ADMEDES
IDEAS. EXPERTISE. PASSION.

IDEAS.
EXPERTISE.
PASSION.

admedes.com

CONTENT.

LIVERMORE, CALIFORNIA, USA FACILITY

- Production since 2010
- 20,000 square feet (1,850 square meters)
- Rapid Response prototyping and commercial production of laser cut nitinol components
- ISO 13485 / FDA registered

PFORZHEIM, GERMANY FACILITY

- 300,000 square feet (30,000 square meters)
- Rapid Response prototyping and production of components from nitinol tubing, sheet and wire
- Full test lab, microassembly, silicone coating services
- ISO certified cleanrooms
- ISO 13485 / FDA registered

Executive Management Team: Dirk Heining, Dr. Axel Pfrommer, Frank Nauheimer

WELCOME TO ADMEDES.

As a customer-centered company, we view ourselves as an extension of your team. That means we keep your best interests in mind at every turn so that we – and you – feel confident that every project we undertake together achieves optimal success.

The collaborative spirit of our in-house engineers, scientists, materials experts and quality staff plays a vital role in every project. Working with you closely allows us to align your product timelines and clinical milestones to the necessary process design controls. We also keep our eyes on manufacturability to ensure that each component is engineered for quality, reliability and cost-effective manufacturing.

As the world's foremost manufacturer of finished nitinol self-expandable components to the medical device industry, we offer everything needed to take your idea from infancy through full-scale production. In addition to our consultative approach to design for manufacturability, you benefit from our:

- Industry-leading Rapid Response prototyping Center that turns concepts into prototypes within days.
- Large and experienced team of engineers, scientists and process experts who provide insight and guidance at every development phase.
- Full-service in-house test lab staffed by materials scientists and analysts who help you choose the best materials for your product and help verify and document material integrity.
- Lean manufacturing experts who assure competitive commercial production.
- Comprehensive array of micromanufacturing and microassembly technologies.
- Stable, long-term relationships with top-quality nitinol suppliers and other material vendors.
- Quality system that both complies with the FDA's Quality System Regulation and ISO 13485 and goes beyond compliance to help your project achieve its milestones.
- Long-term employee tenure and a very low turnover rate, which provides stability and continuity to our customers.
- Ongoing investments in people and technology that keep us at the leading edge of innovation.
- German and U.S. facilities that provide business redundancy and convenience.

Fast Facts

- Founded in 1996
- Headquarters:

  ADMEDES GmbH

  Rastatter Str. 15,

  75179 Pforzheim, Germany
- U.S. Subsidiary:

  ADMEDES Inc.

  2800 Collier Canyon Road,

  Livermore, CA 94551, USA

IDEAS.

No matter where you are on the journey to market – from a roughly sketched concept to a product ready for full-scale manufacturing – our ideas speed you to your goal.

Our ideas have helped clients bring hundreds of products to market.

Every project begins with an idea – your idea. Our job is to turn that idea into a medical device component that matches your vision, delivers optimum performance and is easy and cost-effective to produce.

supporting and manufacturing finished nitinol medical implants and components for clients worldwide. Our scientists, engineers and materials experts share their ideas with you to ensure you receive quality products that further your success.

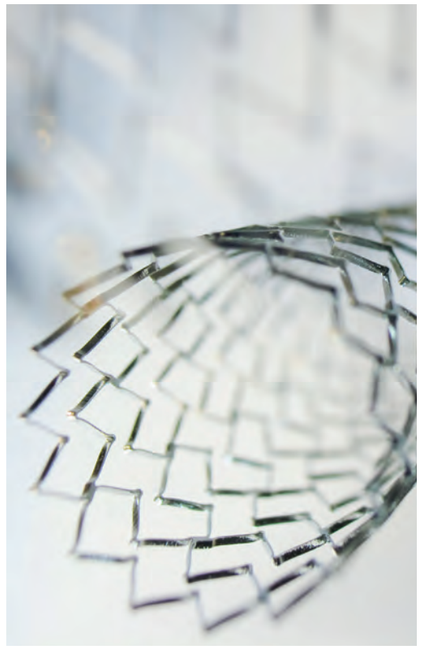
How your idea evolves

Our process begins with a critical first step. We learn everything we can about your concept and its application. Our engineering experts read your specification carefully, listen attentively and ask questions. Once we understand your idea, we present our thoughts on how to cost-effectively produce a component that meets the highest performance standards. Our engineering, test lab and Rapid Response prototyping services allow us to work with you to test and refine designs until we achieve an ideal result.

