

PULSE SYSTEMS

INTELLIGENT LASER MACHINING



WELCOME TO PULSE SYSTEMS

PULSE SYSTEMS PROVIDES CONTRACT MANUFACTURING SERVICES TO THE MEDICAL DEVICE INDUSTRY FOR PRECISION LASER CUTTING AND PROCESSING OF THIN-WALL TUBULAR METAL COMPONENTS, SUB-ASSEMBLIES, AND IMPLANTS.

AFTER 10 YEARS IN THE BUSINESS OF SUPPORTING HUNDREDS OF COMPANIES LIKE YOURS, PULSE SYSTEMS IS KNOWN TO ITS CUSTOMERS FOR QUALITY, SERVICE, TECHNOLOGY, VALUE, AND TEAMWORK.

WE PARTICIPATE WITH OUR CUSTOMERS IN THE ENTIRE PRODUCT LIFE CYCLE, FROM RAPID TURNAROUND FOR LOW-VOLUME ENGINEERING PROTOTYPES, ALL THE WAY THROUGH COST-EFFECTIVE VOLUME PRODUCTION IN 100,000+ UNIT QUANTITIES.

OUR ISO 9001:2000 CERTIFIED MANUFACTURING FACILITY IS LOCATED IN CONCORD, CALIFORNIA.

+ QUALITY

There can be no compromises when it comes to product quality. In the medical device industry, the quality of your product is only as good as the quality standards under which it was produced. At Pulse Systems, we accept nothing less than exceptional quality and conformance to your requirements.

+ SERVICE

We understand that in business, time is money. By producing your prototypes quickly, and by meeting your growing production schedules, we increase your opportunity for success. We also understand that we need to keep you well-informed about the status of your jobs.

+ TECHNOLOGY

We have built our core competency in precision laser machining and related processing services to serve our customers' needs for those capabilities. We continuously expand our technical infrastructure so that you can concentrate your efforts on product design and development while we focus on these highly specialized manufacturing technologies.

+ VALUE

We take pride in providing value to our customers by delivering quality solutions for challenging problems in a timely and cost-effective manner. Through the efforts of our highly motivated team of employees, we have built a successful enterprise that will continue to grow to serve your needs in the future.

+ TEAMWORK

Over the years we have helped our customers grow from entrepreneurial start-up ventures to highly successful public companies. We are in business today because we have cooperatively built good working relations and common understanding of the product requirements with our customers.

LASER CUTTING GUIDELINES

MATERIAL SELECTION HYPOTUBES

- | | | |
|-------------------|--------------|------------|
| + STAINLESS STEEL | + TANTALUM | + ELGILOY® |
| + NITINOL (NiTi) | + HASTELLOY® | + PLATINUM |
| + COBALT CHROMIUM | + MAGNESIUM | + GOLD |
| + TITANIUM | + BRASS | + COPPER |
| + SILVER | | |

(PLEASE CONTACT US REGARDING OTHER MATERIALS.)

DETERMINE CUT WIDTH (LASER KERF WIDTH)

- + Larger kerf = faster cutting = less \$
- + Smaller kerf = slower cutting = more \$\$\$

Thin Wall (.002"-.005")	Normal Wall (.006"-.009")	Thick Wall (.010"-.025")
.0005"-.001" Kerf	.001" - .002"Kerf	.0015"-.004" Kerf

TUBING SIZES

- + WALL = .002"-.025"
- + DIAMETER = .008"-.700" OD
- + TUBING LENGTH: We can accommodate most tubing lengths over 4" but prefer lengths 54" and higher

CALCULATING YIELD FROM RAW MATERIAL

$$\frac{\text{Supplied Tubing Length} - 6"}{\text{Part Length} + .015"} = \text{Maximum Part Yield Per Tubing Length}$$

ND:YAG LASER GUIDELINES

- + Holes cut in tubing create a slight taper effect (fig. 1)*
- + Cuts are made "normal" to surface of tube (fig. 2)
- + Laser cannot cut "off-axis" (fig. 3)
- + Material rotates under fixed laser beam

FLAT OR "UNROLLED" DRAWING FORMATS (fig. 4)

- + DWG
- + DXF
- + PDF (for quoting purposes only, Pulse cannot program from PDF files)
- + SLDDRW (tubing should be created with longitudinal slit so part can be unrolled)

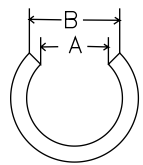


FIG.1



FIG.2



FIG.3

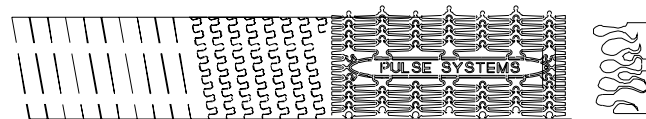


FIG.4**

*IMPORTANT: SPECIFY ON DRAWING WHICH DIAMETER (ID OR OD) IS MORE CRITICAL TO MAINTAIN FOR THRU-HOLE MEASUREMENTS.
**EXAMPLE OF 2D FLAT OR "UNROLLED" DRAWING FILE.

