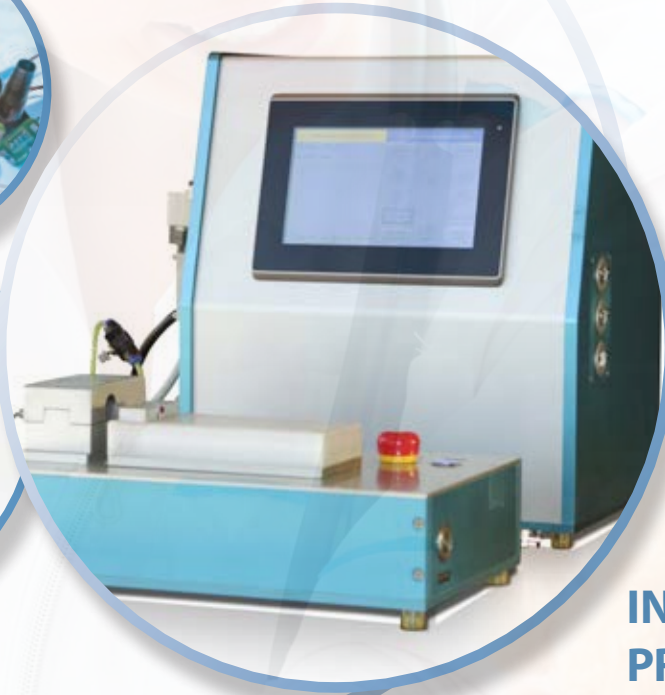


CATHETER MANUFACTURING TURNKEY SOLUTIONS



**INNOVATION
PROCESS EXCELLENCE**

ONEX^{RF}

- TIP FORMING
- BONDING
- FLARING



ONLY EXCELLENCE

We are innovators in pursuit of excellence, delivering turnkey catheter forming solutions for catheter manufacturers worldwide.

Innovative excellence is the driving force behind the ONEX RF brand. We partner with clients and help them with catheter forming and bonding applications.

That being said, ONEX RF is a group of highly qualified and competent engineers who act as an extension to the clients’ R&D, process development and manufacturing groups.

ONEX RF specializes in plastic forming and bonding processes using high frequency plastic melting and induction heating technologies. ONEX RF is a vertically integrated company that provides all the solutions under one roof for clients who are in need of: design services, mold manufacturing, processing systems, process automation and process validation.

Incorporating these advancements, ONEX RF produces user friendly Catheter Forming and Bonding Systems and serves as a lifelong manufacturing partner for our clients, ensuring the timely and successful completion of their catheter design and manufacturing projects.

“Excellence is an art won by training and habituation. We do not act rightly because we have virtue or excellence, but we rather have those because we have acted rightly. We are what we repeatedly do. Excellence, then, is not an act but a habit.”

- Aristotle

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“Quality is found there, where individuals with a disciplined mindset know how to apply and tailor a given technology to produce products with consistency and near zero defects. It is essential that the applied technology is built with self-checking features to confirm the essence of fail-safe manufacturing practices.”

Onik Bogosyan

Dedication to Quality:

ONEX RF systems utilize a unique technology for precise heat control of the tip forming process using a Temperature & RF Power closed loop feedback. The systems are compact and fit on most desktops, including very tight spaces in the manufacturing process. ONEX RF technology does not require any water cooling, making it a contamination free solution for your catheter manufacturing process. The following essential adjustments are controlled by sensor feedback and are stored in the recipe.

- Induction Coil Position
- Forming Slide Position
- Forming Air Pressure

ONEX RF - Your Catheter Manufacturing Partner of Choice

Highly Qualified Team:

- Mechanical Design Engineers
- Control Systems Engineers
- RF Engineers & Technicians
- Precision Tool & Mold Makers
- Process Development Engineers
- Machine Builders

RF Technology Experts:

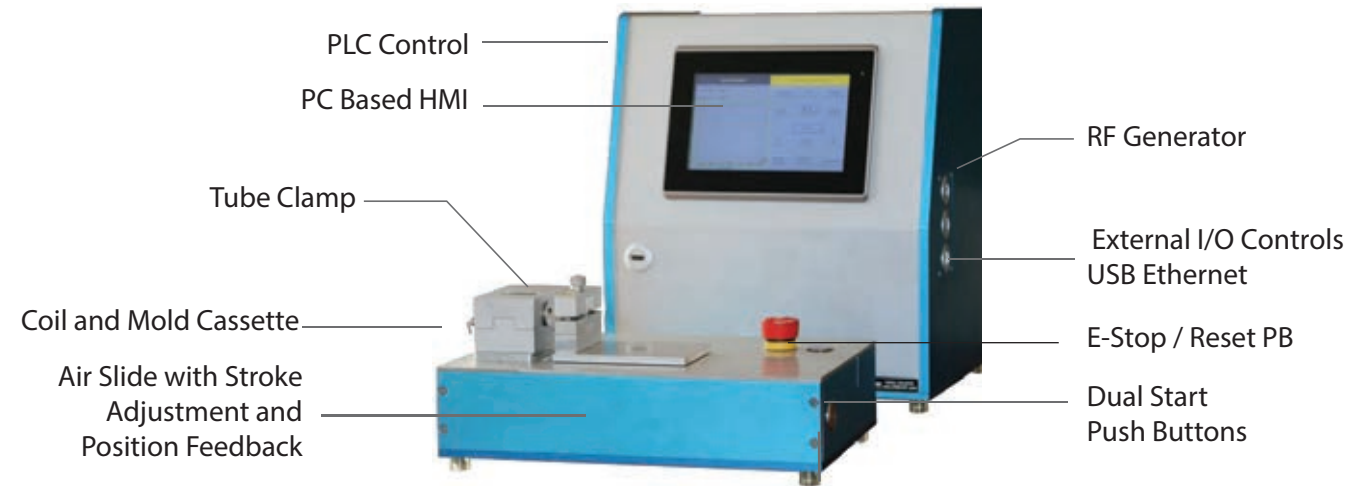
- RF Induction Heating
- RF Dielectric Heating & Bonding
- Process Automation

