



**NeuroWave<sup>™</sup>**  
Micro-Infusion Catheter

## Instructions for Use

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This system is covered by and/or manufactured under one or more of the following patents: U.S. Patent Numbers 6,723,063, 6,585,678, 6,001,069, 5,197,946 and 6,979,293 and European Patent Number EP 1091699B1. Other U.S. and foreign patents pending."

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**Caution:**  
**Federal Law restricts this  
device to sale, distribution and use  
by or on the order of a physician.**

**Intended Use**

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**Peripheral Vasculature**      **The Micro-Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature**

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**Neurovasculature**      **The EKOS Micro-Infusion System is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The EKOS Micro-Infusion System may be used for controlled, regional infusion into selected vessels.**

**The safety and effectiveness of the EKOS Micro-Infusion System for thrombolytic therapy in the neurovasculature have not been established. Further clinical studies are necessary to ensure that use of devices to deliver thrombolytic therapy into the neurovasculature does not result in an increased incidence of adverse events (e.g., intracranial hemorrhage).**

**Coronary Vasculature**      **The EKOS Micro-Infusion system is intended to deliver physician specified fluids to the coronary vasculature.**

**The safety and effectiveness of the EKOS Micro-Infusion system used for intracoronary thrombolytic therapy administration have not been established. In particular, the ultrasound energy delivered by the EKOS Micro-Infusion System is not intended to be therapeutic, and the safety and effectiveness of the EKOS system for coronary thrombolysis or thrombectomy (i.e. clot disruption) have not been established.**

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9. Remove the guidewire from the Micro-Infusion Catheter.
10. Start a sterile fluid infusion through the central lumen of the Micro-Infusion Catheter.

**Warning:**

Never transmit ultrasound energy to the Micro-Infusion Catheter with the Micro-Infusion Catheter in air. Only transmit ultrasound energy to the Micro-Infusion Catheter after it is placed within the patient anatomy and infusion fluid is flowing through the central lumen. Otherwise, overheating may occur, potentially causing damage to the ultrasound element.

**Warning:**

Do not exceed a static pressure of 150 psi (1.03 mPa) on the catheter.

11. Connect the Catheter Electrical Connector to the Catheter Interface Cable. Make sure the spring latches fully engage.

**Warning:**

The reusable Catheter Interface Cable is NOT STERILE. Use caution to maintain a sterile operating field after the Catheter Interface Cable has been connected to the Micro-Infusion Catheter.

12. See the Instructions for Use for the Control System for instructions for operating the Control System.
13. When the infusion procedure has been completed, the Micro-Infusion Catheter should be removed under fluoroscopic guidance.

**Contraindications**

This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition.

This system is not intended for use in neonatal or pediatric applications.

**Warnings**

- Do not exceed a static pressure on the catheter of 150 psi (1.03 mPa).
- Do not use a syringe smaller than 3 cc for hand injections of fluids into the neurovasculature.
- Do not exceed 300 psi (2.07 mPa) during fluid injections into the neurovasculature.
- During normal use, ultrasound energy may cause a temperature rise in the treatment zone. There is a temperature sensor in the EKOS Micro-Infusion Catheter and control circuitry in the Control Unit that monitors the Micro-Infusion Catheter temperature and limits the Micro-Infusion Catheter surface temperature to a maximum of 43° C.
- The reusable Catheter Interface Cable is NOT STERILE. Use caution to maintain a sterile operating field after the Catheter Interface Cable has been connected to the Micro-Infusion Catheter.
- Risk of exposure to Human Immunodeficiency Virus (HIV) and other blood borne pathogens. Use universal blood and body-fluid precautions in the care of all patients.
- 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.
- After use, dispose of in accordance with hospital, administrative, and/or local government policy.
- If product is damaged or found to be unusable in any way, please retain the product and notify EKOS Corporation immediately.
- DO NOT over-tighten a hemostasis valve being used with the system as the Micro-Infusion Catheter may be damaged.
- If the Micro-Infusion Catheter becomes kinked or otherwise damaged during use, discontinue use and replace with a different component
- Do not immerse the catheter electrical connector in fluid.
- Do not shape the tip of the catheter.
- Never transmit electrical energy to the Micro-Infusion Catheter with the Micro-Infusion Catheter in air. Only transmit electrical energy to the Micro-Infusion Catheter after it is placed within the patient anatomy and infusion fluid is flowing through the central lumen. Otherwise, overheating may occur, potentially causing damage to the ultrasound element.

