

Nitinol and how it can be processed

Nitinol is a two element metal alloy utilized for many medical device applications due to its extraordinary properties such as **super-elasticity, shape memory** and **biocompatibility**. Key to processing Nitinol into medical device components is working the material to utilize these properties.

Our precision laser processing capabilities put minimal heat effected zones on the delicate structures made from Nitinol. Additionally, shaping these laser cut components into their final use and placing a medically acceptable surface finish on these components is a science and an art.



Laserage – Decades of Expertise in Laser Machining for Medical Devices

Paragon Medical's expert brand Laserage has been at the forefront of Nitinol laser processing for implantable medical devices for more than 25 years. Laserage offers a comprehensive menu of Process Validation options to meet FDA requirements. Laser-machined Nitinol, along with other materials like stainless alloys, titanium alloys, cobalt chrome alloys, magnesium, and bioabsorbable plastics, all cut with state-of-the-art laser systems.

Nitinol laser processing, especially in the hands of an experienced laser machining brand Laserage, is transforming the landscape of medical device manufacturing. The marriage of Nitinol's unique properties with precise laser cutting opens new possibilities for innovation, making medical treatments more effective and patient friendly.

NITINOL LASER PROCESSING TECHNOLOGIES

Selecting the right laser, setup method as well as post-processing of components are key to successfully harnessing these technologies that offer flexibility with Nitinol.

- Nd:YAG
- Disk
- Fiber
- Ultra-fast (Femto)

Applications:

A) Stents

Coronary, Peripheral or Endovascular tube requirements

- OD <0.5-12mm for long tubes
- Tubes at least 20cm in length
- Special fixtures for short tubes up to 38mm diameter require additional lead time
- Wall thickness 0.075-2mm (ID limited)



B) Delivery System Components

Skives, Introducers, Garages, Reducers, Flexible shafts, etc.



Introducer, Garages



Flexible shaft



Torque shaft



Skive

Precision Tube Laser Cutting

Stents, heart valve frames, flex shafts, skives, surgical components

Standard Process Tolerances:

- Laser cut and finish $\pm 0.001"$
- Shape setting is dependent on the component design and tooling

Reduced Process Tolerances:

- Design and process dependent on the component design and tooling
- Very capable of $< \pm 0.001"$
- Inspection method and equipment to be considered

Tube Materials

Materials supplied by the customer or sourced by Laserage:

- Nitinol
- CoCr
- Stainless
- PLLA
- Titanium
- Specialty tubes

Finishing Capabilities

NiTi Shape Setting

- Expansion & forming
- Special forming tools are required for most Nitinol shape-setting jobs
- Lead-time on tools



Wound closure

Surface Treatments

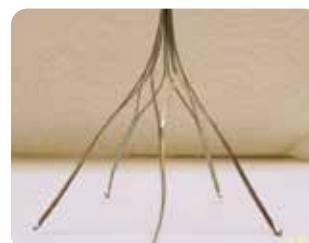
Microblast, etch, oxides, & others



Basket frame

Surface Finishing

Tumbling, electro-polishing of Nitinol



Vena cava filter frame

Limits

Surface area & length for EP. Physical size for tumbling.

Nitinol Forming

Anchors, filters, valve frames, closures, etc.

Forming tools are unique, and lead-time is required

Micro Blasting

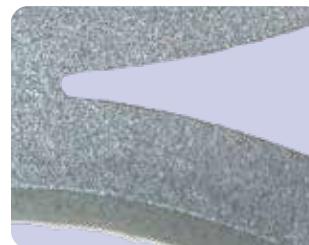
- Fully automated with multi-axis capabilities
- Validated programming
- Oxide removal
- Burr removal
- Splatter removal
- Uniform surface B4 EP



Automated microblasting treatment



Multiple machine multiple blast heads



Microblasting surface

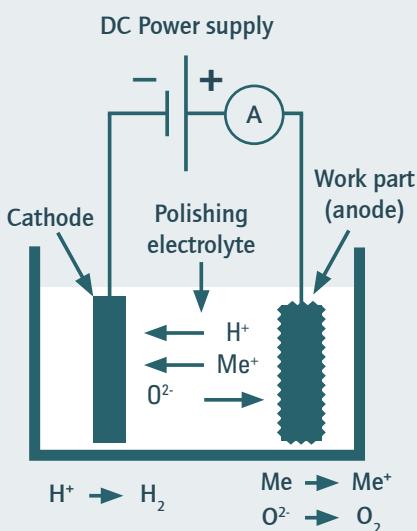
NITINOL PROCESSING

LASERAGE®

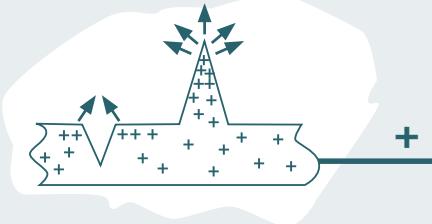
Electro-Polishing (EP):

