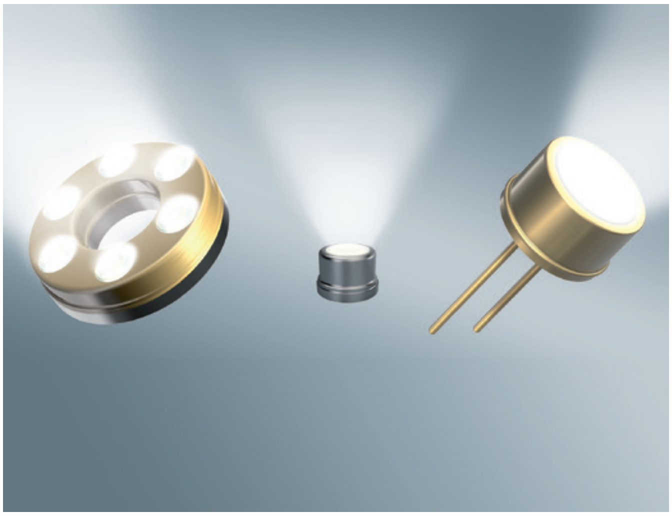
Hermetic Sealing Technology Protects Medical Electronics From Harsh Steam Sterilization

By Jochen Herzberg, Senior Program Manager, Medical Division, SCHOTT Electronic Packaging
First published on: www.meddeviceonline.com

Hopsitals everywhere work constantly to fight against harmful antibiotic-resistant bacteria and hospital-acquired infections, which are extremely dangerous and costly to treat. With an increasing emphasis on infection prevention and safety, there is a growing trend toward using disposable instruments and tools in hospitals. However, medical devices such as high-definition endoscopes, high-tech cameras, computer displays, lighting modules, and expensive surgical drills do not have this throwaway option: they must be sterilized to enable safe reuse. This is done in the autoclave, which uses pressurized, high-temperature steam to kill microorganisms.



Although autoclaving is the tried and true method for sterilizing medical instruments, the heat and moisture it uses to eliminate contaminants can also damage electronic components, potentially resulting in instrument failure after as few as 10 to 20 sterilization cycles. This presents a difficult and potentially costly problem for medical device designers, manufacturers, and end users.

Though the hygiene and reliability challenge with steam sterilization in the equation is a difficult one to solve, there are existing solutions. Hermetic glass-to-metal sealing, which has been used for decades in automotive and military applications to protect electronics in harsh conditions, is now being applied in the medical field. This sealing approach can be used to enclose electronics and microelectronics such as circuits, LED chips, and even imaging chips to provide superior protection that can undergo autoclaving without risk of seal compromise and subsequent damage. The benefits delivered by glass-to-metal sealing create the possibility for more reliable devices with well-protected electronics that offer long-term reliable functionality.

Keeping electronics safe from moisture damage

Microbial spores – a dormant, tough, non-reproductive form of some bacteria – are among the hardest microbes to kill. If they enter a patient's body, the pores can become active again and cause a serious infection. The moist heat produced by autoclaving can penetrate and kill even the toughest microbial spores, which are resistant to all other forms of sterilization. However, the harsh element of moist heat can also be damaging to electronics.

Although polymer sealing materials are sometimes used in electrical connectors to protect electronics in medical devices, the organic material structure breaks down after repeated exposure to steam and heat during sterilization. Eventually, the moisture from repeated autoclaving can penetrate the worn-out seals and reach the electronics in the instrument, causing performance loss or even short-circuiting.

Electrical connectors support device functionality by conducting the electrical current that provides power and transferring electrical signals that communicate various application-specific functions. When a connector fails, it can mean essential functions or even the entire device will no longer work – even if they remain intact – because of this break in the infrastructure chain. Because of this problem, hospitals must sometimes choose between replacing electronic instruments often, using methods of sterilization inferior to autoclaving, or reducing the number of times an instrument is autoclaved.

Glass-to-metal sealing allows expensive and complex electronic instruments from endoscopes to cameras to be autoclaved by using glass and metal in their electrical connectors to create a vacuum-tight, or hermetic, seal to protect electrical components. The gas-and-liquid tight seal prevents humidity from the autoclave from reaching sensitive circuit boards, chips, and other electronics. The high level of protection offered by glass-to-metal sealed connectors and their ability to withstand over 3,500 autoclaving cycles allows medical device manufacturers to cross out problems stemming from their failure from their list of reliability challenges.

