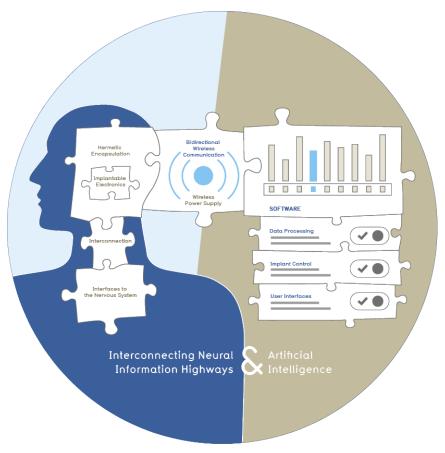


Product Information Brain Interchange System

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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:



- 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 InterfacePowers 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.



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TECHNICAL SPECIFICATIONS

Recording Channels 32 channels + 1 reference + 1 ground	
(ground switchable between dedicate electrode and any other electrode consampling 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 0.1-400 Hz: ≤ 2.7 μVrms voltage noise Amplifier input impedance AC Impedance: 15pF capacitance 0.1 Hz: 10 GOhm 1 Hz: 10 GOhm 10 Hz: 1 GOhm 10 Hz: 100 MOhm 450 Hz: 24 MOhm	J
Stimulation Stimulation Controlled, biphasic, rectangular, asy	metric stimulus
pulses (cathodic amplitude with pulse by an anodic counter pulse of 1/4x and pulsewidth) Current Max6 mA / +1.5 mA within compliance range of Pulse Width -11 V to +5 V Can be directed to any of the 32 elect Negative phase: 10-2,500 µs	mplitude and 4x ce voltage
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 use	ers with a
Functionality Graphical user interface. Visualizing the measured data directly application of a frequency filter (e.g. the data onto a local hard disk.	
APL Windows-based application software	(C++, Python)



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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