



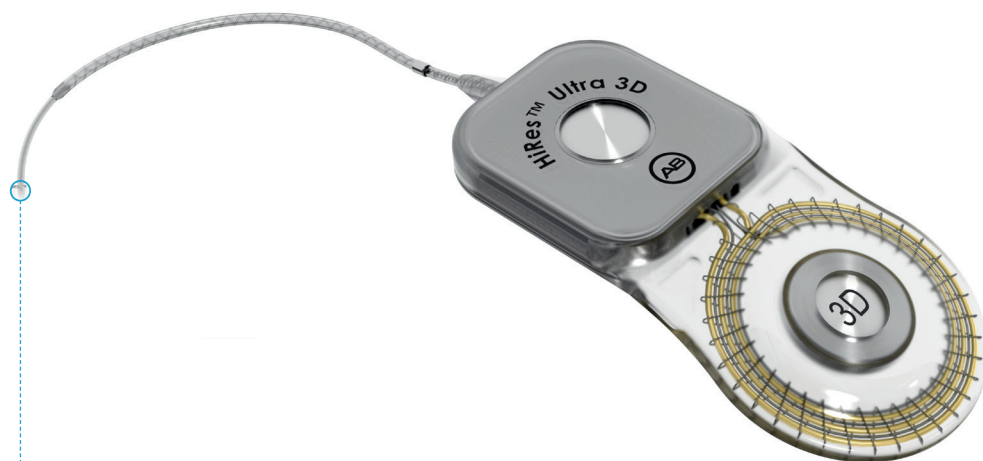
Technical Specifications

HIRES™ ULTRA 3D COCHLEAR IMPLANT

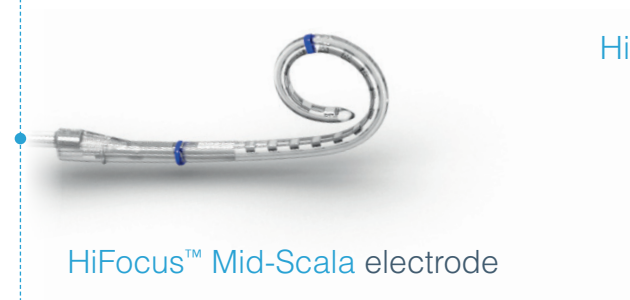
The Foundation of Better Hearing

The new HiRes™ Ultra 3D cochlear implant is designed to provide all the benefits of the HiRes Ultra implant platform but with a hassle free MRI solution. With an innovative design¹ that allows the multi-magnet assembly to stay in place for high-resolution 3T MR scans, your patient can have an MRI procedure without any pain, and enjoy uninterrupted hearing.

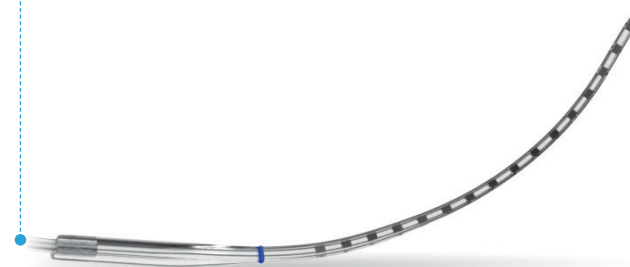
Developed with leading cochlear implant surgeons and using state-of-the-art manufacturing processes, the HiRes Ultra 3D with the HiFocus™ SlimJ and HiFocus™ Mid-Scala electrodes offer unique features designed to suit individual patient anatomy and surgical preferences for the best possible hearing outcomes.



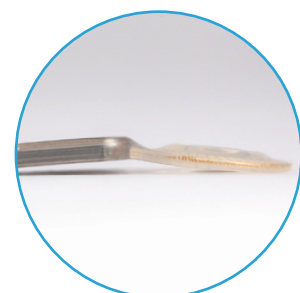
HiRes™ Ultra 3D cochlear implant



HiFocus™ Mid-Scala electrode



HiFocus™ SlimJ electrode



Side View

IMPLANT TECHNICAL SPECIFICATIONS		
Information Update Rate	90 kHz	
Stimulation Rate	Up to 83,000 pps (software limited)	
Independent Output Circuits	16	
Spectral Bands	Up to 120 sites of stimulation (software limited)	
Communication Link	Bi-directional inductive link	
IntelliLink™ Safety Feature	Implant and processor association	
Diagnostics	Neural response imaging (NRI), impedance measurements, ESRT, Integrity testing	
ADC Resolution Sampling Rate	Resolution: 9 bits, Sampling Rate: 25 kHz	
Pulse Amplitude & Width	0 - 2040 µA & 10.78 - 229 µS	
Impedance Accuracy	2.5 kΩ	
STIMULATION DELIVERY SPECIFICATIONS		
HiRes Fidelity 120™ Strategies	HiRes Optima*-P (paired), HiRes Optima*-S (sequential), ClearVoice™ *, HiRes-P with Fidelity 120™* (paired), HiRes-S with Fidelity 120™* (sequential)	
HiResolution™ Sound Strategies	HiRes-P (paired) and HiRes-S (sequential)	
Conventional Strategies	CIS and MPS Modes	
IMPLANT MATERIALS AND DIMENSIONS		
Titanium Case	4.5 mm titanium case including silicone	
Antenna Coil	3.6 mm antenna coil silicone	
Housing	25/28.5 mm x 56.2 mm flexible silicone	
Weight	11 grams	
Volume	4800 mm³	
Multi-Magnet Assembly	Neodymium inside a titanium case	
Telemetry Coil	Gold-braided wire and platinum-shield wire in flexible silicone, reinforced with high-density polymer fiber	
Ground	2 — Case ground and ring electrode ground	
Impact Resistance Value	Exceeds the impact requirements specified in EN45502-2-3:2010	
Pressurized Environment Information	Can withstand a pressure up to a depth of 42 m under water (138 feet) or a gauge pressure of 4 ATM (413 kPa)	
ELECTRODE TECHNICAL SPECIFICATIONS		
	HiFocus SlimJ	HiFocus Mid-Scala
Electrodes	16 platinum contacts; platinum-iridium wires; flexible silicone carrier; integrated ground on lead	
Minimum Exposed Contact Area	0.12 mm²	0.12 mm²
Contact Spacing	1.3 mm	0.975 mm
Active Length	~20 mm	~15 mm
Forceps	Yes	Jeweler's forceps or a similar instrument can be used
Insertion Tool	–	Optional
Freehand	Yes	Yes
Reloadable	–	2 Maximum
Insertions	3 Maximum	3 Maximum
Recommended Insertion	Round window, extended round window and cochleostomy	
SURGICAL PROCEDURES – SEE SYSTEM IFU (REF) FOR DETAILS		
Multi-Magnet Assembly	Can be left in place for 3T and 1.5T MRI scans (no bandaging required), or can be easily removed if necessary. See the MRI Safety Information booklet.	
Electrosurgical Instruments	Monopolar cautery can be used outside of the head and neck, bipolar 1 mm from the implant.	
Extracorporeal Electrical Stimulation	Probes not over the implant.	
Neurostimulation	Not directly over the implant.	
Diathermy	Safe to use shortwave and longwave.	
Radiation	250 Gray using a 15MeV beam strength and 3 cm depth. Diagnostic radiation imaging such as CT, X-Ray, Mammography, etc. are safe to use.	
Diagnostic Ultrasound	Safe to use.	

*Not approved for pediatric use in the United States.

REFERENCES:

1. Lee et al. (2018). U.S. Patent No. 9,919,152B2. Valencia, CA: U.S. Patent and Trademark Office.

For more information please visit
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