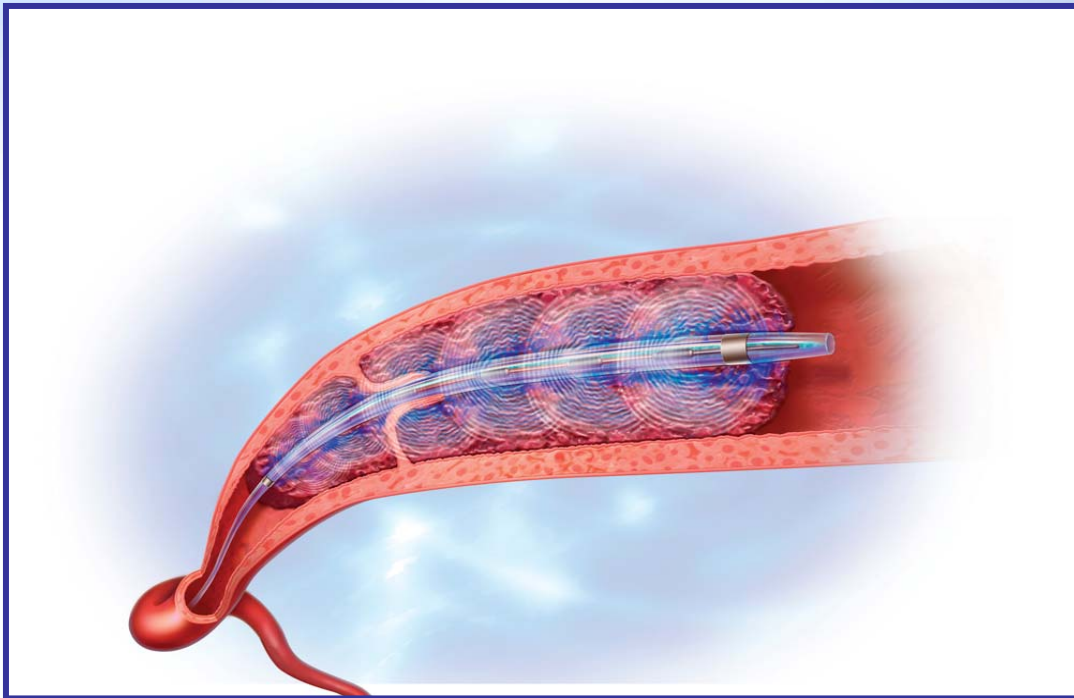


EKOSS)

ULTRASOUND ACCELERATED THROMBOLYSIS



EKOSS)

The EkoSonic® Endovascular System with Rapid Pulse™ Modulation

EKOS)

EkoSonicTM MACH4

Endovascular Device

with
 Rapid PulseTM Modulation



Cleared for the controlled and selective infusion of physician-specified fluids, including thrombolytics into the peripheral vasculature and for the infusion of solutions into the pulmonary arteries.

EkoSonic Device Procedure

- Obtain access per standard endovascular techniques
 - 6F introducer sheath is preferred
 - For contralateral approach use a long supportive sheath.

EkoSonic Device Procedure

- **Select the proper treatment zone length based on the length of the clot:**
 - **106cm working length:**
6, 12, 18, 24, 30, 40, 50cm treatment zones
 - **135cm working length:**
12, 30, 40, 50cm treatment zones

Device Preparation - "Pearls"

- **Prepare and place the EkoSonic Device per the Instructions for Use**
 - DO NOT get the electrical connectors wet during preparation and placement.
 - DO prep the drug lumen of the EkoSonic device with pure heparin (1000 μ ml – fill volume is 0.8ml to 1.0ml) and "lock" with a stopcock.
 - NEVER draw blood back into the drug lumen.
 - The micro pores will be blocked and the device will not infuse

Device Prep

- Select treatment zone and catheter length.
- Box contains two packages.
 - (1) Intelligent Drug Delivery Catheter. (IDDC)
 - (1) MicroSonic Device (MSD)
- Isolate the electrical connector of the devices prior to flushing to ensure they stay dry.
 - **IF THESE CONNECTORS GET WET, THE DEVICE WILL NOT FUNCTION PROPERLY**



Ancillary Supplies

- (2) 3-Way Stopcocks or flow switches:
 - (1) **COOLANT** port
 - (1) **DRUG** port
- (1) 3 or 5cc syringe to flush the Drug port.
- Remove IDDC from the tray and place a stopcock or flow switch on the **DRUG** port and the **COOLANT** port.



