).

- Test rod – a connection rod that can be pressed against the head. The test rod is useful for demonstration and testing.

Note: The hand must not touch the sound processor when holding the test rod since this will cause feedback.

⚠️ Warning!
The test band, head band or soft band must not be placed on top of an abutment or bone anchored implant.

The test band and head band contain small parts that may constitute a choking hazard for children or persons of diminished mental capacity, and should not be used by such individuals without adult supervision.

Audiological measurements
Pure tone and speech audiometry are the main measurements used to evaluate candidates for a bone anchored sound processor. The sound processor works independently of the air-bone gap. It is therefore the bone conduction threshold that determines whether the patient is within the Ponto fitting range (see audiological indications).

For a patient candidate with unilateral sensorineural deafness it is recommended that the patient wears Ponto on a head band in daily situations for at least a week to ensure that the sound processor offers the expected benefits.

Counseling
Realistic patient expectations
It is vital that the patient develops realistic expectations through clear information about the treatment and what the Ponto System may do for that individual patient. In most cases a bone anchored sound processor leads to significantly improved sound quality, comfort and speech intelligibility. In some patients, however, this may not be the case. For patients with chronically draining ears, the main benefit may be reduced infection and a dry ear. The patient should be allowed to try the sound processor in different environments and situations, using the test band or head band.
Note: It is important to inform the patient that the sound performance will be further improved once the sound processor is connected to the abutment. The added gain can be expected to improve by 2-15 dB from 1 kHz and upwards after implant insertion, when the sound vibrations no longer have to pass through the skin.

Important information for the patient
It is important that the patient receives clear information about bone anchored hearing implants and sound processors, and about the evaluation and treatment process.

- It may be useful for the patient to see and understand the actual size of the implant and abutment, and that only the small implant part will be placed inside the skull bone.

- It is also important to inform the patient about the treatment process including healing time and the time left for osseointegration before the sound processor can be fitted.

- The patient should understand the importance of maintaining sufficient hygiene around the abutment and what the patient will be required to do to ensure this.

Side selection
Bilateral fitting produces binaural hearing with improved sound localization and speech recognition in noise. For more information, see bilateral implants, page 6.

For patients with a bilateral hearing loss fitted with a single sound processor, the side with the best cochlear function is preferable from an audiological point of view. In cases where it is difficult to determine which side is the best from the audiogram, the test band may help the patient tell which side is the best for placement of the sound processor.

In addition to the audiological aspect, practical considerations, e.g. manual dexterity, cosmetics, hair growth and frequent situations in everyday life should also be considered when choosing the optimal side for implant placement. Telephone usage should be considered, and if the patient frequently drives a car with a passenger, the side facing the passenger may be the best alternative.

Surgical aspects like bone quality, bone thickness and possible future reconstructive outer ear surgery or outer ear prostheses should also be considered when determining the implant positioning.

Healing time before fitting
Before connecting the sound processor to the abutment, 3-6 months should pass after surgery in order not to load the implant during the osseointegration period. During this period the bone anchors to the implant surface. The longer time period should be applied in the case of children and people with insufficient bone thickness or poor bone quality. (The required healing time is estimated by the surgeon during surgery.)
Single-stage or two-stage surgery?
Pre- and peri-operative assessment of the quality and thickness of the patient’s temporal bone is necessary for planning whether the surgery should be performed in one or two stages. If the surgeon determines that the implantation is appropriate for a patient with a thin bone (<3 mm) or poor bone quality, a surgical procedure in two stages with a prolonged osseointegration period (3 to 6 months or above) is recommended.

Single-stage surgery
Single-stage surgery is applied for most patients. In a single-stage surgical procedure the implant and abutment placement, as well as the skin preparation, are carried out in the same procedure. The sound processor is then generally fitted after 3 months of osseointegration.

**Single-stage surgery is recommended for:***
- adult patients with normal bone quality and thickness (≥3 mm), where no complications during surgery are expected.
- children with normal bone quality and a bone thickness above 4 mm (typically 12 years or older) provided that age, development status and other known factors have been considered and found suitable for single-stage surgery.

Two-stage surgery
Patients with expected soft/poor bone quality or thin bone are indicated for a two-stage surgical procedure, with a prolonged osseointegration period of 3 to 6 months or more between the two stages. The implant is placed and a cover screw connected to it in the first surgical procedure. After osseointegration the second procedure is performed, including connection of the abutment and skin preparation.

The exact time required for osseointegration is based on the surgeon’s assessment of the bone depth and quality during the first stage of the surgical procedure. The sound processor can then be fitted after the soft tissue has healed from the second surgery.