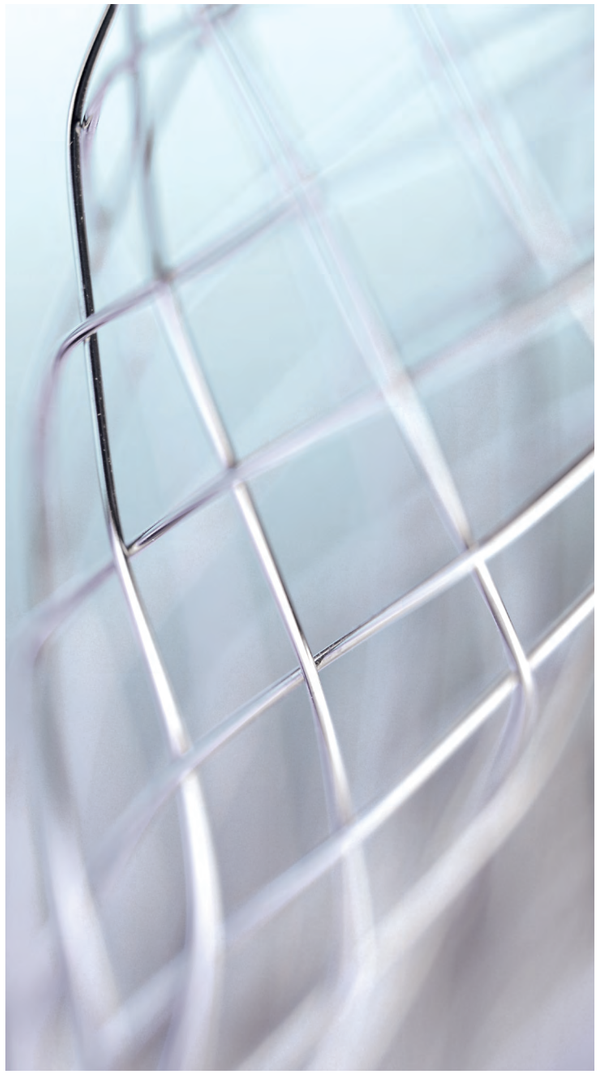
Where our ideas come from

Just as your ideas are born from intimate knowledge of your field, our ideas are grounded in experience advising,

- Heart valve frames and devices
- Peripheral arterial stents
- Coronary and neuro stents
- Venous stents
- Endovascular aneurysm (EVAR and TEVAR) components
- Pulmonary stents
- Gastroenterology stents
- Delivery system and catheter components
- Orthopedic devices
- Ophthalmologic devices
- Distal protection devices
- Vena cava filters
- Bypass connectors
- Ventricular-assist components



"AT ADMEDES, WE BRING OUR EXPERTISE AND PASSION TO YOUR IDEAS."



EXPERTISE.

Owning the best equipment does not make a great company, any more than owning the finest ball makes a champion team. It's the skill and dedication of our people that make ADMEDES one of the world's leading manufacturers of nitinol and other metal-alloy medical implants and components.

One of our unique features is the high percentage of our employees who are engineers or scientists. That engineering focus and material expertise benefits customers by allowing us to continue refining process designs to ensure each component is optimized for cost-effective production and long-term stability following implantation.
Today, we offer services that fully support the metal-alloy component needs of medical device companies around the world, including providing efficient project management that ensures you meet your project timelines.

Research and development
Our deep understanding of the medical device industry also drives us to continue improving and expanding our capabilities to meet current and emerging demands. We employ an advanced research and development group that constantly explores and tests new technologies and manufacturing processes to enable new applications, materials and design options.

Reduced time to market
At each phase, you interact with experts who will answer your questions and recommend actions based on their years of experience producing medical device components for life science companies. The combination of our experience, engineering capabilities and equipment selection enables you to quickly move components from development prototyping to large-scale manufacturing.

