EkoSonic® MACH4 Endovascular Device
Instructions for Use

Indications for Use
The EkoSonic® Endovascular System is indicated for the:

- Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism.
- Infusion of solutions into the pulmonary arteries.
- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

All therapeutic agents utilized with the EkoSonic® Endovascular System should be fully prepared and used according to the instruction for use of the specific therapeutic agent.

Contraindications
- Not designed for peripheral vasculature dilation purposes.
- This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition.

Cautions
- Federal (U.S.) law restricts this device to use by or on the order of a physician.
- Carefully read all Instructions for Use prior to use. Observe all warnings and cautions noted throughout these instructions. Failure to do so may result in complications.
- Only physicians who have a thorough understanding of angiography and percutaneous interventional procedures should use the EkoSonic® MACH4 Endovascular Device.
- This device is intended for one time use only.
- This device is packaged sterile and non-pyrogenic. Prior to use, carefully examine the unit to verify that the sterile package and contents have not been damaged during shipment. Do not use if package is opened or damaged, or if seal is broken; contents may not be sterile and may cause infection in the patient.
- Prior to introduction, and anytime the Infusion Catheter is removed from the vascular system, the Infusion Catheter should be flushed.
- Do not advance if resistance is met without first determining the cause of resistance under fluoroscopy and taking any necessary remedial action. Excessive force against resistance may result in damage to the device or vasculature.
- If flow through the Infusion Catheter becomes restricted, do not attempt to clear by high pressure infusion. Either remove the Infusion Catheter (and Ultrasonic Core, if in place) to determine and eliminate the cause of the obstruction or replace the Infusion Catheter with a new Infusion Catheter of the same model.
- The guidewire must traverse beyond the targeted treatment zone prior to attempt to place the device.
- The EkoSonic® device is designed to provide optimum acoustic output during the first 24 hours of operation.

Warnings
- Always verify that BOTH electrical connectors from a Ultrasonic Core and Infusion Catheter pair are connected to the SAME Connector Interface Cable (CIC). Failure to properly connect both electrical connectors from an Ultrasonic Core-Infusion Catheter pair to the same CIC could result in over-temperature operation of the Ultrasonic Core, potentially causing damage to the patient's vasculature.
- For single use only. Do not re-use, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- If product is damaged or found to be unusable in any way, please retain the product and notify EKOS Corporation immediately.
- Never draw blood back into the drug lumens or the drug lumens and holes may become occluded.
• Do not connect the Infusion Catheter “Drug” or “Coolant” infusion ports to a power injector. Do not exceed 200 psi applied to any infusion port.
• Never transmit ultrasound energy to the Infusion Catheter or Ultrasonic Core with the device in the air.
• Never transmit ultrasound energy to Infusion Catheter or Ultrasonic Core unless it is placed within the patient anatomy, physician-specified fluids are running through the drug lumen and coolant is flowing through the coolant lumen. ALWAYS TURN OFF THE ULTRASOUND BEFORE REMOVING THE ULTRASONIC CORE FROM THE INFUSION CATHETER. OTHERWISE, OVERHEATING MAY OCCUR, POTENTIALLY CAUSING DAMAGE TO THE ULTRASONIC CORE AND/OR INTERRUPTING THERAPY. IF AN ULTRASONIC CORE IS DAMAGED IN THIS MANNER AND THEN ATTEMPTS ARE MADE TO CONTINUE USING THE ULTRASONIC CORE, VASCULAR INJURY COULD OCCUR.
• During normal use, ultrasound energy may cause a temperature rise in the treatment zone. The catheter surface temperature is limited to a maximum of 43° C.
• If an Infusion Catheter or Ultrasonic Core becomes kinked or otherwise damaged during use, discontinue use and replace.
• Do not deform or kink the Ultrasonic Core during delivery into the Infusion Catheter. If the Ultrasonic Core is kinked at any time, do not attempt to use the Ultrasonic Core, as kinking may lead to degraded performance or fracture during use.
• Never attempt to use the Ultrasonic Core with any catheter except the compatible EKOS Infusion Catheter.
• Never place the Ultrasonic Core into the patient without previously placing the Infusion Catheter.
• Never immerse the electrical connectors or the white housing of the Infusion Catheter in fluid.
• Do not use an introducer sheath with a rotating hemostasis valve to introduce the EkoSonic® MACH4 Endovascular Device. Insertion or removal through a rotating hemostasis valve may result in removal of the radiographic marker bands, stretching or other damage to the catheter.
• The EkoSonic® Endovascular System is not intended for use in the neurovasculature.

