EkoSonic™

Endovascular Device

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℞ **ONLY**

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

REUSE WARNING

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.

EKOSONIC ENDOVASCULAR SYSTEM COMPONENTS GLOSSARY

Control Unit: The Control Unit provides power to the device and provides the user interface for operator control.

Connector Interface Cable (CIC): The CIC is the cable assembly that connects the Infusion Catheter and Ultrasonic Core to the Control Unit.

Infusion Catheter: 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.

Ultrasonic Core: The Ultrasonic Core incorporates 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).

DEVICE DESCRIPTION

The EkoSonic Endovascular Device employs high-frequency (2 MHz to 3 MHz), low-power ultrasound.

The EkoSonic Endovascular System (Figure 1) consists of a single use Infusion Catheter and Ultrasonic Core, and a reusable Control Unit 4.0 or PT-3B (hereafter referred to as Control Unit). The device delivers the physician-specified fluids and ultrasound to the intravascular treatment site. The device comes in eleven distinct models with seven treatment zones lengths for the 106 cm working length (6 cm, 12 cm, 18 cm, 24 cm, 30 cm, 40 cm, and 50 cm) and four treatment zones lengths for the 135 cm working length (12 cm, 30 cm, 40 cm, and 50 cm). The reusable Control Unit (available separately) 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.

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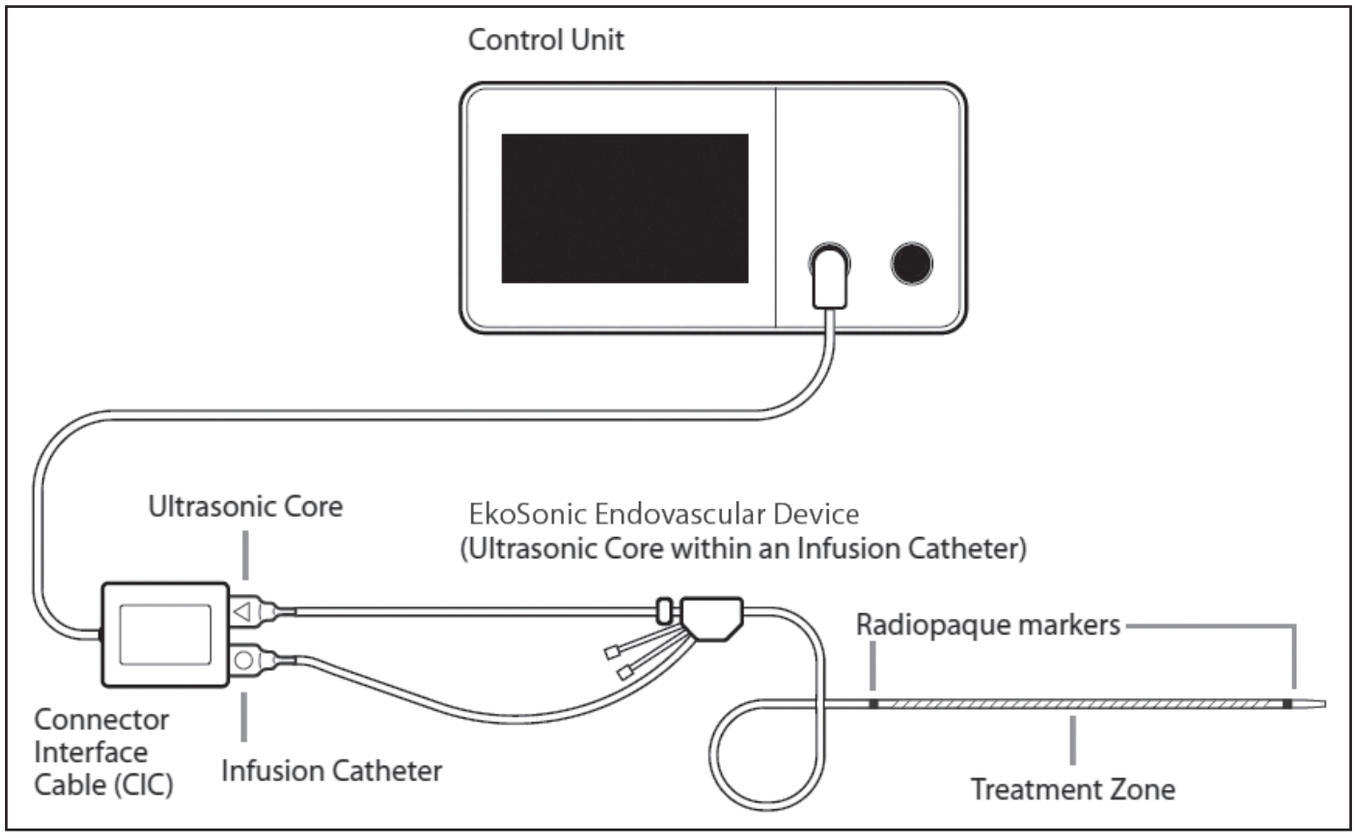

