1

Learner Objectives

- Participant will be able to explain benefits of the MIPS procedure when compared to earlier approaches
- Participants will be able to describe the benefits of the Oticon medical abutment shape and style
- Participants will be able to describe some difference between adult and pediatric surgeries
- Participants will be able to describe considerations that contribute to device feedback and how to solve them

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Ponto™ System
10 years of sound that matters

- The Ponto System has developed immensely over the 10 years since launch
- Today's system is the result of our focus on continuous improvement and lifelong patient outcomes – using advanced technologies from the hearing healthcare industry
- The surgical procedure has significantly changed and today a Ponto surgery is done in minutes, but nonetheless improves patients' quality of life immensely

3

Osseointegration

- Professor Brånemark (May 3, 1929 – December 20, 2014)
  a Swedish physician and research professor, touted as the "father of modern dental implantology".[1]
  - First to recognize osseointegration properties of titanium
  - In 1965 Brånemark, who was by then the Professor of Anatomy at Gothenburg University in Sweden, placed the first titanium dental implant into a human volunteer
- The Brånemark System of dental implants was bought out and is currently available from Nobel Biocare.
- First coined the term osseointegration: "osseo" meaning bone and "integro" meaning new

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Branemark Implants – Nobel Biocare

Brånemark System – the original

The most scientifically documented implant system in the world

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Bone Anchored System

Osseointegration

Process:

- The process by which living bone tissue bonds with titanium
- Makes direct bone conduction possible
- The long-term predictability and success of the bone anchored system is based on the fact that an active bond between tissue and implant is created without capsule formation. The implant is not only accepted, but incorporated into the bone.

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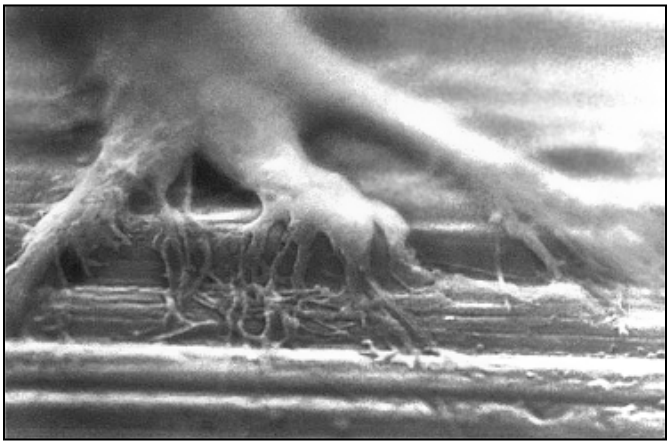
Bone Anchored System

Osseointegration



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History of Bone Anchored Implants

- **Andres Tjellstrom** – ENT in Sweden – created the first Baha surgery
- Dr. Branemark was trying to discover an acoustic way to evaluate the degree of osseintegration in the temporal bone. Tjellstrom worked with his team. He placed an Oticon bone vibrator onto the implant in the patients mouth and they could hear a tone very well. Bo Hakkeson was working with Tjellstrom was conducting research and created a device that measured how much sound was reaching the cochlea through the mastiod. .....

POOF !

- In 1977 first Baha surgery was performed

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First bone anchored device – Bo Hakkenson

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Where Oticon Medical come from?

- Entific originally created as a spin-off of the Swedish oral implant group Nobel Biocare (1999)
- distinguished contributors
  - Bo Hakkenson - creator of first Baha electromagnetic vibrator and coupling
  - Patrick Westerkull - *technology and coupling (founded Otorix)*
  - Lar Jinton (head of hearing division at Nobel Biocare (engineer) *Hex lock, self tapping implants, coupling*

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History

- Entific bought by Cochlear in 2004/2005

  *(Medicare approves/Baha trademarked)

- Oticon acquires technology from **Otorix** (**Patrick's company**) and starts designing Ponto – Changed the snap coupling

  *2006 – first patient implanted with OM implant

  *2007 – patient fit with new snap coupling

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Baha or Ponto?

- B.A.H.A – Bone Anchored Hearing Aid (Entific)
- 2005- Medicare approves insurance coverage of osseointegrated surgeries and devices
- Baha becomes a trade marked name for Cochlear's device
- Fall 2009 Ponto receives FDA clearance and Oticon Medical launches in USA
- Ponto – Italian for "bridge"

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Ponto System FDA Clearances

- The Ponto System was FDA cleared on July 29th 2009
  - Indications for use:
    - Pediatric patients older than 5 years of age
    - Unilateral and bilateral conductive or mixed hearing losses for the indicated ear equal or better than 45 db HL (measured at 0.5, 1,2, and 3 kHz)
    - Profound sensorineural hearing loss unilaterally with normal hearing in the opposite ear and will not or cannot benefit from an AC CROS. Hearing in the better ear should be better than 20 db HL (measured at 0.5, 1,2, and 3 kHz)
- Ponto Power was cleared on June 15th 2011
  - Indications for use:
    - Same indications as the Ponto and Ponto Pro but hearing loss increased to equal or better than 55 db HL (measured at 0.5, 1,2 and 3 kHz)

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Ponto System FDA Clearances

The Ponto implant and processor System can be used among a range of bone anchored product lines.

The Ponto Pro sound processor is intended to be connected to the Oticon Medical bone anchored implant system or to the Baha® Abutment snap coupling from Cochlear BAS. In addition, the Oticon Medical abutments can be used for connection of the Baha® sound processors with snap coupling from Cochlear BAS (Baha Divino®, Baha IntensoTM, Baha Cordelle II, Baha BP100).

