

Hermetic Sealing of Magnets in Implantable Medical Devices

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Abstract

Hermetic sealing is a crucial aspect of ensuring the safety and functionality of implantable medical devices that incorporate magnets. This whitepaper explores the significance of hermetic seals in such devices, delving into their definition, relevance, applications, biocompatible materials, sealing techniques, testing methods, and adherence to standards such as ISO 10993. It provides an in-depth examination of the challenges and considerations in hermetic sealing, with a focus on magnet-integrated implantable devices, and aims to provide a comprehensive resource for researchers, engineers, and manufacturers in the field of medical device development.

Introduction

The development of implantable medical devices has been one of the most significant advancements in modern medicine. These devices have the potential to improve the quality of life for patients suffering from various medical conditions. A common element in many of these devices is the incorporation of magnets. Magnets can serve a wide range of purposes in implantable medical devices, from enabling MRI compatibility to enhancing drug delivery systems and providing sensing capabilities. However, magnets, especially those made of neodymium-iron-boron (NdFeB), are highly susceptible to corrosion in the presence of moisture. To ensure the longevity and safety of these devices, it is imperative to employ hermetic sealing techniques.

This whitepaper aims to provide an extensive exploration of hermetic sealing in implantable medical devices with a focus on those that integrate magnets. We will begin by defining the concept of hermetic sealing and its relevance in medical devices. We will then delve into specific applications of magnetic implantable devices, the importance of biocompatible materials, various hermetic sealing techniques, testing methods, and the adherence to essential standards such as ISO 10993.

Hermetic Sealing: Definition and Significance



What Is Hermetic Sealing?

The term "hermetic seal" finds its origins in the Greek god Hermes, who was believed to have created the first sealed glass tube. In contemporary terms, a hermetic seal refers to a barrier or closure that is impervious to the passage of liquid, gas, and particulate matter, preventing them from entering or escaping from a protective vessel or container. This sealing method ensures a controlled and isolated environment within the container, making it suitable for various applications where environmental protection is crucial.¹

The Relevance of Hermetic Sealing in Implantable Medical Devices

Implantable medical devices are designed to be placed within the human body. These devices may serve diverse purposes, such as supporting damaged bodily functions, monitoring vital signs, or delivering therapeutic agents. In all cases, they must be safe, reliable, and biocompatible. However, the human body is a complex and challenging environment, and implantable devices are exposed to bodily fluids, tissues, and potentially corrosive substances. For medical devices that incorporate magnets, which have various applications, such as MRI-safe implants, magnetic drug delivery systems, or magnetic sensors, hermetic sealing becomes critical. Without proper sealing, these magnets can corrode and degrade, leading to device malfunction, potential harm to the patient, and the need for costly replacements or revisions.

Applications of Magnetic Implantable Devices

Magnetic implantable devices have found applications in various areas of healthcare, improving diagnostics,

treatment, and patient comfort. Here are some notable examples:

1. MRI-Safe Implants

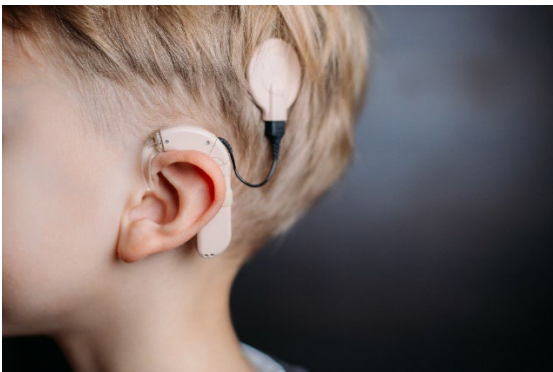


Magnetic resonance imaging (MRI) is a crucial diagnostic tool in modern medicine, allowing for non-invasive imaging of internal structures. However, the powerful magnetic fields generated by MRI machines can pose risks to patients with implanted metal objects. To address this challenge, implantable medical devices, such as artificial joints or cardiac devices, often use hermetic seals and non-ferrous materials like titanium to ensure MRI compatibility. These seals prevent the magnetization or movement of metal components within the body during MRI procedures, making them safe and reliable.

