

EkoSonic® Endovascular Device and Control Unit PT-3B

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

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

Skills to Review	Reviewer Initials
<p>1. Necessary equipment for EKOS® case:</p> <p>a. EkoSonic® Endovascular Device:</p> <ul style="list-style-type: none"> • 106 cm device working length: 6, 12, 18, 24, 30, 40, and 50 cm treatment zones • 135 cm device working length: 12, 30, 40, and 50 cm treatment zones <p>b. 6 Fr or larger sheath; use a long supportive sheath for contralateral approach.</p> <p>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.</p> <p>c. 0.035" exchange length guidewire</p> <p>d. (2) 3-way stopcocks</p> <p>e. (3) sets of sterile IV infusion extension tubing</p> <p>f. Prescribed lytic initial bolus, if ordered.</p> <p>g. (1) 3 or 5 cc syringe for prep of the drug lumen</p>	
<p>2. Handling/prep of the EKOS® Infusion Catheter:</p> <p>a. Carefully remove Infusion Catheter from the protective coil.</p> <p>b. Ensure that the gray electrical connector does not get wet during the prep.</p> <p>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.</p> <p>d. Place a 3-way stopcock on COOLANT port and flush with normal or heparinized saline using a 10 cc syringe. 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.</p> <p>e. Flush guidewire lumen.</p>	

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This checklist is intended as an example to demonstrate the type of checklist you may wish to implement in your clinical practice. Any checklist you implement should reflect your actual clinical practice at your facility. EKOS® makes no recommendations or representations about the content of this sample checklist. The responsibility for such a checklist rests with the clinical practice.

<p>3. Handling/prep of EKOS® Ultrasonic Core:</p> <ol style="list-style-type: none"> a. Isolate the black electrical connector so it doesn't get wet. 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. 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. 	
<p>4. Steps to start therapy once the Infusion Catheter and Ultrasonic Core are in place:</p> <ol style="list-style-type: none"> a. Connect infusion pump lines to Infusion Catheter: <ul style="list-style-type: none"> • Coolant: normal saline or heparinized saline minimum flow rate 35 mL/hr; maximum 120 mL/hr. • Lytic: physician-prescribed dose with flow rate at a minimum of 5 mL/hr, maximum 35 mL/hr. <p>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.</p> b. Secure the sheath and device(s) to patient. Use Tegaderm™ and/or Steri-Strips™. Refrain from coiling the device too severely. c. Hand off the black (labeled MSD) and gray (labeled IDDC) connectors of the device to the circulator. Wait for the circulator to connect the black and gray connectors to the CIC. d. If using two EkoSonic® devices, ensure the Ultrasonic Core and Infusion Catheter cables from one device are connected to the same CIC. e. Confirm infusions are running, then circulator will press the green START button on the CU to initiate ultrasound therapy. 	
<p>5. Process for transporting a patient:</p> <ol style="list-style-type: none"> a. Unplug UPS/battery from AC outlet (battery will last for 60 minutes). b. When UPS/battery is unplugged, an alarm will sound. c. Silence the alarm by pressing and holding the "MUTE" button located on the front of the battery for 2 seconds. d. Transport patient to new location. e. Plug UPS/battery into AC outlet. 	
<p>6. Process for troubleshooting CU alarm conditions:</p> <ol style="list-style-type: none"> a. If a CU alarm sounds it can be muted by pushing the upper right hand soft key beside the Alarm Silence Icon. b. Confirm that the CU Display does not show any red circles indicating a disconnected cable. Reconnect any cable showing a circle and confirm that it goes away. Push the green START button. c. If the alarm condition persists then identify the troubleshooting icon that is flashing at the bottom of the CU display between the two gray bars. d. Call EKOS® Help Line at 888-356-7435 (24/7/365). The Help Line number is located on top of the EkoSonic® CU. e. If unable to resume ultrasound therapy after contacting EKOS®, contact the interventional physician. 	

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| <p>7. Important guidance for proper operation of the EkoSonic® Endovascular System:</p> <ol style="list-style-type: none">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.b. Infusion rate ranges are:<ul style="list-style-type: none">• 5-35 mL/hr for the drug lumen• 35-120 mL/hr for the coolant lumenc. Never transmit ultrasound energy to the Ultrasonic Core-Infusion Catheter (MSD-IDDC) pair unless placed within the patient anatomy and infusions are running.d. Always turn off the ultrasound before removing the Ultrasonic Core from the Infusion Catheter, or before removing the device from the patient.e. Discontinue the infusions before removing the device(s). Turn stopcocks off to both lumens to prevent air from being introduced into the vasculature.f. Never get electrical connectors wet.g. Never connect Infusion Catheter to a power injector. | |
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Name: _____ **Date:** _____

Reviewer: _____