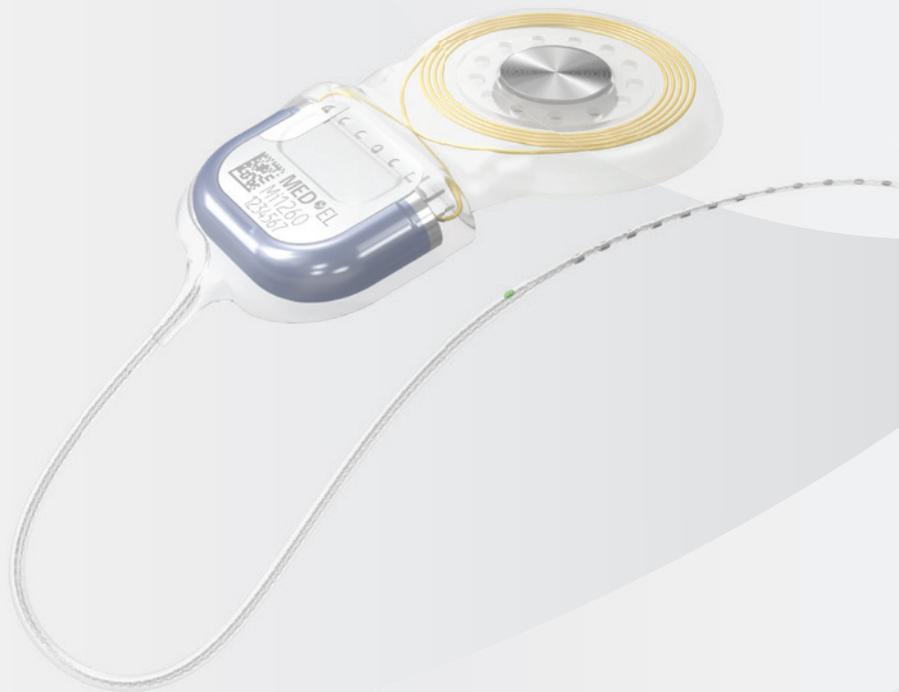


# SONATA 2 Cochlear Implant

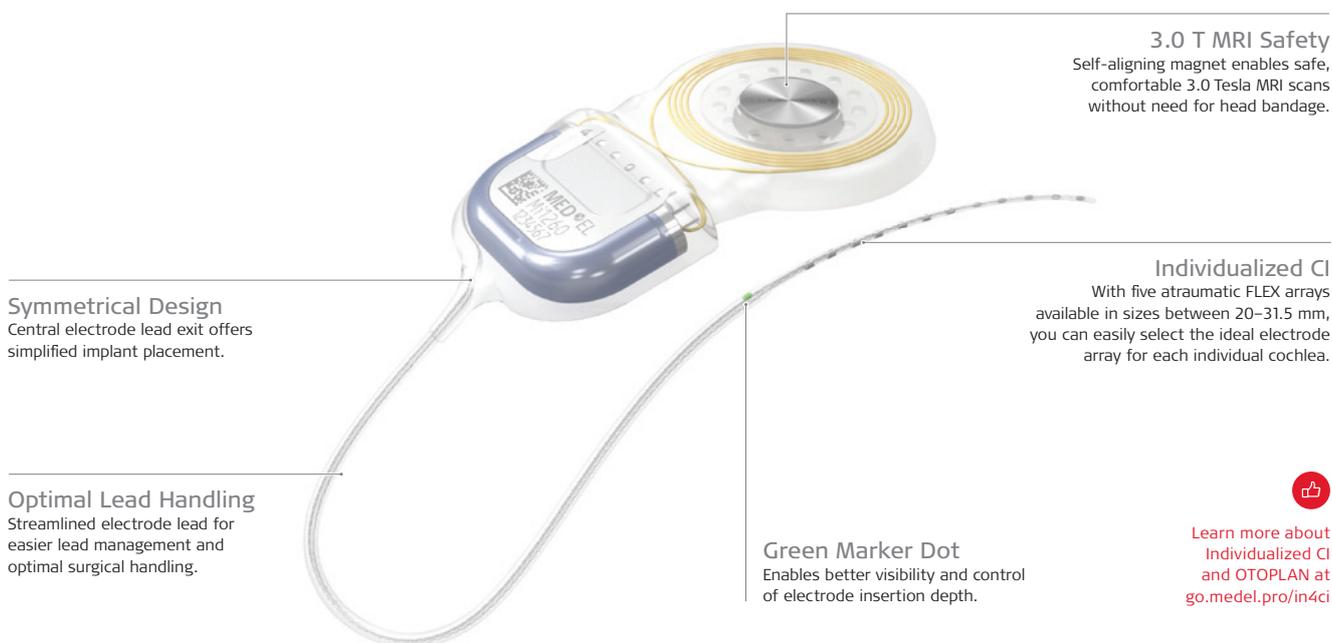
Unparalleled MRI Safety



hearLIFE

# SONATA 2 Cochlear Implant

## 3.0 Tesla MRI—Without Magnet Removal<sup>\*\*</sup>



**Symmetrical Design**  
Central electrode lead exit offers simplified implant placement.

**Optimal Lead Handling**  
Streamlined electrode lead for easier lead management and optimal surgical handling.

**3.0 T MRI Safety**  
Self-aligning magnet enables safe, comfortable 3.0 Tesla MRI scans without need for head bandage.

**Individualized CI**  
With five atraumatic FLEX arrays available in sizes between 20–31.5 mm, you can easily select the ideal electrode array for each individual cochlea.

**Green Marker Dot**  
Enables better visibility and control of electrode insertion depth.

  
Learn more about Individualized CI and OTOPLAN at [go.medel.pro/in4ci](https://go.medel.pro/in4ci)

## Superior Hearing Performance

We engineered our electrode arrays to most closely match the intricate natural design of the cochlea to enable the closest to natural hearing for each individual.

### Structure Preservation

If an electrode array deviates from the scala tympani to the scala vestibuli, it damages critical nerve structures and results in significantly lower hearing performance. Our incredibly flexible free-fitting arrays are designed to gently adapt to the shape of each individual cochlea to protect the delicate natural structures.

### Complete Cochlear Coverage

Our long, flexible arrays can be safely inserted all the way to the apical region to provide natural tonotopic stimulation across two full turns of each individual cochlea. This enables a closer to natural hearing experience and significantly better hearing outcomes.<sup>1,2</sup>

