

Medical Device Solutions

One partner, all possibilities for innovating life-changing medical devices



Your integrated solution provider for the medical device industry

Rooted in science, driven by continuous innovation and relentlessly committed to sustainability

Products and technologies from Evonik's medical device solutions portfolio empower companies to deliver on their promise of a healthier, fuller life to millions of people. We provide a one-stop platform for co-creating next-generation


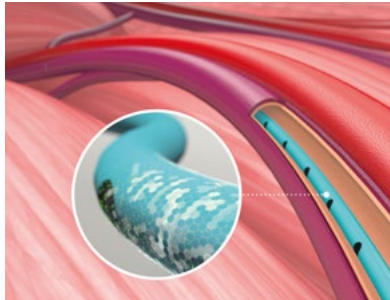
devices – from concept to commercialization, from engineering to process, from prototype to manufacturing – bringing them to market faster thanks to our global reach, manufacturing footprint and regulatory expertise.

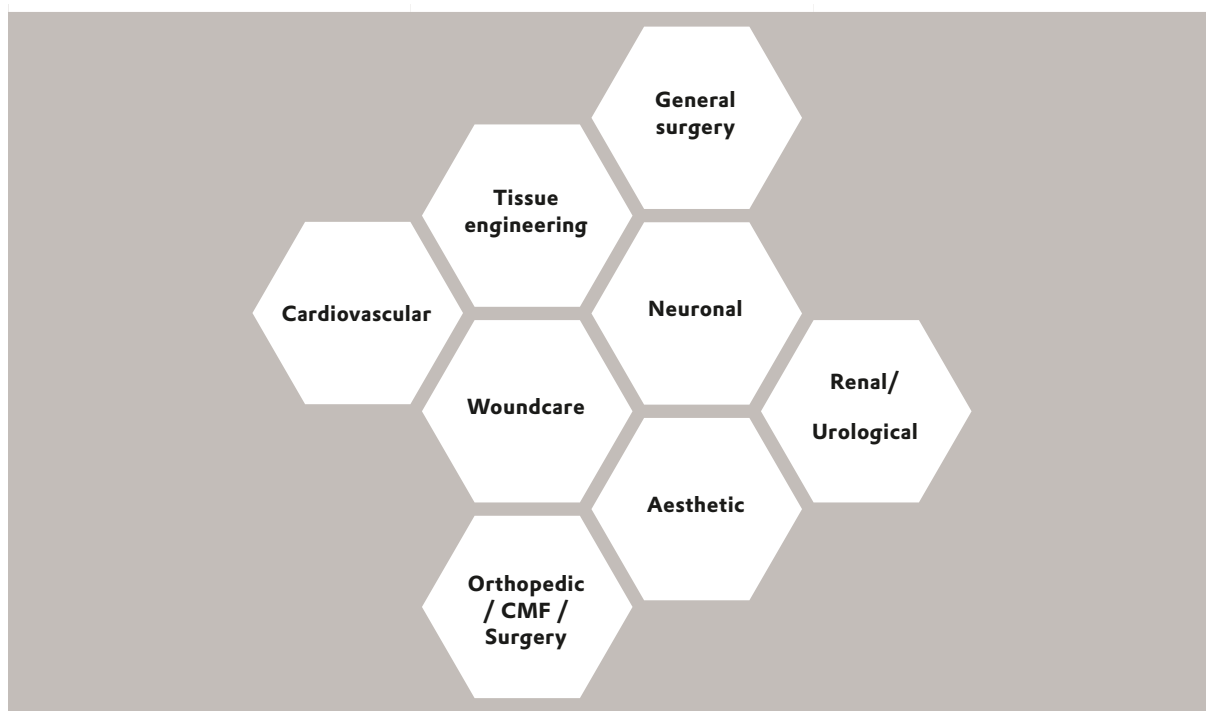
A strong value proposition in all relevant market fields