Potential Complications
• Vessel perforation or rupture
• Distal embolization of blood clots
• Vessel spasm
• Hemorrhage
• Hematoma
• Pain and tenderness
• Sepsis/Infection
• Thrombophlebitis
• Tricuspid and pulmonic valve damage
• Pulmonary infarct due to tip migration and spontaneous wedging, air embolism, and/or thromboembolism
• Right bundle branch block and complete heart block
• Intimal disruption
• Arterial dissection
• Vascular thrombosis
• Drug reactions
• Allergic reaction to contrast medium
• Arteriovenous fistula
• Thromboembolic episodes
• Amputation
• Pneumothorax
• Perforation of the pulmonary artery.
• Cardiac Arrhythmias – most frequently occurring during placement, removal or following displacement into the right ventricle.

Supplied/Storage
• Contents: One EkoSonic® MACH4 Endovascular Device consisting of one Infusion Catheter and one Ultrasonic Core. See package label for specific product features (e.g. working length, guidewire, introducer sheath, and treatment zone size).
• Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Use prior to “Use By” date on package label.

EkoSonic® Endovascular System Components Glossary

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Unit</td>
<td>The Control Unit provides power to the device, and provides the user interface for operator control.</td>
</tr>
<tr>
<td>Connector Interface Cable (CIC)</td>
<td>The CIC is the cable assembly that connects the Infusion Catheter and Ultrasonic Core to the Control Unit.</td>
</tr>
<tr>
<td>Infusion Catheter</td>
<td>The Infusion Catheter is a multi-lumen catheter with a connector system that delivers physician specified fluids into the vasculature (see Figure 2). Refer to the packaging labels for working length and treatment zone size. The Infusion Catheter is sometimes referred to as the Intelligent Drug Delivery Catheter or IDDC.</td>
</tr>
<tr>
<td>Intelligent Drug Delivery Catheter (IDDC)</td>
<td>The IDDC is also called the Infusion Catheter. Please refer to the description of the Infusion Catheter for more information.</td>
</tr>
</tbody>
</table>
MicroSonic Device (MSD)  The MSD is also called the Ultrasonic Core. Please refer to the description of the Ultrasonic Core for more information.

Ultrasonic Core  The Ultrasonic Core incorporates up to thirty fully encapsulated, radiopaque piezoelectric ceramic ultrasound transducers along the distal length of the shaft. The transducers emit ultrasound energy radially along the axis of the treatment zone (see Figure 3). The Ultrasonic Core is sometimes referred to as the MicroSonic Device or MSD.

Device Description
The EkoSonic® MACH4 Endovascular Device employs high frequency (2-3 MHz), low power ultrasound to facilitate the:
- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism.
- Delivery of solutions into the pulmonary arteries.
- Delivery of therapeutic agents in the peripheral vasculature.

The EkoSonic® MACH4 Endovascular System (Figure 1) consists of a single use Infusion Catheter and Ultrasonic Core, and a reusable EkoSonic® Control Unit (hereafter referred to as Control Unit). The device delivers the physician-specified fluids and ultrasound to the intravascular treatment site. The reusable Control Unit provides power to the device, and provides the user interface for operator control. A reusable, non-sterile CIC connects the Control Unit to the Ultrasonic Core and Infusion Catheter.