- The safety and effectiveness of the EKOS Micro-Infusion System for thrombolytic therapy in the neurovasculature have not been established. Further clinical studies are necessary to ensure that use of devices to deliver thrombolytic therapy into the neurovasculature does not result in an increased incidence of adverse events (e.g., intracranial hemorrhage).

- The safety and effectiveness of the EKOS Micro-Infusion system used for intracoronary thrombolytic therapy administration have not been established. In particular, the ultrasound energy delivered by the EKOS Micro-Infusion System is not intended to be therapeutic, and the safety and effectiveness of the EKOS system for coronary thrombolysis or thrombectomy (i.e. clot disruption) have not been established.

### Precautions

- Carefully read all Instructions for Use prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.
- Only trained physicians who have a thorough understanding of percutaneous intravascular techniques and procedures should use this system.
- Continuous application of ultrasound energy should be limited to 120 minutes.
- All agents used with the Control Unit and Micro-Infusion Catheter should be fully prepared and used according to the Instructions for Use for the specific agent.
- This device is sterile and non-pyrogenic. Prior to use, carefully examine the unit to verify that the Micro-Infusion Catheter and the sterile package have not been damaged during shipment. Do not use if package is opened or damaged, or if seal is broken. Contents may not be sterile and may cause infection in the patient.
- Exercise care in handling the Micro-Infusion Catheter during a procedure to reduce the possibility of accidental bending, kinking, or breakage.
- Prior to introduction, the Micro-Infusion Catheter should be flushed with heparinized saline. Anytime the catheter is removed from the vascular system, it should be flushed with heparinized saline before reintroduction.
- 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 vasculature.
- If flow through the Micro-Infusion Catheter becomes restricted, do not attempt to clear the device by high pressure infusion. Either remove the Micro-Infusion Catheter to determine and eliminate the cause of the obstruction or replace the catheter with a new catheter.

3. Connect a syringe to the luer fitting on the proximal end of the catheter and flush the Micro-Infusion Catheter lumen with sterile heparinized saline solution.

#### Precaution:

Prior to introduction, the Micro-Infusion Catheter should be flushed with heparinized saline. Anytime the catheter is removed from the vascular system, it should be flushed with heparinized saline before reintroduction.

4. Prepare the treatment agent for administration according to the clinical dosage recommendations.
5. Select an appropriate introducer sheath to accommodate a 3.3F (1.1 mm) catheter, or, if the catheter is to be placed using a guide catheter, select an introducer sheath to accommodate a 6F (2.0 mm) guide catheter.
6. Using standard percutaneous technique, obtain vascular access and place the introducer sheath.
7. Obtain angiographic images either via the introducer sheath, or a diagnostic angiographic catheter.
8. Once angiographic images have been obtained, advance an 0.035" (0.89 mm) guidewire and a straight exchange catheter, or the guide catheter, to the treatment site.

If not using a guide catheter:

- A. Once the exchange catheter is positioned just proximal to the treatment site, remove the 0.035" (0.89 mm) guide wire and replace it with an exchange length 0.014" (0.36 mm) guidewire.
- B. Remove the exchange catheter leaving the 0.014" (0.36 mm) guidewire in place and then backload the Micro-Infusion Catheter over the 0.014" (0.36 mm) guidewire.
- C. Advance the Micro-Infusion Catheter over the 0.014" (0.36 mm) guidewire until the tip of the Micro-Infusion Catheter is satisfactorily located in the treatment zone.

If using a guide catheter:

- A. Once the guide catheter has been positioned just proximal to the treatment area, remove the 0.035" (0.89 mm) diameter guidewire.
- B. Load a standard length 0.014" (0.36 mm) diameter guidewire into the Micro-Infusion Catheter and place the guide wire and Micro-Infusion Catheter into the guide catheter.
- C. Advance the Micro-Infusion Catheter and 0.014" (0.36 mm) guidewire through the guide catheter until the Micro-Infusion Catheter and guide wire are placed at the desired treatment location.

- Using fluoroscopic guidance, position the tip of the Micro-Infusion Catheter in the area of interest. When the catheter has been successfully placed, gently remove the guidewire from the catheter.

