ONEX RF
ACHIEVE PROCESS EXCELLENCE

CATHETER MANUFACTURING TURNKEY SOLUTIONS

INNOVATION
PROCESS EXCELLENCE

ONEX RF

- TIP FORMING
- BONDING
- FLARING

ONLY EXCELLENCE

We Are Innovators In Pursuit of Excellence Delivering Turnkey Solutions To Our Catheter Manufacturing Clients.

Innovative excellence and a client first directive are the driving forces behind the ONEX RF brand. We distinguish ourselves by partnering with clients to resolve catheter forming or bonding challenges and process inefficiencies.

That said, ONEX RF is exceedingly nimble and is highlighted by a determined, highly qualified team of engineers. They act as an extension of the clients' R&D, Process Development and Manufacturing groups, helping them to design dies, make samples, perform process development and finally provide fully capable systems ready to produce the customer's product.

Incorporating these advancements, we produce Superior Catheter Forming and Bonding Systems and serve as a lifelong business partner for our clients, ensuring their timely success in catheter design and the manufacturing process.

"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

"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

In Search of Quality:

ONEX RF systems employ closed-loop process controls, which are intended to monitor and record various process control parameters: Induction Coil Position, Forming Slide Pressure and Position, the RF Power and Mold Temperature in order to maintain optimal consistency throughout the product Forming Process.

ONEX RF is committed to producing turnkey catheter manufacturing systems that demonstrate Stability in process and produce a perfect catheter every time, in a small tabletop space.

By combining our RF technology experience with the skills in the process development, we are happy to be your unmatched catheter manufacturing partner of choice.

ONEX RF Strengths

Single Source Solutions

ONEX RF is a vertically integrated company where we design and manufacture all the mechanical, electrical and RF systems. ONEX RF consistently delivers perfect solutions to the challenges our clients face and bring new innovative systems to the catheter manufacturers.

Knowledge and Experience

ONEX RF is a team of competent engineers with combined knowledge of thermoplastics, RF systems and plastic forming and bonding processes to support engineers in the catheter manufacturing industry.

Resolving Client System or Process Issues

Almost all ONEX RF and client relations have started from a basic proof of concept trying to resolve client issues related to existing process or equipment.

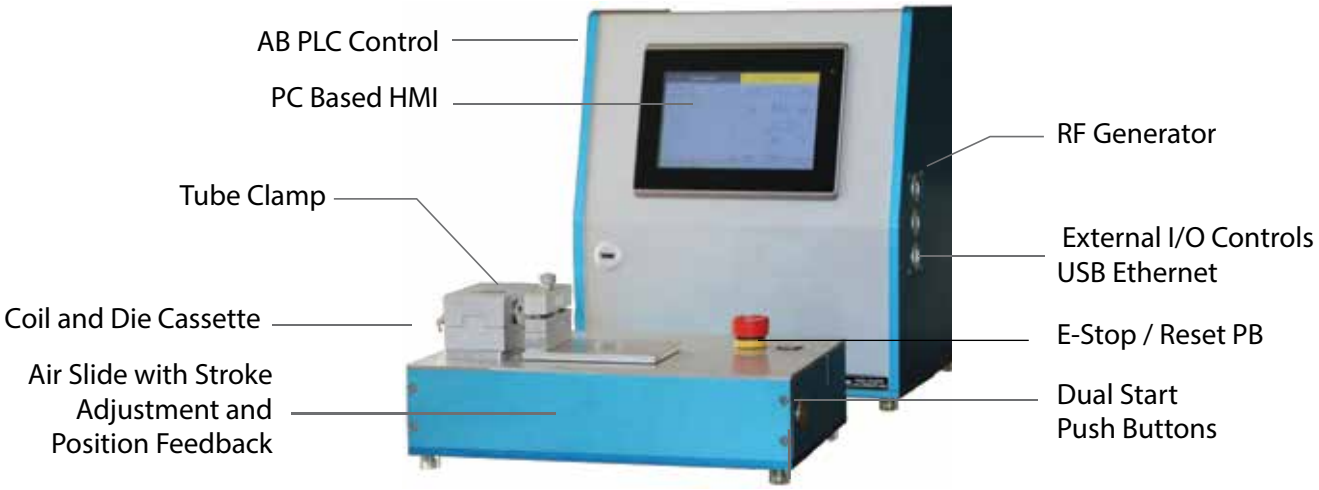
Process Development Services

ONEX RF team can design and manufacture a new die or use the client's die to create a perfect formed or bonded parts using the ONEX RF tipping system.