- Rapid Response prototyping
- Prototype, clinical and full-scale production
  - » Laser-cut component manufacturing
  - » Wire braiding and forming
  - » Microassembly
- Test lab services
- Quality department support

We offer a full array of technologies and manufacturing processes to produce medical devices and components. Even more important, we bring the skill and experience to accelerate your project.

PASSION.

Our engineers look at each new project as a chess master views a worthy opponent over an unplayed board. An air of excitement surrounds the chance to tackle a challenge that will test their skills and push them to think beyond the known boundaries.

At ADMEDES, we bring our expertise and passion to your ideas. By working closely with you, we smooth your path from concept to commercialization.

Our engineering team is far from alone in its passion for perfection. Innovation is encouraged and rewarded throughout ADMEDES. Anywhere you look, you'll find people committed to excellence in their jobs, while also searching for better ways to accomplish your objectives.

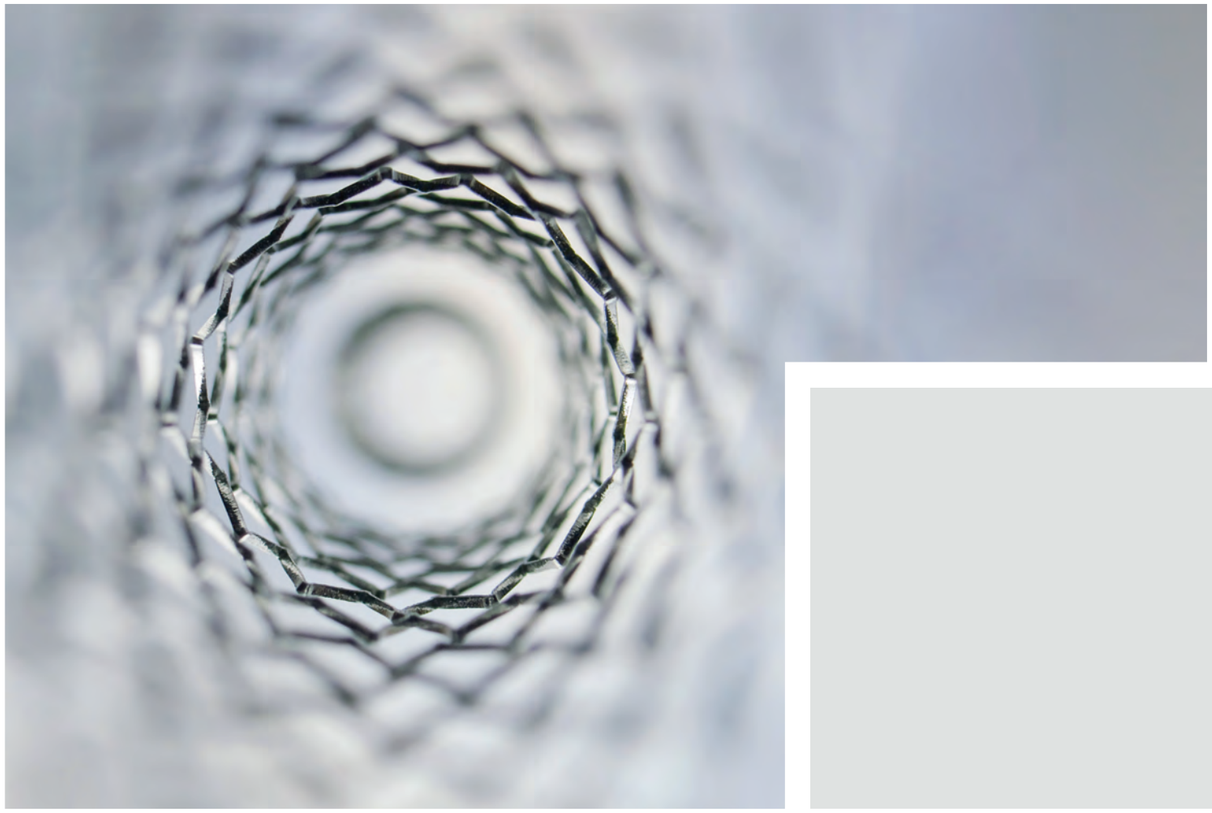
Proud traditions

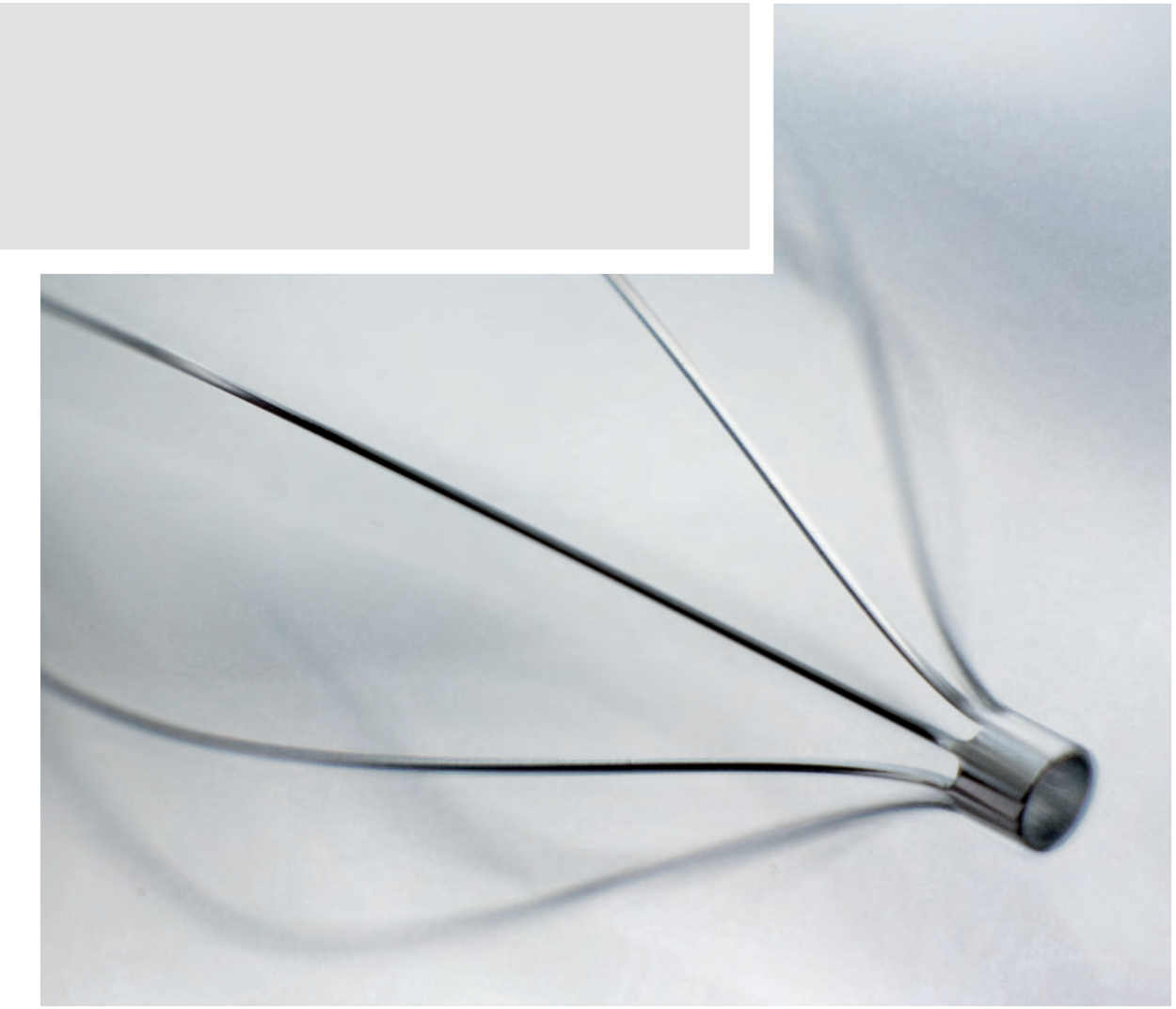
German engineering is celebrated around the world for good reason. At ADMEDES in Germany and the U.S., we proudly embrace that tradition. Efficiency, discipline, perseverance and the desire to pioneer advances are valued virtues. And no other industry requires those qualities more than medical device manufacturing.

