

Advanced Products and Solutions for Medical Device Manufacturing

Implantable Electronic Devices Tubes and Stents • Surgical Tools



Develop and Manufacture Next Generation Components

Cutting Edge Technologies for Innovative Product Design



Orthopedics

- Laser marking metal components
 - ► Serial numbers
 - ► Barcodes
 - ► 2D codes
- Laser welding orthopedic implant devices



Tubes and Stents

- Precision laser tube cutting
- Laser drilling micro orifices
 Laser micro



machiningLaser welding



Implantable Devices

- Hermetic seam
 sealing of metal cases
- Welding electrodes
- Surface roughening for lead adhesion



Wearables

- Reflow soldering of flexible circuits
- ACF bonding



- Laser cutting hypodermic needles
- Resistance welding guidewires
- Laser welding brachyseeds
- Seam sealing drug pumps

Medical Tools

- Black marking of metal and plastic components
- Laser marking serial numbers, barcodes, and other product ID



Wire Processing

- Layer / coating removal
- Kapton (Polyimide) removal
- Spot welding wires and coils
- Selective material ablation

Welding tabs

- Sealing cans / cases
- Lead attachment

Modern Manufacturing of Implantable Medical Devices

FDA regulations differentiate medical devices (Class I - Class III) based on the degree of control necessary to ensure their safety and effectiveness. Class III devices are most strictly controlled because they typically sustain or support life, and are often implanted in the human body. These devices commonly require high quality hermetic seals to protect not only the sensitive electronics contained within, but also the person in whom they are implanted. Identification (marking) requirements for these devices also increase as they must be non-corrosive and biocompatible where they are implanted.

Pacemakers • Drug Pumps • Implantable Valves • Cochlear Implants Brachy Seeds • Gastric Electrical Stimulators • Orthopedic Devices



Pacemaker

Brachy seeds

Orthopedic implant

AMADA WELD TECH provides innovative technology solutions for manufacturing implantable devices to the world's leading medical device companies. These engineered solutions are designed to meet today's regulations, addressing unique applications, facility requirements and budgets. Our technologies in this area include laser welding, resistance welding, laser marking, laser cutting and laser micromachining.

Part Identification: Laser Marking **Meets UDI Requirements for Traceability**

While many industries and applications require permanent, corrosion-resistant marks, these gualities are especially imperative for medical device manufacturers, who need to meet strict FDA-mandated Unique Device Identification (UDI) marking requirements. Laser marks are used for identification, tracking, traceability, branding and directional placement of metal, plastic and biologic medical components.

Black Marking

Some medical devices, like cannulae, catheters, tubes, implantable devices, invasive tools, wires and reusable operating room/surgical instruments need permanent black marks capable of surviving multiple passivation and autoclaving cycles. For this purpose, our applications engineers have found that ultrashort pulse picosecond infrared (IR) lasers are superior for fast, permanent, reliable black marking.

High Contrast Black Marks • High Throughput • Traceability • Quality Assurance



Depth marks on trocar





Pacemaker with company logo

AMADA WELD TECH provides fiber, UV, and ultrashort pulse picosecond laser engines for high speed automation and desktop and floor-standing Class I systems for low volume production and R&D manufacturing. Every laser system is delivered with a process developed by our experienced applications engineers, informed by your requirements. Enhance your productivity with: barcode job loading, integration with ERP/MRP programs, common industrial communication protocols, vision and fixtureless marking.



Tubes and Stents: Precision Cutting

Metal and polymer medical tubes are frequently processed with laser cutting to form devices that are used in countless medical applications. Production numbers are growing rapidly in response to the continued demand for stents, flexible tubing, cannulae and micro cannulae, needles, biopsy devices and other tools utilized in minimally invasive surgical techniques. These devices are critical for enabling advanced surgical procedures and for improving the health and guality of life of millions of patients. They require precision manufacturing, with a focus on improved yield and reduced post-processing needs.

Stents • Drug Delivery Tubes • Biopsy Tools • Cannulae Flexible Guide Wires • Hypodermic Needles • Dilation Balloons



Flexible tubing

Polymer stent



Biopsy tool

AMADA WELD TECH offers both fiber and femtosecond laser-based systems for micro cutting applications. The flexible platform features up to 4 axes of motion and complete tooling options enabling micro processing of 0.2 mm -30.0 mm (0.008" - 1.180") tube diameters.



Micromachining: Drilling, Micro Milling, Texturing

As the population ages and the demand for sophisticated medical devices grows, so does the demand for high performance processes to manufacture the devices in large volumes with high quality. Laser micromachining utilizes a multi-pass process that removes small layers (microns or ten-thousandths of an inch) of material, producing features of high quality, with littleor-no burring, low surface roughness and high dimensional accuracy. Materials include metals, plastics, ceramics, polymers and biologics.

Drilling • Milling • Patterning • Scribing • Ablation



Hypo-tube machining

Metal micromachining

Nanosecond UV laser wire stripping

AMADA WELD TECH offers integrated systems with a range of laser sources to ensure that the optimal laser is selected for each micromachining application. Femtosecond lasers are the premier option, offering unparalleled micromachining quality and precision. With ultrashort pulses that allow cold ablation with limited thermal input, high beam quality that helps to focus the beam down to 10 microns (0.0004") or below, and flexible pulsing parameters that allow for a high degree of process optimization, femtosecond lasers are generally the ideal laser for increasing product throughput and limiting or removing the need for post-process cleaning.

