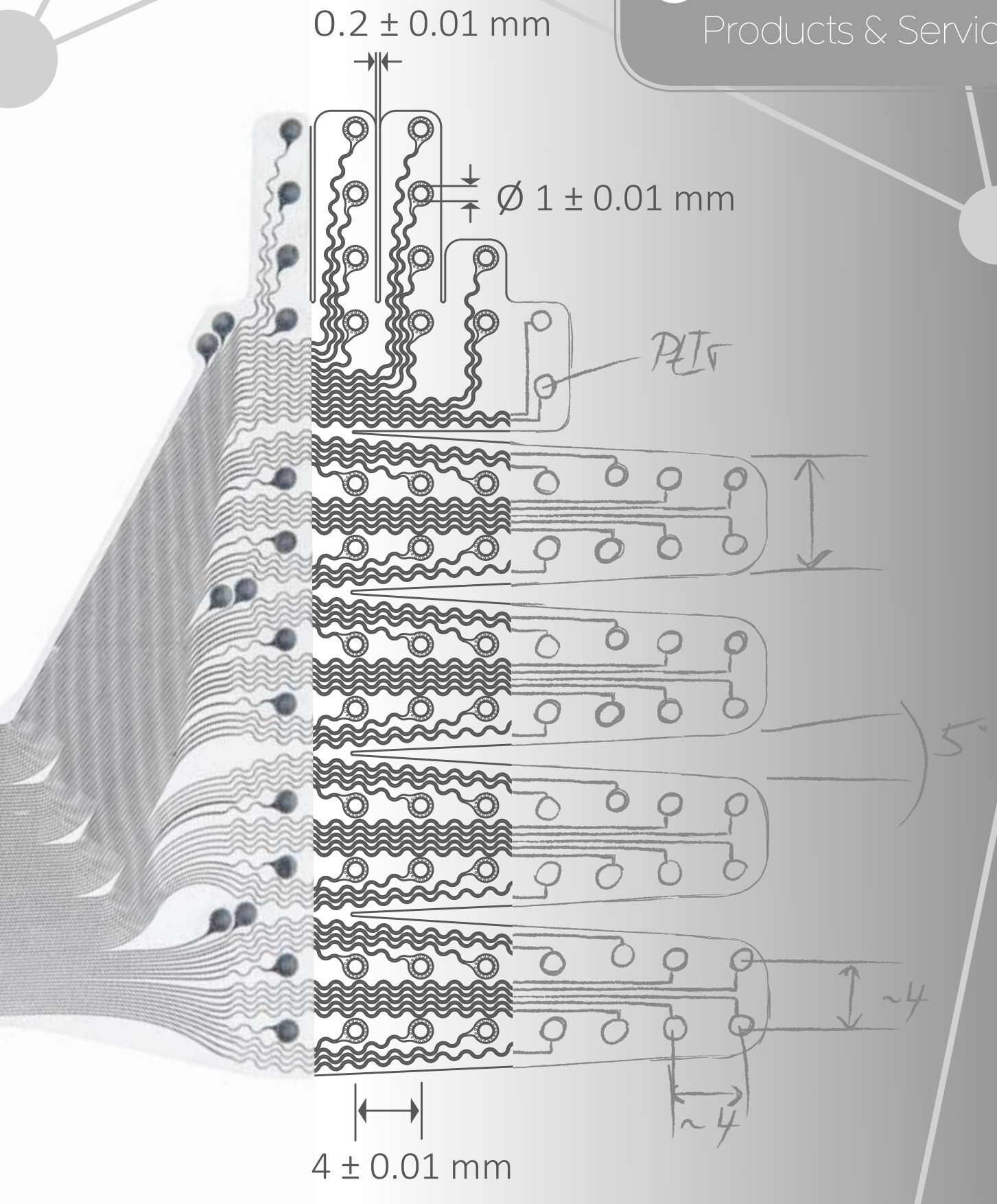
CorTec business

Products & Services



CorTec

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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 products and services.

We are following the vision to take implantable technologies to the next level by providing innovative solutions that enable you to develop highly efficient and personalized therapies.

Based on our flexible technologies we have overcome current limitations. We are therefore able to offer individualized solutions for components of active implants such as electrodes or hermetic encapsulation that combine innovation, precision, and quality.

