Genesis Journal of Surgery and Medicine

Genesis-GJSM-3(2)-29
Volume 3 | Issue 2
Open Access

Surgeons Be Aware of Custom Implant Contamination: They Are Your Best Partner for Success

Rui PLM Coelho*
Project Manager at Boneeasy research Center, Portugal

***Corresponding author:** Rui P. L. M Coelho, Project Manager at Boneeasy research center, Portugal.

Citation: Coelho RPLM. Surgeons Be Aware of Custom Implant Contamination: They Are Your Best Partner for Success. J Oral Med and Dent Res. 5(4):1-6.

Rceived: November 23, 2024 | **Published**: December 6, 2024

Abstract

This article aims to highlight the importance of understanding and controlling contamination in custom-made implants, especially in light of the European Medical Device Regulation (MDR) 2017/745 and the FDA's 510(k) pathway. We will explore how contamination can occur, the types of contamination (both physical and biological), and why surgeons must be actively involved in demanding contamination reports and validation certificates from manufacturers. By understanding contamination risks, surgeons can become better partners in ensuring patient safety and their own surgical success.

Keywords

Custom Implant; Biological Contamination; Raw Material; Boneeasy; Surgeons as Advocates

Introduction

In the fast-paced evolution of 3D-printed custom implants, patient safety remains the highest priority. One of the most critical aspects of ensuring this safety is implant contamination, a concern that has persisted in traditional manufacturing processes and has grown more complex with the advent of metal 3D printing. As implants transition from standard designs to custom, individualized devices, we must holdthem to even higher scrutiny, particularly regarding contamination at all stages—from raw material selection to post-manufacturing sterilization.

This article aims to highlight the importance of understanding and controlling contamination in custom- made implants, especially in light of the European Medical Device Regulation (MDR) 2017/745 and the FDA's 510(k) pathway. We will explore how contamination can occur, the types of contamination (both physical and biological), and why surgeons must be actively involved in demanding contamination reportsand validation certificates from manufacturers. By understanding contamination risks, surgeons can become better partners in ensuring patient safety and their own surgical success (Figure 1).

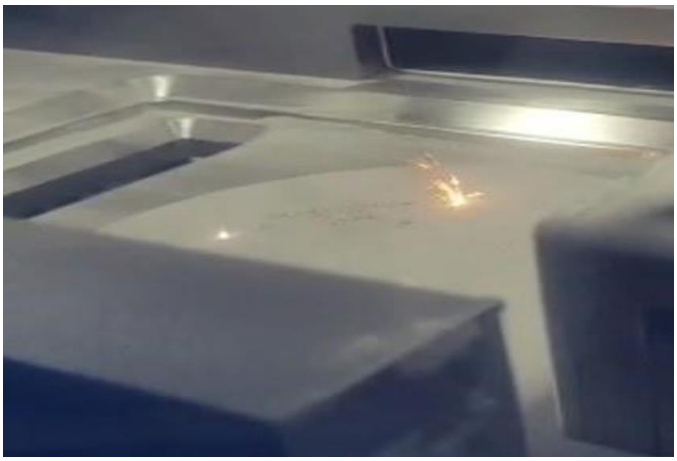

Figure 1: Power bed fusion, the main system for manufacturing custom implants.

The Rising Importance of Custom Implants

Custom implants are becoming a significant tool for surgeons, offering individualized solutions that align with a patient's unique anatomy. These devices are often produced through additive manufacturing, commonly known as 3D printing, which allows for complex geometries that would be difficult or impossible to achieve with traditional methods. However, as exciting as these technological advances are, they also come with new challenges. One major concern is contamination during the manufacturing process, particularly in metal 3D printing, where particles, debris, or even trace elements from previous prints can infiltrate the material. Contamination can occur at any stage, from the raw material to the tools used in shaping and post-processing, ultimately affecting the safety and performance of the implant.

The European MDR 2017/745 is clear in its requirement that manufacturers must ensure safety and performance throughout the lifecycle of the device. Custom-made implants are not exempt from these rules,

which mean that contamination must be addressed through rigorous testing and validation.

Types of Contamination in Custom Implants

There are two main types of contamination in custom implants: physical contamination and biological contamination. Both present risks to patient safety, and both need to be thoroughly managed and tested.