**Warning:**

Never transmit electrical energy to the Micro-Infusion Catheter with the Micro-Infusion Catheter in air. Only transmit electrical energy to the Micro-Infusion Catheter after it is placed within the patient anatomy and infusion fluid is flowing through the central lumen. Otherwise, overheating may occur, potentially causing damage to the ultrasound element.

- Connect the Catheter Electrical Connector to the Catheter Interface Cable. Make sure the spring latches fully engage.

**Warning:**

The reusable Catheter Interface Cable is NOT STERILE. Use caution to maintain a sterile operating field after the Catheter Interface Cable has been connected to the Micro-Infusion Catheter.

- Prepare the physician specified fluid for administration according to the clinical dosage recommendations.
- Fill a syringe with the physician specified fluid and connect to the luer fitting of the hemostasis valve.
- Injection of the physician specified fluid with the ultrasound catheter activated will result in dispersion of the fluid into the area of interest.

**Warning:**

Do not exceed a static pressure of 150 psi (1.03 mPa) on the catheter

**See the Instructions for Use for the Control System for instructions for operating the Control System.**

**Procedure Completion**

- When the procedure has been completed, the Micro-Infusion Catheter should be removed under fluoroscopic guidance.
- Following the procedure, removal of the introducer sheath, attaining hemostasis and patient discharge should be performed per hospital standard of care.

**Procedure with the Micro-Infusion System – Peripheral Vascular**

- Ensure that the patient and a sterile field have been prepared as would normally be done for a percutaneous intravascular procedure.
- Using sterile technique, remove the sterile Micro-Infusion Catheter from its package. Before removing the catheter from the protective coil, fill the coil with sterile heparinized saline and allow the catheter to hydrate for at least 30 seconds. Carefully remove the catheter and inspect it to see that it is not damaged.

**Potential Complications**

The complications that may result from an ultrasound infusion procedure include:

- Vessel perforation
- Emboli
- Vessel spasm
- Hemorrhage
- Ischemia
- Hematoma at the site of entry
- Neurological deficits including stroke and death

**Supplied/Storage**

- Contents: One EKOS Micro-Infusion Catheter. See package label for specific product features (e.g., catheter size, working length, and maximum guidewire diameter).
- Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the “Use By” date on package label.

**Principles of Operation**

**The EKOS Micro-Infusion System is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The EKOS Micro-Infusion System may be used for controlled, regional infusion into selected vessels.**

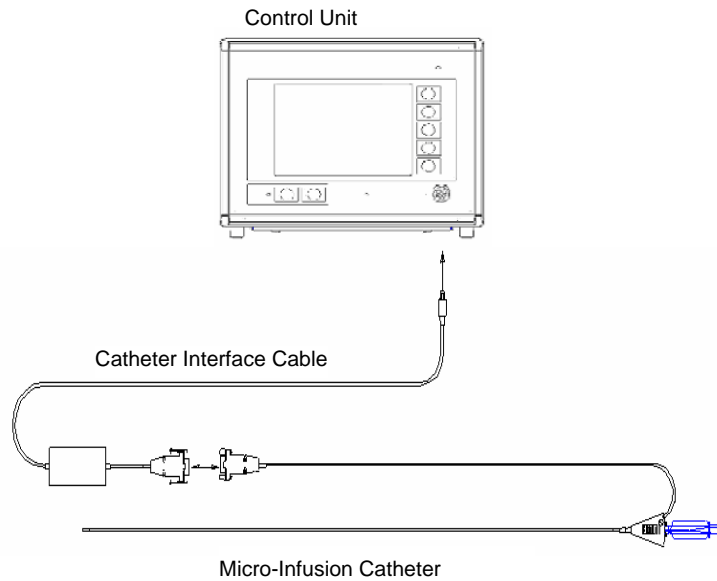
**In peripheral vasculature, the EKOS Micro-Infusion system is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The EKOS Micro-Infusion system is intended to deliver physician specified fluids to the coronary vasculature.**

The system generates ultrasound waves at the Micro-Infusion Catheter tip through the piezoelectric conversion of radio frequency (RF) energy generated by the Control Unit. The ultrasound emanates radially from the treatment zone to disperse the infused fluid within the patient’s vasculature.