### Natural Sound Coding

FineHearing is the only cochlear implant sound coding that mimics the natural time-coding for low frequencies and provides place-pitch match throughout the cochlea. By mimicking natural sound coding, FineHearing provides much more natural sound quality.



<sup>1</sup> Buchman, C.A., Dillon, M.T., King, E.R., Adunka, M.C., Adunka, O.F., & Pillsbury, H.C. (2014) Influence of cochlear implant insertion depth on performance: A prospective randomized trial. *Otol Neurotol.* 35(10), 1773–1779.

<sup>2</sup> O’Connell, B.P., Hunter, J.B., Haynes, D.S., Holder, J.T., Dedmon, M.M., Noble, J.H., Dawant, B.M., & Wanna, G.B. (2017) Insertion depth impacts speech perception and hearing preservation for lateral wall electrodes. *Laryngoscope.* 127(10):2352–2357



## Excellent Surgical Handling

**Central Electrode Lead**  
Symmetrical central electrode lead design for simplified surgical placement.

**Angled Fantail Transition**  
Angled transition for anatomical fit and secure electrode lead placement.

**Green Marker Dot**  
Coloured marker enables better visibility of insertion depth of the FLEX electrode array.

**Optimized Electrode Lead**  
Streamlined electrode lead for improved handling and easier lead management.



## 3.0 Tesla MRI Safety

The unique implant magnet freely rotates to self-align in an MRI scan, making it conditionally MRI safe for 3.0 Tesla MRI scans. The robust conical housing enables secure optional magnet removal for clearer brain imaging adjacent to the implant.