Rely On Our Experience:

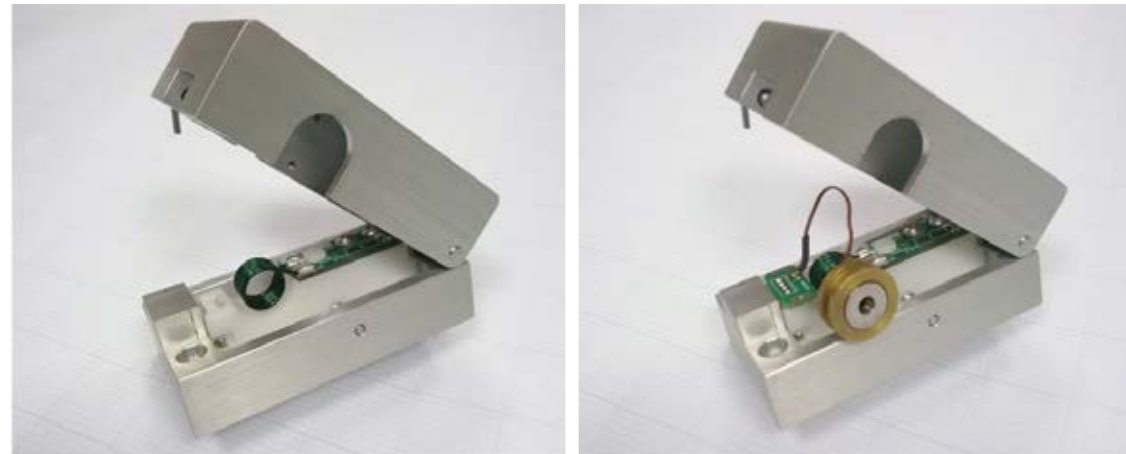
- Mold Design & First Article Inspection (FAI)
- Turnkey RF System Manufacturing
- Design of Experiments (DOE)
- Develop process parameters and form samples
- Provide final inspection and documentation
- Set validation limits and provide samples
- Train customers in the catheter forming process



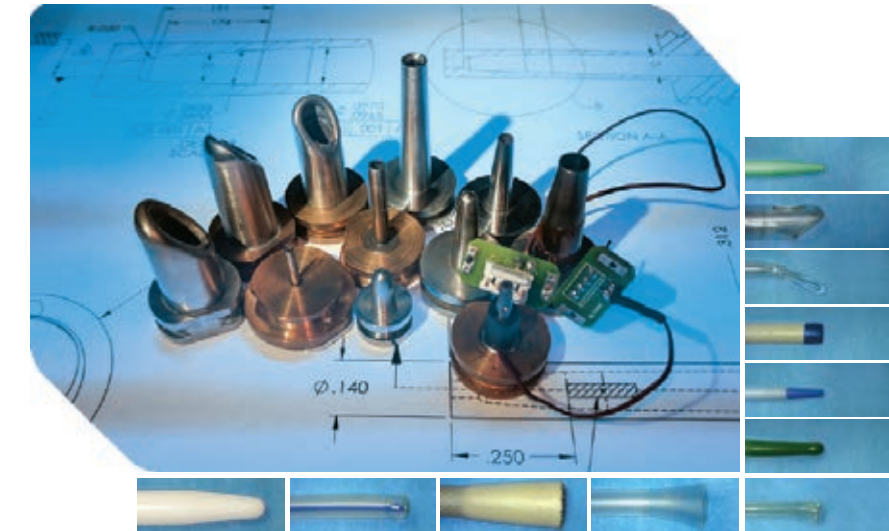
Catheter Tip Forming & Bonding System Overview



Mold Induction Heating Cassette



The Flex-Cassette design lets the customer reuse the same cassette for other catheter manufacturing applications. Just change the coil and mold combination and you're ready to form your ideal catheter.



"Quality begins on the inside... then works its way out"
- Bob Moawad

ONEX RF is well versed in many catheter forming & bonding applications. We have all the internal resources required to create new solutions if the existing systems are not capable of delivering the intended results.