In addition to generating the prescribed ultrasound energy profile, the Control Unit continually monitors output power and temperature at the Micro-Infusion Catheter tip. The system has safeguard circuits to prevent deviation of these parameters from preset ranges.

## EKOS Micro-Infusion System Description

The EKOS Micro-Infusion System (see Figure 1) consists of two main components: (1) a single-use sterile EKOS Micro-Infusion Catheter, consisting of an end-hole infusion lumen with an ultrasound element at the distal tip, and (2) a reusable Control System that controls the ultrasound energy and provides the user interface. The Control System is comprised of two components: a Control Unit and a Catheter Interface Cable.



**Figure 1: EKOS Micro-Infusion System**

## Procedure with the Micro-Infusion System – Coronary Vascular

1. Ensure that the patient and a sterile field have been prepared as would normally be done for a percutaneous intravascular procedure.
2. Obtain vascular access and place a 6 F (2.0 mm) introducer sheath using standard percutaneous technique.
3. Select an appropriate guide catheter, able to accommodate a 3.0 F (1.0 mm) catheter, and a 0.035" (0.89 mm) guidewire.
4. Using fluoroscopic guidance, advance the guide catheter into a position to access the target vessel.
5. Using sterile technique, remove the sterile Micro-Infusion Catheter from its package. Before removing the catheter from the protective coil, fill the coil with sterile heparinized saline and allow the catheter to hydrate for at least 30 seconds. Carefully remove the catheter and inspect it to see that it is not damaged.
6. Connect a syringe to the luer fitting on the proximal end of the catheter and flush the Micro-Infusion Catheter lumen with sterile heparinized saline solution. Wet the outside of the catheter with saline to ensure proper hydration of the catheter.

### **Precaution:**

Prior to introduction, the Micro-Infusion Catheter should be flushed with heparinized saline. Anytime the catheter is removed from the vascular system, it should be flushed with heparinized saline before reintroduction.

7. Attach a hemostasis valve to the luer port.
8. Attach a 3-way stopcock to the side-port of the hemostasis valve.
9. Attach a syringe of heparinized saline to the 3-way stopcock on the side-port of the hemostasis valve and flush the lumen. Be sure that fluid exits from the distal end of the catheter. Close the 3-way stopcock to the catheter.
10. Prepare a standard length 0.014" (0.36 mm) maximum diameter guidewire according to the manufacturer's instructions for use.
11. Loosen the hemostasis valve on the Micro-Infusion Catheter and insert the 0.014" (0.36 mm) guidewire into the catheter.
12. Insert the Micro-Infusion Catheter and guidewire into the guide catheter.

- Using fluoroscopic guidance, position the tip of the Micro-Infusion Catheter in the area of interest. When the catheter has been successfully placed, gently remove the guidewire from the catheter.

**Warning:**

Never transmit electrical energy to the Micro-Infusion Catheter with the Micro-Infusion Catheter in air. Only transmit electrical energy to the Micro-Infusion Catheter after it is placed within the patient anatomy and infusion fluid is flowing through the central lumen. Otherwise, overheating may occur, potentially causing damage to the ultrasound element.

- Connect the Catheter Electrical Connector to the Catheter Interface Cable. Make sure the spring latches fully engage.

**Warning:**

The reusable Catheter Interface Cable is NOT STERILE. Use caution to maintain a sterile operating field after the Catheter Interface Cable has been connected to the Micro-Infusion Catheter.

- Prepare the contrast media for administration according to the clinical dosage recommendations.
- Fill a syringe with the contrast media and connect to the luer fitting of the hemostasis valve.
- Injection of the contrast media with the ultrasound catheter activated will result in dispersion of the contrast into the area of interest.

**Warning:**

Do not exceed a static pressure of 150 psi (1.03 mPa) on the catheter

**See the Instructions for Use for the Control System for instructions for operating the Control System.**

**Procedure Completion**

- When the procedure has been completed, the Micro-Infusion Catheter should be removed under fluoroscopic guidance.
- Following the procedure, removal of the introducer sheath, attaining hemostasis and patient discharge should be performed per hospital standard of care.

**Micro-Infusion Catheter**

The disposable EKOS Micro-Infusion Catheter is a single central lumen end-hole device designed to navigate peripheral and neurovascular vasculature. The catheter incorporates one piezoelectric ultrasound element, positioned at the distal tip of the catheter.

