About HTP

Industry Leader In Precision Medical Tubing & Machining

We Make What Others Can’t!
Significant Business Updates

- February 2016 – Now A Hitachi Group Company
  - Significant Resource Expansion
  - Increased Access To Synergies, Products & Services
- Now Certified For Full Device Manufacturing
- Now An FDA Registered Facility
- Facility Expansion For:
  - Contract Manufacturing Of Subassemblies & Full Medical Devices
  - High Pressure Braided Tubing
- Working In Conjunction With Hitachi Cable America
Our Facilities – Two Companies In One

Ashaway, RI
- Corporate Headquarters
- ~ 25,000 Sq. Ft. Total Space
- ~ 6,500 Sq. Ft. Clean Room ISO Class 8
- ~ 10,000 Sq. Ft. White Room Manufacturing
- 24 Hour Operations (Monday – Friday)
- R&D, Extrusion, Braiding & Molding
- In-House Tool Design & Fabrication Via Hi-Tech Machine & Fabrication

North Stonington, CT
- Extrusion, Braiding & Molding
- ~ 20,000 Sq. Ft. Total Space
- ~ 3,800 Sq. Ft. ISO Class 8 Clean Room
- ~ 3,000 Sq. Ft. White Room Manufacturing
- ~ 6,000 Sq. Ft. For Infrastructure & Warehousing
Current Facility – Ashaway, RI

- Extrusion, Braiding, Secondary Operations, Quality, Final QC Inspection, & Raw Material Inventory
- Some Equipment Is Shifting To The New Facility In Connecticut
- Growing Focus On Braiding & Medical Molding

32 Braiders Currently Support HPBT Business Growth
New Facility - Production Expansion In CT

- New Facility Buildout Underway With Completion By June
- Enough Space For Up To 50 Braiders With Inline Extrusion, Molding & Final Inspection
- New Facility Provides Significant Growth Opportunity & Development Expansion
Our Specialty

Innovative Tubing For Medical Applications

- Advanced Materials
- Multi-layer & Multi-durometer
- Complex Geometries & Tapers
- Small Precision Sizes
- Multi-lumen & Braided Tubing
- Integrated Markings

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A Hitachi Group Company
Our Expertise

- **State-Of-The-Art Equipment**
  - 3/4” to 1-1/2”
  - Proprietary Take-Off Equipment, Pullers & Bump Pullers
  - In-line Continuous Monitoring (O.D. / I.D. / Wall)
  - Proprietary Water Treatment Systems
  - Proprietary Control Systems
  - 100+ Custom Screws, 30+ Custom Heads
  - Extensive Inventory Of Extrusion Tooling & Sizing Rings

- **Specialty Extrusions**
  - Micro-extrusions
  - Single & Multi-lumen Extrusions
  - Taper & Bump Tubes (up to 36 transitions)
  - Transition lumens (i.e. 4 to 3)
  - Multi Material Co-extrusion & Co-joined
  - External Striping (radiopaque)
  - Internal, Encapsulated & Window Stripes
  - Multi-layer
  - Multi-durometer
  - Profile Extrusions
  - Solid Core Extrusions
  - Coated Wire
  - Reeled Tubing
  - Intermittent Extrusions
  - Balloon Tubing
  - Over, Linear & Embedded Wire Tubing
  - Fiber Optic Jacketing
  - Precision Cut-to-length
  - Custom Colors & Materials
Technical Capabilities

- **Outer Diameter:**
  - .004” (0.10 mm) (.33F) Min., Based On Construction
  - .875” (22 mm) (66F) Max., Based On Construction

- **Inner Diameter:**
  - .005” (0.12 mm) (.36F) Min., Based On Construction

- **Wall Thickness:**
  - .001” (0.025 mm) Min.
  - Typical 0.0045-0.010” (0.013 mm To 0.25 mm)