Applications:

✓ Tipping Applications

- ▶ Taper Tips
- ▶ Radius Tips
- ▶ Dilator Tips
- ▶ Hooded Tips

✓ Bonding Applications

- ▶ Soft Tip Bond and Form
- ▶ Butt Welds
- ▶ Braid to Non-Braid
- ▶ Soft Tip to Multi-Lumen

✓ Flaring Applications

- ▶ Distal End
- ▶ Proximal End
- ✓ Neck-Down Application
- ▶ Distal End

The **CTF - 807** model is designed to form the distal and proximal ends of catheter tubes using metallic or non-metallic molds.

Application Configurations:

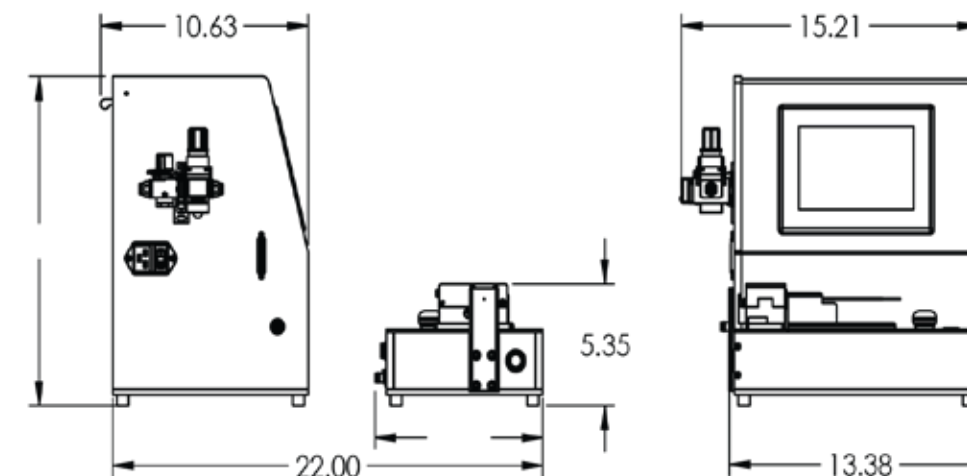
- External Metallic Mold
 - ✓ Straight-Tapered Tips
 - ✓ Rounded Tips
 - ✓ Rounded-Edge Tips
 - ✓ Hood-Formed Tips



MODEL: CTF-807-LX1

Benefits:

- Closed-Loop Process Control with temperature (thermocouple) sensor feedback.
- Tuned molds to produce ideal catheters
- Password protected screens
- Critical parameters saved in "Easy-Tap" recipes
- Recipe backup feature
- Minimal footprint
- Waterless operation



Equipment Specifications

Catheter Sizes	2.5Fr - 36Fr
Forming Method	Induction Heating Coil
Process Control	Temperature / Time & Power
Mold Materials	Stainless, Carbide, Nickel
Mold Cooling	Air Jet
Induction Coil Cooling	Air Jet (No Water Required)
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	70lb
Certification	UL or CE (On Request)



MODEL: STB-807-LX1

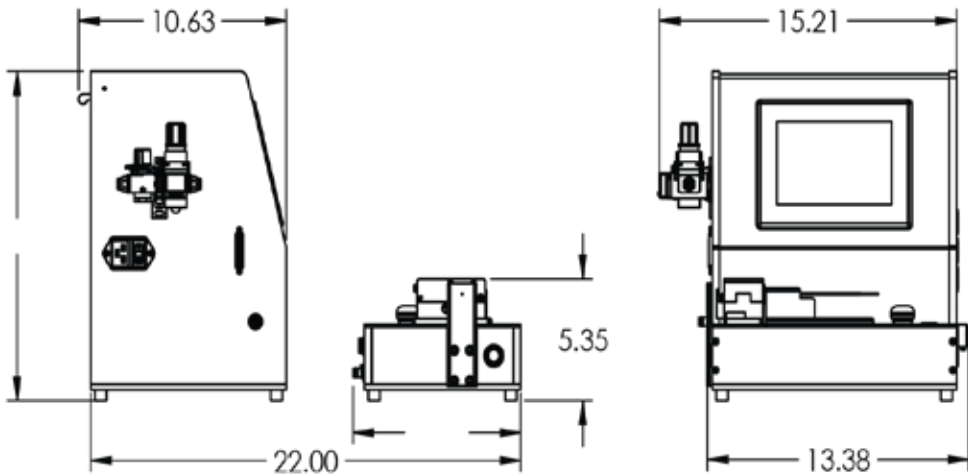
The **STB - 807** model is designed for bonding catheter shafts with softer materials and forming the tips using external heated molds and support mandrels.

Application Configurations:

- External Metallic Mold
 - ✓ Rounded Tips
 - ✓ Bond Soft Tips to Shafts
 - ✓ Bond and Form the Tips
- External Non-Metallic Mold
 - ✓ Butt-Joint
 - ✓ Over Under-Joint

Benefits:

- Closed-Loop Process Control with temperature (thermocouple) sensor feedback.
- R&D Use Mode allows the user to quick test materials by operating the system without a thermocouple, using only Time and Power.
- Coil can be adjusted to control the heat zone on the mold.
- Precise slide stroke adjustment with position sensor.
- Precisely control the the tip forming pressure and speed on the operator screen HMI.