2. Magnetic Drug Delivery Systems

Magnetic drug delivery systems aim to enhance the precision and effectiveness of drug delivery within the body. These systems typically involve the use of magnetically responsive nanoparticles or carriers that can be guided to specific target areas using external magnetic fields. Hermetic seals are essential in these devices to protect the embedded magnets and ensure their functionality within the body. By delivering drugs precisely to the desired location, magnetic drug delivery systems can minimize side effects and increase therapeutic efficacy.

3. Implantable Magnetic Sensors



Implantable magnetic sensors have a wide range of applications, from monitoring pressure and temperature to detecting the presence of specific substances or pathogens within the body. These sensors rely on the interaction between magnetic fields and their surrounding environment. To maintain their sensitivity and accuracy, hermetic seals are employed to protect the sensitive sensor components from bodily fluids and environmental factors. As such, they play a crucial role in the reliability of these sensing devices.

4. Cochlear Implants

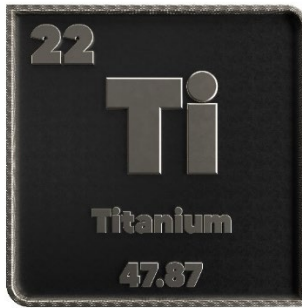
A cochlear implant is an electronic device that improves hearing. It can be an option for people who have severe hearing loss from inner-ear damage who are not able to hear well with hearing aids. The external components include the microphone, battery, speech processor, external magnet, and transmitter antenna. The internal components include the internal magnet, antenna, receiver-stimulator, and electrode array. Sound is first detected by a microphone worn on the ear and subsequently converted into an electrical signal. This signal is then sent to an external sound processor, where, according to one of the several different processing strategies, is transformed into an electronic code. This digital signal is transmitted via radiofrequency through the skin by a transmitting coil that is held externally over the receiver-stimulator by a magnet.

Biocompatible Materials for Hermetic Sealing

Selecting the appropriate materials for hermetic sealing in implantable medical devices is a multifaceted decision influenced by several factors, including the specific application, cost considerations, weight constraints, and the intended device lifespan. Biocompatibility is of paramount importance when choosing materials for devices that will interact with the human body.

1. Metals

Metals have a long history of use in hermetic sealing due to their excellent durability and resistance to corrosion. Some commonly used metals in implantable medical devices include:
Titanium and Titanium Alloys



Titanium is widely used in medical implants due to its excellent biocompatibility, corrosion resistance, and high strength-to-weight ratio. Titanium's compatibility with the human body makes it an ideal choice for hermetic casings in implantable devices. Hermetic seals made of titanium or titanium alloys provide robust protection for embedded magnets and other sensitive components.

Stainless Steel

Stainless steel is another metal commonly used in implantable devices, especially in applications where higher mechanical strength is required. Its corrosion resistance is also advantageous for hermetic sealing, although it may not be as biocompatible as titanium in some cases.

Nickel and Niobium

Nickel and niobium are occasionally used for hermetic sealing, although their use is less common than titanium and stainless steel. They may be employed in specialized applications where their unique properties are advantageous.

2. Non-Metallic Materials

In addition to metals, non-metallic materials are also utilized for hermetic sealing in implantable devices, particularly in cases where weight, electrical insulation, or other specific properties are required:

Glass

Glass-to-metal seals are a classic choice for hermetic sealing in a variety of applications. The combination of glass's hermetic properties and compatibility with metals makes it suitable for encapsulating magnetic components. It is important to ensure that the glass used is biocompatible and meets the necessary safety standards.