**Two-stage surgery is recommended for/when:**
- adult patients with an expected bone depth below 3 mm or expected poor bone quality. (Reasons for expecting poor bone quality or thin bone may for example include disease or history of irradiation.)
- children with a bone thickness below 4 mm, or where age development status or other factors make single-stage surgery unsuitable.
- an implant is placed in association with the removal of an acoustic neuroma.
- contact with the dura mater or the wall of the sigmoid sinus is expected, or if there is any risk of complications.

**Note:** Regardless of surgical technique, the implant must not be loaded during the period of osseointegration.

**Note:** The quality and depth of the bone will be further assessed during the drilling phase of the surgery, to verify or reconsider the choice of surgical procedure and/or to determine the time needed for osseointegration in order to achieve a firm anchorage of the implant before loading.

**Note:** In children a polytetrafluoroethylene (PTFE) membrane may be used to create additional bone for implant anchorage, see pediatric section.
## Procedure schedule

### Single-stage surgery

<table>
<thead>
<tr>
<th>Surgical procedure</th>
<th>Implant with pre-mounted abutment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical follow-up</strong></td>
<td><strong>Time after surgery</strong></td>
</tr>
<tr>
<td>Remove dressing and check implant site. If healed, remove healing cap and sutures and instruct patient on cleaning and aftercare</td>
<td>7-10 days</td>
</tr>
<tr>
<td>If not healed after 7-10 days, repeat step one</td>
<td>14 days</td>
</tr>
<tr>
<td>Osseointegration period</td>
<td>3 months</td>
</tr>
<tr>
<td><strong>Fitting of the sound processor</strong></td>
<td><strong>Time after surgery</strong></td>
</tr>
<tr>
<td>Check the implant, abutment and surrounding skin area</td>
<td>After osseointegration is completed</td>
</tr>
<tr>
<td>Fitting of the sound processor (see Audiological manual)</td>
<td></td>
</tr>
<tr>
<td>Practice connection and disconnecting the sound processor</td>
<td></td>
</tr>
<tr>
<td>Practice managing the sound processor controls</td>
<td></td>
</tr>
<tr>
<td>Explain routines for hygiene and maintenance</td>
<td></td>
</tr>
<tr>
<td>Plan future follow-up appointment frequency</td>
<td></td>
</tr>
<tr>
<td><strong>Routine follow up</strong></td>
<td></td>
</tr>
<tr>
<td>Check sound processor performance</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>Check implant and abutment stability</td>
<td></td>
</tr>
<tr>
<td>Check condition of skin penetration area</td>
<td></td>
</tr>
</tbody>
</table>

### Two-stage surgery

<table>
<thead>
<tr>
<th>Surgical procedure, first stage</th>
<th>Implant with pre-mounted implant adapter and cover screw placement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical follow-up</strong></td>
<td><strong>Time after surgery</strong></td>
</tr>
<tr>
<td>Remove sutures</td>
<td>7-10 days</td>
</tr>
<tr>
<td>Osseointegration period</td>
<td>3-6 months</td>
</tr>
<tr>
<td><strong>Surgical procedure, second stage</strong></td>
<td></td>
</tr>
<tr>
<td>Cover screw removal, tissue reduction and abutment connection</td>
<td></td>
</tr>
<tr>
<td><strong>Surgical follow-up</strong></td>
<td><strong>Time after second stage</strong></td>
</tr>
<tr>
<td>Remove dressing and check implant site. If healed, remove healing cap and sutures and instruct patient on cleaning and aftercare</td>
<td>7-10 days</td>
</tr>
<tr>
<td>If not healed after 7-10 days, repeat previous step</td>
<td>14 days</td>
</tr>
<tr>
<td><strong>Fitting of the sound processor</strong></td>
<td><strong>Time after second stage</strong></td>
</tr>
<tr>
<td>Check the implant, abutment and surrounding skin area</td>
<td>3-4 weeks</td>
</tr>
<tr>
<td>Fitting of the sound processor (see Audiological manual)</td>
<td></td>
</tr>
<tr>
<td>Practice connection and disconnecting the sound processor</td>
<td></td>
</tr>
<tr>
<td>Practice managing the sound processor controls</td>
<td></td>
</tr>
<tr>
<td>Explain routines for hygiene and maintenance</td>
<td></td>
</tr>
<tr>
<td>Plan future follow-up appointment frequency</td>
<td></td>
</tr>
<tr>
<td><strong>Routine follow up</strong></td>
<td></td>
</tr>
<tr>
<td>Check sound processor performance</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>Check implant and abutment stability</td>
<td></td>
</tr>
<tr>
<td>Check condition of skin penetration area</td>
<td></td>
</tr>
</tbody>
</table>
Surgical components and instruments

**Warning!**
Do not use sterile components or instruments if the sterile date has expired or if the packaging has become broken or damaged outside the sterile field.