In medical engineering we have to meet the highest standards in every aspect of our work. From development to individual manufacturing processes up to the further handling of our products – all areas of work strictly comply with our certified quality management system.

Contact us to learn more!

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

TABLE OF CONTENT

ELECTRODES

- CAD-based manufacturing by laser micromachining
- Silicone rubber processing
- Plasma bonding
- Surface functionalization

INTERCONNECTION

- Ball-stud bonding
- Laser welding
- Spot welding
- Parallel gap welding
- Micro soldering
- Coil winding cables

HERMETIC ENCAPSULATION

- Custom designed ceramic implant package
- High number of electrical feedthroughs
- Mechanical robustness proven by hammer impact test
- Hermetic sealing validated by helium leakage test
- Void-free silicone rubber molding

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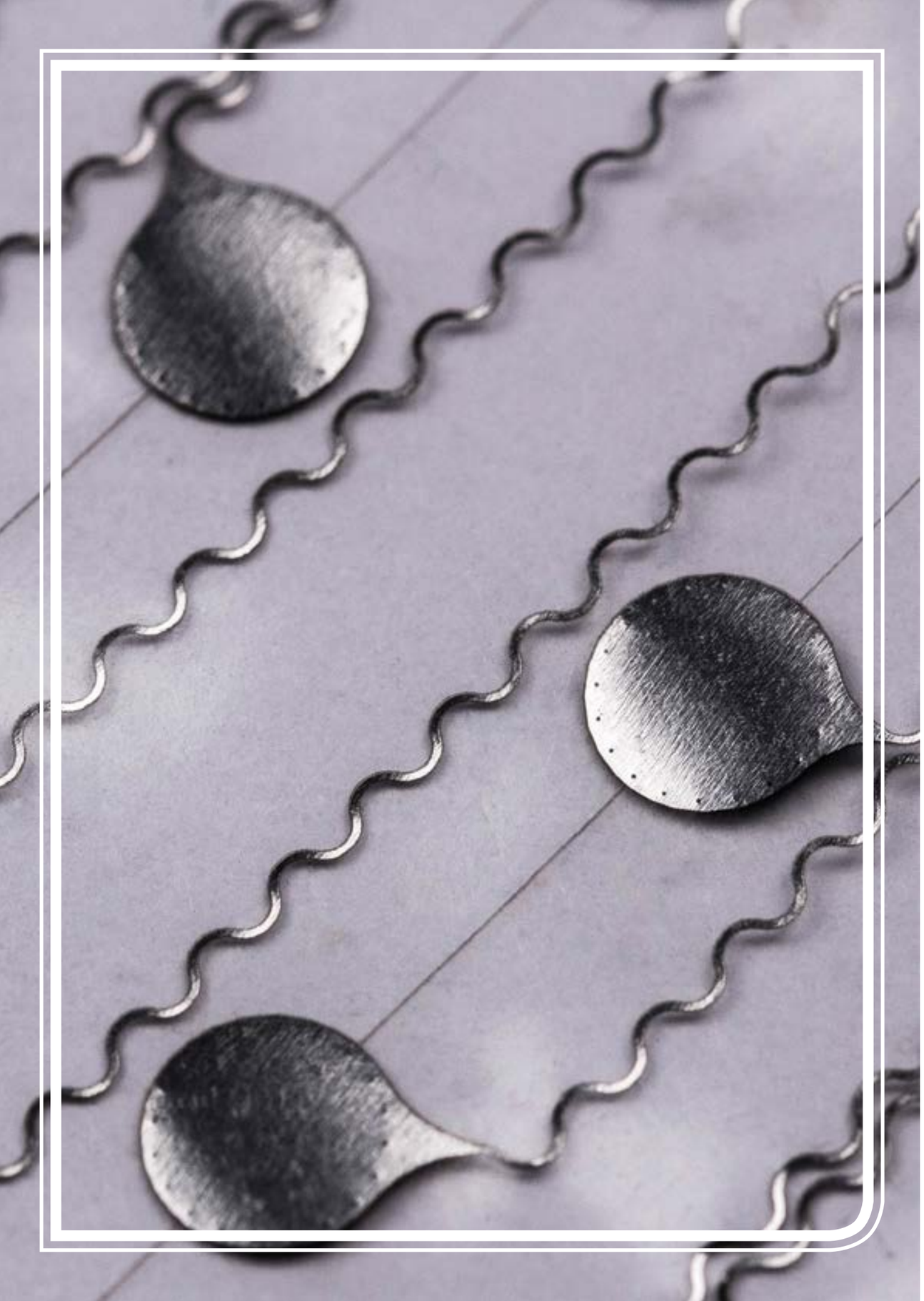


KEY WINNING FEATURES

AirRay™ Electrode Technology
Overcoming current limitations of electrodes with unique product 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.

