

PRODUCTS & SERVICES



WELCOME!

As the leading partner in the development of innovative neurotherapies and implantable Medical Devices we enable the COMMUNICATION WITH THE NERVOUS SYSTEM – FOR THE CURE OF DISEASES.

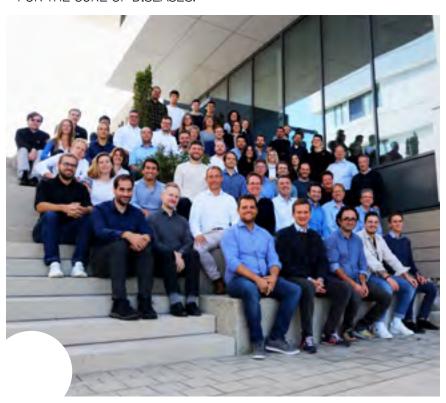


TABLE OF CONTENTS

	4
	6
Grid Flectrodes	7
Strip & Paddle Electrodes	8
Strip & Paddle Electrodes	9
Cuff Electrodes	10
	12
	\frac{1}{2}
	16
Technology Overview	17
Evaluation Kit	
Brain Interchange ONE	



ABOUT CORTEC

WHAT WE DO

CorTec develops and produces implantable neurotechnological devices, components and sub-assemblies for:

- Approved Medical Devices
- Clinical Feasibility Studies
- Animal Research Market

CorTec supports customers from product idea to realization of the product with technological and regulatory experience.

CorTec's class 8 and 6 cleanrooms permit the production of small to medium-size batches in quality controlled environment. CorTec is ISO 13485 accredited by TÜV SÜD.



It all starts with your product idea or vision.

Based on that, we evaluate feasibility, estimate a project timeline and define a first concept based on your input.



Prototyping & Feasibility Testing In mutual exchange, we build mock-ups and prototypes to evaluate design, functionality and usability. We develop and perform tests ranging from bench top tests to first in vivo studies in different animal models.



Product Development & Design Transfer

For your final product, we refine our planning and support you in defining the parts of your medical device file that are your and CorTec's responsibility. Your final product is realized under design control and ISO 13485.

Along the way, we assist with our qualified supply chain, design for manufacturability and finally design transfer to our skilled manufacturing team and certified clean room structure.



Regulatory Support, Technical Documentation & Production

We help you with your technical documentation and provide regulatory support for your submission towards device approval. Our clinical experts are ready to help you with your study and data requirements.

We grow our production capabilities together with your needs. Starting small for testing and study samples and scaling-up for final device production and market distribution.

°AIRRAY ELECTRODES

CorTec's °AirRay electrodes are made from very soft silicone using a high-precision laser manufacturing process. They offer an unprecedented **combination of flexibility, softness, stretchability, thinness and density of contacts.**

The 'AirRay Technology allows electrode customization to fit your specific application:

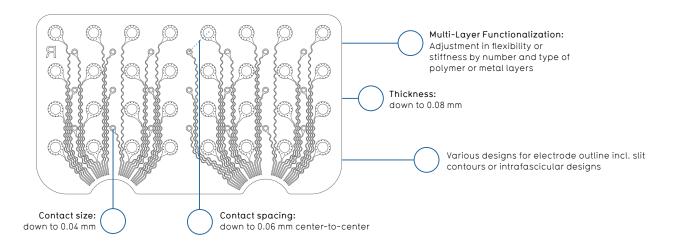
- Number of contacts & contact density
- Grid, Strip, Paddle or Percutaneous electrodes
- Mechanical properties
- Contact materials

ORDER ONLINE VIA CHAMFR, COM

Chamfr is an online market place that offers components from various manufacturers for direct purchase.

