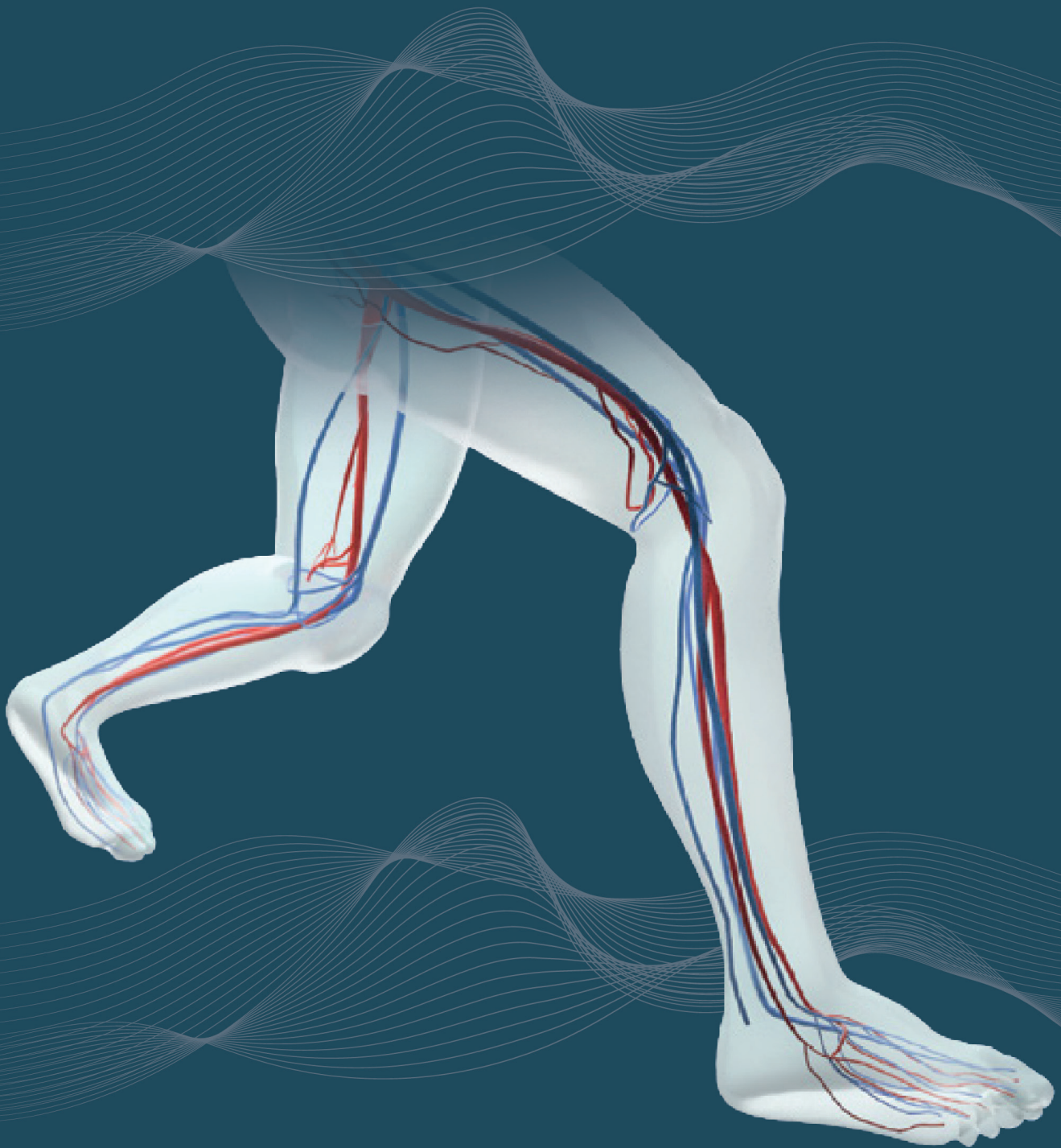


MYTHICA[™]
ULTRASONIC THROMBOSIS CAVITATION SYSTEM



Mythica™ Ultrasonic Thrombosis Cavitation System

- ✓ **Superior Thrombus Clearance**
- ✓ **Increased Drug Uptake**
- ✓ **Reduced Lytic Agent Dose**
- ✓ **No Hemolysis**
- ✓ **No Vessel or Valve Damage**

Mechanism of Action

Mythica™ Ultrasonic Thrombosis Cavitation System is intended to be used in selectively fragmentation, emulsification, irrigation and/or aspiration of soft tissues (e.g., blood clot (thrombus) in the peripheral vasculature) percutaneously. The system comprises an external power generator, a piezoelectric Ultrasonic Piezo Handle, and an ultrasonically driven catheter.

Acoustic cavitation is the formation of vapor-filled “cavities” or microscopic bubbles in a liquid affected by the alternating pressure of ultrasonic energy. The collapse of these microbubbles generates high local pressure charges of up to 20-36,000 atm that disrupt the target thrombus. The size of the microbubbles is inversely proportional to the frequency of ultrasonic energy. The larger bubbles of lower ultrasound frequencies are thought to produce greater force. A study of the effect of ultrasonic frequency on thrombus disruption showed an inverse logarithmic relation between frequency and thrombus disruption.

