Nitinol Implant Design & Manufacturing

The nickel and titanium alloy known as Nitinol, is a super elastic shape-memory alloy responsible for major advances in medical technology over the last 15 years.

Nitinol is a highly elastic material that can be processed to maintain a desired geometry. These properties, combined with high fatigue resistance and its ability to provide constant force over a wide range of displacements makes it ideally suited for use in numerous medical implants and devices including:

- Vascular Stents (Cardio, AAA, Peripheral, Carotid, Venous, Neuro)
- Trans catheter Heart Valves
- Vascular Closure Implants
- Neurovascular Clot Pullers
- Devices and Flow Diverters
- Vena Cava Filters
- Orthopedic Anchors
- Atrial Fibrillation Devices

As well suited as Nitinol is for vascular implant applications, very few manufacturers are able to produce finished goods with it. The major barriers to working with Nitinol are:

- Nitinol knowledge: Working with the alloy requires extensive knowledge of the metal's mechanical properties and fatigue characteristics.
- Low machinability: As a raw material, Nitinol is very difficult to machine with conventional technologies. Multiple proprietary manufacturing processes are required to produce even the most basic Nitinol-based device.
- Electro-polishing and passivation: To protect against the harmful release of nickel into the human body, Electro-polishing or passivation are required to create a protective titanium oxide layer.
- Process validation: Nitinol implant manufacturing requires strict process controls and validation to meet the finished material specifications.

When pursuing a manufacturer to produce a new Nitinol-based implant or device, it is important to consider a number of decision factors:

1. RAW MATERIAL SOURCING

Before committing to any manufacturer, it's crucial to know how they will source Nitinol for a given project.

An Original Equipment Manufacturers' (OEM's) ability to supply the market with product is directly dependent on the contract manufacturer's ability to source the raw material required to maintain continuity of supply. A sustained disruption in supply is often catastrophic for OEM's. At a minimum, ensure the contract manufacturer will qualify and validate two sources of Nitinol for production. Any disruption in the material quality from the primary source can be quickly resolved by increasing supply from the second.

Equally important, the quality, type (sheet or tube) and characteristics of the Nitinol supplied by any given raw material producer is variable. The manufacturer who regularly sources material from many suppliers is able to best match the raw material to your design requirements and product application.

2. DESIGN FOR MANUFACTURABILITY (DFM) AND FINITE ELEMENT ANALYSIS (FEA)

It's important to evaluate product design specifications during the prototyping stage to identify opportunities to reduce cost without compromising the manufactured part's intended function. Any cost-reducing design changes must be implemented prior to design freeze.

For any prospective new device design, extensive design and testing services should be available to help the design engineer perform FEA. This ability to model and simulate mechanical behavior reduces the time needed between design iterations, a critical step in the race to bring products to market.

3. DEDICATED PROCESS ENGINEERING

Each manufacturing step requires the contract manufacturer to custom design that operation for any particular product design. This is done by designing, testing and refining the step using the same model and type of equipment and conditions that will be used in production. The capability to design and manufacture all shape-set tooling and fixturing for each process step in-house is essential to ensure the highest level of quality and process control.

It is important to understand if the manufacturer does this testing using equipment, experienced engineering personnel and facilities dedicated solely to process development, so it does not compete
for time with products already in the production-manufacturing stream.

4. MANUFACTURING PARTS COMPLETE

Producing finished Nitinol parts is a complex, multi-phase endeavor requiring years of experience and numerous manufacturing and finishing process capabilities. It is important to understand upfront if your supplier can completely manufacture your part in-house using special Nitinol processing techniques. Can they handle all manufacturing and finishing required to produce a marketable product without outsourcing any steps?

By handling all steps in the manufacturing process, the supplier can tune each step based on its knowledge of the upstream or downstream capabilities. This produces the highest level of quality assurance and process control.

5. FINISHING BY ELECTROPOLISHING

A product's fatigue and corrosion resistance are major factors in its performance. Finishing polishes, passivates, removes micro-cracks and deburrs the work-piece. There are various finishing methods. Electro-polishing produces the best results for corrosion resistance and biocompatibility. The Electro-polishing process can be designed to sharpen or round dimensional features to meet product requirements. Verify that the supplier will use Electro-polishing and Passivation on the finishing of implants.

6. 100% DIMENSIONAL INSPECTION

Closely regulated, Class 3 medical implants and devices manufactured to the highest specification are life-saving devices. One of the last steps in producing a device, dimensional inspection, is also one of the most critical to verifying a consistent, high quality component that meets design specifications. It is important to know if a supplier has the capability to provide validated, 100% dimensional inspection on each and every implant. Anything less invites risk to the patient and the OEM.

