

For Internal Use Only

InvisiShunt Training Manual



Longeviti Neuro Solutions, LLC

303 International Circle Suite 190

Hunt Valley, MD 21030

info@longeviti.com

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Section 1:

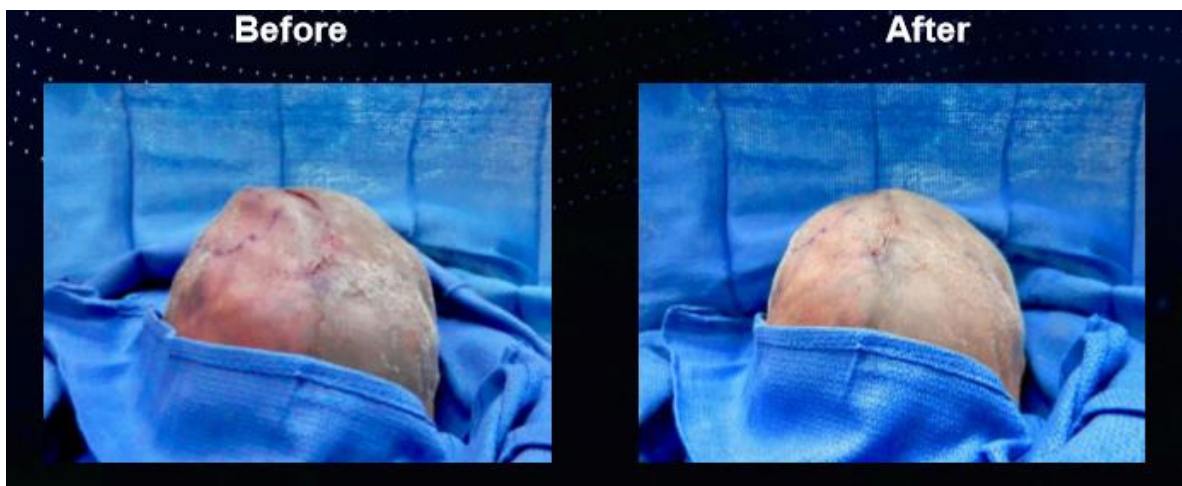
Longeviti Neuro Solutions: InvisiShunt™

What is the InvisiShunt™?

The InvisiShunt™ design was manufactured to restore the natural contour of the cranium which may have resulted from previous neurosurgical procedures. Additionally, the InvisiShunt™ supports location and orientation.

The InvisiShunt™ surgical implants are marketed as single-use sterile implants with various shapes and sizes for different areas of the craniofacial skeleton. Its applications include non-load bearing augmentation and/or reconstruction of the craniofacial skeleton. The InvisiShunt™ uses OmniPore: a high-density polyethylene material. OmniPore has a long, safe history in craniofacial reconstruction and augmentation applications.

Some characteristics of the InvisiShunt's physical composition include: it is 50% porous, the implant can be easily augmented at the site of surgery by a scalpel and/or scissors, and a cutting needle can easily penetrate the surface if the need of attaching the implant to tissue or muscle is necessary.



l o n g e v i t i TM



InvisiShuntTM



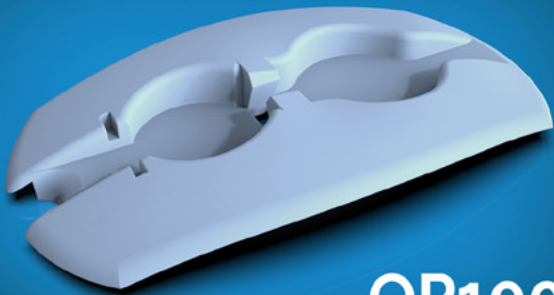
Learn More at LONGEVITI.COM

InvisiShunt™

by l o n g e v i t i

INTRODUCING THE INVISISHUNT

Certain neurosurgical procedures create cranial deformities. The InvisiShunt supports location and orientation while restoring the natural contour of the cranium.