Equipment Specifications:

Catheter Sizes	3Fr - 36Fr
Forming Method	Induction Heating Coil
Process Control	Temperature / Time & Power
Mold Materials	Stainless, Carbide, Nickel
Mold Cooling	Air Jet
Induction Coil Cooling	Air Jet (No Water Required)
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	70lb
Certification	UL or CE (On Request)



MODEL: MTF-807-LX1

Insight Information:

The micro-tipper is comprised of 3 modules:

- I/O Distribution Base Module
- RF Heat Station Module
- Tube Clamp and Slide Station Module

It is a turnkey solution ready to be integrated with automated applications - using only the RF heat station with the mating connectors.

Closed Loop Feedback:

- Mold Temperature
- Forming Pressure
- Slide Position
- Heat Zone

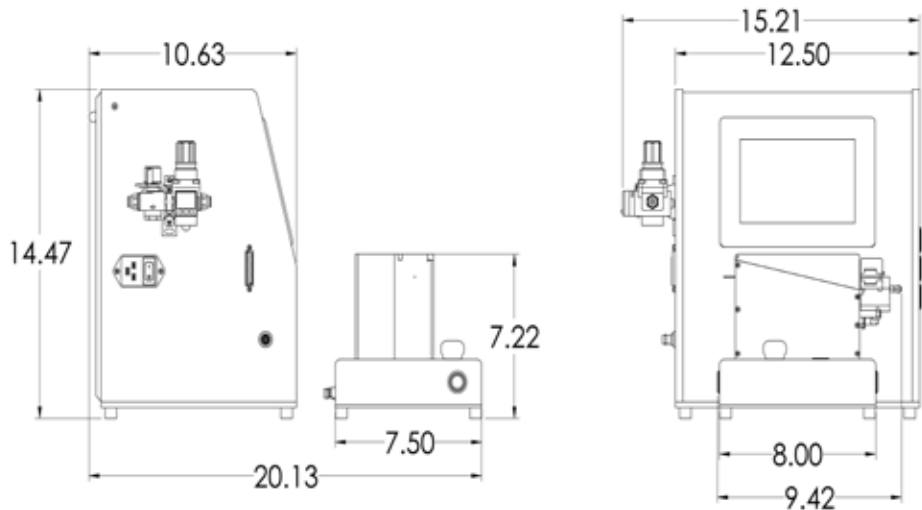
The **MTF - 807** model is designed to form micro-catheter tips with precise process control.

Applications:

- External Metallic Mold
 - ✓ Round Tips
 - ✓ Neck-Downs
 - ✓ Tapered Tips

Achieving Consistent Results:

- Catheter forming speed and precise pressure control.
- Closed-Loop Process Control of temperature and RF power.



Equipment Specifications:

Catheter Sizes	2.5Fr - 7Fr
Forming Method	Induction Heating Coil
Process Control	Temperature / Time & Power
Mold Materials	Stainless, Carbide
Mold Cooling	Air Jet
Induction Coil Cooling	Air Jet (No Water Required)
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	60lb
Certification	UL or CE (On Request)



MODEL: CTF-807-LX2

The **CTF - 807-LX2** model is designed for forming two catheters simultaneously with precise process controls.

Benefits:

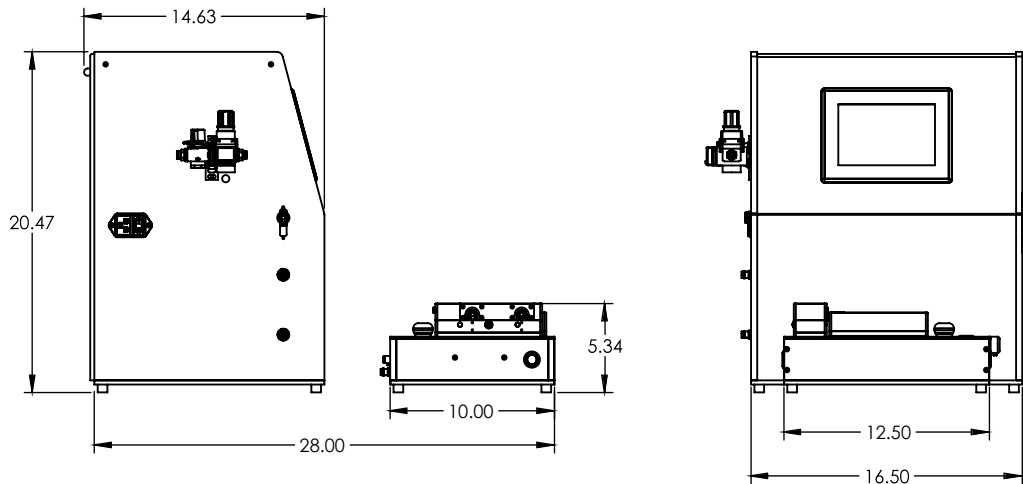
- Increased Production
- Small Footprint
- Perfect Consistency

Application Configurations:

- External Metallic Mold
 - ✓ Straight-Tapered Tips
 - ✓ Rounded Tips
 - ✓ Flared Tips

Process Consistency:

ONEX RF 2-up catheter tipper uses individual RF generators for each cavity mold. Each mold is heated by a seperate induction coil. The mold temperature is monitored individually using thermocouples welded to the mold and is controlled by ONEX RF's closed loop process control.