Ceramics

Ceramic materials are known for their excellent electrical insulation properties and resistance to high temperatures. They are used in situations where the hermetic seal must provide electrical isolation, such as in certain neural implants or sensor applications.

Organic Polymers

Organic polymers are lightweight and versatile materials that can be tailored to specific application requirements. However, their use in hermetic sealing for implantable devices is limited due to concerns about long-term biocompatibility and gas permeability. When used, extensive testing and validation are necessary to ensure safety.

The choice of material ultimately depends on the device's intended use, design constraints, and the potential risks associated with the interaction between the material and the patient's body.

Hermetic Sealing Techniques

The selection of a hermetic sealing technique is influenced by various factors, including the form factor of the device, the materials involved, and the performance requirements. Different sealing methods have distinct advantages and limitations, and the choice should align with the specific needs of the application. Below are some of the common hermetic sealing techniques used in implantable medical devices:

1. Welding Techniques

Laser Welding



Laser welding has gained popularity in the medical device industry due to its precision and ability to create strong hermetic seals without the need for additional materials

like adhesives or solders. In laser welding, a focused laser beam is used to melt and fuse the materials together. The rapid cooling of the molten material results in a solid, hermetic bond. Laser welding is particularly advantageous when sealing materials with different coefficients of thermal expansion, as it minimizes the risk of stress-induced fractures.

Electron Beam Welding

Electron beam welding is another high-energy welding technique used for hermetic sealing. It operates by directing a stream of high-velocity electrons at the materials to be joined. The kinetic energy of the electrons generates heat, causing localized melting and subsequent fusion. Electron beam welding is suitable for materials that are highly reflective to laser light and is often used in applications requiring deep penetration.

2. Thermocompression Bonding

Thermocompression bonding, also known as thermo-compression welding or thermo-compression bonding, relies on the application of heat and pressure to create a hermetic seal. This technique is often used when joining materials that cannot be easily laser-welded or in situations where precise control over the seal's dimensions is crucial. Thermocompression bonding is especially useful when working with glass-to-metal seals, as it allows for fine-tuning of the seal's quality.

3. Compression Seals

Compression seals involve the use of gaskets or elastomers to create a hermetic barrier between two surfaces. These seals are particularly useful in applications where flexibility and ease of assembly are priorities. While compression seals are not as common in implantable medical devices, they can be employed in situations where the device requires periodic access or maintenance.

4. Adhesive Bonding

Adhesive bonding involves the use of specialized adhesives or epoxies to create a hermetic seal. While this technique is not as robust as welding or compression seals, it can be a suitable option for certain implantable devices. Adhesive bonding is often chosen for its ease of use, particularly when sealing irregularly shaped components or joining dissimilar materials.

Each hermetic sealing technique has its own set of advantages and challenges, and the selection should be made after careful consideration of the specific requirements of the device, manufacturing processes, and long-term reliability.

Testing Hermetic Seals

Ensuring the integrity of hermetic seals is critical to the safety and functionality of implantable medical devices. Detecting and addressing leaks early in the development process is essential to prevent potential harm to patients. Various testing methods are employed to assess the quality of hermetic seals. One of the most widely used techniques is helium leak testing.

Helium Leak Testing

Helium leak testing is a highly sensitive method for detecting leaks in hermetic seals. It is based on the principle that helium gas molecules are extremely small and can pass through even the tiniest openings or defects in a seal. The basic steps of helium leak testing are as follows:

Introduce Helium Gas: The sealed device is pressurized with helium gas, either partially or completely filling the internal cavity. Helium is chosen because of its small atomic size, making it an ideal test gas for detecting even minuscule leaks.

Waiting Period: After introducing helium, the device is allowed to equilibrate for a specified period. This allows helium to penetrate any potential leaks in the hermetic seal.

Leak Detection: A mass spectrometer is used to analyze the effluent gas for the presence of helium. If helium is detected, it indicates a leak in the seal. The rate of helium flow is quantified, allowing for an estimation of the size and severity of the leak.

