Product Information Brain Interchange System

Dr. Christina Schwartz | +49 (0) 761 8976 945 20 | sales@cortec-neuro.com
www.cortec-neuro.com

The fully implantable Bi-Directional Implant System for chronic open and closed loop interaction with the nervous system,
consisting of:

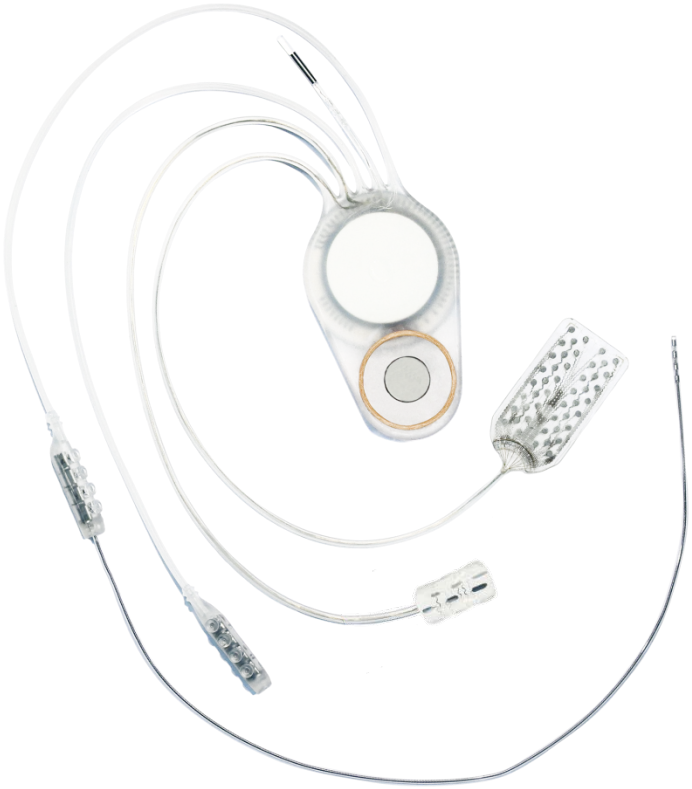
An internal Electronics Unit to which implantable electrodes are connected.

A wireless External Unit that powers the implant, reads out the recorded data and transmits them to a PC. It also receives stimulation commands from the PC and instructs the implant to send electrical pusles to the electrodes.

A Software Package (C++ API) allowing you to program an experimental specific closed-loop algorithm according to your paradigm.

CorTec Brain Interchange currently features 32 channels, all of which can be used for recording and stimulation. No skin breach is involved due to its fully wireless functionality.

Not cleared for clinical use by FDA.



TECHNICAL SPECIFICATIONS

Recording	Channels	32 channels + 1 reference + 1 ground (ground switchable between dedicated ground electrode and any other electrode contact)
	Sampling Rate	1000 Hz
	ADC Resolution	16 bit
	Upper Cutoff Frequency	450 Hz
	Lower Cutoff Frequency	0.5 Hz
Stimulation	Channels	Each of the 32 channels (concurrent stimulation at 4 channels: 3 predetermined channels, 1 switchable to any of the 32 electrode contacts)
	Type	Current controlled stimulation (against ground)
	Current	Max. - 6 mA / +1.5 mA for max. 1.5 kΩ impedance
	Shape	Biphasic, charge balanced
	Pulse Width	Programmable (negative phase: 10 µs - 2,500 µs; positive phase: 4 times the duration of the negative phase, with 1/4 of the amplitude of the negative pulse)
Encapsulation	Dimensions	60 mm x 30 mm x 7 mm
	Encapsulation Material	Ceramics
	Coating	Medical grade silicone rubber
		Designed for long-term use
Software	C++ Interface	

Company Support

VALIDATIONS

Our development and manufacturing comply with highest quality standards. We can offer a wide range of in-house validations or verifications as well as validations together with partners and test laboratories. The listed validations concern all of our products, their developing and manufacturing stages.