LASER CUTTING

- + Cut tolerance of +/- 0.0002"
- + Kerf width: down to .0005"
- + Wall thickness 0.002" to 0.025"
- + Tubing diameter range: 0.008" – 0.700" OD
- + Stainless Steel, Nitinol, Cobalt Chromium, Brass, Platinum/Iridium, Copper, Titanium, Tantalum, Gold, Silver

LASER MACHINING IS THE CORE COMPETENCY OF OUR FIRM. WE HAVE DEVELOPED SPECIFIC PROGRAMMING METHODOLOGIES THAT ENABLE US TO EFFICIENTLY LASER CUT DESIGNS THAT OUR COMPETITION CANNOT PROCESS. WHETHER YOUR DESIGN IS AN INTRICATE, TIGHT TOLERANCE, FRAGILE PART OR A TUBE WITH A FEW FEATURES WITH WIDE TOLERANCES, YOU CAN BE ASSURED WE CAN MAKE COST EFFECTIVE PARTS IN PROTOTYPE AND PRODUCTION QUANTITIES.





ELECTROPOLISHING

ELECTROPOLISHING REMOVES SURFACE IMPERFECTIONS WHILE CREATING A THIN, UNIFORM OXIDE LAYER THAT IMPROVES BOTH BIOCOMPATIBILITY AND CORROSION RESISTANCE. THIS FINISHING PROCESS IS RECOMMENDED FOR PERMANENTLY IMPLANTABLE MEDICAL DEVICES SUCH AS STENTS AND FILTERS DUE TO ITS EXCELLENT CORROSION RESISTANCE PROPERTIES.

- + Nitinol, Stainless Steel, Cobalt Chromium
- + Exceptional repeatability and predictability
- + Removes slag, machining artifacts, and heat affected zones (HAZ) that result from thermo-cutting processes (e.g., laser, and EDM machining)
- + Eliminates surface irregularities
- + Rounds sharp edges
- + Improves performance characteristics of Nitinol parts
- + Dramatically enhances corrosion resistance
- + Improves surface reflectivity and brightness
- + Provides the most superior form of passivation of Stainless Steels and Nitinol
- + Removes metallic and non-metallic inclusions introduced by manufacturing

STENT MANUFACTURING

PULSE SYSTEMS OFFERS THE FULL RANGE OF MANUFACTURING CAPABILITIES REQUIRED TO SUCCESSFULLY PRODUCE YOUR STENT DESIGN.

- + Precision laser cutting of complex geometries
- + Broad expertise in processing of stent materials such as Nitinol, Stainless Steel, and Cobalt Chromium
- + Surface preparation by chemical cleaning, etching, and microblasting
- + Electropolishing for precision material removal and surface conditioning
- + Automated visual inspection system for dimensional measurement, data analysis, and archiving
- + Nitinol shape-setting and heat treating
- + X-ray marker assembly by micro-joining, crimping, and laser welding
- + Cleanroom facility



SHAPE SETTING/ HEAT TREATING

- + Large expansion ratio
- + Radial and complex shape setting capabilities
- + Furnace and fluidized bath treatments
- + Active Af testing: bend, crush and recovery testing of Nitinol

SHAPE SETTING REFERS TO THE PROCESS OF HEAT-FORMING A NITINOL DEVICE INTO ITS FINAL “MEMORY” SHAPE. THE HEATING METHODS USED TO FORM NITINOL INTO ITS FINAL CONFIGURATION VARY DEPENDING ON THE DESIGN REQUIREMENTS. AT PULSE, WE HAVE VARIOUS PROVEN SHAPE SETTING PROCESSES FOR DIFFERENT APPLICATIONS.

CORROSION TESTING/ PASSIVATION

- + Potentiodynamic testing of small implants per ASTM F2129
- + Stainless Steel passivation per ASTM A967
- + Nitric-dip passivation available for Nitinol applications

THE ASTM F2129 TEST STANDARD IS USED TO ASSESS THE CORROSION RESISTANCE OF SMALL METALLIC IMPLANTS OR COMPONENTS. DEVICES WHICH MIGHT BE EVALUATED BY THIS TEST METHOD INCLUDE ENDOVASCULAR STENTS, CLIPS, FILTERS, AND OTHER METALLIC IMPLANTS.