Equipment Specifications:

Catheter Sizes	6Fr - 36Fr
Forming Method	Induction Heating Coil
Process Control	Temperature / Time & Power
Mold Materials	Stainless, Carbide, Nickel
Mold Cooling	Air Jet
Induction Coil Cooling	Air Jet (No Water Required)
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	95lb
Certification	UL or CE (On Request)



MODEL: BJBW-807-V1

The **BJBW - 807-V1** model is designed to bond two shafts of guide wire using intermediate material. The process can be achieved by ID heating or FEP shrink tube heating.

The BJBW system is equipped with a Vision Camera to properly position the tubes outside of the heat zone. The process will automatically insert the two tubes into the heated section and bond them together.

Applications:

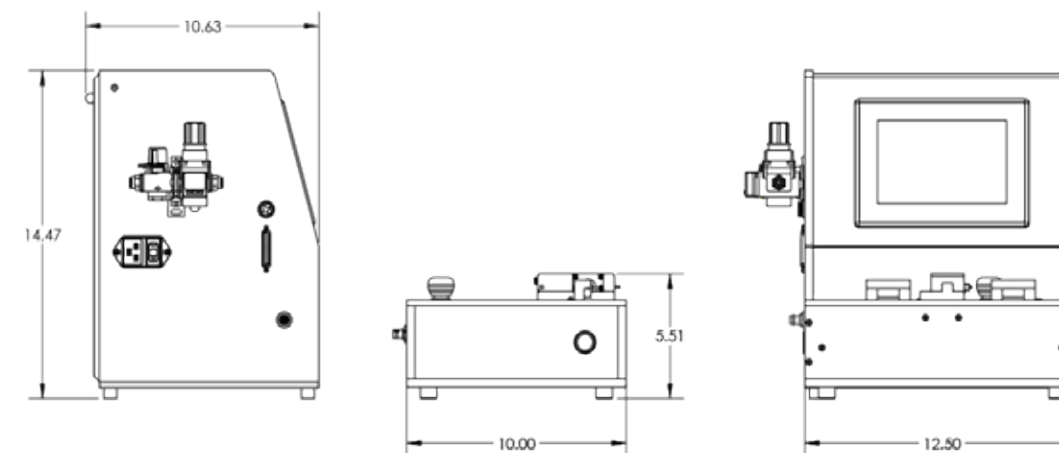
- Internal Mandrel or External Mold
 - ✓ Butt-Weld Joint
 - ✓ Over-Under Joint



ADVANTAGES:

ID Heating: Uses an RF coil to heat the mandrel inside the shaft, which transfers enough heat to bond the two surfaces while simultaneously compressing them together.

OD Heating: Uses FEP shrink tubing inside a proprietary RF heated chamber that maintains a constant temperature and uniformly heats the materials in the target zone.



Equipment Specifications:

Catheter Sizes	4Fr - 10Fr
Forming Method	Induction Heat Coil
Process Control	Temperature / Time & Power
Mold Materials	Stainless, Glass
Mold Cooling	Air Jet
Induction Coil Cooling	Air Jet (No Water Required)
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	60Lbs
Certification	UL or CE (On Request)

TF-803-2/4 STATION



MODEL: TF-803-2/4

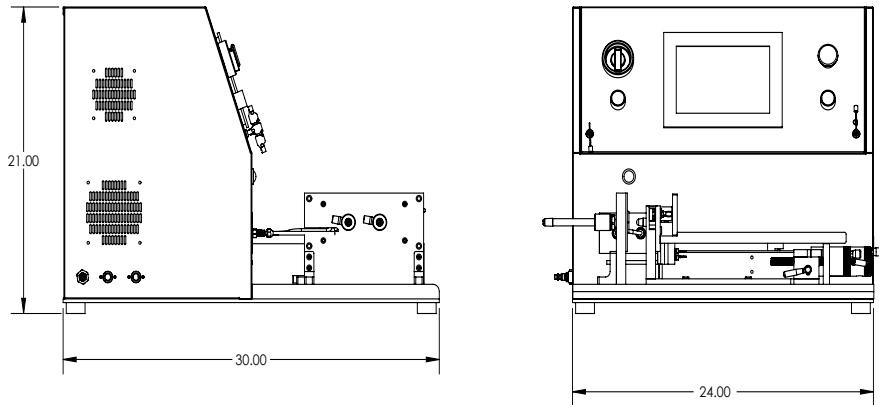
The **TF - 803** model was designed for basic catheter tip forming applications using a 2 or 4 cavity mold heating induction coil.

Applications:

- External Metallic Mold
 - ✓ Bullet Nose
 - ✓ Rounded Tips
 - ✓ Soft Tips
 - ✓ Rounded Edges

Benefits:

- Simple heat zone adjustment by moving the coil across the mold.
- Precise forming stroke adjustment and position feedback.
- Simple mold cassette and tube clamp changeover mechanism.
- Easy set up through PC based HMI.



Equipment Specifications:

Catheter Sizes	8Fr - 36Fr
Forming Method	Induction Heating Coil
Process Control	Time & Power
Mold Materials	Stainless, Nickel
Mold Cooling	Air Jet
Induction Coil Cooling	Water Circulation Required
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	150Lbs
Certification	UL (On Request)

TF-803-2/4 STATION



ATF - Galaxy Line

The ATF-Galaxy Line is a custom automated machine. ONEX RF Automation is ready to design the perfect system that meets your catheter assembly automation requirements.

