

16-year partnership yields family of FDA Class III vascular devices

Therapeutic area

- **Vascular**

Product

- **Medical grade collagen**

Capabilities

- **Biomaterials expertise**
- **Custom prototyping and sampling**
- **Quality Assurance & Regulatory Affairs (QARA) support**
- **Scale-up services**

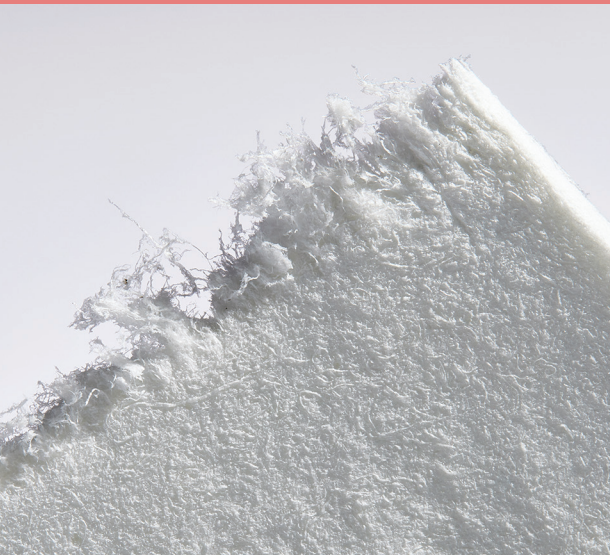


Partnering for the challenge

Our partner had a device design involving a delivery system for a biodegradable sponge. Unable to find an off-the-shelf solution, they initially asked the Biomedical team at dsm-firmenich to help them realize their vision of a porous collagen component and manufacture it at scale for their Class III device.

Why it matters

At the outset of the relationship, we used our skills, market knowledge, and experience to vet our partner's design and business plan. The decision to move forward with our partner's design and develop a unique component manufacturing process had the effect of validating our partner's product, leading to commercial success and eventually an acquisition.



Our innovation

To convert its product vision into a commercially viable set of solutions, our partner leveraged many of our core competencies, including:

- ✓ The timely creation of collagen prototypes enabled our partner to conduct a clinical trial of 2 unique components at the same time.
- ✓ Our cGMP processes as well as our ISO 13485 compliant facility and procedures yielded medical devices suitable for human use, enabling our partner to complete the clinical trial in 6 months.
- ✓ Our regulatory support specific to the collagen portion of the device helped to secure FDA premarket approval for a complete family of vascular devices.

Our impact

Following the success of the initial product launch, our partner chose to work with the Biomedical team at dsm-firmenich again to expand their family of vascular devices in order to address new, unmet clinical needs. Over the past 10 years, the number of Class III medical device components manufactured annually on behalf of our partner has grown nearly 2000%.