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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. Brain Interchange ONE is the first version of the CorTec Brain Interchange Technology which we are currently validating for the use in clinical trials.

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.

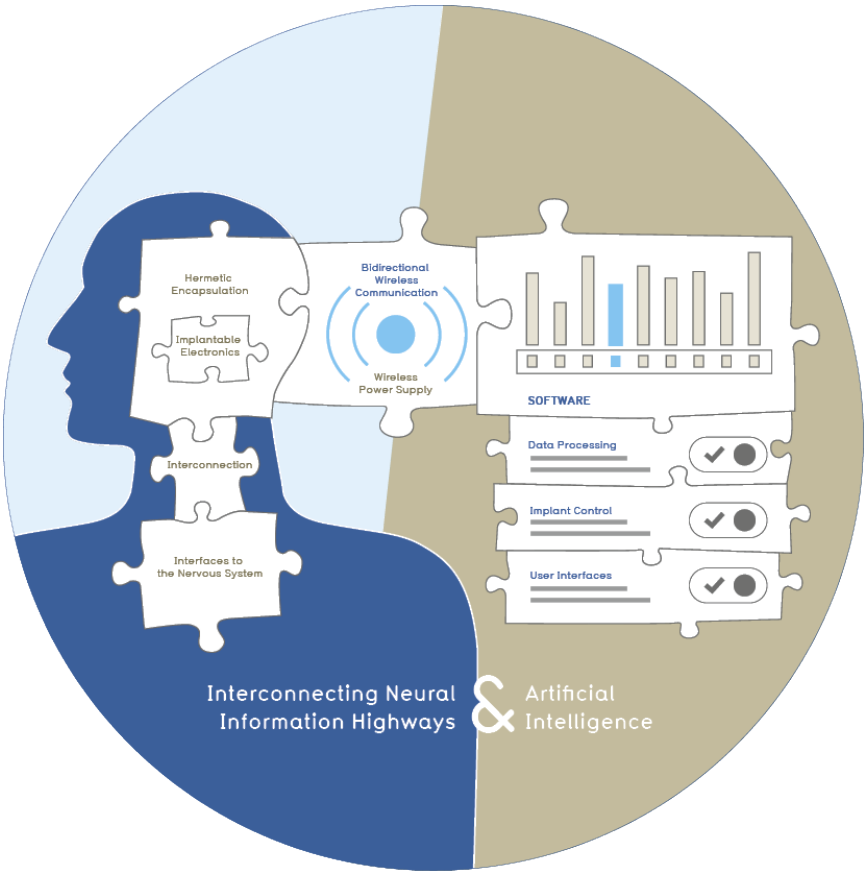
Our hermetic encapsulation is suited to house a wide range of electronic implants. It is designed to enable wireless communication for long-term applications.

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**

I. CorTec Brain Interchange



The CorTec Brain Interchange platform technology is comprised of all components needed for electrically interconnecting the neural system to external software utilizing the full power of artificial intelligence – and thus, enabling communication with the nervous system. 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:

Micro ECoG Electrodes | Strip Electrodes | Cuff Electrodes | Other designs upon request

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

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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:

A Multi-Part Implant

- One or two °AirRay electrodes from CorTec designed according to customer specifications.
- The Brain Interchange platform is also prepared for the use of DBS electrodes.
- The Implanted Internal Electronics Unit is placed inside a proprietary hermetic ceramic encapsulation. It amplifies, filters and digitizes neural signals and electrically stimulates neural tissue via the electrodes. It is inductively powered by the External Unit and communicates with it via a broad-band radio link.

External Unit

- A small, lightweight Head Piece is held attached to the skin by a magnet opposite to the implant.
- The Communication Unit for radio communication with the implant, typically belted to the upper arm or wheel chair of the patient also controls the power supplied to the Head Piece and communicates with the controller computer.

A Personal Computer with Software Interface Powers the external telemetry unit.

- The Computer ensures the energy supply of the Communication Unit.
- It also 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 implemented that allow a response to the neural data stream, e.g. triggering a therapeutic electrical stimulus delivered by the implant.