- Removing peaks and reducing valleys
- Fully automated & semi-automated systems
- Validated programming
- Improved corrosion resistance
- Development per customer component

Basic EP technique:



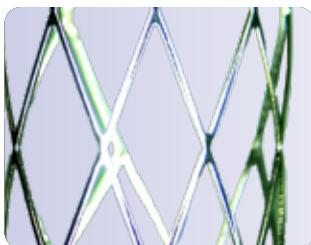
Electrical potential distribution



Surface profile before electropolishing



Surface profile after electropolishing



EP finished stent



EP finished strut

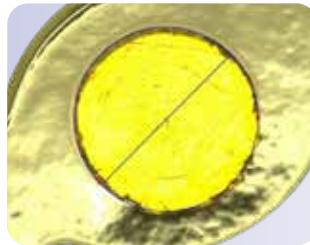


EP stent design

Specialty Processes

Finishing

- Tumbling
- Centrifugal barrel
- Passivation
- Acid cleaning
- Deburring



Radio opaque marker



Tumbled introducer

Testing and Inspection

Nitinol Af Testing

Radio-opaque marker placement

Metal/ceramic heating

- Liquid salt pots
- Air furnaces

Tooling Machine Shop

Inspection Capabilities

Manual & Automated

- Visicon Finescan and Sierra Systems
- Keyence Digital Microscope
- Keyence IM6020 Image Dimension Measuring Systems
- RAM Sprint and OMISII Computerized Video Systems

Other capabilities for Nitinol processing available at Paragon Medical:

Precision Laser Welding:

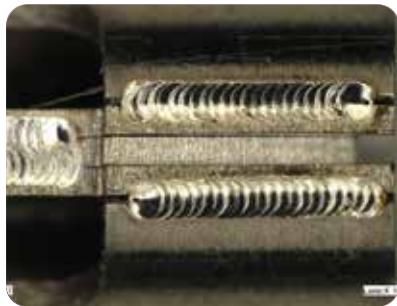
- Nitinol to Nitinol Welding
- Weld site must be accessible to laser head within minimal distance of surface to head
- Need weld penetration details
- Need weld strength details
- Need inspection requirement details

Welding Applications

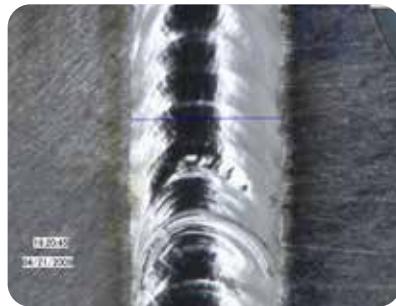
Medical implants, medical equipment, surgical instruments

- Dissimilar materials
- Tooling critical/lead time
- Full automation

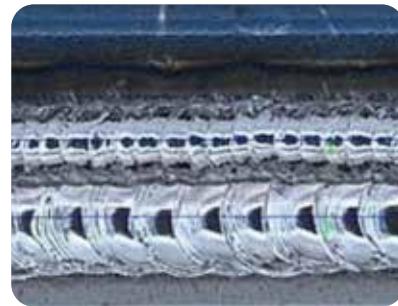
Welding examples:



Nitinol/Nitinol welding



Titanium/Nitinol welding

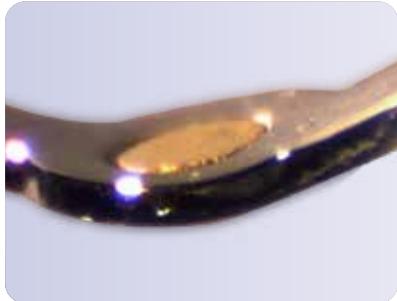


Dissimilar metal welding

NITINOL PROCESSING

LASERAGE®

Nitinol examples:



Structural heart frames



Peripheral stent



Flexible delivery shaft

PARAGON MEDICAL AT A GLANCE

Paragon Medical is a market leader in delivering optimal solutions for the medical device industry. With three expert brands Avicenna, Technical Services for Electronics, and Laserage, Paragon Medical has been serving the medical device industry for more than 40 years.

Each brand is a leader in its respective field of expertise, and is well established in delivering state-of-the-art technology solutions with experience in: product design and development, precision engineering, pre-production to commercialized manufacturing, supply chain management, and quality assurance for cable assemblies and custom interconnects, laser processed polymers, catheter assemblies and sub-components, laser processed metals including NiTi and metal post processing.

Paragon Medical is a business of AMETEK Inc., a leading global provider of industrial technology solutions serving a diverse set of attractive niche markets.

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