Product Information Hermetic Encapsulation

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CorTec´s hermetic encapsulation technology protects what is valuable for an active implant: sensitive electronics even with a uniquely-high amount of electrical feedthroughs. Thick film technology enables hundreds of these electrical channels. Unlike conventional packages with glass-to-metal or ceramic-to-metal feedthroughs which are usually brazed in titanium housings CorTec´s ceramic encapsulation is, furthermore, transparent to electromagnetic waves. This facilitates communication via radio frequency or infrared as well as wireless powering.

Aware the fact, that ceramics are inherently brittle, CorTec has insured a high mechanical robustness by implementing specific design measures. Lifetime calculations based on the hermeticity of the encapsulation attest excellent protection of electronics against moisture – more than 10 times longer than common titanium cases. The application of desiccants extends the lifetime even further. Even small implant volumes below 1 cm^3 sustain a moist environment for decades

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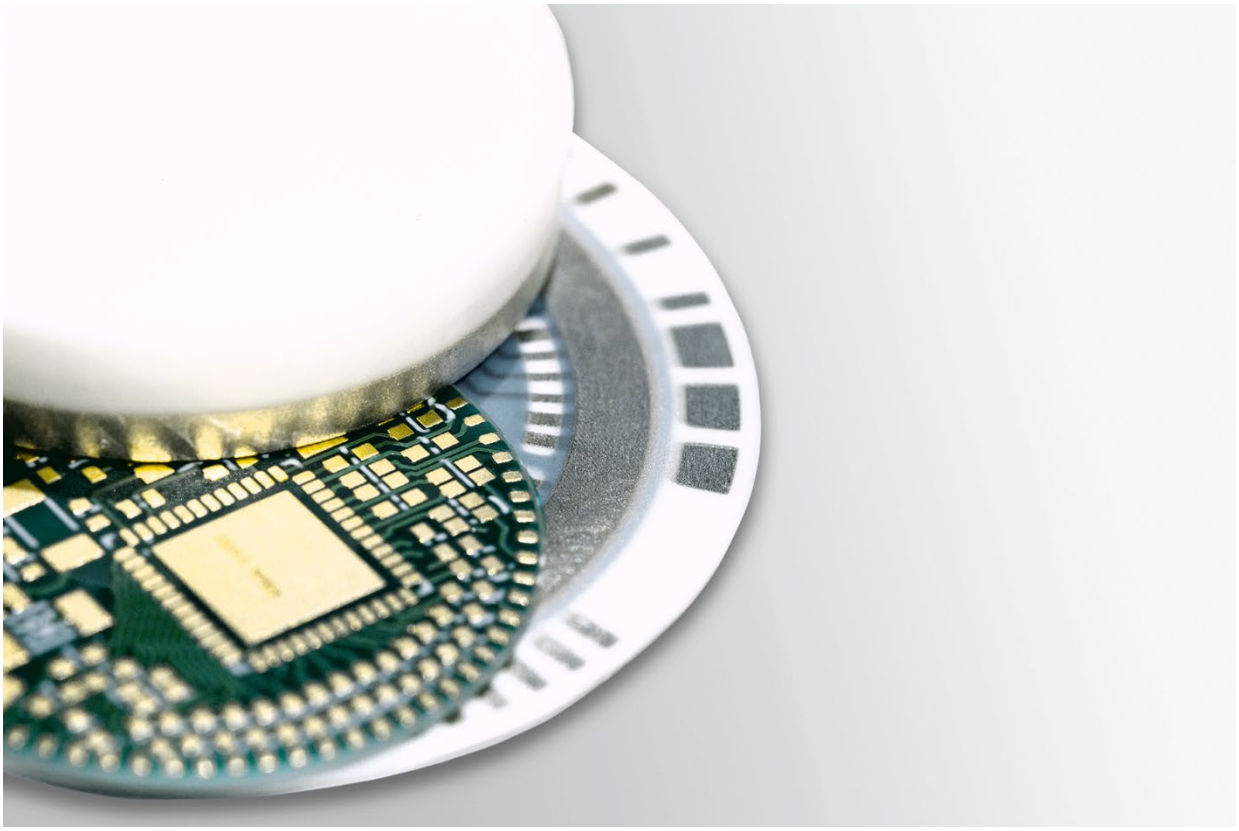
Not cleared for clinical use by FDA, but can be used under IRB and / or IDE guidance for research studies. Technical documentation for IDE Clearance is readily supported.

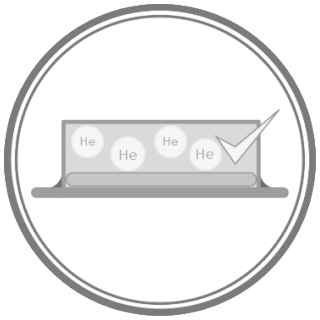


DESIGN OPTIONS

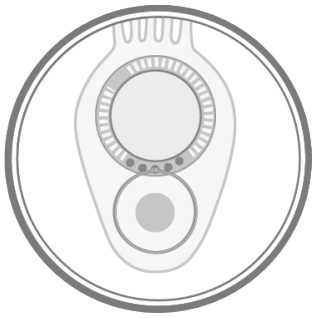
Geometry
- Circular, oval, or rounded-edge rectangular designs.
- Ceramic packages are molded in silicone rubber in application-specific shapes

Dimensions
- Minimum height: 2 mm
- Variable lateral dimensions: maximum footprint of 80 mm x 80 mm

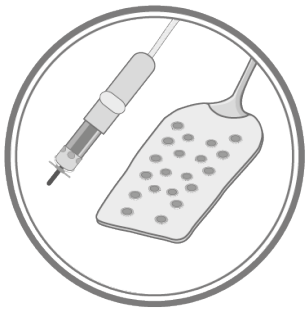
Feedthrough Dimensions and Spacing
- Feedthroughs come as metal tracks on ceramic base substrate
- Minimum track width: 0.08 mm
- Minimum pitch: 0.2 mm
- Minimum pad area: 0.1 mm x 0.5 mm



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

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.

PERFORMANCE/TESTING

- Selected designs pass the pendulum hammer test method Eha according to IEC 60068-2-75:1998 – 2.5 J impact.
- Helium fine leak testing for hermeticity:
  Extremely low leak rates qualify our packages for rejection thresholds below 10-10 mbar l s-1.
- Functionality Testing

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
- Assembly and packaging of customer electronics
- Interconnection technologies
- Customized silicone rubber mold design and processing