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	1 kHz
	Sampling dynamic range	16 bit (74 nV increment)
	High pass filter cut-off	0.1 kHz
	Low pass filter cut-off	450 Hz
	Amplifier band pass gain	631
	Band pass roll-off	20 dB/dec
	Amplifier input-referred voltage noise	0.1-400 Hz: ≤ 2.7µVrms
	Amplifier input impedance	AC Impedance: 15pF capacitance 0.1 Hz: 100 GOhm 1 Hz: 10 GOhm 10 Hz: 1 GOhm 100 Hz: 100 MOhm 450 Hz: 24 MOhm
Stimulation	Stimulation	Controlled, biphasic, rectangular, asymetric stimulus pulses (cathodic amplitude with pulsewidth followed by an anodic counter pulse of 1/4x amplitude and 4x pulsewidth)
	Channels	32
	Current	Max. -6 mA / +1.5 mA within compliance voltage range of -11 V to +5 V
	Current source	Can be directed to any of the 32 electrode contacts
	Pulse Width	Negative phase: 10–2,500 µs
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	The Application Software provides users with a graphical user interface.
	Functionality	Visualizing the measured data directly or after the application of a frequency filter (e.g. notch) or storing the data onto a local hard disk.
	APL	Windows-based application software (C++, Python)

II. °AirRay® Electrodes

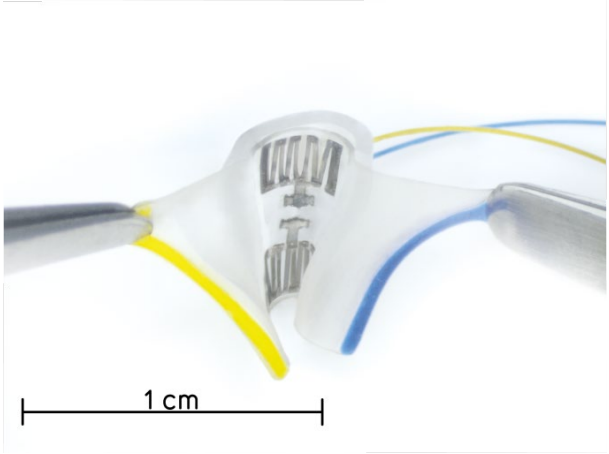
With the proprietary °AirRay® electrode technology we have overcome the current limitations for neural electrodes with outstanding mechanical properties and highest manufacturing precision. It also allows very small feature sizes of 25 µm and high integration densities of electrical contacts. The °AirRay® electrode can be designed with variations in thickness, contact size, contact spacing, contact shape and overall electrode size.

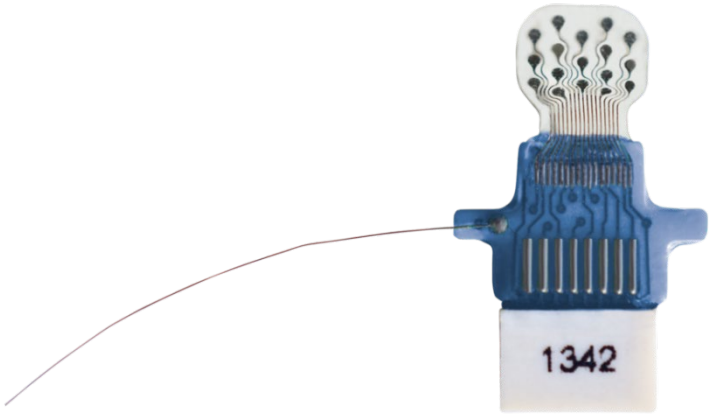
By using ultra-short-pulse laser micromachining this technology enables a very high reproducibility. In addition, prototyping of °AirRay® electrodes is very fast. First prototypes can be produced within a day, implantable electrodes require only one week to be manufactured.

The electrodes provide excellent electrochemical properties. By default, Platinum-Iridium is used as electrode material, 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.

°AirRay® Cortical Electrode (see following pages) is cleared for clinical use by FDA.