Fast Prototyping
First prototypes can be produced within a day. Functional electrode samples require only one week to be manufactured.

Easy Adaptation of Shape and Functionality
Electrodes can be modified to build 3-dimensional assemblies as well as nerve cuff electrodes to be wrapped around peripheral nerves.
Further adaptions include the integration of microfluidic channels for drug delivery into electrode arrays.

Excellent Electrochemical Properties
Platinum-Iridium or MP35N are used as electrode materials, optionally with high performance coatings for enhanced charge transfer.

High Level of Patient Safety
Mechanical interlocking mechanisms prevent electrode contacts from dislocations and ensure safe contact to neural tissue.

Improved Usability and Reliability
High flexibility in design and great mechanical adaptability make surgical handling significantly easier. Superior reliability maintains full electrode functionality even under recurring loads.

Customized to Your Needs
With our patented AirRay™ electrode technology we can design and manufacture electrodes according to your actual requirements – in any geometrical shape, with hundreds of contacts, and for numerous applications.

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

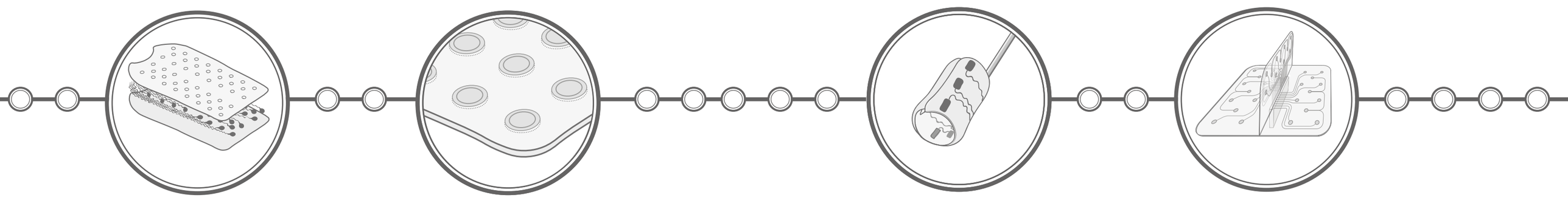
  Depending on number of contacts
- Contact shape:
  round, rectangular or arbitrary
- Design geometry maximum: 90 mm x 90 mm
- Various designs for electrode outline incl. slit contours

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	Impedance[1] (Diameter 1 mm) 10 Hz	Impedance[1] (Diameter 1 mm) 1 KHz	Impedance[1] (Diameter 2.7 mm) 10 Hz	Impedance[1] (Diameter 2.7 mm) 1 KHz
MP35N	max. 0.03 [4]	260 kΩ	5 kΩ	32 kΩ	0.6 kΩ
Platinum-Iridium (90/10)	0.09 mC/cm² [2]	47 kΩ	1 kΩ	8 kΩ	0.2 kΩ
Platinum	0.05 mC/cm² [3]				
Sputtered Iridium Oxide (SIROF)	≥ 1 mC/cm² [5]				
Platinum Black	0.25 mC/cm² [6]				

1 Setup: three electrode configurations in 0.9% saline.
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, matching Cogan et al.: Sputtered iridium oxide films (SIROFs) for low-impedance neural stimulation and recording electrodes, 2004.
6 Own investigations.

RELATED SERVICES

- Device design
- Tests/validations of new designs incl. technical documentation (please see page 28ff.)
- Impedance spectroscopy
  Characterization of the electrode's recording performance.
- Pulse testing
  Characterization of the electrode's stimulation performance.
- Sterilization
  We offer ethylene oxide sterilization including peel-pouch or blister packaging in collaboration with external partners. Upon request steam sterilization using sterile pouches is offered as in-house service.
- Corrosion testing
  Evaluating the corrosion resistance of a particular electrode design for a given stimulation paradigm.
- Reliability testing
  Common cyclic bending and pull tests under different environmental conditions but also setups tailored to the customer's needs.