Ensuring Manufacturing Success with Process Monitoring

Product failure. Upset customers. Product on stop shipment. For the process manufacturing engineer, it's a worst-case scenario. When this situation occurs, it requires swift attention and accurate resolution: do you know the fundamental underlying issue? Can you calmly and expertly identify the source of the problem and what to do to get back on track? This is where process monitoring comes in. By observing and measuring the process, it is possible to discern good from bad product and, when bad occurs, specify defect signatures. In fact, process monitoring can help manufacturers avoid this situation altogether.

For laser welding, detect and record thermal signals and set an envelope (min/max) to determine good and bad welds by identifying errors such as gaps between parts, missing parts, over-penetration, incorrect focus, and cover gas absence. For resistance welding, monitor parameters like weld current, voltage drop across the electrodes, workpiece expansion and deformation, electrode force, electrode movement (displacement) and more.

The monitor data can also be used to develop better manual or automated workstations that can avoid weld inconsistencies. Plus, data collected with monitors can provide value *after* a product is sold in case of a recall or similar situation, as weld data can be correlated with serial numbers.



Improve Quality • Reduce Downtime • Reduce Scrap

AMADA WELD TECH offers real-time process monitors for **laser welding**, **resistance welding**, **micro TIG welding and hot bar reflow soldering**. These stand-alone monitors are invaluable tools for product development, improving quality and throughput in production, and storing data for traceability.

Off-axis laser weld monitor



Portable resistance weld monitor with a touchscreen interface

Laser weld monitoring



Graphical representation of an instantaneous judgement of measured waveform versus limits that were determined during a DOE. The Good signal results when the newly measured waveform falls within acceptable values. The NG occurs when the waveform falls outside those limits.

Innovative Products for Manufacturing

Since 1948, AMADA WELD TECH has worked to achieve one goal: to solve customers' manufacturing challenges. Knowing there is no one solution that fits all, we strive to provide customers with innovative and reliable manufacturing technology solutions in an effort to be their single source provider.

AMADA WELD TECH's broad range of core technologies - provided as benchtop single operator units, semiautomated workstations or fully automated systems - means that you will get exactly the right solution for your specific application depending on factors like materials, part accessibility and desired throughput.

Core Technologies

Resistance Welding

- High frequency DC power supplies
- Mid frequency DC power supplies
- Linear DC power supplies
- Capacitive discharge power supplies
- Alternating current power supplies
- Motorized electromagnetic weld heads
- Motorized servo weld heads
- Pneumatic weld heads
- Manual weld heads
- Resistance weld process
 monitors

Laser Welding

- Fiber lasers
- Nd:YAG lasers
- Blue diode lasers
- Laser weld process monitors

Laser Marking

- Fiber lasers
- UV nanosecond lasers
- Picosecond lasers

Laser Cutting

- Femtosecond lasers
- Fiber lasers

Laser Micro Machining

- Femtosecond lasers
- Picosecond lasers
- UV nanosecond lasers
- IR fiber lasers

Laser Soldering

· Direct diode lasers

Hot Bar Reflow Soldering

- Power supplies
- Hot bar reflow soldering heads
- Hot bar reflow soldering process monitors

Hermetic Sealing

- Projection welders
- Parallel seam sealers
- Gloveboxes

Micro TIG Welding

- Power supplies
- Torches
- Micro TIG weld process monitors

Our Philosophy: Define - Design - Deliver

Developing a unique solution geared for advanced manufacturing is complicated. Our approach? Define-Design-Deliver. This methodology helps us design the ideal system to meet your manufacturing needs and budget while maximizing your equipment ROI and meeting your production goals.



Value Added Services

Training

We offer application support and process development services at our Technical Centers in Monrovia, California; Wixom, Michigan; High Point, North Carolina, or on-site at your facility. These services can be tailored to meet your specific needs and may include hands-on equipment training.

Topics

- Technology fundamentals
- Developing process success
- Equipment troubleshooting

Location Options

- On-demand webinars
- Live webinars with Q&A
- · Factory hands-on
- On-site training (specific to your equipment)



Around the Clock Service Support to Minimize Downtime

Inevitably something may go wrong. This can be caused by a multitude of reasons, but ultimately the longer that the product is out of order, the larger the impact to your business.

We are there when you need us.

24/7 Field Service

- +1-866-751-7378
- service@amadaweldtech.com

Our Resources, Your Success

Understanding the product and the process - ensuring success! Not sure your application is feasible? Want to know which technology is best suited to your process? Does your existing process require some modification or re-optimization? Our experienced team of Application Engineers are ready to provide assistance!

Technical Centers

- Western Technical Center
 Monrovia,CA
- Midwest Technical Center
 Wixom, MI
- Eastern Technical Center - High Point, NC

Experienced Application and Process Engineers

• 12 full-time application engineers and technicians

Dedicated Development Resources

- Core Technologies Laser welding, resistance welding, laser marking, laser micro machining, laser tube cutting, micro TIG welding, reflow aoldering, hermetic seam sealing
- Facilities 10 state-of-theart application labs for all core technologies
- Range of Lasers CW, QCW and dual beam fiber lasers, diodepumped solid-state (DPSS) lasers, Nd:YAG lasers, picosecond lasers and femtosecond lasers

- Range of Beam Delivery Options Fixed, 2D and 3D galvo-scanning, wobble head, trepanning head, multi-axis taper-free cutting head
- Range of Resistance Welding Power Supplies Linear DC, High Frequency, Cap Discharge, and AC Resistance Spot Welding Controls (5 A - 100,000 A)
- 4 and 5 Axis Laser Welding and Laser Micromachining Workstations
- Gloveboxes for Processing in an Inert Atmosphere



Western Technical Center



Your Global Partner





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