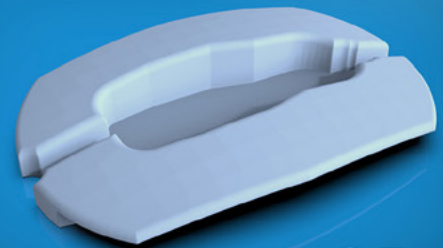
OP1000



OP4000



OP2000



OP5000

Coming Soon



OP3000



OP6000

OP7000

Coming Soon



Contact Us to Learn More about the InvisiShunt™

OFFICE 410-527-1803 | FAX 410-527-1022 | INFO@LONGEVITI.COM | LONGEVITI.COM

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PATENT PENDING - CAT # 004

Section 2:

Equipment Preparation

Equipment Images and Description:

1. **InvisiShunt™ Kit** (ex. OP4000)

- 1 InvisiShunt™ Implant
- 1 Cutting Guide

2. **Perforator:** this instrument is used to drill the burr holes



3. **Router:** this instrument is used to perform the craniectomy by cutting around the marked cutting guide line



4. **5mm Screws:** these are used to fixate the InvisiShunt™ onto the skull (we recommend 6 screws, but it is ultimately up to the surgeon's discretion)



Discussion Points with Surgical Tech:

1. Before the surgery, ensure that the surgical tech has prepared **5mm self-drilling screws**, the **cranial perforator** and the **cranial router**.
 - The **cranial router** is not traditionally used in shunt valve implantation, only the **perforator**.
2. Open the **implant kit** as early as acceptable by the circulator.
 - Explain that the **cutting guide** will be used early in the procedure and is critical to successful implantation.
3. Make sure the surgical tech has the **cutting guide** ready right after the first perforation is completed.
4. Make sure he/she has the **screws loaded** right after the **craniotomy** is completed.

Section 3

Procedural Preparation (For optimal reimbursement, it is critical to document the acquired deformity of the skull code, M95.2, **prior to surgery**)

InvisiShunt™ Information Resources:

- Animated InvisiShunt™ procedure (www.invisishunt.com)
- InvisiShunt™ product brochure
- Step by Step procedure brochure

Important Pre-Op Discussion Points:

1. Size & Location of Incision

- Perform a **“C” incision** around the auriculotemporal artery and nerve
 - o Ensure skin flap is the widest at the base
 - o Importance: avoid compromising blood flow and numbness
- If revision surgery:
 - o Should make use of existing incisions
 - o Incisions over implants are associated with higher infection rates
- An undersized incision can be extended, or a sub-periosteal exposure can be performed
 - o Any modification that allows the **cutting guide** to maintain its shape is acceptable

2. Starting the Craniectomy

- Surgeon should plan their trajectory by performing the first **perforator/burr hole**
- The **cutting guide** should then be placed over the existing burr hole and oriented in the desired location, posterior portion should be slightly angled downward or towards C1 so there is no sharp angle for the catheter to the abdomen.
 - o The skull should be marked with a **marking pen** (permeant side)
- The craniectomy can proceed with a second perforator hole at the most posterior portion of the tracing.
- The **contiguous cuts** should extend from the outer diameter of the burr holes and continue along the **outside** perimeter of the **marked cutting guide lines**

**Optional method: tracing first, burr holes, contiguous cuts outside tracings*

3. Fixating the InvisiShunt™ (when a shunt is being used in conjunction with the InvisiShunt)

- First, the ventricular catheter is placed in the ventricle
- **Before the ventricular catheter is cut**, the InvisiShunt™ should be fixated with **5mm screws**
- **Slightly bend catheter to shunt valve to mark for cutting**
- Ensure that the ventricular catheter can be connected to the shunt in the InvisiShunt™ without displacing the ventricular catheter
 - o Once cut, the ventricular catheter should be connected to the shunt valve
- The shunt valve should be placed in the InvisiShunt™
- Once flow is confirmed, a closure of interrupted subgaleal sutures is recommended