We provide the following services:

- Assistance with Product Design and Material Selection
- Help to ensure Design For Manufacturability (DFM)
- RF Tip Forming, Bonding, Die Design and Fabrication
- Material Testing and Process Development
- Loan equipment to test process at client site

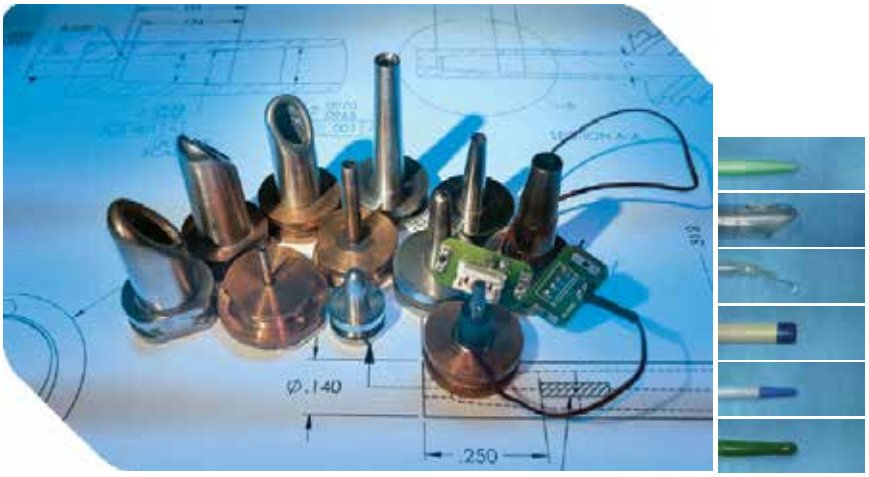
Catheter Tip Forming & Bonding System Structure



The Ultimate Design Flexibility

The Forming Die and Coil are mounted inside the Modular Cassette. The Coil can be adjusted to set the heat zone for optimum results.

DIE DESIGN & MANUFACTURING



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

Need Dies Fast?

- Die Design
- Die Manufacturing
- Material Testing
- Sample Run
- Basic Process Development
- Full Process Development
- Process Limit Setting & DOE
- IQ, OQ, Validation support

Applications

✓ Tipping Applications	✓ Bonding Applications	✓ Flaring Applications
▶ Taper Tips	▶ Soft Tip Bond and Form	▶ Distal End
▶ Radius Tips	▶ Butt Welds	▶ Proximal End
▶ Dilator Tips	▶ Braid to Non-Braid	✓ Neck-Down Application
▶ Hooded Tips	▶ Soft Tip to Multi-Lumen	▶ Distal End

CTF-807-LX1
RF Catheter Tip Forming System 1-Up

Do it yourself with confidence:

ONEX RF systems come with many essential features and benefits to serve the client needs on the R&D and manufacturing floor.

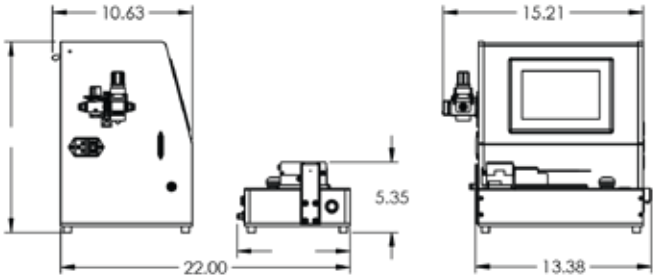
Process development will become a joy when you can solely rely on the system capabilities instead of others to finish your tasks on schedule.

ONEX RF will help you reach the level of confidence to do it yourself.

The CTF - 807 model is designed to form the distal or proximal end of a catheter tubing using a metallic or non-metallic mold with mandrel or without.