**Disposable instruments**

- **M50287**  Guide drill, 3-4 mm
- **M50289**  Countersink, 4 mm
- **M50288**  Countersink, 3 mm

**Biopsy punch Ø 4 mm:** Please contact your local Oticon Medical sales representative for more information about this product.

Disposable components and instruments are pre-sterilized by irradiation and may be used until the expiry date.

**Surgical Components**

- **M50358**  Implant, 4 mm, with abutment
- **M50220**  Implant, 4 mm
- **M50319**  Implant, 3 mm
- **M50349**  Abutment, 6 mm
- **M50318**  Abutment, 9 mm
- **M50098**  Cover screw hexagon
- **M50317**  Healing cap
**Surgical Equipment**

*Dermatome*
A dermatome may facilitate the skin reduction during surgery. It is important that the dermatome creates a skin graft that is 22.28 mm wide and 0.5-1.0 mm thick. This kind of dermatome is available and can be ordered from various specialized medical manufacturers. For more information please contact your local Oticon Medical sales representative.

*Drilling equipment*
It is important that the correct type of drilling equipment is used during the surgical procedure. The unit should be able to carry out the drilling with a drill bit speed of 1500-2000 rpm and the implant installation on a low speed setting, 15 rpm, with a torque setting of between 10-40 Ncm, depending on the bone quality.

We recommend the ImplantMed drive unit supplied by W&H (www.wh.com) with the 20:1 handpiece. Please contact your local Oticon Medical sales representative for more information.

*Note: Use only CE-marked drilling equipment.*
## Non-disposable instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M5032</td>
<td>Counter torque wrench</td>
</tr>
<tr>
<td>M50230</td>
<td>Torque wrench</td>
</tr>
<tr>
<td>M50437</td>
<td>Handle with screwdriver</td>
</tr>
<tr>
<td>M50384</td>
<td>Screwdriver, machine, 35 mm</td>
</tr>
<tr>
<td>M50533</td>
<td>Abutment inserter, machine</td>
</tr>
<tr>
<td>M50386</td>
<td>Square fit connection, machine</td>
</tr>
<tr>
<td>M50428</td>
<td>Sound processor indicator</td>
</tr>
<tr>
<td>M50534</td>
<td>Screwdriver hexagon</td>
</tr>
<tr>
<td>M50535</td>
<td>Ampoule holder</td>
</tr>
</tbody>
</table>

**Dissector:** Please contact your local Oticon Medical sales representative for more information about this product.
Cleaning of non-disposable instruments

Limitations on reprocessing
Repeated reprocessing has a minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

Instructions
Containment and transportation
It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Preparations for cleaning
The screwdriver, machine, 35 mm should be removed from the screwdriver handle during cleaning.

Automated cleaning
All non-disposable instruments can be cleaned in a washer-disinfector using a low alkaline detergent recommended by the washer-disinfector manufacturer.

Manual cleaning
The non-disposable instruments are cleaned using water and a mild detergent to remove blood and other contaminants. If additional cleaning is necessary an ultrasonic bath can be used.

Disinfection
Isopropyl alcohol should be used in accordance with label instructions.

Drying
When drying is achieved as a part of a washer-disinfector cycle do not exceed 137°C/278.6°F. When performing manual cleaning let each instrument air dry in controlled conditions.

Inspection
Visually inspect all instruments for damage, wear and complete removal of visible soiling.

Packaging
Standard sealable pouches in accordance with EN 868 should be used.

Sterilization
Vacuum autoclave in saturated steam at 134°C/273.2°F minimum holding time 3 minutes. The sterilization parameters should conform to EN 554 or be set by a validation study. Do not exceed 137°C/278.6°F and ensure that the autoclave’s maximum load is not exceeded.

Storage
Sterilized and packed instruments should be stored in a controlled environment protected from dust, moisture and large temperature fluctuations.

⚠️ Warning!
Do not exceed 137°C/278.6°F.
Patient preparation

In the operating room the patient is prepared as for conventional ear surgery. The patient is positioned in a way that gives optimal access to the skull bone on the implant side, and the incision area is shaved and sterilized. An adhesive surgical draping is recommended.

In adults either local or general anesthesia may be used, while general anesthesia is always recommended for children.

Local anesthetics and pre-medication
As pre-medication, Valium 10–20 mg/ml i.v. is recommended for adults.

10 mg/ml Xylocain with 5 µg/ml adrenalin s.c. solution is recommended as local anesthesia. 10–15 ml is usually enough, but this may vary depending on the number of implants to be installed. The anesthetic should infiltrate the periosteum at the implant site.

