# EkoSonic® Endovascular Device and EKOS® Control Unit 4.0
# Scrub Skills Checklist

**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.

**Please refer to the Instructions for Use for indications, contraindications, precautions, warnings, and full operational instructions.**

Terms and Abbreviations

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|---|---|
| Control Unit | CU |
| Connector Interface Cable | CIC |
| EkoSonic® Endovascular Device | Device |

| | Skills to Review | Reviewer Initials |
|---|---|---|
| 1. | Necessary equipment for EKOS® case:<br>a. EkoSonic® Endovascular Device:<br>• 106 cm device working length: 6, 12, 18, 24, 30, 40, and 50 cm treatment zones<br>• 135 cm device working length: 12, 30, 40, and 50 cm treatment zones<br>b. 6 Fr sheath; use a long supportive sheath for contralateral approach.<br><br>**WARNING:** Do not use an introducer sheath with a rotating hemostasis valve to introduce the EkoSonic® 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.<br><br>c. 0.035" exchange length guidewire<br>d. ( 2 ) 3-way stopcocks<br>e. ( 3 ) sets of sterile IV infusion extension tubing<br>f. Prescribed lytic initial bolus, if ordered.<br>g. (1) 3 or 5 cc syringe for prep of the drug lumen | |


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| 2. | Handling/prep of the EKOS® Infusion Catheter:<br>a. Carefully remove Infusion Catheter from the protective coil.<br>b. Ensure that the gray electrical connector does not get wet during the prep.<br>c. Place a 3-way stopcock on **DRUG** port and flush with heparin (or physician-specified fluids) using a 3 or 5 cc syringe. Turn stopcock OFF to the lumen.<br>d. Place a 3-way stopcock on **COOLANT** port and flush with normal or heparinized saline. Flush will exit the proximal guidewire lumen. Place finger over the lumen and continue to flush until fluid exits the distal tip of the catheter. Turn stopcock OFF to the lumen.<br>e. Flush guidewire lumen. | |
| 3. | Handling/prep of EKOS® Ultrasonic Core:<br>a. Isolate the black electrical connector so it doesn't get wet.<br>b. Moisten the outside of the Ultrasonic Core by either infusing heparinized saline into the luer fitting of the protective coil or remove it from the protective coil and wipe it with a wet 4x4 gauze sponge, taking care to avoid kinking the device.<br>c. When the Infusion Catheter is in position, the guidewire will be removed and the physician will insert the Ultrasonic Core into the Infusion Catheter. Ensure the Ultrasonic Core is luer-locked into the manifold of the Infusion Catheter. | |
| 4. | Steps to start therapy once the Infusion Catheter and Ultrasonic Core are in place:<br>a. Connect infusion pump lines to Infusion Catheter:<br>• Coolant: normal saline or heparinized saline minimum flow rate 35 mL/hr; maximum 120 mL/hr.<br>• Lytic: physician-prescribed dose with flow rate at a minimum of 5 mL/hr, maximum 35 mL/hr.<br>**WARNING: If the drug is not ready to infuse, use the 3 cc syringe to flush the catheter every 10 minutes to keep the lumen patent. Never aspirate or draw blood back into the drug lumen. Purge any air bubbles out the side port of the stopcock then turn the stopcock ON to the catheter and FORWARD flush only.**<br>b. Secure the sheath and device(s) to patient. Use Tegaderm™ and/or Steri-Strips™. Refrain from coiling the device too severely.<br>c. Hand off the black and gray connectors of the device to the circulator. Wait for the circulator to connect the black and gray connectors to the CIC.<br>d. If using two EkoSonic® devices, ensure the Ultrasonic Core and Infusion Catheter cables from one device are connected to the same CIC.<br>e. Confirm infusions are running, then circulator will press the green START button(s). Note: There are two channels to accommodate bilateral therapy. Each channel has its own START button. | |



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| 5. | Process for transporting a patient:<br>a. Check the battery level prior to transport to ensure it is adequately charged.<br>b. Unplug CU from AC outlet. The CU will automatically switch to battery power and continue to provide ultrasound therapy. The internal battery will provide ultrasound therapy for approximately two hours if one channel is used and approximately one hour if two channels are used.<br>c. Secure the housing end of the CIC near the patient to prevent the device from dislodging.<br>d. Secure the power cord.<br>e. Use carrying handle or an approved infusion stand to transport CU with patient.<br>f. When transport is complete, securely place CU on table, cart, or approved infusion stand near patient.<br>g. Plug CU into a hospital-grade outlet. | |
| 6. | Process for troubleshooting CU alert conditions:<br>a. If an alert occurs, press the Audio Pause button in top right corner to silence alert for 5 minutes.<br>b. Read the message displayed on the CU screen and follow instructions for corrective action or troubleshooting steps to take. When the error is corrected, the alert icon disappears and the Ready to start instruction is displayed. Push the green **Start** button to restart ultrasound.<br>c. If the issue cannot be resolved, note the error code in parentheses at the end of the message and call the EKOS® Help Line at 1-888-356-7435 (24/7/365). The Help Line number can also be found in the System Information tab of the CU.<br>d. If unable to resume ultrasound therapy after contacting EKOS®, contact the interventional physician. | |
| 7. | Important guidance for proper operation of the EkoSonic® Endovascular System:<br>a. Never aspirate from the DRUG or COOLANT ports. This will clog the lumens with blood and render the catheter inoperable. Never piggyback any solutions on the drug or coolant infusions.<br>b. Infusion rate ranges are:<br>• 5-35 mL/hr for the drug lumen<br>• 35-120 mL/hr for the coolant lumen<br>c. Never transmit ultrasound energy to the Ultrasonic Core-Infusion Catheter pair unless placed within the patient anatomy and infusions are running.<br>d. Always turn off the ultrasound before removing the Ultrasonic Core from the Infusion Catheter, or before removing the device from the patient.<br>e. Discontinue the infusions before removing the device(s). Turn stopcocks off to both lumens to prevent air from being introduced into the vasculature.<br>f. Never get electrical connectors wet.<br>g. Never connect Infusion Catheter to a power injector. | |

**Name:** _____**Date:** _____

**Reviewer:** _____

**EKOS Brief Summary**



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**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

**Indications for Use**
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• 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.

**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
PI_726201_AA
• 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.


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