7. VALIDATION AND INSPECTION

All operational process steps and tooling used to manufacture Nitinol implants must be within established and tested control limits. Validation ensures that the manufacturing process conforms to the control limits. Inspection ensures the manufacturing output does as well. Insist on 100% Automated Inspection for peak quality.

Validation must be conducted in accordance to ISO 13485:2012 standards. The contract manufacturer should employ an experienced validation engineering team to provide the strategy and protocols needed to complete all validation activities.

Additionally, the contract manufacturer should have in-house verification technologies to support validation, including:

- Metallography expertise and Scanning Electron Microscopy (SEM), which is required to verify removal of Heat Affected Zones (HAZ).
- Corrosion testing capabilities per ASTM F2129.
- Bend and Free Recovery (BFR) and Differential Scanning Colorimeter (DSC), to verify material Austenite Finish (Af), Mf, Ms, and As transformation temperatures.

8. ATHERMAL LASER MACHINING FOR NEXT-GENERATION IMPLANTS

The demand for smaller devices and entirely new neurovascular applications requires even more innovative manufacturing methods.

If the ability to test and produce next-generation implants is a priority, determine if the contract manufacturer has an athermal laser machining capability.

AGNOTEX, Inc.'s proprietary S.T.E.A.L.T.H. Athermal Laser Technology is capable of manufacturing parts with kerf widths of .0004" with no heat-affected zone.

CASE STUDY

A medical device startup company approached AGNOTEX with a manufacturing challenge:

Produce a two-piece, Nitinol-based Heart Valve Frame Implant of the company's design.

The company's product engineering team began by visiting AGNOTEX Inc. to perform a Design for Manufacturability (DFM) review.

The product was presently in production with another contract manufacturer, but ongoing issues with the manufacturing output and quality led the startup company to seek another manufacturing source or to rework the design.

The company advised AGNOTEX on the challenges they were facing with the current supplier, including:

- Inconsistent delivery due to sub-optimal Nitinol tubing quality.
- Issues providing consistent laser cut quality and electropolishing finish.
- Lack of welding capability to produce a two-piece implant assembly.
- A deficit of in-house capabilities to perform 100% dimensional inspection or validation.

Accordingly, the finished parts had dimensional defects related to the shape-set form that did not meet specifications to the extent they could be seen without the aid of a microscope.

AGNOTEX conducted a process review, which resulted in the idea to eliminate two manufacturing steps by using an athermal laser, which produces no heat affected zone. This resulted in a significant cost reduction that allowed the production pricing to be significantly below the startup company's target.

Electro-polishing with minimum material removal would be used to finish the piece and provide a
mirror-like, passive biocompatible finish.

Satisfied with the potential for the product design and manufacturing process improvements to make the product viable, the startup company instructed AGNOTEX to proceed with prototyping and feasibility analysis. In short order, we:

- Developed custom shape setting tooling to ensure all finished part specifications were achieved.
- Established the best primary tubing supplier for the short term and at the same time, developed a plan for qualification of a second raw material source to maintain continuity of supply.

Prototype parts were manufactured in 8 days and then shipped to the company for initial design verification testing. A second iteration was required and manufactured in 3 days to complete design verification testing.

The validation strategy was developed by AGNOTEX and submitted to the startup company using a parallel path to the prototype manufacturing and functional testing. Upon completion of verification testing, the validation was executed and a full report was provided in 27 days.
Ultimately, a large medical OEM that had worked with AGNOTEX Inc. previously acquired the startup company. The large OEM confided that the supply chain was a key part of their decision to make the acquisition.

The product is quickly becoming the standard of care for its innovative application and is in use treating patients in many countries around the world.

ABOUT AGNOTEX, INC.

Based on 70 years of family experience, AGNOTEX, Inc. remains a family-owned and -operated company offering the most advanced processes for ultra-precision micromachining. The company is known for its exceptional ability to achieve sub-miniature precision beyond the reach of most manufacturers. AGNOTEX, Inc. is a supplier to most of the largest OEM's and well-known names in the medical device industry.

AGNOTEX manufactures medical implants and devices to customer specifications in compliance with FDA regulations and ISO 9001 and ISO 13485. We offer validated manufacturing processes for Vascular Implants and Orthopedic Implants. State-of-the-art processes include laser machining and welding, Swiss turning and milling, conventional and wire EDM, high-speed 7-axis contour milling, Nitinol shape setting and clean room assembly and packaging. Prototype services are available in separate and fully dedicated process development centers.