Figure 1. EkoSonic Endovascular System

Contents

One EkoSonic Endovascular Device consisting of one Infusion Catheter and one Ultrasonic Core. See package label for specific product features (e.g. working length, compatible guidewire, compatible introducer sheath, and treatment zone size).

Operating Principle

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.

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 central coolant lumen is used for insertion of a guidewire to facilitate access to the infusion site. The guidewire is then removed from the central 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 central coolant lumen may be used for injections of contrast media when the guidewire or Ultrasonic Core is not inserted. Within the drug lumens are encapsulated thermocouples that continuously measure temperature in the treatment zone.

The treatment zone of the Infusion Catheter is marked with a radiopaque marker bands at both the proximal and distal ends. Within the treatment zone, the outer walls of the drug delivery lumens are perforated with holes designed to deliver physician-specified fluids along the treatment length.

The proximal end of the Infusion Catheter contains a connector assembly. Two luers 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 central coolant lumen luer allows passage of a guidewire or the Ultrasonic Core into the central coolant lumen, or connection of a syringe for contrast injection. An electrical connector, which is color coded gray, couples to the Connector Interface Cable, which connects to the Control Unit.

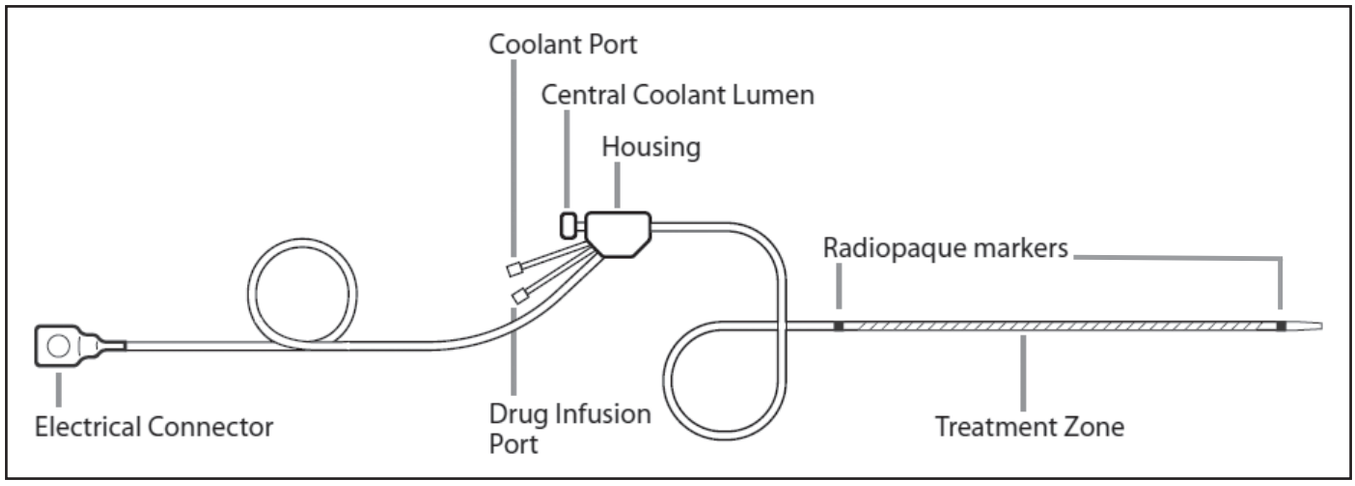

Figure 2. Infusion Catheter

Ultrasonic Core

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

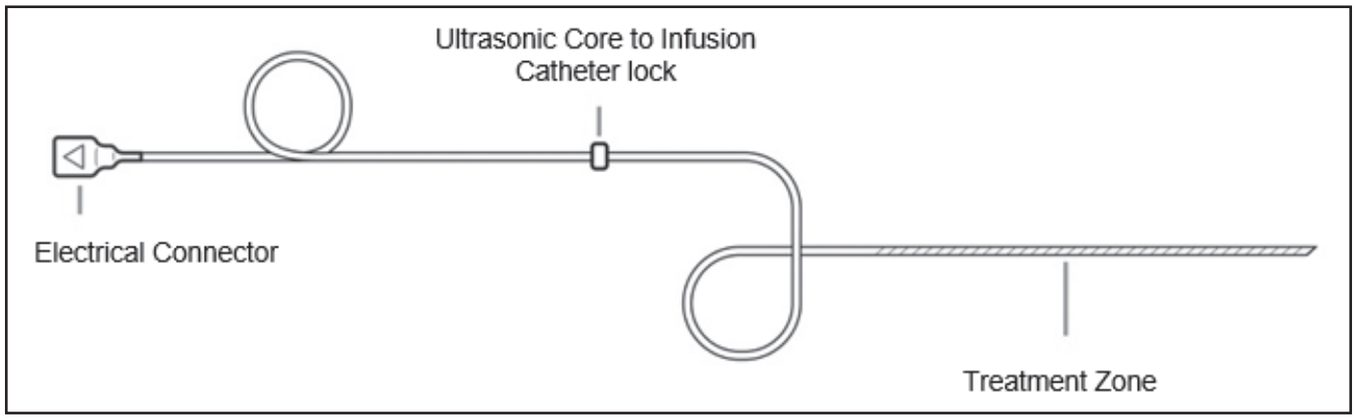

Figure 3. Ultrasonic Core

The Ultrasonic Core incorporates both a stiffening wire and electrical leads that extend from the transducers to an electrical connector at the proximal end. This electrical connector, which is color coded black, couples to the Connector Interface Cable, which connects to the Control Unit.

Control Unit

The Control Unit provides the user interface, electrical power, and monitoring of the device via the non-disposable Connector Interface Cable. EkoSonic Endovascular devices can be operated with the following Control Units:

- EKOS Control Unit 4.0
- EkoSonic Control Unit PT-3B

Note: All EkoSonic Endovascular Devices will function as intended, whether connected to Control Unit 4.0, or Control Unit PT-3B. For further information, please refer to the Instructions for Use for the relevant Control Unit.

Materials

The Infusion Catheter:

