

Cook Biotech Incorporated Supplier assurance



Biodesign[®]
BIOLOGIC GRAFT PORTFOLIO



cookbiotech.com

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Introduction

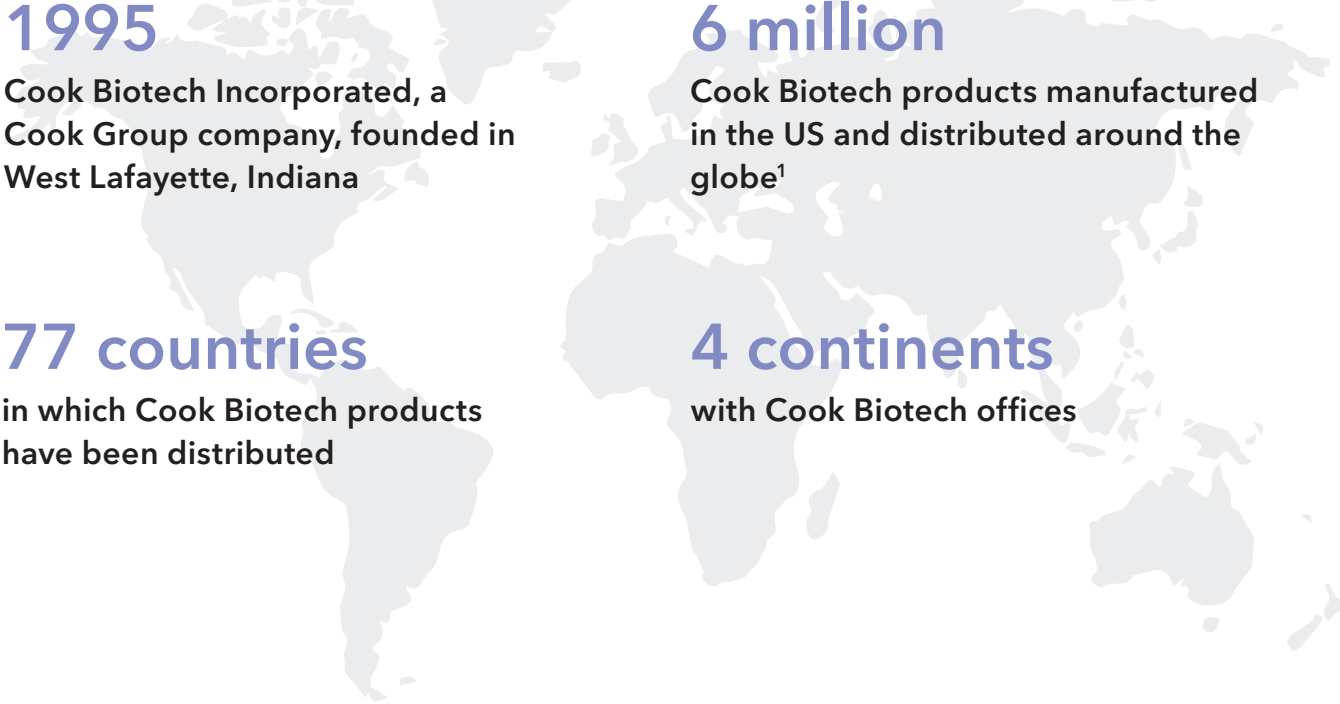
How Cook Biotech serves healthcare providers

From our early work on the beneficial properties of porcine small intestinal submucosa (SIS) to our current [Biodesign® Biologic Graft Portfolio](#), Cook Biotech Incorporated has been committed to meeting the needs of healthcare providers and their patients through product innovation, continuous improvement, and evidence-based practices for more than 25 years.

In today’s healthcare and supply-chain environments, medical device manufacturers must deliver more than excellent products. Our consistent, on-time supply of products helps healthcare providers achieve the lowest possible cost of care while providing a high-quality, efficient, and safe patient experience.

Cook Biotech’s quality policy is “to deliver quality products in a timely manner” through operational efficiency, customer satisfaction, and compliance with regulatory standards.