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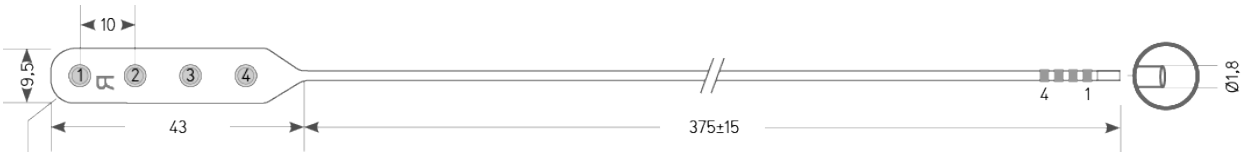
°AirRay® Cortical Electrode

°AirRay® Cortical Electrode has received market clearance from the Food and Drug Administration (FDA) in the USA for invasive neuromonitoring in the central nervous system. The product portfolio includes all possible contact arrangements from 1×4 to 8×8 electrode contacts.

In the following we list the designs that we offer as part of our standard catalogue. Please contact us for other configurations.

Strip-Electrodes

1x4 Strip Electrode | 4 Contacts

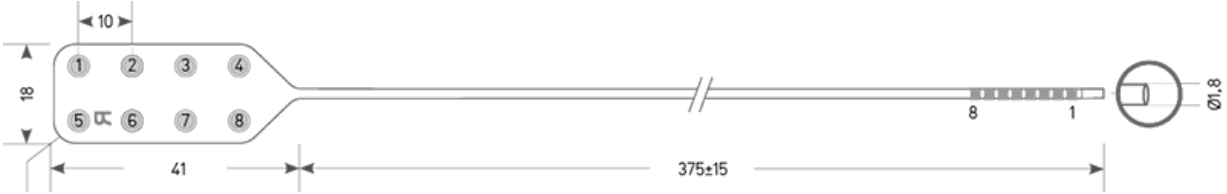


1x6 Strip Electrode | 6 Contacts

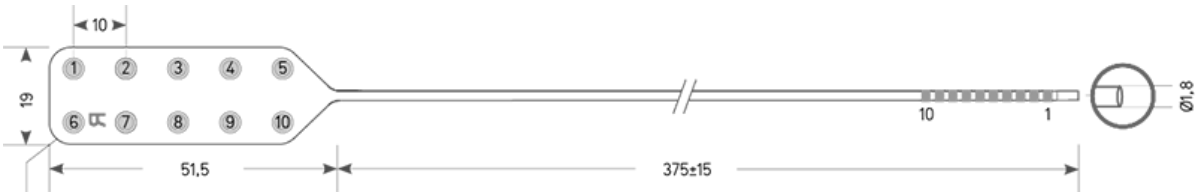
1x8 Strip Electrode | 8 Contacts

Grid-Electrodes

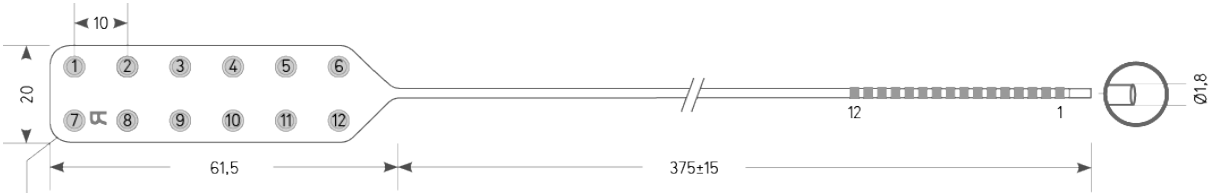
2x4 Grid Electrode | 8 Contacts



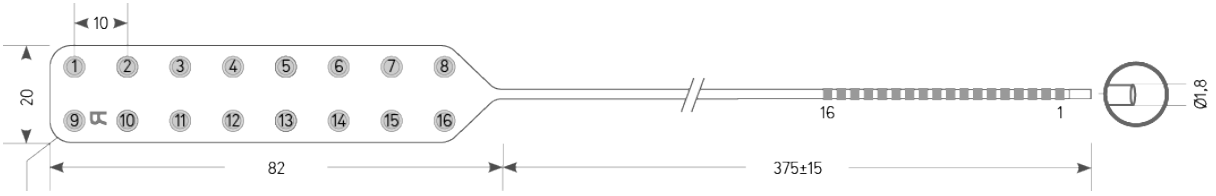
2x5 Grid Electrode | 10 Contacts