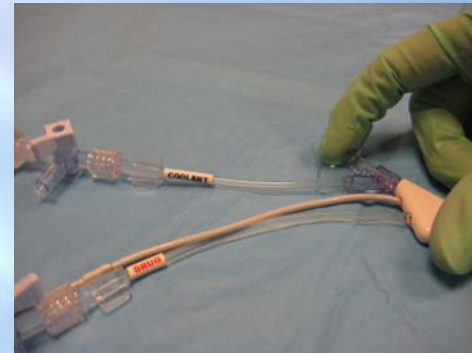
Intelligent Drug Delivery Catheter (IDDC)

- Flush the **DRUG** port with heparin using a 3 or 5cc syringe until fluid exits the most distal perfusion pores.
- Turn stopcock **OFF** to the 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 MICRO PORES BECOME BLOCKED, the IDDC MUST BE REPLACED.**



Intelligent Drug Delivery Catheter (IDDC)

- Flush **COOLANT** port 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 catheter.
- Turn stopcock **OFF** to the catheter to keep air from being introduced into the vasculature.



MicroSonic Device (MSD)

- Isolate the black electrical connector of the MSD
 - **DO NOT GET THIS CONNECTOR WET**
- Flush protective coil with heparinized saline to moisten the MSD until ready for use or wipe with a wet 4 x 4 prior to inserting into the IDDC.



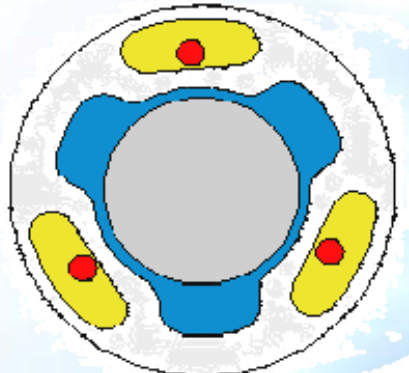
EKOS



Specific design ...performance driven micro transducer
(Actual size comparison with dime)



EkoSonic® Mach 4 Endovascular Device



- Drug Delivery Lumens
- Therapy Optimization Sensor
- Central Coolant Lumen
- MicroSonic Device in central lumen

Cross section of the Intelligent™ drug delivery catheter

Procedure

- Place Intelligent Drug Delivery Catheter (IDDC) through a 6FR sheath over an 0.035" exchange length guide wire.
- Position the distal marker on the catheter 1cm beyond the clot
- Remove 0.035" guidewire
- Flush the guide wire lumen
- Insert MicroSonic Device (MSD) into the guidewire lumen

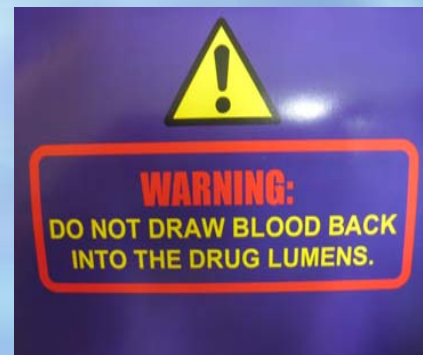
Micro Sonic Device (MSD)

- Insert MSD in 1cm increments to prevent kinking or bending
- Luer lock MSD into the hub of the IDDC



BEGIN FLUID INFUSION

- Consider using sterile extension tubing to begin infusions before breaking down the sterile field.
- Infuse Heparinized Saline or Normal Saline through the **COOLANT** port at 35 ml/hr. (Max 120 ml/hr)
- Infuse Lytic through the **DRUG** port and a prescribed dose with a flow rate range from 5ml to 35ml/hr.



EkoSonic Control Unit

- 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 MACH 4 cables to the Connector Interface Cable (CIC).
- **Black to Black, Gray to Gray**, and symbols $\Delta\Delta$ ∞ .
- MAKE SURE THE MSD and IDDC CABLES ARE A "PAIR" IN THE PATIENT. CROSS CONNECTING AN MSD AND IDDC FROM 2 DIFFERENT PAIRS COULD RESULT IN PATIENT INJURY.



Catheter Connector Clip

- Prevent disconnection alarms by using the catheter connector clip

CIC. Push the MSD and IDDC electrical connectors into the CIC Clip. Make sure
[see Figure 2].

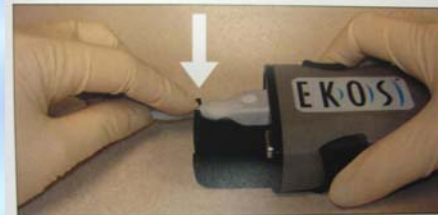


Figure 2. IDDC being secured into CIC Clip.

