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

Thinking ahead - CorTec is developing new standards for implantable devices under engineering design control.

CorTec Brain Interchange is a highly efficient closed-loop technology for measuring and stimulating the brain's activity in long-term use. CorTec Brain Interchange controls itself autonomously: based on the recorded data and any externally available information it can calculate its activities and send out needs-oriented stimulation impulses within biological reaction times. CorTec Brain Interchange ONE is a complete 32-channel system designed for exploring new clinical applications.

As part of the Grant Program, CorTec also offers individualized solutions for components of active implants such as our °AirRay Electrodes or our Hermetic Encapsulation.

°AirRay, our silicone electrode offers high-data acquisition and stimulation in the central and peripheral nervous system. Thanks to a special patented laser structuring process the electrode has a high density of contacts, is thin and soft and can easily be produced in individual designs. We are not bound by a specific grid outline – we can realize any shape from the classical square to sectional, curved, or circular designs. Additional safety for patients is achieved by electrode contacts interlocking with the material, preventing their separation from the silicone. Accessories such as connectors and connection cables allow the use of our electrode with common amplification or stimulation systems.

Our hermetic encapsulation is suited to house a wide range of electronic implants. It is designed to enable wireless communication for long-term applications.

To fulfill your needs and requirements for the medical device, we offer you the total package of know-how. Our processes undergo detailed analyses of failures, modes, and effects (PFMEA).

CorTec has implemented a comprehensive quality management system (QMS) according to DIN EN ISO 13485 (notified body: TÜV SÜD), including a conformity assessment procedure according to Annex II (93/42/EEC Medical Device Directive) and Annex 2 (90/385/EEC Active Implantable Medical Device Directive). All manufacturing steps are carried out in ISO 14644-1 class 6 - 9 cleanrooms.

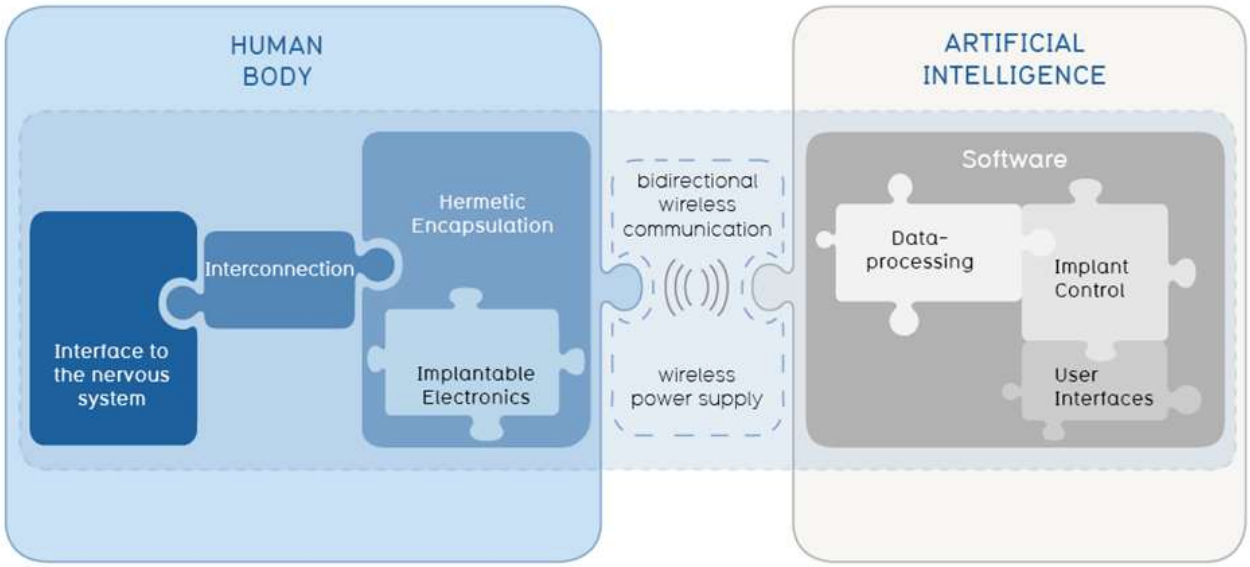
- ✓ **High Documentation Standards**
- ✓ **Cleanroom ISO 14644-1**
- ✓ **QMS according to DIN EN ISO 13485**
- ✓ **Development under design control**
- ✓ **All documents related to the product are archived**
- ✓ **Document Management System**