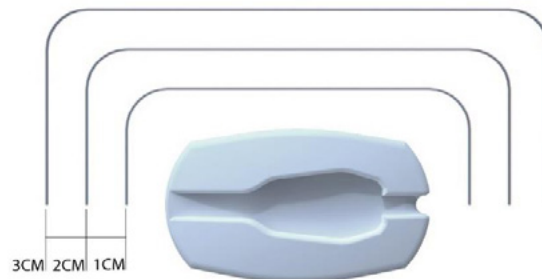
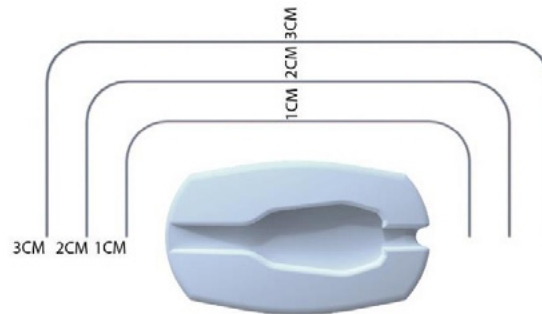
Incision Guide:

Acceptable incision range: **1cm-3cm** from the perimeter of the InvisiShunt™

- **3cm incision = ideal**
- 2cm incision = okay but not ideal
- 1cm incision = satisfied but not preferred

3cm incision is recommended to avoid scalp dissection

- Most neurosurgeons will perform a hockey stick or “C” incision. The key is to make sure that the incision is large enough to fully fit the InvisiShunt and ideally it does not fall under the incision line.



Section 4

InvisiShunt™ Procedure:



InvisiShunt Reconstruction Procedure Guide

Step One: Make Incision

- ⇒ Make an Appropriate Size Incision To Accommodate the InvisiShunt Implant



Step Two: Mark The Craniectomy

- ⇒ Trace with a marking pen the inner diameter of the InvisiShunt Cutting Guide over the desired fronto/temporal/parietal anatomy



Step Three: Perform Craniectomy

- ⇒ Make a burr hole on each end of the tracing and use the cranial router along the outer border of the tracing to complete the craniectomy



Step Four: Place and Fixate InvisiShunt Implant

- ⇒ Insert the InvisiShunt Implant into the craniectomy defect and secure with rigid fixation



Section 5:

Closing Technique

Dr. Chad Gordon's Recommendation:

The scalp is closed meticulously in 3 layers. The galea is approximated with 3-0 delayed, absorbable monofilament suture in an interrupted buried fashion. Monofilament sutures have a delayed rate of absorption as opposed to the braided type, which is critical in areas of delayed wound healing such as irradiation and malnutrition.

Next, a deep dermal running subcuticular suture is placed using 3-0 dissolvable braided suture. The skin edges are then aligned tension free with 3-0 nylon in an interrupted fashion with precise dermal ridge alignment and wound eversion.

Of note, we do not offer this pericranial-onlay technique to active smokers because of concerns about small vessel perfusion via the dermal-subdermal plexus, those with previous irradiation, and patients with genetic disorders affecting wound healing such Ehlers-Danlos syndrome.

Reference:

Gordon, Chad R., et al. *Neurosurgery*, U.S. National Library of Medicine, June 2014, www.ncbi.nlm.nih.gov/pmc/articles/PMC4703091/.

Section 6:

Possible Complications as per:

Dr. Luciano/ Dr. Gordon: *Johns Hopkins Hospital*

Causes of Complications:

1. Pressure on the sub-galeal scalp
 - May compromise local blood supply
 - May lead to shunt extrusion through scalp (also contributed to by thin scalp & irradiated patients, i.e. Elderly patients)
 - The shunt itself, being coded silicone, becomes encapsulated and encapsulation tissue is also avascular
- **The combined scarcity of local blood supply is likely a major contributor to infection and wound dehiscence.**
2. Mobility
 - Micromotion results from the shunt that is placed in an excessively large pocket and not fixated
 - Micromotion will still result if the shunt is sutured to the pericranium or fixated to the pericranium cranium via screws on the flange. Both macro and micro motion cause inflammation.
 - Migration of shunt due to not being fixated can lead to disconnected catheter/valves
- **It is well understood from craniofacial principles that motion caused inflammation can lead to sterile abscess or infection.**
3. Natural Cranial Deformity Caused by a Shunt
 - the cranial deformity itself is something that can catch a comb or brush or fingernails and therefore the scalp near the incision can become scabbed or compromised.