Physical Contamination

- Physical contamination refers to the presence of unwanted particles or residual substances on the implant's surface. Even when raw materials, such as titanium bars or blocks, come certified from suppliers, it is crucial to assess contamination at every stage of the manufacturing process.
- For example, titanium is a popular material for implants due to its biocompatibility. However, during the process of sandblasting, used to roughen the surface of titanium for better osseointegration, particles of abrasive material (such as AlO3) can become embedded in the implant's surface. This was highlighted in the Surface Comparison of Three Different Commercial Custom-Made Titanium Meshes Produced by SLM for Dental Applications by Nuno Cruz et al. (2020), which found that contamination from processes like sandblasting can leave behind significant residue, potentially affecting implant performance.
- Even after cleaning, some degree of contamination remains. Clean Implant Foundation guidelines allow for a minimal level of particles, setting a tolerance for what can be considered a clean implant. Achieving zero contamination is impossible, but thorough cleaning methods and validation tests must be in place to ensure contamination levels are within acceptable limits.
- The challenge with 3D-printed implants, especially those made using Selective Laser Melting (SLM) or Electron Beam Melting (EBM), is that contamination can be introduced not only on the surface but deep within the structure of the implant. As the implant is built layer by layer, particles from the printing process or previous builds can get trapped inside. This contamination, if not properly identified and controlled, can compromise the implant's mechanical integrity and biocompatibility.

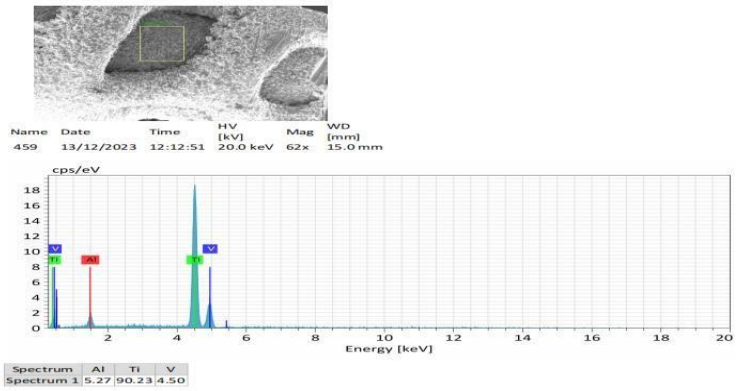

Figure 2: EDS showing the purity of the surface.

Biological contamination

- Equally important is the risk of biological contamination. This involves the presence of microorganisms such as bacteria or fungi on the implant surface. Even when an implant undergoes sterilization, if it was contaminated during manufacturing or handling, it can lead to serious complications post-implantation.
- Sterilization is not a catch-all solution. For the sterilization process to be effective, the bioburden—the number of viable microorganisms on the implant before sterilization—must be kept low. The Sterility Assurance Level (SAL), which is defined as the probability of a single unit being non-sterile after sterilization, is typically set at 10^{-6} for medical devices. However, if the bioburden is too high, the sterilization process may leave behind dead bacteria, which can release endotoxins. These endotoxins can cause inflammation and significantly delay healing, undermining the success of even the most perfectly executed surgical procedure.
- As seen in Javier Gil Mur and João Paulo Tondela's studies on contamination, it's essential that manufacturers not only sterilize implants but also limit the amount of biological contamination present before sterilization to prevent an excessive endotoxin load post-surgery.

The Importance of Raw Material and Tool Validation

- Contamination concerns start with the raw materials used to create the implants. The material used must not only meet biocompatibility standards, but the tools used in shaping and processing the material must also be validated to ensure they do not introduce additional contamination.
- MDR 2017/745 mandates that manufacturers validate the entire production process, including the tools and equipment used. For instance, machining tools that shape implants can leave behind oils, metallic particles, and other contaminants. This is particularly concerning in 3D printing, where the very tools used to clean or post-process the implant can add contaminants that compromise its safety.

The Role of Surgeons in Ensuring Clean Implants

While manufacturers are responsible for producing clean implants, surgeons have a vital role in ensuring that the implants they use meet the highest safety standards. Surgeons must be proactive and demand contamination reports and certificates of validation from manufacturers.