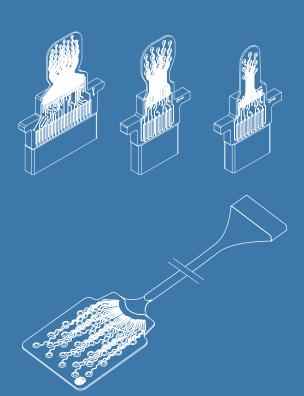
Our ^oAirRay Electrodes can be found here: www.chamfr.com/sellers/cortec/





GRID ELECTRODES

Our °AirRay Grid electrodes are electrical interfaces to the central nervous system. They are the ideal solution for ECoG or intraoperative recordings but also electrical stimulation.



Micro Hexagonal Grid Electrodes with 0.3 mm contact diameter in hexagonal contact arrangement

Micro 8 Hexagonal

- 8 contacts

Micro 16 Hexagonal

- 16 contacts
- 5.7 × 7.5 mm

Micro 32 Hexagonal

- 32 contacts 7 × 8.5 mm

Micro 4 x 8 Square 45°

- 32 contacts
- micro-contacts | 1 mm Diameter 20 × 20 mm
- contact arrangement shifted by 45°

STRIP & PADDLE ELECTRODES

Our paddle electrodes are electrical interfaces to the central nervous system. They are the ideal solution for spinal cord stimulation but can also be used for recording.

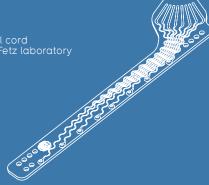
Below you can find two typical designs for pre-clinical and clinical research.

*AirRay Courtine 2 x 3 + 2 Rhesus Lumbar Array

- Oblong electrode arrangements
- Optional fixation strap
- Developed in cooperation with Gregoire Courtine
- For recording and stimulation of the spinal cord
- 8 contacts
- Linear contact arrangement

Fetz Spinal Cord 8

- For recording and stimulation of the spinal cord Developed in cooperation with Eberhard Fetz laboratory
- Linear contact arrangement





PERCUTANEOUS ELECTRODES

The °AirRay Percutaneous Electrodes are electrical interfaces to subcutaneous, intraspinal or deep brain locations of the nervous system. They can be used for recording and stimulation.

Arrangement of circumferential contacts on flexible or rigid tubes for recording and stimulation. We offer individual configurations according to your application.





CUFF ELECTRODES

Our Cuff Electrodes offer a wide spectrum of closing mechanisms and sizes to design specific electrodes for your application.

Sling or Tunnel Cuff Electrodes are ideal for small nerves in animal research. The larger designs such as the Spiral and Helix Cuff electrodes are ideal for chronic applications in pre-clinical and clinical settings for human application.

ORDER ONLINE VIA CHAMFR, COM

Chamfr is an online market place that offers components from various manufacturers for direct purchase.



FEATURES

Cuff electrodes are electrical interfaces to the peripheral nervous system.

CorTec offers design families for individual applications, which strongly depend on the implantation site (e.g. nerve size) and character of the interface:

- · Neural signal recording
- Electrical stimulation of nerves
- Blocking of propagation of neural signals

The cuffs are built from soft silicone to minimize the risk of mechanical nerve irritation. CorTec's micro-machining technology permits the electrical contacts to be produced as very flexible micro meanders. At the same time they prevent the effect of plastic deformation of the cuffs during handling.

The following page presents the typical design options of these electrodes. Of course, we also offer custom-tailored designs to meet your specific requirements, e.g. high-channel versions.

Sling and Tunnel Cuff Electrodes are very easy to handle. These electrodes can be removed from the implantation site without affecting its functionality and are available in different diameters and with varying numbers of contacts.

TUNNEL CUFF ELECTRODE

- Closing mechanism with color-coded flaps enables easy handling.
- Diameter starting from 0.2 mm

SLING CUFF ELECTRODE

- Buckle-and-belt closing mechanism
- Diameters starting from 0.1 mm





Spiral and Helix Cuff Electrodes are self-adjusting Cuffs that can accommodate nerve swelling to some extent and are suitable for low-trauma electrical stimulation. They also offset the differences in nerve diameters from individual to individual.