The EKOS Micro-Infusion System employs high-frequency (1.4 – 1.9 MHz), low-power (<0.45 W) ultrasound to enhance the dispersion of delivered agents into the target location.

**Product Features**

Characteristics	NeuroWave
Tip length	3.5-4.2 mm/.138-.165 in
Tip OD	3.0 F/1.00 mm/.039 in
Distal length	7-16 cm/2.8-6.3 in
Distal OD	2.8 F/0.92 mm/.036 in
Proximal OD	3.0 F/1.00 mm/.039 in
Shaft ID	0.45 mm/.018 in
Guidewire OD	0.36 mm/.014 in
Useable length	137-155 cm/54-61 in
Cable length	71 cm/28 in
Guide catheter	6 F (2.0 mm)
Priming volume	.34-.40 cc

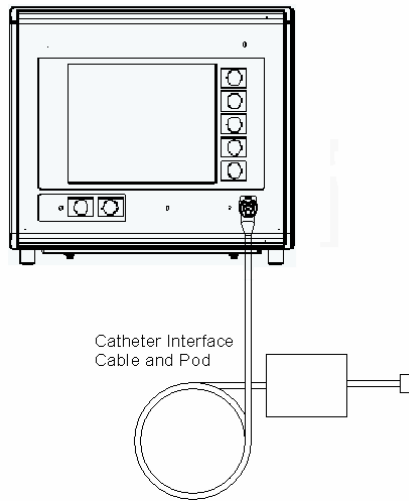
Acoustic	-
Tip treatment zone ID	0.43 mm/.017 in
Frequency	1.4 – 1.9 MHz
Power	0.45 watts

Performance	-
Static (occluded)	150 psi (1.03 mPa), max
Dynamic (infusion)	300 psi (2.07 mPa), max
Saline infusion rates	-
100 psi	0.44 ml/sec
300 psi	0.93 ml/sec
Contrast* infusion rates	-
100 psi	0.24 ml/sec
300 psi	0.62 ml/sec

\*Oxilan 350 diluted 50%

## Control Unit

The Control System consists of a Control Unit and a Catheter Interface Cable. The Control Unit provides electrical power to the piezoelectric element at the tip of the Micro-Infusion Catheter and monitors operating parameters during operation via the Catheter Interface Cable. The Control Unit also provides the user interface through the front panel display and keypad (See Figure 2).



**Figure 2:** Control Unit front panel connections

## Directions for Use

### Procedure with the Micro-Infusion System - Neurovascular

1. Ensure that the patient and a sterile field have been prepared as would normally be done for a percutaneous intravascular procedure.
2. Obtain vascular access and place a 6 F (2.0 mm) introducer sheath using standard percutaneous technique.
3. Select an appropriate guide catheter, able to accommodate a 3.0 F (1.0 mm) catheter, and a 0.035" (0.89 mm) guidewire.
4. Using fluoroscopic guidance, advance the guide catheter into a position to access the target vessel.
5. Using sterile technique, remove the sterile Micro-Infusion Catheter from its package. Before removing the catheter from the protective coil, fill the coil with sterile heparinized saline and allow the catheter to hydrate for at least 30 seconds. Carefully remove the catheter and inspect it to see that it is not damaged.
6. Connect a syringe to the luer fitting on the proximal end of the catheter and flush the Micro-Infusion Catheter lumen with sterile heparinized saline solution. Wet the outside of the catheter with saline to ensure proper hydration of the catheter.

#### **Precaution:**

Prior to introduction, the Micro-Infusion Catheter should be flushed with heparinized saline. Anytime the catheter is removed from the vascular system, it should be flushed with heparinized saline before reintroduction.

7. Attach a hemostasis valve to the luer port.
8. Attach a 3-way stopcock to the side-port of the hemostasis valve.
9. Attach a syringe of heparinized saline to the 3-way stopcock on the side-port of the hemostasis valve and flush the lumen. Be sure that fluid exits from the distal end of the catheter. Close the 3-way stopcock to the catheter.
10. Prepare a standard length 0.014" (0.36 mm) maximum diameter guidewire according to the manufacturer's instructions for use.
11. Loosen the hemostasis valve on the Micro-Infusion Catheter and insert the 0.014" (0.36 mm) guidewire into the catheter.
12. Insert the Micro-Infusion Catheter and guidewire into the guide catheter.