EKOS® Acoustic Pulse Thrombolysis™
Endovascular Lab In-Service

EKOS Corporation is a BTG International group company

US-EKO-1800191

Imagine where we can go.
Forward-looking statements

This presentation and information communicated verbally to you may contain certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of BTG plc (“BTG”). These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors which could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Nothing contained in this presentation or communicated verbally should be construed as a profit forecast or profit estimate. Investors or other recipients are cautioned not to place undue reliance on any forward-looking statements contained herein. BTG undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances. Neither this presentation nor any verbal communication shall constitute an invitation or inducement to any person to subscribe for or otherwise acquire securities in BTG.
Indications

The EkoSonic® Endovascular System is indicated for:
• controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature
• infusion of solutions into the pulmonary arteries
• the ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism

NOTE: The contraindications, warnings and precautions are listed in the IFU.
https://www.btg-im.com/EKOS/US/Customer-support/Indications-Instructions-for-use/
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Components</td>
<td>5</td>
</tr>
<tr>
<td>Device Preparation</td>
<td>7</td>
</tr>
<tr>
<td>Device Placement</td>
<td>13</td>
</tr>
<tr>
<td>Infusions Set-up</td>
<td>15</td>
</tr>
<tr>
<td>Control Unit Set-up</td>
<td>16</td>
</tr>
<tr>
<td>Starting &amp; Monitoring Ultrasound</td>
<td>19</td>
</tr>
<tr>
<td>Patient Transport</td>
<td>22</td>
</tr>
<tr>
<td>Control Unit Troubleshooting &amp; Helpline</td>
<td>25</td>
</tr>
</tbody>
</table>
System components

Other Supplies

(2) 3-way stopcocks or flow switches:
  - (1) COOLANT port
  - (1) DRUG port

(1) 3 or 5 cc syringe to flush the DRUG lumen
**Device detail**

**Infusion Catheter cross-section**

- **Radiopaque marker**
- **Ultrasound transducer**
- **Central Coolant Lumen**
- **Therapy Optimization Sensor**
- **Drug Lumen (x 3)**
- **Guidewire or Ultrasonic Core (0.035” diameter)**

```
Device detail

Radiopaque marker

Ultrasound transducer

Ultrasonic Core

Infusion Catheter

Infusion Catheter cross-section

Central Coolant Lumen

Therapy Optimization Sensor

Drug Lumen (x 3)

Guidewire or Ultrasonic Core (0.035” diameter)
```
Device preparation

• Obtain access per standard endovascular techniques
  – 6 Fr introducer sheath is preferred
  – Use a long supportive sheath for contralateral approach

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.

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

• Select the proper treatment zone length based on the clot length
  – 106 cm working length
    6, 12, 18, 24, 30, 40, 50 cm treatment zones
  – 135 cm working length
    12, 30, 40, 50 cm treatment zones
Keep the electrical connectors dry

Box contains two packages

- (1) Infusion Catheter
- (1) Ultrasonic Core

Isolate the electrical connectors prior to flushing to ensure they stay dry.

IF THESE CONNECTORS GET WET, THE DEVICE WILL NOT FUNCTION PROPERLY.
Infusion Catheter preparation

- Remove Infusion Catheter from the tray
- Isolate the gray electrical connector.

! DO NOT GET THIS CONNECTOR WET

- Place one stopcock or flow switch on the DRUG port and one on the COOLANT port.
Flush the **DRUG** lumen

- Attach a 3 or 5 cc syringe to the **DRUG** port. Flush the **DRUG** lumen with heparin until fluid exits the most distal perfusion pores.
- Turn stopcock **OFF** to the Infusion Catheter to keep air from being introduced into the vasculature.

**NEVER DRAW BACK BLOOD INTO THE DRUG LUMEN OR INFUSE ANYTHING BUT HEPARIN, SALINE, OR DRUG THROUGH THE DRUG LUMEN. IF THE LUMEN MICRO-PORES BECOME BLOCKED, THE INFUSION CATHETER MUST BE REPLACED.**
Flush the COOLANT lumen

- Attach a 10 cc syringe to the COOLANT port. Flush COOLANT lumen with heparinized saline.
- Fluid will exit the central guidewire lumen. Place your finger over the central lumen and continue to flush until you see fluid exit the distal tip of the Infusion Catheter.
- Turn stopcock OFF to the Infusion Catheter to keep air from being introduced into the vasculature.
Ultrasonic Core preparation

• Isolate the black electrical connector of the Ultrasonic Core.