SPIRAL CUFF ELECTRODE

- We suggest spiral cuffs with at least 2.5 turns around the targeted nerve diameter. This will also help to avoid the nerve escaping the electrode as well as electrical insulation issues.
- Diameters starting from 1.5 mm

HELIX CUFF ELECTRODE

- The concept is based on designs of the Huntington Medical Research Institute.
- They can be designed for minimal compression forces in order to avoid nerve irritation.
- Diameters starting from 2.0 mm



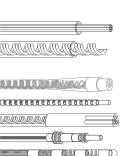
ADDITIONAL SERVICES & INFORMATION

CUSTOMIZATION AND INDIVIDUAL DESIGNS

Our ^oAirRay Electrode Technology offers various designs for neural interfaces to the peripheral and central nervous system. With our experience we help you to realize your specific product.

We offer individual designs and additional services, such as surface treatment or impedance spectroscopy. It all starts with your idea of a product or component and our team is ready to discuss design possibilities tailored to your application.





CABLES & CONNECTORS

Cables

- Straight Wire Cable
- Coiled Cable (solid wires inside silicone tubing)

Connectors

- Extracorporal (Omnetics, Pig Tail, Touch Proof Connectors)
- Percutaneous (Plastics One)
- Implanted (Craggs, IS-1, Inline Connector)

CorTec's fully implantable In-Line connector.

The full implantable connector allows interconnection to common 8 channel DBS leads (e.g. Abbott, Medtronic, Boston Scientific) or other electrodes with proximal in-line connection. Our in-line connector technology is based on the Bal Seal Sygnus system and uses PtIr contacts and medical silicone seals.

Contact us for customizations.

HIGH CHANNEL IMPLANT HOUSING

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

- Individual designs with +100 feedthroughs
- Radio frequency and infrared transparency
- Integration of coils and antennas without additional circuit boards
- Ceramic cover can be replaced by metal cover if needed

SILICONE OVERMOLDING

Non-hermetic encapsulations using silicone molding. The benefits of using a silicone molded encapsulation include the following:

- Reduced tissue reaction inside the body
- Long-term stability of system components
- Protection of electronics or other parts of the implant
- Use of medical grade silicone to meet biocompatibility requirements

Depending on your individual active implant we create your ideal silicone overmolding design.

- Fast design iterations and in-house tool production
- Rapid prototyping and mock ups

MECHANICAL CHARACTERIZATIONS / TESTING

- Flex-fatigue electrode lead and cable testing
- Tensile strength testing
- Impact testing of housings

ELECTRICAL AND FUNCTIONAL CHARACTERIZATIONS / TESTING

- Impedance / continuity / insulation measurements
- Dielectric breakdown voltage measurements
- Leakage current measurements
- Many aspects of IEC 60601-1 measurements
- Heating of implanted devices in simulated environment
- Heating of implanted devices in MRI scanners
- X-Ray Analysis

ELECTROCHEMICAL CHARACTERIZATIONS

- Impedance spectroscopy
- Cyclic voltammetry
- Pulse testing (e.g. corrosion studies)
- Transfer function measurement (e.g. cuff neural recording properties)

ACCELERATED AGING

- Storing at elevated temperatures, still or agitated
- Different media, still or agitated
- Pressure, dry or wet

DESIGN OPTIMIZATION BY COMPUTER SIMULATION

- Coupling of nerve electrodes to target tissue
- Various RF simulations (e.g. aspects of MRI interaction)

ELECTRODE SURFACE TREATMENTS

By standard, neural electrode arrays are produced using Pt90Ir10 as commonly established electrode material.

