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ASIA EDITION

Advancing embolization with purified gelatin

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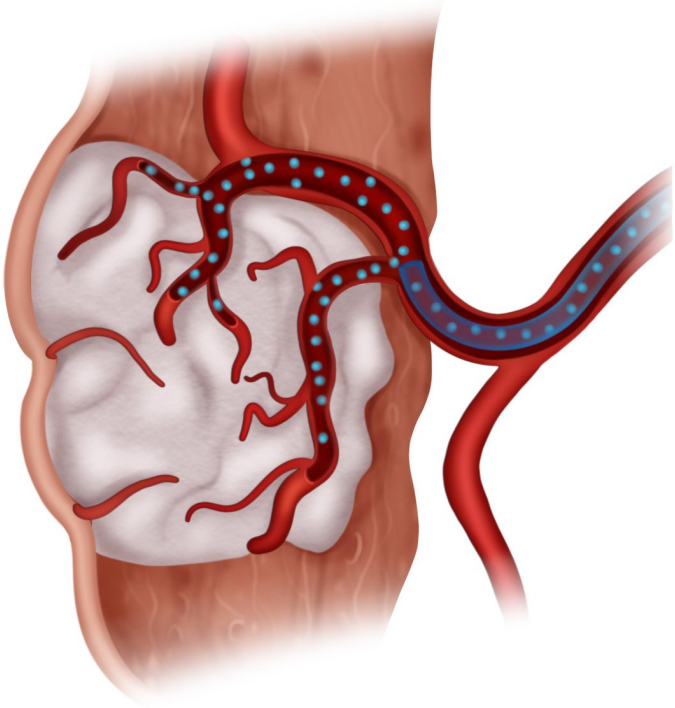
Introducing the use of purified gelatin in embolization, a revolutionary approach in medical procedures that holds immense promise. Discover why gelatin is the preferred biomaterial, how it's advancing embolization applications, and the crucial factors to consider when selecting gelatin for these procedures. Explore Rousselot's X-Pure range, specially designed to meet embolization requirements, and learn about our commitment to providing tailored gelatin solutions for improved patient outcomes and accelerated research. Join us in envisioning a future where interdisciplinary collaboration continues to shape innovative embolization techniques and enhance patient care.



What makes purified gelatin the biomaterial of choice for embolization?

Embolization, a medical procedure that involves intentionally blocking blood vessels or abnormal tissue growth, requires a biomaterial that possesses specific properties to ensure its effectiveness and safety.

Three key reasons why purified gelatin has emerged as the preferred biomaterial for embolization:

- Derived from the natural protein collagen, gelatin is inherently biocompatible with the human body meaning it is less likely to trigger immune responses or cause adverse reactions, promoting better patient outcomes. It is also biodegradable, meaning it breaks down naturally in the body over time, minimizing the risk of long-term complications associated with permanent implants.
- Gelatin offers a precise degradation rate that can be tailored based on the specific needs of the procedure. This controlled breakdown ensures that the embolizing material is gradually replaced by natural tissue as the body heals, preventing complications and allowing for a predictable clinical outcome.
- Gelatin can be easily molded into different shapes and sizes, including microspheres, which are commonly used in embolization procedures. This flexibility in shaping and control over particle size allows for customization of the embolizing agents, enabling physicians to target specific vessels or tissues more accurately.

How is gelatin advancing embolization applications?

Typically, embolization is achieved using materials like coils, particles, or liquids to block or reduce blood flow in specific blood vessels or tissues. In recent years, new types of gelatin-based embolic materials have become an increasingly popular choice, offering many advantages over traditional gelfoam blocks. Thanks to its versatility and adaptability, gelatin can be used in either microsphere or gel format and used to treat a wide range of conditions such as arteriovenous malformations, tumors and aneurysms.

The increasing availability of gelatin-based biomaterials with customizable properties, consistent quality and proven biocompatibility, is providing a new, reliable solution for pharmaceutical manufacturers and medical professionals seeking the most effective embolization materials. For example, Rousselot's X-Pure range of purified, medical grade gelatins are currently being used in approved and marketed medical devices in the United States. We are seeing growth in the development of new gelatin-based embolic devices in other markets such as Asia, which are rapidly expanding onto the global stage.