- **Braid Or Coil I.D.:**
  - .006” (0.15 mm) With Variable Pitch

- **Max. # Of Lumen:**
  - Up To 24

- **# Of Layers:**
  - Up To 5

- **# Of Durometer Changes:**
  - Up To 4

- **# Of Taper Transitions:**
  - Up To 10
Our Markets

**NEUROVASCULAR**
- Micro-Catheters
- Coil Delivery Systems
- Thrombectomy
- Embolization Catheter
- Access Catheters

**VASCULAR ACCESS**
- Procedural Devices
- Peripheral Catheters
- Central Catheters
- Dialysis

**PAIN MANAGEMENT**
- Neuroablation Devices
- Neurostimulation Devices
- Access Catheters

**CARDIOVASCULAR**
- Procedural Devices
- Fluid Management Systems
- Imaging & Diagnostic Catheters
- Drainage Catheters
- Thrombectomy Catheters
- Atherectomy Catheters
- Occlusion Catheters
- Balloon Catheters
- Delivery Catheters

**ELECTROPHYSIOLOGY & CRM**
- Pacing Leads
- Mapping Catheters
- Ablation Catheters
- Cryotherapy Catheters
- Lead Placement Devices

**STRUCTURAL HEART**
- Transapical & Transseptal Access Systems
- PFO Closure Devices
- Valves
- Dilators & Introducer Sheaths
- Sizing Balloon Catheters
## Solutions By Segment

<table>
<thead>
<tr>
<th>Market Segment</th>
<th>Key Technology Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology &amp; Peripheral Vascular</td>
<td>Braiding, Co-extrusion, RF tipping, Multi-lumen, High Precision Single Lumen</td>
</tr>
<tr>
<td>Vascular Access</td>
<td>Precision Polyurethane, Tapered / Bump, Multi-lumen, RF Tipping</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>Co-extrusion, Precision Single Lumens, Multi-lumen, RF Tipping</td>
</tr>
<tr>
<td>Urology</td>
<td>Single Lumen, Multi-lumen, RF Forming, Skiving &amp; Punching</td>
</tr>
<tr>
<td>Surgery</td>
<td>High Temperature Materials, Multi-lumen, Precision Single Lumen</td>
</tr>
<tr>
<td>Neurovascular</td>
<td>Braiding, Co-extrusion, Micro-extrusion, Striping</td>
</tr>
<tr>
<td>Structural Heart</td>
<td>RF tipping, Over-jacketing Extrusion, Single Lumen Extrusion</td>
</tr>
</tbody>
</table>
Braided Tubing

- Nylon & S.S. Braid
- Small Diameter
- Multi-durometer
- Tapered Shafts
- Variable Pitch Coils
- Multi-lumen Shafts

**Applications:**
- Contrast Injection
- Pressure Monitoring
- Aspiration
- Fluid Administration
- Pressure Balloons
- Diagnostic Sheaths
- Composite Catheter Replacement
- Microcatheters
- Inflation
- Vacuum Procedures
- Waste Management
- Placement Devices

Custom Sizes & Lengths Can Be Manufactured

High & Low Pressure Tubing – From 500 To 1,200 PSI
Secondary Operations

- Reflow
- Marker Bands (Polymer And Solid)
- Annealing
- Inline Printing
- Injection Molding
- Overmolding

- Cut To Size & Laser Cutting
- Necking, Tipping & Forming
- Hole Punching, Drilling, & Skiving
- Welding (Laser, Heat, & Ultrasonic)
- Bonding (Adhesives, Solvent & Thermal)
- Pad Printing, Assembly & Packaging
Molding & Assembly Services – Class 8 Cleanroom

- Component Molding & Overmolding
- Subassemblies, Full Devices & Packaging
- Product Identification (Pad Printing)
- Package Sealing (Pouch, Tray/Tyvec, & Heat Shrink)
- Contract Manufacturing
Design & Tooling Services

- CAD/CAM – SolidWorks
- Process Development
- Rapid Prototyping Services
- 3D Printing
Precision Machining Services – ITAR Compliant

