

# Quality

*Right From The Start*

The Meier quality system is designed to meet the most rigorous standards of our medical device customers. This includes advanced quality planning during the tool design and build stages through validation and transfer of the product to the manufacturing floor. Meier recognizes that the quality of your device is only as good as the quality of the parts supplied so we invest significant time and effort to assure that the components we manufacture meet your exacting requirements.

## Certified Quality System

- EN ISO 13485:2012
- ISO 9001:2008

## Advanced Quality Planning

## Comprehensive and Proven Validation Processes

- Component verification testing
- Tooling & Process IQ, OQ, PQ
- Production Part Approval Process (PPAP)

## State of the Art Quality Lab

- Vision measurement systems
- XRF Testing of incoming raw materials

## Meier Precision Metal Stamping Solutions



Custom metal stamping, specializing in small and miniature metal-formed components and assemblies.



Contract manufacturing of medical devices and assemblies using state-of-the-art machining technology.



Custom instrument manufacturing combined with design and fabrication of sterilization cases and trays; focus on fast turnaround of prototype and production requirements.



Medical device design, contract manufacturing and assembly, specializing in micro-molding, insert molding and multi-shot injection molding technology.



Contract laser micromachining and assembly of implantable devices and components for medical device manufacturers.

## Meier Precision Metal Stamping Solutions



Contact us today for your next project, to arrange a tour of our facility or just to learn more.



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# When you demand precision in your metal stamped components – *Meier Delivers*

For more than 30 years Meier has produced high-precision metal stampings and subassemblies for the medical device industry. By paying attention to the smallest details we excel at developing lower-cost solutions to the complex and micro-sized design challenges our customers face. Our comprehensive design assistance, prototype services and manufacturing capabilities provide support throughout the product life cycle from concept to high-volume production. Meier's in-house tool design and build capabilities, investments in cutting-edge technologies and ISO 13485 quality systems have made Meier a world leader in the stamping of precision medical components.

## History of Excellence.

Demanding markets require innovative solutions and Meier excels in providing the complex and micro sized components required to meet the needs of today's innovative life-saving medical technologies. Rooted in our history of tooling design and fabrication, Meier has assembled a world class team equipped with modern technologies to produce and maintain the high precision tools required to consistently and repeatedly meet our customer's most rigorous requirements. Meier serves many market segments including:

*Neurostimulation*  
*Pacing*  
*Endoscopy*  
*Electrosurgery*  
*Hearing Health*  
*Orthopaedic*

## Customer Experience – The real measure of success

*Producing high quality components is only one measure of success. What really matters - and what keeps customers returning to Meier - is the superior experience of working with our development and manufacturing teams supported by lean manufacturing and advanced quality systems. Every step of the process - from Tooling Design and Validation through Production Release - is closely controlled by our dedicated and highly skilled project team of engineers and toolmakers. But the support does not stop there. Throughout the product life cycle we constantly look for opportunities to take the cost out of the process - delivering exceptional value and savings.*



# Prototypes



## Prototyping

Prototypes are often an essential part of the design process, allowing designers, engineers and clinicians to test the product concept before investing in the production tooling. For this purpose, Meier has assembled a fully integrated prototyping center, utilizing our unique stage die system, to quickly and cost-effectively simulate a progression tool in a fraction of the time. This allows you to:

- Try several design concepts and iterations and choose the best solution
- Demonstrate proof of concept
- Test the design and materials
- Evaluate the manufacturability of the component
- Build prototypes that will closely simulate the production components
- Perform early design verification testing
- Produce pre-clinical test units

## Tool Design and Build

**Dedicated Project Management**  
Formalized development process; focused on customer interaction from kick-off through production ramp.

- Project Plan and Milestones
- Design For Manufacturability (DFM) review
- Process Failure Mode and Effects Analysis (PFMEA)
- Tooling Failure Mode and Effects Analysis (TFMEA)

**Complete in-house tooling capability**

- CNC Machining
- CNC Wire EDM
- Precision Surface & Form Grinding



## Value Added Capabilities

- Assembly
- Laser Welding
- EDM
- Machining
- Finishing
- Passivation
- Secondary Processing
  - Heat Treat
  - Plating: Gold, Silver, Etc.
  - Anodizing
  - Electropolishing

## Support Throughout the Product Lifecycle

- Lean Manufacturing
- Focus on the Customer
- Inventory Replenishment
  - KanBan
  - Consignment
- Tool Maintenance and Repair for the Life of the Program



# Materials Expertise



## Alloy

- Medical Grade Stainless Steel
  - 303
  - 304
  - 316L
  - 400 Series
  - 17-7 PH
- Titanium
  - Titanium Alloys
- Tantalum
- Tungsten
- Nitinol
- Cobalt Chrome
- MP35N
- Beryllium Copper
- Inconel
- Phosphorus Bronze
- Nickel 200
- Other Materials and Alloys

## Precious Metals

- Platinum
  - 99.9%
  - Platinum Iridium Alloys
- Gold
  - Gold Foil Inlaid
  - Gold Plated
- Silver
- Iridium

## Material Thicknesses

.002" through .125"

## Tolerances

.0005"

