Despatch

Thermal Processing Technology

ITW EAE

Ovens for Catheter Manufacturing

Solutions for applications including annealing, curing, drying, and shape-setting catheters









Despatch

Solutions for:

- Braided catheter reflow
- Peripherally inserted central catheters (PICCs)
- Central venous catheters
- Intravenous catheters
- Urinary catheters
- ♦ Implantable ports
- Annealing balloon catheters to increase tensile strength
- Curing of hydrophilic gel and silicone coatings
- Curing antibacterial silver coating on Foley catheters
- Shape setting Nitinol used in cardiac ablation catheters
- Drying medication coatings
- Distal adhesive curing

Key features

- Hanging solutions and vertical height to accommodate part length up to 80 inches long
- Hooks/mandrels to discourage parts from impinging on each other
- Shape setting in vertical or horizontal orientation
- ◆ Clean process: Class 100
- Safe handling of solvent based coatings
- Solution for curing coating on distal or proximal tip only
- Continuous or batch

Catheter manufacturing solutions

Despatch is a trusted supplier of thermal processing solutions for catheter manufacturing

Despatch has extensive experience and thoroughly understands the thermal processing challenges inherent in catheter manufacturing. Despatch offers high-quality ovens ideally suited to the application requirements of this market.

Despatch ovens are used for curing and drying of coatings and linings that protect against urinary tract infection or increase lubricity to ease the discomfort of insertion. They are used for thermal curing for adhesive bonding of the ports and attachments and for annealing which provides flexibility and hardness to suit specific applications. Braided catheters require a reflow oven to fuse the lubricious inner liner, braided reinforcement and polymer outer jacket. Despatch ovens are also used for shape-setting catheters to change the form of these catheters. The catheters or sheaths are setup in a mold and then heated to a specified temperature to impart a different shape.



Despatch solutions for catheter manufacturing

While long catheters are becoming more common, short catheters are still in demand. For these shorter catheters a variety of batch and conveyor ovens may be suitable. For applications where just the distal tip requires thermal processing, an oven with a slotted door is a good solution.

A clean process oven with Class 100 HEPA filtration may be required to meet regulations for some catheters. At a minimum, a stainless-steel interior is recommended for easy cleaning. When processing solvent-based coatings, a Class A oven may be needed to safely handle flammable solvents or large amounts of moisture removal. These ovens include a pressure relief panel, purge timer and exhaust fan.

LCC Clean Process Oven

- Max temp: 662°F (350°C)
- ◆ HEPA filtered: ISO Class5
- ◆ Stainless steel inside and out

Chamber sizes available:

- ◆ 15 x 14 x 14 inches
- 23 x 20 x 20 inches
- ◆ 25.5 x 26 x 37 inches







LAC Clean Process Oven

- Max temp: 500°F (260°C)
- ◆ 304 stainless steel interior

Chamber sizes available:

- ◆ 19 x 18 x 19 inches
- ◆ 24 x 20 x 24 inches
- ◆ 24 x 24 x 36 inches
- 36 x 24 x 36 inches



LFC Class A Oven

- Max temp: 500°F (260°C)
- ◆ 304 stainless steel interior
- Class A (NFPA 86) for flammable solvents

Chamber sizes available:

- ◆ 19 x 18 x 19 inches
- 24 x 24 x 36 inches

PCC Series Conveyor Oven

- Max temp: 500°F (260°C)
- ◆ HEPA filtered: Class1000
- Stainless steel interior
- Vertical down airflow
- Class A option
- Variable speed conveyor

Chamber sizes available:

- ♦ 18 x 42 x 9 inches
- ◆ 24 x 60 x 9 inches
- ◆ 30 x 120 x 6 inches







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DESPATCH PRC2-63 FEATURES

- ◆ Maximum temperature of 260°C (500°F)
- ◆ Vertical up airflow
- ◆ Small footprint
- ◆ 84 inch tall chamber to hang catheters
- ◆ 304 stainless steel interior
- ◆ 5-year heater warranty
- PC interface for remote input, monitoring and recording (RS485 connection)
- UL and C-UL listed open industrial control panel

Processing Long Catheters

A unique solution for annealing, curing and reflowing

Catheters range anywhere from 3" to over 6' (7.5 cm to 2m) long. To manufacture such catheters, parts are hung in an oven anywhere between 30 minutes to an hour at a temperature dictated by the material.