- **In-house Design & Manufacture**
  - Extrusion Tooling
  - Spiral Flow Heads
  - Tips & Dies
  - Crossheads & Inline Extrusion Heads
  - Mold Tooling

- **Services**
  - Milling
  - EDM
  - Turning
  - Grinding
  - Swiss Screw (Partner Service)
  - Inspection & Measurement

- **Medical Component Machining**
  - Titanium & Specialty Metals
  - Tool Carts & Stands
  - Custom Fixtures

- **Tool Maintenance & Repair**
Facility Equipment

TWO 5 AXIS MAZAK CNC MACHINES
Both of our Mazak Machines bring together extreme speed and accuracy for small, medium and large complex components.

WIRE EDM MACHINES
Our Wire EDM Machines provide a high speed, high precision, and high quality cutting for a wide range of applications.

PRECISION SMALL HOLE WIRE EDM
Our precision EDM with integrated rotating spindle allows automated erosion of holes at multiple locations.
HAAS VM-2
These are designed specifically for mold makers, the VM-2 is a high-performance machine with high-speed control.

HAAS VM-3
These are designed for large mold makers, the VM-3 is a high-performance machine with high-speed control.

MAXIEM 2040 WATERJET
Our waterjet is faster, smoother, more precise, and is ideal for a wide range of modern machining needs.
Facility Equipment

**HAAS SL-30**
Our high-performance turning centers were designed to provide heavy cutting ability, extreme rigidity, and high thermal stability.

**HAAS VF-1**
The HAAS VF-1 is a rugged, small-footprint VMC that yields reliability and accuracy in a small-framed machine.

**HAAS VF-3**
The HAAS VF-3 is a rugged, medium-sized VMC that yields full reliability and accuracy in a moderately-sized machine.
Facility Equipment

MAZAK DUAL 5 AXIS CNC
Both of our Mazak CNC machines bring together extreme speed and accuracy for small, medium and large complex components.

HAAS SL40 LARGE CAPACITY CNC LATHE
The HAAS SL40 CNC Turning Center has a 25.5” x 44” (648 x 1118 mm) max capacity, 40” (1016 mm) swing, 40 hp (30 kW)

AV350+ OPTICAL MEASURING MACHINE
These systems are multi-purpose CNC measurement systems, ideal for quality assurance, manufacturing, and assembly.
Machining Materials

Metal Materials:
• Tool Steel (S7, M2, D2, O1)
• Stainless Steel (302, 304, 316, 416, 420, 440, 17-4, 15-5)
• Alloy Steels (4140)
• Carbon Steels (10xx, Low-Medium-High Carbon Content)
• Aluminum (5052, 6061, 7075, Alumec 99)
• Beryllium Copper

Machined Plastics:
• ABS
• Acrylic
• G10 (A.K.A. FR4)
• Delrin

High Performance Materials:
• MONEL (400, K500)
• INCONEL (600, 625, 718, X-750)
• Titanium (Grade 2, 5)
• Hastelloy (C-276, X)
• Nitralloy (135)
• Aluminum Bronze (C63000, C63200)
• HY80 Leaded Steel
• CPM (S90V, S30V)

Typical Requirements:
• Chemical / Physical Test Reports
• Certificates Of Compliance To Specified Standard
• Mercury Free (Material & Processing)
• Domestic / DFARS Compliant
Common Extrusion Materials

- Co-extrusion & Multi-Layers Bonding:
  - Common Materials: Pebax, Nylon, HDPE, TPE, Polyurethane, Polyethylene, Polyester, Teflon, Polyimide and PEEK
  - Why Multi-layer?: Lubricious I.D.’s, Increased Physical Properties, Bondability, Delamination, & Encapsulation

- Reinforcement:
  - Polymer: Kevlar, PLLA, UHMWPE, PP, Aramid (Nylon), TPEs, and Polyester (PET)
  - Metals: Stainless Steel, Copper, Alloys, Nitinol (Nickel Titanium) – Round, Flat & Tempered Wire Available
  - Type: Linear, Spiral, Braided, Layered, Variable Pitch, Winding Direction