*** See attached FDA Clearance**

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Snap Coupling - Features and benefits

- The coupling design separates the spring function and the wear-and-tear parts
  - Reliable coupling
  - Small changes in the connection forces.
  - Better sound quality over the couplings life time

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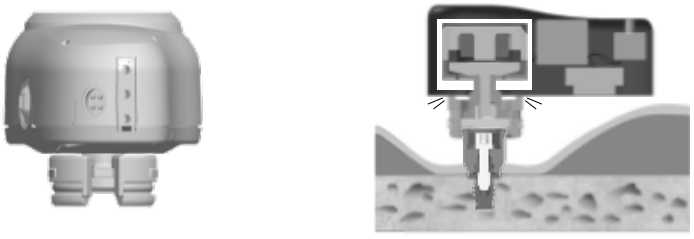
Transducer impact protection

- Protects the vibrator from the strong forces applied when connecting the device to and disconnecting it from the abutment



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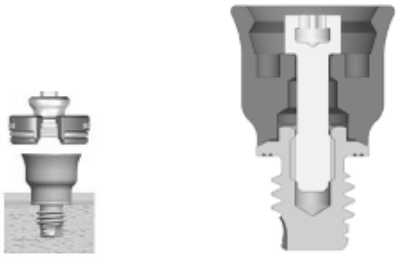
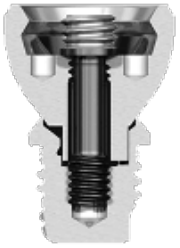
Differences in implant and abutments

Oticon Medical Ponto System



Baha Implant System Standard



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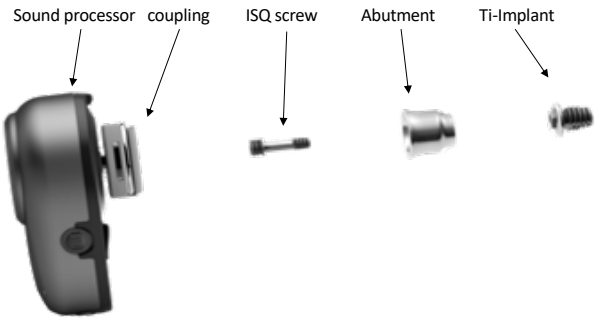
Osseointegration and Direct Bone Conduction Stimulation



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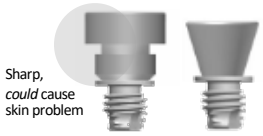
Abutment Design 1977 - current

Chalmers/Nobel
Entific
1977 - 2005



Cochlear
2005 -

Oticon Medical
2009 -

32250-01

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FDA Milestones 10 years

Ponto Bone Anchored Hearing System

- Nov 2006 — Ponto Bone Anchored System: Implant 3.75 & Ponto
- July 2009 — Ponto Pro (RISE)
- July 2011 — Ponto Pro Power
- Sept 2012 — Wide Implant & 12mm Abutment
- Dec. 2013 — Ponto Plus & Ponto Plus Power (RISE)
- Jan 2015 — 14mm Abutment
- Nov 2015 — MIPS
- Jan 2016 — BHX implant
- Sept 2016 — Ponto 3, Ponto 3 Power, Ponto 3 SuperPower (Inium Sense)
- May 2019 — Ponto 4 (Velox S)

6/16/20

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Surgical Procedure

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10 Years of Surgical Instruments

Guide Drill & Countersinks 3mm/4mm for 2009 implant

Guide Drill & Wide Countersinks 3mm/4mm for 2012 wide implant

Minimally Invasive Ponto Surgical Kit

6/16/20

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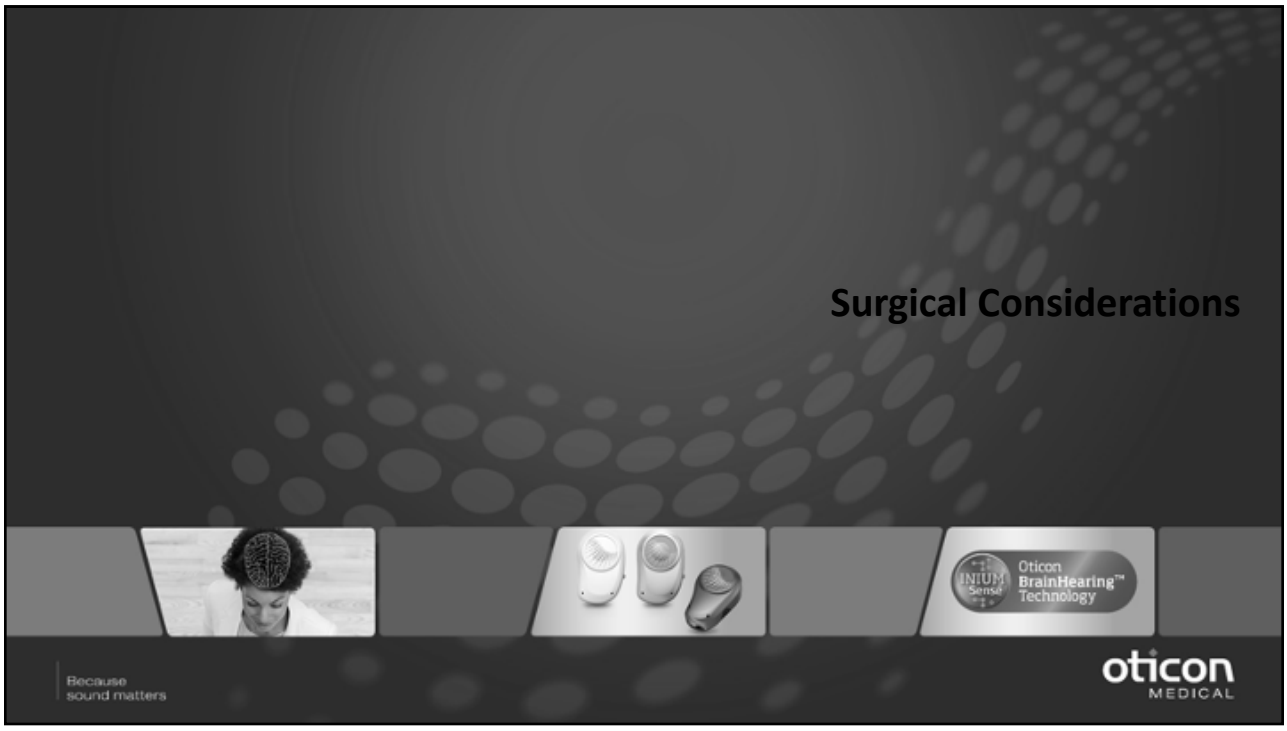