The catheter consists of a multi-lumen polymer shaft. Within the lumens of the shaft are thermocouples and metallic wires. A silicone lubricant is used in the inner lumen. There are two metallic marker bands on the distal end of the polymer shaft to denote the treatment zone. The proximal end of the catheter consists of multiple polymer injection-molded components. The drug and coolant lumens are connected to the device with polymer tubing and luers. Within the injection molded shells is a printed circuit board connecting the thermocouple wires to the cable and control unit

connector. The printed circuit board is sealed with a silicone sealant. The cable consists of multiple wires with polymer jackets. A polymer connector is on the proximal end of the cable assembly which allows for connection to the Control Unit. Solder, flux, and adhesives are used within the catheter.

Ultrasonic Core:

The catheter consists of multiple piezoelectric transducers soldered to a metallic core wire. Each transducer is connected to wires that run the length of the catheter. The treatment zone is encapsulated with epoxy and polymer tubing. The shaft is multi-layer polymer shaft with internal metallic braiding. The proximal end of the catheter consists of multiple polymer injection molded components and is connected to a cable assembly. The cable consists of multiple wires with polymer jackets. A polymer connector is on the proximal end of the cable assembly which allows for connection to the Control Unit. Solder, flux, and adhesives are used within the catheter.

Non-pyrogenic

This device meets pyrogen limit specifications.

User Information

Only physicians experienced in endovascular interventional procedures should use the EkoSonic Endovascular Device.

INTENDED USE

The EkoSonic Endovascular Device is intended to be used with EKOS-branded control systems to employ high frequency (2 MHz to 3 MHz), low-power ultrasound to facilitate the infusion of physician-specified fluids, including procedural fluids and thrombolytics, into the pulmonary and/or peripheral vasculature of adults. It is intended to be used by physicians experienced in endovascular interventional procedures. The EkoSonic Endovascular System is not intended for use in the neurovasculature.

Refer to the product insert supplied with the physician-specified fluid for fluid-specific preparation, contraindications, side effects, warnings, and precautions.

INDICATIONS FOR USE

The EkoSonic Endovascular System, consisting of the Infusion Catheter and the Ultrasonic Core, is indicated for the:

- Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis.
- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or peripheral vasculature.

Clinical Benefit Statement

The EkoSonic Endovascular Device is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature or the pulmonary arteries. The clinical benefit can be measured by overall clinical outcomes, including, but not limited to, improved right ventricular heart function and hemodynamic stability when treating PE or the ability to infuse physician-specified fluids into the peripheral vasculature, along with low rates of hemorrhage, recurrent PE, and all-cause mortality.