Resources to Reference: Links & Highlights of Articles

Extrusion:

Joo, Jae Doo, et al. “**Cranial Defect Overlying a Ventriculoperitoneal Shunt: Pressure Gradient Leading to Free Flap Deterioration.**” *Archives of Craniofacial Surgery*, The Korean Cleft Palate-Craniofacial Association, Sept. 2017, www.ncbi.nlm.nih.gov/pmc/articles/PMC5647847/.

- Free flap deterioration may have been **induced by pressure gradient** resulting from cranial defect overlying a VP shunt.
- Scalp skin flap surrounding VP shunt collapsed and showed signs of **necrosis**, and **shunt extrusion**.
- Conclusion of study indicates that complications may be reduced through the adjustment of the pressure that the VP shunt has on the scalp.

Nguyen, T A, and P R Cohen. “**Scalp Necrosis Overlying a Ventriculoperitoneal Shunt: a Case Report and Literature Review.**” *Dermatology Online Journal*, U.S. National Library of Medicine, 16 Oct. 2015, www.ncbi.nlm.nih.gov/pubmed/26632796.

- **VP shunt complications occur in up to 29% of adults** and approx. half of pediatric cases.
- The insertion of a shunt beneath the scalp invites possibility of **pressure-induced scalp necrosis**.
- Early recognition of **VP-shunt induced scalp necrosis** is essential to prevent infection and future complications.
- Patients with friable skin or those with prolonged external pressure on the scalp are at increased risk for developing **pressure necrosis overlying a VP shunt**.

(Singh, M, et al. “**Countersinking’ of Reservoir in an Irradiated Patients Can Decrease Tension on Scalp Closure.**” *Surgical Neurology International*, U.S. National Library of Medicine, 23 July 2015, www.ncbi.nlm.nih.gov/pubmed/26236553.)

- “**Countersinking**” of a reservoir can result in a **tension-free** closure of scalp and allow durable coverage of the reservoir.
- “Countersinking” technique is used to prevent complications such as **wound dehiscence**, and **extrusion** in any patient, but in irradiated patients with very thin skin enables a tension-free closure of the wound.
- With wound dehiscence, a superficial wound can easily track to the CSF and intracranial activity resulting in serious intracranial complications.

Infection, Extrusion, Migration

(“**UK Shunt Registry.**” *SBNS*, Society of British Neurological Surgeons, 2017, www.sbns.org.uk/index.php/audit/shunt-registry/.) -UK Shunt Registry

- There are approx. 1400 adult shunt surgeries in the UK each year (53% primary and 47% revisions).
- Revision %: Underdrainage- 35%, Disconnection- 5%, Fracture- 2.2%, **Infection & extrusion**- < 10%
- **Underdrainage** is by far the commonest reason for revision. Revisions for **shunt infection** take place early whereas revisions for underdrainage, over drainage, disconnection, **migration** and particularly shunt fracture have a longer time course.

Section 7:

Facility Coding for Cranial Reconstruction with Implants

Revenue Code

Facilities may report **Revenue Code 278**, *Medical/Surgical supplies and devices, other implants*, when billing the InvisiShunt Implant. Payment will be based on the negotiated contract terms of a payor's agreement.

Documentation

The patient's chart should include documentation of the device and an invoice for the supply being billed to the carrier. The surgeon's operative report should clearly identify the supply used during the procedure.

Hospital Inpatient

ICD Procedure Codes

The following ICD procedure codes may be used to report the use of the InvisiShunt Implant for cranial/craniofacial reconstruction procedures.

ICD-10	2015 ICD-9	Description
0NR00JZ	02.05	Supplement Skull with Synthetic Substitute/Open/Insertion of skull plate
0NQ00ZZ	02.06	Repair Skull, Open Approach/Other cranial osteoplasty
0NQ00ZZ	0299	Repair Skull, External Approach

MS-DRG

Under the Inpatient Prospective Payment System (IPPS), inpatient hospital procedures are grouped into a Medical Severity-Diagnosis Related Grouping (MS-DRG). The MS-DRG is determined based on the primary procedure code as well as the supporting diagnoses.

Outlined below are some applicable MS-DRG codes for use in reporting cranial/craniofacial reconstruction procedures utilizing the InvisiShunt Implants.