Process Validations (together with external partners and test laboratories)
- Cleaning process validation
- Packaging process validation
- Sterilization process validation (ETO)

Mechanical and Electrical Validations/Verifications
- Design and product specifications
- Bending load
- Tensile testing
- Micro IRHD testing (together with external partners)
- Impedance
- Dielectric strength
- Corrosion
- Layer pull strength
- Hermeticity
- Shear strength

GENERAL SERVICE

For the Hermetic Encapsulation we offer the following services:
- Device design
- Tests/validations of new designs incl. technical documentation
- Sterilization
- Cleaning

Product Information °AirRay® Electrodes

Dr. Christina Schwartz | +49 (0) 761 8976 945 20 | sales@cortec-neuro.com
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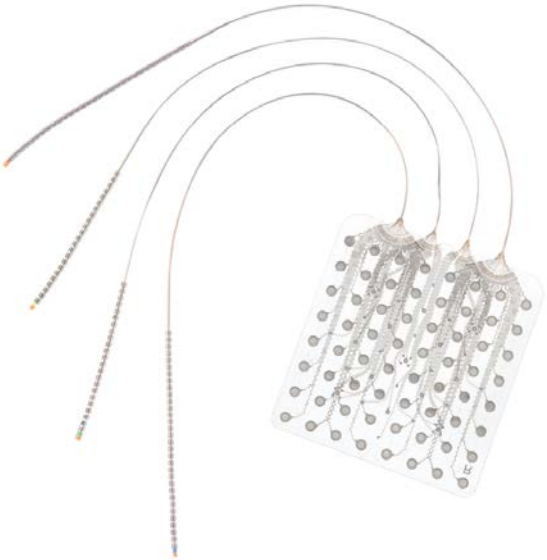
With the proprietary AirRay® electrode technology we have overcome the current limitations for neural electrodes with outstanding mechanical properties and highest manufacturing precision. It also allows very small feature sizes of 25 µm and high integration densities of electrical contacts. The AirRay® electrode can be designed with variations in thickness, contact size, contact spacing, contact shape and overall electrode size.

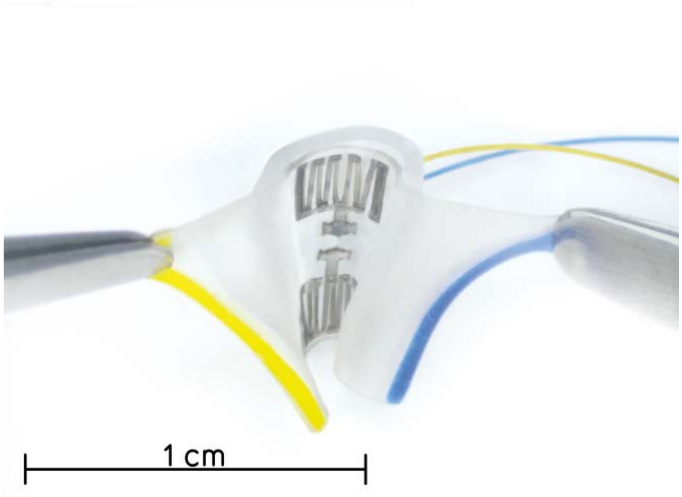


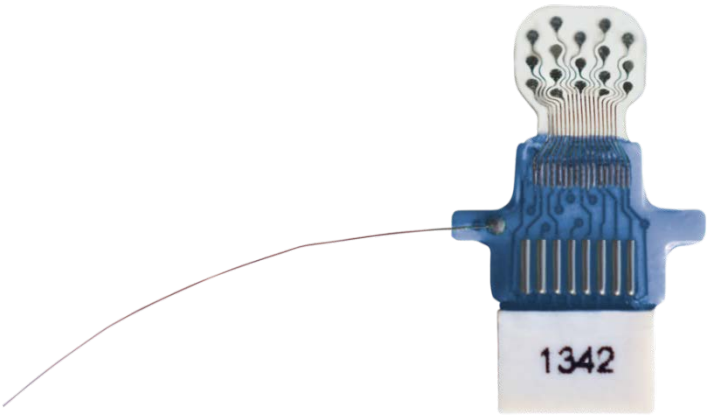
By using ultra-short-pulse laser micromachining this technology enables a very high reproducibility. In addition, prototyping of AirRay® electrodes is very fast. First prototypes can be produced within a day, implantable electrodes require only one week to be manufactured.