CONTRAINDICATIONS

The EkoSonic Endovascular Device is contraindicated for use in:

- Patients in whom thrombolytic and/or anticoagulation therapy is contraindicated.
- Any situation in which the medical judgment of the physician determines such a procedure may compromise the patient's condition.

WARNINGS

The following warning statements provide important information for safe operation of the EkoSonic Endovascular System. Observe all warnings provided in these Instructions for Use. Failure to do so may result in patient injury, operator injury, or product damage.

- Always verify that BOTH electrical connectors from an 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.

- If product is damaged, do not use, please retain the product and notify your Boston Scientific representative immediately.
- Never aspirate blood back into the drug lumens as perfusion pores and/or drug lumens may become occluded.
- Do not connect the Infusion Catheter "Drug" or "Coolant" infusion luers to a power injector.
- Do not exceed 200 psi applied to any infusion luer.
- If flow through the Infusion Catheter becomes restricted, do not attempt to clear by high pressure infusion or with a 1 cc syringe. 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.
- Never activate ultrasound energy with the Infusion Catheter or Ultrasonic Core's working length exposed to the air. The device should be placed within the patient anatomy, with physician-specified fluids running through the drug lumen and coolant flowing through the coolant lumen. Otherwise, overheating may occur, potentially causing burns, damage to the Ultrasonic Core, and/or interrupting therapy.
- Always turn off the ultrasound before removing the Ultrasonic Core from the Infusion Catheter. Otherwise, overheating may occur, potentially causing burns, damage to the Ultrasonic Core, and/or interrupting therapy. Use of a damaged Ultrasonic Core may result in vascular trauma.
- If an Infusion Catheter 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.
- Do not attempt to use non-compatible working lengths (i.e., 135 cm Infusion Catheter and 106 cm Ultrasonic Core and vice-versa). Incorrect size matching may be harmful to the patient and require additional intervention or surgery.
- 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 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.
- 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 vessel trauma.
- Do not use instruments (e.g. hemostats) to advance the Infusion Catheter over the guidewire or Ultrasonic Core into the Infusion Catheter. This may damage or kink the device and may lead to degraded performance or fracture during use.
- 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 seal is broken; contents may not be sterile and may cause infection in the patient.
- Do not use if package is damaged or unintentionally opened before use.
- Do not use if labeling is incomplete or illegible.

PRECAUTIONS

Carefully read all Instructions for Use prior to use. Observe all precautions noted throughout these instructions. Failure to do so may result in complications.

- Prior to introduction, and each time the Infusion Catheter is removed from the vascular system, the Infusion Catheter should be flushed.
- 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.
- Confirm the guidewire traversed the treatment zone prior to Infusion Catheter placement. Never advance the Infusion Catheter without the guidewire extending from the catheter tip.
- The EkoSonic device is designed to provide optimum acoustic output during the first 24 hours of operation.
- Do not suture through the catheter tubing or around it tightly enough to restrict flow or damage the catheter.

- The EkoSonic device should only be used to infuse physician-specified fluids, including thrombolytics. Other types of fluids, outside of thrombolytics and procedural fluids (heparinized saline, saline, contrast media, etc.), have not been evaluated for use with the EkoSonic Endovascular Device.
- This device is not designed for use as a peripheral vascular dilator.
- 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.
- Therapeutic agents, such as thrombolytics, should be administered through the drug port whereas the procedural fluids (such as saline and contrast agent) should be administered through the coolant port or central lumen.
- Take care not to dislodge the device during connection of the IV line.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the EkoSonic Endovascular System when used as indicated include, but are not limited to:

- Allergic Reaction (contrast, device, or other)
- Arrhythmia
- Burn
- Cardiac Tamponade
- Cardiac Trauma
- Death
- Embolism (air, device, plaque, thrombus, tissue, or other)
- Hematoma
- Hemorrhage
- Hypotension
- Infection/Sepsis
- Ischemia/Necrosis
- Need for additional intervention or surgery
- Pain
- Pneumothorax
- Renal Insufficiency/Failure
- Respiratory Failure
- Thrombosis/Thrombus
- Vasospasm
- Vessel Occlusion
- Vessel Trauma (AV fistula, dissection, perforation, pseudoaneurysm, rupture or injury)