Ultrasound when applied to the thrombosed vessel during thrombolysis enhances the thrombolytic process by accelerating the contact of the lytic agent with plasminogen receptor sites within the thrombus. Acoustic microstreaming created by the ultrasound pulses augments the transportation of the lytic agent, disseminating it throughout the clot. The energy transmitted by the ultrasound waves also separates/loosens the fibrin strands, increasing the surface area of the thrombus and making more plasminogen activator receptor sites available to the lytic agent.

Principle of Operation

Ultrasonic surgery is realized between 20-100 kHz. In principle, the outlet voltage is supplied at 50 to 60 hertz. The generator boosts the frequency to 20-36 kHz. The resulting ultrasonic frequency is delivered into the hand-piece and amplified to the motion.

The Ultrasonic Piezo Handle, which is made up of PZT crystals, converts the electrical energy into high-power ultrasonic energy. The ultrasonic catheter is connected at the proximal end of the Ultrasonic Piezo Handle. The ultrasonic energy is transmitted through the catheter to the target thrombus. High frequency, low energy ultrasound and sterile (e.g., tissue plasminogen activator (tPA)) for the prevention of blood clot in the peripheral artery (e.g., thrombus or thromboembolus) percutaneously are designed for intravascular injection.

Indications

Mythica™ Ultrasonic Thrombosis Cavitation System is indicated for fragmentation, emulsification and aspiration of blood clot in the peripheral vasculature (e.g., thrombus or thromboembolus) percutaneously designed for intravascular minimal invasive surgery.

Mythica™ Ultrasonic Thrombosis Cavitation System should be used by surgeons or medical staffs who have received the appropriate training.

Mythica™ Ultrasonic Thrombosis Cavitation System is indicated for fragmentation, emulsification, aspiration and fragmentation of blood clot in the peripheral vasculature (e.g., thrombus or thromboembolus). Indications, contraindications and instructions for use can be found on the product labeling supplied with each device.

PRODUCT LIST	REF NO
Ultrasonic Generator with Integrated Peristaltic Pump (Nonsterile, Reusable)	MYT-USG01-N
Foot Switch (Non-Sterile, Reusable)	MYT-FW01-N
Ultrasonic Piezo Handle (Non-Sterile, Re-sterilizable)	MYT-UPH01-N
Ultrasonic Piezo Handle (Non-Sterile, Re-sterilizable)	MYT-UPH02-N
Probe Torque Tool (Non-Sterile, Re-sterilizable)	MYT-PTTRQ-N
Canister Holder Ring (Non-Sterile, Re-sterilizable)	MYT-CHR-N
Serum Hanger (Non-Sterile, Re-sterilizable)	MYT-SHA01-N
Sterilization Case (Non-Sterile, Re-sterilizable)	MYT-STE01-N
Ultrasonic Thrombosis Wire Cavitation Catheter 5 Fr 110 cm (Sterile, Single-Use)	MYT-1105W-S
Ultrasonic Thrombosis Wire Cavitation Catheter 6 Fr 110 cm (Sterile, Single-Use)	MYT-1106W-S
Ultrasonic Thrombosis Wire Cavitation Catheter 7 Fr 110 cm (Sterile, Single-Use)	MYT-1107W-S
Ultrasonic Thrombosis Wire Cavitation Catheter 8 Fr 110 cm (Sterile, Single-Use)	MYT-1108W-S
Ultrasonic Thrombosis Wire Cavitation Catheter 5 Fr 165 cm (Sterile, Single-Use)	MYT-1655W-S
Ultrasonic Thrombosis Wire Cavitation Catheter 6 Fr 165 cm (Sterile, Single-Use)	MYT-1656W-S
Ultrasonic Thrombosis Wire Cavitation Catheter 7 Fr 165 cm (Sterile, Single-Use)	MYT-1657W-S
Ultrasonic Thrombosis Wire Cavitation Catheter 8 Fr 165 cm (Sterile, Single-Use)	MYT-1658W-S
Ultrasonic Thrombosis Piezo Cavitation Catheter 5 Fr 110 cm (Sterile, Single-Use)	MYT-1105P-S
Ultrasonic Thrombosis Piezo Cavitation Catheter 6 Fr 110 cm (Sterile, Single-Use)	MYT-1106P-S
Ultrasonic Thrombosis Piezo Cavitation Catheter 7 Fr 110 cm (Sterile, Single-Use)	MYT-1107P-S
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Ultrasonic Thrombosis Piezo Cavitation Catheter 7 Fr 165 cm (Sterile, Single-Use)	MYT-1657P-S
Ultrasonic Thrombosis Piezo Cavitation Catheter 8 Fr 165 cm (Sterile, Single-Use)	MYT-1658P-S
Irrigation Tubing Set (Sterile, Single-Use)	MYT-IRTS-S
Aspiration Tubing Set (Sterile, Single-Use)	MYT-ATS-S
Canister Set with Tubing (Sterile, Single-Use)	MYT-CST-S



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BEYOND FROM WITHIN™

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U.S. and foreign patents pending

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