General anesthesia
When the surgery is performed under general anesthesia, the use of 5–10 ml 5 mg/ml Xylocain with 5 µg/ml adrenalin s.c. for hemostasis is recommended.
Single-stage surgical procedure

The instructions below focus on the standard single-stage procedure. The procedural steps in which two-stage surgery differs are described in a separate section.

Note: Throughout the whole procedure electro coagulation should be used with care, especially in irradiated patients, in order to reduce tissue trauma.

Operating room preparations
The single-stage surgical procedure should always be planned so that back-up components and instruments necessary for placing a 3 mm implant, or performing the surgery in two stages, are available.

Procedure-specific disposable components and instruments for standard single-stage surgery in adults

- Implant, 4 mm with abutment
- Guide drill, 3-4 mm
- Countersink 4 mm
- Healing cap
- Biopsy punch Ø 4 mm

Note: For obese patients and patients with rare conditions, an extra long abutment (9 mm long) is available as a separate component.
Implant position

The position and orientation of the implant will determine the exact position of the sound processor, and is therefore crucial for the lifelong cosmetic and practical outcome for the patient. Possible future reconstructive outer ear surgery or outer ear prostheses should be considered when determining the implant positioning.

Implant positioning should be performed with great care. Anatomical landmarks should be identified, especially for patients with congenital malformation and/or prior surgery.

The implant should preferably be positioned in the temporal line or at the same height as the center of the upper half of the pinna. The implant position should be 50-55 mm in a 10 o’clock direction from the ear canal. To aim for a correct implant position a sound processor indicator should be used to find the position in relation to the ear. (1)

The preferred implant position is marked through the hole of the sound processor indicator. It is recommended to mark the implant site down to the bone with a needle and dye.

The sound processor must not touch the pinna since this will cause acoustic feedback and discomfort. On the other hand the sound processor should not be placed too far back, since both the position of the microphones and the aesthetics may then be compromised. Placement of the implant low in the mastoid tip should also be avoided.

An incision area about 24 mm width and 30 mm height is marked. The incision area should be planned so that the implant site is positioned slightly into the lower half of the graft area. (2) Mark the area of the subcutaneous tissue reduction with an approximately 50-60 mm diameter area.
Incision and initial skin reduction
The incision and initial skin reduction may be performed using a dermatome or manually. Regardless of the technique, the skin area surrounding the skin penetration should be hairless and very thin (<1.0 mm) to keep the implant site clean and prevent skin thickening and irritation through movement and friction against the abutment.

Note: Regardless of the incision technique used, the reduction of the tissue surrounding the flap area should not be made before drilling, when the final implant location has been determined.

Manual technique
A number of different incision techniques are used. In this manual the u-flap technique is described. If the linear, semi-circular or some other incision technique is used, the size and thickness of the graft area must still be as described below.

Note: A superiorly based skin graft is preferred since this offers better blood supply and healing.

A scalpel is used to make the incision down to the periosteum along the marking of the incision area and to separate the tissue from the underlying periosteum. (3) All subcutaneous tissue in the graft area must be separated from the periosteum.

The subcutaneous tissue is carefully separated from the skin graft, and all hair follicles are removed. (4) Manual skin thinning should be performed with great precision. This should create a skin graft of around 0.5-1.0 mm thickness.

Note: Make sure to keep the skin graft moist during the remainder of the procedure. When a manual incision technique is used the thinning of the graft can be done after implant installation to facilitate this.

Alternative Incision using a dermatome
The initial incision may be performed using a 22-28 mm wide dermatome that creates a skin graft of around 0.5-1.0 mm thickness (see dermatome instructions for use). After creating the graft with the dermatome an incision is then made down to the periosteum along the edges of the incision area, and the subcutaneous tissue is carefully separated from the periosteum and removed. (5) All subcutaneous tissue under the graft area must be separated and removed from the periosteum.
Incision of the periosteum
The periosteum is incised separately. A biopsy punch Ø 4 mm can be used to punch a hole in the periosteum at the planned implant position, which, if possible, should be right under the preferred position as initially marked on the skin. (6)

A scalpel can then be used to make four small incisions in a radial direction outwards from the Ø 4 mm hole to push the periosteum further aside from the planned implant position. (7) It is important to leave the periosteum around the implant site to support the healing of the skin graft.

Drilling
The drilling procedure is of decisive importance for a successful osseointegration and treatment. The following aspects related to the drilling are of great importance:

- Generous cooling of the drill and bone in order to prevent heat induced bone tissue trauma, which may impede osseointegration.
- Use of a drill bit speed of 1500-2000 rpm.
- The position and orientation of the drilling, which will determine the lifelong position of the sound processor on the patient.
- Continuous assessment of the quality and thickness of the bone during the drilling procedure to determine the possibility of a successful osseointegration and treatment.

