When Failure is not an Option – Packaging Materials and Technologies for the Reliable Protection of Medical Electronics

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Abstract

Enabling high-level electrical performance and smooth optical signal transmission is a key requirement for microelectronics packaging materials. This becomes even more relevant for biomedical applications, in which protection requirements must be met alongside standard performance and signal transmission benchmarks. The major challenge: medical packaging must to provide absolute reliability. Microelectronic components face potentially damaging working environment hazards such as high humidity, extreme temperatures, corrosive chemicals, and bodily fluid – especially in the application cases of implantable, ingestible, and wearable devices.

Hermeticity is an important factor in the performance of medical packaging. Non-hermetic packaging, sometimes known as "quasi-hermetic" uses organic materials, such as silicone or plastic over-moldings, that are not designed to withstand extreme conditions and break down over time. Material break down in these types of packages can lead to limited protection by allowing permeation of water and other gases through the polymer structure. Non-hermetic packages typically reach critical permeation levels after a very short period of time. For microelectronic components, even the smallest, hardly detectable traces of hydrogen and water vapor inside a package can compromise the performance and reliability of the encapsulated chips and circuits and potentially lead to interconnect failure, one of the most common reliability failure modes in microelectronic applications.

The only way to overcome the challenge of achieving absolute reliability is by using hermetic packaging technologies with inorganic materials, such as glass, ceramics and metal. Unique manufacturing processes of these hermetic components create vacuum-tight seals that prevent moisture and harmful gases from penetrating into the package. Hermetically sealed packages deliver uncompromised reliability, offering long-term protection of sensitive electronics in medical devices – even after thousands of surgical procedures and steam sterilization cycles.

This technical presentation will introduce the different reliability levels of packaging materials and provide an in-depth comparison of the respective advantages, disadvantages, and typical application areas of various hermetic packaging technologies. The latest insights into materials and technologies available for high-reliability packaging of medical electronics will be presented.

Key words

gas-tight, hermetic packaging, inorganic material, medical electronics packaging, vacuum seal

I. Introduction

Glass-to-Metal seals (GTMS) and Ceramic-to-Metal seals (CerTMS®) are commonly used for electronic packaging applications in industrial fields where a high reliability level is required to protect packaged electronic devices. The main reasons for using these types of packages are safety, cost considerations, or even enhanced protection as a preventative measure for internal electronic components that are difficult to access in cases of defects or necessary repairs. Examples of such applications include automotive electronics (e.g. airbag ignition), aerospace systems (e.g. communication satellites), and oil & gas exploration and drilling (e.g. MWD – measure while drilling projects). In all of these applications, amongst others, electronic devices must exhibit proper long-term protection against harmful influences such as extreme temperatures, moisture, gases, and other environmental hazards. When the electronics packaging does not properly protect against these influences, they can cause detrimental effects such as corrosion, electrochemical damage, and electrical shorts that lead to degradation of performance and even complete failure of an electronic device. Similar challenges exist for electronic devices in medical applications, where extremely high reliability levels area critical. However, environmental hazards to electronic components are bountiful – especially when it comes to the steam sterilization process in the autoclave to prevent cross-contamination. These hazards include extreme temperatures, high humidity, and exposure to corrosive chemicals (e.g. bodily fluids). The challenges are heightened during the autoclaving process for surface areas and interfaces between different materials in device packaging, as these areas are acutely targeted in the effort to eliminate any harmful contaminants.

II. Hermetic Packaging

Based on decades of experience with the encapsulation of electronic and opto-electronic devices in the previously mentioned industrial fields, it is possible to examine a direct comparison between fully hermetic packaging solutions based on inorganic materials with extremely low permeability (e.g. glass, ceramics and metals) and quasi-hermetic or non-hermetic solutions based on polymeric encapsulation materials. Theoretical investigations, experimental data, and empirical studies can be found in numerous publications about vacuum-sealing technology. These underline the differences between inorganic packaging materials (including considerable differences between permeation properties for various gases e.g. H_2, He, H_2O, etc.) and organic packaging materials (including their tendency to allow permeability levels that are magnitudes higher for most critical gases, e.g. water vapor) [1]. Therefore, it is important to differentiate between hermetic packaging solutions, which provide leak rates well below 10^{-8} mbar·l/sec, and quasi or non-hermetic packaging solutions, which have higher leak rates and can cause unwanted risk of water penetration into a cavity containing an electronic device [2, 3].