MANUFACTURING SOLUTIONS

APPLICATION TECHNOLOGY AND VALUE-ADDED SERVICES

A global network of regional labs and competence centers

Synthetic bioresorbable polymers RESOMER®	Nature identical materials biocellic+ Vecollan®	Surface modification technology Endexo®
		

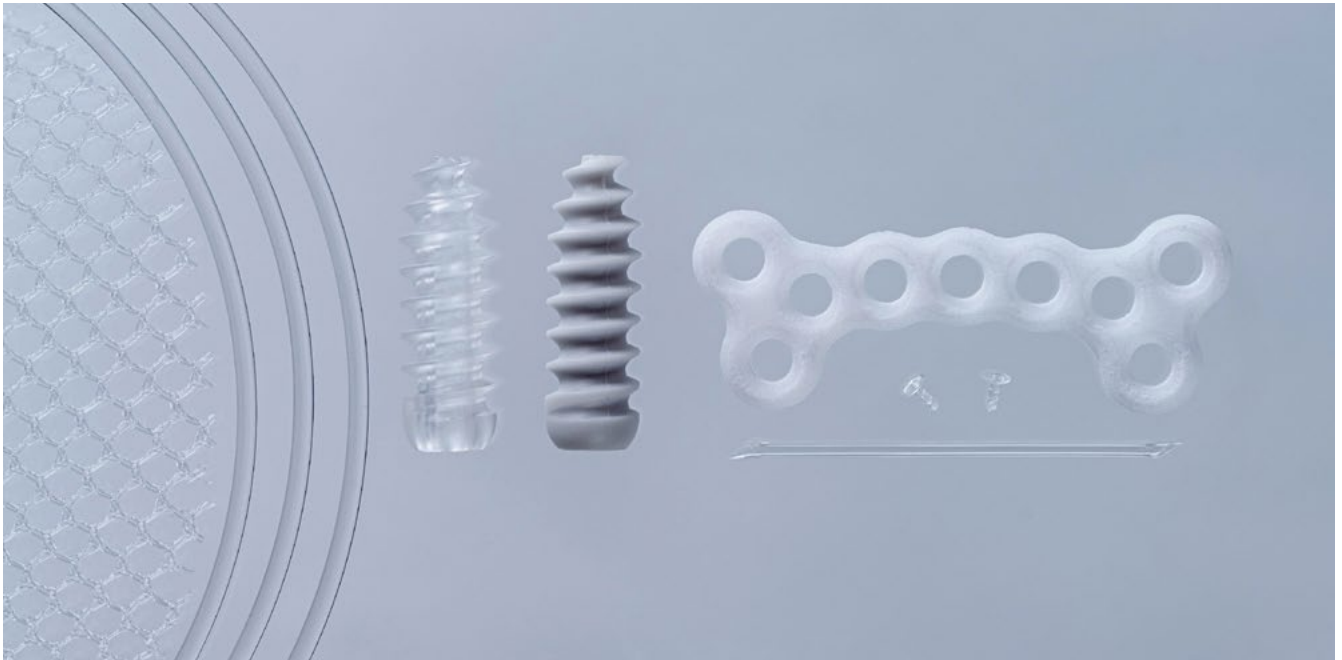


RESOMER®

Our portfolio of bioresorbable materials

RESOMER® brings together the essential polymer characteristics and versatility in mechanical and chemical properties that companies require to optimize the biocompatibility and functionality of implantable devices.