Correct settings on the drill equipment and handpiece are essential to ensure that the drill bit speed is 1500-2000 rpm. Efficient cooling through irrigation with room temperature saline solution should be directed towards the tip of the drill during the entire drilling procedure. Separate cooling equipment is recommended for this. The drill must be moved up and down to facilitate the cooling.
Initial drilling

Drilling is initiated using the guide drill with the plastic spacer. (8) The plastic spacer limits the drill depth to 3 mm, which is suitable when preparing for the placement of a 3 mm implant. During the initial penetration the quality and quantity of the cortical bone and the spongiosa air cells should be observed.

Note: It is important that all drilling is carried out perpendicular to the bone surface.

The bone quality and volume must be checked regularly during drilling, both visually and using a blunt dissector, to make sure that there is enough bone at the base of the site. The quality of the bone will determine both the torque that should be used when inserting the implant and the time that should be left for osseointegration before loading the implant. The thickness of the bone will also determine whether a 3 or 4 mm implant should be placed.

If bone thickness is sufficient, the plastic spacer can be removed and the guide drill will then allow drilling down to a drill depth of 4 mm, which is suitable when preparing for the placement of a 4 mm implant.

If the bone thickness and/or bone quality is found to be insufficient for a successful treatment with the single-stage procedure, the surgery may have to be re-planned into a two-stage procedure. If the bone thickness and/or bone quality is found to be insufficient for a successful treatment even if performed in two stages, the surgery may have to be discontinued.

Note: Proceed with care so that the wall of the sigmoid sinus is not penetrated.

Countersinking

To widen the hole, the 3 or 4 mm drill countersink is used, depending on the depth of the hole. The drill countersink is moved up and down so that the irrigation reaches the tip of the drill. (9) The drill flutes should be cleared regularly of bone tissue. The countersink part of the drill should just slightly flatten the bone surface to prepare for the implant. The drill tip is blunt to minimize the risk of tissue damage at the bottom of the hole.

Note: Make sure not to over-widen the hole, which may reduce the initial stability of the implant.

Note: Especially in thin bone it is important not to countersink too much, in order to save the upper cortical layer of the bone. In case of very thin bone it is recommended to avoid countersinking.
Tissue reduction of the subcutaneous tissue

In addition to the initial skin reduction the tissue must also be reduced in the area surrounding the graft, in order to create a gradual slope down to the graft. This undermining of the surrounding tissue should be generous and should reach around 15-20 mm out from the graft edges in all directions (creating a ø 50-60 mm undermining). (10)

After undermining the surrounding tissue, the skin graft is sutured down at the corners of the base to the periosteum. The skin graft is laid back and stretched out with skin hooks over the periosteum. A hole is punched over the site of the implant hole using a ø 4 mm biopsy punch. (11) The graft is then folded away again.

**Note:** As an alternative the hole can be punched, using a ø 4 mm biopsy punch, after the implant installation. If the hole is punched after implant installation it is important to be careful to avoid scratching the surface of the abutment.
Implant installation
The implant installation is carried out with the drilling equipment on the low speed setting (15 rpm). The torque setting is adjusted to suit the quality of the bone, as judged by the surgeon during drilling; 30-40 Ncm in compact bone and 10-20 Ncm in soft bone are recommended.

The implant with pre-mounted abutment is seated in a plastic ampoule with a pack sleeve and delivered in a peel open pack which constitutes the sterile barrier. The implant should not come into contact with anything but the pack sleeve prior to insertion in the bone in order to avoid contamination, which could jeopardize successful osseointegration. The pre-mounted assembly is picked up using the abutment inserter connected to the handpiece (12), and the implant is inserted (13).

It is important to make sure that the implant engages the hole correctly before the installation is initiated. If the implant enters the hole incorrectly the drilling machine should be put in reverse, the implant unscrewed, the angle corrected and the implant re-inserted. When the flange of the implant has reached the bone surface it will stop automatically.

If the flange does not reach the bone surface, the torque setting may be increased. Alternatively, the counter torque wrench may be used, with great care, to insert the implant manually until the flange reaches the bone surface.

When the implant has been inserted the abutment inserter is carefully disconnected from the abutment. (14)
Repositioning of the graft
The skin graft is repositioned by pulling the punched hole of the graft over the abutment. (15)

The skin graft is then sutured in position. (16)

Healing cap and dressings
A healing cap is attached to the abutment, either before or after placing the dressing, depending on the type of dressing that is being used. (17)

The healing cap holds the dressing in place and prevents hematoma.