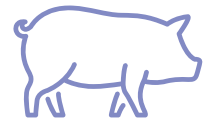
Cook Biotech at a glance



1. Internal Cook Biotech document: D00278582.

Tightly controlled, consistent supply

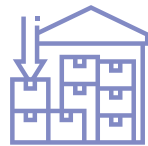
From the launch of our Surgisis® biologic graft product line in 1998 to our current Biodesign portfolio, Cook Biotech has always maintained a controlled, consistent supply of products for the US healthcare sector.



Certified animal production



On-site packing plant inspections



Robust, continuous inventory management



History of minimal back orders

Our most crucial raw material is porcine small intestines, and our long-term relationships with hog production facilities ensure that we have a constant supply. These facilities are audited by Cook Biotech and a consulting veterinarian to ensure that hogs are raised to internal specifications and herd health standards.

These hogs are then shipped to Cook Biotech-qualified packing plants that are inspected on-site by the USDA. Small intestines are carefully harvested to Cook Biotech requirements; our tissue-sourcing program meets the standards of ISO 22442. The hog production facilities and packing plants we work with are geographically dispersed and have excess capacity to meet our growing needs.

The Cook Biotech manufacturing system continuously monitors the inventory of all critical components and supplies to ensure that we always have enough material to make the products you need for your patients.

We actively engage with our suppliers to understand lead times and potential supply disruptions, and we have redundant suppliers for critical items.

We have a long history of minimal back orders for Biodesign biologic grafts. In fact, throughout the COVID-19 pandemic, there were no product disruptions due to back orders of components or supplies.

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Manufacturing process

Our SIS is produced by our highly trained, skilled production staff with minimal manufacturing automation.



When we process SIS, we remove contaminants such as bacteria and cellular debris while maintaining the structure and components of the extracellular matrix (ECM).

The manufacturing process does not include chemical processes like cross-linking. Biodesign biologic grafts undergo controlled drying processes, such as lyophilization, which make them ideal for storage at room temperature with no special storage requirements.



Unlike many biologic products, Biodesign biologic grafts are designed for specific clinical applications. The products are tailored to meet specific mechanical, handling, and procedural needs and are suitable for open, laparoscopic, and robotic applications.



Flexibility and excess capacity are built into our manufacturing system, which allows us to react to market needs in a dynamic manner while maintaining a consistent supply. This agile and robust manufacturing process is the product of our continuous improvement culture, which is built on advanced manufacturing principles like Lean manufacturing.

We have systems in place to proactively monitor customer demand and adjust manufacturing accordingly. This gives us the ability to react quickly and efficiently to changes in demand and provide accurate lead times for our customers.

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Product delivery



Our logistics pathways ensure that products arrive to you in a timely and consistent manner. By utilizing multiple shipping partners and national distribution networks, we can maintain efficient supply while aligning with your specific purchasing needs.

Quality and safety

Cook Biotech is an FDA-registered medical device manufacturer (#1835959). All devices in the Biodesign Biologic Graft Portfolio have FDA 510(k) clearance. To date, we have 175 clearances and licenses worldwide. We are also proud to participate in the [FDA Case for Quality VIP Program](#).

Additionally, we hold the following accreditations:

- ISO certification: ISO 13485*
- MDSAP certification*

In addition to complying with US quality standards, we comply with standards in the 76 other countries where we supply products. This means that we are constantly aligning with global authorities so our products meet the highest standards of quality and safety.

Cook Biotech has a formal customer complaint and post-market clinical follow-up program for its products. This information feeds into the product risk management process, which evaluates the product risk profile.



Cook's Supplier Risk Dashboard monitors our ability to manufacture and deliver products and provides supply-chain visibility to customers.

Additionally, we monitor our ability to manufacture and deliver the product to you. This analysis is performed via Cook's Supplier Risk Dashboard on the [Cook Customer Portal](#), and these data are monitored and reviewed by executive management to ensure that the products distributed meet risk acceptance standards.

*Available at [cookbiotech.com](#)

Summary

We recognize that confidence in on-time supply is vital to meeting the needs of your patients. Our robust processes ensure that you receive the products you order when you need them.

Cook Biotech is a proud member of the Cook Group family of companies. Our commitment to patients and the healthcare providers who serve them drives everything we do, from the development of new technologies to the delivery of medical devices. We are here to meet your ever-growing supply needs.

To learn more about our company, principles, and products, please visit [cookbiotech.com](#) or speak to your local Cook Biotech representative.



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