- Jackets:
  - Thermoplastic Elastomers TPEs:
    - Low Cost: PVC, ABS, HDPE, LDPE, LLDPE, XLPE, PP, PPCO
    - Medium Cost: TPUs, AR TPU, ETPU, PC, POM / ACL, PA 6 / 66 / 11 /12, PBT, PE, PET, PETG
    - Higher Cost: PEBA, PEEK, TPV, TPR, TPO, EVA copolymer, PEVA copolymer, PES, PSF / PSU, PPS, LCP, PPSU, PESU, PEI, PAI, & Custom Compounds
  - Fluorinated Polymers: FEP, EFEP, ETFE, ECTFE, PFA, PCTFE, PVDF
    - Common Tradenames: CHEMFLUOR®, PharmaFluor®, Tefzel®, Kel-F®, Neoflon®, Kynar®, Hylar®
  - Bioabsorbable Resins: PLA, PLLA, PDLA, PGA, PLG / PGLA, PCL, PDL, PLDL, PDLG, PEG, PDO
    - Common Tradenames: Pureasorb®, Resomer®, Absorv®

HTP-MEDS
External Partner Services

- Silicone, PTFE & Polyimide
- Custom Polymerization & Compounding
- Guide Wire & Nitinol Resources
- Medical Molding
- Color Matching
- Specialty Materials, Additives & Coating Technologies
  - Kink Resistant Materials For Tie & Tri-layer Devices
  - UV Stabilizers
  - Antioxidants
  - Flame Retardants & Heat Stabilizers
  - Impact Modifiers
  - Anti-static Agents
  - Lubricants & Fillers
  - Coatings (Antimicrobial, Biomimetic, & Improved Lubricity)
  - Surface Modifications
  - Nanocomposites
  - Radiopacifiers (Barium Sulphate, Bismuth, Tungsten & Proprietary Fillers)
Quality Capabilities (Certified Since 2010)

- Comprehensive Quality Verification Of All Products
- Verification Performed In An ISO Class 100,000 Clean Room
- Equipment Validations Performed (IQ / OQ)
- First Article Inspection Upon Request
- In-process Production Monitoring
- Process Validation (OQ / PQ) Upon Request
- Statistical Analysis
- Fully Automated Programmable Vision measuring System
- Environmentally Controlled Product Storage
- Successfully Completed Over 50 Customer Audits
Choose HTP-MEDS

• Strong Competent Staff With Deep Technical Expertise

• Speed To Market
  ➢ Fast Quoting & Prototype Development
  ➢ On-time Delivery
  ➢ Robust Quality System
  ➢ Technical Support For Challenging Projects
  ➢ In-house Tooling Design & Fabrication

• Strong Partner Relationships With Key Material Suppliers

• Large Inventory Of Raw Materials & Resins

• Hitachi’s Global Infrastructure & Resource Support For Large Programs & Commitments

We Are Commitment To Excellence
A new chapter in Hitachi’s history is now beginning as we work towards our new Vision; a vision aimed to inspire the world that enables all people to live together more comfortably and safely.

No. 89 on the 2015 FORTUNE Global 500®

Hitachi is one of the world's largest conglomerates. Hitachi Ltd. is Japan's largest manufacturer of electrical machinery and a leading producer of semiconductors.
Hitachi began as a repair shop within the Kuhara Mining Company in Hitachi City, Ibaraki Prefecture, Japan in 1910.

Corporate Mission:
Contribute to society through the development of superior, original technology and products
Hitachi’s Principles

Harmony / Trust / Respect
The willingness to respect the opinions of others and discuss matters in a manner that is thorough and frank, but fair and impartial, and once a conclusion has been reached, to cooperate and work together to achieve a common goal.