We also embrace open discourse. Within the company and in our interactions with clients, our openness manifests as straightforward honesty, disciplined scheduling and a no-nonsense approach to achieving goals. We understand that you are both busy and budget conscious and we believe that our approach honors your need for swift, cost-effective solutions.

Passion for people

Finally, we are deeply invested in our employees and customers. We hire the finest people for each position and provide them with the tools and training to perform at their best. The appreciation and respect we show our employees translates directly into the care and service they provide to you, our valued customer.





RAPID RESPONSE PROTOTYPING.

Time equals money when turning an idea into a marketable medical device. To accelerate your journey to profitability, we created a Rapid Response department staffed with some of our best engineering, material and technology experts. Our Rapid Response team works hand in hand with you to convert your idea into a prototype – within a few days.

Whether you bring a sketch drawn on a napkin or a sophisticated 3-D engineering model, we go through development with you to arrive at a prototype design that delivers what you want with optimized manufacturability. The department is well-equipped with laser cutting, wire technology and microassembly capabilities and works closely with our test lab team and experts throughout the company to deliver top-quality prototypes.

Refinement process

At the next stage, the initial prototype undergoes testing and inspection, providing data we use to move toward a more refined design, which we translate into a next-generation prototype. We continue the design-and-refine process until your idea is ready for benchtop and clinical testing.

We never sacrifice details for speed. Instead, we record each step so that you can provide documentation when presenting your idea to internal stakeholders, investors and regulatory agencies.

- Dedicated team of engineers and other experts
- Access to test lab and hundreds of ADMEDES engineers and scientists
- Laser micromanufacturing capabilities: Ablating, cutting, profiling and drilling
- Wire braiding, winding and shape setting
- Capability to handle various geometries: flat sheet, tubular, alternate profiles and wire
- Surface finishing

Rapid Response prototyping is more than a department title. It’s our promise to deliver your prototype within a few days.

LASER TECHNOLOGY.

ADMEDES customers benefit from the deep process know-how we have earned since our founding in 1996. We were among the first to use lasers to fabricate nitinol medical device components and continue to be the industry's laser technology leader.

The depth and breadth of experience we bring to laser cutting can give you an important competitive advantage.

Throughout our history, we have advanced the science of laser cutting to produce countless components from nitinol and other structural and functional materials. Expertise gained from that experience makes it possible for us to streamline even the most complex development projects and refine product designs to facilitate high-yield, rapid-throughput manufacturing.

Technology selection

Today, our array of fiber-pulsed and ultrashort-pulsed lasers allows us to cut complex geometries for devices ranging from large, rigid heart valve frames to highly flexible and fragile neuro devices. Our skill, capacity and range of laser technology shorten your time to market by enabling us to select the best technology and create and refine prototypes with surprising speed. Following development, we offer ample capacity to move your device into full-scale production.

Special capabilities

We have developed a number of processes that enhance precision and extend the horizon of possibilities. If you feel your idea reaches beyond what is currently achievable in the industry, contact us. We welcome the opportunity to take on your challenge.

- Lasers: Fiber, ultra-short pulse, Nd:YAG
- Laser welding: various material combinations
- Surface finishing: Electropolishing, patented blue oxide treatment, microblasting, chemical etching and polishing, mechanical polishing, passivation
- Materials: wide range of materials
- Material formats: Tube, sheet, strip, foil, wire, rods
- Tubing outer diameter: 0.2 mm to 40 mm
- Tubing wall thickness: 20 µm to 1 mm
- Minimum kerf width: 5 µm
- Minimum possible strut width: < 25 µm

"WHEN OTHERS TELL YOU AN IDEA CAN'T BE MANUFACTURED, WE VIEW IT AS A CHALLENGE."

"OUR BRAIDING CAPABILITIES ALLOW YOU TO CREATE UNIQUE, COMPLEX AND VARIED STRUCTURES."

WIRE TECHNOLOGY.

Our comprehensive selection of wire technologies helps our customers meet the widest array of medical applications. Capabilities include wire processing, forming, braiding and winding, as well as surface treatments that enhance biocompatibility and durability.