PASSIVATION OF STAINLESS STEEL IS A CHEMICAL PROCESS FOR THE REMOVAL OF IRON CONTAMINATION FROM THE SURFACE. THIS PROCESS DOES NOT SIGNIFICANTLY AFFECT THE BULK OF THE STAINLESS STEEL BUT PROVIDES FOR THE FORMATION OF A PASSIVE PROTECTIVE FILM. PASSIVATION IS COMMONLY UTILIZED TO IMPROVE THE CORROSION RESISTANCE OF STAINLESS STEEL COMPONENTS USED IN MEDICAL DEVICES.

PASSIVATION OF NITINOL, LIKE THAT OF STAINLESS STEEL, ALSO ALTERS THE SURFACE OF THE MATERIAL WITHOUT SIGNIFICANTLY AFFECTING THE BULK MATERIAL PROPERTIES. HOWEVER IN THIS CASE, PASSIVATION IS ACHIEVED THROUGH FORMATION OF A PROTECTIVE OXIDE LAYER.

MICROBLASTING

- + Ideal for overmolding and bonding applications
- + Yields superior adhesion characteristics
- + Various degrees of surface abrasion available
- + Part deburring
- + Surface preparation for electropolishing
- + Can be used for quick turn prototypes compared to other finishes

MICROBLASTING IS USED TO CLEAN, TEXTURE AND DEBURR SMALL PARTS AND HARD-TO-REACH AREAS. MICROBLASTING IS A METHOD OF REMOVING BOTH THE OXIDE LAYER AND THE REMELT THAT OCCURS DURING LASER CUTTING.

THE MICROBLASTING EQUIPMENT UTILIZES A VERY FINE DRY-ABRASIVE POWDER WHICH IS PROPELLED BY COMPRESSED AIR THROUGH A SMALL NOZZLE ONTO THE SURFACE TO BE PROCESSED. A VARIETY OF MEDIA TYPES AND SIZES ARE AVAILABLE TO PROVIDE THE DESIRED SURFACE ROUGHNESS.



LASER WELDING

- + Computerized 4-axis Nd:YAG laser welding workstations
- + Component assembly fixturing
- + Weld types: spot, seam, butt, lap, circumferential, penetration
- + 0.004" minimum spot size
- + Welding of similar & dissimilar metals
 - Stainless to Platinum, Gold, Tantalum, or Copper
 - Copper to Nickel Chromium alloys
 - Nitinol to Tantalum
 - Stainless to Nitinol (limited strength)
- + Cleanroom environment

LASER WELDING IS THE PROCESS OF JOINING METAL PARTS USING INFRARED LASER ENERGY. THE PARTS ARE FIXTURED SO THEY CAN BE FUSED TOGETHER IN A NON-CONTACT MANNER. THIS PROCESS DOES NOT USE FILLER METALS AND IS DONE IN AN INERT ATMOSPHERE, SO IMPURITIES ARE NOT INTRODUCED INTO THE FINISHED ASSEMBLY. LASER WELDING IS A VERY EFFECTIVE METHOD FOR JOINING THIN-WALLED TUBULAR COMPONENTS USED IN MEDICAL DEVICES.