Achieve 600-1200 parts per hour at 90-95% OEE.

Contact ONEX RF for your next automated catheter manufacturing project.



Modular Catheter Assembly Automation

- Tube Feed Cutting
- Rotary Tip Forming
- Robotic Tube Transfer
- Linear Tube Indexing
- Hole Punching or Skiving
- Pad or Digital Printing
- Connector Assembly
- Vision Inspection



Develop Prototypes Faster with ONEX

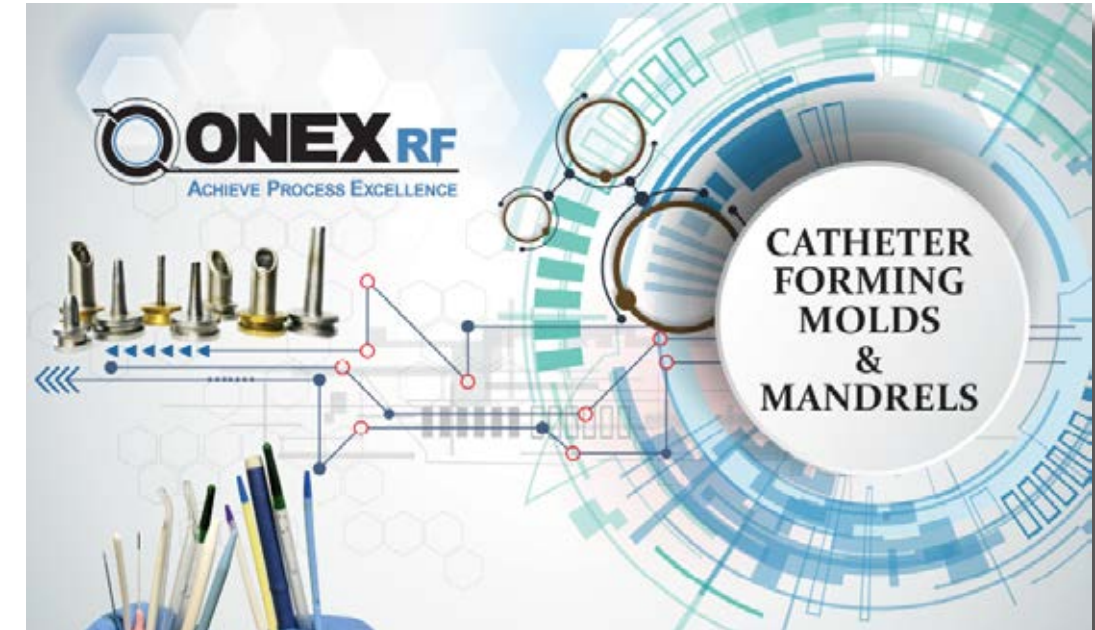
Mold Design

DOE

Prototyping

ONEX RF In-House Services:

- Quick Mold Design and Fabrication
- New Material Feasibility Tests
- Process Development
- Sample Runs
- Support R&D and PD Engineers
- Perform First Article Inspection (FAI)
- Design of Experiments (DOE)
- Validation Assistance (IQ & OQ)



Catheter Molds in Less Than 3 Weeks

Tip Forming

Bonding

Flaring Application

Neck-Down

Taper Tips

Soft Tip Bond-Form

Distal End

Distal End

Radius Tips

Radius Tips

Proximal End

Dilator Tips

Butt Welds

Hooded Tips

Soft Tip-Multi-Lumen

Material Type

Stainless Steel

Carbide

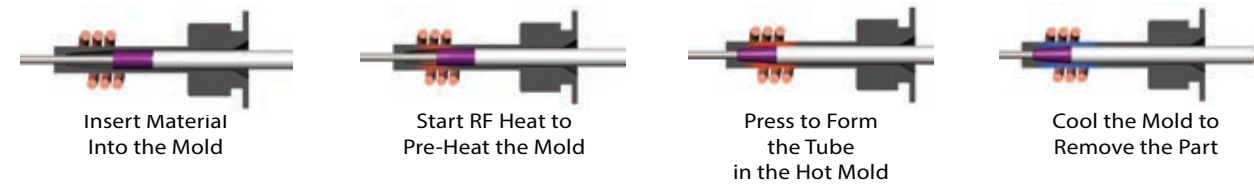
Nickel

Mold Sizes

2.5Fr-36Fr

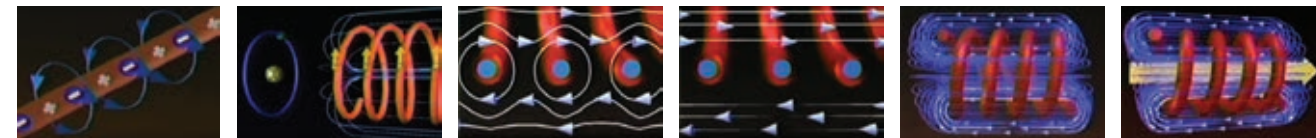
CATHETER TIP FORMING PROCESS USES INDUCTION HEATING METHOD

The catheter tip forming mold is heated by an induction coil in the electromagnetic field. The catheter tube is pressed into the heated mold, which melts and flows into the mold cavity. After the cooling process, the catheter is removed with a solid formed tip.



