The Ponto System: 2016 Update

Because sound matters

oticon MEDICAL

Technology and Procedure Go Hand in Hand

NEW

Longer abutments

NEW

More stable implants

Patient benefit

Less invasive techniques

NEW

NEW

Earlier Activation*

"Fitting of the Ponto system is based on the individual patient evaluation, at the earliest:
– In Europe, CE countries, 2 weeks
– In USA, 3 months"

Because sound matters

oticon MEDICAL

Minimally Invasive Ponto Surgery (MIPS)

Because sound matters

oticon MEDICAL

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

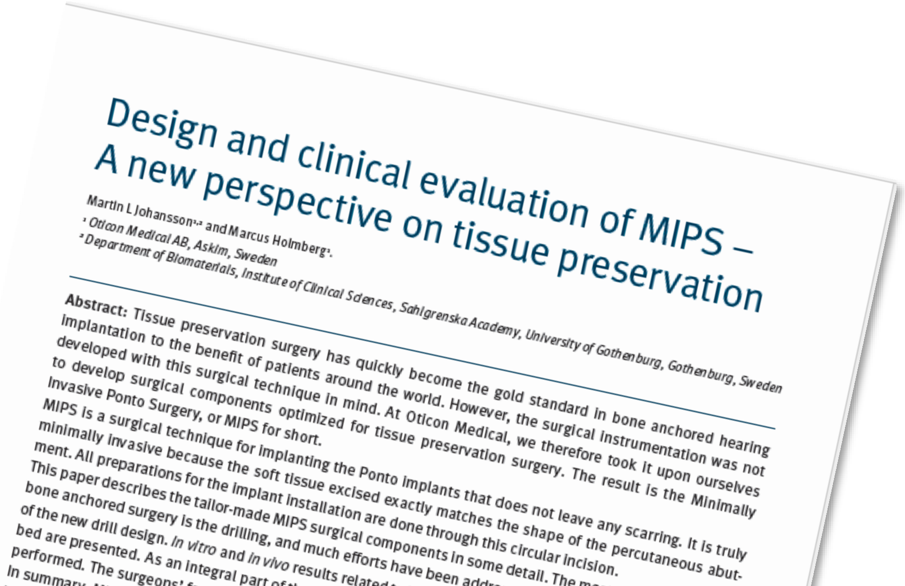
Evidence Based Development

- Tissue preservation surgery has quickly become the gold standard in bone anchored hearing implantation to the benefit of patients around the world.
- Tissue preservation surgery has fundamentally changed bone anchored hearing surgery.
  - The long-term results show a huge patient benefit in terms of cosmetic outcomes and reduction in numbness around the implant.

(Hultcrantz and Lanis 2014; Johansson et al, 2014).

Based on the Proven Tissue Preservation Technique

- The development of MIPS has taken more than two years and involved some of the world's leading bone anchored implant surgeons.
- A new surgical technique is a big step. Therefore, an evaluation of the MIPS technique was performed in 16 centers in six countries.

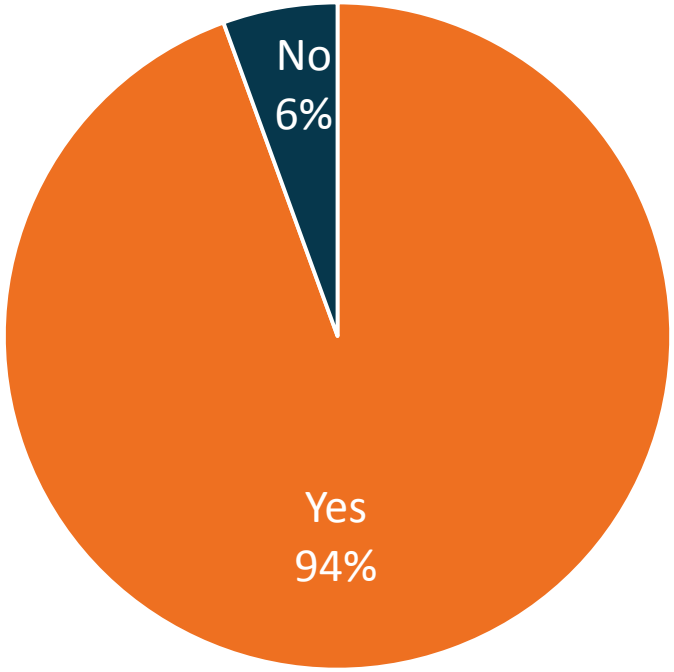


Design and clinical evaluation of MIPS – A new perspective on tissue preservation

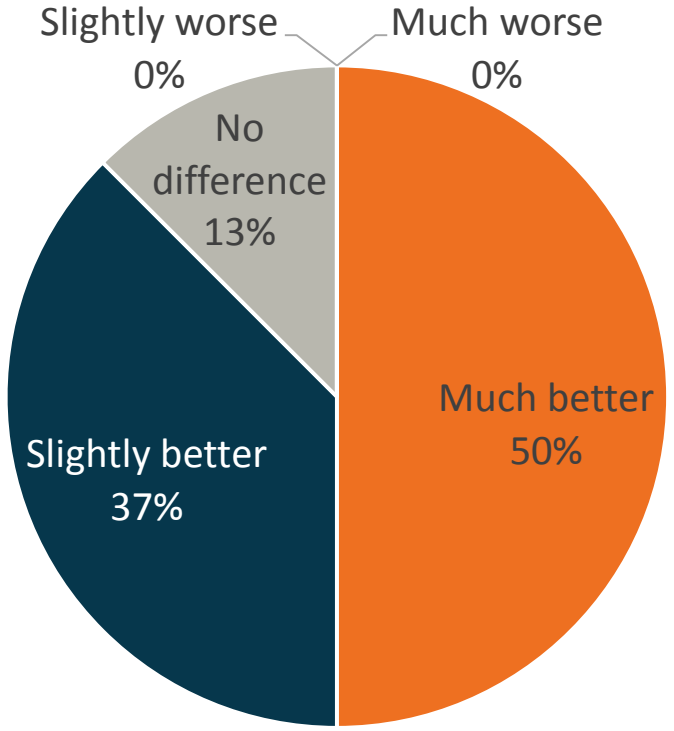
Martin L Johansson[1,2] and Marcus Holmberg[1].
[1] Oticon Medical AB, Askim, Sweden
[2] Department of Biomaterials, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