The electrodes provide excellent electrochemical properties. Platinum-Iridium or MP35N are used as electrode materials, optionally with high performance coatings for enhanced charge transfer to biological tissue. By varying the thickness of silicone rubber or parylene C reinforcement layers the mechanical properties can be adjusted to individual requirements. Electrodes can thus be very soft or hard enough to be pushed under the skin or into fascicular tissue.

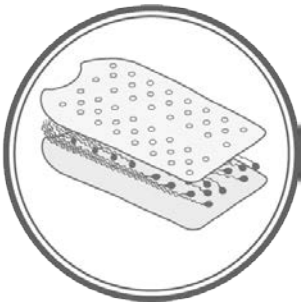
The electrode can be modified for example to build three-dimensional assemblies as well as nerve cuff electrodes that wrap around peripheral nerves. Further adaptions cover the integration of microfluidic channels for drug delivery into electrode arrays. It is, furthermore, possible to fold planar AirRay® electrodes or to establish combinations with other technologies.

Not cleared for clinical use by FDA, but can be used under IRB and / or IDE guidance for research studies. 510(k) is in process for a set of product configuration.



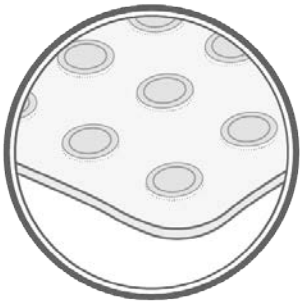


DESIGN OPTIONS



Multi-Layer Functionalization

- Adjustment of thickness and flexibility by number and type of polymer or metal layers
- Adaptation of contact density and functionality by number and type of metal layers
- Integration of microfluidic channels and ports



General Dimensions

- Thickness:
  - Silicone electrodes: 0.15 mm – 1 mm
  - Hybrid silicone-parylene electrodes: 0.08 mm – 1 mm
- Contact size:
  - Silicone electrodes: down to 0.1 mm
  - Hybrid silicone-parylene electrodes: down to 0.05 mm
- Contact spacing:
  - Silicone electrodes: down to 0.3 mm center-to-center
  - Hybrid silicone-parylene electrodes: down to 0.06 mm center-to-center
  Depending on number of contacts
- Contact shape: round, rectangular or arbitrary
- Design geometry maximum: 90 mm x 90 mm
- Various designs for electrode outline incl. slit contours

Design Variation – Cuff Electrodes

- Inner diameter: starting from 0.1 mm
- Number of contacts: arbitrary
- Closing mechanisms:
  - Split cylinder
  - Buckle-and-belt
  - Self-spiraling
  - Piano hinge
- Further closing mechanisms for chronic implantation can be developed

Other Variations

- Folding planar AirRay® electrodes
- 3D assembly of multiple AirRay® electrodes
- Intrafascicular electrodes
- Combination with other technologies:
- Depth electrodes
- 3D metal parts
- Functional components such as surgical mesh or suture material

MATERIALS

Polymers	Medical grade silicone rubber • Long-term (≥ 30 days) • Short-term (< 30 days)	Parylene-C	
Metals	Medical grade metal alloys: • Platinum-Iridium (90/10) • Platinum • MP35N	High-performance coatings: • Sputtered Iridium Oxide (SIROF) • Platinum Black	Physical surface modification permits additional adaptations to the individual application.