- ✓ No surgery
- ✓ No discomfort
- ✓ No hearing downtime

# Technical Data

## SONATA 2 Cochlear Implant (Mi1260)



### SONATA 2 Cochlear Implant (Mi1260)

#### Stimulation Features

- Sequential non-overlapping stimulation on 12 electrode channels
- Simultaneous (parallel) stimulation on 2 to 12 electrode channels
- 24 independent current sources
- Stimulation reference electrode on titanium housing
- Stimulation rates of up to 50,704 pulses per second
- Range of pulse phase duration: 2.1-425.0  $\mu$ s/phase
- Time resolution (nominal values): 1.67  $\mu$ s
- Current range (nominal value): 0-1200  $\mu$ A per pulse phase

#### Pulse Shapes

- Biphasic, symmetric triphasic and triphasic precision pulses

#### Comprehensive Diagnostic Toolkit

- Status Telemetry
- Impedance and Field Telemetry (IFT)
- Electrophysiology measurements reference electrode on titanium housing
- Auditory Nerve Response Telemetry (ART™)
- Electrically Evoked Auditory Brainstem Response (EABR)
- Electrically Evoked Stapedius Reflex Threshold (ESRT)
- Electric Acoustic Evoked Potential (EAEP)

#### Housing Design

- Impact resistance  $\geq$  2.5 Joule
- Raised implant step for additional stability
- Hermetically sealed titanium housing
- Recommended flattening depth for the stimulator: 2 mm
- Stimulator: 18.8 mm x 24 mm x 5.7 mm (typical)
- Coil: 29.0 mm diameter x 3.3 mm thick (typical)
- Weight: 8.7 g (typical)

#### Safety Features

- Independent safety capacitors for each electrode channel
- Unique Implant ID (IRIS)
- Biocompatible according to Standard ISO 10993-1
- Latex-free\*
- MRI Conditions\*\*
- MR Conditional at 0.2, 1.0, 1.5 and 3.0 Tesla
- No magnet removal required even at 3.0 Tesla

#### Removable Magnet

- Magnet removable for minimised image distortion
- Rotatable magnet within hermetic titanium housing
- Self-aligning to external magnetic field
- Conical shape for secure placement

### Electrode Arrays

#### FLEX Series

The softest and most flexible electrode arrays, designed for Structure Preservation and Complete Cochlear Coverage. Featuring 19 platinum electrode contacts and FLEX-tip technology for atraumatic insertion. All FLEX series electrodes feature a green orientation marker for improved visibility and positioning during insertion.

#### FLEXOFT

- 26.4 mm stimulation range
- Diameter at basal end: 1.3 mm
- Dimensions at apical end: 0.5 x 0.4 mm

#### FLEX28

- 23.1 mm stimulation range
- Diameter at basal end: 0.8 mm
- Dimensions at apical end: 0.5 x 0.4 mm

#### FLEX26

- 20.9 mm stimulation range
- Diameter at basal end: 0.8 mm
- Dimensions at apical end: 0.5 x 0.3 mm

#### FLEX24

- 20.9 mm stimulation range
- Diameter at basal end: 0.8 mm
- Dimensions at apical end: 0.5 x 0.3 mm

#### FLEX20

- 15.4 mm stimulation range
- Diameter at basal end: 0.8 mm
- Dimensions at apical end: 0.5 x 0.3 mm

#### FORM Series

Designed specifically for malformed cochleae and for instances where leakage of cerebrospinal fluid (CSF) is expected. Featuring 24 platinum electrode contacts and SEAL technology designed to aid closing of the cochlear opening.

#### FORM24

- 18.7 mm stimulation range
- Diameter at basal end: 0.8 mm
- Diameter at apical end: 0.5 mm

#### FORM19

- 14.3 mm stimulation range
- Diameter at basal end: 0.8 mm
- Diameter at apical end: 0.5 mm

#### CLASSIC Series

Features 24 platinum electrode contacts.

#### STANDARD

- 26.4 mm stimulation range
- Diameter at basal end: 1.3 mm
- Diameter at apical end: 0.5 mm

#### MEDIUM

- 20.9 mm stimulation range
- Diameter at basal end: 0.8 mm
- Diameter at apical end: 0.5 mm

#### COMPRESSED

- 12.1 mm stimulation range
- Diameter at basal end: 0.7 mm
- Diameter at apical end: 0.5 mm

\* Whereby "free" means "not made with latex" according to current FDA guidance: "Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex", 2014.

\*\* It has been demonstrated that no known hazards exist in specified MRI environments under conditions as described in the SONATA 2 Cochlear Implant product labelling. Recipients with a SONATA 2 Cochlear Implant may be safely MRI scanned at 0.2, 1.0, 1.5, and 3.0 Tesla following the conditions detailed in the Medical Procedures Manual.