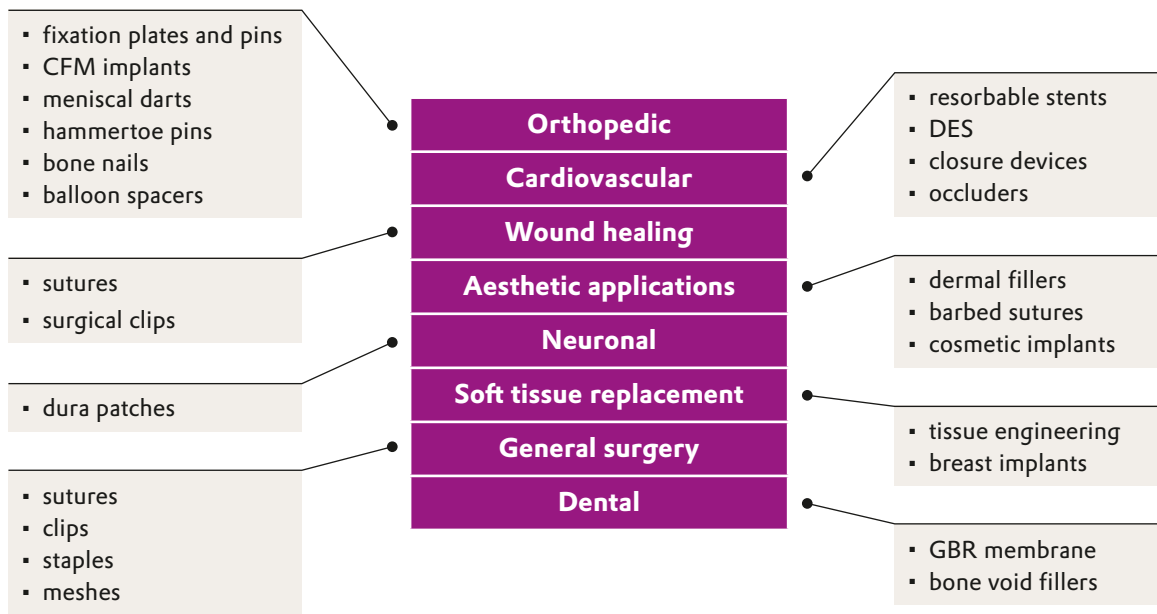
All catalog and custom polymers are 100% bioresorbable and completely metabolized by the body. With established safety profiles, they have a 30-year track record for commercial use across multiple application areas.



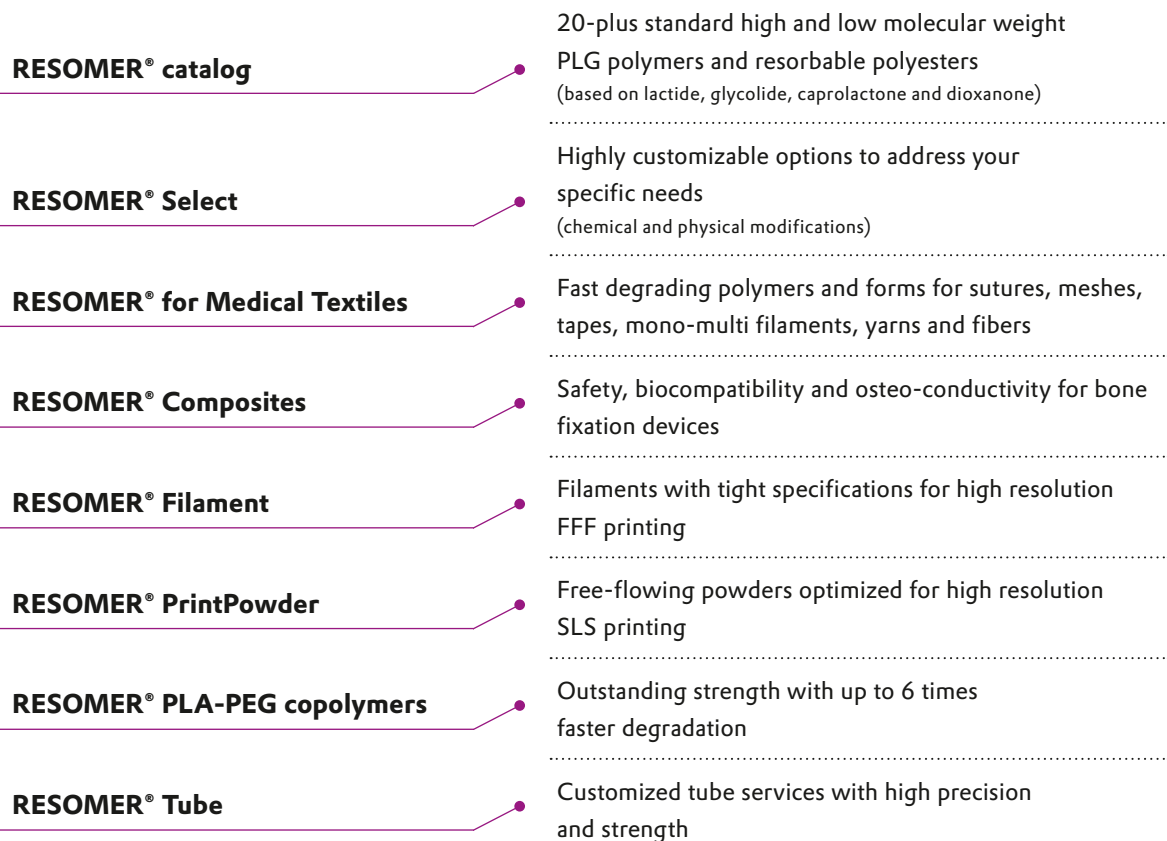
A broad portfolio of polymers for bioresorbable implant devices