Surgeons should ask for detailed reports on:

- Surface contamination analysis (e.g., through Scanning Electron Microscopy (SEM) and Energy Dispersive Spectroscopy (EDS)).
- Cleanliness validation from independent bodies like the Clean Implant Foundation.
- Lixiviation tests to assess how many metallic ions are released from the implant, which is crucial for understanding long-term biocompatibility.
- Bioburden analysis and evidence of compliance with the required SAL of 10^{-6}
- Registration of the device with notified bodies, ensuring it complies with regulatory standards.

It is crucial for surgeons to verify the implant's registration with the relevant notified bodies, ensuring that the

custom-made device adheres to all necessary safety regulations under MDR/745 and 510(k).

Custom Implants and the Need for Stricter Regulations

Custom implants should have more stringent contamination controls than standard implants. However, the reality is that regulatory bodies often do not differentiate between the two. This gap in regulation leaves room for potentially dangerous practices in the production of custom-made devices.

For example, in dental labs where custom implants are made, there is often insufficient oversight, and implants are produced without the necessary contamination controls. As [1] demonstrated, some 3D-printed titanium meshes were found to contain high levels of chromium-cobalt (CrCo) particles, a material known for its carcinogenic properties. The presence of such particles raises significant concerns about the long-term safety of these implants. Surgeons should be vigilant and ensure that any custom-made implant they use has undergone rigorous contamination testing. Failing to do so can result in implant failure, increased patient risk, and legal liability for the surgeon.

Boneeasy's Approach to Ensuring Clean Implants

- At Boneeasy, all 3D-printed implants are manufactured in cleanrooms, with printers exclusively dedicated to processing implantable-grade titanium. This strict control of the manufacturing environment helps minimize the risk of contamination. Furthermore, every implant undergoes comprehensive contamination testing before it reaches the surgeon.
- Boneeasy's approach reflects the principles outlined in MDR/745, which emphasizes that patient safety must be built into the entire design and production process, including the management of contamination risks. Moreover, the company is constantly investing in new methods to improve cleanliness and biocompatibility, such as developing advanced cleaning protocols and continuously monitoring for physical and biological contaminants.

As mentioned earlier, biocompatibility is not just about using biocompatible raw materials; it's about ensuring that the entire manufacturing process does not introduce contaminants that couldalter the implant's safety. This is why Boneeasy's focus on both physical and biological contamination is essential for guaranteeing patient safety

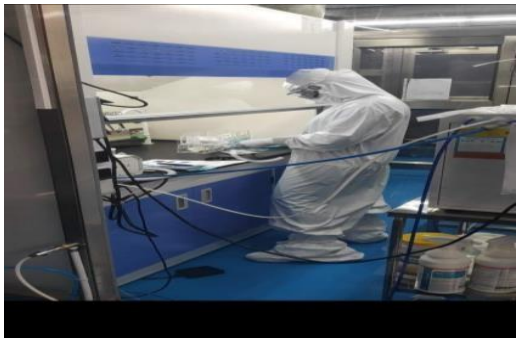

Figure 3: Boneeasy cleaning process.

Conclusion

Surgeons as advocates for clean implants

- In conclusion, contamination is a critical issue in the production of custom-made implants, and surgeons play a vital role in ensuring that the implants they use meet the highest standards of cleanliness and safety. By asking the right questions and demanding thorough contamination reports from manufacturers, surgeons can protect their patients and ensure their own success.
- The future of custom implants lies not only in advanced technology but in the commitment to rigorous safety standards. Surgeons must be proactive partners in this journey, advocating for clean implants and setting a higher standard of care.
- By holding manufacturers accountable and staying informed about contamination risks, surgeons can contribute to better patient outcomes, fewer complications, and greater success in their practice.

References

1. Cruz N, Martins M.I, Santos J.D, Mur JG, Tondela JP. (2020) Surface Comparison of Three Different Commercial Custom-Made Titanium Meshes Produced by SLM for Dental Applications. Materials (Basel).13(9):2177.
2. European Parliament. (2017) Regulation (EU) 2017/745 on Medical Devices (MDR). Official Journal of theEuropean Union, L117.
3. U.S. Food and Drug Administration (FDA). (2021) 510(k) Premarket Notification.
4. Clean Implant Foundation. (2021) Guidelines for Clean Implants.
5. Gil Mur J, Tondela J.P. (2020) Biocompatibility and Contamination in Custom Implants. J Implant Dent.29(4):455-63.