Ointment soaked ribbon gauze wrapped around the abutment may be used. The gauze must be applied evenly and in appropriate quantities to secure proper blood supply. Other dressing materials are also available and may be used, e.g. foam dressing, soft silicone mesh or antiseptic dressing.

A mastoid pressure bandage is placed outside the dressing and healing cap.

Note: It is important that the pressure from the dressing is not too tight as this can stop the blood supply and delay the healing of the wound or cause necrosis.
Healing and aftercare

Removal of dressings

The pressure bandage may be removed the day after surgery.

The dressing and stitches may be removed after 1-2 weeks, when the soft tissue has healed. Removal of the dressing may be facilitated if the dressing is wet. The healing cap and dressing are carefully removed, and the wound is gently cleaned using saline and gauze. The wound site is examined and treated if needed. At this stage the patient should be informed about how to take care of the abutment and surrounding skin to maintain proper hygiene and avoid problems with skin irritation and infection.

If the skin is not yet fully healed a new visit for removing the healing cap and dressing is planned approximately one week later.

Aftercare

It is very important that the patient is instructed to maintain a good daily cleaning routine, using soap and water, in order to avoid debris build-up.

The skin should be cleaned more thoroughly to remove debris every few days. During hair washing with shampoo, debris becomes softer and is more easily removed.

During the first period before the skin is fully healed a non-alcoholic baby wipe can be used to clean the area around the abutment. Once healing has progressed sufficiently an extra soft cleaning brush should be used around the outside and towards the inside of the abutment. Note the importance of cleaning both inside and all around the skin-penetrating abutment. This is important to prevent debris build-up.

Antibacterial soap is recommended and the area may be dried with a non-alcoholic baby wipe. The cleaning brush should be replaced about once every 3 months.

Precautions

The patient must be made aware of the following precautions:

- The wound should not be exposed to water until the healing cap and dressing has been removed and the wound has healed.

- A traditional bone conductor or a sound processor on a soft band, head band or test band should not be placed on top of an abutment, implant or sleeper implant.

- Some activities, such as certain sports, may expose the implant to trauma and should be avoided.

- If a hair dryer is used it should not be directed closely towards the abutment for too long, since this might heat up the abutment and implant.

- If the patient needs to undergo MRI (Magnetic Resonance Imaging) the sound processor must be disconnected. The implant and abutment can remain in place.5
Two-stage surgical procedure

The instructions below focus on special considerations and procedural steps for two-stage surgery. Wherever the single- and two-stage procedures are similar we refer to the instructions for single-stage surgery.

Note: Patients suitable for a two-stage procedure may require extra caution.

First stage

During the first stage of a two-stage surgery the implant and possible sleeper implant are placed, see pediatric section.

Note: Throughout the whole procedure electro coagulation should be used with care, especially in irradiated patients, in order to reduce tissue trauma.

Operating room preparations

If the placement of a 4 mm implant is planned, instruments and components for placing a 3 mm implant should still be available in the operating room as a back-up, in case of insufficient bone depth for a 4 mm implant.

Procedure-specific disposable components and instruments for the first stage of a two-stage surgery

- Implant, 4 mm
- Cover screw hexagon
- Guide drill, 3-4 mm
- Countersink 4 mm
- Biopsy punch Ø 4 mm

Patient preparation and implant position

Preparation of the patient and choice of implant position is carried out in the same way as for the single-stage surgical procedure.

Incision

An incision down to the periosteum is performed with the scalpel, based on the manual incision technique, and the subcutaneous tissue is separated from the periosteum. The periosteum is then incised separately.

Note: Skin reduction will be performed during the second stage of the surgery. Do not use the dermatome during a two-stage surgical procedure.

Drilling

See drilling instructions under single-stage surgery. The same procedure is applied here.

Note: 3-6 months or more should be left to allow for sufficient osseointegration of the implant between the first and second stage procedure. Observation of the thickness and quality of the bone during drilling will determine the length of the osseointegration period that is required. The thinner or the softer the bone, the longer time should pass before the second stage of the surgery is performed.
Implant installation
An implant with pre-mounted implant adapter is connected to the square fit connection, and the implant is installed in the same manner as in a single-stage procedure (see instructions for implant installation under single-stage surgery). (18)

When the flange of the implant has reached the bone surface it stops automatically. Carefully disconnect the square fit connection from the implant adapter. (19)

The implant adapter is removed with the screwdriver, while using the open end of the counter torque wrench as a counter torque. Proceed with care to avoid forces due to a lever-arm effect.

Cover screw placement
The placement of a cover screw is important in order to prevent bone from growing on top of, or into, the implant.