Abstract: Tissue preservation surgery has quickly become the gold standard in bone anchored hearing implantation to the benefit of patients around the world. However, the surgical instrumentation was not developed with this surgical technique in mind. At Oticon Medical, we therefore took it upon ourselves to develop surgical components optimized for tissue preservation surgery. The result is the Minimally Invasive Ponto Surgery, or MIPS for short.
MIPS is a surgical technique for implanting the Ponto implants that does not leave any scarring. It is truly minimally invasive because the soft tissue excised exactly matches the shape of the percutaneous abutment. All preparations for the implant installation are done through this circular incision.
This paper describes the tailor-made MIPS surgical components in some detail. The ...
bone anchored surgery is the drilling, and much efforts have been ...
of the new drill design. *In vitro* and *in vivo* results related ...
bed are presented. As an integral part of ...
performed. The surgeons' ...
In summary ...

What Do The Professionals From The Evaluations Say?



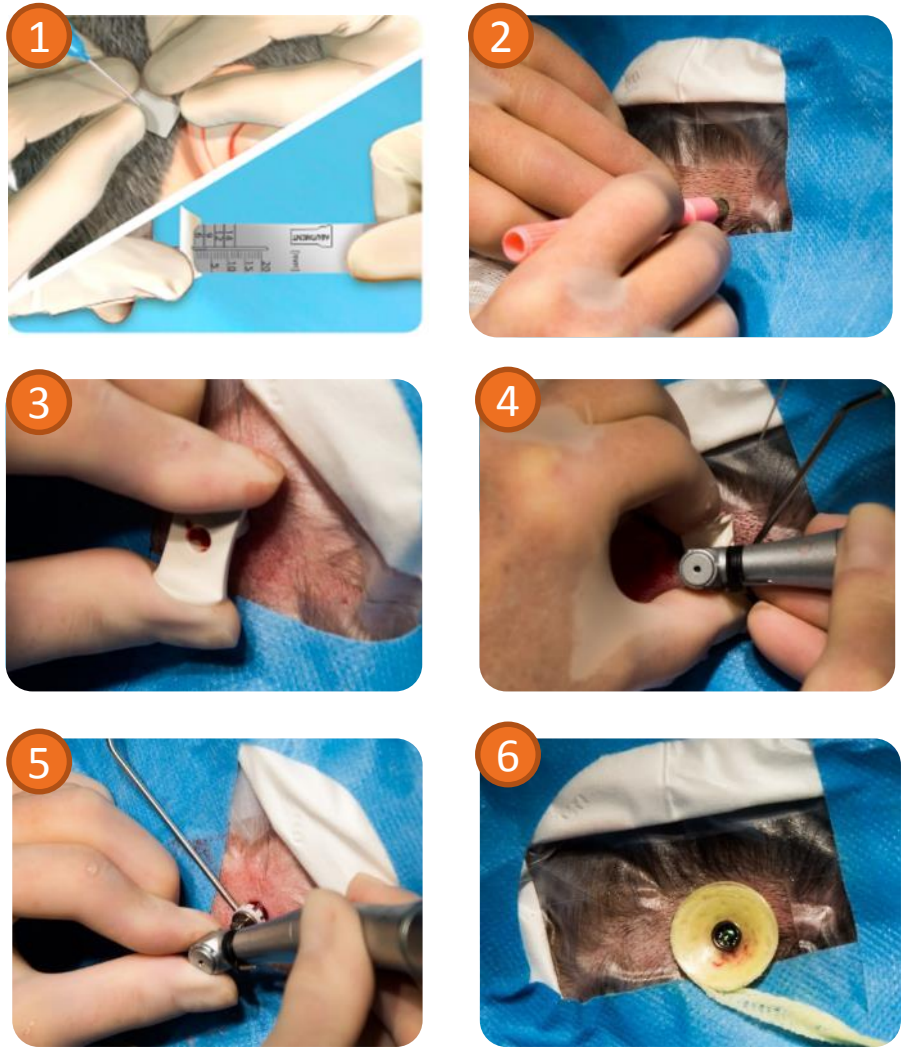
Are you likely to continue to use the MIPS procedure?



Using MIPS, do you feel that you help your patients in a better way?