Principles of Operation
The system generates ultrasonic energy waves at the treatment zone through the piezoelectric transduction of radio-frequency (RF) energy generated by the Control Unit. The ultrasound emanates radially from the treatment zone into and through blood, thrombus, or tissue surrounding the treatment zone, within the patient’s vasculature. The ultrasound acts locally to increase the dispersion of the delivered physician-specified fluids into the treatment region. Please refer to published literature to determine appropriate use.

Infusion Catheter
The Infusion Catheter (Figure 2) is a multi-lumen catheter with a connector system. Refer to the packaging labels for working length and treatment zone size.

The Infusion Catheter shaft is comprised of three small lumens disposed radially around a coolant lumen for delivery of physician-specified fluids. The coolant lumen is used for insertion of a guidewire to facilitate access to the infusion site. The guidewire is then removed from the coolant lumen and replaced with the Ultrasonic Core. Additionally, the coolant lumen allows for delivery of a continuous infusion of saline to cool the Ultrasonic Core during use. The coolant lumen may be used for injections of contrast...
media when the guidewire or Ultrasonic Core is not inserted. Within the drug lumens are stiffening wires to improve pushability and trackability of the Infusion Catheter and encapsulated thermocouples that continuously measure temperature in the treatment zone.

The distal length of the Infusion Catheter, marked with a radio-opaque marker at both the distal and proximal end, is the "treatment zone". Within the treatment zone, the outer walls of the drug delivery lumens are perforated with holes designed to deliver physician-specified fluids along and around the treatment length. The drug delivery lumens are closed at the distal end of the infusion treatment zone.

The proximal end of the Infusion Catheter is a connector assembly. Two luer connectors are marked with colored labels to differentiate the drug lumen (labeled “DRUG” in red lettering) from the coolant lumen (labeled “COOLANT” in blue lettering). A coolant lumen luer allows passage of a guidewire or the Ultrasonic Core into the coolant lumen, or connection of a syringe for contrast injection. An electrical connector is color coded (gray) for attachment to the Control Unit.

Ultrasonic Core
The Ultrasonic Core (Figure 3) incorporates up to thirty fully encapsulated, radiopaque piezoelectric ceramic ultrasound transducers along the distal length of the shaft. The transducers emit ultrasound energy radially along the axis of the treatment zone.

EkoSonic® Control Unit
The Control Unit provides the user interface, electrical power, and monitoring of the device via the non-disposable CIC. For further information, please refer to the Control Unit instructions for use.
Procedure
Prior to initiation of the procedure, ensure that the following components of the system are available:

- Control Unit
- Connector Interface Cable (CIC)
- Ultrasonic Core
- Infusion Catheter

Vascular access
1. Prepare two infusion pumps as directed by the manufacturer’s instructions for use. Prepare one pump with heparinized saline. Prepare the second pump with the physician-specified fluids to be infused following the manufacturer’s instructions. To ensure proper infusion and reduce the potential for infusion pump alarms, the infusion pressure on the pumps should be set to the highest value allowed by hospital policy.

WARNING: DO NOT CONNECT THE INFUSION CATHETER “DRUG” OR “COOLANT” INFUSION PORTS TO A POWER INJECTOR. DO NOT EXCEED 200 PSI APPLIED TO ANY INFUSION PORT.

2. For the Pulmonary Arteries:
Obtain venous access and place a 6 Fr (2.00 mm) or larger sheath up to or through the right atrium per your standard practice.

For the Peripheral Vasculature:
Obtain access and place a 6Fr (2.0mm) or larger introducer sheath of the desired length. If crossing the aortic bifurcation, a long reinforced sheath should be used.

