

DYNAROLL

PRECISION IN MOTION

CONTRACT MANUFACTURING
*SPECIALIZING IN MANUFACTURING, ASSEMBLY AND TESTING
OF HIGH PRECISION COMPONENTS FOR MEDICAL DEVICES*



*“Committed
to Quality”*



ISO 13485
CERTIFIED

ISO 9001
CERTIFIED

ISO 14001
CERTIFIED

OSHAS 18001
CERTIFIED



Production: Gear Cluster, Sub-Assemblies,
Plated & Laser Marked

Dynaroll Corporation is a vertically integrated contract manufacturer of high precision assemblies used in medical devices, medical robotics, surgical equipment and medical disposable products that require FDA critical compliance.

Dynaroll is a preferred “dock to stock” supplier for many Fortune 500 medical companies globally.

Our expertise in precision electro-mechanical and mechanical assemblies, NPI management, mechanical design and testing allows Dynaroll to provide fast and economical turnkey solutions for a wide range of medical industries and applications.

From single use products to complex multi-item Bill Of Materials (BOM), our process control and vertically integrated manufacturing insures your assembly and precision components will meet or exceed your specifications.

Our NPI team helps facilitate your application from the initial design phase to high volume production. Dynaroll is your complete solutions provider.

- Medical Robotics
- Medical Instruments
- Infusion Pumps
- Insulin Pumps
- Medical Hand Tools
- Dental Disposable Handpieces
- Surgical Devices
- Surgical Tools
- Bio-Medical Devices
- Laboratory Equipment
- Disposable Instruments
- Endoscopic Devices
- Liposuction Devices
- Peristaltic Pumps
- Analytical Instruments
- Other Medical Devices

THE DYNAROLL PROCESS:

1 DESIGN

- Customer Files
- AutoDesk - Solidworks - ProE
- Bearing System Life Software

2 PRINTS AND SOLID MODELS

- IGES
- STP
- SAT
- PDF
- DWF
- DWG

3 NPI TEAM REVIEW

- Design Review
- Manufacturing Review
- Cost Analysis
- Process Validation
- Assembly Review
- Testing Review

4 MATERIALS

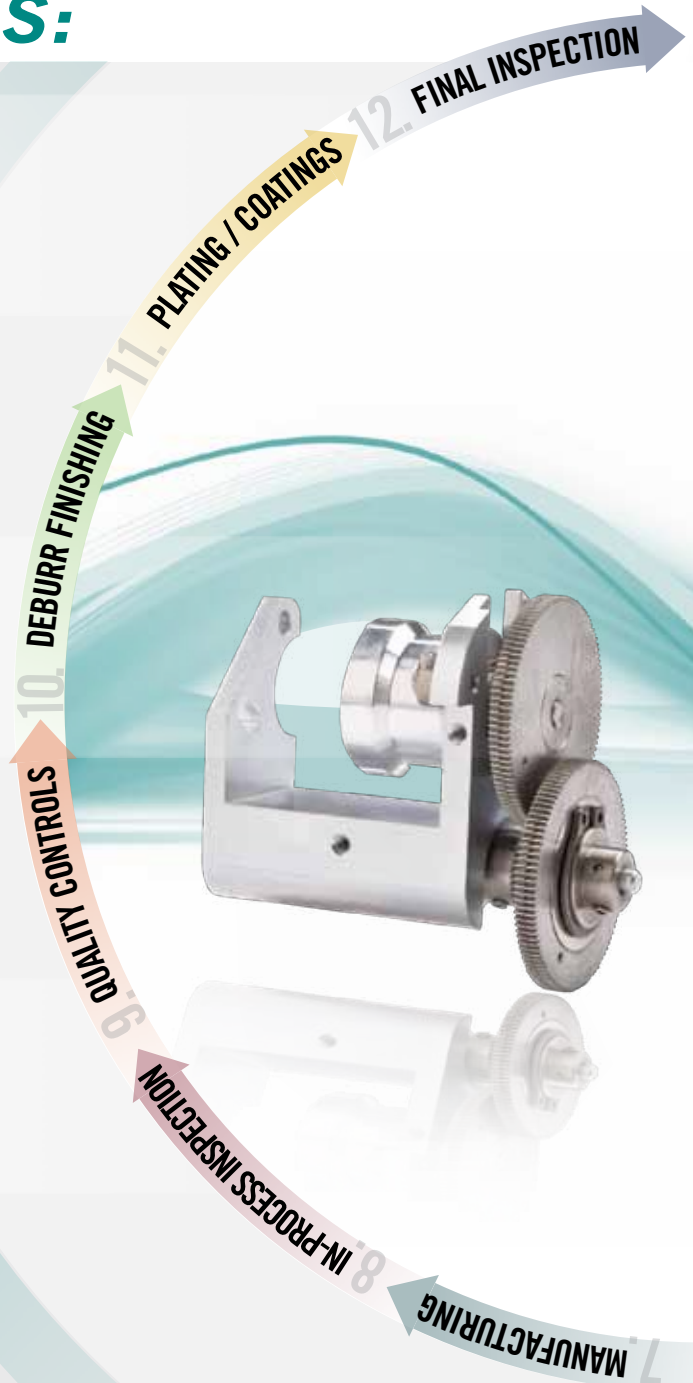
- Stainless Steel
- Aluminum
- Titanium
- Acetal
- Plastics
- Castings