Hospital Inpatient

MS-DRG	Description	2014 Medicare Payment National Average
024	Craniotomy with Maj. Device Implant/Acute Complex CNS Principal Diagnosis without MCC or Chemo Implant	\$20,370.98
023	Craniotomy with Maj. Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant	\$30,244.37
131	Cranial/Facial Procedures with CC/MCC	\$12,781
132	Cranial/Facial Procedures without CC/MCC	\$7,455

Physician Coding Guidelines:

Outlined below are the applicable CPT codes for use when implanting an InvisiShunt Implant to fill cranial/craniofacial bony voids.

CPT Code	Description	2014 RVU	2017 National Average Medicare Payment
62140	New prefabricated cranial implant is 62140 (Cranioplasty for skull defect; up to 5 cm diameter)	30.22	\$1,176.90
62141	New prefabricated cranial implant is 62140 (Cranioplasty for skull defect; greater than 5 cm diameter)	33.37	\$1,300.13
62143	Replacement of bone flap or prosthetic plate of skull	29.78	\$1,190.95

ICD-10	ICD-9	Description
M95.2	738.19	Acquired Deformity of the Skull

Comment: In some instances, the above listed procedures may be performed with another separately identifiable procedure. When this occurs, the code with the highest relative value should be listed as the primary procedure and modifier -51; multiple procedures may be appended to any additional procedures.

Applicable ICD-10 Diagnosis Codes

Claim form submitted for payment must include a supporting ICD-10 diagnosis code. The provider should always report the patient's diagnosis that supports their reasoning for providing the procedural services. Reimbursement claims with a date of service on or after October 1, 2015 require the use of ICD-10-CM codes.

HOSPITAL OUTPATIENT AND AMBULATORY SURGERY CENTERS

CPT Code(s) 62140, 62141 and 62143 are considered inpatient procedures only. Therefore, there is no applicable coding for the outpatient setting.

*Inpatient national reimbursement levels are based on the Medicare Inpatient Prospective System as published in the Federal Register. National payment estimates are determined using the book DRG Expert, 2014 Edition, Appendix D, "The national average payment for each DRG is calculated by multiplying the current relative weight of the DRG by the national average hospital Medicare base rate. The national average hospital Medicare base rate is the sum of the full update labor-related and nonlabor-related amounts published in the Federal Register, FY2014 Final Rule, Table 1A. National Adjusted Operating Standardized Amounts; Labor/Nonlabor (if wage index is greater than 1) or Table 1B. National Operating Standardized Amounts; Labor/Nonlabor (if wage index is less than or equal to 1). This information is provided as a benchmark reference only.

CC=Complications and co morbidities, MCC=Major complications and co morbidities

**CPT Copyright 2017, Novitas Solutions, Medicare Part B Fee Schedule January 2017. American Association of Professional Coders AAPC.com CPT/Surgical Procedures on the Skull, Meninges, and Brain/ Repair Procedures on the Skull, Meninges and Brain Published 2017

***www.cms.gov

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Section 8: Billing/Part Numbers

Instructions:

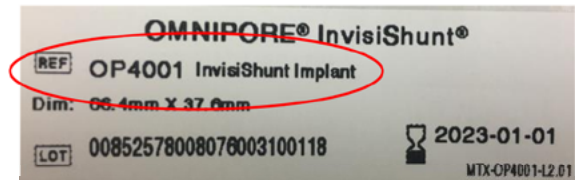
The InvisiShunt™ package contains **two labels** identifying part numbers:

- InvisiShunt™ Implant Number: OP4001
 - InvisiShunt™ Part Numbers: OP4000
 - The InvisiShunt™ Kit contains:
 - InvisiShunt™ Implant
 - Cutting Guide
- When you are billing the hospital, you will **NOT** bill for individual part numbers.
- You **WILL** bill for the entire **kit part number**, ex. OP4000.

