Accelerating New Product Introductions
While Redefining the Supply Chain

Accelerating New Product Introductions While Redefining the Supply Chain

NPI/Medical accelerates New Product Introductions while redefining the supply chain through a firm understanding of the product development lifecycle. Our process is designed to facilitate a seamless transition throughout all stages of new product development. At NPI/Medical, our priority is helping our customers navigate the chaos and uncertainty of the product development lifecycle from concept to prototype development to production launch.

NPI/Medical's 66,000 square foot facility is equipped with state-of-the-art equipment aimed at executing your next medical device product launch. All machines utilize IQMS ERP system for real time monitoring of your job. NPI/Medical has the technical and quality expertise to support each critical phase of our customers' medical device programs from Prototype-to-Production (P2P).

Product Development Lifecycle

New Product Introduction Capabilities Include:

- Multiple prototype tooling options with DynaClass® Tooling and Molding for short run production quality prototyping using process validations and custom quality plans
- Quick-turn bridge tooling development to ISO 13485 protocols to support initial production launch
- Grade 8 Class 100,000 Cleanroom medical production molding
- Grade 7 Class 10,000 Cleanroom molding, assembly, and packaging for medical device products
- Integrated kitting solutions via dedicated climate controlled kitting room in a secured white room environment for full box build, complete component procurement plus fulfillment
- Assembly, procurement, decorating, packaging and inventory management to drive down supply chain costs and reduce customers' working capital needs

Quality is Never Compromised

NPI/Medical is an ISO 13485:2003 and ISO 9001:2008 certified company. Our Quality/Process Engineering team helps our customers through their chaos during the product development stages through the trials and errors providing Full Process Validations.

The fully equipped metrology lab includes:

- *3 OGP's 2 with CMM capabilities 1 with Laser capabilities*
- *2 ROI (Ram Opticals) omis II 4x8 omis II 6x9*
- Micrometer, calipers, drop indicators, pin gages, torque gages, thread gages, force gages
- Nikon Profile Projector
- SPC Software (Light House systems limited) SPC light, Statistical Software Mini Tab
- Moisture Analyzer

Accelerating New Product Introductions While Redefining the Supply Chain

Quick-Turn Manufacturing (QTM) refers to our process for rapidly turning your CAD files into high quality molded parts, based on your specific project requirements. ***It all starts with a firm understanding of your needs and letting us work with you to find the best solution for your project.***

Selecting the right tooling and molding option is critical to your New Product Introduction. ***At NPI/Medical, our engineering team leverages our unique DynaClass® Tooling and Molding System*** to help you select the appropriate prototype tooling level for your project. With 4 DynaClass® tooling options available, NPI/Medical can accommodate all of your prototyping needs.

When you choose to partner with NPI/Medical one project manager will guide you from initial concept to launch. A single point-of-contact ensures transparency and eliminates multiple channels of communication to maximize efficiency and save time during the product development prototyping phase.

Additionally, our seasoned project managers understand both speed-to-market and precision are crucial to the successful execution of your program. Thus, timelines and on-time delivery remain a priority throughout the prototyping lifecycle and beyond. Your result - seamless communication, OTD and the advantage of working directly with your project manager.

Our customers' generally come to us with design expectations that can't be met with a standardized "black box" tooling approach. DynaClass® fills this void by understanding the importance of iterative design for effective prototyping. Part geometry is not compromised during the molding process, unlike other "rapid" molding processes where other draft or radii may be required. We have CAD engineers design all of our mold halves, and use CNC machined EDM to burn or wire all critical mold geometry that cannot be milled.

DynaClass® parts come standard with 3 to 6 critical-to-function (CTF) inspection requirements to assure accuracy and part function. Our DynaClass 2 and DynaClass 3 offer full process validations. DynaClass 4 and DynaClass 5 offer prototype tooling with custom quality plans in addition to process validations as required.

DynaClass® Tooling and Molding at NPI/Medical offers one of the most diverse tooling and molding options to service all of your prototyping needs.