Sincerity / Fairness / Honesty / Integrity
To approach issues openly and honestly, without drawing false distinctions between oneself and others. "Sincerity" is the spirit that inspires the confidence that society has placed in us.

Pioneering Spirit / Challenge
A purposeful approach to one’s work based on individual initiative, to create new business by pursuing novel, new goals. This spirit is manifested in a keen desire to be at the forefront of technology and the top of our chosen fields of expertise. These objectives are achieved by promoting the limitless potential of each individual member of Hitachi.

Hiroaki Nakanishi
Hitachi President, 2014
"Hitachi delivers innovations that answer society’s challenges. With our talented team and proven experience in global markets, we can inspire the world."
Importance of Social Innovation

Social Innovation for Healthcare

Healthcare landscapes are dramatically changing today, along with issues such as an aging society, expanding lifestyle related disease and an increase in national medical expenditure.

Hitachi understands that healthcare is an integral part of our social infrastructure. Through it’s innovative technologies and systems/solutions, Hitachi is striving to support a healthy and secure life in the 21st century.
Hitachi Markets

Revenue: Year ended March 31, 2015

$86 Billion USD

- 17.9% - Information & Telecommunication
- 14.1% - Social Infrastructure & Industrial
- 13.5% - Electronic System & Equipment
- 10.0% - Construction Machinery
- 8.6% - Power System
- 8.3% - High Functional Materials
- 7.2% - Automotive System
- 6.7% - Smart Life & Ecofriendly Systems
- 4.1% - Others
High Functional Materials Group Structure

C-Company Is Under Hitachi Metals America, Which Is Under Hitachi Metals Ltd., Which Is Under Hitachi Ltd.
Manufacturing over 4,500 different products

**Product Offerings:**
- Medical Grade Micro-coax
- Premise & Category Cable
- Fiber Optic Cable
- Electronic Cable
- Fiber & Copper Assemblies
- High Speed Active & Passive Assemblies
- Low Friction Cross-Linked PTFE
- Heat Resistant Plastic Optical Fiber (POF)
- Flame-Retardant Polyflex Insulated Wire
HCA Technology Offerings

Fine Wire & Cable Applications

- Surgical
- Ultrasound
- Catheters
- Endoscopy
- Ablation
- Wearables
- Industrial Inspection
- Cleanroom
- Robotics

Growing Focus on Diversification
HML Medical Operations

- **NH, U.S.A.**
  - Bulk cables
  - Medical N.P.I.

- **Kiev, Ukraine**
  - HLA, LLA assemblies
  - Product Development

- **Suzhou, China**
  - Bulk cables

- **Shenzhen, China**
  - Full-probe assemblies
  - HLA, LLA assemblies

- **Hitachi, Japan**
  - Bulk cables
  - R&D

- **(HCA) - ISO9001**

- **(HCSZ) - ISO9001**

- **(Akutron) - ISO9001**

- **(SNHC) - ISO13485**
HML Wire Core

Improve **Tensile Strength & Flex Life** Without Sacrificing **Conductance**

**Hitachi Copper Alloy** With Conductors As Fine As 50 AWG (7/0.010mm)

High Conductivity, Tensile Strength, Heat Resistance & Flexibility

YES ... It’s that small!

- Single Wire (OD 10um)
- Stranded Conductor (OD 25um / 7 Wires)
- Wrapped Around A Human Hair (80μm)
HCA / HML Cabling

Ability To Mix & Match Cable Technologies (Fluid, Power, Optics & Signaling)

- 46 AWG Coax
- 46 AWG Shielded Twisted Pair
- 30 AWG Hookup Wire
- 46 AWG Hookup Wire
Fine Pitch Soldering And Terminations

- Image of fine-pitch soldering with 50AWG 8pcs and 0.15mm Pitch.
- Image of a component with wires and a flex cable covered in pink rubber wrap.

HTP-MEDS

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A Hitachi Group Company
Thankyou

Contract Medical Device Manufacturing Excellence
Come see why we are number one in medical device manufacturing

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