CLINICAL STUDIES

The prospective, multi-center, single-arm study conducted by Garcia et al[1] evaluated the safety and efficacy of ultrasound-accelerated thrombolysis (USAT) for the treatment of deep vein thrombosis (DVT) in subjects (n=78) with post-thrombotic syndrome (PTS) in whom conservative treatment had failed. Efficacy was evaluated by improvement in clinical PTS assessed by the Villalta scale, venous patency assessed by duplex ultrasound imaging, and multiple generic and venous disease-specific quality of life (QOL) measures including Short Form-36 Physical Component score, Venous Insufficiency Epidemiological and Economic Study (VEINES)-QOL score, and Venous Clinical Severity Score (VCSS). Post-thrombotic syndrome-related healthcare use, major bleeding episodes, and mortality were documented. Results from the study demonstrated that change in average Villalta score from baseline was -5.9 ± 5.8 at 30 days post-procedure, -6.9 ± 6.5 at 90 days post-procedure, -7.8 ± 6.1 at 180 days post-procedure, and -8.2 ± 6.4 at 365 days post-procedure, constituting considerable improvement in clinical PTS that was sustained through 1 year. Nearly two-thirds of limbs (51/79; 64.96 %) met the primary endpoint of a reduction of ≥4 in the Villalta score 30 days after procedure with that number increasing to 51/66 (77.3 %) at 1 year. Rates of PTS- related healthcare use, which included emergency room visits, unplanned physician office visits, and hospitalization for symptomatic PTS, within 30 days and 1 year were 27.0 % (21/78) and 50.0 % (39/78), respectively. Thirteen (16.7 %) patients experienced bleeding of any kind within 30 days of the procedure. Major bleeding occurred in 2.6 % (2/78) of patients within 72 hours of initiating USAT treatment. One patient suffered from an intra-abdominal hemorrhage that resolved within 30 days while the other presented with epistaxis, later developed multi-organ failure that resulted in death 39 days after the procedure. Recurrent DVT or pulmonary embolism (PE) within 30-days of the procedure was observed in 3.8 % (3/78) of patients.

The prospective, multi-center, randomized, investigator-sponsored study conducted by Notten et al[2] assessed the safety and efficacy of ultrasound-accelerated catheter-directed thrombolysis (UACDT), in addition to standard anticoagulant therapy, for preventing post-thrombotic syndrome (PTS) in patients (n=152) with iliofemoral deep vein thrombosis (DVT). Patients were randomly assigned to either standard treatment with UACDT (n=77) or standard treatment alone (n=75). Presence of PTS, assessed using the original Villalta criteria, and major bleeding were the primary efficacy and safety endpoints, respectively. Other outcomes evaluated included recurrent venous thromboembolism, pulmonary embolism, in-stent

thrombosis, death, and quality of life (QOL). At a median follow up of 12.0 months (IQR 6.0-12.0 months), 29 % of UACDT patients (22/77) and 35 % of standard treatment patients (26/75) had PTS (OR 0.75 [95 % CI 0.38–1.50], P = 0.42). Levels of severity observed between patients receiving UACDT and those receiving standard treatment alone were comparable [None (<5): 71 % vs. 65 %, Mild (5-9): 13 % vs. 13 %, Moderate (10-14): 14 % vs. 16 %, and Severe (≥15): 1 % vs. 5 %, respectively, P>0.05]. Change in quality of life measures from baseline to 12 months were similar between groups and improved during follow-up in all measurements other than the VEINES Quality of Life/Symptoms (VEINES-QOL/sym) T score (P = 0.71). Major bleeding occurred in 4/77 (5 %) UACDT patients and 0/75 standard treatment patients (OR 9.25 [CI 0.49-174.7]). No serious adverse events occurred. No intraspinal or intracranial bleeding occurred, but 1 major bleeding event caused peroneal nerve neuropraxia. All events required additional intervention, and all were related to the thrombolytic treatment. In-stent thrombosis occurred in the UACDT group only (10/77;13%).Ratesofpulmonaryembolism(0vs.3%;OR0.19 [CI0.01-4.02]),recurrent(non-stent)DVT(6%vs.5%;OR1.23 [CI 0.32-4.78]), and non-treatment or procedure related death (1 % vs. 4 %; OR 0.32 [CI 0.03-3.11)] were similar between the UACDT and standard treatment groups, respectively.

Taken together, clinical data suggest that use of EkoSonic Devices can improve clinical PTS and durable venous patency and support the use of these devices in the treatment of DVT. However, the data also show that treatment of DVT with UACDT does not necessarily relate to reduced PTS when compared to standard of care (anti-coagulants alone) as observed in the above trial that demonstrated comparable rates of PTS rates at 1-year in the UACDT (29 %) and standard treatment (35 %) groups in patients with iliofemoral DVT.

