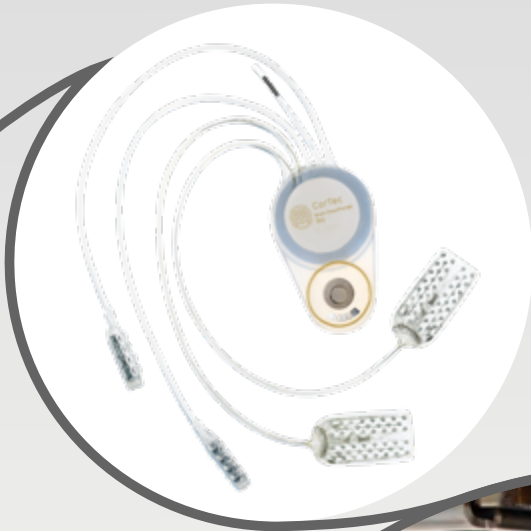




# CorTec business

## Products & Services



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# WELCOME

## EXPERIENCE THE FUTURE OF IMPLANTABLE TECHNOLOGY

**The first year in our new premises was very exciting. We have established our new manufacturing and qualified our cleanroom for the production of implanted devices for human use. With increased capacities we are here to accompany you all the way from pre-clinical studies leading to human applications and medical devices in the end.**

As leading experts for innovations in the field of medical engineering we are following the vision to take implantable technologies to the next level. By providing innovative technological solutions we enable you to develop highly efficient new active implants.

Based on our flexible technologies we have overcome current limitations. We are, therefore, able to offer the full range of services starting with design creation, testing, technical documentation as well as manufacturing of implantable technology starting with single components up to complete systems. All our products combine innovation, precision, and quality.

CorTec stands for cutting-edge technology for the next generation of active implants. On the following pages we will introduce you to the competences and services we offer to enable you to develop the next generation of therapies with our cutting-edge technology.

**Contact us to learn more!**

Thinking ahead,  
we are providing  
the technology of  
tomorrow already  
today.



# OUR SERVICE

**CorTec** is offering a wide spectrum of services accompanying you all the way through the development of innovative technologies leading to an approved medical therapy in the end.

Based on your idea we support you in the process of designing your device. We provide you with cutting-edge technology for your trials.

Once we have jointly identified the ideal design of your device we are paving your way to market approval based on our documentation.

**We support your market success as a reliable supplier.**

Our services include all important steps from providing solutions to realize your idea of a product over development and testing up to manufacturing the approved medical device.

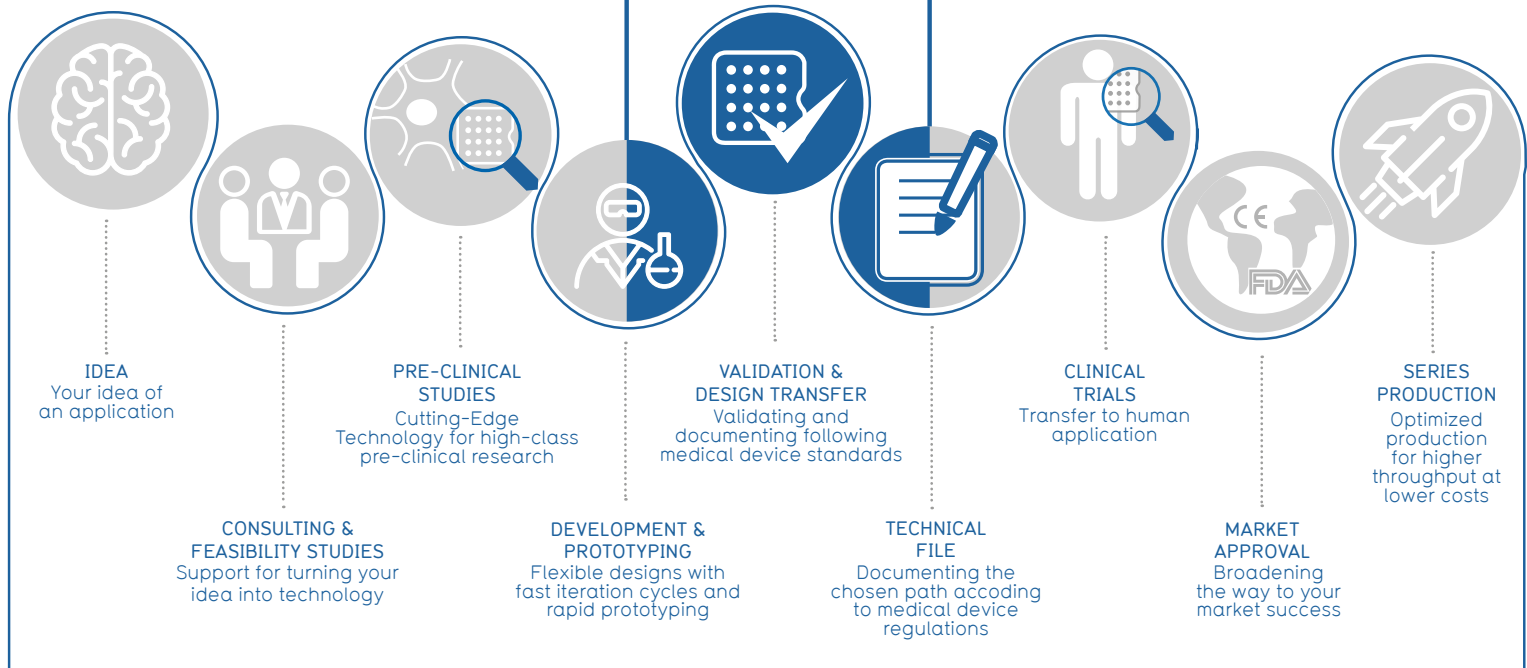
With our application-related, technological and regulatory know-how we support every step on the way to your implant.