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

I. CorTec Brain Interchange

The CorTec Brain Interchange Technology serves all levels of interconnecting the neural system to artificial intelligence.

The implantable technology platform joins the scope of CorTec's competences ranging from electrodes as interfaces to neural tissue over hermetic encapsulation of electronic parts and wireless functionalities up to processing neural information for application control.



CorTec Brain Interchange can be connected to various types of electrodes:

- Standard designs are available as well as individual solutions.
- Electrodes for intracortical field potential recording are available upon request.

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

Here we are providing an outlook on CorTec Brain Interchange ONE, our fully implantable system for chronic open and closed loop interaction with the system consisting of:

An implanted device comprising

- Neural electrode arrays for bi-directional interfacing with the neural system.
- Electronic circuit inside a proprietary hermetic ceramic package that amplifies, filters and digitizes neural signals and electrically stimulate neural tissue via the electrodes. It is inductively powered by the external unit and communicates with it via a broad-band radio link.

A body-external telemetry unit comprising

- A small, light-weighted head piece which is held attached to the skin opposite to the implant by a magnet.
- A transceiver device for radio communication with the implant, typically belted to the upper arm or wheel chair of the patient. It also controls the power supplied by the head piece and communicates with the controller computer.

A controller computer that

- Powers the external telemetry unit.
- Runs the application software which manages the stream of neural recording data coming from the implant via the external unit. At this point, innovative experimental algorithms can be plugged that allow a response to the neural data stream.

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
	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	PC Application APL	Visualization of recorded data. Electrical Stimulation manage Electrode impedance and other implant status reports Software interface for customer-specific applications in C++ and Python 2 (Win 7)