Billing/Reorder Sticker:

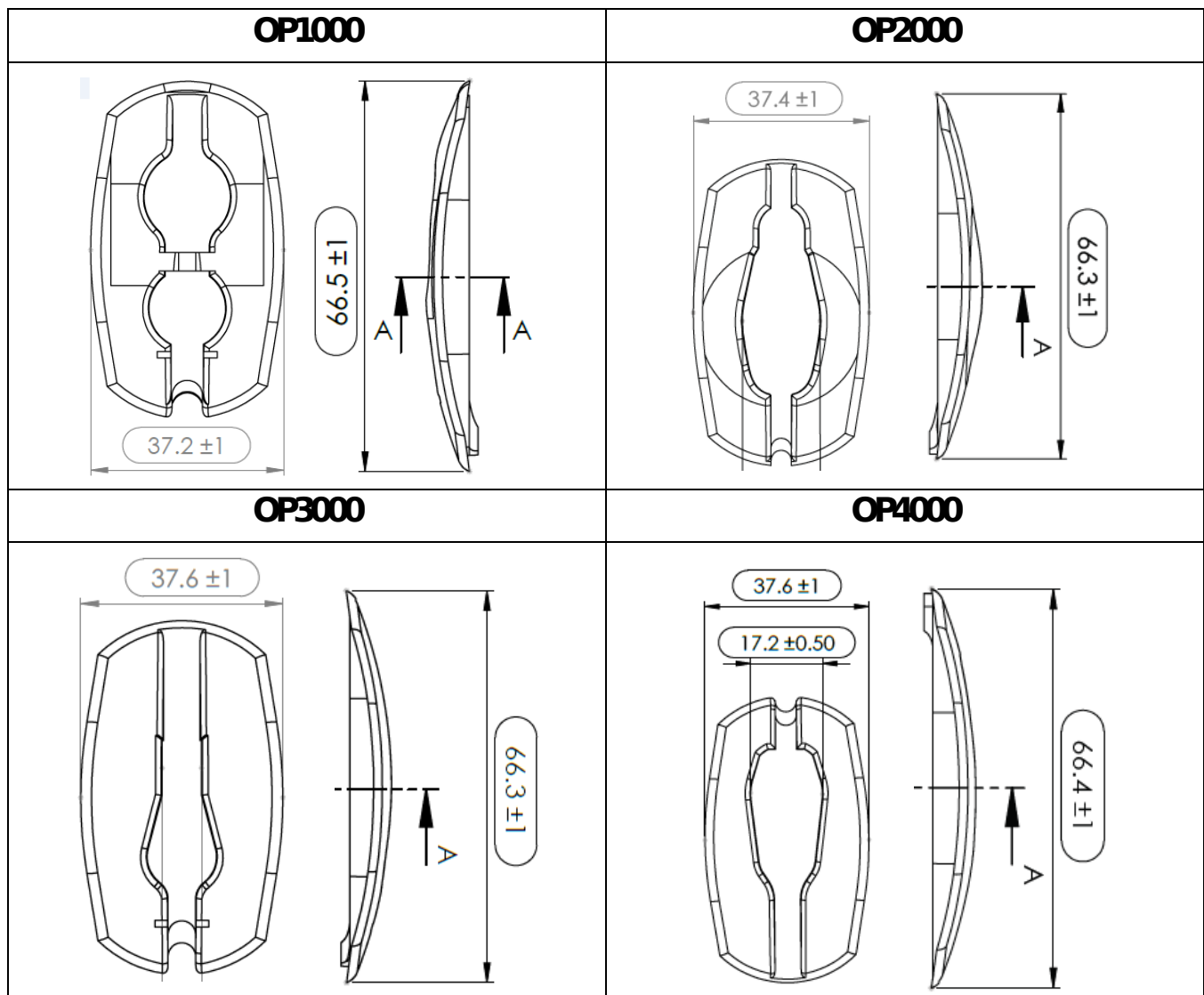


Implant sticker:



Section 9: InvisiShunt Product Dimensions

Product	Width	Length	Profile w/ InvisiShunt	Profile w/o InvisiShunt
OP1000	37.2 mm	66.5 mm	0.81 mm	7.26 mm
OP2000	37.6 mm	66.3 mm	2.52 mm	8.52 mm
OP3000	37.4 mm	66.3 mm	1.32 mm	8.52 mm
OP4000	37.6 mm	66.4 mm	1.69 mm	7.85 mm



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