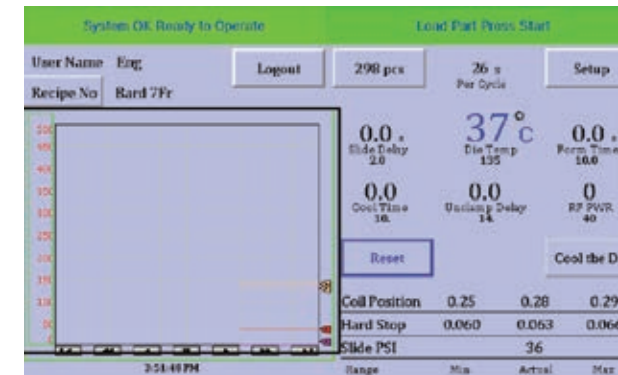
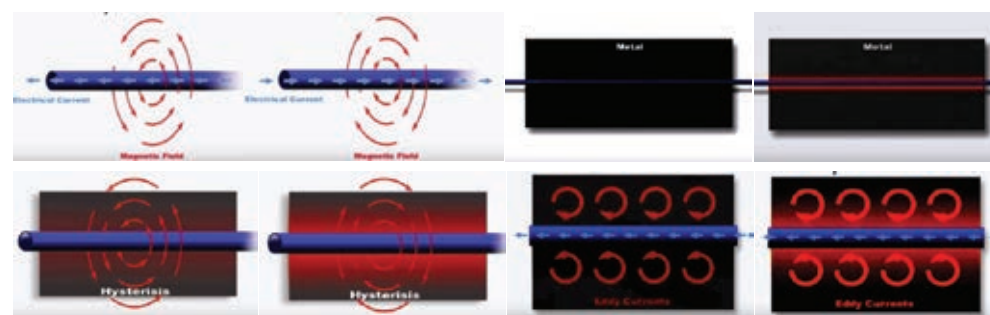
MAGNETIC FIELD IS A RESULT OF - ELECTRON FLOW THROUGH A COIL OR WIRE

An electromagnetic field (EMF) is generated around the coil when high frequency is applied to the coil. The EMF induces an alternating current on the mold surface, which is positioned inside the coil.

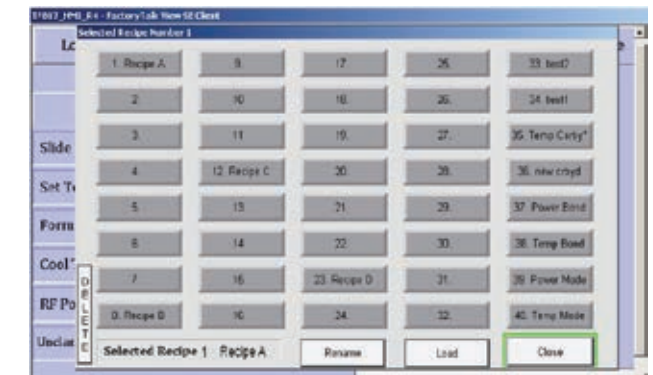


INDUCTION HEAT IS A RESULT OF - EDDY CURRENTS AND HYSTERESIS

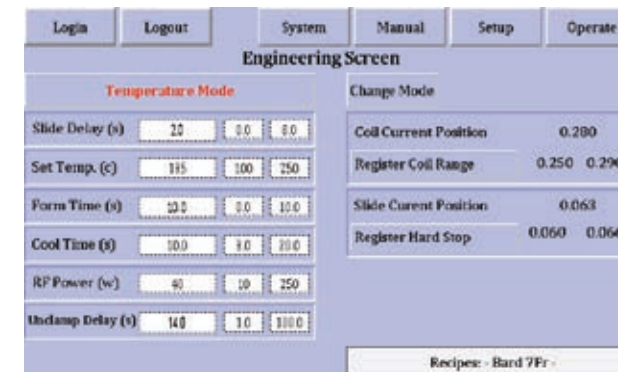
The induced alternating current flows in the section covered by the coil (where the field is strongest), which creates Eddy Currents in the mold. The alternating magnetic flux creates Hysteresis. The Eddy Currents combined with Hysteresis Effect create heat on the mold surface due to the mold's material properties.



