LASERAGE®

Developing Quality Medical Devices with Precision Laser Processing

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Laser processing technology plays an important role in every stage of the development and production of medical devices. It enables rapid prototyping from basic concepts to support initial development, user testing, clinical trials, and regulatory approvals. The technology allows the use of standard or advanced materials in manufacturing.

Laser processing provides the essential repeatability and exacting tolerances that ensure consistent quality to the highest standards, even on high-volume production runs.

This guide provides a brief overview of the role and benefits of laser processing for medical devices, and it explains how manufacturers, such as Laserage Technology Corporation, meet the demanding requirements of the industry.

From Concept to Detailed Design

The initial concept for a new device can take many forms, from a sketch on a piece of paper to an idea inside a developer's head. To transform that concept into a working product, the development team must go through a number of iterative stages, including:

- Market research
- Concept testing
- Internal approval
- Prototyping
- Design validation
- User testing
- Clinical trials
- Regulatory approval
- Production planning

This can be a time-consuming process, so manufacturers are constantly looking for ways to reduce time to market. Laser processing supports quick prototyping, design verification, and iteration to speed up testing, validation, and approval submissions.

Design Considerations

Developers must ensure medical devices provide accurate, consistent results for patients. To achieve this, they can take advantage of the capabilities of laser processing technology.

- Laser Cutting
  Enables developers to create products with intricate shapes and extremely tight tolerances. Stents, for example, can be produced with features as small as 0.002 inches.

- Laser Welding
  Creates extremely strong, clean joints for critical applications such as surgical tools and Catheter tubing.

- Laser Drilling
  Creates precise holes in liquid and gas flow delivery devices.

- Laser Marking
  Supports accurate traceability with flat surfaces that do not harbour bacteria.

Design for Manufacturing

Laserage believes that it is also important to design for manufacturing at the development stage. Designers should concentrate on factors, such as:

- Reducing the parts count
- Developing a modular design
- Using standard components where feasible
- Designing for ease of fabrication
- Minimizing and simplifying assembly

Laser processing allows design and manufacturing teams to take account of those factors by enabling extreme precision, complex shapes, customization, repeatable quality and elimination of secondary materials.

Research and Submissions

Initial research should have established that there is a market for the new product. It may be a completely new device or an improved version of an existing product. The research process must also include a submission to the US Food and Drugs Administration (FDA).

Information on the submission requirements for different device categories is available on the FDA Website.

Approvals

To obtain approval for a planned new device, manufacturers must submit detailed information to the FDA, including:

- Design controls
- Non-clinical testing in line with Good Laboratory Practices
- Clinical studies in line with Good Clinical Practices
- Labelling to comply with FDA regulations.

Guidance on obtaining approvals is available here -

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

Regulatory approval is also important for development teams seeking funding for their projects. This website provides information on sources of funds and application guidelines -

- http://grants.nih.gov/grants/oer.htm

Prototyping

Quick, accurate prototyping is essential for teams that are presenting concepts to users, regulators and funding bodies. Laser technology supports precise, quick prototyping that can be easily customized for iterative design processes.

Meeting Industry Standards

Accurate prototypes help to demonstrate that new products can meet the stringent standards set by the FDA for different device categories. Information on the standards is available at these websites:

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidanceMedicalDeviceQualityandCompliance/default.htm

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

Suppliers are required to make a declaration of conformity with the appropriate standards at the pre-market application stage.

Materials Selection

During the prototyping stage, developers should make decisions about the type of material to be used for volume production. Medical devices can be manufactured from a range of materials to meet specific needs, including:

- Stainless Steels
- Titanium
- Nitinol
- Nickel alloys
- Platinum Alloys
- Magnesium Alloys
- Niobium
- Tantalum
- Cobalt Chromium
- L605
- MP35N
- PLGA
- PLLA

Selecting Suppliers

Suppliers that provide prototyping and production services for medical devices must comply with the standards set by the FDA. The FDA publishes a database of establishments that are registered with it. Laserage is a component manufacturer, rather than a finished medical device manufacturer, so the company is not FDA registered—however, Venta Medical, a subsidiary of Laserage, is a registered firm.

Both firms comply with ISO 13485:2003, the international standard for medical devices and must comply with the following requirements:

- Publish Quality Manuals that outline quality management goals and procedures.
- Hold certification with vital industry standards.
- Conduct both internal and external audits.
- Use process validation services, such as Design of Experiment (DOE) and Validation Plan.
- Invest in product inspection capabilities and equipment.
- Comply with RoHS and export control policies.
- Practice global codes of conduct.
- Comply with REACH regulations.
- Employ full-time quality assurance personnel.

Quality Control

When new devices move into production, quality control is critical. That's when laser processing provides a level of control that is unmatched by traditional manufacturing methods. Laserage's quality process reflects the stringent standards that laser processing meets. The process includes:

- Compliance with the framework set by the FDA
- Corrective and preventative action (CAPA)
- First article inspection
- First part setup

- Process capability analysis
- Process monitoring and validation
- Risk management
- Statistical process control.
- Commitment to continuous improvement utilizing Six Sigma and Lean methodologies.
- Compliance with ISO and regulatory requirements.
- External audits by independent licensed ISO registrar
- Internal audits performed quarterly by trained personnel.

Laser processing can help companies meet quality standards by providing extremely close control over power, cycle times and surface finish. Laser processing can maintain the same repeatable quality standards, even during high-volume production runs.

Continuous testing

Medical devices continue to be subject to quality control when they are in the field. The FDA conducts post-approval studies and oversees third-party inspections of sites registered for manufacture of medical devices.

Choose Laserage for your Production Needs

Developing and manufacturing medical devices is a highly regulated process that requires high-performance solutions. By working with manufacturers using laser processing techniques, medical device suppliers can be confident of creating products that meet regulatory requirements and provide patients and practitioners with quality products they can rely on. So, partner with Laserage to bring your next medical device to market.

About Laserage Technology Corporation

Through more than 35 years of experience, Laserage has become the expert in precision laser contract manufacturing. We have state-of-the-art facilities in the Midwest and northern California, in order to better meet our customers' engineered laser solution and production laser processing requirements.

We have the experience and resources to help you reap the cost and quality benefits that laser processing has to offer. Our Design for Manufacturability methodologies help reduce the cost and number of components, as well as streamline and simplify assembly operations.

We have a deep understanding of materials, both metals and polymers, and employ design guidelines that ensure the most robust performance at minimum cost. As a full-service manufacturer, our technical competencies encompass a broad range of secondary and finishing operations, such as laser welding, passivating, shape setting and electro-polishing, with an emphasis on the specific needs of the medical, aerospace, industrial and microelectronics industries.

"Our priority has always been to build relationships with our customers based on honesty and integrity. In addition, we have always been committed to excellence at every level of our operation."

–Steve Capp, President & CEO of Laserage Technology Corporation