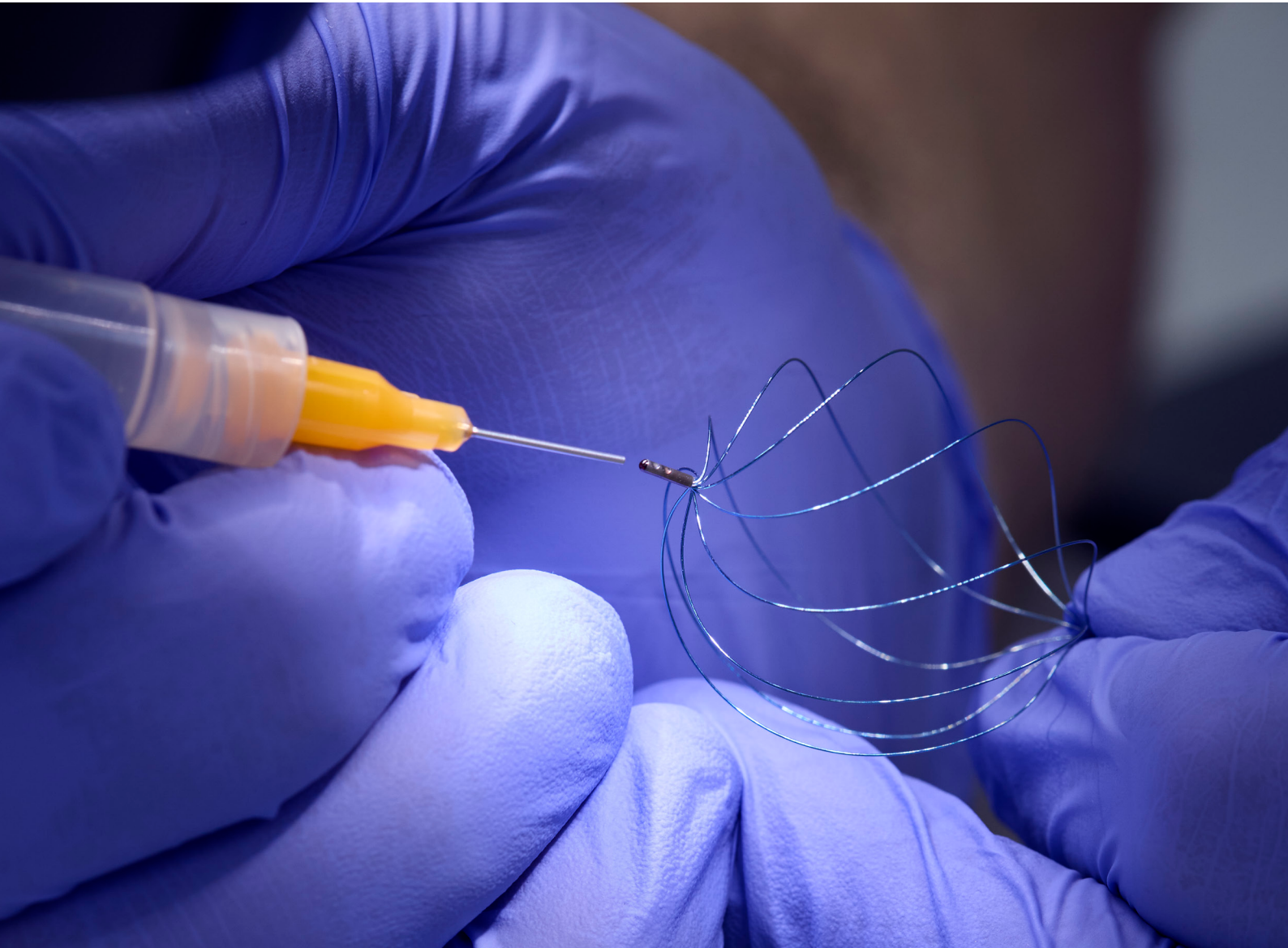




Contract Development

Innovation starts with your idea.

«We had our first near-production prototype within minutes – and we were genuinely impressed, not only by the speed, but by how seamlessly we were able to test ideas, thanks to the close collaboration between engineers and production operators within the same room.»

R&D Project Leader, MedTech Start-up

Bringing an idea quickly to a near-series product requires expertise, close collaboration, and open dialogue — allowing us to guide our customers from vision to market-ready medical technology solutions.