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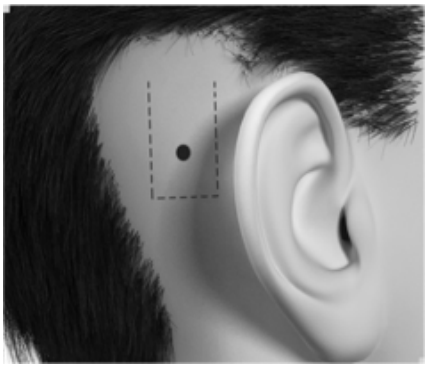
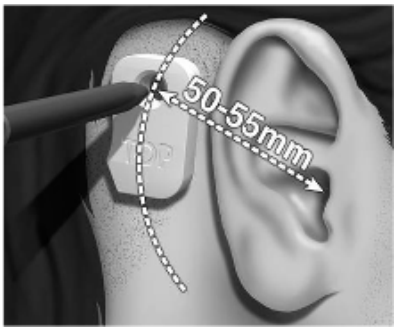
Original Surgical Procedure

Placement of implant – one stage surgery





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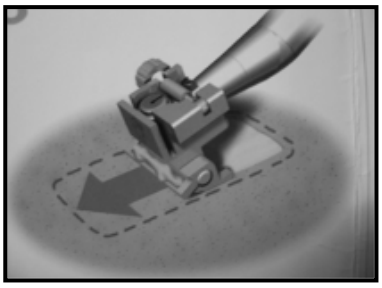
Use dermatome to cut STSG

- 24 mm wide
- .6mm thick (baha dermatome)
- Direction of base
  - Not critical
  - Toward ear common



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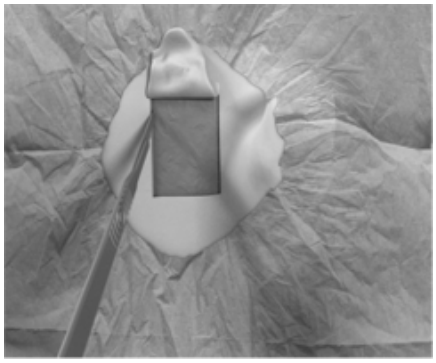
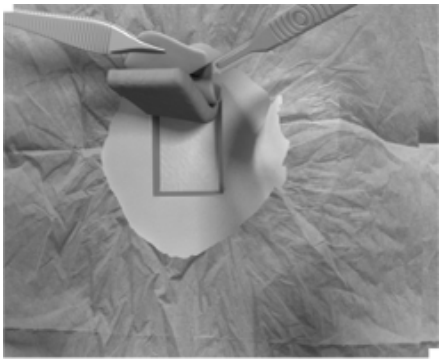
Surgical Procedure





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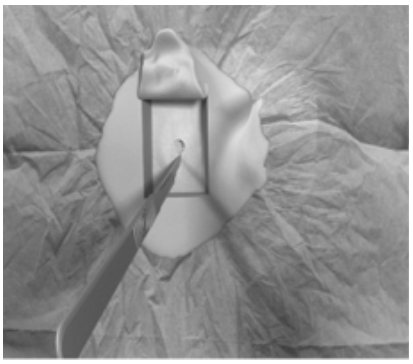
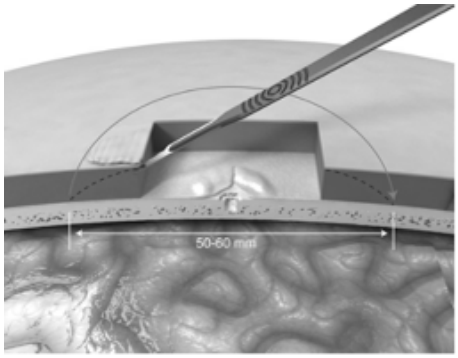
Surgical Procedure





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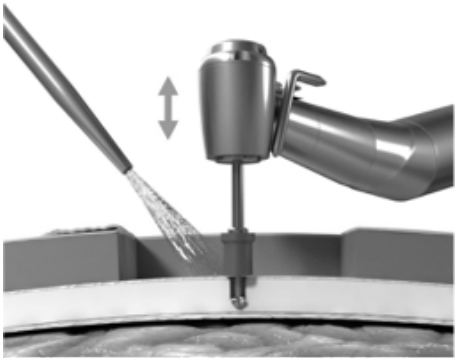
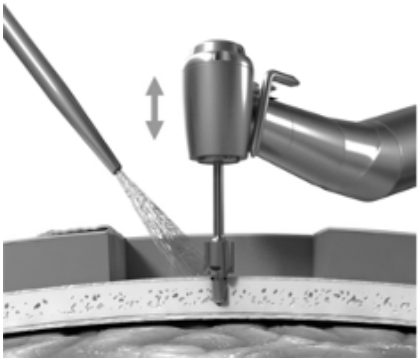
Surgical Procedure – Guide drill and Countersink





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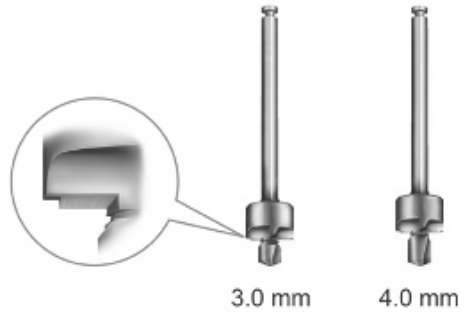
Countersink with stop

Built-in stop feature – designed to give more accurate countersinking for improved safety during surgery (no deeper than .2mm)



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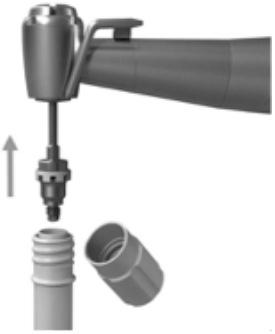
Surgical Procedure