KEY WINNING FEATURES

Ceramic Encapsulation Technology
Taking hermetic packaging to the next level with unique product 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 are 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 works 10 times longer compared to standard titanium packages – even for small implant volumes below 1 cm^3. Lifetime is extendable by additional application of desiccants.[1]

Freedom of Design
CorTec´s ceramic encapsulations allow application-specific shapes and designs.

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

1 Calculations based on accelerated aging scenario.

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 [1]

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

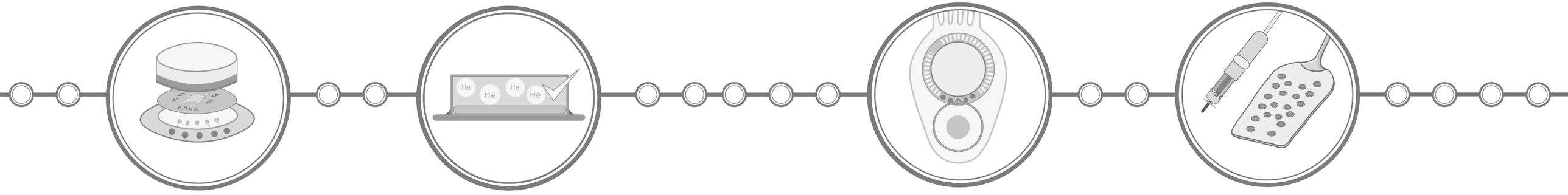
- Hand-crafted high precision coils
- Materials: Gold or copper
- Up to 50 windings
- Adaptation to the needs of customer-specific inductive power and data interfaces

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



1 Depending on the interconnection interface.

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MATERIALS

IN CONTACT WITH THE BODY

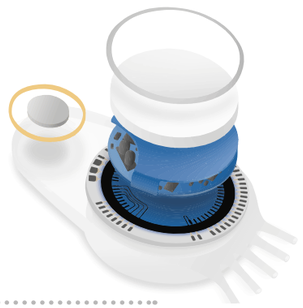
Smooth implant shell and cables made of medical grade silicone rubber.

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

PERFORMANCE

- Selected designs pass the pendulum hammer test method Eha according to IEC 60068-2-75:1998 – 2.5 J impact.[1]

- Helium fine leak testing for hermeticity:
  Extremely low leak rates qualify our packages for rejection thresholds below 10^{-10} mbar l s^{-1}.



1 As demanded by the international cochlear standard ISO 14708-7:2013 and the harmonized European equivalent EN 45502-2-3:2010.

RELATED SERVICES

- Device design and preliminary studies
- Tests and validations incl. technical documentation (please see page 28ff.)
- Assembly and packaging of customer electronics
- Interconnection technologies
- Functionality testing
- Hermeticity qualification (He-leak testing)
- Customized silicone rubber mold design and processing
- Validated cleaning procedures

KEY WINNING FEATURES

Interconnection Performed by CorTec
Building upon industry standards to create innovation in technology

High Integration Density
Interconnection technologies such as resistance and laser welding as well as micro soldering or ball-stud bonding (microflex interconnection) allow high integration densities.
Together with highly skilled manual cable manufacturing we can provide increased channel counts per cable compared to other manufacturers.

High Variability
CorTec's interconnection technologies permit a combination of versatile electrode and substrate materials. Almost any electrode material can be interconnected – 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.

Reliability Testing
Continuous monitoring of processes and repeated testing allow the creation of cutting-edge interconnection solutions of highest reliability and stability in their biological environment.

Functionality Enhancement of Commercially Available Solutions
Commercially available connectors can be customized with interconnections such as our flat ribbon cables 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. Apart from the technologies we can realize in-house, we have a large network of partners available to offer the full range of solutions according to your requirements.