1. Garcia MJ, Sterling KM, Kahn SR, et al. Ultrasound-Accelerated Thrombolysis and Venoplasty for the Treatment of the Postthrombotic Syndrome: Results of the ACCESS PTS Study. *J Am Heart Assoc*. 2020;9(3):e013398.
2. Notten P, Ten Cate-Hoek AJ, Arnoldussen C, et al. Ultrasound-accelerated catheter-directed thrombolysis versus anticoagulation for the prevention of post-thrombotic syndrome (CAVA): a single-blind, multicentre, randomised trial. *Lancet Haematol*. 2020;7(1):e40-e49.

HOW SUPPLIED

The Infusion Catheter is packaged inside a tray and sterile pouch. The Ultrasonic Core is also packaged inside a tray and sterile pouch. The Infusion Catheter and Ultrasonic Core sterile pouches are placed into one shelf carton.

Contents supplied STERILE using an Ethylene Oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess, or resterilize.

Handling and Storage

This product has no special handling or storage requirements.

OPERATIONAL INSTRUCTIONS

Preparation

Prior to initiation of the procedure, ensure that the following components of the system are available:

- Control Unit (4.0 or PT-3B)
- Connector Interface Cable (CIC)
- Ultrasonic Core
- Infusion Catheter

Ultrasonic Core and Infusion Catheter Treatment Zone Compatibility

Whenever possible, ensure that the treatment zone (TZ) lengths of the Infusion Catheter and Ultrasonic Core match. If needed, Infusion Catheters with TZ lengths of 6 cm, 12 cm, 18 cm, 24 cm, and 30 cm can be operated with Ultrasonic Cores with the following TZ lengths (6 cm, 12 cm, 18 cm, 24 cm, and 30 cm), to support patient therapy.

Warning: Do not attempt to use non-compatible working lengths (i.e., 135 cm Infusion Catheter and 106 cm Ultrasonic Core and vice-versa). Incorrect size matching may be harmful to the patient and require additional intervention or surgery.

Infusion Catheter TZ Longer Than Ultrasonic Core TZ

If the treatment zone of the Infusion Catheter is longer than the treatment zone of the Ultrasonic Core, all groups of the Ultrasonic Core will operate, and drug will be infused along the entire length of the Infusion Catheter treatment zone, however, some portion of the Infusion Catheter treatment zone will not have corresponding ultrasound output.

Infusion Catheter TZ Shorter Than Ultrasonic Core TZ

If the treatment zone of the Infusion Catheter is shorter than the treatment zone of the Ultrasonic Core, only ultrasound groups within the Infusion Catheter treatment zone will operate.

Note: Ultrasonic Core TZ lengths of 40 cm and 50 cm will only operate with Infusion Catheter TZ lengths of 40 cm and 50 cm, respectively.

Preparing Infusion Pumps

Prepare two infusion pumps as directed by the manufacturer's Instructions for Use. Prepare one pump with normal saline or 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 setting on the pumps should be set to the highest value allowed by hospital policy. A minimum of 10 psi or 500 mmHg will reduce the potential of downstream occlusion alarm.

Vascular Access

Before beginning procedure, read the Contraindications, Warnings, Precautions, and Adverse Events sections in this IFU.

Warning: Do not connect the Infusion Catheter "Drug" or "Coolant" infusion ports to a power injector.

Warning: Do not exceed 200 psi applied to any infusion port.

For the Pulmonary Arteries:

Obtain venous access and place a 6F (2.0 mm) or larger sheath per standard practice.

For the Peripheral Vasculature:

Obtain access and place a 6F (2.0 mm) or larger introducer sheath of the desired length. If crossing the aortic bifurcation, a longer reinforced sheath should be used.

Warning: Do not use an introducer sheath with a rotating hemostasis valve (Tuohy-Borst) 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.

Procedure

Preparing and Placing The Infusion Catheter and Ultrasonic Core

1. Using fluoroscopic guidance, advance an 0.035 inch (0.89 mm) exchange length guidewire through the occlusion.
2. Select the device with the appropriate treatment zone.
3. Remove the pouches from the box and, using sterile technique, place the contents of the pouches onto the sterile field.
4. Remove the Infusion Catheter from the protective coil.
5. Attach stopcocks to the luer fittings labeled "Coolant" and "Drug.

Warning: Never immerse the electrical connectors or the white housing of the Infusion Catheter in fluid.