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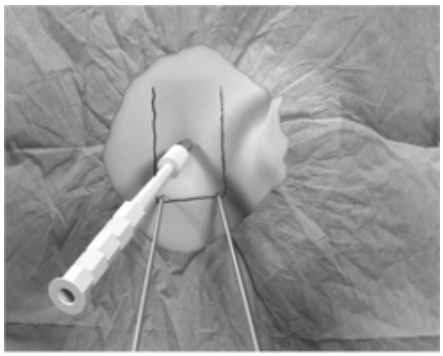
Surgical Procedure



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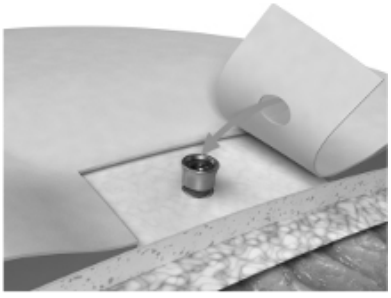
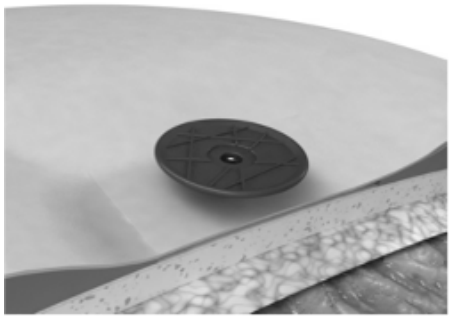
Surgical Procedure





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Surgical procedures

- Fixture with dermatome and skin reduction/thinning

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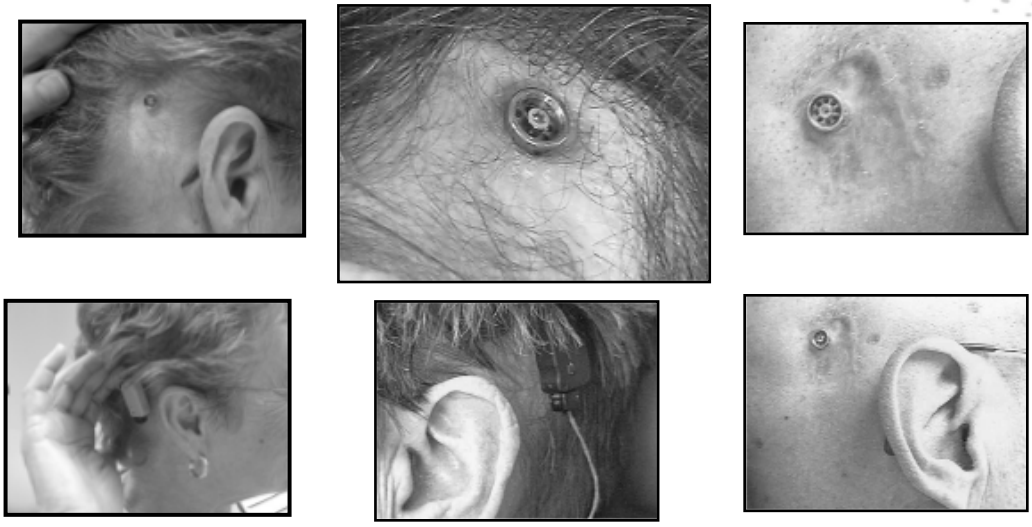
Surgical sites with dermatome and skin thinning



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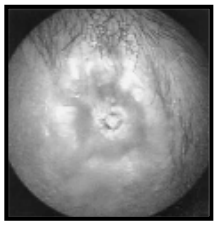
Post op Complications

- Implant loss – Poor bone quality, infection, lack of irrigation, trauma
  10% in children
  5% in adults
- Inflammation and infection around abutment – poor hygiene, air pocket
  (70% none, 20% mild, 5% moderate)
- Skin overgrowth (5-10% require revision)
- Numbness and pain
- Keloids



Evaluation of implant losses and skin reactions around extraoral bone-anchored implants: A 0- to 8-year follow-up.
Reyes RA, Tjellstrom A, Granstrom GOtolaryngol Head Neck Surg. 2000 Feb;122(2):272-6

Review of Complications in Children Zeitoun H, et.al.J Laryngol Otol. 2002 Feb;116(2):87-91

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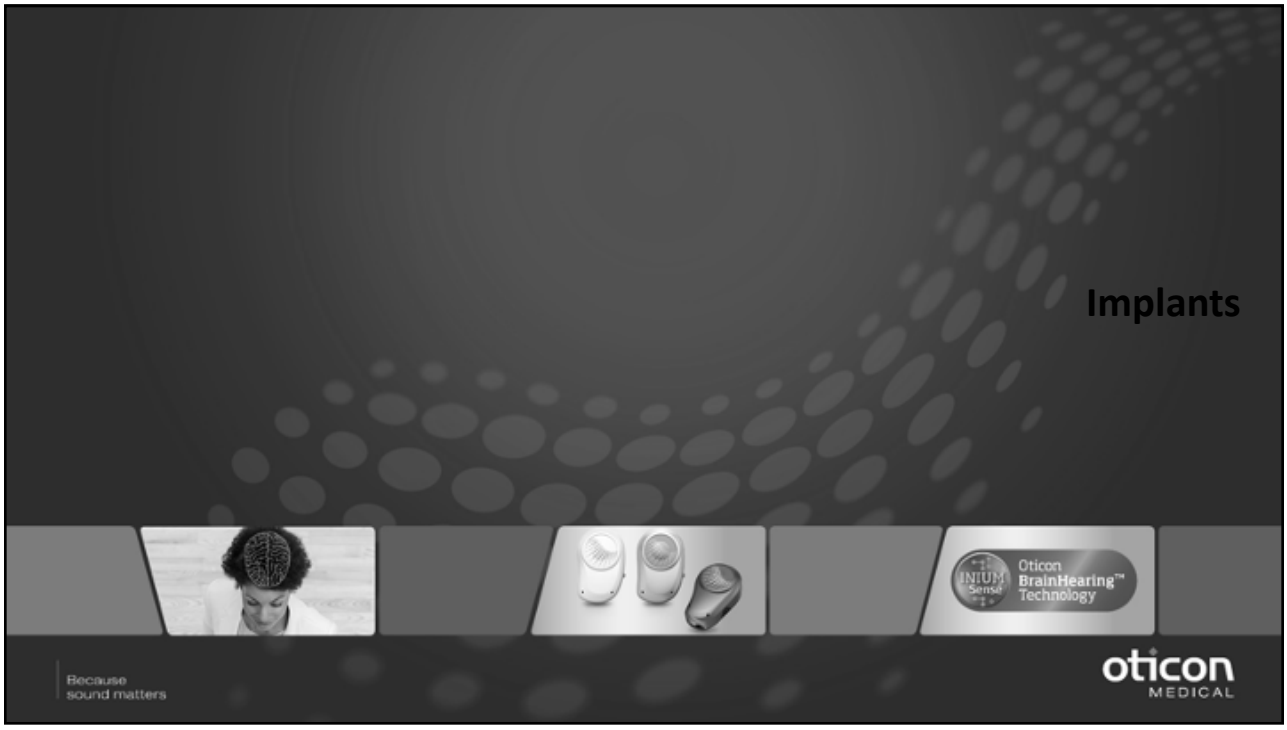