A passionate team of experts, supported by modern, fully equipped facilities, assists you in design, regulatory compliance, and production. This way, we create added value for you, your patients, and the future of healthcare.

In addition, we offer our customers a diverse standard portfolio of guidewires, stone retrieval instruments, and other medical components for minimally invasive interventions.

As a second-generation family business, EPflex has successfully been a leading innovator in the industry for more than 30 years. Still growing, we now employ over 400 staff members.

UNSERE LEISTUNGEN

- Contract Development
- Sampling and series production
- Standard portfolio and collaborative product development
- Different packaging options (bulk/dispenser/sterile)
- Made in Germany
- **CE** certification possible for selected products and specific applications
- **DIN EN ISO 13485** certification





YOUR BENEFIT

With our highly skilled team of experts, in-house production capabilities, and an exceptionally flexible approach, we provide a range of advantages to guarantee the success of your development project.

MODULAR CONCEPT

- modular concept enables project scope from proof of concept studies to full ISO 13485/21 CFR 820 compliant medical device development and regulatory approval
- from single component up to finished devices
- customer specific development or individual adaption of EPflex devices

NEARBY SERIAL PRODUCTION

- access to stock of thousands of materials and supply chain of our serial production
- serial production at the same site allows for swift design transfer to serial production
- One-Stop-Shop: development and scalable serial production from one supplier with continuous process optimization

DECADES OF EXPERIENCE

- specialized in instruments for minimally invasive surgery, such as: guide wires, stone retrieval devices, stent and valve delivery systems, bioptomes, thrombectomy devices & many more
- regulatory approval/support for Europe, Asia, Africa, North and South America

OUR KNOW-HOW

Leverage our extensive expertise throughout the entire development journey — from the very first idea to a fully approved medical device.



Product
Design



Prototyping



Design
Verification



Design
Validation



Design
Transfer



Regulatory
Approval

OUR CAPABILITIES

Our expertise, facilities, and infrastructure ensure seamless product development — all from a single source.

TECHNOLOGY CENTER

- 380 qm lab
- 160 qm office space
- maker space
- chemical lab
- test lab
- rapid prototyping
- black zone
- ex-vivo/phantom suite
- meeting point

INHOUSE TOOL SHOP

- 440 qm tool, machinery and production line construction
- CAD
- SPS
- assembly
- micro milling
- drilling
- turning
- welding

TEAM

- mechanical, chemical, design and test engineers
- product designers
- tool manufacturers
- material and biocompatibility experts
- regulatory and clinical affairs specialists

OUR TESTING SERVICES AT A GLANCE

To complete our portfolio, we provide a variety of in-house testing procedures, giving your prototypes a thorough evaluation.

Please note: EPflex is not certified or accredited as a testing laboratory for the tests listed.

DEVICE TESTS

Guidewire specific (DIN EN ISO 11070)

- fracture test
- flexing test
- tensile strength test
- corrosion test

Dimensional attributes

- diameter
- length
- markings
- tip shape

Other tests

- Visual evaluation incl. coating integrity
- Material and bond strength testing
- Functional testing
- Application simulation as preconditioning possible

STERILE BARRIER SYSTEM - PACKAGING

- peel test
- foil strength
- seal strength
- seal seam integrity

SHELF LIFE & STABILITY

- accelerated aging
- real time aging

IN COOPERATION WITH OTHER TEST LABORATORIES AVAILABLE

- biocompatibility ISO 10993
- radiopacity
- MR compatibility
- transport simulation
- microbial barrier





EPflex is one of the world's leading manufacturers of components for minimally invasive medicine.

We develop and produce state-of-the-art instruments of the highest quality for various procedures – made in Germany.

With our innovative medical products, we push the boundaries of minimally invasive surgery every day. For patients, this means shorter procedures, less pain and faster recovery.

OUR MANUFACTURING TECHNOLOGIES

- Coating (PTFE, hydrophilic, ...)
- Electrochemical Marking
- Electropolishing
- Gluing
- Grinding
- Laser Marking
- Sandblasting
- Shrinking
- Turning & Milling
- Welding (Laser & Plasma)
- Wire Forming

FURTHER BROCHURES



GASTRO



PACKAGING



URO



VASCULAR SURGERY

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