If required, this material can be pre-treated or coated to improve e.a. electrical stimulation performance:

- Laser-roughening of PtIr
- Sputter-coating of IrOx films
- Electroplating of PEDOT









0000

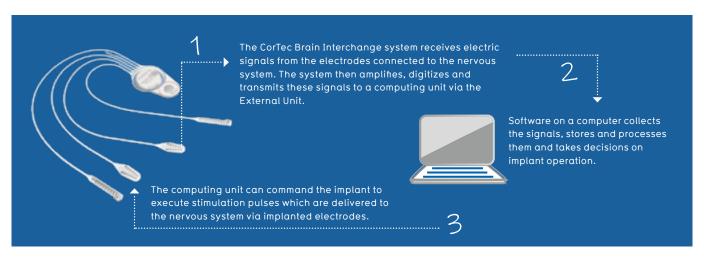
Malle

BRAIN INTERCHANGE

TECHNOLOGY OVERVIEW

The Brain Interchange System enables interconnection of the nervous system to external information technologies. An interchange of information is realized to modulate the nervous system.

As an investigational device, the fully implantable system is designed for both recording and stimulating on 32 channels. The system can be used in the central and peripheral nervous system to develop new therapies.





THE BRAIN INTERCHANGE EVALUATION KIT

The Evaluation Kit is a bench-top-version of the Brain Interchange System. It is electrically identical to the implant, but much easier to handle. The Evaluation Kit is the ideal entrance to the clinical use of the Brain Interchange.

Evaluation Kit used on the laboratory bench

- Learn programming of the Brain Interchange & write your own Brain Interchange therapy code.
- Check Brain Interchange properties, like recording quality, noise level, wireless link robustness, latencies, stimulation output, and others.
- Easy access to Brain Interchange using existing lab equipment like oscilloscopes and signal sources.

Evaluation Kit used in clinical setting

- Electrode implanted with externalized leads.
- Electrode leads connected to Evaluation Kit.
- Check: Does your clinical hypothesis work in sub-chronic settings?
- Is your application software usable by patients?

Brain Interchange is fully implanted

- Brain Interchange is implanted with electrodes
- Fine-tuning of operation easily possible (algorithms run outside the implant)



Request your Evaluation Kit today! sales@cortec-neuro.com

BRAIN INTERCHANGE ONE

Brain Interchange ONE is the first implantable version of our Brain Interchange Technology that is available for pre-clinical and clinical research. This first version can be used to develop novel therapies for neurological diseases.

The system description is found on the following pages. If you would like to learn more about the system for your specific application please reach out to us.

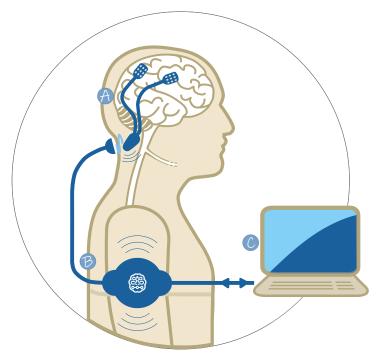
Brain Interchange ONE features fully wireless functionality for chronic open– and closed–loop interaction with the nervous system.

It consists of:

Implantable Unit

External Unit

Computing Unit

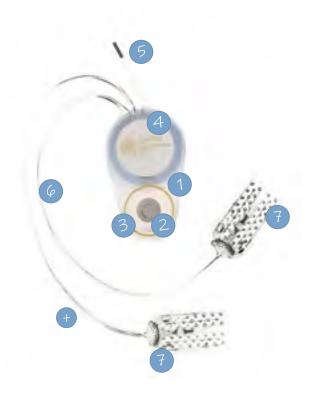


IMPLANTABLE UNIT

The Implant is comprised of the Implanted Electronics Unit and one or two ECoG electrodes plus one optional ground (GND) electrode contact.