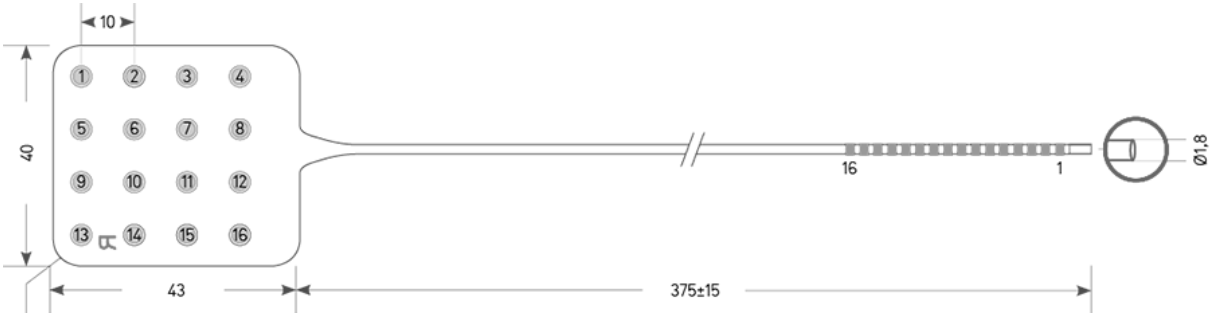
2x6 Grid Electrode | 12 Contacts



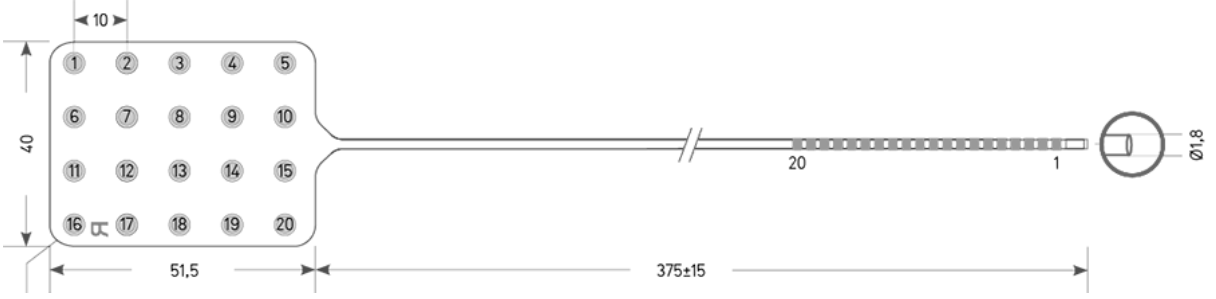
2x8 Grid Electrode | 16 Contacts



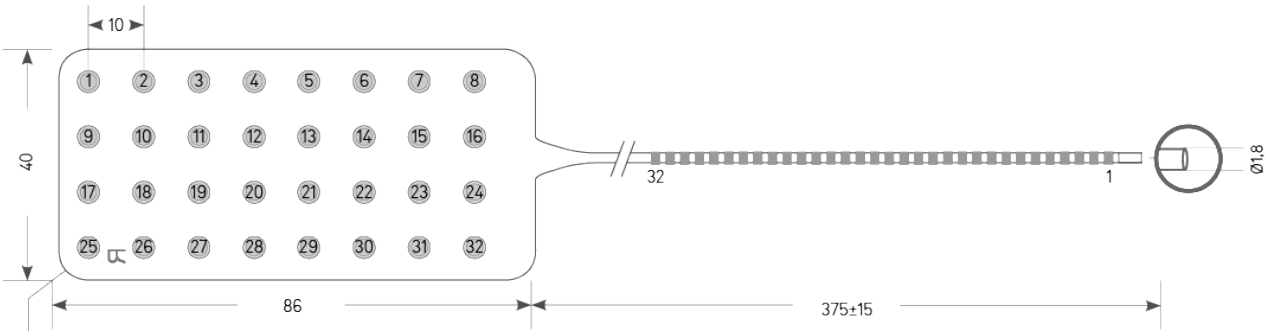
4x4 Grid Electrode | 16 Contacts



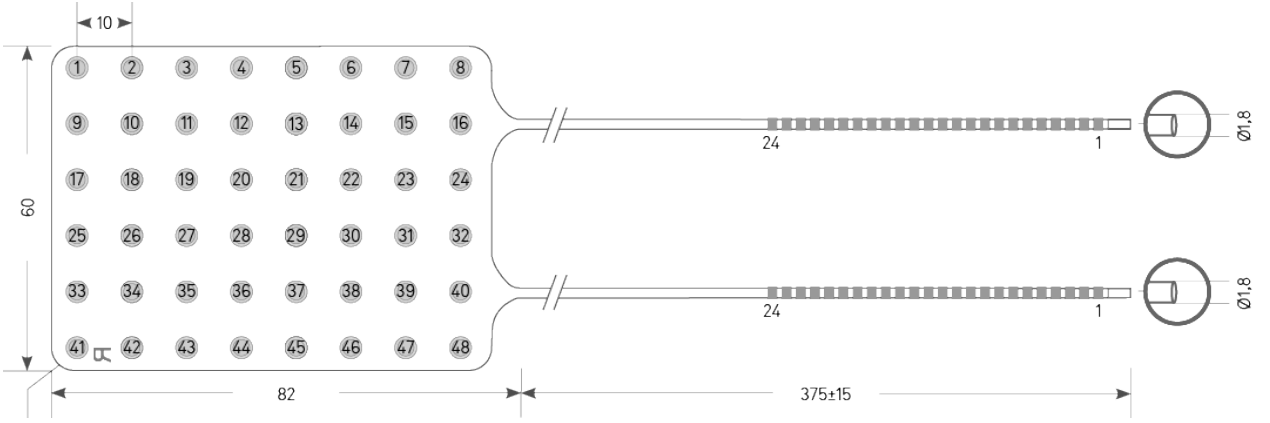
4x5 Grid Electrode | 20 Contacts



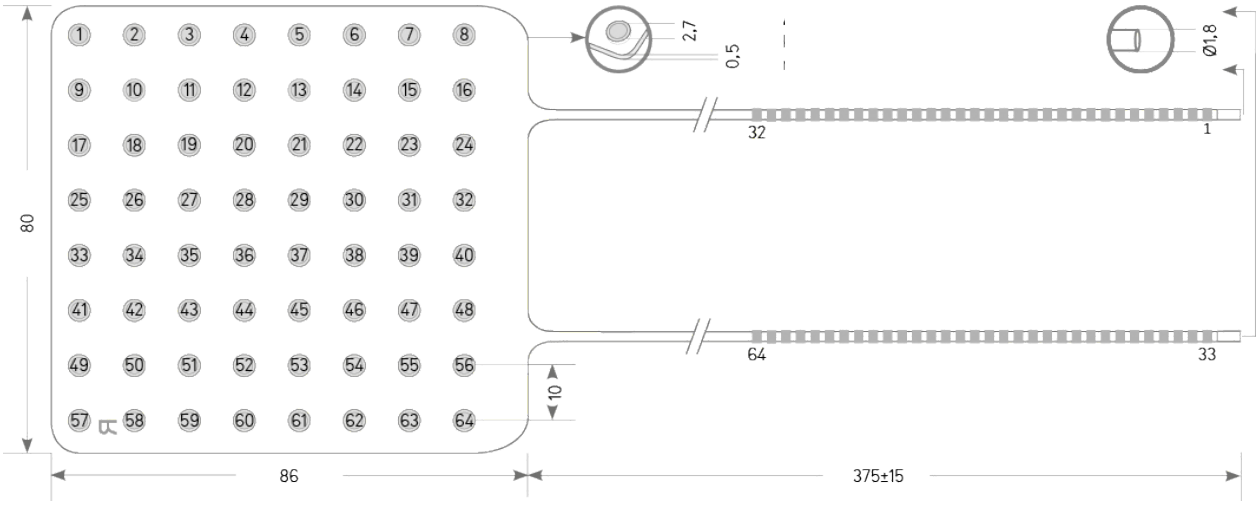
4x8 Grid Electrode | 32 Contacts



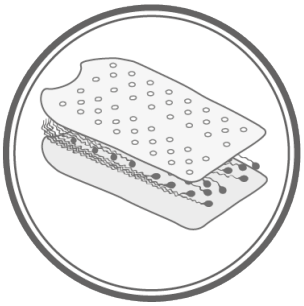
6x8 Grid Electrode | 48 Contacts



8x8 Grid Electrode | 64 Contacts

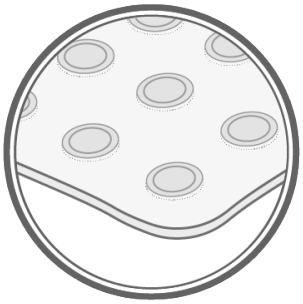


DESIGN OPTIONS



Multi-Layer Functionalization

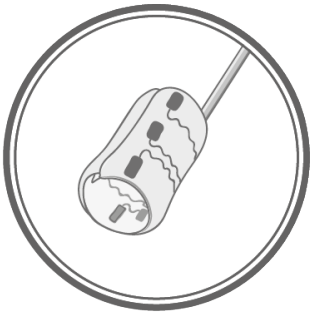
- Adjustment of thickness and flexibility by number and type of polymer or metal layers
- Adaptation of contact density and functionality by number and type of metal layers
- Integration of microfluidic channels and ports



General Dimensions

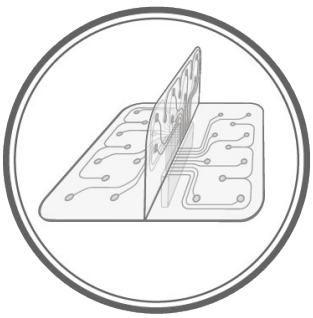