6. Attach a 3 cc or 5 cc syringe of heparin (or physician-specified fluids) to the stopcock on the drug lumen and flush the lumen. Priming volume of the drug lumen is

   106 cm: 0.8 cc

   135 cm: 1.0 cc

   Be sure that fluid exits from the most distal catheter perfusion pores, which are located near the distal radiopaque marker. Close the stopcock to "lock" the heparin (or physician specified fluids) in the catheter and remove the syringe.
7. Attach a syringe of normal saline or heparinized saline to the stopcock on the coolant lumen. Inject fluid until it flows from the central coolant lumen luer. Place finger over central coolant lumen luer (guidewire lumen) and inject until saline or heparinized 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. Priming volume of the 106 cm Infusion Catheter is 1.5 ml while priming volume of the 135 cm Infusion Catheter is 1.9 ml.

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.

8. Back-load the Infusion Catheter onto the proximal portion of the guidewire.
9. Using fluoroscopic guidance, advance the Infusion Catheter across the treatment site making sure the distal radiopaque marker of the catheter is 1 cm beyond the occlusion. When the Infusion Catheter has been successfully placed, remove the guidewire gently from the Infusion Catheter and flush the central coolant lumen (guidewire lumen).
10. Taking care not to kink the device or to get the connector wet, moisten the outside of the Ultrasonic

Core by either infusing normal saline or heparinized saline into the luer fitting of the protective coil or remove it from the protective coil and wipe it with a wet gauze sponge.

Warning: Never immerse the electrical connectors or the white housing of the Infusion Catheter in fluid.

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11. Insert the Ultrasonic Core into the central coolant lumen luer 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.

Warning: Do not use instruments (e.g. hemostats) to advance the Infusion Catheter over the guidewire or Ultrasonic Core into the Infusion Catheter. This may damage or kink the device and may lead to degraded performance or fracture during use.

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12. 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.
13. Attach a 5 ml syringe with heparinized saline to the stopcock connected to the coolant port. Forward flush through the side port of the stopcock to eliminate air bubbles then turn the stopcock on to the device and flush to remove blood from the central coolant lumen prior to starting the coolant infusion.
14. Connect the IV line on the infusion pump containing the physician-specified fluids to the stopcock attached to the port labeled "DRUG".

Caution: Therapeutic agents, such as thrombolytics, should be administered through the drug port whereas the procedural fluids (such as saline and contrast agent) should be administered through the coolant port or central lumen.

Caution: Take care not to dislodge the device during connection of the IV line.

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15. With the stopcock off to the catheter, 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 fluid flow rate (minimum 5 ml/hr to maximum 35 ml/hr) and begin infusion.

Warning: Never aspirate blood back into the drug lumens or the drug lumens and perfusion pores may become occluded.

Note: Forward flush with heparinized saline through the drug and coolant ports to maintain patency if there's a delay in starting the infusions.

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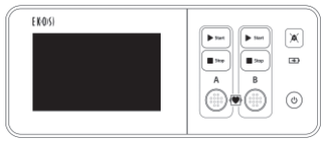
16. Attach the IV line on the infusion pump containing normal saline solution to the stopcock attached to the port labeled "Coolant". With the stopcock off to the catheter, flush saline from the infusion pump through the stopcock to clear any air from the line. Turn the stopcock to connect the IV line to the coolant lumen. Set the infusion rate (minimum 35 ml/hr to maximum 120 ml/hr) and begin infusion.
17. Secure the device using appropriate catheter stabilization methods (for example, Tegaderm, steri-strips, etc.) following standard hospital stabilization protocol. Refrain from coiling the catheter too severely.

Operation of the Device with a Control Unit

EkoSonic Endovascular Devices can be operated with the following EKOS Control Units:



Control Unit 4.0

Control Unit PT-3B

1. Place the Control Unit on a firm surface within 5 feet (1.6 meters) of the patient. If Control Unit 4.0 is used, it can also be attached securely to a compatible infusion stand. Please see the Control Unit 4.0 Instructions for Use for infusion stand specifications.
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. For PT-3B also 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. For PT-3B, also 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 "Start" button on the Control Unit.

For Control Unit 4.0	For Control Unit PT-3B
When ultrasound is running, a runtime clock counts up, white bands animate in the channel message area and a green Running indication displays. The running status is displayed independently for each channel or device.	The yellow flashing light and flashing waves of the EKOS logo on the front panel of the Control Unit indicates 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 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.