DynaClass® Tooling and Molding

NPI/Medical	DynaClass 5	DynaClass 4	DynaClass 3	DynaClass 2	SPI Class 101
Uses	Prototype	Tight Tolerance, Advanced Prototypes	Low Volume Molding	Bridge Tooling, Pre-Production	Tight Tolerance Production
Applications	Form, Fit, Function	Part Validation/ Design Verification	Production	High Volume, Pre-Production	Extremely High Production
Cost/Complexity	Low	Low to Moderate	Moderate	Premium	Premium
Maximum Part Size	3"x 4"	6" x 8"	6" X 8"	8" X 8"	10 X 10
Lead Time	1-4 weeks	2-4 weeks	3-6 weeks	4-8 weeks	12-14 weeks
Mold Life	up to 5,000	up to 50,000	up to 100,000	up to 500,000	1,000,000 Plus
Mold Base	Aluminum/P-20 Steel	P-20 or #2 Steel	P-20 or #2 Steel	P-20, #2, #3, & # 7 Steel	#2, #3, #7
Mold Inserts	Limited/Hand Loads	Hand Load & Actions as Needed	Automated	Automated	Automated
Cavity Creation	Machined with Limited EDM	Machined with Some EDM	Machined & EDM	Machined & EDM	Machined & EDM
Inserts	Hardened Steel Cores, Cavities & Inserts as Needed	Hardened Steel Cores, Cavities & Inserts as Needed	Hardened Steel Cores, Cavities & Inserts	Hardened Steel Cores, Cavities & Inserts	Hardened Steel Cores, Cavities, and Inserts
Action	Limited/Hand Loads	Hand Load & Actions as Needed	Automated	Automated	Automated
Standard Tolerances	+/-.005" unless otherwise predetermined	+/-.005" unless otherwise predetermined	+/-.005" unless otherwise predetermined	+/-.005" unless otherwise predetermined	Standard Production molding tolerances
Controlled Environments	Clean Room Molding Options	Clean Room Molding Options	Clean Room Molding Options	Clean Room Molding Options	Clean Room Molding Options
Quality Systems	Custom Quality Plans/ Process Validation	Custom Quality Plans/ Process Validation	Full Process Validation	Full Process Validation	Full Process Validation
Class Equivalent	Class 105	Class 104	Class 103	Class 102	Class 101

DynaClass 5	
Uses	Prototype
Applications	Form, Fit, Function
Maximum Part Size	3"x 4"
Lead Time	1-4 weeks
Mold Life	up to 5,000
Mold Base	Aluminum/P-20 Steel

Your Key Advantage - work with 1 project manager throughout the entire project lifecycle.

Prototype Tool Option	proto labs®	SEAWAY PLASTICS ENGINEERING LLC	NPI/MEDICAL
Material	Aluminum	Aluminum	Steel
Cost/Complexity	Low-Moderate	Moderate-Premium	Premium
Lead Time	1-2 weeks	3-4 weeks	3-4 weeks

Accelerating New Product Introductions While Redefining the Supply Chain

Medical device OEM's face intense market pressures to consolidate their supply chains and drive down costs. A well-designed supply chain network can significantly improve margins, support expansion into new markets, enhance the customer experience, and reduce operating costs. **NPI/Medical's solution to these pressures is to redefine traditional supply chain management through optimized processes aimed at efficiency and continuous improvement.** Our streamlined approach brings cost reductions, consolidation of your supplier base, and faster product launch utilizing a speed-to-market approach. We understand managing and optimizing your supply chain is critical for the seamless execution of the entire New Product Introduction (NPI) lifecycle from initial design to manufacture in a cost-effective and accelerated manner.

For example, NPI/Medical offers kitting from P2P (Prototype-to-Production) for its medical device customers to accommodate all phases of the NPI lifecycle. NPI/Medical seeks to exceed customers' expectations and maintain hard delivery times whether a product is shipped to forecast, or shipped on demand-driven basis without anticipated timelines. By maintaining set or anticipated forecasting via inventory storage, the result customers' receive is significant cost savings for product distribution. Following production, the challenges of strategic sourcing, procurement, fulfillment and distribution all are handled by NPI/Medical.

We offer two levels of kitting solutions depending upon customer requirements:

1. **Prototype assembly and packaging:** dedicated Grade 7 Class 10,000 soft wall Cleanroom for small volume kitting, assemblies, testing, and packaging.
2. **Production kitting:** full box build and complete component fulfillment.

Flexibility for assembly guides our kitting operations thus product changeovers can be kitted, presented to the assembly system and changed again if required. The U-shape assembly design and KANBAN allows the operator to move freely from right to left providing optimized ergonomic flow and ease of assembly. The bins allocate the daily requirements for the build and are bar coded for inventory accuracy and confirmation of component count. All products are weighed to ensure components are properly assembled through hourly kit inspections. **Customers benefit from cost reductions, streamlined inventory management, and on-time delivery for distribution.**

Let NPI/Medical Redefine Your Supply Chain.