## ACCOMPANYING YOU FROM THE IDEA OF AN APPLICATION TO MARKETING A MEDICAL PRODUCT

### PROVIDING TECHNOLOGICAL INNOVATION TO IMPLANTABLE DEVICES

### PAVING THE WAY TO HUMAN APPLICATION

### SUPPORTING THE MARKET SUCCESS OF INNOVATIVE MEDICAL PRODUCTS





### CONSULTING & FEASIBILITY STUDIES

- Design and application related consulting
- Investigation of feasibilities



With our strong expertise in engineering as well as in electrophysiology we support your way from the idea to designing a product not only by consulting but also by investigating possible solutions.

### DEVELOPMENT & PROTOTYPING

- Device design + fast design creations
- Preliminary studies
- Design studies
- Process development



We turn your idea into a product. Thanks to our development process and modern production technologies we can rapidly iterate designs and produce prototypes of your device.

### VALIDATION & DESIGN TRANSFER

- Manufacturing process validations incl. risk based sampling plans
- Design validations
- Biocompatibility evaluations and validations
- Cleaning process validations
- Packaging and transport validation
- Sterilization process validations (ETO)
- Transfer to manufacturing
- Pilot series production



Our development as well as our manufacturing comply with highest quality standards. We offer a wide range of in-house validations as well as validations together with partners and test laboratories.

### TECHNICAL DOCUMENTATION

- Development under design control
- Design History File (DHF) and Design Dossier (STED)
- Highly efficient document management system for fast review cycles
- Detailed manufacturing documentation
- Regulatory support of product approvals in many countries



For every development project we create an individual test plan and define the level of technical documentation in cooperation with you as the customer.

### SERIES PRODUCTION

- Qualified equipment and processes (IQ, OQ, PQ)
- Process monitoring
- Professional tool construction with external partners
- Supplier qualification Sterilization (ETO)
- Optimization of production lines
- Upscaling of production throughput



We transfer your prototype or pre-clinical device to production and establish production lines for higher throughput at lower cost.





## Quality

**CorTec** has implemented a quality management system (QMS) according to DIN EN ISO 13485 (notified body: TÜV SÜD).

Please download our certificate via the following link:  
[www.cortec-neuro.com/company/quality/](http://www.cortec-neuro.com/company/quality/)

High process quality is maintained by staff training, process improvements and continuous internal and external audits. This provides an important basis for the certification of our products as well as for our OEM business in the medical device market.

We have established several processes to support the consistency of our quality standards, the compliance to regulations, as well as the continuous improvement of our processes. We produce our products under design control. Our processes undergo detailed analyses of failures, modes, and effects (PFMEA).

## Cleanroom

In line with our business strategy we have established all core manufacturing steps in our cleanrooms inhouse. Our manufacturing is located in the heart of our new premises, consisting of different laboratories and the cleanroom. All production steps can be watched from the outside.

In our cleanroom we have set up an optimal production line to be able to manufacture small quantities as well as very large volumes of the same product. To make this possible we put a strong focus on the room layout and the selection of the right equipment as well as on the design of ergonomic workstations.

To achieve highest quality of our products, we are performing all manufacturing steps in the constantly controlled environments of our qualified ISO class 6 and 8 cleanroom facilities. The manufacturing of intermediate products like for example electrode arrays from raw materials using high-precision laser micromachining is followed by the interconnection of the array to other components like cables or packaged electronic units. To finalize the product, various cleaning steps are performed including packaging and labeling before sterilization or shipment for the execution of further processing steps.

The technical construction of our cleanroom facility not only complies with regulatory requirements but also takes into account aspects of climate protection. We have installed a modern control system in order to keep our energy consumption as low as possible.



# Testing & Characterization

## Electrical and Electrochemical Tests

- **Impedance spectroscopy**  
Characterization of the recording performance of the electrode.
- **Corrosion testing inclusive SEM inspection**  
Evaluating the corrosion resistance of a particular electrode design for a given stimulation paradigm.

## System Integration Tests

- **Functionality testing**
- **Hermeticity qualification (helium gross and fine leak testing)**
- **Long-term functionality testing**  
If desired also under accelerated aging conditions.