Application Configurations:

- External Metallic Mold
  - √ Straight-Tapered tips
  - √ Rounded tips
  - √ Rounded-Edge tip
  - √ Hood-Formed tips



Equipment Specs

Catheter Sizes	3Fr to 26 Fr
Forming Method	Induction Heating Coil
Process Control	Temperature / Time & Power
Die Materials	Stainless, Carbide, Nickel
Die Cooling	Air Jet
Induction Coil Cooling	Air Jet (No Water Required)
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	80Lbs
Certification	UL or CE (Per Request)

ESSENTIALS FOR CATHETER TIPPING PROCESS

ONEX RF IS CONTINUALLY REDEFINING THE MEANING OF PROCESS EXCELLENCE IN CATHETER DEVICE MANUFACTURING

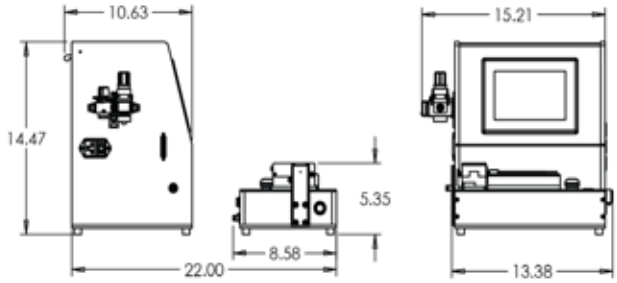
ONEX SYSTEM BENEFITS:

- No more worrying about your existing dies and past investments.
- We will tune your existing die to form perfect catheters on our CTF-807.
- You can only change the process parameters via password protected screens.
- Save the validated process parameters into 40 "Easy-Tap" recipe fields.
- Save each recipe into an archive file or create full back-up of all 40 Recipes.
- Cut your workspace needs in half by using a small footprint tipping station.
- Eliminate water contamination - just use air to cool the die and coil.
- No water!

The STB - 807 model is designed for bonding and forming tubing surfaces by an external or internal heating method.

Application Configurations:

- External Metallic Mold
  - Butt-Joint
  - Bond soft tip to a shaft
  - Bond and form the tip
- External Non-Metallic Mold
  - Butt-Joint
  - Over Under-Joint



STB-807-LX1
Soft Tip Bonding System 1-Up

Insight Information:

When using the External Metallic Mold, the process temperature is measured off the Mold surface and the temperature feedback is used for closed loop process control.

When using internal heating methods, the Mold temperature is not readily available; the induction heat is controlled by Time & Power. To prevent a residual heat build-up, ONEX RF uses a special algorithm to maintain a stable heating process without temperature feedback.

Equipment Specs

Catheter Sizes	3Fr to 26 Fr
Forming Method	Induction Heating Coil
Process Control	Temperature / Time & Power
Die Materials	Stainless, Carbide, Nickel
Die Cooling	Air Jet
Induction Coil Cooling	Air Jet (No Water Required)
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	80Lbs
Certification	UL or CE (Per Request)

ESSENTIALS FOR BONDING PROCESS

ONEX RF IS COMMITTED TO PROVIDING PROCESS STABILITY AND CONTROL TO PRODUCE A PERFECT BOND EVERY TIME.

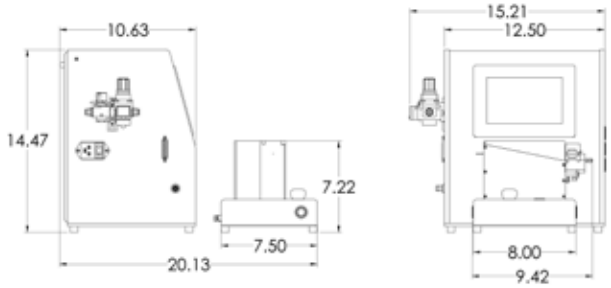
HOW CAN YOU ACHIEVE PROCESS CONSISTENCY?

- Closed-Loop Process Control
  - Measure and maintain the forming temperature for process consistency.
  - Measure and control RF power for optimum heating process-curve.
- Adjust and measure the coil position to control the heat zone of bonding surfaces.
- Adjust and measure the slide stroke to control the bond formation.
- Adjust and measure forming pressure to control the bond strength.
- Use these essential tools to control your process and save the measured parameters as part of the recipe to prevent operator error.

The MTF - 807 model is designed for forming the tips of micro catheters.

Application Configurations:

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



MCTF-807-LX1
Micro Tip Forming System 1-Up

Insight Information:

The micro-tipper is designed with high precision components and measuring devices.

The feedback devises are .