5 FIXTURING

- Custom Part Fixturing
- Pallet Fixtures / Rotary Tables
- Automated Testing Fixtures

6 PROCESS DEVELOPMENT

- Process Review
- Parts Validation
- Documentation Review
- Inspection/IQC
- Process Validation
- Customer Sign-off



"The Dynaroll Process" has been developed to ensure each individual process focuses on quality, producing a reliable "dock to stock" assembly.

1. DESIGN

2. PRINTS/SOLID MODELS

3. NPI TEAM REVIEW

4. MATERIALS

5. FIXTURING

6. PROCESS DEVELOPMENT

DYNAROLL
PRECISION IN MOTION

"Committed to Quality"

MANUFACTURING

- Vertical Integration
- SPC/Cpk
- Pre Controls
- Programming
- Multi-Axis Machining
- Lights-Out Manufacturing

IN-PROCESS INSPECTION

- CMM
- SPC Data
- Optical
- Laser Micrometer
- Critical Dimensions Stored

QUALITY CONTROLS / TESTING

- Rotational Torque
- Noise Testing
- Hardness
- Burn-In
- Circuit Testing
- High Level Testing

DEBURR FINISHING

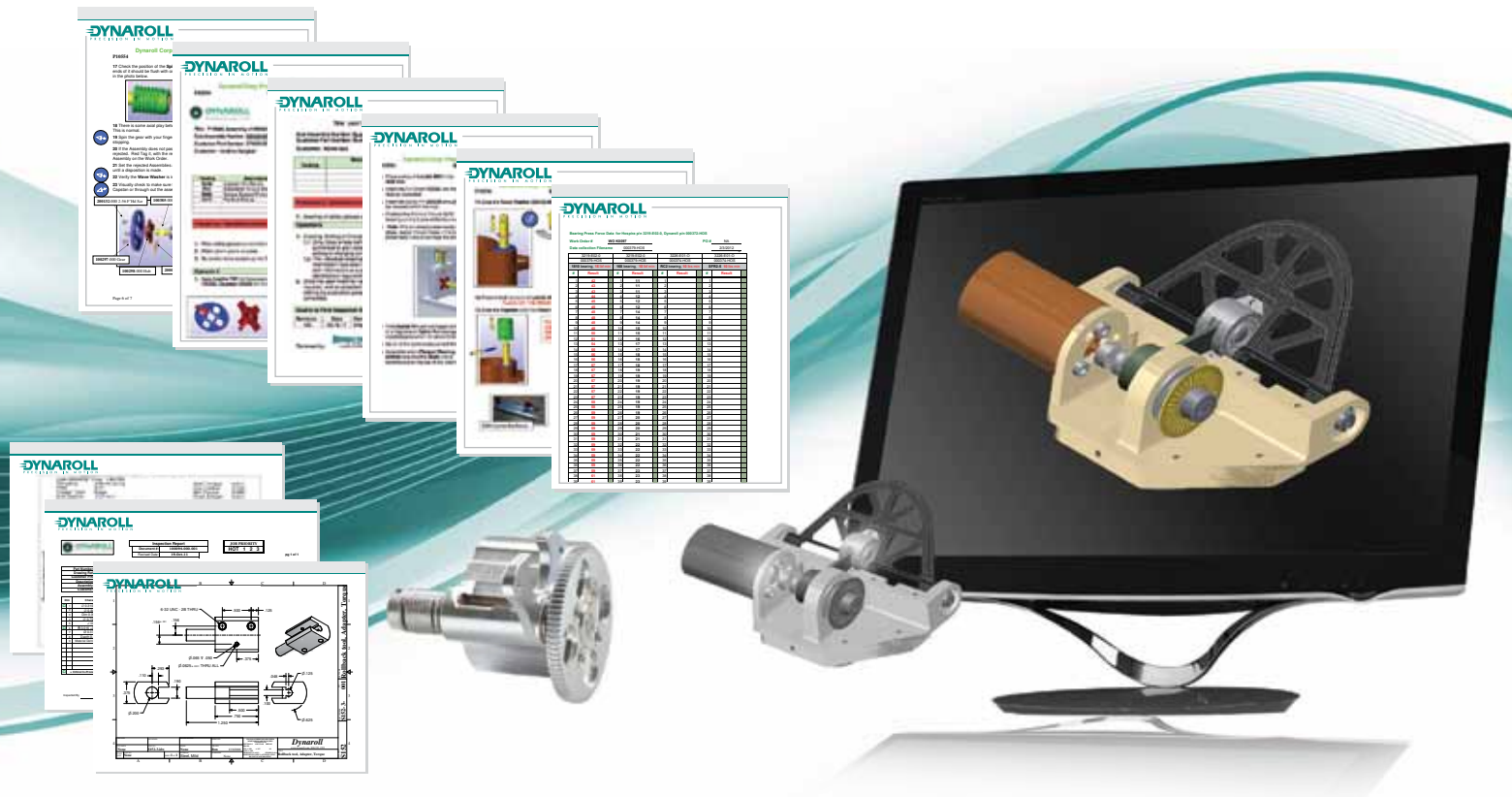
- Spinners
- Tumblers
- Vibratory
- Hand Tools