Preparing and placing the Infusion Catheter and Ultrasonic Core
3. Select the device with the appropriate treatment zone.
4. Remove the pouches from the box and, using sterile technique, place the contents of the pouches onto the sterile field.
5. Remove the Infusion Catheter from the protective coil.
6. Attach stopcocks to the luer fittings labeled “Coolant” and “Drug”.
7. Attach a syringe of heparin (or physician-specified fluids) to the stopcock on the drug lumen and flush the lumen. Priming volume of the drug lumens is:

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.4 F, 106 cm</td>
<td>0.8 cc</td>
<td></td>
</tr>
<tr>
<td>5.4 F, 135 cm</td>
<td>1.0 cc</td>
<td></td>
</tr>
</tbody>
</table>

Be sure that fluid exits from the most distal catheter holes which are located near the distal radiopaque marker. Close the stopcock to “lock” the heparin in the catheter and remove the syringe.
8. Attach a syringe of heparinized saline to the stopcock on the coolant lumen. Inject saline until saline flows from the coolant lumen luer. Place finger over coolant lumen luer and inject saline until saline exits from the distal end of the Infusion Catheter. To ensure no air bubbles remain in the Infusion Catheter, close the stopcock to the Infusion Catheter.

WARNING: DO NOT CONNECT THE INFUSION CATHETER “DRUG” OR “COOLANT” INFUSION PORTS TO A POWER INJECTOR. DO NOT EXCEED 200 PSI APPLIED TO ANY INFUSION PORT.

9. Insert a standard length 0.035” maximum diameter guidewire into the Infusion Catheter, or back load the Infusion Catheter over an exchange length guidewire already in place across the treatment site.

WARNING: DO NOT USE AN INTRODUCER SHEATH WITH A ROTATING HEMOSTASIS VALVE TO INTRODUCE THE EKOSONIC™ MACH4 ENDOVASCULAR DEVICE. INSERTION OR REMOVAL THROUGH A ROTATING HEMOSTASIS VALVE MAY RESULT IN REMOVAL OF THE RADIOGRAPHIC MARKER BANDS, STRETCHING OR OTHER DAMAGE TO THE CATHETER.

10. Using fluoroscopic guidance, position the Infusion Catheter across the treatment site. The distal radiopaque marker is located near the distal tip of the Infusion Catheter. The proximal radiopaque marker is located near the proximal end of the treatment zone. When the Infusion Catheter has been successfully placed, remove the guidewire from the Infusion Catheter.

11. Connect a 10cc syringe with heparinized saline to the stopcock on the coolant lumen. Withdraw fluid until blood appears to ensure the coolant lumen has no bubbles. Flush with saline. Priming volume of the coolant lumen is1.9cc. Turn the stopcock to connect the coolant IV line to the coolant lumen, and remove the syringe.
12. Remove the Ultrasonic Core from the protective coil and moisten the outside of the Ultrasonic Core with heparinized saline, taking care to avoid kinking the device.

**WARNING: NEVER IMMERSE THE ELECTRICAL CONNECTORS IN FLUID.**

13. Insert the Ultrasonic Core into the coolant lumen of the Infusion Catheter taking care not to kink the Ultrasonic Core as it is being advanced.

**WARNING: DO NOT DEFORM OR KINK THE ULTRASONIC CORE DURING DELIVERY INTO THE INFUSION CATHETER. IF THE ULTRASONIC CORE IS KINKED AT ANY TIME, DO NOT ATTEMPT TO USE THE ULTRASONIC CORE, AS KINKING MAY LEAD TO DEGRADED PERFORMANCE OR FRACTURE DURING USE.**

13. When the Ultrasonic Core has been fully advanced into the Infusion Catheter, attach the luer connector on the Ultrasonic Core to the luer fitting on the Infusion Catheter.

14. Connect the IV line on the infusion pump containing the infusion physician-specified fluids to the stopcock attached to the fitting labeled “DRUG”. Turn the stopcock to open the IV line to air and flush the physician-specified fluids from the infusion pump through the stopcock to clear any air from the line. Turn the stopcock to connect the IV line to the drug lumen. Set the physician-specified fluids flow rate (minimum 5 ml/hr – maximum 35 ml/hr) and turn on the infusion pump.