Equipment Specs

Catheter Sizes	6 Fr and under
Forming Method	Induction Heating Coil
Process Control	Temperature / Time & Power
Die Materials	Stainless, Nickel
Die Cooling	Air Jet
Induction Coil Cooling	Air Jet (No Water Required)
Utilities	110-240VAC / 15A / 80PSI
Shipping Weight	70Lbs
Certification	UL or CE (Per Request)

ESSENTIALS FOR MICRO-TIPPING PROCESS

ONEX RF IS READY TO SUPPORT CUSTOMERS THAT DEVELOP and MANUFACTURE CATHETERS SMALLER THAN 4-Fr.

HOW CAN YOU ACHIEVE MICRO-TIP PROCESS CONSISTENCY?

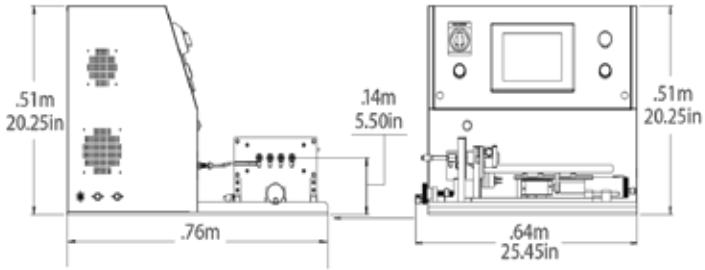
- Precise control of forming pressure
- Precise control of forming and speed.
- Precise control of forming stroke
- Closed-Loop Process Control
    - Measure and maintain the forming temperature for process consistency.
    - Measure and control RF power for optimum heating process-curve.

TF - 803 model was designed for non-precision applications where multiple catheters are formed simultaneously and slight tip variations are tolerable.

Application Configurations:

- External Metallic Mold
  - Bullet Nose
  - Rounded tips
  - Soft Tips
  - Rounded edges

Typical applications include: urinary catheters and suction catheters.



TF - 803 - 2/4

Catheter Tip Forming System 2 or 4 Up

SINCE THE INCEPTION

The TF-803 is the first catheter tipping system we designed over a decade ago.
We entered the market to fulfill the need for necessary feedback controls and critical adjustments of the forming process:
Faster cooling cycles, sensor position feedback and precise heat zone adjustment with feedback.

Equipment Specs

Catheter Sizes	8Fr to 26 Fr
Forming Method	Induction Heating Coil
Process Control	Time & Power
Die Materials	Stainless, Nickel
Die Cooling	Air Jet
Induction Coil Cooling	Water Circulatory Required
Utilities	220VAC / 20A / 80PSI
Shipping Weight	150Lbs
Certification	UL (Per Request)

The TF-803 Model Uses First Generation Low Frequency Technology

REPLACE YOUR OLD SYSTEM

The TF-803 is the perfect substitute for your older RF tipping system, where replacement parts or support is not available.

ONEX RF will help you in process development and in transitioning to the new system with modern and better process controls.

ONEX RF Systems Benefits

- Simple heat zone adjustment by moving the die cassette in and out of the coil
- Precise forming stroke adjustment and position feedback
- Simple die cassette and tube clamp changeover mechanism
- Easy set up through PC based HMI

ATF - Galaxy Line

Modular Automated RF Catheter Tipping Line

You choose the modules and we make it happen

- ATF-Galaxy Line
- Tube feed cut station
- Tube transfer station
- Tube rotary indexing station
- Rotary tip forming station
- Robotic tube transfer station
- Linear tube indexing
- Hole punching or skiving station
- Print station
- Connector feed and insert station
- Vision inspection
- Unload station

CATHETER MANUFACTURING AUTOMATION

IT'S A TEAM EFFORT

The ATF-Galaxy Line is a custom automated machine.
ONEX Automation and ONEX RF combined, bring close to 30 years experience in RF systems and Med-Device assembly automation. We work closely with the client to design the right systems that meet product forming, assembly and inspection requirements.

