FRED®

Flow Re-Direction Endoluminal Device

INSTRUCTIONS FOR USE

MicroVention® TERUMO

IFU100043 Rev. B
Revised 2022-03

A. DEVICE DESCRIPTION

The MicroVention Flow Re-Direction Endoluminal Device (FRED®) System [Figure 1 through Figure 4] consists of a self-expanding nickel titanium implant and a delivery system that can be simultaneously delivered and deployed by a single operator. The implant is designed to expand to a pre-determined diameter when released from the delivery system. The implant features integrated dual layer coverage designed to focus mainly at the neck of an aneurysm. The implant has distal and proximal markers on its ends as well as interwoven helical marker strands delineating the inner working length of the implant to provide fluoroscopic visibility. The FRED System is packaged sterile as a single unit with the implant, introducer sheath and a detachable delivery pusher. It is available in 7 different implant diameters ranging from 2.5 mm to 5.5 mm and in different implant lengths ranging from 7 mm to 39 mm. The FRED System 2.5 mm and 3.0 mm implants are compatible with the Headway 21 Microcatheter (FRED-21 System). The FRED System 3.5 mm to 5.5 mm implants are compatible with the Headway 27 Microcatheter (FRED-27 System).

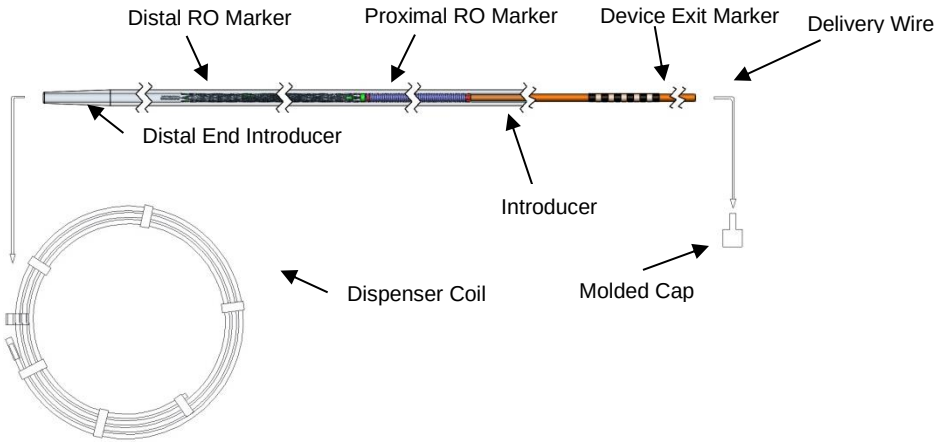


Figure 1: FRED System Setup

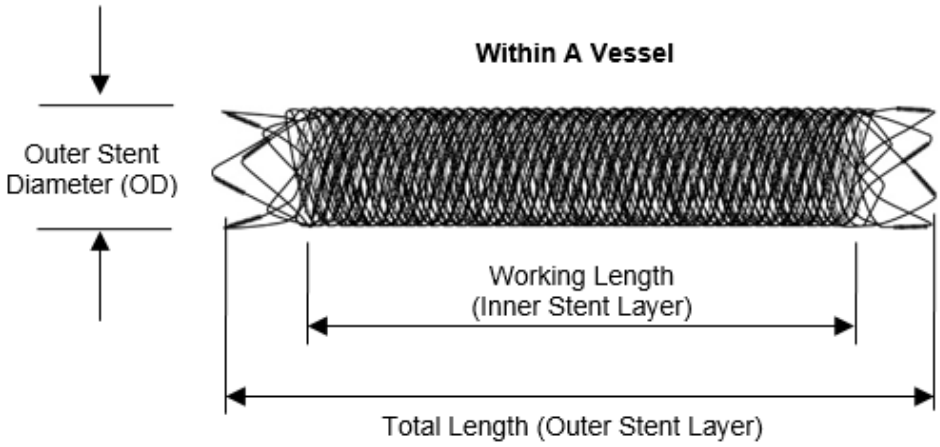


Figure 2: FRED Implant Nomenclature

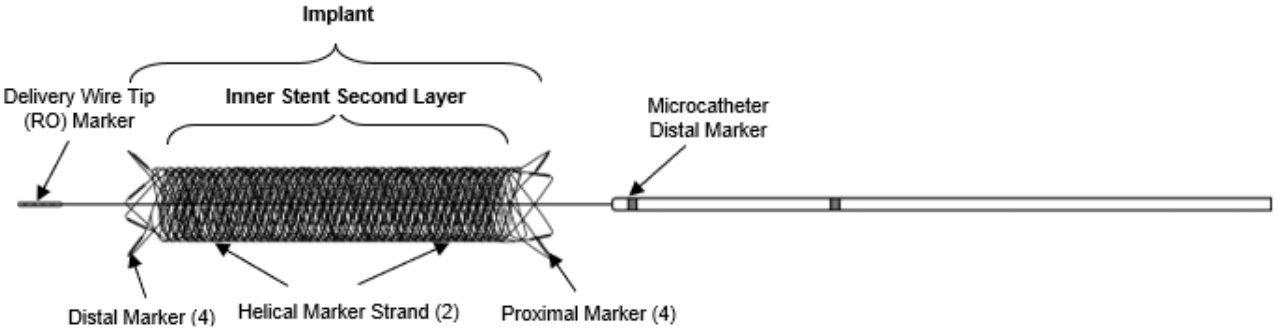


Figure 3: FRED 27 System Marker Nomenclature

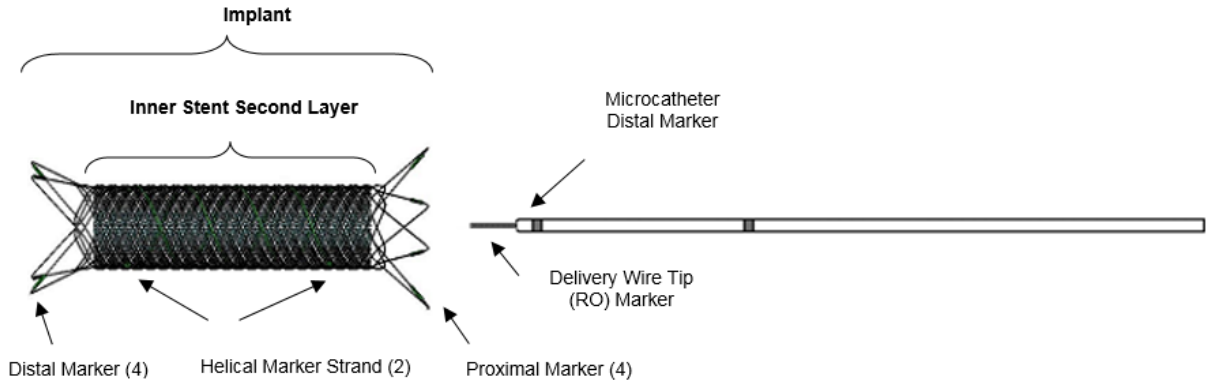


Figure 4: FRED 21 System Marker Nomenclature

Table 1: FRED System Models and Dimensions

Device	Outer Diameter (mm)	Total Lengths (mm)	Working lengths (mm)
FRED System	2.5	13 to 30	8 to 26
	3.0	13 to 32	9 to 27
	3.5	13, 15, 17, 19, 22, 31 and 40	7, 9, 11, 13, 16, 24 and 36
	4.0	13, 15, 18, 20, 23, 32 and 44	7, 9, 12, 14, 17, 26, and 38
	4.5	15, 17, 20, 25, 31, 34 and 45	8, 11, 13, 18, 24, 28 and 39
	5.0	15, 18, 21, 26, 32 and 36	9, 11, 14, 19, 26 and 29
	5.5	22, 28 and 32	14, 19 and 26

B. INDICATIONS FOR USE

The Flow Re-Direction Endoluminal Device (FRED) System is indicated for use with or without embolic coils for the treatment of intracranial aneurysms that are not amenable to treatment with surgical clipping with parent vessels that are ≥ 2.0 mm and ≤ 5.0 mm in diameter.

C. CONTRAINDICATIONS

Use of the FRED System is contraindicated under these circumstances:

- Patients in whom anticoagulant, anti-platelet therapy or thrombolytic drugs are contraindicated.
