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Part Number: 5916-001 Rev A
 Revision date: 05/08

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**EkoSonic™ MACH4 Endovascular Device (and EkoSonic™ Endovascular Device)¹
 Instructions for Use in Pulmonary Artery**

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Intended Use

The EkoSonic™ Endovascular Device, consisting of the Intelligent™ Drug Delivery Catheter (IDDC) and the MicroSonic™ Device (MSD), is intended for the infusion of solutions into the pulmonary arteries.

The safety and effectiveness of the EkoSonic™ Endovascular System for thrombolytic therapy administration in pulmonary embolus have not been established. In particular, the ultrasound energy delivered by the EkoSonic Endovascular System is not intended to be therapeutic, nor has it been cleared with an indication for thrombolysis in pulmonary emboli.

STERILE	EO	Sterilized by Ethylene Oxide
		For Single Use Only, Do Not Resterilize
		Read all instructions before use.
		Use By: The catheter should not be used after the end of the month indicated

**Customer Support Help Line: 888-EKOSHELP
 888-356-7435**

This system is covered by and/or manufactured under one or more of the following patents:
 U.S. Pat. Nos. 6,723,063, 6,585,678, 6,001,069, and 5,197,946 and European Patent No. EP 1091699B1. Other U.S. and foreign patents pending.

Contraindications

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 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 IDDC is removed from the vascular system, the IDDC 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 IDDC becomes restricted, do not attempt to clear by high pressure infusion. Either remove the IDDC (and MSD, if in place) to determine and eliminate the cause of the obstruction or replace the IDDC with a new IDDC of the same model.
- The guidewire must traverse beyond the targeted treatment zone prior to attempt to place the device.

Warnings

- Always verify that BOTH electrical connectors from a MicroSonic Device (MSD) and Intelligent Drug Delivery Catheter (IDDC) pair are connected to the SAME Connector Interface Cable (CIC). Failure to properly connect both electrical connectors from an MSD-IDDC pair to the same CIC could result in over-temperature operation of the MSD, potentially causing damage to the patient's vasculature.
- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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.

¹ The EkoSonic MACH4 Endovascular Device and EkoSonic Endovascular Device are differentiated by the rapid pulse modulation software; for convenience and clarity in this IFU, both devices are referred to as the EkoSonic Endovascular Device.

- Never draw blood back into the drug lumens or the drug lumens and holes may become occluded.
- Do not connect the IDDC “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 IDDC or MSD with the device in the air.
- Never transmit ultrasound energy to IDDC or MSD unless it is placed within the patient anatomy, solution is running through the drug lumen and coolant is flowing through the coolant lumen. **ALWAYS TURN OFF THE ULTRASOUND BEFORE REMOVING THE MSD FROM THE IDDC.** Otherwise, overheating may occur, potentially causing damage to the MSD and/or interrupting therapy. **IF AN MSD IS DAMAGED IN THIS MANNER AND THEN ATTEMPTS ARE MADE TO CONTINUE USING THE MSD, 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 IDDC or MSD becomes kinked or otherwise damaged during use, discontinue use and replace.
- Never attempt to use the MSD with any catheter except the IDDC.
- Never place the MSD into the patient without previously placing the IDDC.
- Never immerse the electrical connectors in fluid.

Potential Complications

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

Supplied/Storage

- **Contents:** One EkoSonic Endovascular Device consisting of one Intelligent Drug Delivery Catheter and one MicroSonic Device. 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.

Device Description

The EkoSonic Endovascular Device employs high frequency (2-3 MHz), low power ultrasound to facilitate the delivery of solutions in the pulmonary arteries. The EkoSonic Endovascular Device (Figure 1) consists of a single use Intelligent Drug Delivery Catheter (IDDC) and MicroSonic Device (MSD), and a reusable EkoSonic Control Unit or PT-3B Control Unit (hereafter referred to as Control Unit). The device delivers the solutions 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 MSD and IDDC.

Follow-up

When the infusion procedure has been completed, the EkoSonic Endovascular Device should be removed under fluoroscopic guidance.

