



CorTec business
Products & Services

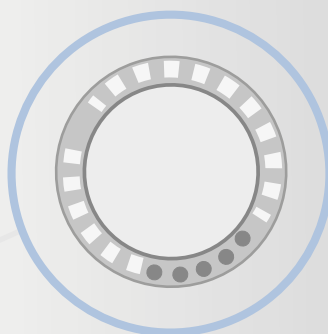
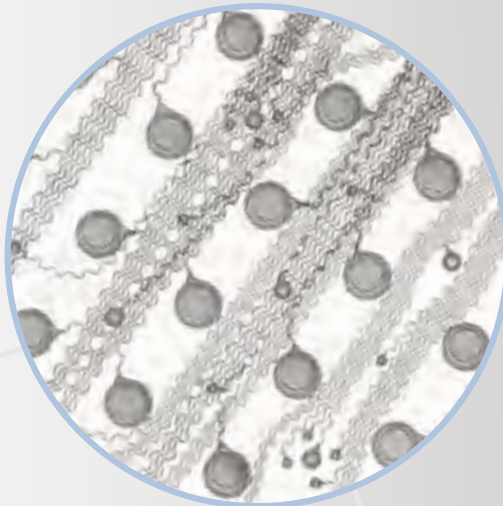


TABLE OF CONTENT

WELCOME	4
> Cleanroom	5
> Quality	5
 COMPETENCES	 6
> Electrodes	8
> Active Implant Technology	10
> Testing & Characterization	16
 OUR SERVICE	 18



EXPERIENCE THE FUTURE OF IMPLANTABLE TECHNOLOGY

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

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 and personalized new therapies.

Based on our flexible technologies we have overcome current limitations. We are, therefore able to offer the full range of implantable technology starting with single components up to complete system design. All our products combine innovation, precision, and quality.

In medical engineering we have to meet the highest standards in every aspect of our work. All areas of work strictly comply with our certified quality management system. To enlarge our manufacturing capacities we are currently setting up a new facility where we commence operation in the course of 2018.

Contact us to learn more!

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



WELCOME



> CLEANROOM

In line with our strategy we have established all core manufacturing steps in our cleanrooms in-house.

Beginning with the manufacturing of electrode arrays from raw materials using cutting-edge laser micromachining to the production of implantable cables from medical grade wires and silicone tubing up to the interconnection of electrodes and cables we are performing manufacturing steps in qualified and constantly controlled environments.

The final assembly steps of our hermetic ceramic encapsulations are also carried out in the cleanroom: Once the electronics are sealed in and the electrode cables are joined, the ceramic encapsulation is carefully cleaned, dried and overmolded with medical grade silicone rubber, cleaned again, and eventually packaged for sterilisation.

Manufacturing steps are carried out in ISO 14644-1 class 6 – 9 cleanrooms.

> QUALITY

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

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

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



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.