- High-quality implants, resorbed by body to match target healing time
- Degradation times from < 6 months to > 4 years and long-term implants
- Highly versatile mechanical properties to match specific application requirements
- Processable by standard extrusion, injection molding, medical textile, 3D printing and electrospinning technologies
- Compatible with common sterilization techniques
- Average shelf life of 5 years

The portfolio's breadth and flexibility ensures that key requirements of the following applications are met

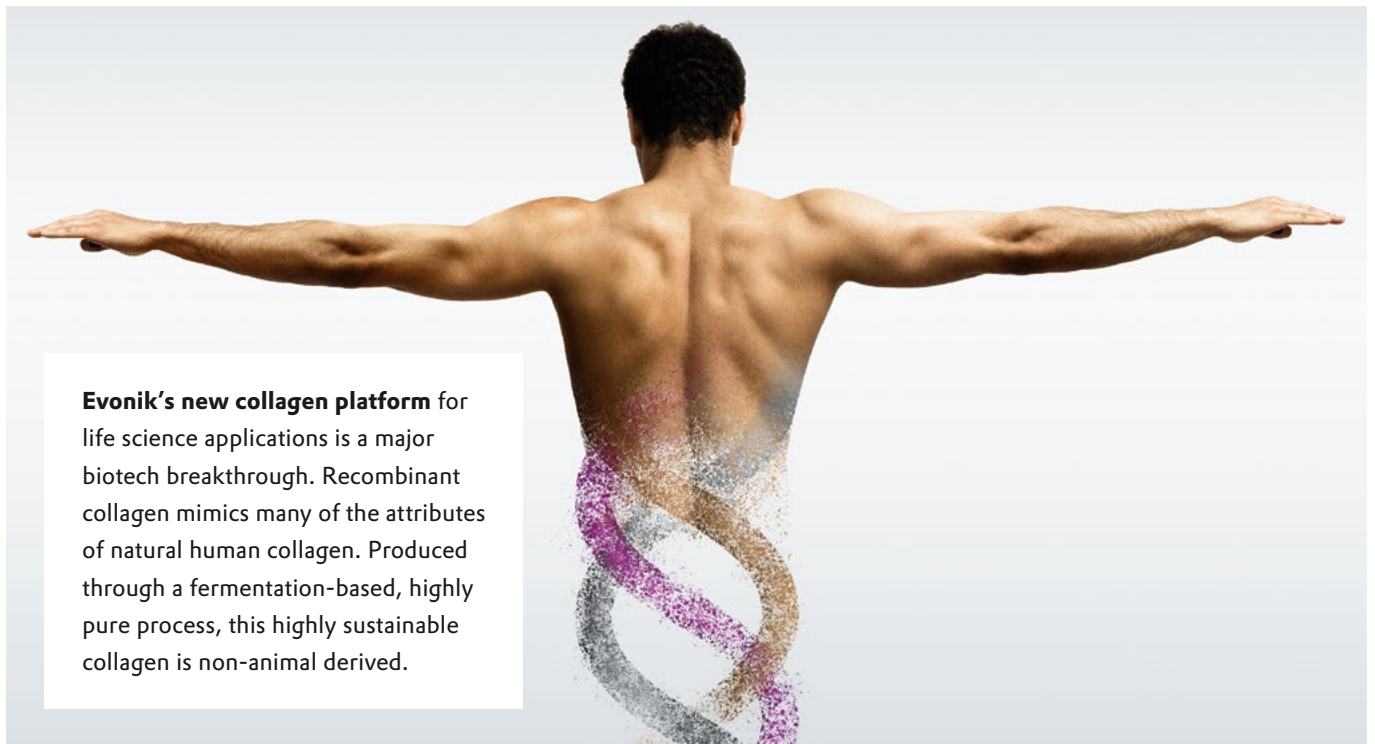


The RESOMER® portfolio offers a full range of standard, custom and specialized polymer solutions



Vecollan®

A unique, highly tunable vegan collagen platform technology



Evonik's new collagen platform for life science applications is a major biotech breakthrough. Recombinant collagen mimics many of the attributes of natural human collagen. Produced through a fermentation-based, highly pure process, this highly sustainable collagen is non-animal derived.

Your advantages with Vecollan®

A recombinant vegan collagen with excellent tolerability effectively substituting the use of animal-derived collagen.

Reproducible high quality created by a fermentation-based highly pure process

Highly adjustable platform technology with similar or improved performance to animal-derived collagen

Enables simplified and straightforward regulatory medical device authorization

Highly sustainable with a fully secured global supply chain

Possible areas of application

Diagnostics	Vascular
Hemostat	Cosmetic surgery