**WARNING: DO NOT DRAW BLOOD BACK INTO THE DRUG LUMENS.**

15. Attach the IV line on the infusion pump containing saline solution to the stopcock attached to the fitting labeled “Coolant”. Open the stopcock to air and flush saline from the infusion pump through the stopcock to clear any air from the line. Turn the stopcock to connect the IV line to the coolant lumen. Set the infusion rate to the maximum rate of 120 ml/hr unless the patient cannot tolerate that fluid volume, in which case a lower volume is acceptable. However, a minimum flow rate of 35 ml/hr should be maintained. The higher the coolant infusion rate, the more cooling of the Ultrasonic Core takes place. The patient’s ability to tolerate fluid input should dictate the maximum amount of coolant flow.

16. Turn on the coolant infusion pump.

**Operation of the device**

1. Locate the Control Unit on a firm surface within 5 feet (1.6 meters) of the patient.
2. Provide power to the unit as instructed in the Control Unit instructions for use.
3. Turn on the power switch. The Control Unit will complete a self-test and then transition to the “Ready Mode”.
4. Connect the CIC to the Control Unit.
5. Connect the Infusion Catheter connector to the appropriate connector on the CIC and secure it by pushing the Infusion Catheter connector into the CIC Clip.
6. Connect the Ultrasonic Core connector to the appropriate connector on the CIC and secure it by pushing the Ultrasonic Core connector into the CIC Clip. The Control Unit will automatically perform an electrical check of the Ultrasonic Core. For further information, please refer to the Control Unit instructions for use.
7. Press the green “Start” button on the Control Unit. The yellow “Ultrasound On” indicator and flashing waves of the EKOS logo on the front panel of the instrument will start to slowly blink and continue to blink as long as ultrasound is being delivered. The timer on the display will start to time the therapy.

**WARNING: ALWAYS VERIFY THAT BOTH ELECTRICAL CONNECTORS FROM AN ULTRASONIC CORE - INFUSION CATHETER PAIR ARE CONNECTED TO THE SAME CONNECTOR INTERFACE CABLE (CIC). FAILURE TO PROPERLY CONNECT BOTH ELECTRICAL CONNECTORS FROM AN ULTRASONIC CORE - INFUSION CATHETER PAIR TO THE SAME CIC COULD RESULT IN OVER-TEMPERATURE OPERATION OF THE ULTRASONIC CORE, POTENTIALLY CAUSING DAMAGE TO THE PATIENT’S VASCULATURE.**

**WARNING: NEVER TRANSMIT ULTRASOUND ENERGY TO THE ULTRASONIC CORE - INFUSION CATHETER PAIR UNLESS IT IS PLACED WITHIN THE PATIENT ANATOMY, PHYSICIAN-SPECIFIED FLUIDS ARE RUNNING THROUGH THE DRUG LUMENS AND COOLANT IS FLOWING THROUGH THE COOLANT LUMEN. ALWAYS TURN OFF THE ULTRASOUND BEFORE REMOVING THE ULTRASONIC CORE FROM THE INFUSION CATHETER. OTHERWISE, OVERHEATING MAY OCCUR, POTENTIALLY CAUSING DAMAGE TO THE ULTRASONIC CORE AND/OR INTERRUPTING THERAPY. IF AN ULTRASONIC CORE IS DAMAGED IN THIS MANNER AND THEN ATTEMPTS ARE MADE TO CONTINUE USING THE ULTRASONIC CORE, VASCULAR INJURY COULD OCCUR.**
WARNING: IF AN INFUSION CATHETER OR ULTRASONIC CORE BECOMES KINKED OR OTHERWISE DAMAGED DURING USE, DISCONTINUE USE AND REPLACE.