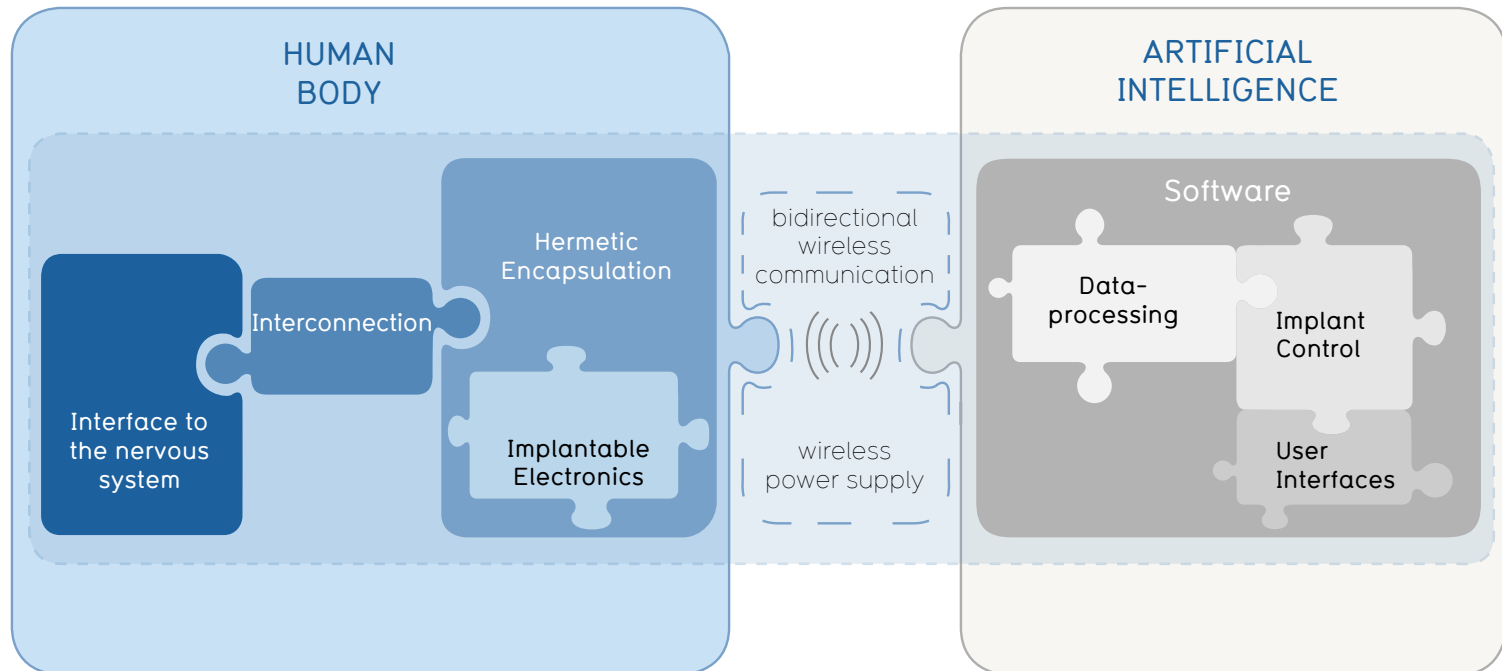
CorTec serves all levels of interconnecting the human body to artificial intelligence.

As innovation leaders in neurotechnology we endorse the development of new therapies: Either we develop and manufacture single individual components like electrodes and encapsulations or we set up active implantable systems which can process neural information from the human body to control therapeutical applications.

COMPETENCES



INTERCONNECTING THE HUMAN NEURAL SYSTEM AND ARTIFICIAL INTELLIGENCE



ELECTRODES

> KEY WINNING FEATURES

High Precision

Ultra-short pulse laser micromachining allows for very small feature sizes of down to 25 µm 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.

> 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

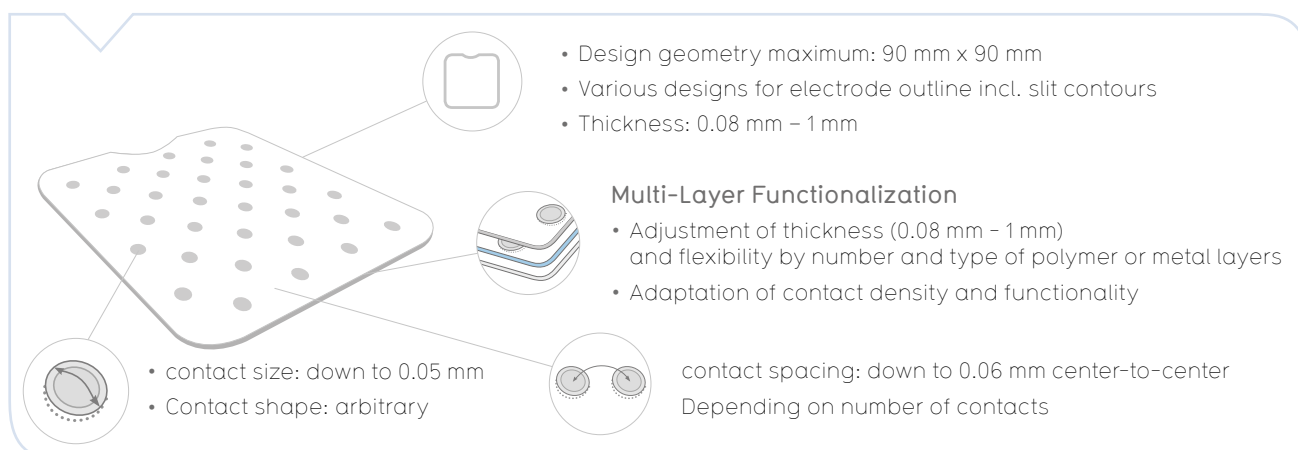
Physical surface modification permits additional adaptations to the individual application.