DESIGN OPTIONS

Cable Manufacturing

- Bundled straight wires
- Coil winding cables
- Ribbon cables

Dimensions

- Minimum cable diameter: 0.65 mm (outer diameter)
- Maximum wire counts:
  - Bundled straight wires: varies with configuration
  - Coil winding cables: 18 wires
- Maximum lengths:
  - Bundled straight wires: 1.5 m
  - Coil winding cables: 1 m
- Other dimensions available in cooperation with external partners

Research Standard Connectivity

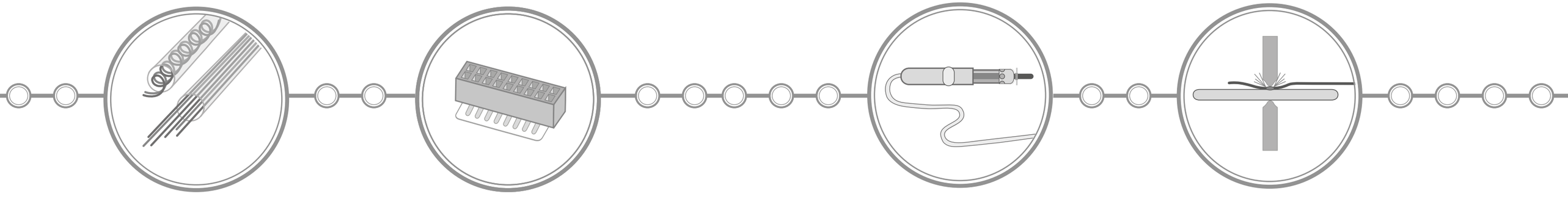
- ZIF connectors
- Omnetics connectors
- Harwin connectors
- Molex connectors
- Other connector types can be attached upon request
- Open cable ends – for highest flexibility in individual interconnection applications

Medical Standard Connectivity

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

Interconnection Technologies

- Ball-stud bonding
  Interconnection option for connecting electrode arrays to printed circuit boards (PCB)
- Laser welding
  Common method for connecting wires to metal parts such as sleeves or platelets
- Spot welding
  Common method for connecting wires to laser-patterned metal foil (e.g., contact area of AirRay™ electrodes)
- Parallel gap welding
  Standard interconnection for connecting wires to PCBs
- Micro soldering
  Standard procedure for connecting wires to connectors or PCBs



MATERIALS

WIRES	INSULATION	SUBSTRATES
• Platinum–Iridium (90/10) • MP35N • MP–DFT Ag (silver core) • Gold	• Polyesterimide • Fluoropolymer • Silicone	• Printed Circuit Board, e.g. FR4 • Screen printed ceramics • Other materials upon request

PERFORMANCE

Our interconnections are tested to fulfill different standards in the medical device industry (e.g. EN 45502-2-3 or ISO 14708-1) to guarantee highest reliability.

Mechanical Characterization:
• Bending tests (cyclic loads)
• Tensile or shear tests

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

Electrochemical Characterization:
• Impedance analysis (usually together with electrodes)
• Corrosion tests

RELATED SERVICES

• Functionality testing
• Electrochemical testing
• Mechanical testing
• Aging and accelerated aging tests
• Reliability testing
• Tests and validations incl. technical documentation (please see page 28ff.)
• Customized interconnections
• Design studies
• Process validation
• More connectivity options in cooperation with external partners

COMPETENCES & SERVICES

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.

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[1]
- Tensile testing[1]
- Micro IRHD testing (together with external partners[1])
- Impedance[1]
- Dielectric strength[1]
- Corrosion[1]
- Layer pull strength
- Hermeticity
- Shear strength

1 Also in combination with real or accelerated aging scenarios

TECHNICAL DOCUMENTATION

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

Documentation Standards:
- Development under design control
- All documents related to the product are archived
- Highly efficient document management system for fast review cycles
- Detailed manufacturing documentation

Competences in Neurotechnological Applications:
- International network of researchers and clinicians
- High wealth of experience
- Interdisciplinary team with expertise from neurophysiology to engineering

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INFRASTRUCTURE & QUALITY

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 all 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.

All manufacturing steps are carried out in ISO 14644-1 class 6 - 9 cleanrooms.

STANDARDS AND PROCESSES

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).

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 the latest regulations, as well as continuous improvement of our processes. Therefore, all of our products are developed under design control. Our processes undergo detailed analyses of failures, modes, and effects (PFMEA).

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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