Assembly Options

- Automatic label print, bag, and seal
- Fully automated assemblies
- Leak testing
- Multi-component paint and coatings
- Multi-colored pad printing
- Painting, plating and decorating
- Semi-automated assemblies
- Sub-assemblies

Packaging Options

- 1D & 2 D barcode capable
- Clamshell packaging
- Direct thermal printing
- E-Z open plastic bags
- Inert gas purged
- Label printing
- Laser engraving
- Trays, lids, and pouches
- Tyvek static dissipative
- Vapor proof

Tool Room Capabilities

- In-house fixture design & build
- In-house tooling

Advantages

- Consignment programs
- Cost containment
- Full lot number product traceability
- On-time delivery
- Order and received quantity reconciliation
- Procurement and fulfillments to a single-source vendor
- Supply chain management

NPI/Medical offers comprehensive kitting solutions to manage your entire supply chain.

Kitting & Assembly Operations

- Dedicated climate controlled white room environment for kitting
- 24/5 kitting
- Short run or low volume kitting defined as 200-500 kits per day to higher volume kitting 1,000+ kits per day
- 1 Grade 8 Class 100,000 Cleanroom equipped with six injection molding machines from three 40 ton to three 110 ton for Cleanroom molding
- 2 Grade 7 Class 10,000 Cleanrooms for assemblies, sub-assemblies, testing, packaging, and decoration

Our Kitting and Assembly Services Enable Us To:

- Fulfill individual customer orders
- Manage inventory of purchased components and packaging supplies
- Manage sourcing and labor
- Rapidly react to increased demand for custom packaged products
- Reduce customer inventory by warehousing molded and purchased components to finalize product kits for just-in-time delivery
- Schedule and work to long range customer forecasts
- Support 3PL and VMI programs

Summary of Benefits

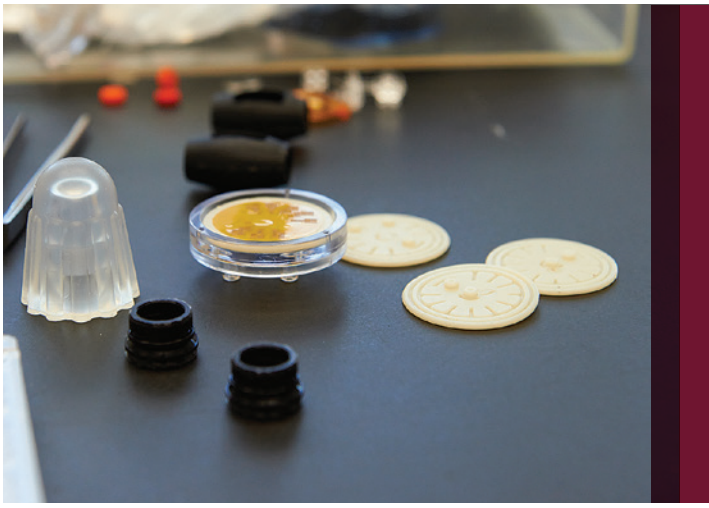
- Work with one supplier from product development through to full production launch to guarantee speed-to-market
- Reduction in supply chain costs and working capital needs
- Proven processes for your NPI needs
- Industry leading on-time delivery

Liquid Silicone Rubber

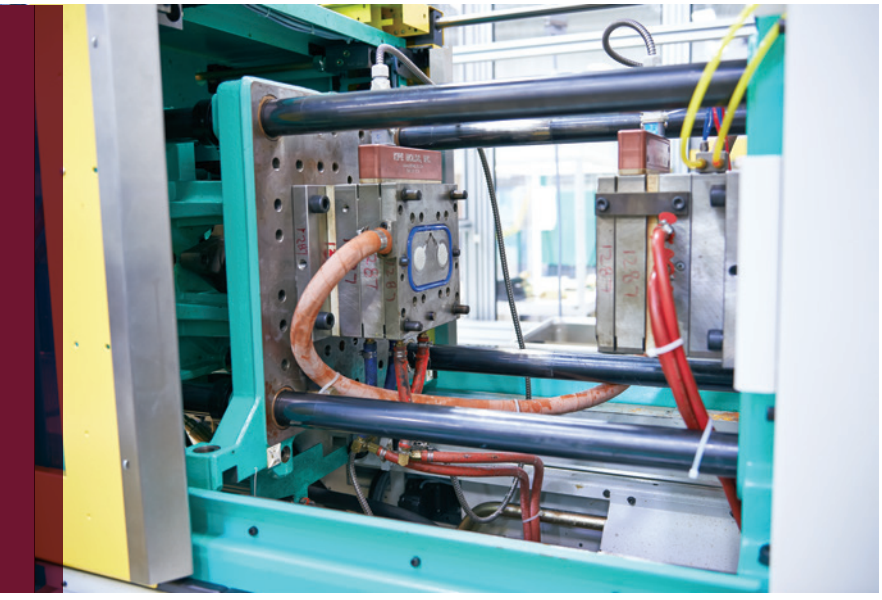
NPI/Medical is a recognized leader in liquid silicone rubber of medical grade components. Our 10+ year history of tooling and processing LSR components results in quick turnaround, cost-effective, mixed volume prototypes and production parts. Customers receive high quality, flash free molds and components. NPI/Medical has considerable experience in healthcare, consumer, and industrial applications.