Main Screen



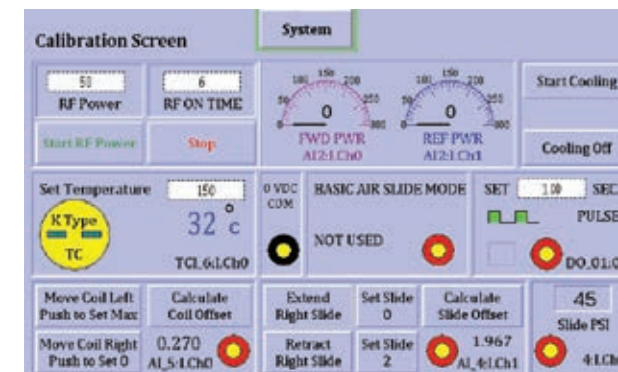
Recipe Screen



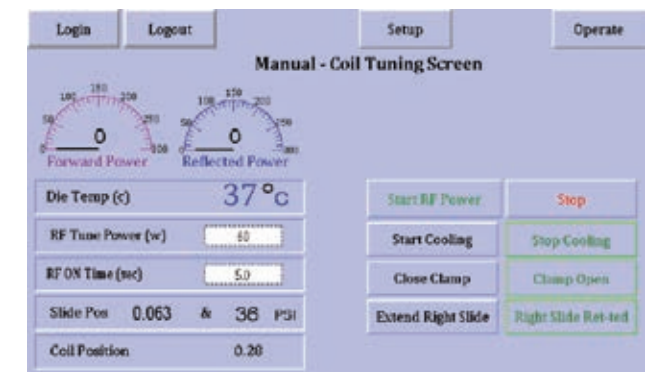
Engineering Setup Screen



Process Data Log Screen



Calibration Screen



Manual Screen



Master Your Skills:

We offer advanced RF Training Seminars at the client site or at **ONEX RF** in Los Angeles, CA. The training will help you understand general RF Theory combined with the RF Heating Process.

We work with many R&D Engineers to help them gain practical knowledge on how RF Induction Heating works and how to apply RF Heating in various Catheter Forming and Bonding applications.

Typical Class Size: 2-6 Engineers

Seminar Topics:

- RF Induction Heating
- Plastic Melting and Forming
- RF Heat Concentration and Mold Design Principles

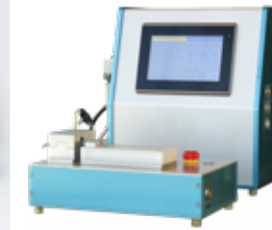
Contact us to set up your Training Seminar at www.onexrf.com or +1.626.358.6639

Take ONEX RF training seminars to master your process development skills in catheter tip forming and bonding applications.

PRODUCTS & SERVICES



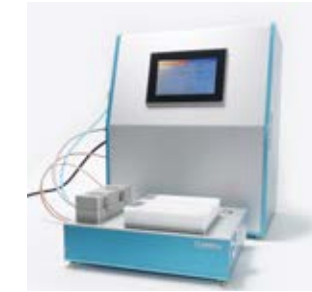
CTF-807-LX1



STB-807-LX1



MTF-807-LX1



CTF-807-LX2



TIP FORMING MOLDS



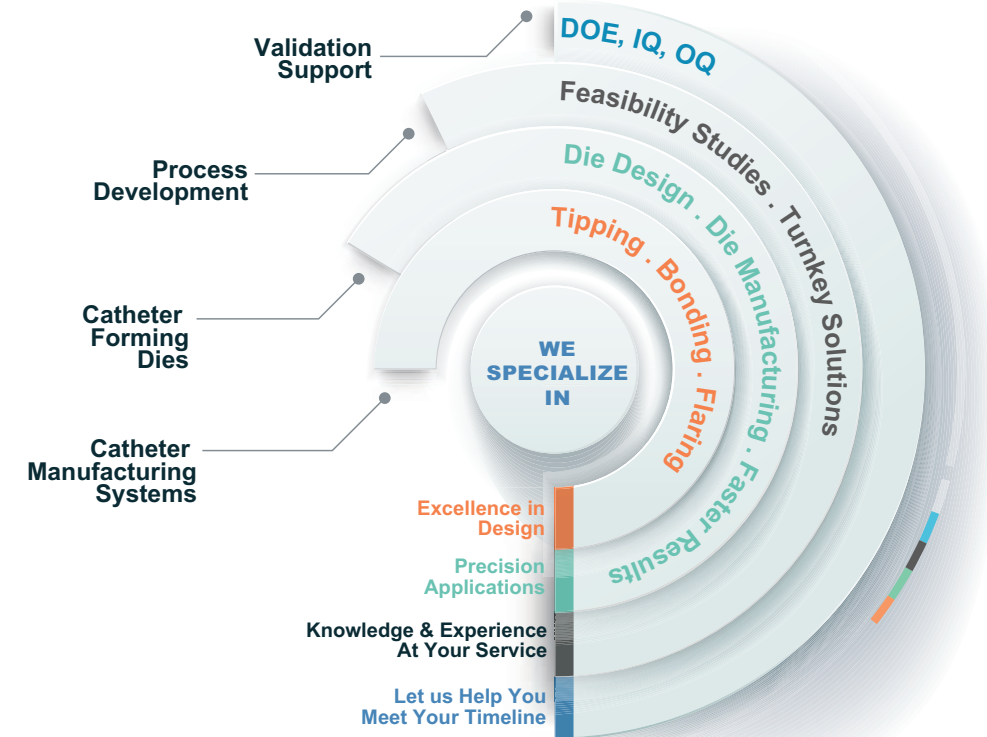
BJW-807-V1



TF-803-2/4



ATF-GALAXY



**YOUR CATHETER MANUFACTURING
PARTNER OF CHOICE**

EXPECT **ONLY**
EX EXCELLENCE

ONEX RF, Inc.
1824 Flower Ave., Duarte, California 91010 USA
www.onexrf.com
+1.626.358.6639