Especially for the most critical water penetration through a package wall, materials can be characterized by material specific parameters *K* and *D* (Permeability(*K*)=Solubility(*S*) ·Diffusion coefficient(*D*)). From this, at given geometrical dimensions for a package and considering the fact that S is strongly temperature dependent, a pressure *Q* of the permeating gas (water) after a certain time *t* can be calculated by the formula

$$Q = \Delta p \cdot (1 - e^{-\frac{KA2D}{2DVd+KAd^2}t})$$

[3] where

Δp: partial pressure difference between inside and outside [atm]
A: surface area [cm²]
V: Volume of the cavity [cm³]
d: Wall thickness [cm]
t: time [sec]

At *t*=0 there is basically no water inside the cavity. Typical parameters used for this equation are shown in Table1.

Table I: *K and D for H_2O molecules and different materials at room temperature*

	Polymers	Glasses	Ceramics	Metals
Permeability *K* [cm^2/sec]	$10^{-5}…10^{-7}$	$10^{-10}…10^{-12}$	No consistent data available	$<10^{-15}$
Diffusion constant *D* [cm^2/sec]	$10^{-6}…10^{-9}$	$10^{-9}…10^{-11}$	No consistent data available	$<10^{-15}$

While metals demonstrate almost zero water permeability, glass and ceramics still show values of typ. $<10^{-9}$ cm^2/sec. Organic materials such as epoxy resins or silicones show considerably higher permeability – several orders of magnitude – due to the internal network structure of the polymer chains. This structure allows sufficient space for water molecule penetration and diffusion into the enclosed electronic cavity, leading to a higher risk for corrosion and fatal failure of electronic devices [3, 4]. Example calculations show typical time constants τ with

$$\tau = \frac{2DVd + KAd^2}{KA2D}$$

in the order of days for organic materials and years for typical glass sealed packaging designs.

Materials and technologies

In general, most fully hermetic packaging concepts are based on the platform of a larger housing forming a cavity for accommodation of electronics, small feedthroughs for electrical signals, and – if required – a dielectric window for transmission of optical signals or even RF signals for data or power transmission. Finally, a lid must be sealed hermetically onto the assembly at ambient conditions that do not harm the electronic devices and the joints between them, i.e. a N_2 gas filling at temperatures as close as possible to room temperature. In cases where metal housings are used, an electrical insulation material is required between the feedthrough pin(s) and the housing. The hermetic bonds between the metals and the insulator are created using either glass or a ceramic component. They are formed by using a high temperature sealing process near the softening point of the glass insulator for GTMS packages, or a braze or soldering material for CerTMS® packages. In both cases, a strong chemical or mechanical bond is required between the metal and the insulator material.

For GTMS, different sealing strategies are utilized to form either compression seals or matched seals [2]. In both cases, the physical properties (especially the temperature dependencies of the CTE – coefficient of thermal expansion), are crucial for the process. Other material properties, such as yield stress, are also of significant importance. Packaging concepts for medical applications, which mostly use Titanium Grade 2 material, must be especially cognizant of these properties in order to create a permanent hermetic seal and to provide a maximum level of reliability.

Additionally, these packaging concepts are based on insulation / dielectric materials and are dominated by special glass and ceramic materials like alumina. They make use of medical grade glass materials such as silicate glasses and high temperature fired alumina ceramics, which bear electrical feedthroughs in form of vias and/or screen printed metallizations (High Temperature Cofired Ceramics).

One particular and special design concept uses metal vias-penetrating glass substrates with high density and small pitch: These "through glass vias" (TGV) substrates [see also SCHOTT HermeS®] provide a wafer-scale production option for high pin count medical applications, such as cochlear or retinal implants. In this scenario, full glass packaging is possible if wafer scale production of cavities in glass substrates is combined with novel room temperature laser-bonding techniques [5].

Common types of materials used for hermetic packaging for medical electronics are shown in table II, including some notable advantages / disadvantages.

Table II

Material	**Advantages**	**Disadvantages**
	Housings	
Titanium	Weldability, Chemical resistance due to passivation layer	High CTE, Low yield stress
Borosilicate glasses	RF and optical transparency, Chemical resistance, Wafer scale production possible, CTE match to silicon	Require special bonding technologies
Inconel	High yield stress, Chemical resistance	Machinability
Stainless steel	Machinability, Chemical resistance, Weldability, High ductility	High CTE, Ni-content, Critical corrosion characteristics [6]
	Feedthroughs / Pins	
Tungsten	CTE matches to many glass types, High electrical conductivity	Must be coated with noble metals
Pt / Ir	Standard for implantables	High cost
Nb	Chemical resistance due to passivation layer	Soft material, Must be coated with noble metal for bonding
Pt	Standard for implantable pins	High cost
Mo	High electrical and thermal conductivity, High chemical resistance due to passivation layer	Risk for delamination
	Insulator	
Glass	Adaptable physical and chemical properties	Must avoid tensile stress
Alumina-ceramics	High temperature resistance, High mechanical strength	Additional metal layer required

Final sealing of the package after assembly of the electronics typically utilizes high-strength methodologies such as laser soldering, seam welding, and laser beam welding. The latter welding methods do not require additional materials for joining two interfaces, which help to prevent unwanted chemical or electrochemical effects in terms of corrosion or biocompatibility. In addition, the thermal impact of these sealing methods on the electronics is negligible. In the special case of implants, sealing methods that are performed at room temperature without any additional sealing material requirements are preferred.