Pass/Fail Criteria: Specific criteria are established to determine whether the hermetic seal passes or fails the test. The allowable leak rate is typically defined based on the device's intended use and safety requirements. Helium leak testing is highly accurate and can detect leaks as small as 10^{-9} atm·cc/s (atmospheres cubic centimeters per second), making it a reliable method for quality control. This testing technique is particularly important for implantable medical devices, as any leaks could compromise patient safety and device functionality.

In addition to helium leak testing, other methods such as bubble testing, pressure decay testing, and electrical-based tests may be employed depending on the nature of the device and the sealing materials used. However, helium leak testing remains the gold standard for detecting and quantifying hermetic seal leaks.

Applicable Standards: ISO 10993

The International Organization for Standardization (ISO) has established a set of standards, known as ISO 10993, that provide guidance on the evaluation of the biocompatibility of medical devices. Biocompatibility refers to the ability of a material or device to perform its intended function within the human body without causing adverse effects, such as inflammation, toxicity, or immune responses.

ISO 10993 outlines various tests and considerations for assessing the biocompatibility of materials used in medical devices, including those with hermetic seals. Adhering to ISO 10993 is essential to ensure that implantable medical devices are safe for use within the human body. Key aspects of ISO 10993 that are relevant to hermetic sealing in implantable medical devices include:

1. Biological Evaluation of Medical Devices

ISO 10993-1 provides an overview of the biological evaluation of medical devices and outlines a risk-based approach for determining the extent of testing required based on device characteristics and patient contact duration. It emphasizes the need for manufacturers to consider potential risks associated with materials, including those used in hermetic seals.

2. Cytotoxicity Testing

ISO 10993-5 specifies test methods for evaluating the cytotoxicity of medical devices and materials. Cytotoxicity testing assesses whether the materials used in hermetic seals have a harmful effect on cells. Ensuring that materials are not cytotoxic is crucial for the safety of implantable devices, as harmful interactions with surrounding tissues can lead to adverse reactions.

3. Sensitization and Irritation Testing

ISO 10993-10 and ISO 10993-10 provide guidelines for evaluating the potential for materials to cause skin or mucosal irritation and sensitization. While these standards are more relevant to external medical devices, they may

still be applicable in cases where an implantable device's components or materials come into contact with tissues or bodily fluids.

4. Systemic Toxicity Testing

ISO 10993-11 addresses systemic toxicity testing, which assesses the potential for materials to cause adverse effects when they enter the bloodstream or have systemic exposure within the body. While implantable devices are designed to remain sealed and isolated from the bloodstream, the materials used in hermetic seals must still be evaluated for systemic toxicity to ensure patient safety.

5. Genotoxicity and Carcinogenicity Testing

ISO 10993-3 and ISO 10993-7 provide guidance on evaluating the genotoxicity and carcinogenicity of medical device materials. Although the risk of these effects from hermetic seal materials is generally low, manufacturers should consider these factors in the overall biocompatibility assessment.

6. Chemical Characterization

ISO 10993-18 emphasizes the importance of characterizing the chemical composition of materials used in medical devices. Manufacturers must identify and quantify any potentially harmful substances present in the materials, which includes those used in hermetic seals.

7. Biological Evaluation Plans

Manufacturers of implantable medical devices, including those with hermetic seals, are required to establish biological evaluation plans (BEPs) based on ISO 10993-1. These plans outline the specific tests and evaluations to be conducted to assess the biocompatibility of the device and its materials. BEPs ensure a systematic and comprehensive approach to biocompatibility assessment. Adhering to ISO 10993 standards is not only a regulatory requirement but also a fundamental step in ensuring the safety and efficacy of implantable medical devices. Manufacturers must thoroughly evaluate the biocompatibility of hermetic seal materials and consider the specific risks associated with their devices.