Orientation of long catheters relative to airflow is critical. Using airflow perpendicular to the catheters (for example hanging catheters with horizontal airflow) will result in defects including bubbles and surface blemishes where parts have touched due to airflow impingement and movement. An oven that is tall enough to accommodate long catheters in a vertical orientation is critical. Hanging catheters with vertical airflow prevents airflow impingement.

Despatch PRC2-63 Catheter Curing and Annealing Oven

The Despatch PRC2-63 is designed specifically to address the unique requirements of catheter manufacturers. It features vertical airflow with room to hang catheters up to 80 inches long inside the chamber, and a stainless-steel interior for easy cleaning.

Trucks and fixtures designed for hanging catheters

Trucks with fixtures can be built from which to hang the catheters, and anchors can be added to further minimize movement. Using two trucks, the operator can set the process recipe for a batch of parts to be coated, and once the process is complete for



Catheter manufacturing

Thermal processing applications for catheters

Curing and Drying Catheter Coatings

To minimize the risk of spreading infections, catheters often have antimicrobial coating applied. After coating is complete, which usually takes only a few minutes, the catheters go through a dry time, followed by a thermal cure. This material is bio-absorbable in nature and involves a solvent, so the oven needs to be rated for flammable solvents. Moisture is another consideration when it comes to processing catheters, so humidity control is an important aspect when selecting an oven to manufacture catheters.





Braided catheters require a reflow oven to fuse the lubricious inner liner, braided reinforcement and polymer outer jacket. A removable heat shrinkable sleeve is used to apply compression while the out jacket reflows through the braid and fuses to the inner liner. Braided catheters add strength and torsion resistance needed for steerable medical devices.

Annealing of Balloon Catheters

A balloon catheter is required to be high pressure resistant, resistant to fatigue, have thin walls for free movement. Annealing increases the tensile strength of the material allowing the balloons to be used with small wall thickness and makes it pressure resistant. Annealing also helps relieve internal pressure or stresses that could jeopardize performance.

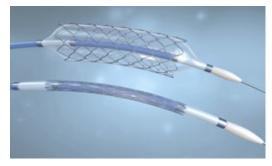
Annealing is usually a batch process. It involves placing the balloon in an oven while controlling the moisture content and heating it to annealing temperature at a controlled rate. Many times, the catheter or the balloon is pre-heated to accelerate the annealing process. The balloon is then held at the annealing temperature for a specific period. The balloon is then cooled down, either naturally or by artificially accelerated cooling at a specific rate.















Annealing and Shape-setting Ablation Catheters

Catheters are used extensively for cardiovascular procedures. Cardiac ablation catheters use micro wires to transmit Radio Frequencies (RF) to the site of the ablation and detect metrics such as temperature, pressure, flow rate, etc. These micro wires are manufactured through a process called drawing. After drawing, annealing is used to eliminate stress created in the drawing process. The annealing temperature is typically one-third the melting temperature of the metal. Finally, a coating is applied to the catheter using previously mentioned processes.

The metals used in catheters go through a process called shape setting. This process imparts a specified shape into the metal through fixturing and heat treating. Nitinol, a Nickel-Titanium alloy, is shaped by wrapping the wire around a mandrel or fixture and heat treating it at a controlled temperature for a specified time to impart the desired shape. The temperature at which the wire is heated exceeds the temperature at which the shape of the fixture becomes programmed into the wire. The assembly is then cooled, and the wire is removed from fixture and straightened. Following this, the wire is inserted inside a sheath inserted into the catheter tip and wrapped in a heat shrink.



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