DESIGN OPTIONS

General Dimensions

CorTec adapts 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.



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

PERFORMANCE

	Charge Injection Capacity	Typical Impedance ¹ (Diameter 1 mm)		Typical Impedance ¹ (Diameter 2.7 mm)	
		10 Hz	1 KHz	10 Hz	1 KHz
MP35N	max. 0.03 mC/cm ² ⁴	260 kΩ	5 kΩ	32 kΩ	0.6 kΩ
Platinum-Iridium (90/10)	0.09 mC/cm ² ²	47 kΩ	1 kΩ	8 kΩ	0.2 kΩ
Platinum	0.05 mC/cm ² ³				
Platinum Black	0.25 mC/cm ² ⁵				
Sputtered Iridium Oxide Film (SIROF)	≥ 1 mC/cm ² ⁶				

.....

1 Setup: three electrode configurations in 0.9% saline. Typical impedance readings.

2 Cogan et al.: In Vitro Comparison of the Charge-Injection Limits of Activated Iridium Oxide (AIROF) and Platinum-Iridium Microelectrodes, 2005.

3 Rose et al.: Electrical stimulation with Pt electrodes, 1990.

4 Ning et al.: Pitting Corrosion of High Strength Alloy Stimulation Electrodes under Dynamic Conditions, 1989.

5 Own investigations.

6 Own investigations, matching Cogan et al.: Sputtered iridium oxide films (SIROFs) for low-impedance neural stimulation and recording electrodes, 2004.

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 right up to full active systems.

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

HERMETIC ENCAPSULATION

➤ KEY WINNING FEATURES

High Channel Count

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

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 cm³.

Freedom of Design

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

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.



> 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.

> 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)

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⁻¹.

Connects to Other Products

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



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

> MATERIALS

WIRES

- Platinum-Iridium (90/10)
- MP35N
- MP-DFT Ag (silver core)
- Gold

INSULATION

- Polyesterimide
- Fluoropolymer
- Silicone

SUBSTRATES

- Printed Circuit Board, e.g. FR4
- Screen printed ceramics
- Other materials upon request



➤ DESIGN OPTIONS

Cable Manufacturing

- Bundled straight wires
- Coil winding cables
- Ribbon cables

Research Standard Connectivity

- 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

Medical Standard Connectivity

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

➤ PERFORMANCE

To guarantee highest reliability our interconnections 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 interconnection solution.



SOFTWARE & ELECTRONICS

➤ 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 a strong 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-based application software (C++, Python, Java) to embedded systems programming (C) for processors used in CorTec's implants and body-external transmitters.





CORTEC BRAIN INTERCHANGE ONE

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

The implantable platform with full wireless functionality for chronic open and closed loop interaction with the nervous system consists of:

> An implanted device comprising

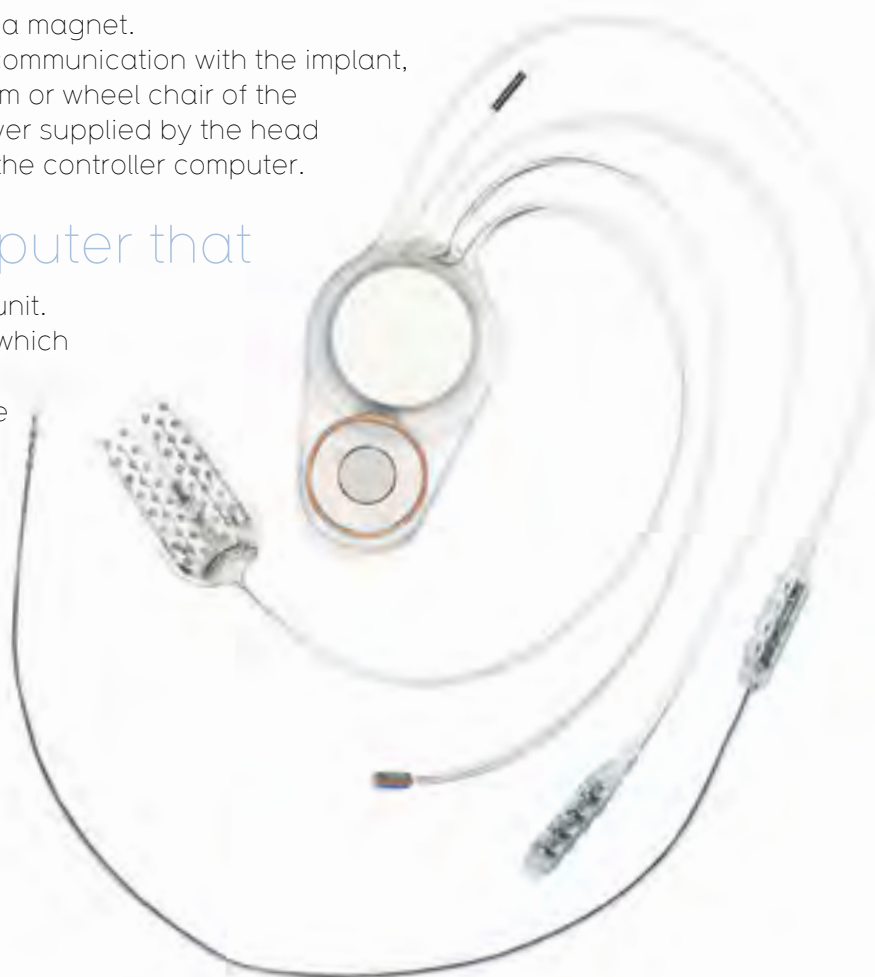
- Neural electrode arrays for bi-directional interfacing with the neural system.
- Electronic circuit inside a proprietary hermetic ceramic package that amplifies, filters and digitizes neural signals and electrically stimulate neural tissue via the electrodes. It is inductively powered by the external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