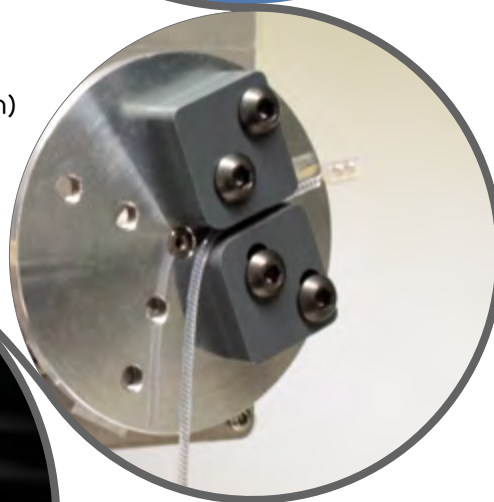
## Mechanical Tests

- **Reliability testing**  
Cyclic bending and pull tests to obtain typical lifetime characteristics of electrodes or interconnections – if desired under particular environmental conditions, such as HALT (highly accelerated lifetime tests).
- **Tensile or shear tests**
- **Bending and flexing tests (cyclic or ultimate strength)**
- **Layer pull strength (adhesion)**
- **Hardness testing (micro IRHD)**

All tests can be tailored and individualized to your needs.

We coordinate all test protocols with our customers. Our test reports include comprehensive documentation of all results.

We perform individual analyses tests if desired and deliver all raw data to our customers.





Based on our technological competences we are providing solutions for the most innovative therapies of tomorrow already today – starting from single components right up to full active systems.



## COMPETENCES

**Based on our technological competences we are providing solutions for the most innovative therapies of tomorrow already today – starting from single components up to complete systems.**

CorTec enables the communication between the nervous system and technology using the means of artificial intelligence. Based on our Brain Interchange technology we are providing high-performance interfaces to the nervous system like electrodes in flexible designs, encapsulations and electronics with an unprecedented number of channels including a software for controlling the application. United in our complete closed-loop system Brain Interchange ONE or custom design systems we overcome current limitations of active implantables.

To do so we rely on established implant materials which we process using innovative manufacturing methods. We are thus building on the experience of decades of implant technology, while at the same time remaining on the already established regulatory path. On the other hand we can leverage the innovation potential of our technology to the maximum to enable you to develop innovative therapeutic approaches.



# Brain Interchange Technology Platform

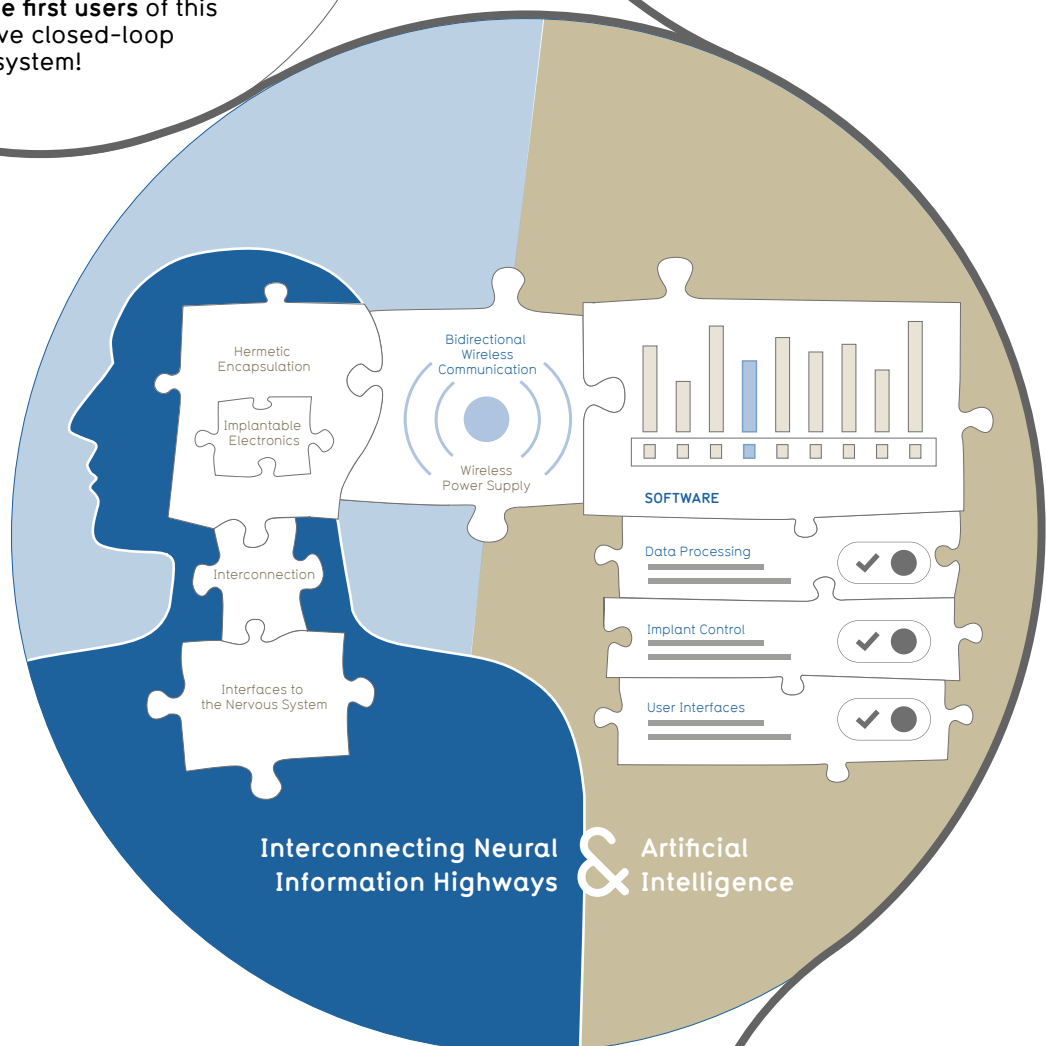
The **CorTec Brain Interchange** platform technology is comprised of **all components** needed for electrically **interconnecting the neural system to external software** utilizing the full power of artificial intelligence – and thus, **enabling communication with the nervous system**.

