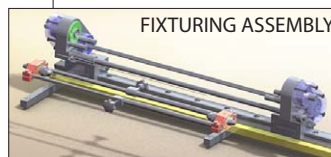


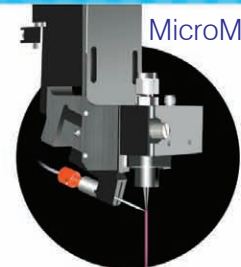
Ultrasonic Balloon Catheter Coating System



ULTRASONIC NOZZLE



FIXTURING ASSEMBLY

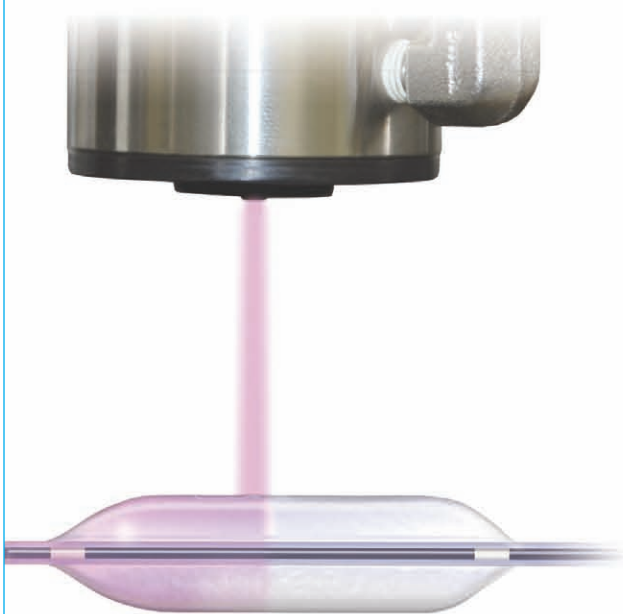


MicroMist



AccuMist

For applying uniform coatings of anti-restinosis drugs, hydrophilic solutions, anti-coagulents, Paclitaxel or other advanced drug delivery applications for PCTA angioplasty balloon catheters or other in vivo balloon devices.



Sono-Tek's precision ultrasonic nozzles have been an industry standard for coating arterial and peripheral implantable stents with drug eluting polymers for close to three decades. Our patented ultrasonic nozzles have proven to be well suited to coating high pressure medical balloons with drug eluting polymers such as Paclitaxel and other bioabsorbable drugs for dilation procedures including coronary angioplasty or stent delivery applications.

Ultrasonic coating advantages include:

- Ultrasonic coatings adhere well to balloon surfaces.
- Superior, more uniform thin films than dipping methods with the ability to manipulate coating morphology.
- Minimal overspray of expensive solutions.
- Easy to load fixturing with included cartridge or customer designed holder.
- Ultrasonic nozzle vibrations keep solutions evenly mixed with no clogging.
- Tight drop distribution resulting in coatings that provide accurate rapid-release of drugs at the target site.
- Ability to customize droplet sizes depending on frequency of nozzle used.
- Integrated control of the nozzle, liquid delivery, and balloon rotation.