Cartilage repair	Bone graft
Wound care	Dental applications
Soft tissue repair	Tissue scaffold

Processible for a range of shapes and forms including

Powders
Solutions
Bioinks

Hydrogels
Fibers and meshes
Sponges



biocellic+

A nature-identical biosynthetic cellulose for wound care and more

Our biosynthetic cellulose is a natural, non-animal derived, fermentation-based renewable biopolymer. Its homogenous network structure and high fluid absorption makes it suitable for a variety of medical and pharmaceutical applications. Forms include membranes, films, fiber suspensions and more. The properties of biosynthetic cellulose can be adjusted during biosynthesis, allowing tailormade product design.

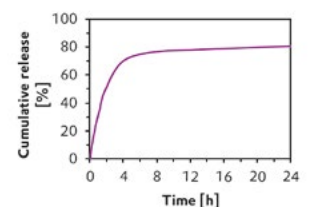
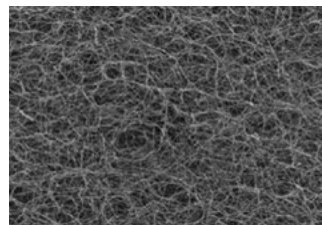


Our base material biocellic+ can be used in medicine, cosmetics, and dermatology

Characteristics

- Non-animal derived
- Medical / Pharma grade materials
- Highly reproducible properties
- IP-protected production process
- Chemically pure cellulose

Biosynthetic cellulose is a platform for high-value-added products



WOUND CARE

- Healing promoting moist environment
- Pain reduction/mild cooling
- Easy handling, high wearing comfort, painless removal
- Burn treatment
- Acute and chronic wounds

SKIN CARE

- Supports the regeneration of the skin
- Soothes skin irritation
- No preservatives or additives
- Purely natural
- Dermatology

IMPLANTS

- Nature-identical structures
- Reduces fibrotic tissue
- High mechanical stability for long-term applications in the human body