Challenges and Considerations in Hermetic Sealing

While hermetic sealing is crucial for the success of implantable medical devices, it comes with its own set of challenges and considerations that must be carefully addressed during device development. Some of the key challenges include:

1. Miniaturization

Many implantable medical devices, including those with integrated magnets, are becoming increasingly miniaturized to reduce invasiveness and improve patient comfort. Miniaturization presents challenges in terms of sealing techniques, as smaller components may be more difficult to hermetically seal. Manufacturers must develop innovative sealing methods to accommodate these miniaturized designs.

2. Material Compatibility

The choice of materials for hermetic sealing is critical, as some materials may interact with the magnetic components or other device elements in undesirable ways. Compatibility between the sealing material and the embedded magnets, as well as other device components, must be thoroughly evaluated to prevent degradation or malfunction.

3. Long-Term Reliability

Implantable medical devices are intended to remain within the body for extended periods. Ensuring the long-term reliability of hermetic seals is essential, as any degradation over time can lead to device failure. Manufacturers must conduct accelerated aging tests and durability assessments to predict the performance of hermetic seals throughout the device's expected lifespan.

8. Biocompatibility



Biocompatibility is a paramount concern when selecting materials for hermetic seals, but it goes beyond material

selection. The entire sealing process, including any cleaning or passivation steps, must be evaluated for potential biological effects. Any residues or byproducts from the sealing process must be biocompatible and non-toxic.

4. Regulatory Compliance

Medical device manufacturers must navigate a complex landscape of regulatory requirements and standards. Achieving regulatory compliance, including adherence to ISO 10993 and other relevant standards, is a time-consuming and resource-intensive process. Manufacturers must plan for thorough testing, documentation, and regulatory submissions.

5. Manufacturing Consistency

Maintaining consistent hermetic seals during mass production can be challenging. Variability in manufacturing processes, even at a small scale, can result in differences in seal quality. Manufacturers must implement robust quality control measures to ensure that each device meets the required standards for hermeticity.

6. Cost Considerations

The selection of materials and sealing techniques can significantly impact the overall cost of device production. Manufacturers must balance the need for high-quality hermetic seals with cost considerations, especially when producing devices for widespread use. Addressing these challenges requires collaboration among multidisciplinary teams of engineers, materials scientists, biocompatibility experts, and regulatory affairs specialists. Manufacturers must also stay abreast of advancements in materials and sealing technologies to continually improve the reliability and safety of implantable medical devices.

Conclusion

Hermetic sealing is a critical aspect of ensuring the safety, functionality, and longevity of implantable medical devices, particularly those that incorporate magnets. These devices play a crucial role in improving patient care, from enabling MRI-safe implants to enhancing drug delivery systems and providing vital sensing capabilities.

The choice of materials for hermetic seals is of paramount importance, with biocompatibility being a primary consideration. Materials such as titanium, stainless steel, glass, ceramics, and organic polymers each have their

own advantages and are selected based on the device's specific requirements.

Various hermetic sealing techniques, including laser welding, electron beam welding, thermocompression bonding, compression seals, and adhesive bonding, offer different advantages and should be chosen based on the device's design and materials.

Testing the integrity of hermetic seals, with a focus on helium leak testing, is essential to ensure that devices are free from defects that could compromise patient safety.

Adherence to standards such as ISO 10993 is a regulatory requirement and a fundamental step in assessing the biocompatibility of implantable medical devices.

Manufacturers must carefully plan and execute biological evaluation plans to demonstrate the safety of hermetic seals and materials.

Challenges in hermetic sealing, including miniaturization, material compatibility, long-term reliability, biocompatibility, regulatory compliance, manufacturing consistency, and cost considerations, must be addressed through meticulous research, development, and quality control.

As the field of medical device technology continues to advance, hermetic sealing will remain a critical aspect of ensuring the success of implantable medical devices. The ongoing pursuit of innovation and excellence in hermetic sealing techniques and materials will contribute to the continued improvement of patient care and medical device safety.

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