MIPS Procedure, Summary

1. Decide Position and Measure Skin Thickness
2. Punch
3. Insert Cannula
4. Drill. Guide and Widening Drilling
5. Insert Implant
6. Fit Soft Healing Cap



A Truly New Perspective on Tissue Preservation

- Minimizing post-op complications
- Suture free surgery - No scarring
- Tailor-made surgical components

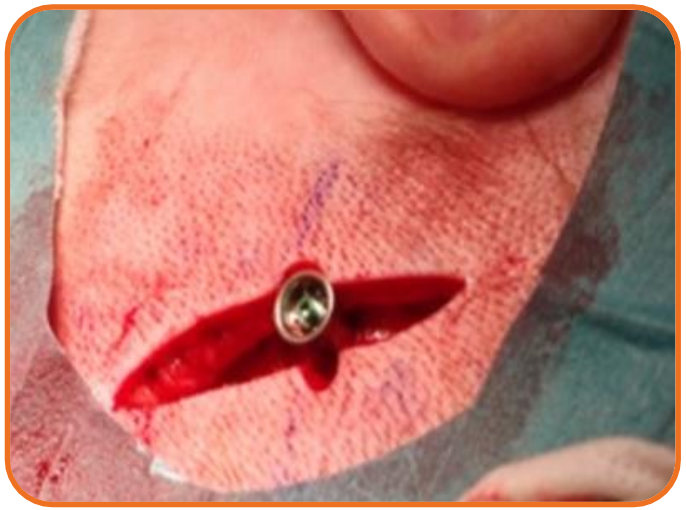
Minimizing Post-op Complications

Tissue preservation surgery
3 months post- op

MIPS surgery 1 week post-op

*Johansson M, Holmberg M, Hultcrantz M, “Bone anchored hearing implant surgery with tissue preservation – A systematic literature review,” Oticon Medical white paper, M52107, 2014

Suture Free Surgery - No Scarring



Tissue preservation surgery
with linear incision

MIPS Surgery

Tailor-Made Surgical Components

Current system

MIPS Surgery kit, 4mm

- New components for MIPS includes a unique cannula and state-of-the-art drills for tactility and control during the procedure.

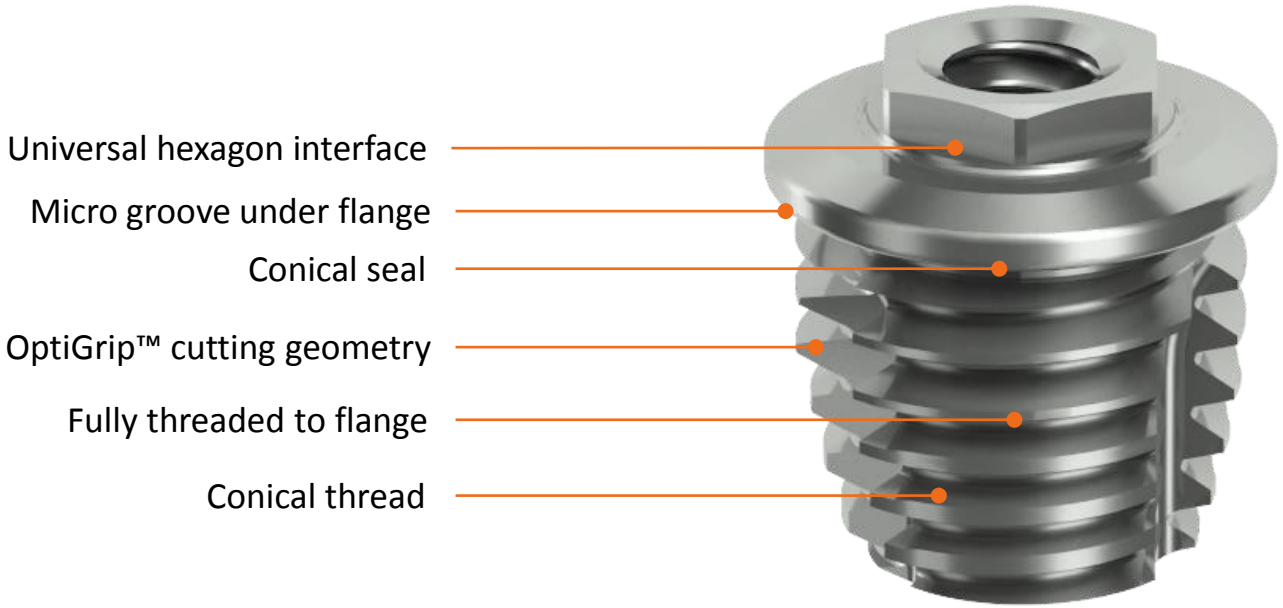
Minimally Invasive Ponto Surgery (MIPS)