DELIVERY SYSTEMS

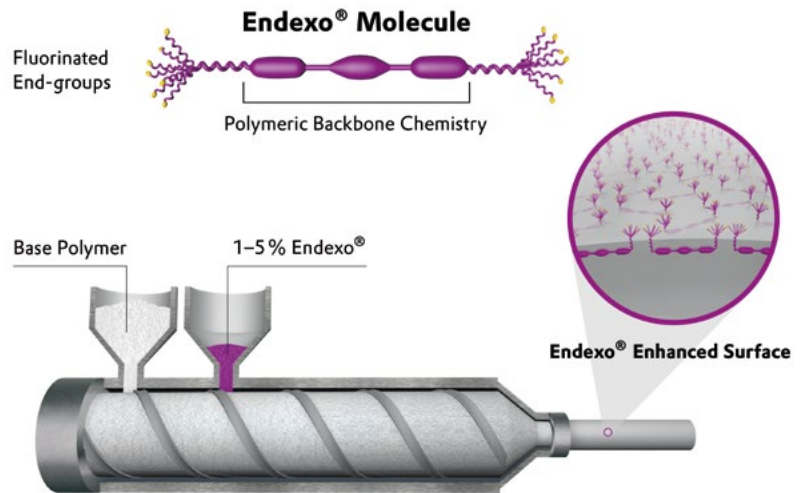
- Controlled loading and release of active ingredients
- Typical biphasic release profile (initial burst and plateau phase)
- Transdermal drug delivery

Endexo®

Surface modification for enhanced biocompatibility and performance

Implantable or externally communicating medical devices are subject to biofouling such as protein or bacterial adhesion, immune cell adhesion and the deposition of inorganic precipitates from biological fluids. These events can lead to clinically significant complications including thrombosis, infection, encrustation, and device failure. Endexo® is a surface modification technology that creates a unique surface chemistry.

MANUFACTURING PROCESS



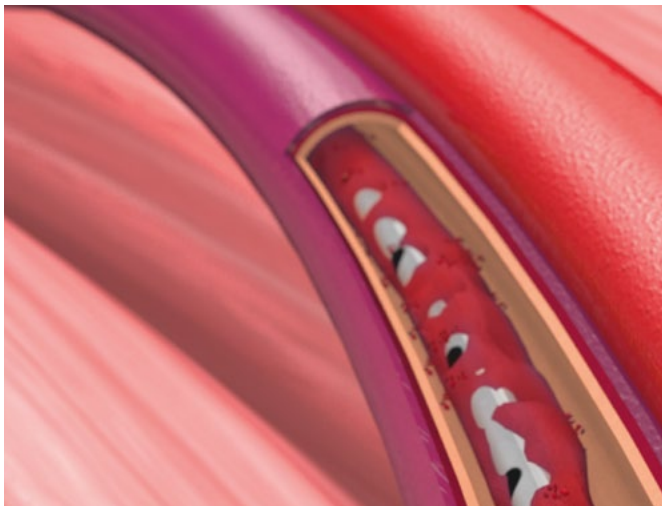
Multi-functional surface modification to enhance device performance in the target application

Up to **99%**
reduction in platelet adhesion
and thrombus formation

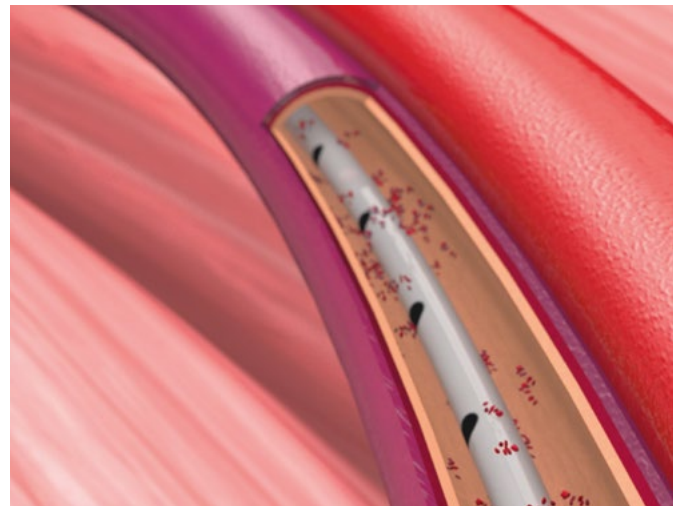
Up to **5 log**
reduction in bacterial adhesion
across multiple species