Capable of producing 800-1200 units/hr

- Fully Automated
- Modular Design
- System OEE - 90-95%

WE HELP CUSTOMERS TO DEVELOP & LUNCH THEIR PRODUCTS FASTER

Services you can depend on:

- Catheter material selection
- New material forming tests
- Tipping die design
- High quality and faster die manufacturing
- Custom forming applications
- Run samples on the new dies
- Transfer process from old to new ONEX system
- Perform validation runs
- Perform DOE, IQ, and OQ reports
- Assist customer on-site validation

FROM DESIGN TO COMPLETION

JOIN THE GROUP OF OUR HAPPY CUSTOMERS LIST

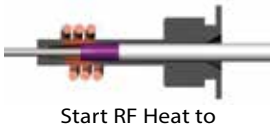
WE CAN HELP YOU MAKE FEASIBILITY STUDIES ON MATERIALS AND PROCESSES

- Design & manufacture catheter forming dies
- Perform feasibility studies on various catheter materials
- Execute DOE analyses and create process parameters
- Run batch of samples for customer evaluation
- Inspect formed parts and create reports for customer review
- Design and manufacture turnkey catheter tipping system & process

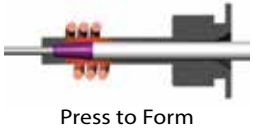
CATHETER TIP FORMING PROCESS USING INDUCTION HEATING METHOD

The catheter tip forming die is heated by an Induction Coil Electro-Magnetic Field.
The die surface heat is a result of the Eddy Currents and Hysteresis effect due to the alternating magnetic field..
As the catheter tubing is inserted into the heated die, the catheter material melts and flows inside the die cavity. After cooling the die, the tip of the catheter takes the shape of the inner shape of the die cavity.

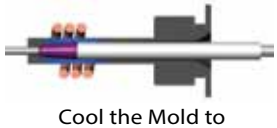
Insert Material
Into the Mold



Start RF Heat to
Pre-Heat the Mold



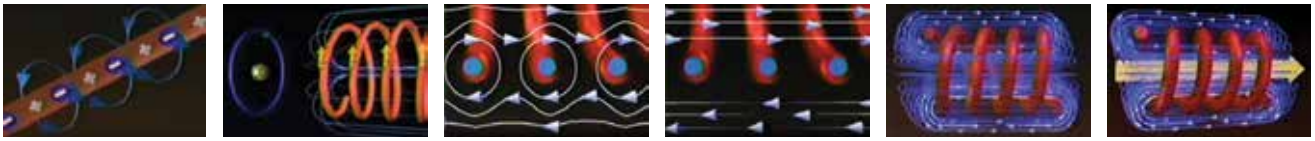
Press to Form
the Tube
in the Hot Mold



Cool the Mold to
Remove the Part

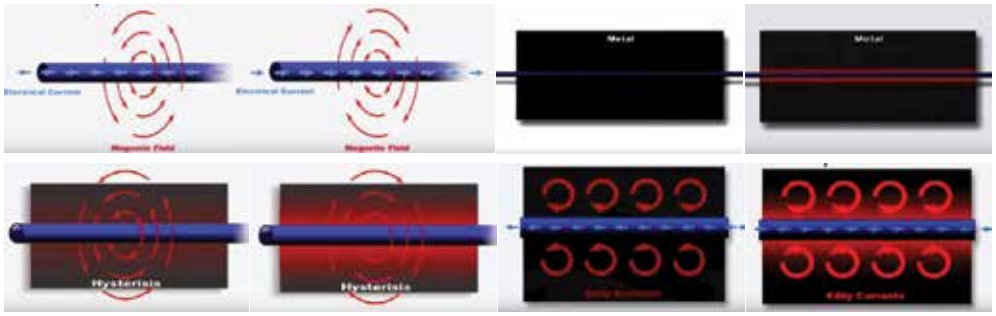
MAGNETIC FIELD - IS A RESULT OF ELECTRON FLOW THROUGH A COIL OR WIRE

By applying high frequency energy through a coil, a magnetic field is generated around the coil. The alternating field induces an alternating current on the section of the die 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 die section. The alternating magnetic Flux creates Hysteresis. The Eddy Currents combined with Hysteresis create heat on the die surface due to the properly selected die material properties.