usable Connector Interface Cable (CIC) is NOT STERILE. Use caution

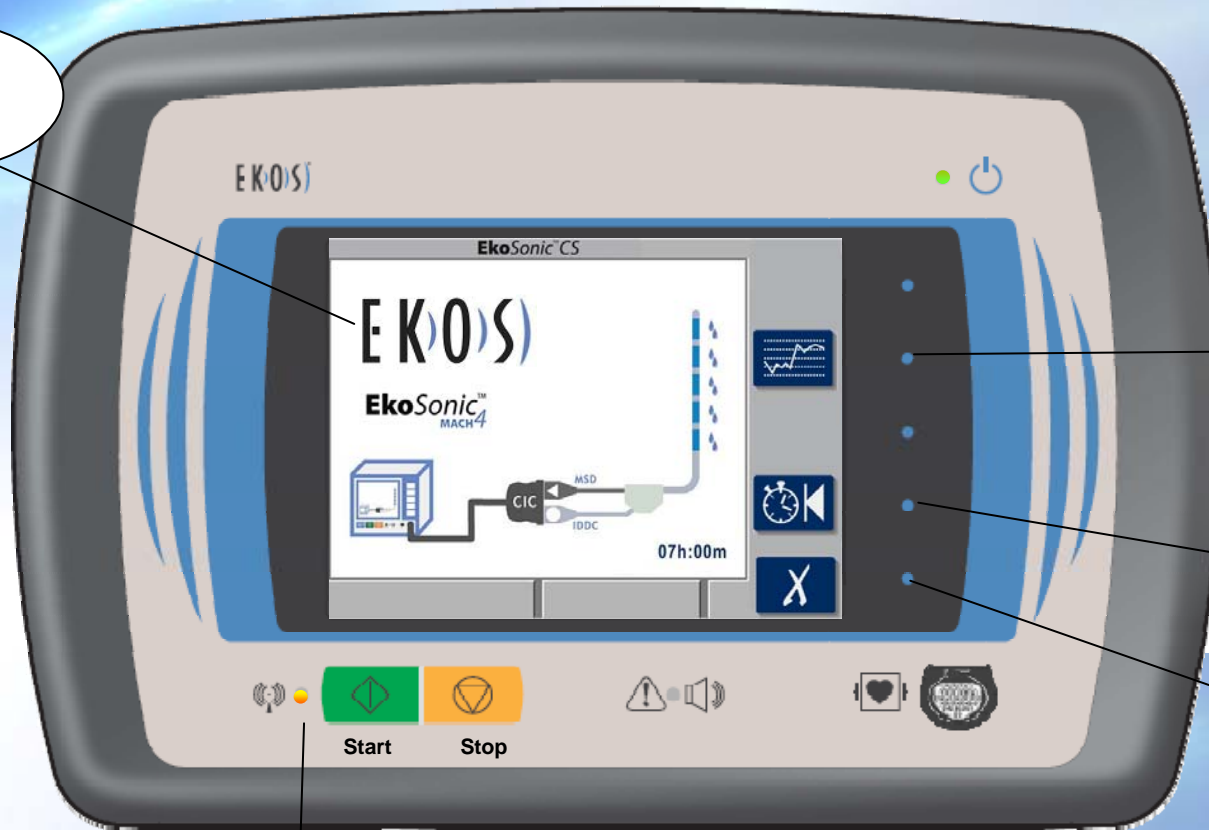


EkoSonic MACH 4

- Confirm connections on the schematic screen.
(**Red** circles will disappear).
- Confirm fluids are infusing.
- Press **GREEN** START button



Therapy Running Indicator



Screen Selector Button

Time Reset Button

Cancel Button

Yellow Light Flashing

Intuitive Interface



% Total Average Power

Rising Average Power

Elapsed Time

Therapy Running Indicator

Intuitive Interface

Summary of the MACH 4 Device



Secure Device

- Secure device with Tegaderm[®], steri-strips, or tape.
- Refrain from coiling the catheter too severely.
- Move patient onto a bed or stretcher.
- Inform the patient that they will be on bed rest and will have to keep the affected extremity straight at the insertion site and treatment zone.

Transport

- Unplug the EKOS system from the outlet.
- The battery will alarm. Locate the MUTE button on the front left hand corner of the battery. Press MUTE for two seconds to silence.
- Transport patient.
- Plug the EKOS system into a red outlet.
- Confirm the “**YELLOW**” light is flashing.
 - If not, push the **GREEN** START button to activate therapy.

Removal of the EkoSonic Endovascular Device

- ALWAYS turn off the ultrasound by pressing the **ORANGE** "STOP" button before removing the MSD from the IDDC
 - If the MSD is removed while running, it will turn off automatically, but in the few seconds it takes to turn off, it can become very hot.
- Decontaminate the MSD and IDDC
- Remove the MSD from the IDDC
- Insert a guidewire through the IDDC and remove as one or leave guidewire in place while removing IDDC
- Angiography may be performed to assess the treatment site.
- **WARNING: NEVER** connect IDDC to a power injector.

ALARMS

For 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.



ALARM

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 24/7 EKOS Helpline.
- Follow IFU or helpline suggestions.
- Restart ultrasound by pressing the **Green** button.



EKOS

EKOS 24/7 HELP LINE:

1 (888) 356-7435