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

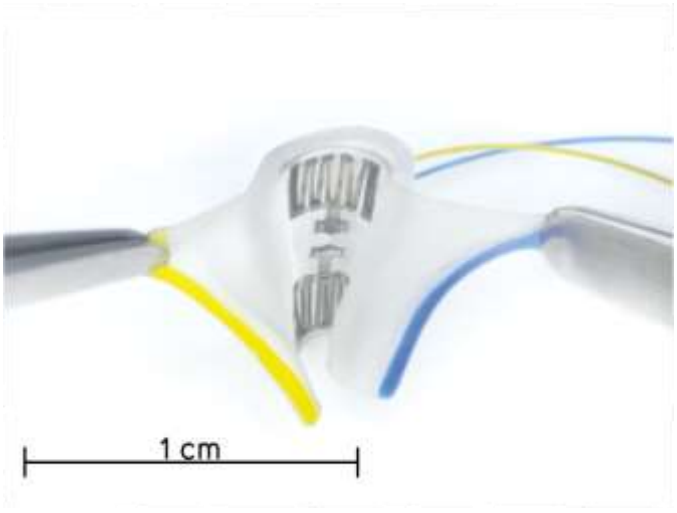
II. °AirRay® Electrodes

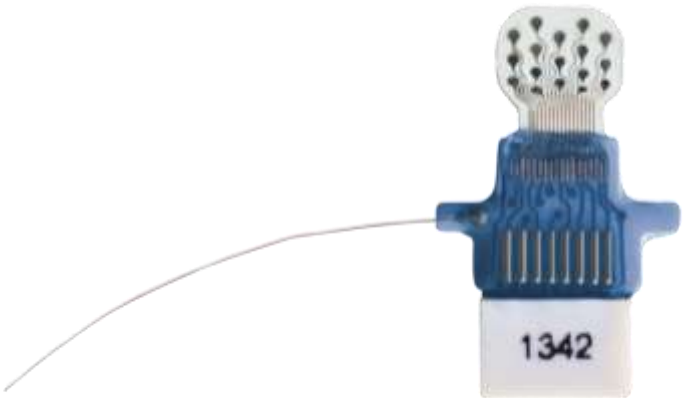
With the proprietary °AirRay® electrode technology we have overcome the current limitations for neural electrodes with outstanding mechanical properties and highest manufacturing precision. It also allows very small feature sizes of 25 µm and high integration densities of electrical contacts. The °AirRay® 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.

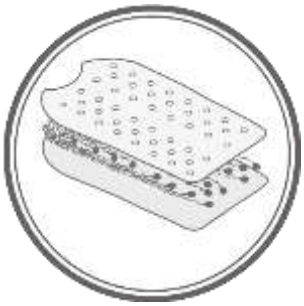
The electrodes provide excellent electrochemical properties. Platinum-Iridium or MP35N are used as electrode materials, optionally with high performance coatings for enhanced charge transfer to biological tissue. By varying the thickness of silicone rubber or Parylene C reinforcement layers the mechanical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



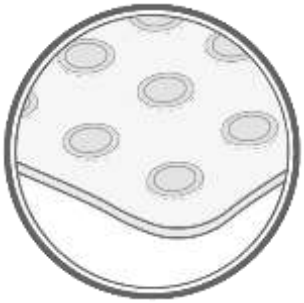


DESIGN OPTIONS



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 0.08 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 • Stainless Steel • Gold	High–performance coatings: • Sputtered Iridium Oxide (SIROF) • Platinum Black	Physical surface modification permits additional adaptations to the individual application.

PERFORMANCE

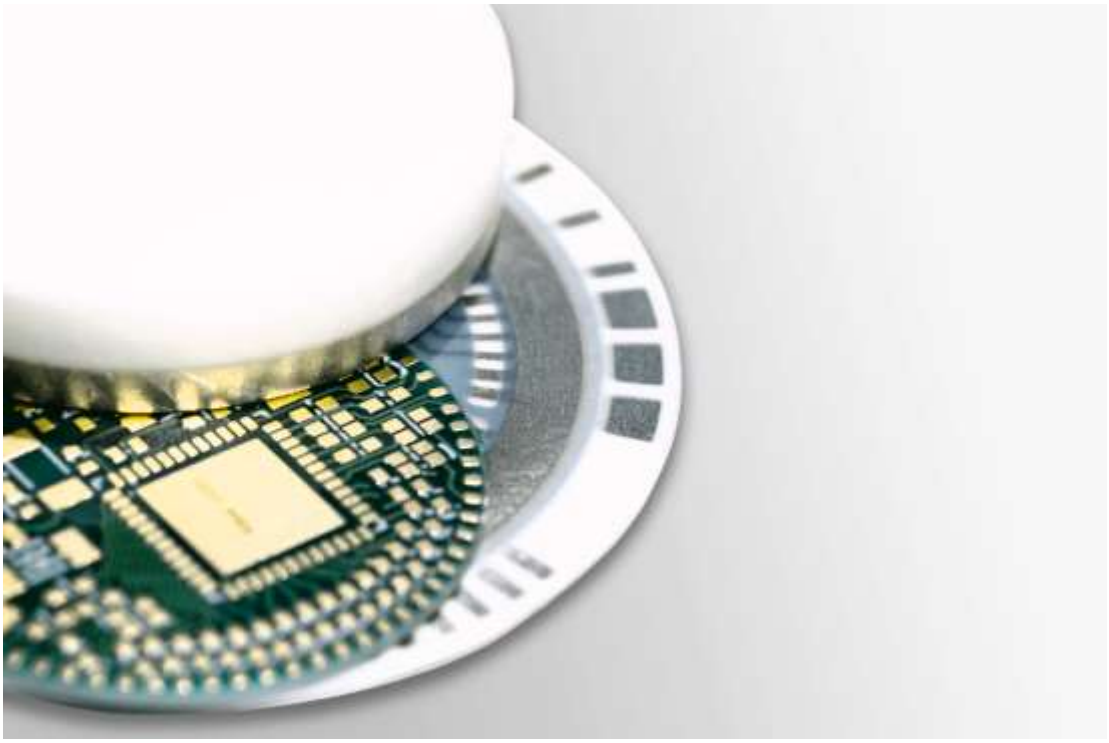
	Charge Injection Capacity	Impendance (Diameter 1 mm) 10 Hz	1 KHz	Impendance (Diameter 2.7 mm) 10 Hz	1 KHz
MP35N	Max. 0.03 mC/cm²	260 kΩ	5 kΩ	32 kΩ	0.6 kΩ
Platinum-Iridium (90/10)	0.09 mC/cm²	47 kΩ	1 kΩ	8 kΩ	0.2 kΩ
Platinum	0.05 mC/cm²	available on request		available on request	
Sputtered Iridium Oxide (SIROF)	≥ 1 mC/cm²	available on request		available on request	
Platinum Black	0.25 mC/cm²	available on request		available on request	