> An 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.



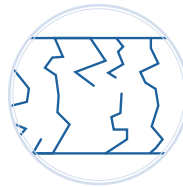
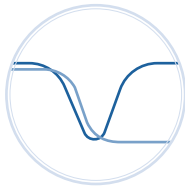
TESTING & CHARACTERIZATION

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 for the tests if desired and deliver all raw data to our customers.

➤ Electrical and Electrochemical Tests

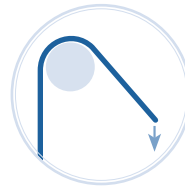
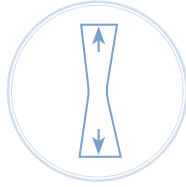
- Impedance spectroscopy
Characterization of the recording performance of the electrode.
- Pulse testing
Characterization of the stimulation performance of the electrode.
- Corrosion testing inclusive SEM inspection
Evaluating the corrosion resistance of a particular electrode design for a given stimulation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





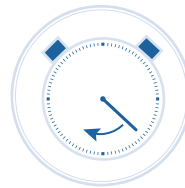
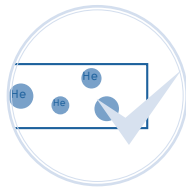
> Mechanical Tests

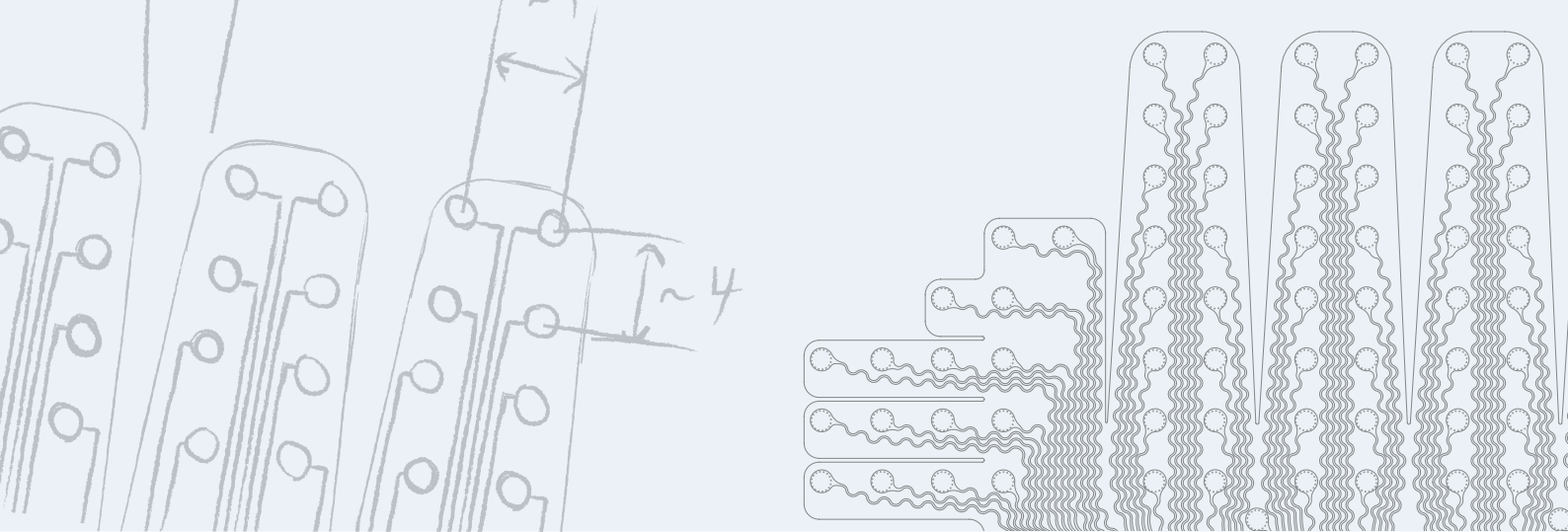
- Reliability testing
Cyclic bending and pull tests to obtain typical lifetime characteristics of electrodes or interconnections – if desired under particular environmental conditions, such as HALT (highly accelerated lifetime tests).
- Tensile or shear tests
- Bending and flexing tests (cyclic or ultimate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