1. To prepare the patient for transport, press the orange “Stop” button, disconnect the MSD and IDDC 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 MSD and IDDC, and remove the MSD.
3. Angiography may be performed at this point to assess the treatment site.
4. Place the guidewire through the IDDC and then remove both the IDDC and the guidewire, or if definitive vascular intervention is required, leave the guidewire in place to facilitate placement of interventional devices.
5. Following the procedure, removal of the introducer sheath, attaining hemostasis and patient discharge should be performed per hospital standard of care.

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 IDDC connector to the appropriate connector on the CIC and secure it by pushing the IDDC connector into the CIC Clip.
6. Connect the MSD connector to the appropriate connector on the CIC and secure it by pushing the MSD connector into the CIC Clip. The Control Unit will automatically perform an electrical check of the MSD. 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 MSD-IDDC PAIR ARE CONNECTED TO THE SAME CONNECTOR INTERFACE CABLE (CIC). FAILURE TO PROPERLY CONNECT BOTH ELECTRICAL CONNECTORS FROM AN MSD-IDDC PAIR TO THE SAME CIC COULD RESULT IN OVER-TEMPERATURE OPERATION OF THE MSD, POTENTIALLY CAUSING DAMAGE TO THE PATIENT'S VASCULATURE.

WARNING: NEVER TRANSMIT ULTRASOUND ENERGY TO THE MSD-IDDC PAIR UNLESS IT IS PLACED WITHIN THE PATIENT ANATOMY, SOLUTION IS RUNNING THROUGH THE DRUG LUMENS AND COOLANT IS FLOWING THROUGH THE COOLANT LUMEN. ALWAYS TURN OFF THE ULTRASOUND BEFORE REMOVING THE MSD FROM THE IDDC. OTHERWISE, OVERHEATING MAY OCCUR, POTENTIALLY CAUSING DAMAGE TO THE MSD AND/OR INTERRUPTING THERAPY. IF AN MSD IS DAMAGED IN THIS MANNER AND THEN ATTEMPTS ARE MADE TO CONTINUE USING THE MSD, VASCULAR INJURY COULD OCCUR.

WARNING: IF AN IDDC OR MSD BECOMES KINKED OR OTHERWISE DAMAGED DURING USE, DISCONTINUE USE AND REPLACE.

WARNING: NEVER ATTEMPT TO USE THE MSD WITH ANY CATHETER EXCEPT THE IDDC.

WARNING: NEVER PLACE THE MSD INTO THE PATIENT WITHOUT PREVIOUSLY PLACING THE IDDC.

8. Secure the MSD-IDDC 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.

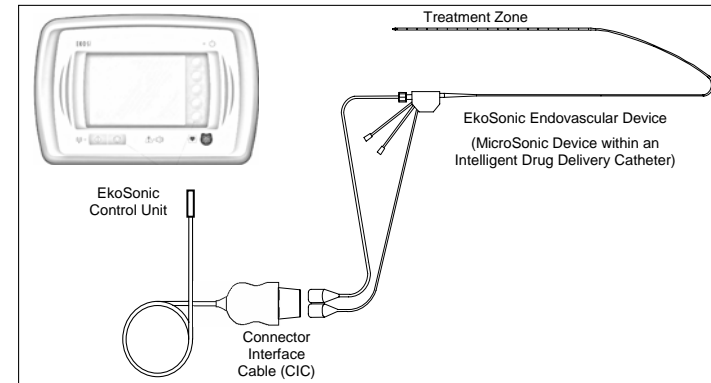


Figure 1: EkoSonic Endovascular Device and EkoSonic Control Unit (or PT-3B).

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 pulmonary arteries. The ultrasound acts locally to increase the dispersion of the delivered solution into the treatment region.

Intelligent Drug Delivery Catheter

The IDDC (Figure 2) is a 5.2 Fr, multi-lumen catheter with a connector system. Refer to the packaging labels for working length and treatment zone size.

The IDDC shaft is comprised of three small lumens disposed radially around a coolant lumen for delivery of solutions. 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 MSD. Additionally, the coolant lumen allows for delivery of a continuous infusion of saline to cool the MSD during use. The coolant lumen may be used for injections of contrast media when the guidewire or MSD is not inserted. Within the drug lumens are stiffening wires to improve pushability and trackability of the IDDC and encapsulated thermocouples that continuously measure temperature in the treatment zone.

The distal length of the IDDC, 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 solutions 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 IDDC 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 MSD 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.