! DO NOT GET THIS CONNECTOR WET

• Flush protective coil with heparinized saline to moisten the Ultrasonic Core until ready for use, or wipe with a wet 4 x 4 prior to inserting into the Infusion Catheter.
Device placement – Infusion Catheter

- Place Infusion Catheter through a 6 Fr sheath over an 0.035” exchange length guidewire
- Position the distal marker on the Infusion Catheter 1 cm beyond the clot
- Remove 0.035” guidewire
- Flush the guidewire lumen
Device placement – Ultrasonic Core

- Insert Ultrasonic Core into the guidewire lumen in 1 cm increments to prevent kinking or bending
- Luer lock Ultrasonic Core into the manifold of the Infusion Catheter

IF AN INFUSION CATHETER OR ULTRASONIC CORE BECOME KINKED OR OTHERWISE DAMAGED DURING USE, DISCONTINUE USE AND REPLACE
Infusions set-up

- Consider using sterile extension tubing to begin infusions before breaking down the sterile field.
- Flush forward to purge any air out of side port of the stopcocks attached to the **DRUG** and **COOLANT** ports. Turn stopcocks on to the device, set the rate, begin infusion.
- Infuse heparinized saline or normal saline through the **COOLANT** port at 35 ml/hr (Max 120 ml/hr).
- Infuse lytic through the **DRUG** port at a prescribed dose with a flow rate range from 5 ml to 35 ml/hr.
- Sheath maintenance is at physician discretion.
Control Unit set-up

• Locate the power switch on the back of the control unit.

• Turn on the control unit.

• Wait for self test screen to disappear
Connect cables

- Schematic screen appears with **RED** circles.
- Connect Connector Interface Cable (CIC) to the Control Unit.
- Connect device cables to CIC.
- Ensure proper connections
  - **Black** to **Black** and △ to △
  - **Gray** to **Gray** and O to O

If using two devices and two control units ensure the black and gray pair of wires from one device is connected to the same (CIC) Connector Interface Cable. **CROSS CONNECTING AN ULTRASONIC CORE AND INFUSION CATHETER FROM TWO DIFFERENT PAIRS COULD RESULT IN PATIENT INJURY.**
Catheter Connector Clip

- Prevent disconnection alarms by using the Catheter Connector Clip
Starting ultrasound

• Confirm connections on the schematic screen. (Red circles will disappear).

• Confirm infusions are running.

• Press **GREEN** START button.
Monitoring ultrasound

YELLOW LIGHT FLASHING INDICATES ULTRASOUND IS ON
Power Graph

CHART % TOTAL AVERAGE POWER or YELLOW LIGHT FLASHING EVERY HOUR TO DOCUMENT THERAPY IS RUNNING.

% Total Average Power

Rising Average Power

Elapsed Time

YELLOW LIGHT FLASHING

Therapy Running Indicator

EKO(S) 24/7/365 Help Line 888-356-7435
Preparation for patient transport

- Secure device with Tegaderm™, Steri-Strips™, or tape.
- Refrain from coiling the catheter too severely.
- Move patient onto a bed or stretcher.
- Inform patient that they will be on bed rest and will have to keep the affected extremity straight at the insertion site and treatment zone.
• Unplug UPS/battery from AC outlet (battery will last for 60 minutes).
• When UPS/battery is unplugged, an alarm will sound.
• Silence the alarm by pressing and holding the “MUTE” button located on the front of the battery for 2 seconds.
• Transport patient to new location.
• Plug UPS/battery into AC outlet.
• Confirm the “YELLOW” light is flashing.
  - If not, push the GREEN START button to activate therapy.
1. ALWAYS turn off the ultrasound by pressing the **ORANGE “STOP”** button before removing the Ultrasonic Core from the Infusion Catheter.
   - If the Ultrasonic Core is removed while running, it will turn off automatically, but in the few seconds it takes to turn off, it can become very hot.

2. Disconnect the Ultrasonic Core and Infusion Catheter from the CIC.

3. Turn stopcocks off to the **DRUG** and **COOLANT** ports so no air is introduced into the catheter. Discontinue infusions.

4. *[Endovascular lab only]* Decontaminate the exposed portions of the device and drape in a sterile fashion. Angiography may be performed at this time to assess the treatment site.

---

**Never connect Infusion Catheter to a power injector**
Control Unit troubleshooting tips

Disconnect:

• Press the Mute button in the top right hand corner of the control unit

• Confirm reason for alarm as indicated by the **RED** circle.

• Make correction.

• Activate ultrasound by pressing the **GREEN START** button.
Control Unit troubleshooting tips (continued)

General Alarm:

• MUTE alarm.

• Locate alarm icon blinking at the bottom of the screen between the two gray bars.

• Locate explanation for icon in the IFU kept in the back pocket of the EKOS cart or call the EKOS Helpline at 1 (888) 356-7435.

□ The EKOS® Help Line is staffed by customer service experts and clinical specialists 24/7/365. Call any time you have questions.

□ After the issue is resolved press the GREEN start button. Make sure the YELLOW light is flashing.
More instructional materials online

Please check the Learning Center on the EKOS Corporate website for additional instructional information

https://www.btg-im.com/EKOS/US/Learning-Center/