Warning: Never activate ultrasound energy to the Infusion Catheter or Ultrasonic Core with the device in the air. It should be placed within the patient anatomy, with physician-specified fluids running through the drug lumen and coolant flowing through the coolant lumen. Otherwise, overheating may occur, potentially causing burns, damage to the Ultrasonic Core, and/or interrupting therapy.

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 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 Connector Interface Cable 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 AC power cord from the wall outlet 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 system into AC power.

Note: If an EKOS Control System Cart is not available or the Control Unit 4.0 is not attached to an infusion stand, unplug AC power cord from the wall outlet and secure it for transport with the patient. When the patient reaches the patient care area where they will be monitored during therapy, plug the system into AC power. If necessary, turn on the power switch and press the start button to restart the ultrasound.

Note: If using a PT-3B with a cart and a battery, the battery will beep when unplugged. Press the mute button on the front of the battery to silence. Plug the battery into an outlet upon arrival in the patient care area where they will be monitored during therapy.

During therapy, the ultrasound may be stopped at any time by touching the "Stop" button. The ultrasound may be restarted by pushing the "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.

Infusion Completion / Catheter Removal

When the infusion procedure has been completed, the EkoSonic Endovascular Device may be removed at bedside without fluoroscopic guidance or it may be removed under fluoroscopic guidance according to physician's order.

1. To prepare the patient for transport leave the infusions on and unplug AC power cord from the wall outlet.

   Note: If an EKOS Control System Cart is not available or the Control Unit 4.0 is not attached to an infusion stand, unplug AC power cord from the wall outlet and secure it for transport with the patient.

   Note: If using a PT-3B with a cart and a battery, the battery will beep when unplugged. Press the mute button on the front of the battery to silence.

2. After placing the patient on the fluoroscopic table, stop ultrasound therapy, turn off the Control Unit and disconnect the Ultrasonic Core and Infusion Catheter connectors from the CIC. Turn stopcocks off to the drug and coolant ports so no air is introduced into the catheter. Discontinue infusions.
3. Decontaminate the exposed portions of the Ultrasonic Core and Infusion Catheter, and drape in a sterile fashion. Angiography may be performed at this time to assess the treatment site. For full assessment, angiography in the treatment zone may be preferable to a contrast injection through the sheath.

   Warning: Do not connect the Infusion Catheter "Drug" or "Coolant" infusion ports to a power injector.

   Warning: Do not exceed 200 psi applied to any infusion port.

4. If additional intervention is required, remove the Ultrasonic Core. Place the guidewire through the Infusion Catheter and then remove the Infusion Catheter leaving 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 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, remove the introducer sheath and attain hemostasis.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose of the device and packaging as follows:

After use, device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Assess patient for hematoma and/or other signs of bleeding at the puncture site.

Patient discharge should be performed per hospital standard of care.

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

INFORMATION TO BRIEF THE PATIENT

The physician should consider the following points while counseling the patient on the use of the EkoSonic Endovascular System in association with the interventional procedure:

- Discuss the risks and benefits, including review of potential adverse events listed in this document, both for EkoSonic Endovascular System and for other interventional treatments likely to be employed.
- Discuss post-procedure instructions, including any lifestyle changes, medications, home care, and rehabilitation guidelines.
- Discuss the risks and benefits of antiplatelet therapy including risk of thromboembolism should the patient be allergic or discontinue use.

No separate patient information is provided because the EkoSonic Endovascular System is used in association with other interventional procedures. Risks and benefits to the patient are similar to and, from the patient's perspective, a part of those interventional procedures.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324D), eIFU, MB, EkoSonic, en, 51320907-01A

REF Catalog Number

Consult instructions for use.


Contents

EC REP Authorized Representative in the European Community


Manufacturer

LOT Lot Number


Recyclable Package


Use By

AUS Australian Sponsor Address

ARG Argentina Local Contact


Single use. Do not re-use.

Do Not Resterilize


Do not use if package is damaged.


Date of Manufacture

MD Medical Device under EU Legislation

UDI Unique Device Identifier


Single sterile barrier system

SN Serial Number

STERILE EO Sterilized using ethylene oxide.


Non-Pyrogenic

EC REP Authorized Representative in the European Community

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY NSW 1455 Australia
Free Phone +1-800-676-133
Free Fax +1-800-836-666

ARG Argentina Local Contact

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Manufacturer

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300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service +1-888-272-1001

www.bostonscientific.com


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Recyclable Package

BSC (MB eFU Template 8.2677 x 11.6929 A4, 92524324D), eIFU, MB, EkoSonic, en, 51320907-01A