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

Join us on the exciting journey to personalized neurotherapies and **be one of the first users** of this innovative closed-loop system!

**CorTec Brain Interchange** is a versatile technology platform designed for use in a wide range of investigational studies that require recording and/or stimulation of the brain.

In particular the Brain Interchange technology has been developed for closed-loop neuromodulation.



# Electrodes

## Key Winning Features

### High Precision

Ultra-short pulse laser micromachining allows for very small feature sizes of down to 25  $\mu\text{m}$  at highest reproducibility.

### Easy Adjustment of Mechanical Properties

Varying the thickness of silicone, Parylene-C, or metal layers creates softer or harder electrode structures.

### Adaptation of Shape and Functionality

Electrodes can be modified to build 3-dimensional assemblies as well as nerve cuff electrodes. Further adaptations include the integration of microfluidic channels for drug delivery.

### Excellent Electrochemical Properties

Platinum-Iridium is used by standard as electrode material. Other materials are available upon request. For improving charge injection capacity, high performance coatings can be provided.

### High Level of Patient Safety

Mechanical interlocking mechanisms prevent electrode contacts from dislocation and ensure safe contact to neural tissue.

### Improved Usability and Reliability

Great mechanical adaptability makes surgical handling significantly easier. Superior reliability maintains full electrode functionality even under recurring loads.

### Freedom of Design

Freedom of Design of the shape of electrode contacts and outlines allows for significantly higher performance of planar or cuff electrodes during stimulation and recording.

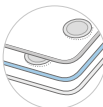
A portfolio of strip and grid electrodes has received FDA clearance for invasive neuromonitoring

Contact us to learn more about the status of validations of our technology

## Design Options

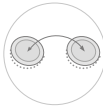


- Design geometry maximum: 90 mm x 90 mm
- Various designs for electrode outline incl. slit contours or intrafascicular designs
- Thickness: 0.08 mm – 1 mm



#### Multi-Layer Functionalization

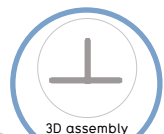
- Adjustment of thickness (0.08 mm – 1 mm) and flexibility by number and type of polymer or metal layers
- Adaptation of contact density and functionality
- Functional components such as surgical mesh or suture material



contact spacing: down to 0.06 mm center-to-center depending on number of contacts



Contact size: down to 0.04 mm



3D assembly

Surface treatment

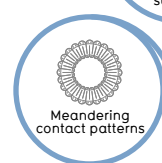


Coating

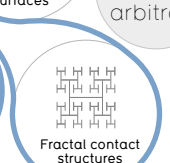


Roughened surfaces

Contact shape: arbitrary



Meandering contact patterns



Fractal contact structures

## Materials

### POLYMERS

Medical grade silicone rubber

- Long-term ( $\geq 30$  days)
- Short-term ( $< 30$  days)

Parylene-C

### METALS

Medical grade metal alloys:

- Platinum-Iridium (90/10)
- Platinum
- MP35N
- Stainless Steel

High-performance coatings:

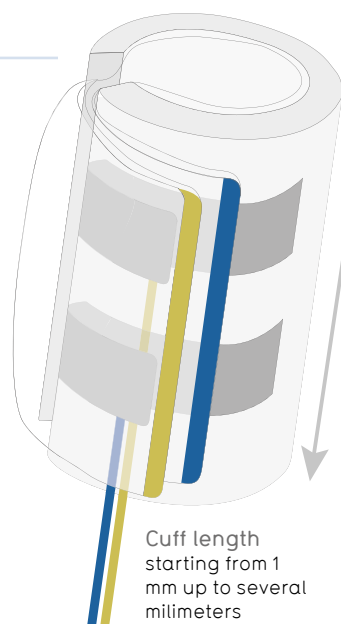
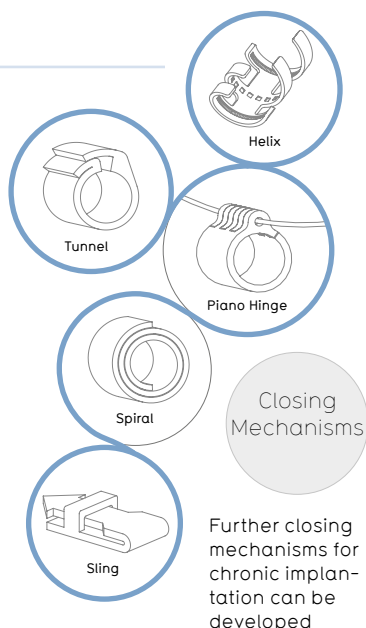
- Sputtered Iridium Oxide (SIROF)
- Platinum Black

Physical surface modification like laser roughening permits additional adaptations to the individual application.

## Performance

	Charge Injection Capacity	Typical Impedance <sup>1</sup> (Diameter 1 mm)		Typical Impedance <sup>1</sup> (Diameter 2.7 mm)	
		10 Hz	1 KHz	10 Hz	1 KHz
MP35N	max. $0.03 \text{ mC/cm}^2$ <sup>2</sup>	260 k $\Omega$	5 k $\Omega$	32 k $\Omega$	0.6 k $\Omega$
Platinum-Iridium (90/10)	$0.09 \text{ mC/cm}^2$ <sup>3</sup>	47 k $\Omega$	1 k $\Omega$	8 k $\Omega$	0.2 k $\Omega$
Platinum	$0.05 \text{ mC/cm}^2$ <sup>4</sup>				
Platinum Black	$0.25 \text{ mC/cm}^2$ <sup>5</sup>				
Rough Platinum-Iridium (laser-treated)	$0.27 \text{ mC/cm}^2$ <sup>5</sup>				
Sputtered Iridium Oxide Film (SIROF)	$0.75 \text{ mC/cm}^2$ <sup>6</sup>				

- 1 Setup: three electrode configurations in 0.9% saline. Typical impedance readings.
- 2 Ning et al.: Pitting Corrosion of High Strength Alloy Stimulation Electrodes under Dynamic Conditions, 1989.
- 3 Cogan et al.: In Vitro Comparison of the Charge-Injection Limits of Activated Iridium Oxide (AIROF) and Platinum-Iridium Microelectrodes, 2005.
- 4 Rose et al.: Electrical stimulation with Pt electrodes, 1990.
- 5 Own investigations.
- 6 Own investigations, matching Cogan et al.: Sputtered iridium oxide films (SIROFs) for low-impedance neural stimulation and recording electrodes, 2004.



Contacts  
2-20 or more meander  
contacts made of PtIr,  
Platinum, IrOx, MP35N  
or other

### General Dimensions

CorTec tailors the fabrication processes to meet the customer's requirements. The two most typically used processes involve

- metal structures embedded in silicone rubber and
- metal structures sandwiched between a layer of silicone rubber and a layer of Parylene-C.



+49 761 70 888 200

# Active Implantable Technology

Based on our technological competences we are providing solutions for the most innovative therapies of tomorrow already today – starting from single components up to active complete systems.

Our service comprises the full range from designing and encapsulating implantable electronics over to interconnections to electrodes up to developing firmware and software for CorTec manufactured systems.

## I. Hermetic Encapsulation

### Key Winning Features

#### High Channel Count

Thick film technology enables hundreds of electrical feedthroughs – unlike conventional titanium packages with metal pin feedthroughs.

#### Customized to Your Needs

Our ceramic encapsulation technology is the first complete packaging solution for implants with a very high channel count with additional options for electronics and software available on the market. Designed according to your requirements it ensures a protection of the implant electronics for decades.

#### Electromagnetic Transparency

The ceramic encapsulation is transparent to electromagnetic waves facilitating communication via radio frequency or infrared as well as inductive powering.

#### Mechanical Robustness

CorTec's ceramic packages can be designed to survive mechanical impact as for example required for cochlear implants according to EN 45502-2-3:2010 and ISO 14708-7:2013.

#### Superior Hermeticity

Protection of electronics against moisture with tested helium leak-rates down to the detection limit of state-of-the-art leakage detections – even for small implant volumes below 1 cm<sup>3</sup>.

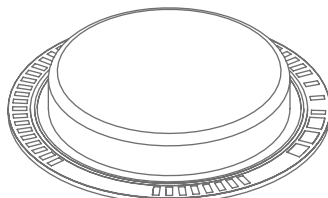
#### Freedom of Design

CorTec's ceramic encapsulations allow application-specific shapes and designs.