The cover screw is picked up from the pack sleeve with the screwdriver hexagon and screwed onto the implant. (20)

Note: The cover screw should not be fastened too tightly as it may then be difficult to remove it during the second stage of surgery.

Repositioning of the flap
The flap is sutured back in position. (21)

Dressings
A standard mastoid dressing is left in place for 1-2 days and is then replaced by a small bandage, at which point most patients can resume normal activity.

Note: If initial skin reduction has already been performed, as when a planned single-stage procedure becomes a two-stage procedure, appropriate pressure must be applied to the skin graft during healing. The healing cap is not applicable in this case. Instead a 40 mm pad may be placed over the graft for 1 week. A number of sutures across the gauze and into the surrounding tissue may be used to create pressure.

Note: A period of 3-6 months or more should pass between the first and second procedures, depending on the thickness and quality of the bone, to allow for osseointegration.
Second stage

During the second stage, the tissue reduction is performed. The cover screw is removed and the abutment is connected to the implant.

*Note: Throughout the whole procedure electro coagulation should be used with care, especially in irradiated patients, in order to reduce tissue trauma.*

Operating room preparations

*Procedure-specific disposable components and instruments for the second stage of a two-stage surgery*

- Abutment, 6 mm
- Healing cap
- Biopsy punch Ø 4 mm

Patient preparation

Preparation of the patient is carried out in the same way as for the single-stage surgical procedure.

Tissue reduction

The incision area is marked and the flap is raised using a manual incision technique. The skin area and the surrounding tissue are then prepared with great care in the same way as for a single-stage surgery (see instructions on initial skin reduction and tissue reduction of the subcutaneous tissue under single-stage surgery). A hole is made over the cover screw through the skin graft and periosteum using the biopsy punch Ø 4 mm.

Connection of the abutment

The cover screw is removed from the implant using the hexagon screwdriver. (22)

The abutment is picked up from the plastic ampoule with the counter torque wrench and correctly placed onto the hexagon on the implant.

*Note: It is important to make sure that the hexagon on the implant is fitted into the hexagon of the abutment so that it does not rest on top of the hexagon, as this may cause the abutment to loosen.*
The abutment connection screw is initially tightened with the screwdriver. (23)

Continue with the drilling machine with the screwdriver machine connected to the handpiece. (24) The counter torque wrench is used in both steps counteracting the screwdriver force to minimize the load on the implant. The torque controller should be set to low speed with a torque of 25 Ncm.

The skin graft is repositioned by pulling the punched hole over the abutment. The graft is then sutured back in position.

Note: As an alternative the skin graft can be repositioned and sutured back in position before the connection of the abutment.

Note: A torque wrench and screwdriver can be used instead of the drilling equipment when tightening the abutment connection screw.

Healing cap, dressings and aftercare
Healing cap and dressing is applied and the patient informed about healing and aftercare in the same manner as after single-stage surgery.
Troubleshooting

**Surgery**

**Damage to the skin graft**

If the skin graft becomes too damaged and is not suitable to be put back in place, it may become necessary to use a hairless skin graft, for example from the retroauricular fold. This technique may also be used if the skin around the preferred implant site is uneven due to scar tissue from previous surgery.

**Air pockets**

An air pocket can sometimes be entered during the drilling procedure. This is not of any significance unless the drill is redirected. If this occurs a new site should be chosen.

**Hard bone**

In hard bone additional pressure on the implant may be required at the beginning of the insertion procedure. If the flange does not reach the bone surface using the electric drilling equipment, the counter torque wrench may be used, with great care, to insert the implant manually until the flange reaches the bone surface.

**Damage to the dura**

Damaging the dura mater during drilling is very rare. If it should happen and there is enough bone volume the implant should be placed to seal the cerebrospinal fluid (CSF) leak. If the bone is thin a new implant site should be chosen and the leak sealed with soft tissue or bone wax.

**Implant mobility**

If the implant is mobile after insertion, find a new implant site at least 5 mm from the first implant site.

**Post surgery**

**Skin irritation**

The three most common reasons for skin irritation are:

- Poor hygiene
- Too thick skin around the abutment
- A loose abutment connection screw

In case of poor hygiene the patient should be instructed how to maintain adequate hygiene. Long-standing infection around the implant should be cultured and treated with suitable antibiotics.

*Note: All skin infections should be treated according to normal hospital procedures.*

**Additional subcutaneous tissue reduction**

If the skin around the abutment grows up to half the length of the abutment or more there may be an increased risk of skin irritation, since the skin may move in relation to the abutment. Cleaning will also be difficult. In exceptional cases, where the patient has very thick skin or where there is constant re-growth of subcutaneous tissue, the 9 mm abutment is recommended. In case of skin hyper-mobility it may be necessary to perform additional subcutaneous tissue reduction.