PERFORMANCE

	Charge Injection Capacity	Impendance (Diameter 1 mm) 10 Hz	1 KHz	Impendance (Diameter 2.7 mm) 10 Hz	1 KHz
MP35N	Max. 0.03 mC/cm^2	260 kΩ	5 kΩ	32 kΩ	0.6 kΩ
Platinum-Iridium (90/10)	0.09 mC/cm^2	47 kΩ	1 kΩ	8 kΩ	0.2 kΩ
Platinum	0.05 mC/cm^2	available on request		available on request	
Sputtered Iridium Oxide (SIROF)	≥ 1 mC/cm^2	available on request		available on request	
Platinum Black	0.25 mC/cm^2	available on request		available on request	

TESTING

- Impedance spectroscopy
- Pulse testing
- Corrosion testing
- Reliability testing

Company Support

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GENERAL SERVICE

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Product Information Hermetic Encapsulation

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CorTec´s hermetic encapsulation technology protects what is valuable for an active implant: sensitive electronics even with a uniquely-high amount of electrical feedthroughs. Thick film technology enables hundreds of these electrical channels. Unlike conventional packages with glass-to-metal or ceramic-to-metal feedthroughs which are usually brazed in titanium housings CorTec´s ceramic encapsulation is, furthermore, transparent to electromagnetic waves. This facilitates communication via radio frequency or infrared as well as wireless powering.

Aware the fact, that ceramics are inherently brittle, CorTec has insured a high mechanical robustness by implementing specific design measures. Lifetime calculations based on the hermeticity of the encapsulation attest excellent protection of electronics against moisture – more than 10 times longer than common titanium cases. The application of desiccants extends the lifetime even further. Even small implant volumes below 1 cm^3 sustain a moist environment for decades

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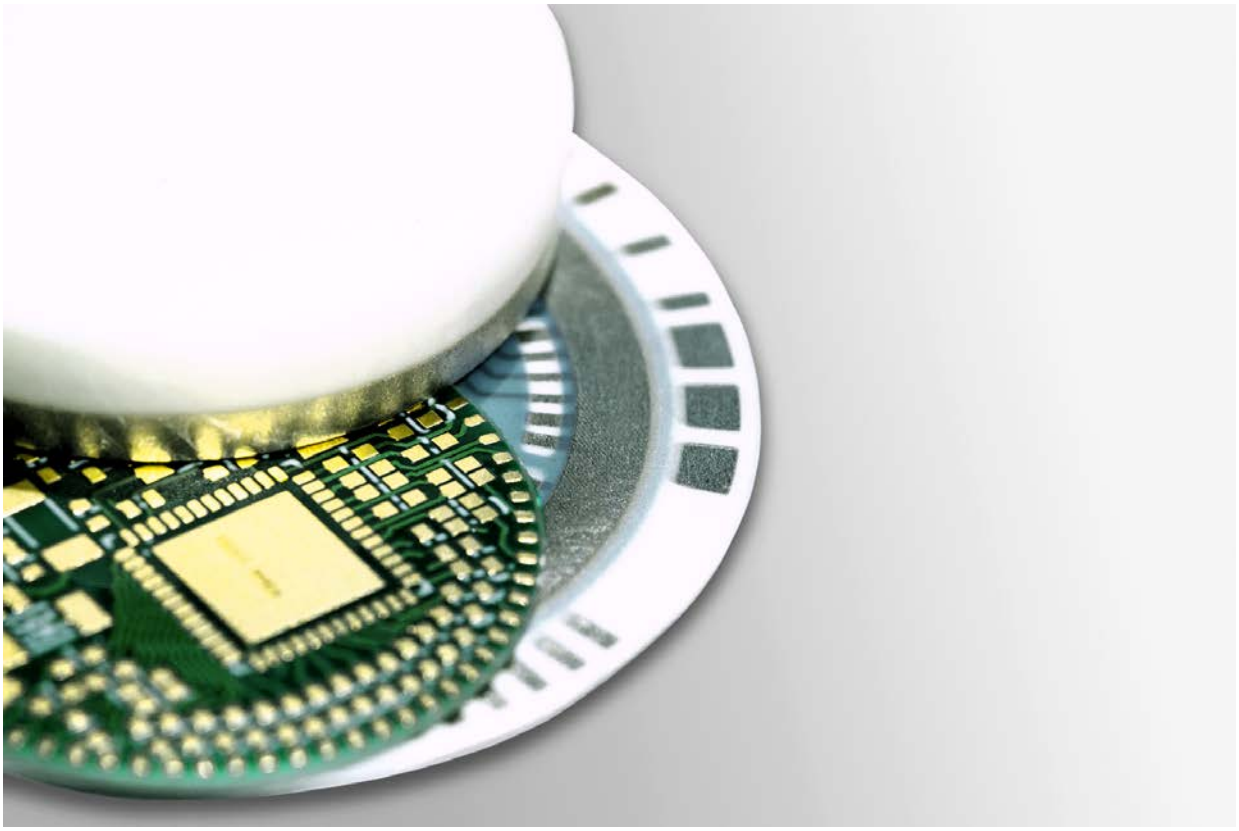
Not cleared for clinical use by FDA, but can be used under IRB and / or IDE guidance for research studies. Technical documentation for IDE Clearance is readily supported.