How to choose a gelatin for embolization?

While gelatin is a preferred biomaterial for embolization due to its unique properties, it is not without its challenges. Selecting the right biomaterial from the start of the research and development process is key to achieving success. Here are the most important features to look out for when selecting a gelatin for embolization:

- **Customization:** Tailoring gelatin properties to meet the specific requirements of different embolization procedures can be time-consuming and requires careful formulation and testing. Choosing a gelatin supplier that offers customized gelatin ensures seamless product manufacturing and optimal performance.
- **Degradation Rate Control:** Degradation rate can be tailored based on the specific needs of the product developed for the embolization procedure, preventing complications and allowing for predictable performance.
- **Consistency:** Ensuring consistent properties in gelatin microspheres or embolic agents is crucial. Variations in gelatin properties can lead to unpredictable results, making quality control and standardization essential.
- **Purity:** Choosing purified gelatins with low levels of endotoxins helps to ensure safe and effective medical interventions.
- **Availability and Sourcing:** The availability and sourcing of high-quality gelatin for medical use can impact the consistency and reliability of the embolic material. Choosing a well-established gelatin supplier with a good track record and a secure supply chain is essential to ensure a reliable and stable source of biomaterials.
- **Compatibility:** Gelatin can be engineered to be compatible with various imaging modalities, allowing interventional radiologists to visualize the embolic material's precise location during the procedure. This real-time imaging can enhance the accuracy and safety of embolization.

- **Documentation**: The new European Medical Device Regulation (MDR) requires rigorous documentation, quality assurance and product performance assessments. All Rousselot products come with supporting documentation for compliance of medical devices with the new MDR requirements ((EU) 2017/745), documented traceability up to the farm (ISO 22442-2), validated viral inactivation (ISO 22442-3) and IPEC GMP Compliance.

Why choose X-Pure?

Rousselot's X-Pure range has been designed to address the specific requirements of embolization procedures. Offering customizability, purity and consistency, X-Pure serves as the ideal foundation for creating various embolic agents like gelatin microparticles/microspheres and hydrogels. X-Pure is compatible and easily blended with a wide variety of different drugs, cells and molecules for accurate drug delivery and imaging. As such, X-Pure can support a wide range of embolization applications, including transarterial embolization (TAE), transarterial chemoembolization (TACE) and radioembolization.

Rousselot's X-Pure range has been developed to ensure maximum quality and safety, with endotoxin levels of (<10 endotoxin units (EU)/g). All X-Pure gelatins support regulatory compliance with main international guidelines, coming with traceability, readily available documentation and validated viral safety. Importantly, our research and GMP grades are functionally equivalent, minimizing the need to revalidate data ahead of clinical trials and helping to accelerate research from the lab to the clinic.

Rousselot offers tailored gelatin solutions

With 130 years of gelatin expertise, Rousselot has a deep understanding of the properties and functionalities of gelatin. We listen carefully to our customers to understand their embolization challenges and provide expert solutions tailored to their needs. From choosing the right product all the way through to testing and optimizing a formulation, we offer support to help our customers get the most from our products and achieve their goals.

Through our unique offering of customized gelatins, comprehensive technical support, and collaborative development for innovative embolization techniques, we aim to help our customers to reach the market as quickly as possible, delivering speed without compromising on quality.

Advancements and future directions

Embolization was introduced more than 40 years ago as a therapeutic modality, but it has seen significant growth in the last decade. The list of indications continues to grow, with embolization for fibroids, prostate, and some types of liver tumors offering new treatments for patients in recent years. As technology, devices and imaging quality continue to improve, we are likely to see novel applications and better patient outcomes in different diseases.

Interdisciplinary collaboration between biomaterial scientists, interventional radiologists and medical professionals is driving innovation in gelatin-based embolization materials. By further refining gelatin-based embolic agents and exploring novel applications, the medical community can enhance the safety and efficacy of embolization procedures, ultimately benefiting patients with various vascular conditions.