A light pressure dressing should be applied for 2-3 weeks, and the patient should then be monitored closely in the post-operative period.

**Tightening of the abutment connection screw**

Movement of the abutment may lead to skin infection as well as poor sound quality. The abutment connection screw should be tightened to 25 Ncm with the help of the torque wrench. The counter torque wrench should be held in a steady position to prevent the screwdriver torque from loading the implant. In case of skin irritation, replacement of the abutment may be necessary.
Replacement of the abutment
The area around the abutment is washed and cleaned. The counter torque wrench is attached to the abutment and the abutment connection screw is unscrewed with the screwdriver. After removing the abutment, the opening in the skin is cleaned, and a new abutment is mounted onto the implant using the counter torque wrench and the screwdriver. The abutment connection screw should be tightened to 25 Ncm using the screwdriver and torque wrench. The counter torque wrench should be held in a steady position to prevent the screwdriver torque from loading the implant.

⚠️ Warning! ⚠️
When tightening or replacing the abutment the counter torque wrench should be held in a steady position. The counter torque wrench must only be used to counteract the force when tightening the connection screw, in order to minimize the load on the implant.

Graft necrosis
Partial or, rarely, sub-total graft necrosis has been seen in the first weeks after surgery. In most cases an extended healing period is enough to overcome the problems.

Loose implant
Should the implant become loose there is generally bone available for surgical placement of a new implant close to the old site.

Note: Should an implant loss occur, this must be reported to Oticon Medical.
Complications

Prior to surgery, the patient should be made aware that the following possible complications may occur:

- Implant instability with possible implant loss
- Loss of skin graft
- Insufficient bone depth for implant insertion
- Numbness around the abutment
- Bone infection, potentially causing osseonecrosis or periimplantitis
- Perforation of the dura mater, during surgery or due to trauma
- Subdural hematoma
- Meningitis
- Local or systemic infection
- Loss of implant due to excessive force on the abutment or sound processor if the sound processor fails to come loose
- Osteoradionecrosis if the implant is installed in irradiated implant sites

Complications should be treated according to general practice.
Pediatric surgery

The risk of implant trauma is greater in children, especially young children (age <12 years), due to physical activity as well as soft and/or thin bone. A number of special considerations should therefore be applied for children. X-ray examination is recommended as part of the surgical planning. For children, general anesthesia is recommended.

Choice of surgical procedure
Two-stage surgery is recommended for most children with a bone thickness of 4 mm or below, while children with a bone thickness exceeding 4 mm (typically children above the age of 12) may be treated with the single-stage procedure. Children with a bone thickness of between 3-4 mm may also be considered for the single-stage procedure, provided that bone quality, age, development status and other known factors have been considered and found appropriate for single-stage surgery.

Additional precautions should be taken to leave enough time for osseointegration between the first and second stage of surgery. In children the time left for osseointegration is often longer (3-6 months) than the time applied for adults.

Sleeper implant
Children are often very dependent on their sound processor for social and language development. It is therefore recommended that an extra sleeper implant with a cover screw is “banked” approximately 10-15 mm from the primary implant for possible future use. In case of implant trauma, the child can then be fitted with the sound processor again directly after a new abutment has been connected to the sleeper implant and the soft tissue has healed.

Drilling
Due to thin and soft bone, drilling during surgery must be performed with great care. Countersinking should be carried out very carefully to take advantage of all the bone needed for a good anchoring of the implant.

Implant installation
The lowest torque setting should be used for implant installation (10-20 Ncm). It is very important to ensure that the threads in the bone are not stripped during insertion.

Bone thickness ≤ 3 mm
In order to increase implant stability by creating thicker bone in the local area around the implant, an expanded polytetrafluoroethylene (PTFE) membrane of about 20 mm in diameter may be placed on top of the implant, and kept in place by the cover screw. A minimum of six months for the formation of new bone should elapse before the membrane is removed and the abutment is connected.

If the bone thickness is less than or equal to 3 mm, countersinking should be avoided when using the countersink drill.

Note: It is recommended that experience of implant surgery in adults is gained before performing surgery in children.
List of symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Reference number</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code/Lot number</td>
</tr>
<tr>
<td></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td></td>
<td>Use by date</td>
</tr>
<tr>
<td></td>
<td>Single use</td>
</tr>
<tr>
<td>STERILE</td>
<td>Sterilized using irradiation</td>
</tr>
<tr>
<td></td>
<td>Do not use if package is open or damaged</td>
</tr>
<tr>
<td></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>CE 0413</td>
<td>CE mark</td>
</tr>
</tbody>
</table>

References