PLATING / COATINGS

- Passivation
- Anodize
- Alodine
- Chem Film
- Dry Film Lubricant
- Paint, Powder Coat

FINAL INSPECTION

- Performance Testing
- Critical Dimensions
- Visual/Packaging
- Laserfiche™ Document Storage



Engineering, Inspection and Process Documentation

DYNAROLL ENGINEERING

Dynaroll's Engineering Team reviews each print and solid model to determine the most efficient processes to manufacture each precision component. The design and manufacturing engineers then provide expertise with engineered enhancements and recommendations for optimum productivity / machining.

- Dynaroll Assembly processes are validated
- Critical in-process and final inspection criteria established
- Approval sign-off of completed production processes
- Dynaroll Inspection and Pre-Control qualification programs allow (DTS) Dock-to-Stock deliveries, minimizing Customer (IQC) Incoming Quality Control inspections



FIXTURING & PROCESS DEVELOPMENT

Within the Dynaroll Process, custom fixtures for each assembly process are designed and developed by our in-house manufacturing team. During **"The Dynaroll Process,"** the careful development of each individual process step allows Dynaroll to accurately assemble each component on your BOM to produce a final **Dock to Stock** assembly. The Dynaroll Process insures detailed preparation and project management of each custom assembly. From our custom fixturing and assembly processes to testing and thorough documentation, Dynaroll complies with ISO 13485 meeting FDA audit requirements.



Each Process document is carefully created with simple detailed images for each process step.

The Process documents are approved by the customer and operator/technician training is validated at each step.



Dynaroll: Turning / Milling / Deburr
Machining Centers

VERTICAL INTEGRATION: MANUFACTURING

Dynaroll has extensive experience in mechanical sub-assemblies and precision manufacturing using a variety of materials. For integration into our customers custom assemblies, Dynaroll manufactures and assembles components to high tolerance specifications, typically to .0001 inch.

- Swiss Turning Machines
- Large O.D. Lathes
- Palletized Milling Centers
- Multi Axis Milling Centers
- Grinding
- Various Deburr Stations
- Cleaning and Passivation
- Clean & Temperature Controlled Environment
- Integrated Process Control
- Dedicated In-process inspection at Machine Level



QUALITY PROCESS CONTROLS - Cpk, Cp, Pre-Control

Dynaroll's manufacturing processes utilize state-of-the-art component machining, fixturing, assembly and testing equipment. In-process quality inspections follow each part from raw material through manufacturing and assembly. Every machine is equipped with pre-control software to monitor Cpk and minimize inspection time. Our highly skilled machine operators monitor the Cpk and make necessary adjustments to meet or exceed our 1.33 minimum Cpk requirements. Static and Dynamic testing continues throughout the process while our Top Down / Bottom Up traceability system maintains compliance to ISO 13485 and FDA critical compliant regulations.

Dynaroll has been manufacturing FDA Critical assemblies for nearly 20 years and we continue to expand all aspects of our Contract Manufacturing division.

Dynaroll offers Cpk,Cp, PQ, and PFMEA for customers as necessary.



Dynaroll: Class 1,000 Clean Room

ASSEMBLY CLEAN ROOM ENVIRONMENT

CLASS 100 | CLASS 1,000 | CLASS 10,000

Dynaroll has clean rooms and static-free production areas in which static sensitive electronic circuits and contamination free Electro-Mechanical and Mechanical Assemblies can be manufactured/assembled and tested to our Customers' high-level specifications.

Dynaroll is certified to ISO 9001, ISO 13485, ISO 14001 and OHSAS 18001 quality standards.