Biohelix™

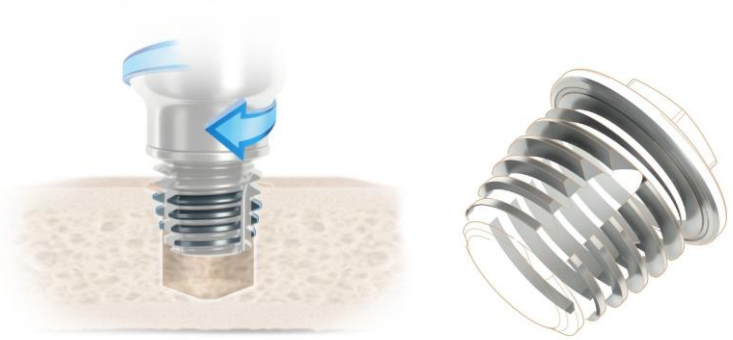
Because
sound matters

oticon
MEDICAL

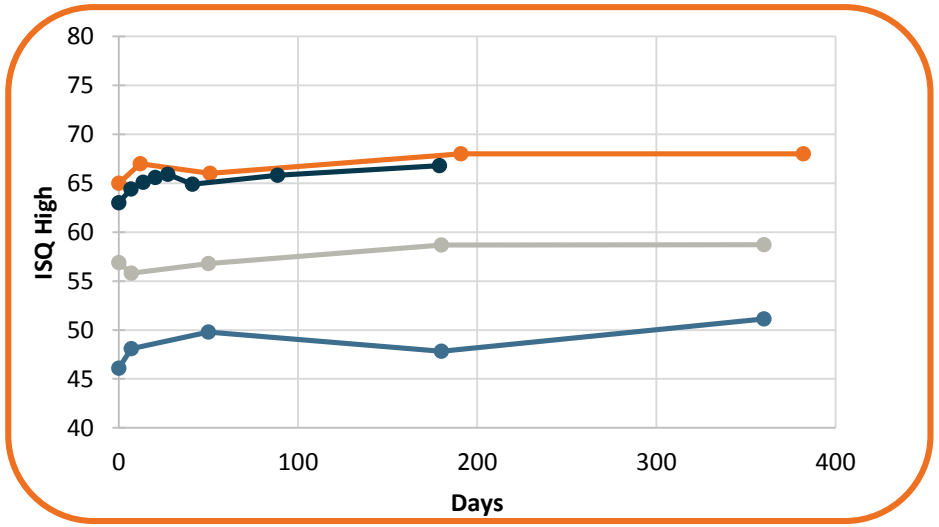
A Great Starting Point – Wide Ponto Implant



OptiGrip™ Geometry



- **Maximized surface**
  -Unique implant geometry
- **Maximized bone/implant contact**
  -Deeper engagement of threads along the full length of the implant
  -Bone preservation, 27% less bone removal*



ISQ data from 3 studies, 6, 9 &12 mm abutments

Foghsgaard & Caye (2014)
Hultcrantz (2015)
Nelissen et al. (2015)

Because
sound matters

oticon MEDICAL

Setting New Standards for Implant Technology

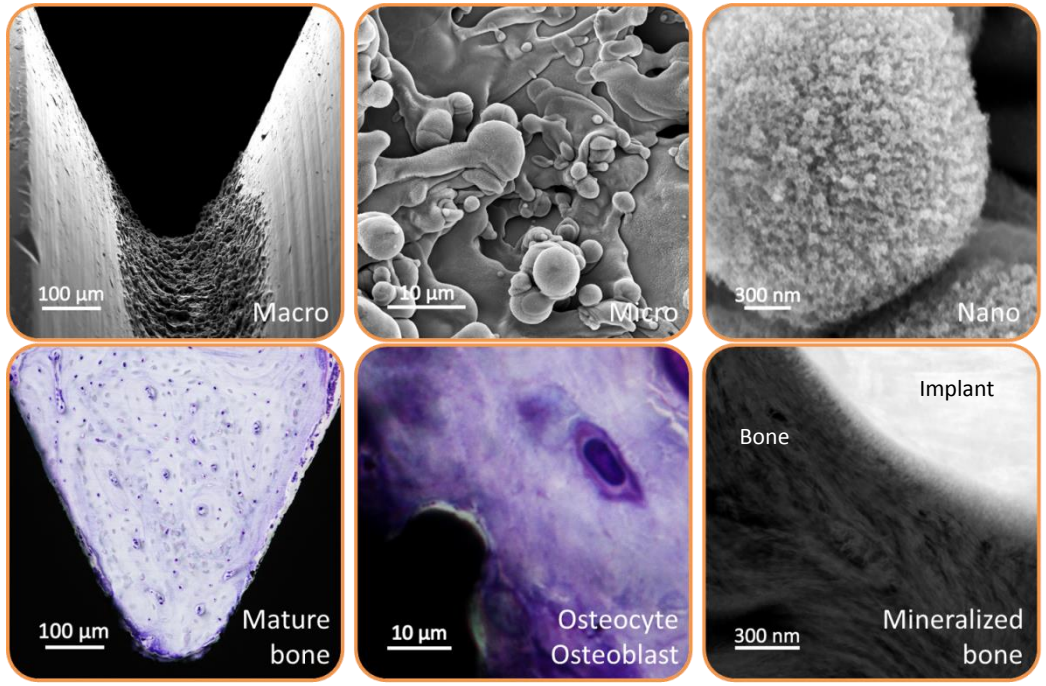
The Ponto BHX Implant is the perfect match between the proven OptiGrip™ geometry and the latest surface technology. With its micro- and nano-sized structures it takes osseointegration to the next level - bone bonding

- **First laser-ablated titanium surface**
- **Stronger than bone**
- **Highest stability from day one**

First Laser-Ablated Titanium Surface

Biohelix™ is the outcome of the latest research from the world leading experts of osseointegration in Gothenburg, Sweden. The unique Biohelix™ laser-ablation technology enables a site specific modification at the root of the threads of the proven OptiGrip™ geometry. This creates a three level surface topography matching the natural bone structure at macro-, micro-, and nano-scale.

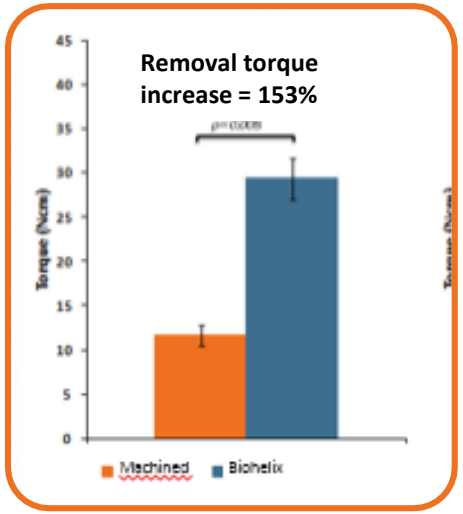
The surface of Ponto BHX Implant matches the building blocks of bone:

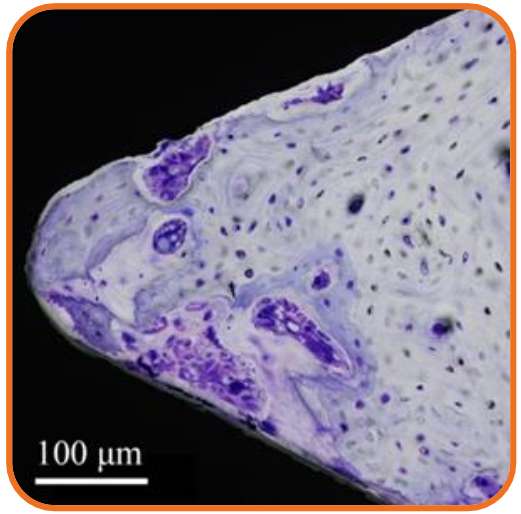


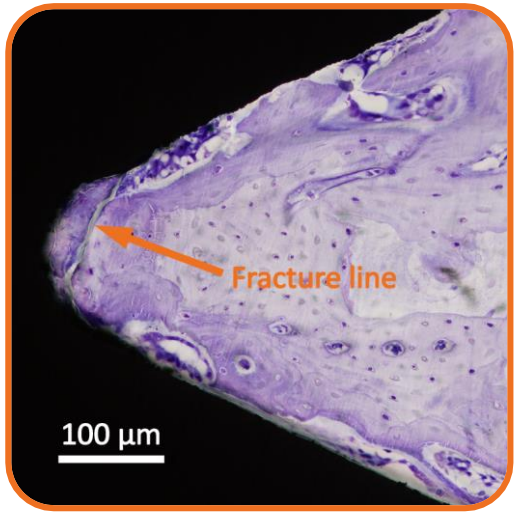
"Nanometer roughness plays an important role in osseointegration. The improvement in biomechanical capacity is even greater than I imagined."
R. Brånemark, Associate Professor MD Msc. PhD

Stronger Than Bone

Biohelix™ increases the strength of the bone to implant interface by more than 150%. Studies prove that the bone bonding to the Ponto BHX Implant, is in fact stronger than the bone itself[1]





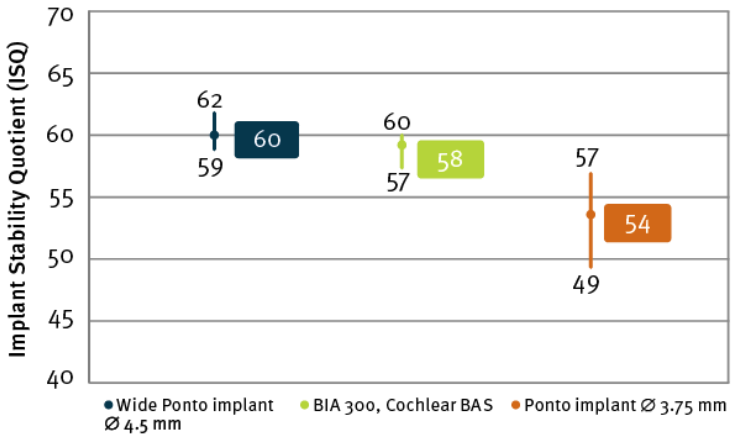


1. Johansson M L, et. al., "Site-specific laser modification promotes higher osseointegration of titanium implants". Present. at Osseo, Lake Louise, Canada, May 2015

Highest Stability From Day One

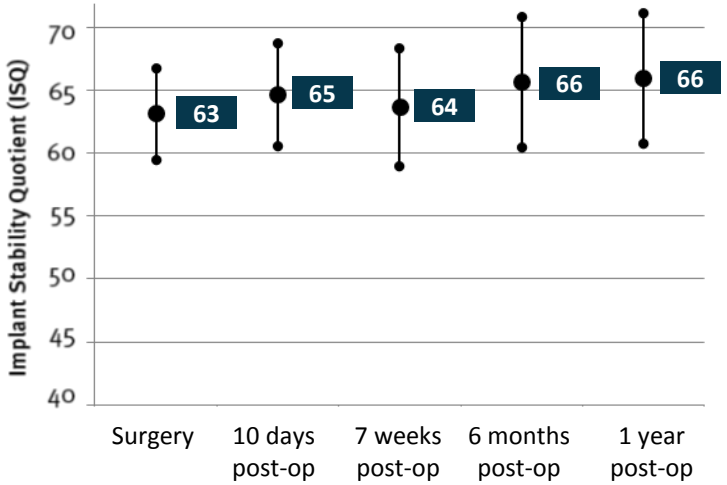
- The highest initial stability based on the proven OptiGrip™ geometry

Initial implant stability comparison



Initial ISQ values measured in pre-clinical tests in artificial bone[1]

Implant stability development over time



ISQ values measured in clinical study: Average of 20 patients during the first year after implantation[2]

Because sound matters

[1] *Westerkull & Jinton (2012)*
[2] *Foghsgaard & Caye-Thomasen (2014)*

oticon MEDICAL

So What Are The Benefit For The Patients?