### Design Options

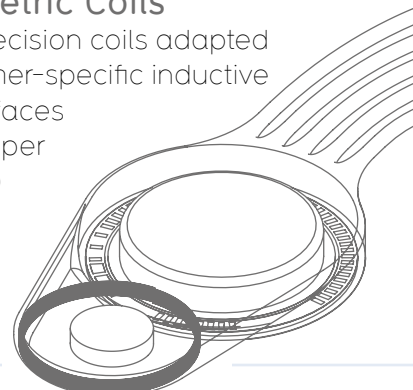
#### Feedthrough Dimensions and Spacing

- Feedthroughs realized as metal tracks on ceramic base substrate
- Minimum track width: 0.08 mm
- Minimum pitch: 0.2 mm



#### Customized Telemetric Coils

- Hand-crafted high precision coils adapted to the needs of customer-specific inductive power and data interfaces
- Materials: Gold or copper (for feasibility studies)



We realize customer specific projects. Next to our hermetic encapsulation we are also able to manufacture non-hermetic encapsulations using silicone moulding.

## Materials

### IN CONTACT WITH THE BODY

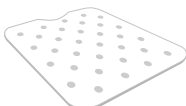
Smooth implant body and cables made of medical grade silicone rubber.

All other materials such as the ceramic encapsulation, the feedthroughs, and the hermetic seal for the package are covered by this silicone shell.



### Connects to Other Products

- AirRay® electrodes
- Commercially available neural electrode arrays (Utah array) and implantable connectors
- DBS electrodes



### 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 lifetime prediction based on helium leakage measurements
- Extremely low leak rates qualify our packages for rejection thresholds down to  $10^{-10}$  mbar l s<sup>-1</sup>.



## II. Interconnection

### Key Winning Features

#### High Integration Density

Varying interconnection technologies together with highly skilled manual cable manufacturing enable high channel counts per cable compared to other manufacturers.

#### High Variability

Versatile electrode and substrate materials connect almost any electrode material — from a variety of flexible wires to rigid FR4 substrates for PCBs or even ceramics.

#### Reliable Process Portfolio

A wide range of processes are validated for the most common material combinations. Equally high standards for customer individual solutions are guaranteed.

#### Functionality Enhancement of Commercially Available Solutions

Commercially available connectors can be customized with custom interconnections to create new solutions for previously unsolved implant wiring challenges.

Customized  
to Your  
Needs

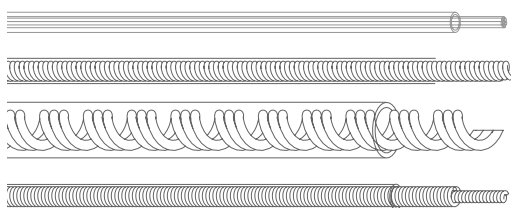
To make sure your implants benefit from the innovation of our components we are building on industry standards of connection options.

Through a large network of partners we cover the full range of connection solutions according to your requirements.

### Design Options

#### Cable Manufacturing

- Bundled straight wires
- Coil wound cables
- Ribbon cables



#### Research Standard Connections

- ZIF connectors
- Omnetics connectors
- Harwin connectors
- Molex connectors
- Other connector types can be attached upon request

#### Interconnection Technologies

- Ball-stud bonding
- Laser welding
- Spot welding
- Parallel gap welding
- Micro soldering

## Materials

WIRES	INSULATION	SUBSTRATES
<ul style="list-style-type: none"><li>• Platinum-Iridium (90/10)</li><li>• MP35N</li><li>• MP-DFT (Ag silver core)</li></ul>	<ul style="list-style-type: none"><li>• Polyesterimide</li><li>• Fluoropolymer</li><li>• Silicone</li></ul>	<ul style="list-style-type: none"><li>• Printed Circuit Board, e.g. FR4</li><li>• Screen printed ceramics</li><li>• Other materials upon request</li></ul>

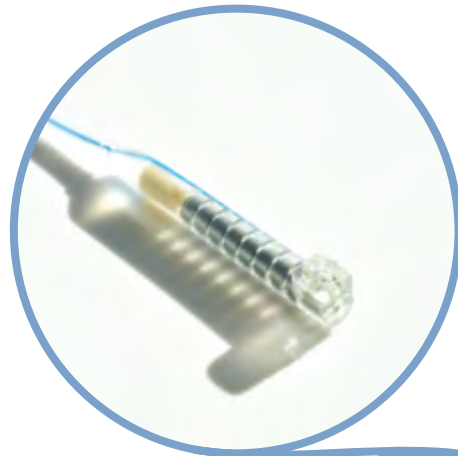
## Performance

To guarantee highest reliability our inter-connections are tested to fulfill different standards in the medical device industry (e.g. EN 45502-1 or ISO 14708-1).

For particularly challenging mechanical requirements we are happy to engineer strain relieving concepts for your individual inter-connection solution.