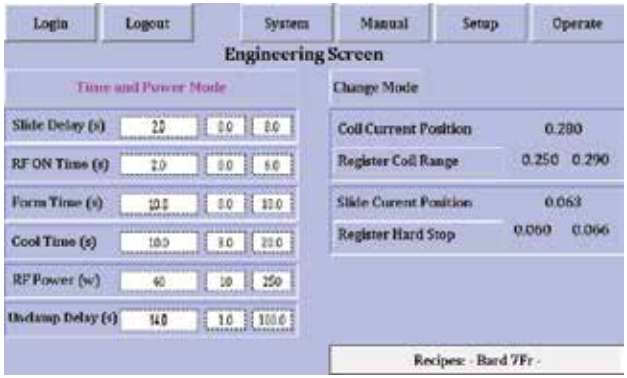


ONEX RF HMI CONTROL SCREENS

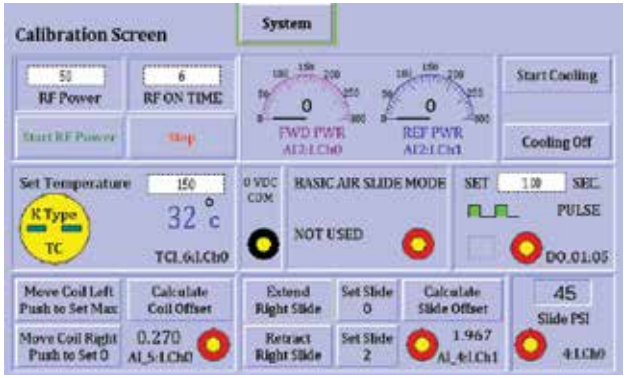
Main Screen

Recipe Screen

Engineering Setup Screen (Temperature Mode)



Engineering Setup Screen (Time & Power Mode)



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.

Usual class size is 2-6 Engineers.

SEMINAR TOPICS:

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

Take ONEX RF Training Seminars to master your Process Development Skills in Catheter Tip Forming and Bonding Applications.

Contact us to setup your Training Seminar at www.onexrf.com or (626)-358-6639.

OUR PRODUCTS AND SERVICES

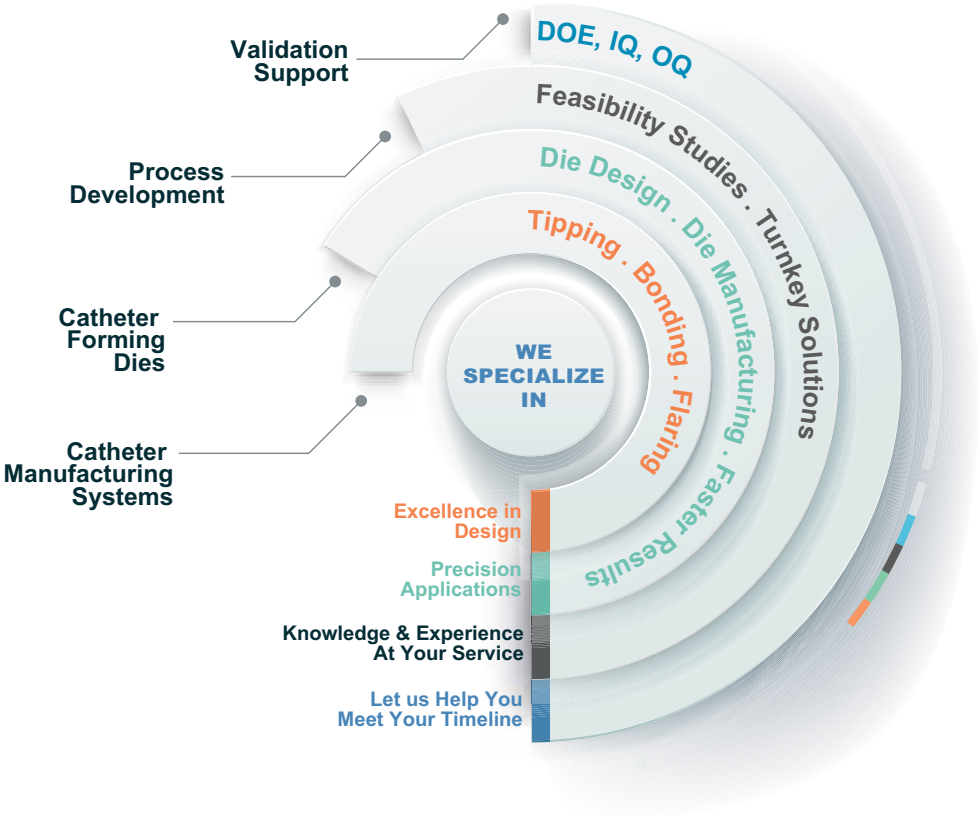
TIP FORMING DIES

CTF-807-LX1

STB-807-LX1

TF-803-L2

ATF-Galaxy-PMCA



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