> System Integration Tests

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





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.

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.

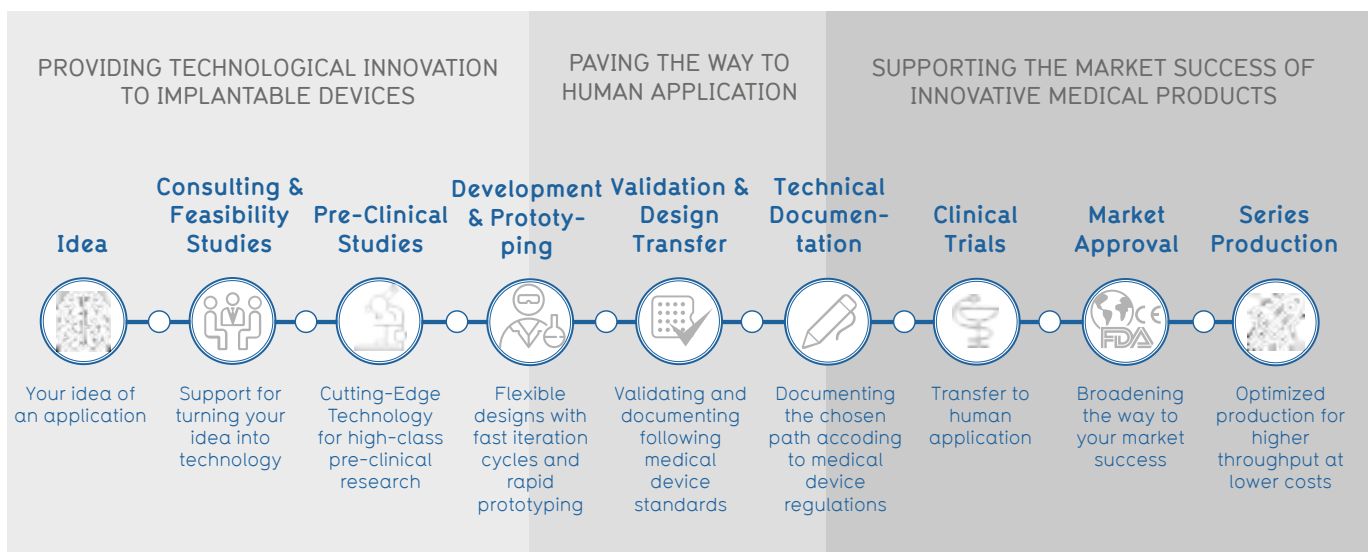
Based on your idea we support you in the process of designing your device. We provide you with cutting-edge technology for your trials.

Once you have 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 SERVICE



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



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.

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

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.



CONSULTING & FEASIBILITY STUDIES



- Design and application related consulting
- Investigation of feasibilities



DEVELOPMENT & PROTOTYPING



- Device design
- Preliminary studies
- Design studies
- Process development



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



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

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



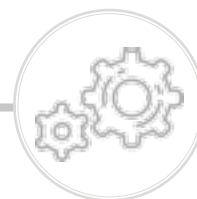
TECHNICAL DOCUMENTATION



- 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



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



Please contact us with your specific 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.



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Thinking ahead

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