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10 Years of Implants

2009 Implant

- Micro size threads
  - Increase bone implant surface contact
  - Aimed at reducing bone resorbtion

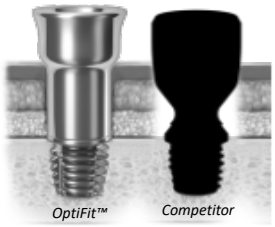
2012 Implant

- Wide diameter 4.5mm
  - Opti Grip implant geometry
  - ISQ Compatible

40

Tissue preservation surgery with Ponto

- OptiFit™ – Designed for Tissue preservation
  - OptiFit's Ti surface is the best documented solution for tissue preservation[1]
  - A smooth tissue interface without pockets and pathways for bacteria
  - FDA-cleared for tissue preservation surgery



The skin-abutment interface

- Tissue preservation – the surgery that makes a difference[2]
  - Quicker surgery
  - Quicker healing
  - Less numbness and pain
  - Less esthetical concerns

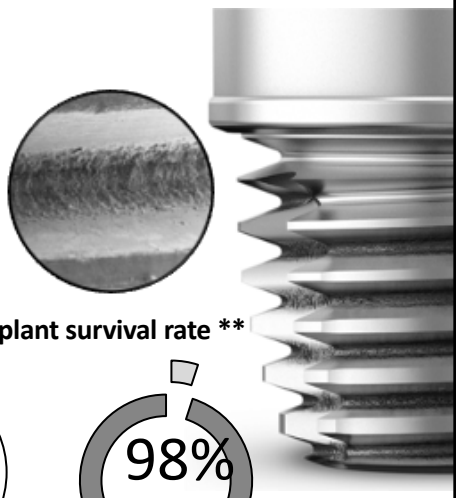
[1] Proven by 7 clinical studies, see previous slide
[2] E.g., Hultcrantz (2011)

41

10 Years of Implants

2016 Ponto BHX Implant

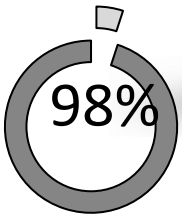
- First laser-ablated titanium surface
  - Fast and stronger Osseointegration
  - Matches natural bone structures at macro-, micro-, and nano-scale
- Stronger than bone due to bone bonding
- Opti Grip implant geometry
- ISQ Compatible



Before...Implant Reliabilty

Very high success rate (**94%**)** for adults

Now…Overall implant survival rate **



*McDermott, et.al., Bpone Anchored Hearing aids in Children. Curr Opin Otolaryngologist Head Neck Surg 2009: 17:488-93.
***Lagerkvist, H, et al. (2020). Ten years' experience with the Ponto bone anchored hearing system – a systematic literature review. Clinical Otolaryngology (under review).*

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Ponto Abutment Family with OptiFit™ Geometry

- The Ponto abutment family with its OptiFit™ geometry *Different* abutment lengths

Natural skin thickness	Abutment length
0.5-3 mm	6 mm
3-6 mm	9 mm
6-9 mm	12 mm
9-12 mm	14 mm

Wide Ponto implant with 6 mm abutment

Wide Ponto implant with 9 mm abutment

Wide Ponto implant with 12 mm abutment (2012)

Wide Ponto implant with 14 mm abutment (2015)

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[1] Johansson, Holmberg & Hultcrantz (2014)
[2] E.g., Hultcrantz (2011)

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Easy identification

Green connection screw

- Easy identification of the Ponto abutment and universal hexagon interface
- A clear signal on available options for the patient
- ISQ compatible