**Clean room: Class 100 Flow benches,
Class 1,000 and 10,000 Clean rooms**



Electro-Mechanical Sub-Assemblies

ELECTRO-MECHANICAL ASSEMBLY PRODUCTION FEATURES:

- Detailed Bill of Materials (BOM)
- Bearing Installation: Controlled fits and press forces
- Critical Miniature and Instrument Bearing Assembly
- Gear Clocking and Installation
- Soldering: PCB and wire harness assemblies
- Adhesives Application
- Frozen process system
- In-Process Inspection
- Rotational (Noise and Torque), functional testing
- High Level Testing: Customer specified
- Traceability: Top Down / Bottom Up to ISO 13485
- Laserfiche™ Document Storage



Dynaroll's Custom Automated Assembly Devices for Volume

ELECTRO-MECHANICAL ASSEMBLY: CUSTOM AUTOMATION

Dynaroll's highly trained Electro-Mechanical assembly teams provide support for **prototypes** as well as **high volume production**. Our manufacturing engineers create assembly drawings and detailed process instructions to document the production from manufacturing to final assembly and testing.



MicroTorque™ Testing: MRI™ M15-W-N utilized for testing to gm-cm, oz-in

PRECISION ROTATIONAL TORQUE TESTING

Dynaroll is the industry leader in the design and manufacture of MicroTorque™ testers used extensively by the hard disk drive and medical industries to assure rotational performance. In addition to MicroTorque testing, Dynaroll has multi-stage testing capabilities, from bearing failure to system analysis, dimensional, radial play, hardness, noise, and theoretical life via our bearing analysis software.

Press Force Monitoring: Every bearing pressed onto a shaft or into a housing is carefully monitored. The press forces are recorded against position to give a force profile that indicates the interference of the mating parts. Results are stored on our ISO 13485 compliant server system.



Dynaroll's High Precision Machined Components for Sub-Assemblies

MECHANICAL ASSEMBLY

Dynaroll's highly trained Mechanical assembly teams provide support for prototypes as well as volume production.

- Manufacturing engineers create assembly drawings
- Detailed process instructions document production from manufacturing to final assembly and testing.

Dynaroll will process your **Bill of Materials from 2 to 200 line items**, from concept to final assembly, on one purchase order, reducing the need for multiple suppliers. We offer an all-inclusive process that eliminates the customers' costs associated with incoming inspection of each individual component, creating a competitive, cost effective process.

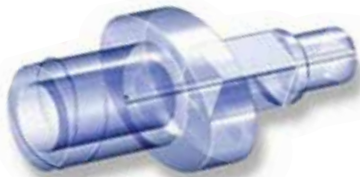
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Dynaroll's Class 10,000 Clean Room



DYNAROLL APPLICATIONS: MEDICAL

- Medical Robotics
- Medical Instruments
- Medical Infusion Pumps
- Medical Insulin Pumps
- Bio-Medical Devices
- Laboratory Equipment
- Blood Analyzers
- Medical Hand Tools
- Dental Disposable Drills
- Surgical Tools
- Disposable Instruments
- Endoscopic Devices
- Veterinarian Devices
- Analytical Instruments
- Liposuction Devices
- Peristaltic Pumps
- Cardiopulmonary Bypass Heart Pumps
- Biotechnology Laboratory Equipment
- Surgical Devices
- Ophthalmology Devices
- Other Medical Devices



*“Dynaroll offers stereolithography
for engineering prototype analysis.”*



Electro-Mechanical assemblies staged for final testing

DYNAROLL APPLICATIONS: MEDICAL

At Dynaroll, our Mechanical Engineers and Manufacturing Teams can assist with rapid prototyping and **in-process engineering enhancements**.

Our experience in mechanical and electro-mechanical materials and assembly make it possible to quickly produce intricate prototype designs for new products and quickly ramp-up volume manufacturing, assembly and testing for new product introductions.



High Precision Mini Programmable CMM's

COMMITTED TO QUALITY

Dynaroll is committed to continuously improving the quality of our products. This is an easy statement to make, and is one which is often echoed by many other companies. The difference is that, in today's world, there are international standards for many aspects of quality control that are used to qualify a company's true commitment to quality. These standards are hard-earned and continuing compliance is regularly audited by certified third-party organizations. Achieving these certifications is the real measure of a company's quality system.

Dynaroll has consistently earned the highest ratings from quality audits and has received the "Award of Excellence" for 2 years running from Dynaroll's ISO registrar. Dynaroll Corp. uses the latest in SPC software to monitor our processes. We work closely with our suppliers and customers, using project teams to oversee our processes targeting the customers' needs.

CERTIFICATIONS

ISO 13485
CERTIFIED

ISO 9001
CERTIFIED

ISO 14001
CERTIFIED

OSHAS 18001
CERTIFIED



M15-W-N MicroTorque™ tester
manufactured by Dynaroll subsidiary
Measurement Research, Inc. (MRI)
www.Measurement-Research.com



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