- With its superior primary stability the OptiGrip™ geometry of the Wide Ponto implant is an optimal starting point for a successful percutaneous implant

- We see Ponto BHX Implant as a further improvement aiming at faster osseointegration and a stronger bonding to the bone

Thereby supporting

- The minimally invasive approach and the longer abutments needed for tissue preservation
- Earlier fitting of the sound processor*
- Aiming for even lower loss rates also in children and patients with soft and compromised bone

A better way to the optimal hearing experience

* In Europe, CE countries, 2 weeks, In USA, 3 months

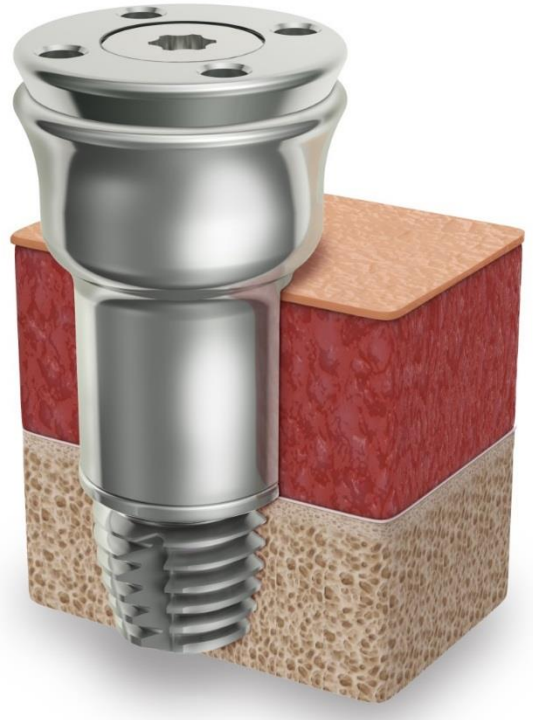
The Abutment Extension

Because
sound matters

oticon
MEDICAL

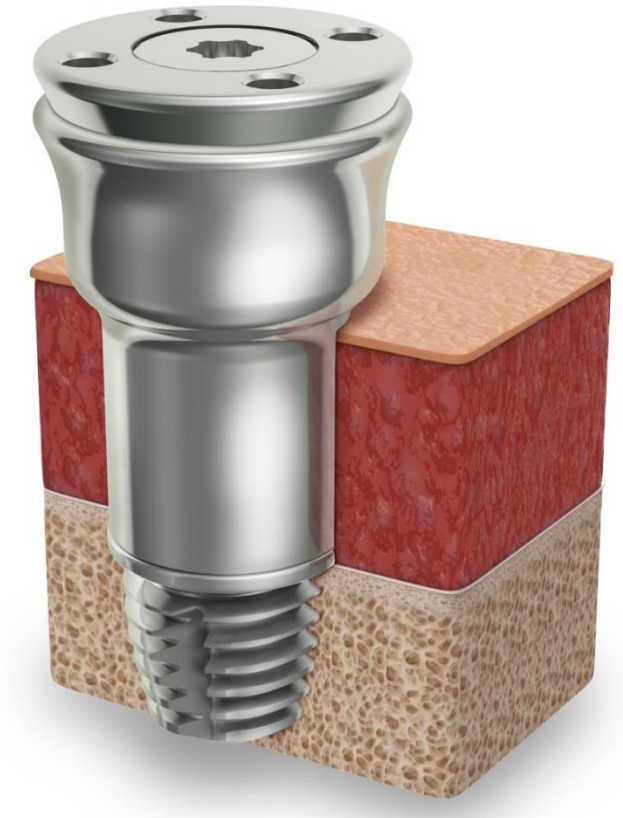
Small Change. Big Difference

- Freedom of choice
- No surgery
- Seamless fit on existing abutment



Small Change. Big Difference

- No surgery
  - The Abutment extension is connected on the existing abutment without any surgery involved.
  - It is delivered non-sterile.
  - Placement can take place outside the surgical theatre.
  - The Abutment extension does not work with BAHA processors. It must be removed if a BAHA is fitted

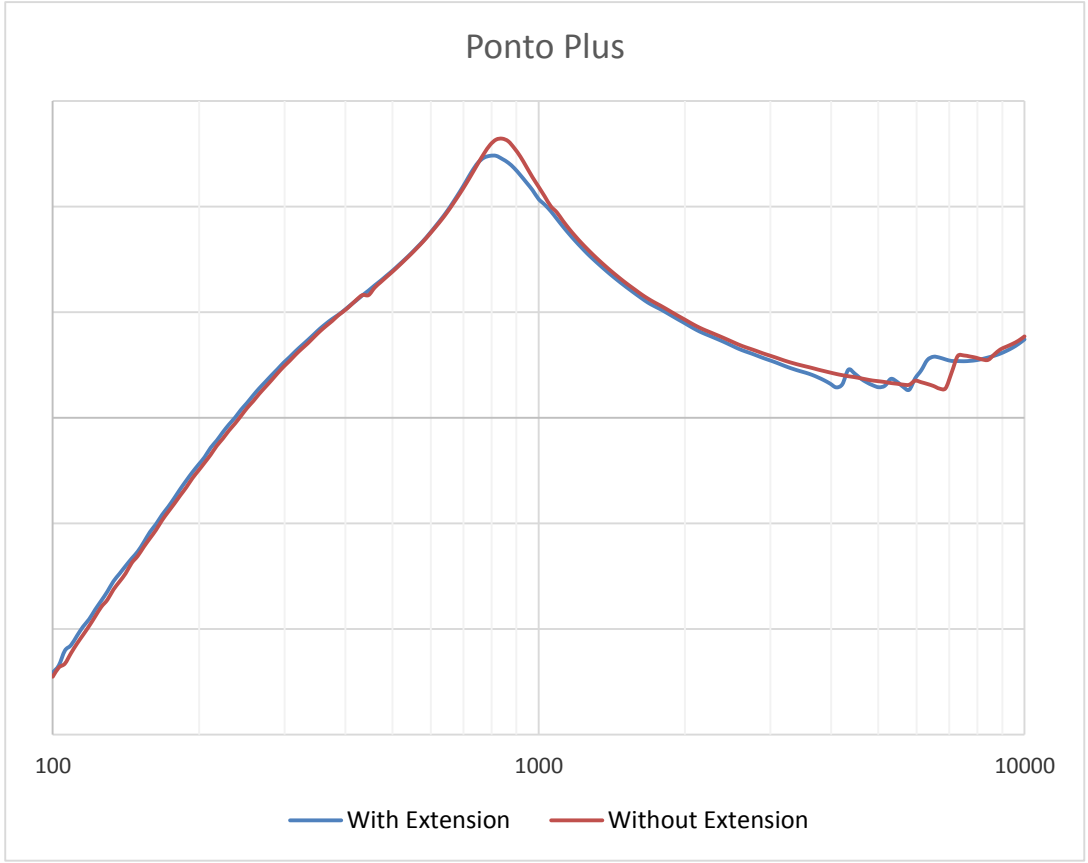


Is The Sound Transmission Affected By The Abutment Extension?