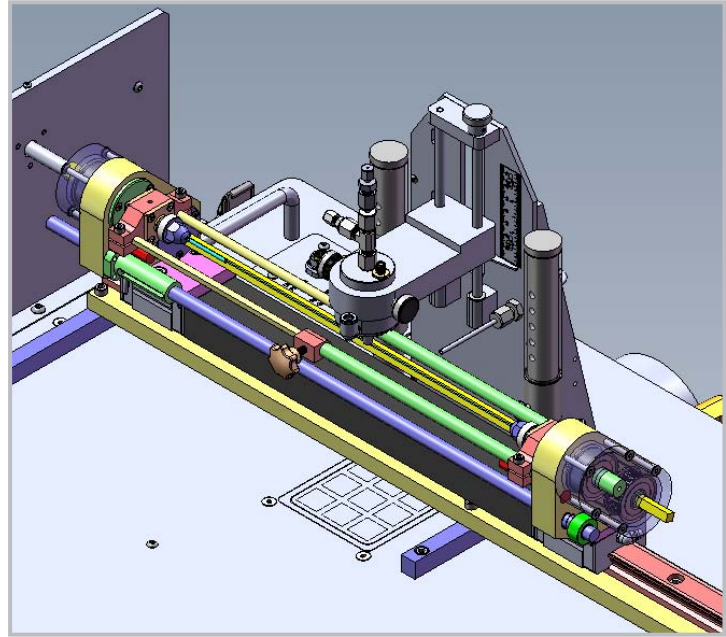
SONO•TEK Corporation

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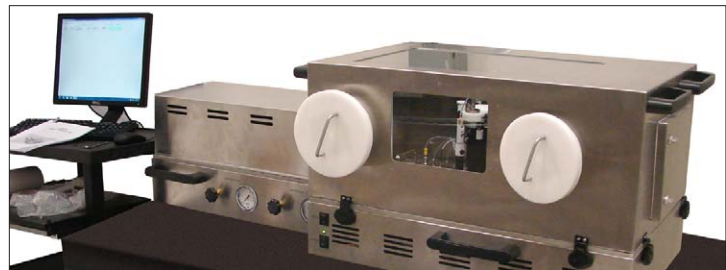
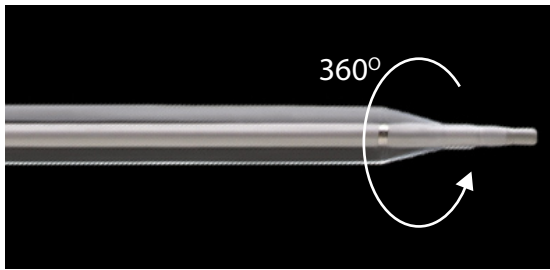
Operating Principle

The Balloon Catheter Coating System is a fully enclosed, sealed glovebox unit designed to coat common sizes and types of balloon catheters using Sono-Tek ultrasonic nozzles combined with our AccuMist or MicroMist precision air shaping systems. The spray pattern diameter and drop size are variable, depending upon the nozzle and air shaping system used. A proprietary holding device secures both ends of the catheter while rotational motors spin the catheter for 360° coverage of the entire balloon surface. The ultrasonic nozzle traverses across the catheter as required to coat desired lengths.

The system includes controls for air flow rate, air pressure as well as continuous digital metering of humidity and temperature.



INTERIOR VIEW OF SPRAY ASSEMBLY



BALLOON CATHETER COATING SYSTEM SPECIFICATIONS

Liquid Delivery Specifications

For high accuracy liquid delivery, the AccuMist™ and MicroMist systems are typically used in conjunction with either a Sono-Tek syringe pump or the MicroFlow pump.

	Sono-Tek Syringe Pump	MicroFlow Pump
Controls	Microprocessor operated, LCD display, keyboard	PC Windows-based software
Input/Output Interfaces	RS232 and TTI types for control of pump and nozzle	RS232, DB9 Serial communications port
Capacity	Two syringes: up to 60 ml each, or one syringe: up to 140 ml	Unlimited continuous feed from reservoir
Flow Rate Range	0.01 μ l/hr - 71 ml/min	1 μ l/min to 30 ml/min
Flow Rate Stability	\pm 1%	\pm 0.5%

Requirements

Power	100-240 VAC, 50/60 Hz single phase, 2.5A
Compressed Air	15-150 psi/100-1000 kPa, clean, dry air or gas

Enclosure Specifications

Total Spray Length	Up to 25 cm (10") balloons (without catheter)
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Ultrasonic Nozzle Specifications

Materials	
Nozzle Body*	Titanium alloy 6Al-4V
Nozzle Housing	316 stainless steel
O-rings	Kalrez®
Precision Holder (MicroMist)	Anodized Aluminum
Air Shroud (AccuMist)	Delrin®/316 stainless steel
Liquid Inlet*	316 stainless steel (1/8" or 1/16" tubing)
Air Inlet (1/4" tubing)	316 stainless steel
Ultrasonic nozzles are available in four (4) operating frequencies, each of which produces drops of a different size range. Median drop diameter (based on water): 180 kHz (13 microns), 120 kHz (18 microns), 60 kHz (31 microns), 48 kHz (38 microns)	
Operating Temperature	20 - 150° C
Air Pressure	0 - 10 psi
Flow Rate	AccuMist: 1 - 100 ml/hr MicroMist: 0.3 - 9 ml/hr
Spray Pattern Diameter	AccuMist: 0.070 - 0.250 inches (1.778 - 6.35 mm) MicroMist: 0.010 - 0.030 inches (0.26 - 0.27 mm)

*Wetted materials
Teflon®, Kalrez® and Delrin® are registered trademarks of E.I. DuPont de Nemours & Company
Specifications may change without notice

Global Solutions in Ultrasonic Spray Technology

Sono-Tek's corporate headquarters are located in Milton, NY USA, with additional offices in Hong Kong. Our extensive global support and distribution network provides factory trained personnel with local language support in dozens of countries worldwide.



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Comprehensive Solutions in Process Automation and Technology