- Implanted Electronics Unit
- Magnet for suspension of External Unit (location and number of magnets can vary)
- Coil for electromagnetic power reception
- Hermetic encapsulation of implant electronics

- Ground lead (GND) Contact
- Electrode cables
- *AirRay ECoG electrodes (customizable)
- Upcoming: Adapter for commercial DBS Electrodes



SPECIFICATIONS

FEATURE

Recording channels Sampling rate

Sampling dynamic range High pass filter cut-off

Low pass filter cut-off Amplifier band pass gain

Band pass roll-off

Reference

Stimulation

Stimulation channels

Current

Current source Pulse width

Power supply Wireless data transmission Closed Loop latency

VALUE

32 1 kHz

16 bit (74 nV smallest increment)

ca. 2 Hz 325 Hz

Adjustable: 100-750

20 dB/dec

Any (subset) of the recording channels selectable by software or

one dedicated hard-wired additional contact

Current-controlled, biphasic, rectangular, asymmetric stimulus pulses (cathodic

amplitude with pulse width followed by an anodic counter pulse of 1/4x amplitude

and 4x pulse width)

Max. -6 mA / +1.5 mA (24 μ A increments) within compliance voltage range of -11 V to +5 V

Can be directed to any of the 32 electrode contacts

Negative phase: 10 µs - 2,500 µs

Wireless inductive, 120-140 kHz

Bi-directional, radio frequency in 2400-2483.5 MHz band

≤ 40 ms

EXTERNAL UNIT

The External Unit consists of the Head Piece which supplies power inductively to the Implantable Unit and the Communication Unit. Magnets ensure proper alignment of Implantable and Head Piece. The Implantable Unit communicates with the External Unit wirelessly through the skin via radio frequency transmission.

It ensures safe communication by state of the art encryption between the External Unit and Implantable Unit via RF link.

As part of Brain Interchange ONE, the Communication Unit is typically worn on the upper arm. Apart from exchanging data with the Implanted Electronics Unit it controls the power supplied to the Head Piece. It is cable-connected to the Computer on which the Application Software is running.





- A CABLES
 - USB connection to computer or tablet
 - Optional: trigger cable
 - Head Piece cable
- STATUS LEDS

SPECIFICATIONS

FEATURE

Connection of Communication Unit to computer or tablet with software interface Size of Head Piece Weight of Head Piece Size of Communication Unit Weight of Communication Unit

VALUE

USB 2.0 or 3.0 data transmission and power supply

55 x 40 x 15 mm3 35 g (incl. 750 mm cable) ca. 90 x 98 x 48 mm3 150 g (without cable)



COMPUTING UNIT

PERSONAL LAPTOP OR TABLET WITH APPLICATION SOFTWARE OR PROGRAMMING INTERFACE

The Application Software runs on a Microsoft Windows-based laptop or tablet and represents the interface between the user and the system. The Application Software provides users with a graphical user interface.

The computer manages the telemetry (programming of stimulation parameters, accessing the system information, and data transmission) and analyses the data.

When requested, the software creates commands, which are sent to the implanted electronics. They translate into stimulation patterns that can modulate the nervous system.

SPECIFICATIONS

1. CorTec Medtech Application Software

Function: Assist the surgeon during the implantation.

Designed for intraoperative tests with the following main features:

- Live measurement data visualization
- Establish connection to implants after implantation
- Error display of implants
- Stimulation function editor (graphical editor for complex stimulation patterns)
- Definition of reference electrodes for recording + counter electrode for stimulation

2. CorTec Medtech Application Programming Interface API

Function: Permits researchers to investigate novel therapies by writing own software applications Interfaces for implant control on Windows 10 systems:

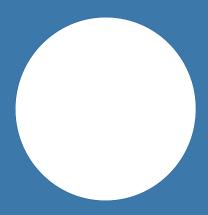
C and Python, developed according to IEC 62304 (medical device)

Together we will make new therapies reality – all the way from pre-clinical research to human application!

We are happy to hear about your next project in Medical Device development, therapy development or research.

Visit our website and join our LinkedIn community for additional information about CorTec.

Reach out to our sales and development team to request your individual quotation for active implantable solutions and components.



Neuer Messplatz 3 79108 Freiburg | Germany Fon: +49 761 70 888 222 Fax: +49 761 70 888 399 sales@cortec-neuro.com

ENABLING THE COMMUNICATION WITH THE BRAIN – FOR THE CURE OF DISEASE.