- No

- The graph shows the output as measured with accelerometer on counterweight mounted on patient's abutment; with and without abutment extension.

- The curves show that they are on par with no major difference.



*When normal Genie Medical fitting flow is followed.

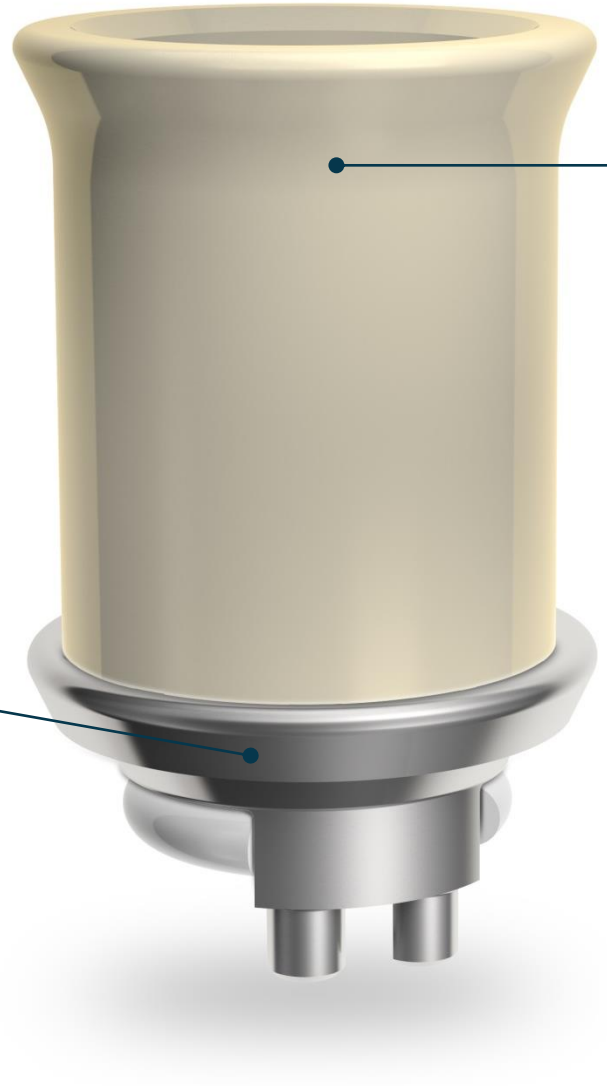
The Product

Intended use

The Abutment extension is intended as a non-invasive extension of the abutment, as a point of attachment for the Ponto sound processor.

Abutment extension

The part that stays on the abutment once connected. The two pins match two of the holes in the abutment and guides the Abutment extension to fit. It allows the Ponto processor to be fitted on most abutments.



Adapter

- Is mounted to the Abutment extension and act as connection point for the counter torque wrench.
- Please make sure that you do not apply any force to the abutment during installation.
- The adaptor must be used when connecting or disconnecting. Once the Abutment extension is connected to the abutment, the adapter is simply snapped off
- The adapter can be ordered separate if the Abutment extension is to be removed at a later stage.
- *Single use only!*