### Medical Standard Connectivity

- IS-1
- IS-4
- DF-1
- DF-4
- Bal Seal







## III. Electronics & Software

### Electronics Development

We are developing circuitry for active implanted medical devices and their corresponding body-external telemetry units within the EN ISO 13485 environment, incorporating all relevant electromagnetic compliance and patient safety requirements, originating from e.g. EN ISO 14708, EN 60601 and the FCC.

**CorTec** electronics utilize application specific integrated circuits (ASICs), particularly designed for **CorTec** implants. **CorTec** has additional expertise in implanted stimulators/amplifiers, demand-adaptive wireless power transmission and high-bandwidth bi-directional wireless communication.

### Software Development

Our software department practices agile development of medical device grade software according to IEC 62304. The development ranges from windows 10-based application software (C++, Python, Java) to embedded systems programming (C) for processors used in CorTec's implants and body-external transmitters.

In case of our Brain Interchange ONE System the Application Software runs on a Microsoft Windows-based Computer and represents the interface between the user and the system comprising External Unit and Multi-Part Implant.

The Application Software provides users with a graphical user interface.

The functionality of the Application Software includes 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.

Additionally, it is able to visualize implant status data such as impedance, humidity and temperature inside the Hermetic Encapsulation. It is also able to define stimulation signals within the implant's technical capability and safety limits as well as to execute stimulation commands.



The CorTec software department practices agile development of medical device grade software according to IEC 62304.