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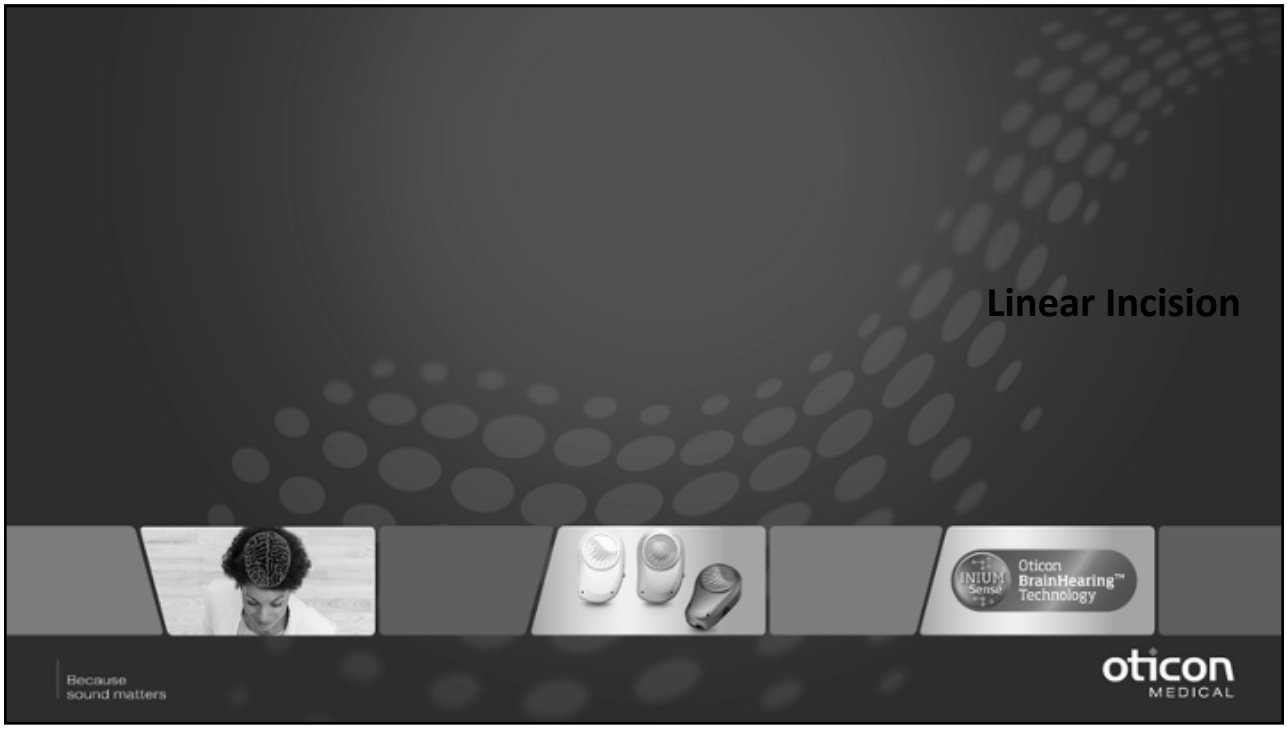

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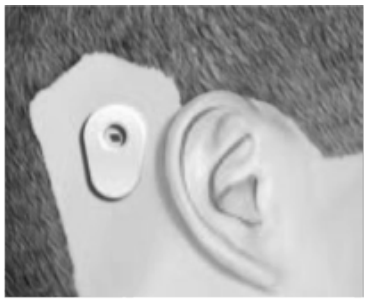
Linear Incision



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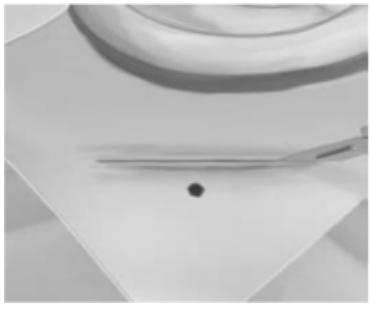
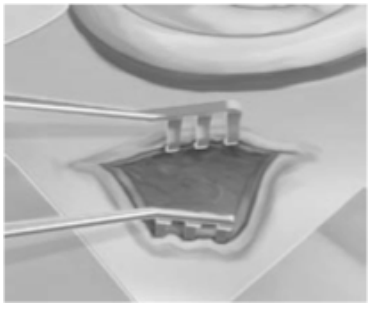
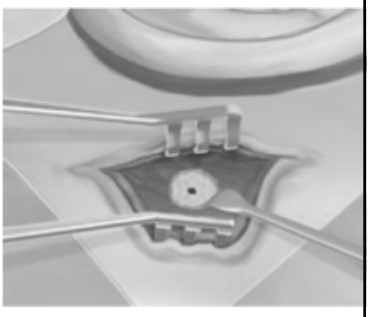
Linear Incision Cont.

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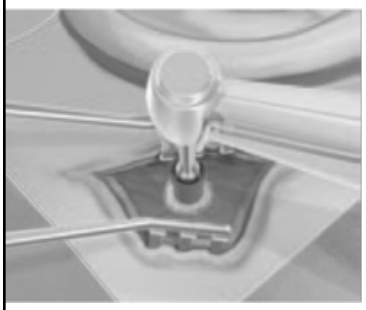
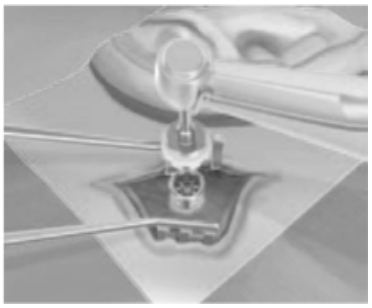
Countersink and implant insertion





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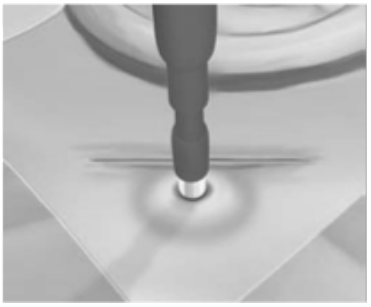
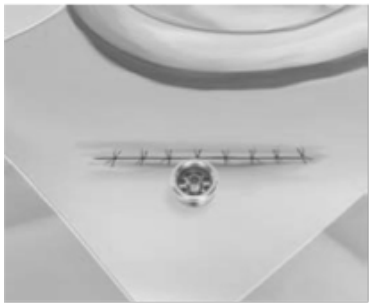
Implant insertion





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Linear surgical Procedure

- **Less invasive approaches**
  - Linear – approximately 4 cm incision with minimal soft tissue reduction