As medical science advances, we support our customers who are creating the next-generation of implantable stents, filters and other devices. We work with you closely to achieve the best possible results, whether that requires conventional technology, any of our many patented and proprietary approaches, or something entirely new. We offer a broad array of wire technology capabilities.

Wire braiding
Interweaving or twining wire for conventional, flexible, closed-loop and single-wire braiding

Wire winding
Fully automated, tension controlled process produces high-quality and uniform dimensions, characteristics and surface finish in three dimensional structures.

Wire forming
Two- and three-dimensional shapes and unique structures in a wide range of wire diameters and types.

When you work with us, you gain access to the extensive capabilities and in-depth knowledge earned across our more than 20 years of design-for-manufacturing experience. Equally important, you gain an ally you can depend on for support and guidance at every turn.

- Braiding materials: Nitinol, cobalt-chrome, DFT composite
- Braiding wire diameter: 25 µm to 400 µm
- Winding wire diameter: 15 µm to 600 µm
- Winding wire material: wide range of materials
- Laser welding: various material combinations
- Crimping: various material combinations
- Shape setting: Conventional and proprietary tools and processes
- Surface finishing: Electropolishing (including patented blue oxide treatment), microblasting, mechanical polishing, passivation

The variety of wire technology we offer allows you to move effortlessly from initial prototype through full-scale production.

MICRO-ASSEMBLY.

At ADMEDES, our goal is to simplify your journey by providing all services needed to transform your idea into a premium product.

We bring our innovative approach to microassembly to ensure you achieve the highest quality in every finished piece.

Our microassembly team uses well-documented supply chain management and employs innovative finishing, joining and manual and automated production to combine components into devices. If a process does not exist, we also have the people, facilities and experience to build machines and tools to create new processes.

Supply chain management

Our start-to-finish services and long-term relationships with carefully chosen suppliers reduce your steps to market – saving time and costs. Working with us allows you to qualify a single supplier, reduces handling and inspections. Our rigorous documentation system also protects you from information gaps.

Joining

We join components using laser welding, certified adhesives, soldering and crimping. Our pioneering approach to device manufacturing has included developing novel processes proven to create more durable bonds.

Production

Whether manual or automated, prototype or commercial production, our production processes incorporate rigorous inspections to ensure each product meets superior quality standards. When needed, our facilities offer production and packaging services within ISO certified manufacturing clean rooms.

- Centerless profile grinding: Multi-tapered grinds, long taper grinds
- Laser welding: various material combinations
- Crimping: various material combinations
- Adhesive Bonding: UV curing acrylate, cyanoacrylate, 2K-epoxy, implantable adhesives
- Shape setting: Conventional and proprietary tools and processes
- Heat shrinking: PTFE, FEP/ PFA, PUR, PI, FPO, PEEK
- Coatings: Silicone
- Clean rooms: ISO 14644-1 certified with regular microbiological and particle monitoring

"IF A PROCESS DOES NOT EXIST, WE HAVE THE PEOPLE AND EXPERIENCE TO CREATE NEW PROCESSES."

"OUR ONSITE TEST LAB ENABLES US TO DELIVER FAST RESULTS ON STANDARD AND CUSTOMIZED TESTS."

TEST LAB SERVICES.

The components and devices we manufacture must stand up to unrelenting physical, biological and chemical forces. To help our customers deliver products that provide long-term efficacy, our in-house test lab team provides a full array of standard and proprietary testing methods.

As with all areas of our company, our test lab professionals employ the latest technology, stay abreast of emerging advances and apply their innovative skills to develop or improve test methods. We adhere to rigorous test standards that meet or exceed FDA, ASTM, CE and ISO criteria. We can also develop test methods to address unanswered questions.

Our test lab team works closely with the project team and with customers to provide standard or customized tests that deliver data that informs the development process. Ready access to onsite testing keeps projects moving quickly and along the right path. Ongoing testing during prototype, clinical and serial production plays a critical role in assuring quality. Testing categories include the following:

- Material
- Functional
- Analytical
- Metallography
- Surface characterization

Our experience working in the medical device industry means that you can have confidence in our ability to carefully document test protocols and findings to provide evidence of product performance.