When glass-to-metal sealing is used in connectors, a feedthrough consisting of wire pin surrounded by glass and enclosed in a metal housing is used. The assembly is then superheated in a furnace at carefully controlled temperature profiles, bonding the glass to both the metal housing and metal feedthrough pins to form a fully vacuum-tight seal.

The electrical conductivity of the wire pin remains intact, so signals and power can move in and out of the component. Glass-to-metal sealed medical connectors can be manufactured in custom shapes, sizes, and pin configurations to match exact requirements for seamless integration in medical devices.

Robust, autoclavable LEDs

LEDs are used in surgical room lighting and to provide lighting for instruments such as endoscopes or cameras used inside the body. Like connectors, organic polymer materials are sometimes used to protect the critical internal components of LED lighting modules. This material can begin to break down after just a handful of autoclaving cycles, leaving a weakened seal that could allow moisture to enter and cause premature failure of the LED chip inside.

Glass-to-metal sealing can be used in LED housing modules to protect LED chips from harsh environments encountered during use, cleaning, or autoclaving. The glass is placed over the LED chip and sealed to a ceramic or metal housing to achieve long-term protection and performance with a stable color rendering index, even after many autoclaving cycles. An experienced glass manufacturer has the expertise to create the perfect glass shape and incorporate optical properties that allow the LED to meet all necessary specifications. The glass itself can even be used to modify the LED's optical properties if necessary.

Because many of the LEDs used in instruments are tiny, it is important that the glass shield be designed carefully so it does not add unnecessary bulk to the device. In fact, the smallest available autoclavable, high-brightness LED is only 2.3 millimeters in diameter and utilizes glass-to-metal sealing.

Ultra-small autoclavable LEDs allow light sources to be integrated directly into instruments, eliminating the need for external light sources. These LEDs also further expand device capabilities and design options. For example, they enable battery-powered devices and are being incorporated into instruments that have never before included integrated lighting, such as endoscopes, surgical tools, drills, and dental mirrors.

Improved reliability

Although somewhat new to medical applications, glass-to-metal sealing has been used for years to protect sensitive components exposed to harsh or corrosive environments This sealing technology is found in cars to protect safety systems from humidity and chemicals, helping keep them functional for Internal years. It also protects critical components from harsh environments in aerospace and defense applications as well as nuclear power plants.

It may seem counterintuitive to use a material considered breakable for protection, but the seals maintain integrity because glass is inorganic, non-porous, does not age, and is resistant to drastic environmental changes. Impact tests have proved glass-to-metal sealed connectors are resistant to damage and breakage from basic physical stress, such as an instrument being dropped.

Incorporating glass-to-metal sealed components into medical instruments contributes to greater reliability and reduced total cost of ownership because the electronics are protected to withstand thousands of autoclaving cycles. This increased reliability can improve safety by helping mitigate risk of device failure during procedures and eliminates downtime from dealing with instruments experiencing electrical problems.

Glass-to-metal sealing also has the potential to expand the use of autoclaving by reliably protecting electronics in instruments that were previously considered unable or unusual to be autoclaved. For example, it could enable more widespread use of autoclaving in dental offices, where removable plastic covers and spray disinfectants are often used to keep expensive tools and instruments free of contaminants.

Creating the best seal

A high degree of design freedom is available when using glass-to-metal sealing in electrical connectors and electronic housings to protect LED chips, laser diodes, and imaging sensors. For example, they can be produced in a way that provides very specific electrical insulation, conductivity, or optical properties necessary for a given application.

When considering incorporating glass-to-metal sealing into a medical device design, it's important to partner with a company experienced in glass and glass-to-metal sealing. Creating a fully hermetic, vacuum-tight seal is a complicated process that requires complete understanding of the glass and metal material properties. Because the seal is created inside a furnace, the thermal properties of the glass and metal must closely match to ensure the glass creates a strong and permanent seal with the metal. Although some suppliers purchase standard glass for glass-to-metal seals, a glass manufacturer will understand the material formulations and, most importantly, how the glass interacts with the metal in order to create the strongest and most secure bond possible.

Glass-to-metal sealing is very application-specific, so it's also critical to work with a partner that can customize the glass and seal to meet the specific demands and the medical instrument. A glass manufacturer will work directly and hands-on with equipment designers and device manufacturers to match or exceed design capabilities and meet all instrument requirements. Glass-to-metal sealing can typically be incorporated into existing connectors or LED module designs to match an instrument's design specifications for simple integration while offering greater reliability and longevity.

Partnering with a glass company to incorporate glass-to-metal sealing into medical instruments can boost reliability and longevity by offering superior electronics protection and providing unmatched capability to be autoclaved thousands of times.