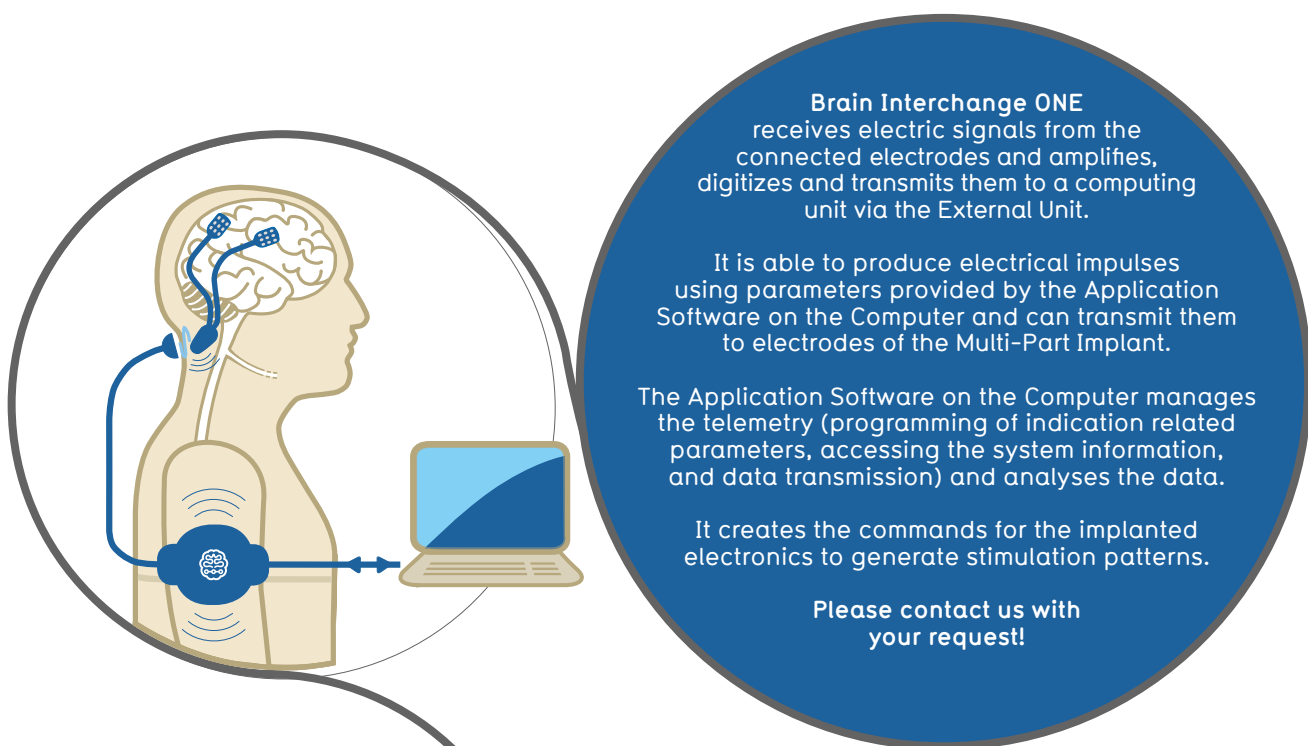


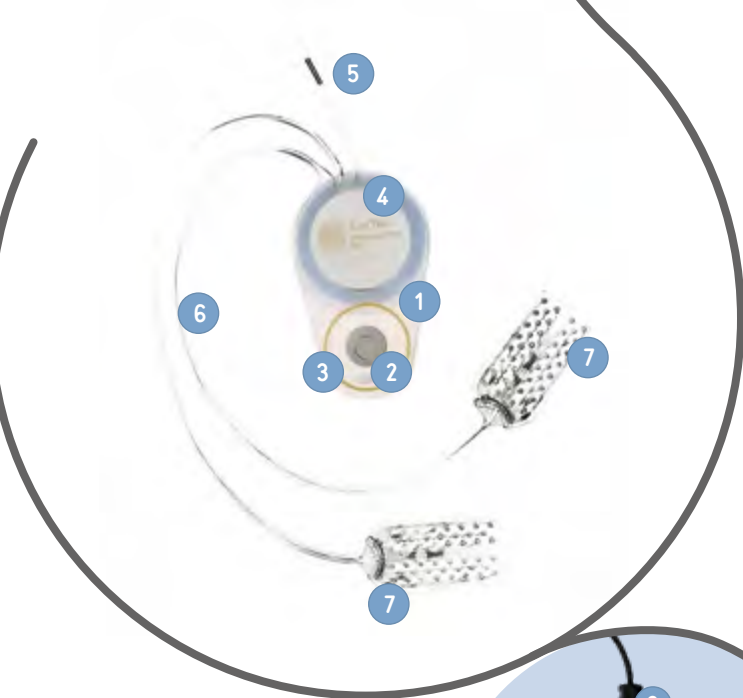
## IV. CorTec Brain Interchange ONE

The best example for the great scope of our competences is CorTec Brain Interchange ONE. The implantable system for recording and stimulation both on 32 channels is available in customized versions for exploring and developing innovative neurotherapies.

**The implantable platform features full wireless functionality for chronic open- and closed-loop interaction with the nervous system. It consists of 3 components:**

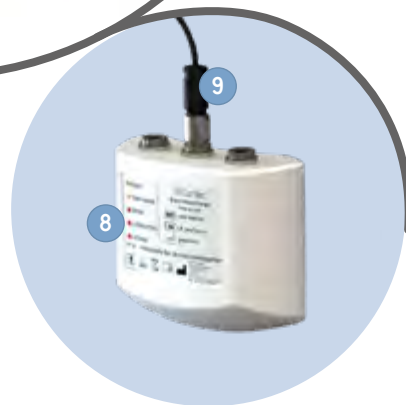
- Multi-Part Implant**
- One or two **AirRay** electrodes from CorTec designed according to customer specifications.
  - The Brain Interchange platform is also prepared for the use of DBS electrodes.
  - The Implanted Internal Electronics Unit is placed inside a proprietary hermetic ceramic encapsulation. 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.
- Personal Computer with Software Interface**
- 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.





## Multi-Part Implant

- 1 Implanted Internal Electronics Unit
- 2 Magnet for attachment of External Unit (location and number of magnets can vary)
- 3 Coil for electromagnetic power transmission
- 4 Hermetic encapsulation of implant electronics
- 5 Ground lead (with variable cable length)
- 6 Electrode leads
- 7 <sup>®</sup>AirRay ECoG electrodes (customizable)



## External Unit

- 8 STATUS LEDs  
LEDs indicating system status like powering or active communication between Implanted Internal Electronics Unit and External Unit
- 9 CABLES
  - USB connection to PC
  - Optional: trigger cable
  - Head Piece cable

## Implanted Internal Electronics Unit

FEATURE	VALUE
Recording channels	• 32
Sampling rate	• 1 kHz
Sampling dynamic range	• 16 bit (74 nV increment)
High pass filter cut-off	• 0.1 Hz
Low pass filter cut-off	• 400 Hz
Amplifier band pass gain	• 631
Band pass roll-off	• 20 dB/dec
Reference	• Any (subset) of the recording channels selectable by software or one dedicated hard-wired additional contact
Stimulation	• Controlled, biphasic, rectangular, asymmetric stimulus pulses (cathodic amplitude with pulsewidth followed by an anodic counter pulse of 1/4x amplitude and 4x pulsewidth)
Stimulation channels	• 32
Current	• Max. -6 mA / +1.5 mA within compliance voltage range of -11V to +5V
Current source	• Can be directed to any of the 32 electrode contacts
Pulse width	• Negative phase: 10 µs – 2,500 µs
Thermal monitoring	• Protection against overheating
Electrical Isolation of patient from electronics	• DC-decoupled using blocking capacitors
Power supply	• Wireless inductive, 120-140 kHz
Wireless data transmission	• Bi-directional, radio frequency in 2400-2483.5 MHz band

## External Unit

FEATURE	VALUE
Connection of Communication Unit to Personal Computer with Software Interface	• USB 2.0 or 3.0 data transmission
Method of keeping Head Piece unit in place	• Suspended by magnets
Size of Head Piece	• 38 mm Ø, Height = 14mm
Weight of Head Piece	• 13 g (without cable)
Size of Communication Unit	• ca. 85 x 95.9 x 48.1 mm <sup>3</sup>
Weight of Communication Unit	• ≤ 300 g

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## CONTACT

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Please contact us with your  
design requests!

We are happy to support you and your projects!

For more information about us, our products, and services visit our  
website or follow us on our social media channels.



**CorTec**

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