Typical application areas

Electronic packaging based on GTMS and Ceramic-To-Metal Sealing is well suited for long-term implant applications such as pacemakers, cochlear implants, and other neuro stimulators. They enable integration of electrical interfaces and subsequent additional functionalities, such as power supply, communication ports, and possibilities for wireless adjustments. These applications are prime examples of the potential for high reliability packaging made with inorganic materials to be used for protection of sensitive electronics in challenging and complex environmental conditions. Fig. 1 and 2 show some simple examples for hermetic electrical feedthroughs, which demonstrate application potentials outside and inside of the medical field. These can be used as starting designs for new ideas for highly reliable electronic packaging solutions for e.g. implants.

Another notable application area is the integration of autoclavable medical connectors and LED modules into non-implant, reusable medical devices for procedural uses. Examples of such devices include endoscopes, surgical- and dental drills, cameras, and other surgical tools. Autoclavability is a key quality that makes these components suitable for such applications: they are required to be sterilized before each procedural use and would therefore benefit from the ability to withstand many thousands of steam sterilization cycles at typical conditions up to 140°C at 3 bar absolute pressure, with 100% relative humidity. The housing materials and sealing of the packaging are able to adequately protect enclosed electronic devices from the effects of exposure to harmful liquids and vapors. Additionally, the maintained integrity of the electrical insulation properties of the sealing material, either glass or ceramics, is of utmost importance for the lifespan of reusable medical devices with electronic functionalities. Special glasses with high SiO_2 content provide a long-term solution as an electrical insulation material. In cases when high complexity and miniaturization are necessary, (multilayer-) ceramics are also a strong candidate for application use.

III. Conclusion

Hermetic packaging solutions that are already well known in many industrial applications also provide an intriguing option for high reliability packaging of medical electronics. Inorganic materials such as glass, metal and ceramics serve as ideal selections in the design and manufacture of hermetic packages for long-term reliability. These materials, when designed properly and paired with specialized sealing technologies, can provide superior levels of hermetic protection for medical electronics packaging. This delivers numerous benefits, including reduced risk of water penetration and resulting malfunction of the packaged electronic devices. These packages can also be an integral part of creating proper electrical and optical interfaces, which are necessary for the optimal functionality of medical devices.

References

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Images

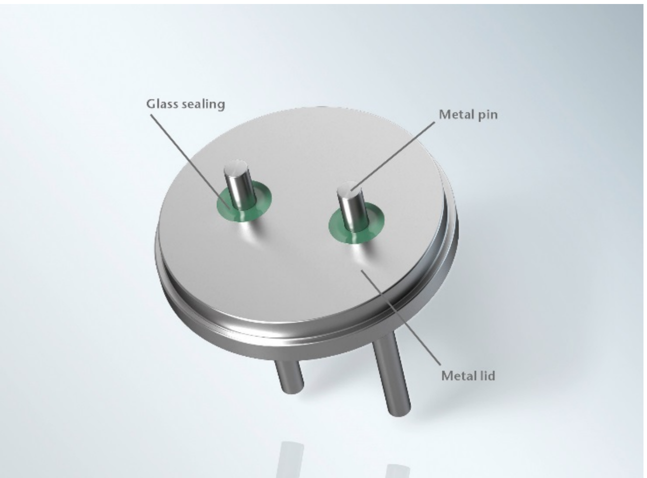

Figure I:

Simple 2-pin example for a hermetic GTMS feedthrough based on pins, glass beads and eyelet, which can be welded into a larger housing platform.

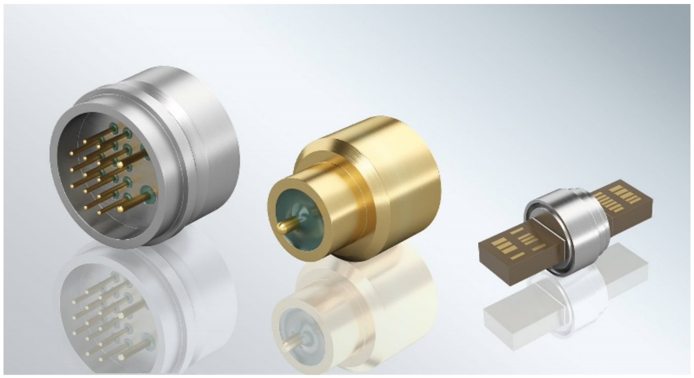

Figure II:

Glass-to-metal sealed connectors for power and data supply in medical applications.