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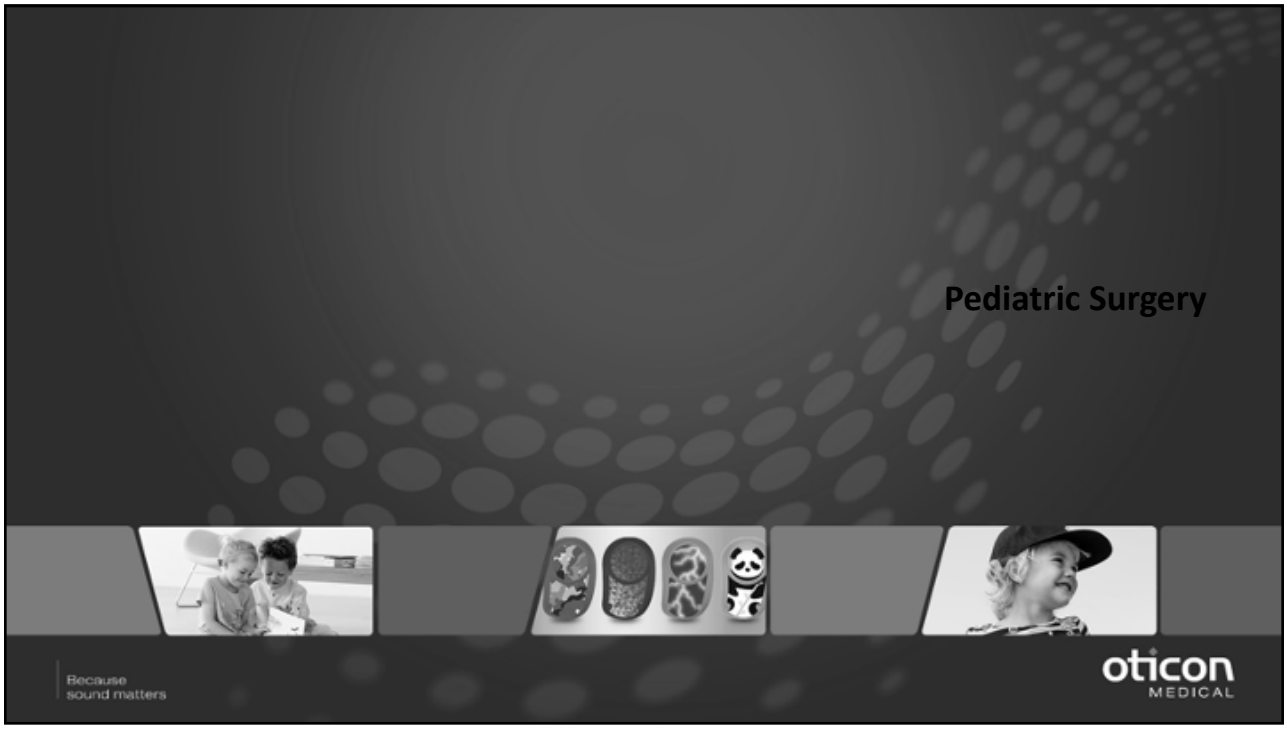

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Pediatric/Irradiated Bone – Two Stage Surgery

- Two-Stage Surgery
  - First stage: fixture implantation.
    Recommend placement of a “sleeper”
  - 3-6 month osseointegration period.
  - Second stage: abutment installation
    Primary fixture.
    Fitting of the sound processor

Pediatric Considerations

Drilling

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

Creating additional bone

- In children, bone chips may be used to create additional bone for implant anchorage.

Sleeper implant

- The risk of trauma to the implant is greater in children, especially young children (age < 12 years), due to physical activity as well as soft and/or thin bone.
- Children are often very dependent on their sound processor for development of social and language skills. It is therefore recommended that an extra sleeper implant with a cover screw is “banked” approximately 10mm from the center of the primary implant.
- In case of implant loss, 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.

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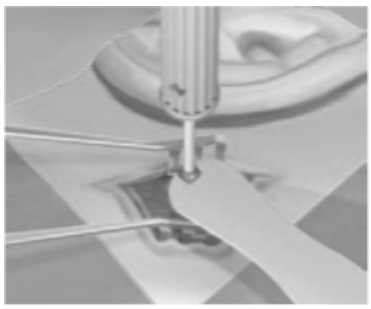
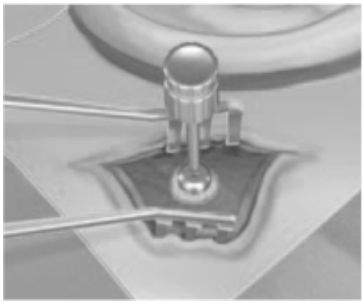
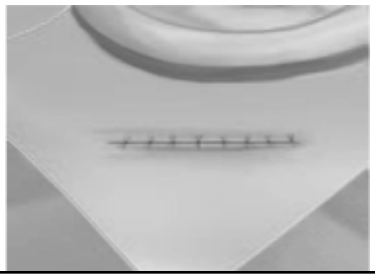
2 stage surgery - pediatric







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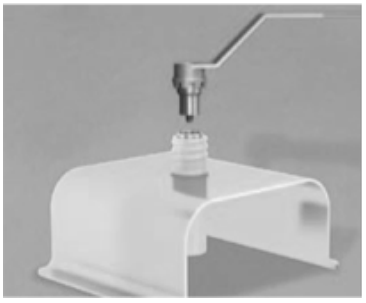
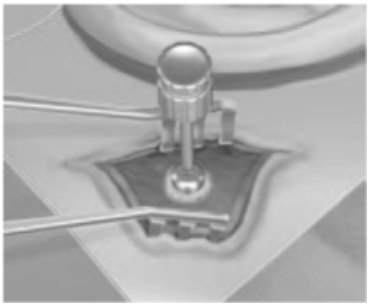
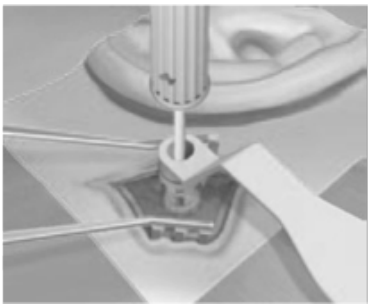
2nd Stage – Abutment attachment







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New soft healing cap

Resilient design

- The soft healing cap is made of a specially selected thermoplastic elastomer material
- It's flexible design allows the cap to stay in place if subjected to impact

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6/16/20

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MIPS - A truly new perspective on tissue preservation

"Tissue preservation has been a great improvement for patients. With MIPS, the cosmetic outcomes are even better"
Malou Hultcrantz, Professor, MD, PhD

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Minimally Invasive Ponto Surgery