LSR Capabilities Include:

- Two in-house 55-ton LSR production molding machines, both capable of horizontal/vertical molding and equipped with full robot automation
- One 55-ton press dedicated to LSR prototype and short run production
- Two 5 & 55 gallon microprocessor controlled drum feed pumps
- One 5 gallon manually regulated feed pump
- One microprocessor controlled cartridge pump
- Prototype injection molding capable with heated LSR master frame and custom manual mix/feeding system for all LSR's
- Post mold curing options



The feed pumps are 1:1 and 2:1 ratio capable; employ a manual system of any ratio and all have third stream color additives of up to 30%. All pumps are prototype injection molding capable with heated LSR master frames and a custom manual mix/feeding system for LSR. **Additionally, our LSR Molding is Grade 8 Class 100,000 cleanroom compatible**.



Quality Management System (QMS)

NPI/Medical has a fully equipped Metrology Laboratory that consists of CMM, non-contact vision systems, force gages, and hand held inspection equipment. NPI/Medical's Quality/Process Engineering team helps our customers through their chaos during the product development stages through the trials and errors providing Full Process Validations which consists of Process Development, First Article inspections, MSA studies, Capability studies, FMEA, Flow Charts and Control Plans as well as other documents as required.

NPI/Medical's Process Engineering team through APQP (Advanced Product Quality Planning) activities decide the best practice and implements these processes prior to production release. During these activities we work with our customer's fixtures, perform methods of inspections, decide on CTO (Critical-to-Quality) criteria as well as packaging needs. Once a product is approved, NPI/Medical controls production using the established control plan, FMEA (Failure Mode Effects Analysis), and tools such as SPC (Statistical Process Control).

Our Quality Department Includes:

- Process Engineering
- Quality Engineering
- Quality Analysts
- Quality Inspectors

Quality Registrations:

- ISO 13485:2003 Certified
- ISO 9001:2008 Certified

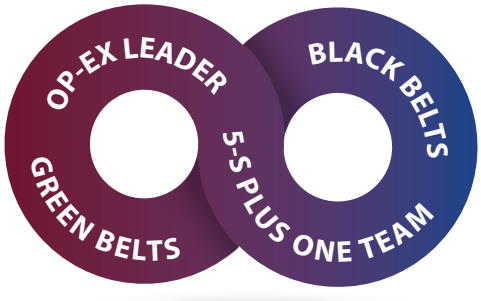
Modern Technology:

- Fully equipped Metrology lab
- 3 OGP's: 2 with CMM capabilities and 1 with Laser capabilities
- SPC software- Prolink Q.C. Calac Version 3.0
- 2 ROI (Ram Opticals) Omis II 4X8, Omis II 6X9
- Measurement software- Automap Version 3.0
- Nikon Profile Projector
- SPC Software- Light House Systems Limited SPC light
- Statistical Software Mini Tab
- Moisture Analyzer

Other Inspection Equipment:

- Calipers
- Drop indicators
- Force gages
- Pin gages
- Torque gages
- Thread gages

CONTINUOUS IMPROVEMENT



ISO 13485 certified
ISO 9001 certified

Request a Quote Today!

Contact a Member of Our Sales Team

Terry Gleason, ***Director of New Business Development***

↳ tgleason@npi-med.com → 516.581.8891

Chad Mayer, ***Sales Executive***

↳ cmayer@npi-med.com → 940.206.1604

Dan Singer, ***Sales Executive***

↳ dsinger@npi-med.com → 203.446.7118

or go to **npi-med.com** and click on **REQUEST A QUOTE**
provide your project details and upload your files.

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NPI/MEDICAL

ISO 13485 and ISO 9001 Certified

401 Birmingham Blvd.
Ansonia, CT 06401

203.736.5200

fax 203.732.2075

sales@npi-med.com