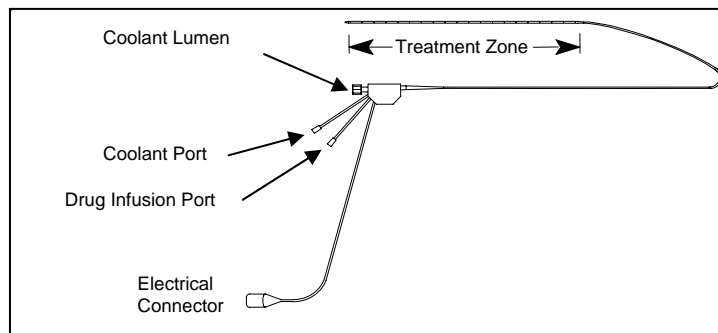


Figure 2: Intelligent Drug Delivery Catheter (IDDC).

MicroSonic Device

The MicroSonic Device (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.

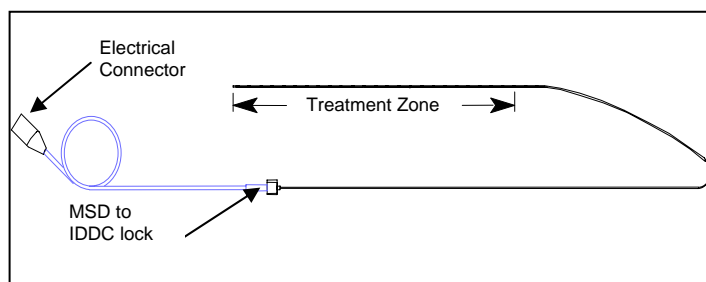


Figure 3: MicroSonic Device (MSD).

The MSD incorporates both a stiffening wire to enhance pushability and trackability within the IDDC, and electrical leads that extend from the transducers to a connector at the proximal end. This connector couples to the CIC, which connects to the Control Unit.

EkoSonic Control Unit (or PT-3B 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)
- MicroSonic Device (MSD)
- Intelligent Drug Delivery Catheter (IDDC)

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 solution 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 IDDC "DRUG" OR "COOLANT" INFUSION PORTS TO A POWER INJECTOR. DO NOT EXCEED 200 PSI APPLIED TO ANY INFUSION PORT.

2. Obtain venous access and place a 6Fr or 7Fr sheath up to or through the right atrium per your standard practice.

Preparing and placing the IDDC and MSD

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 IDDC from the protective coil.
6. Attach stopcocks to the luer fittings labeled "Coolant" and "Drug".
7. Attach a syringe of heparin to the stopcock on the drug lumen and flush the lumen. Priming volume of the drug lumens is: 106cm = 0.6cc, 135cm = 0.75cc. 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. Connect the IV line on the infusion pump containing the infusion solution to the stopcock attached to the fitting labeled "DRUG". Turn the stopcock to open the IV line to air and flush the solution 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 solution 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.

9. 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 IDDC. To insure no air bubbles remain in the IDDC, close the stopcock to the IDDC.
10. 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 150 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 MSD takes place. The patient's ability to tolerate fluid input should dictate the maximum amount of coolant flow.

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

11. Insert a standard length 0.035" maximum diameter guidewire into the IDDC, or back load the IDDC over an exchange length guidewire already in place across the treatment site.
12. Using fluoroscopic guidance, position the IDDC across the treatment site. The distal radiopaque marker is located near the distal tip of the IDDC. The proximal radiopaque marker is located near the proximal end of the treatment zone. When the IDDC has been successfully placed, remove the guidewire from the IDDC.
13. 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 is: 106cm = 1.5cc, 135cm = 1.9cc. Turn the stopcock to connect the coolant IV line to the coolant lumen, and remove the syringe.
14. Remove the MSD from the protective coil and moisten the outside of the MSD with heparinized saline, taking care to avoid kinking the device.

WARNING: NEVER IMMERSER THE ELECTRICAL CONNECTORS IN FLUID.

15. Insert the MSD into the coolant lumen of the IDDC taking care not to kink the MSD as it is being advanced.
16. When the MSD has been fully advanced into the IDDC, attach the luer connector on the MSD to the luer fitting on the IDDC.
17. Turn on the coolant infusion pump.