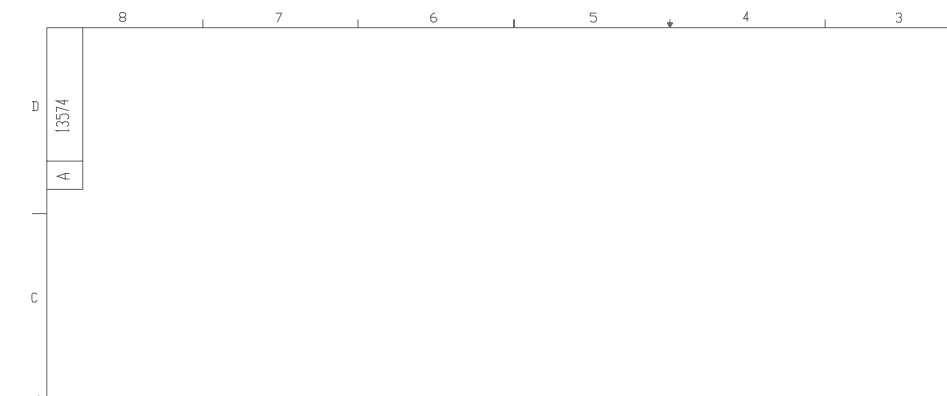
CLEANROOM ASSEMBLY

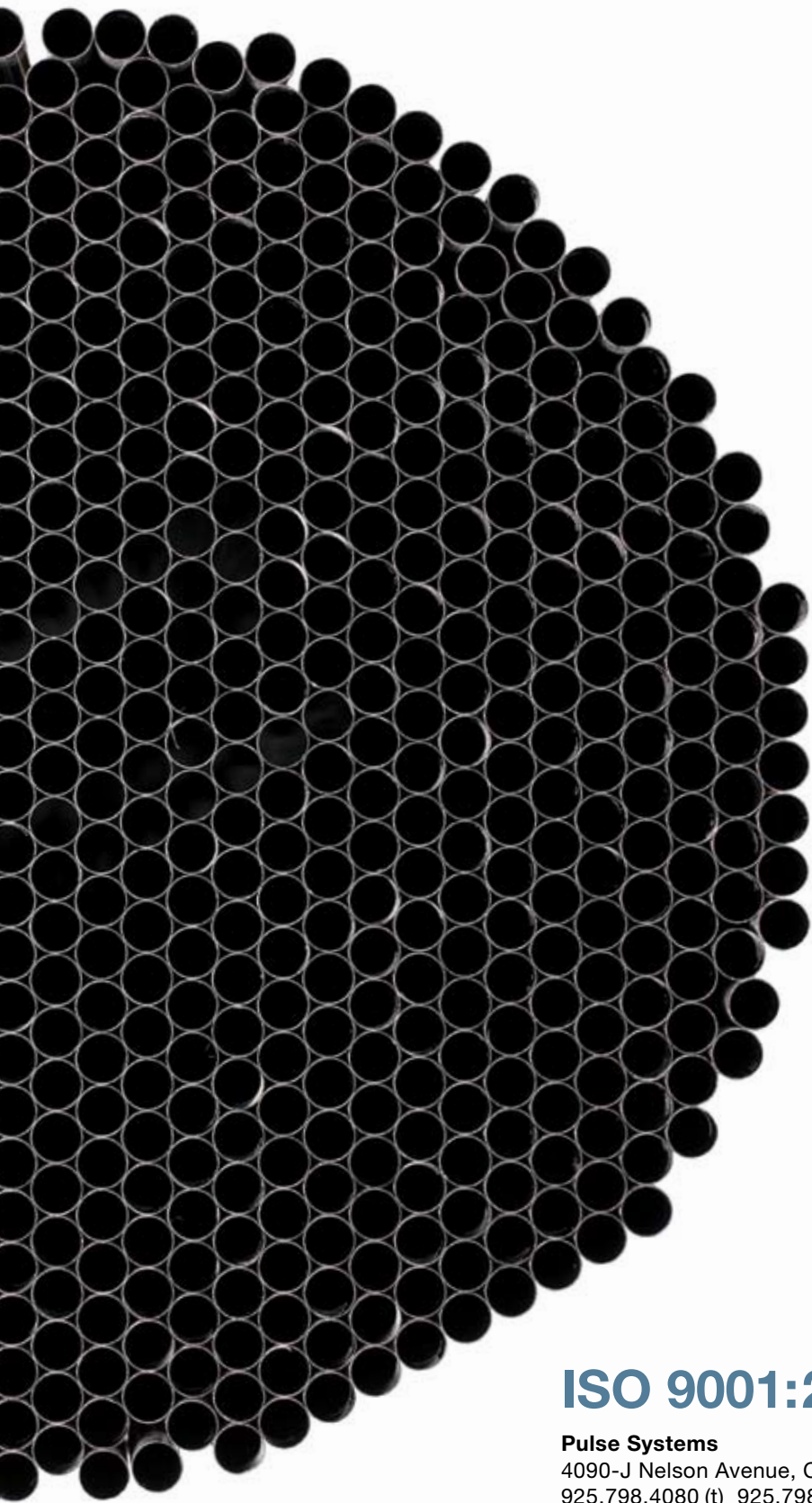
PULSE SYSTEMS OFFERS CLEANROOM ASSEMBLY AS A VALUE-ADDED SERVICE TO OUR CUSTOMERS.

WITHIN OUR CLEANROOM FACILITY, WE CAN PROVIDE A WIDE RANGE OF MECHANICAL ASSEMBLY CAPABILITIES SUCH AS LASER WELDING, MICRO-JOINING, CRIMPING, AND BONDING.

WE OFFER TOOLING AND FIXTURE DESIGN AND FABRICATION TO FACILITATE START-UP AND EXPANSION OF YOUR PRODUCTION.

WITH OUR IN-HOUSE TESTING CAPABILITY WE CAN FURNISH TENSILE TESTING OF COMPLETED ASSEMBLIES. IN CONJUNCTION WITH OUR ASSEMBLY SERVICES, WE CAN PERFORM TURN-KEY MATERIAL OUTSOURCING, HANDLING OF CONSIGNED MATERIALS, PRODUCTION MANAGEMENT, AND QUALITY CONTROL.





ISO 9001:2000 CERTIFIED

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