- Finite element analysis (FEA) based on real data
- Corrosion testing
- Tensile and microtensile testing
- Torsion testing
- Radial-force and crush-force testing
- Fatigue testing
- Af temperature testing (BFR, DSC)
- Scanning electron microscope (SEM) investigation
- Energy-dispersive X-ray spectroscopy (EDX)
- Metallography: Grain size, inclusion size and distribution, heat-affected zone (HAZ) analysis
- Hydrogen testing
- Auger electron spectroscopy (AES)

Finite element analysis (FEA) is an essential part of our R&D toolbox, providing valuable data for concept selection, development and regulatory submissions.

QUALITY.

No industry faces a higher mandate for quality than medical device manufacturing. At ADMEDES, we understand that and we are proud that our history proves our commitment to quality. To date, several million ADMEDES products have been implanted in patients.

At ADMEDES, quality is a mindset demonstrated through countless actions that occur at every step – from initial prototyping through manufactured product delivery.

As an FDA-registered facility, we operate under the most stringent guidelines for quality assurance. Each customer receives an individualized inspection plan that conforms with regulatory directives and company requirements.

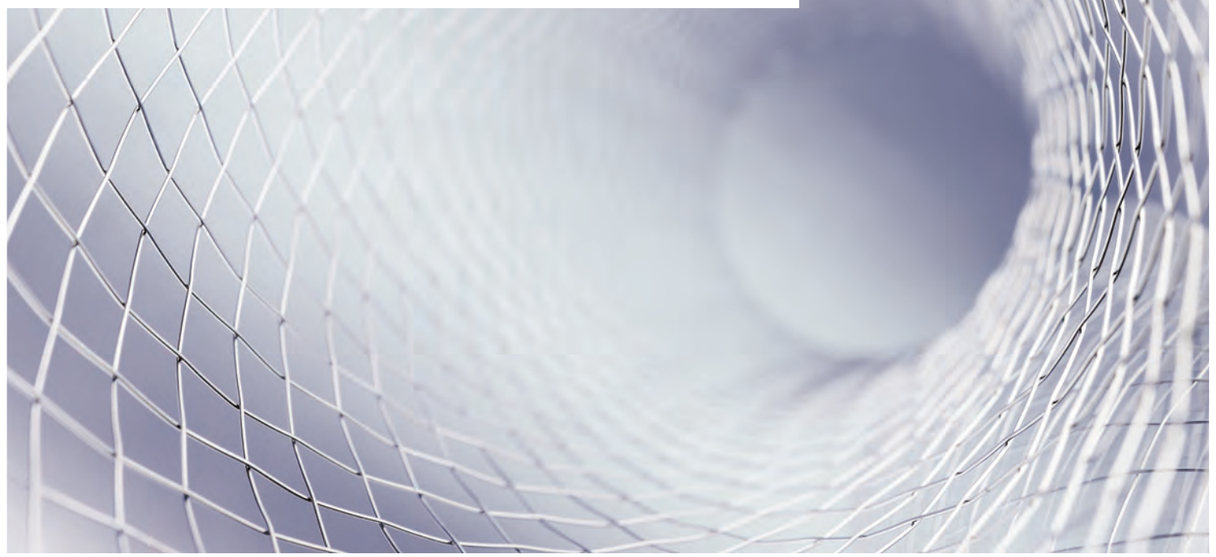
Maintaining a culture of quality

It's no accident that our focus on quality permeates every level of the company. New employees receive extensive training before beginning their jobs. We also provide ongoing training to refresh and further our employees' understanding of the parts they play in producing the finest medical devices available.

Quality-verification processes

Our quality system offers unparalleled oversight of the production process – from material sourcing to product delivery. We are the recognized leader in OEM nitinol component manufacturing, in part because of the care we take in selecting raw material sources and inspecting each piece we receive. As products move through design for manufacturing and into production, we test, inspect and validate. Each individual device undergoes functional testing, dimensional and visual inspection before release.

- FDA registered and audited
- Compliant with current FDA guidelines, including GMP QSR guidelines (21 CFR Part 820)
- Support for PMA, IDE & 510k approval processes
- DIN EN ISO 13485 certified



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