- Thickness:
  - Silicone electrodes: 0.15 mm – 1 mm
  - Hybrid silicone-parylene electrodes: 0.08 mm – 1 mm
- Contact size:
  - Silicone electrodes: down to 0.1 mm
  - Hybrid silicone-parylene electrodes: down to 0.05 mm
- Contact spacing:
  - Silicone electrodes: down to 0.3 mm center-to-center
  - 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)**		**Impendance (Diameter 2.7 mm)**	
		10 Hz	**1 KHz**	**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 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.

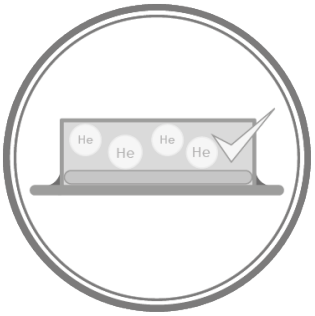
Not cleared for clinical use by FDA, but can be used under IRB and / or IDE guidance for research studies. Technical documentation for IDE Clearance is readily supported.

DESIGN OPTIONS

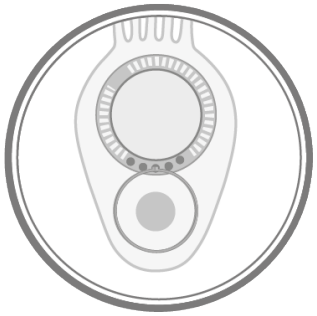
Geometry
- Circular, oval, or rounded-edge rectangular designs.
- Ceramic packages are molded in silicone rubber in application-specific shapes

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

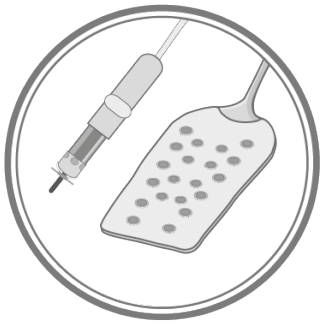
Feedthrough Dimensions and Spacing
- Feedthroughs come as metal tracks on ceramic base substrate
- Minimum track width: 0.08 mm
- Minimum pitch: 0.2 mm
- Minimum pad area: 0.1 mm x 0.5 mm



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 body and cables made of medical grade silicone rubber.
All other materials such as the ceramic encapsulation, the feedthroughs, and the hermetic 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
- Micro IRHD testing (together with external partners)
- Impedance
- Dielectric strength
- Corrosion
- Layer pull strength
- Hermeticity
- Shear strength

GENERAL SERVICE

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

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

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