WARNING: NEVER ATTEMPT TO USE THE ULTRASONIC CORE WITH ANY CATHETER EXCEPT THE COMPATIBLE EKOS INFUSION CATHETER.

WARNING: NEVER PLACE THE ULTRASONIC CORE INTO THE PATIENT WITHOUT PREVIOUSLY PLACING THE INFUSION CATHETER.

8. Secure the Ultrasonic Core - Infusion Catheter pair and CIC to the patient using standard hospital technique.

Infusion procedure
The patient may now be moved to the appropriate care unit of the hospital and monitored per usual hospital standard of care. To prepare for moving the patient, unplug the instrument and secure it for transport with the patient. When the patient reaches the patient care area where they will remain for the duration of the therapy, plug the Control Unit into A/C power.

NOTE: If an EKOS Control System Cart is not available, press the orange “Stop” button on the Control Unit. Unplug the instrument and secure it for transport with the patient. When the patient reaches the patient care area where they will remain for the duration of the therapy, plug the Control Unit into A/C power and power on. The Control Unit will again perform the self test and reset the therapy timer. Press the green “Start” button to re-start the ultrasound.

During therapy, the ultrasound may be stopped at any time by touching the orange “Stop” button. The ultrasound may be restarted by pushing the green “Start” button.

If the supply of coolant fluid is low, stop the ultrasound therapy before stopping the coolant flow to replace the supply of coolant. The ultrasound therapy may then be re-started after the coolant flow is re-started.

Follow-up
When the infusion procedure has been completed, the EkoSonic® MACH4 Endovascular Device may be removed at bedside without fluoroscopic guidance or it may be removed under fluoroscopic guidance.

1. To prepare the patient for transport, press the orange “Stop” button, disconnect the Ultrasonic Core and Infusion Catheter from the CIC, then unplug the Control Unit and secure it for transport with the patient.
2. After placing the patient on the fluoroscopic table, decontaminate the exposed portions of the Ultrasonic Core and Infusion Catheter, and remove the Ultrasonic Core.
3. Angiography may be performed at this point to assess the treatment site.
4. Place the guidewire through the Infusion Catheter and then remove both the Infusion Catheter and the guidewire, or if definitive vascular intervention is required, leave the guidewire in place to facilitate placement of interventional devices.

WARNING: DO NOT USE AN INTRODUCER SHEATH WITH A ROTATING HEMOSTASIS VALVE TO INTRODUCE THE EKOSONIC® MACH4 ENDOVASCULAR DEVICE. INSERTION OR REMOVAL THROUGH A ROTATING HEMOSTASIS VALVE MAY RESULT IN REMOVAL OF THE RADIOGRAPHIC MARKER BANDS, STRETCHING OR OTHER DAMAGE TO THE CATHETER.

5. Following the procedure, removal of the introducer sheath, attaining hemostasis and patient discharge should be performed per hospital standard of care.
<table>
<thead>
<tr>
<th><strong>STERILE EO</strong></th>
<th>Sterilized by Ethylene Oxide.</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Circled 2" /></td>
<td>For Single Use Only.</td>
</tr>
<tr>
<td><img src="image" alt="Circled 2" /></td>
<td>Do Not Re-sterilize.</td>
</tr>
<tr>
<td><img src="image" alt="Exclamation Mark" /></td>
<td>Read all instructions before use.</td>
</tr>
<tr>
<td><img src="image" alt="Hourglass" /></td>
<td>Use By: The catheter should not be used after the end of the month indicated.</td>
</tr>
</tbody>
</table>

**Customer Support**
In the US, call the Customer Help Line 888-EKOSHELP (888-356-7435) or 425-415-3100.

Outside the US contact your local EKOS representative or call +1-425-415-3100.

This product is covered by one or more patent numbers listed at www.ekoscorp.com/privacy_policy.htm.

6998-001 Rev B