Up to **50%**
reduction in bacterial
mediated encrustation

Up to **97%**
lower coefficient of
friction (CoF)



Standard device



Endexo®-modified device

- Highly versatile platform of anti-thrombotic and anti-fouling additives
- Passive, stable, uniform and durable surface protection with no elution
- Compatible with a range of base polymers and standard manufacturing processes
- Clinically proven across multiple applications over more than 10 years of commercial use

Application technology and development services

The expertise to reduce project complexity, accelerate speed to market and enhance device performance

- Material testing to demonstrate product performance
- Development of mechanical property information
- Process development support and prototyping
- Critical material engineering expertise
- Technical training at our application labs
- On-site scale-up and production support

Our application technology services

Material selection and customization

- Chemical composition
- Molecular weight
- Additives

Prototyping and processing

- Compounding
- Injection molding
- Extrusion
- Medical textile
- 3D printing

Analytical services

- Analysis and characterizations
- Mechanical testing
- Sterilization support
- Degradation studies
- In vitro data support

Quality and regulatory documentation

Biomaterial solutions for target application

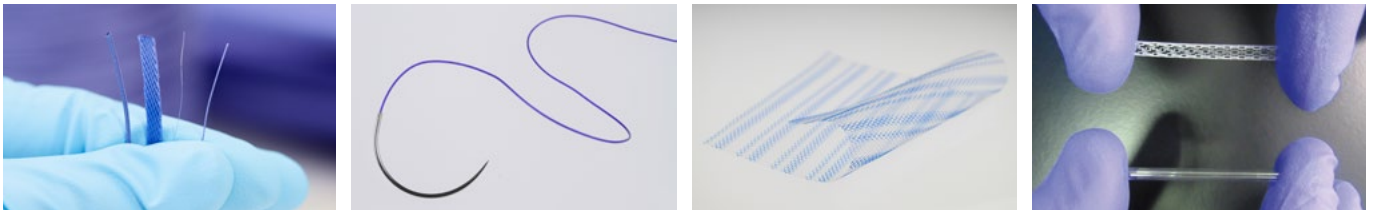


For supply security and to ensure our proximity to our customers, we operate a network of facilities in the **U.S.** (**Medical Device Competence Center (MDCC)**, Birmingham), **Germany** (**Medical Device Application Lab**, Darmstadt and **JeNaCell**, Jena) and **China** (**Medical Device Application Lab**, Shanghai)

From development to manufacturing of implantable products

Fully integrated solution provider with specialized manufacturing capabilities and a global footprint

- Individual customizable biodegradable materials
- Compounding services for individual customer requirements
- Extrusion manufacturing services: filaments, tubes, sheets, rods
- Textile manufacturing services: Mono- and multifilament yards, sutures and thread-lifts, meshes and tapes, foils/ membranes and non-woven
- Manufacturing services for biosynthetic cellulose-based devices
 - Various qualities, shapes, sizes and dimensions possible
 - Formulation development for the realization of loading ingredients into biosynthetic cellulose
 - Incorporation of various (active) ingredients into biosynthetic cellulose for medical or cosmetic purposes
 - Loading and release studies of biosynthetic cellulose



We provide a global quality system combined with robust regulatory support

QUALITY SERVICES

- Full service analytical labs in-house
- Documentation with each shipment
- Certificates of Analysis
- Material Safety Data Sheets
- Analytical reports (development)
- Quality and supply agreements available

REGULATORY SUPPORT

- Appropriate Master Files (MAFs) maintained as Required
- Technical Dossiers

EVONIK

QUALITY STANDARDS

- ISO 9001 & 13485 Certification
- IPEC-GMP Good Manufacturing Practices Guide for Pharmaceutical Excipients, 2009

This information and all further technical advice are based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

RESOMER®, Endexo® and Vecollan® are registered trademarks of Evonik Industries AG and its subsidiaries.

Biocellic® is a registered trademark of JeNaCell GmbH.

202210