III. Hermetic Encapsulation

CorTec´s hermetic encapsulation technology protects what is valuable for an active implant: sensitive electronics even with a uniquely-high number 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 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.

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.



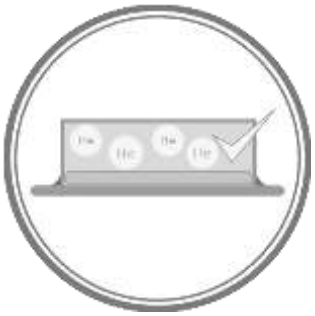
Dr. Joern Rickert | +49 (0) 761 8976 945 20 | sales@cortec-neuro.com
www.cortec-neuro.com

DESIGN OPTIONS

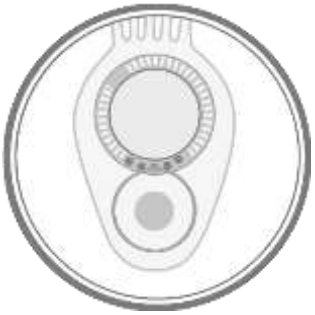
Geometry
- Circular, oval, or rounded-edge rectangular designs.
- Ceramic packages are molded in silicone rubber in application-specific shapes

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

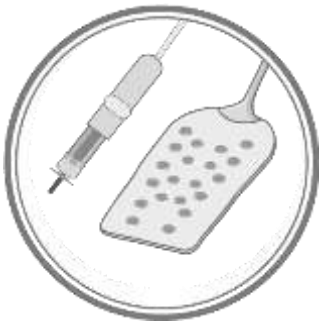
Feedthrough Dimensions and Spacing
- Feedthroughs come as metal tracks on ceramic base substrate
- Minimum track width: 0.08 mm
- Minimum pitch: 0.2 mm
- Minimum pad area: 0.1 mm x 0.5 mm



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

I. 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
- Reliability testing
- Micro IRHD testing (together with external partners)
- Impedance spectroscopy
- Pulse Testing
- Dielectric strength
- Corrosion testing inclusive SEM inspection
- Layer pull strength
- Hardness testing
- Shear strength

System Integration Tests

- Functionality testing
- Hermeticity qualification
- Long-term functionality testing

GENERAL SERVICE

For all our °AirRay® Electrodes we offer the following services:

- Device design
- Tests/validations of new designs incl. technical documentation
- Sterilization
- Cleaning

For the Hermetic Encapsulation we offer the following services:

- Device design
- Tests/validations of new designs incl. technical documentation
- Sterilization
- Cleaning
- Assembly and packaging of customer electronics
- Interconnection technologies
- Customized silicone rubber mold design and processing