10 Years of sound that matters

- A *truly* new perspective on tissue preservation
  - Over 50% of all BAHS surgeries are done with MIPS
  - Numbness is almost nonexistent nowadays because of MIPS
  - Soft tissue outcomes are excellent
  - Cosmetic outcomes are better then ever
- Our long-term goal is to further reduce the need for treatment after surgery

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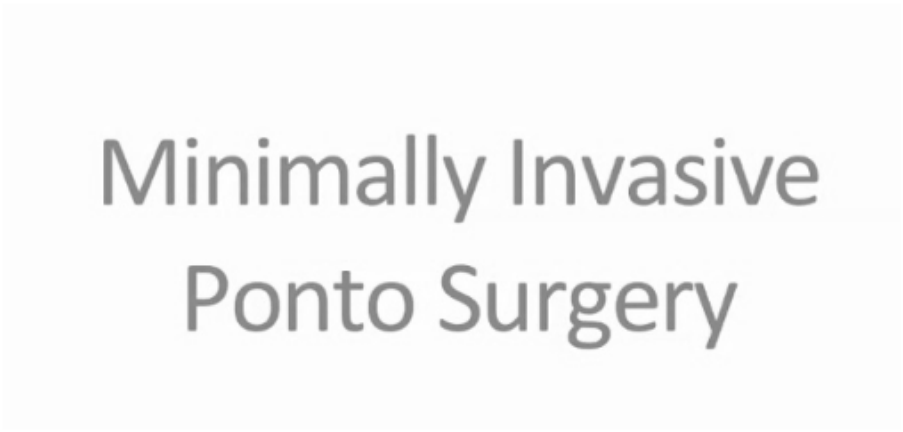
MIPS SURGICAL VIDEO



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Designed for simple, easy care

- Participants:
  Twenty-seven studies evaluating more than 1,100 patients with conductive or mixed hearing loss and single-sided deafness.

- Conditions:
  Adverse skin reactions according to *Holgers (across visits) up to five years follow-up (mean follow-up time 16 months).

- Task: *Holgers score ≥2 indicates need for skin-related aftercare treatment.

1. *Lagerkvist, H, et al. (2020). Ten years' experience with the Ponto bone anchored hearing system – a systematic literature review. Clinical Otolaryngology (under review).*

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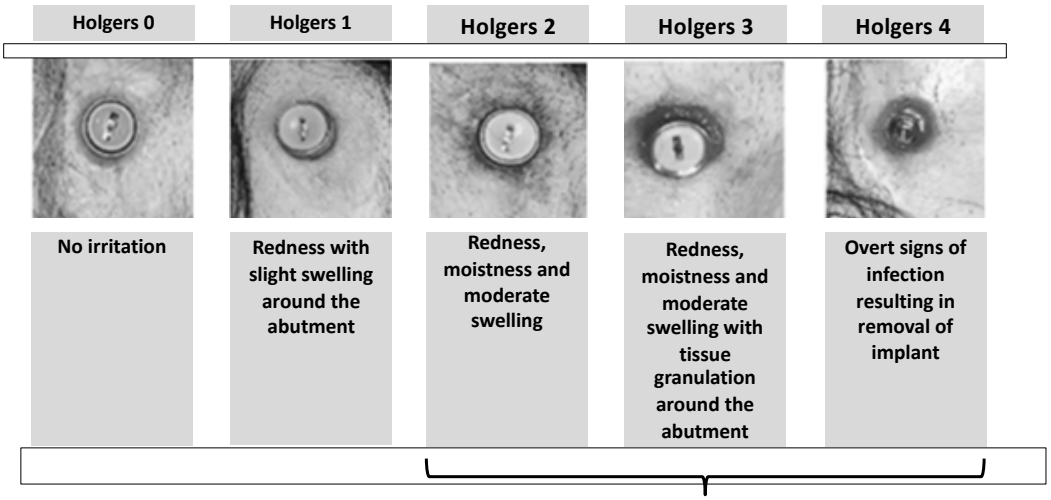
The Holgers score



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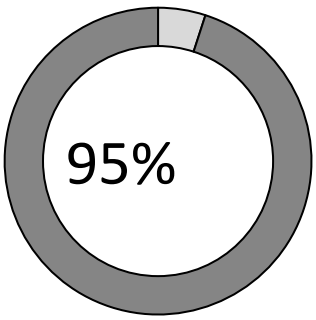
Designed for simple, easy care

In 95% of follow-up visits no skin-related aftercare treatment* is required[1]



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The Ponto System Today

- Ponto 4 and Ponto 3 Superpower share the same basic foundation
- Both have the widest frequency bandwidth in the market
- The same durable design and coupling
- The vast experience of Oticon sound processing and feedback management

World's most powerful abutment-level sound processor

World's smallest and most up to date sound processing

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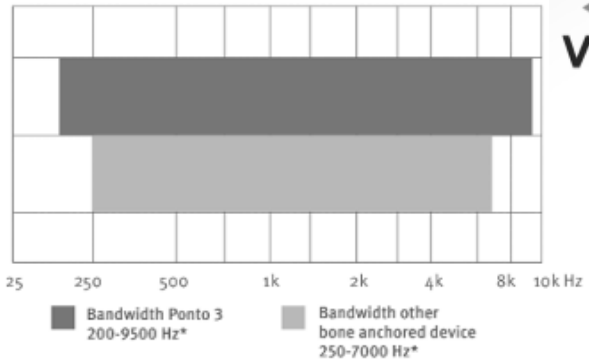
Industry widest frequency bandwidth

Frequency bandwidth is needed for the full spectrum of sound and particularly important for speech understanding.



**Linear comparison of equivalent bone anchored sound processors. The perceptual performance has not been evaluated.*

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In Summary

- 98% of users report improved quality of life after Ponto surgery
- In 95% of follow-up visits, no skin-related treatment is required
- Ponto 3 SuperPower with its high output, and Ponto 4 with is superior sound processing, offer hearing excellence to all bone anchored users
- It can be concluded that the Ponto System offers people at all stages of life a simple, safe procedure with proven results. The procedure can be done in minutes and changes users' lives forever

The Ponto™ System: 10 years of Sound that Matters