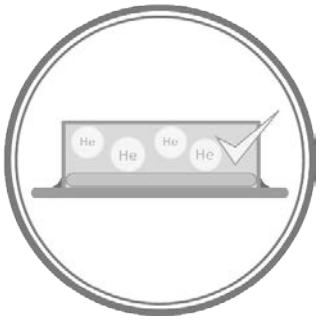


DESIGN OPTIONS

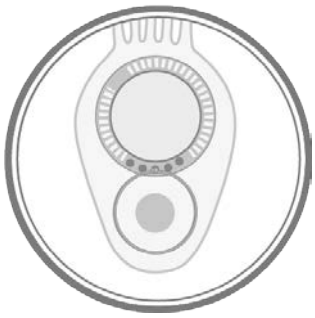
Geometry
- Circular, oval, or rounded-edge rectangular designs.
- Ceramic packages are molded in silicone rubber in application-specific shapes

Dimensions
- Minimum height: 2 mm
- Variable lateral dimensions: maximum footprint of 80 mm x 80 mm

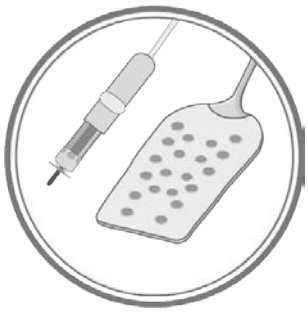
Feedthrough Dimensions and Spacing
- Feedthroughs come as metal tracks on ceramic base substrate
- Minimum track width: 0.08 mm
- Minimum pitch: 0.2 mm
- Minimum pad area: 0.1 mm x 0.5 mm



Hermetic Sealing in Controlled Helium Environment
- Elaborated cleaning & drying procedure minimizes trapping of water molecules inside the package before sealing
- Packages are sealed in 100% helium atmosphere permitting the best possible lifetime prediction based on helium leakage measurements



Customized Telemetric Coils
- Hand-crafted high precision coils
- Materials: Gold or copper
- Up to 50 windings
- Adaptation to the needs of customer-specific inductive power and data interfaces



Medical Grade Silicone Rubber Shell
- Customized void-free silicone molding
- Structural and surface biocompatibility

Connects to Other Products
- AirRay® electrodes
- Utah array
- Commercially available implantable connectors

MATERIALS – IN CONTACT WITH THE BODY

Smooth implant shell and cables made of medical grade silicone rubber.
All other materials such as the ceramic encapsulation, the feedthroughs, and the metal seal for the package are covered by this silicone shell.

PERFORMANCE/TESTING

- Selected designs pass the pendulum hammer test method Eha according to IEC 60068-2-75:1998 – 2.5 J impact.
- Helium fine leak testing for hermeticity:
  Extremely low leak rates qualify our packages for rejection thresholds below 10-10 mbar l s-1.
- Functionality Testing

Company Support

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GENERAL SERVICE

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- Device design
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- Sterilization
- Cleaning
- Assembly and packaging of customer electronics
- Interconnection technologies
- Customized silicone rubber mold design and processing