The Product

Part

- M52321 Abutment extension, 1mm

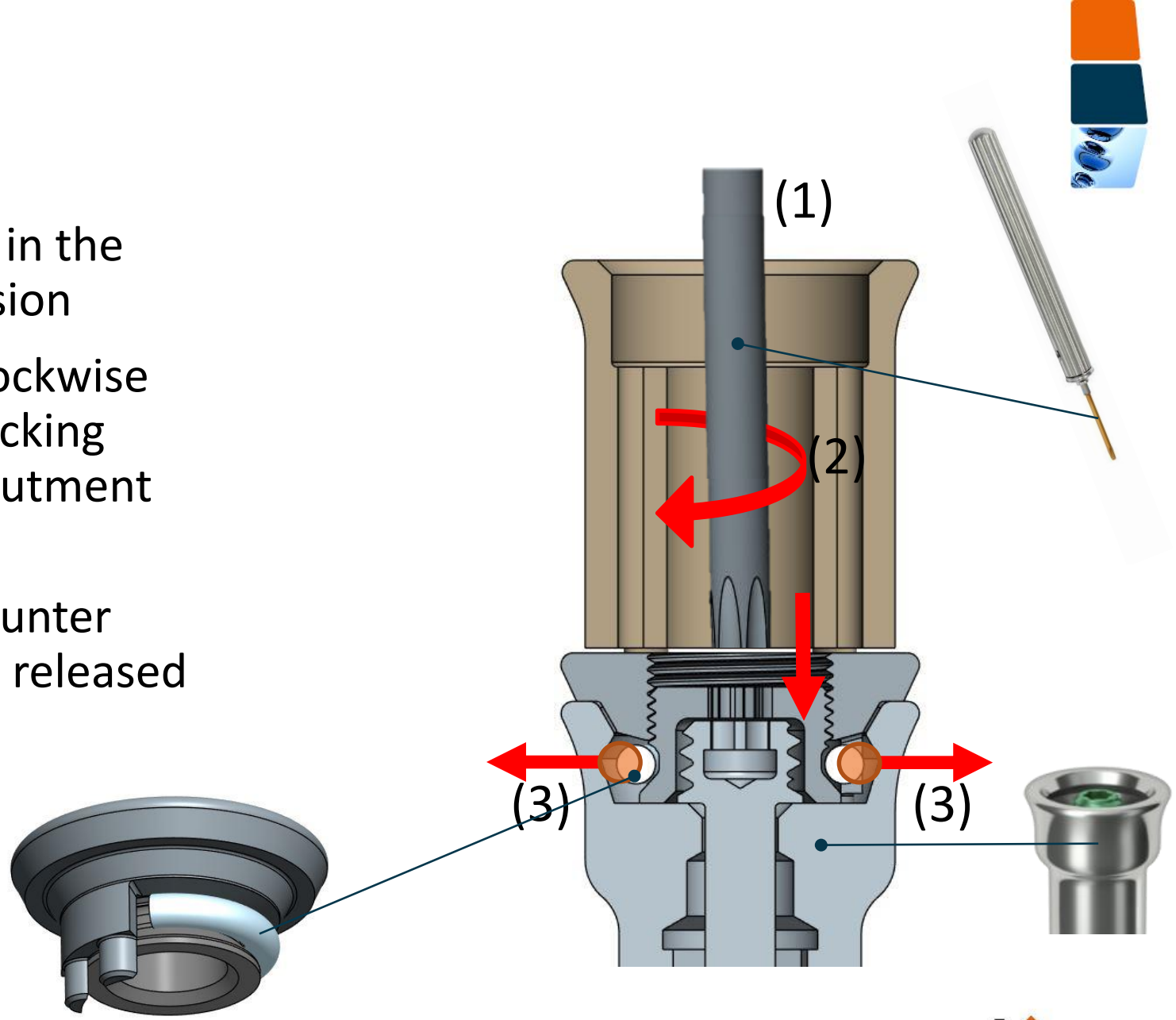
  The Abutment extension, 1mm is delivered together with an adapter. *Single use only*

- M52322 Adapter, Abutment extension

  The adapter is available as single product. When removing the abutment extension an adapter is needed, this article is only ordered when abutment extension removal is planned. *Single use only*

How Does It Work?

- The screwdriver (1) is inserted in the center of the Abutment extension
- By turning the center screw clockwise (2), the mechanics force the locking spring out (3) and locks the Abutment extension to the abutment
- By turning the center screw counter clockwise, the locking spring is released



Bimodal Use of the Oticon Medical Streamer

Because sound matters

oticon MEDICAL

What Does “Bimodal” Use Mean in Regard to Oticon Medical Streamer?

- A patient wearing a wireless Ponto sound processor on one ear and an Oticon hearing aid* on the other can receive information from the same Oticon Medical Streamer.

- *However*, bimodal use of Oticon Medical Streamer does not mean that the two hearing devices can talk to each other – They still must be programmed separately, and changes made on one device are not reflected in the other.

* Find the full list of Oticon Medical Streamer-compatible hearing aids on the following slide, and at www.oticonmedical.com/OMStreamerHA

Which Oticon Hearing Aids Can Be Used in a Bimodal Setup?

- Currently, there are six models that can be used bimodally with OM Streamer*:

- ***Dynamo:***
  - Dynamo SP4
  - Dynamo SP6
  - Dynamo SP8
  - Dynamo SP10

- ***Sensei SP:***
  - Sensei SP
  - Sensei SP Pro

Because sound matters

* Find the full list of Oticon Medical Streamer-compatible hearing aids at www.oticonmedical.com/OMStreamerHA

oticon MEDICAL

Bimodal Fitting Tips

Because
sound matters

oticon
MEDICAL

How Do We Recommend That Oticon Medical Streamer is Used in Bimodal Fitting Cases?

- Leave Oticon Medical Streamer **OPEN**.
  - The wireless Ponto sound processor and the Oticon hearing aid can both be used with the Oticon Medical Streamer without linking, right out of the box, in the **OPEN** condition

Which Streamer Can I Use Bimodally?

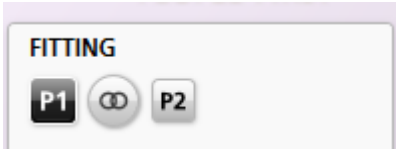
	Oticon Medical Streamer	Ponto Streamer	Streamer Pro
			
How does it come out of the box?	Always open, with the possibility to be linked	Always open, with the possibility to be linked	Two versions: One always linked, one open with the possibility to be linked. Availability depends upon country.
	✓	✓	✗
	✓ Only with selected hearing aids*	✓ Only with selected hearing aids*	✓

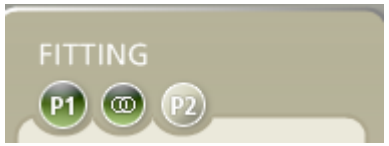
* Dynamo (Dynamo SP4, Dynamo SP6, Dynamo SP8 and Dynamo SP10)
Sensei SP (Sensei SP and Sensei SP Pro)

Bimodal Fitting Tip

- **Program Ponto and the hearing aid with the same number of programs**

  - It’s easiest to control both devices together via OM Streamer if the wireless Ponto sound processor and the hearing aid have the same number of programs.





How Will The ConnectLine App Work With Bimodal Fittings?

- The CL App works the same way with bimodal fittings as it does with two Ponto wireless sound processors

Questions???

Abutment Extension Demonstration