- Patients with known hypersensitivity to metal, such as nickel-titanium and metal jewelry.
- Patients with anatomy that does not permit passage or deployment of the FRED System.
- Patients with an active bacterial infection.
- Patients with a pre-existing stent in place at the target aneurysm.

D. WARNINGS

Placement of multiple FRED devices may increase the risk of ischemic complications.

The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.

The FRED System is not intended for peripheral vessel use.

The FRED System is not intended for intracranial atheromatous disease.

Delayed rupture may occur with large and giant aneurysms.

Extreme caution should be exercised before using stent-assisted coiling in patients who have suffered SAH and such techniques should be reserved only for the most extreme or necessary situations in these patients.

Should unusual resistance be felt at any time during access or removal, the introducer/guide catheter/microcatheter and FRED System should be removed as a single unit. Applying excessive force during delivery or retrieval of the FRED System can potentially result in loss or damage to the device and delivery components.

The FRED System should only be used by physicians trained in endovascular interventional neuroradiology, radiology, neurosurgery or interventional neurology for the treatment of intracranial aneurysms or other vascular lesions.

The FRED 27-system should only be delivered through a Headway® 27 microcatheter and the FRED 21-system should only be delivered through a Headway® 21 microcatheter. If repeated friction is encountered during FRED System delivery, verify microcatheter is not kinked or in extremely tortuous anatomy. Confirm that the microcatheter does not ovalize. Confirm that there is adequate sterile heparinized flush solution.

Do not reposition the FRED System in the parent vessel without fully retrieving the device. The FRED System MUST be retrieved/resheathed into the microcatheter and re-deployed at the desired target location or removed completely from the patient.

Do not attempt to re-position the FRED implant after deployment/detachment.

E. PRECAUTIONS

The foreshortening of FRED devices based on preclinical bench testing in various target vessel diameters are up to 53% for 2.5 to 3.5 mm diameter FRED devices and up to 61% for 4.0 to 5.5 mm diameter FRED devices.

This product should only be used by experienced physicians who have completed endovascular training in the use of the FRED System.

The FRED System does not contain latex or PVC materials.

The FRED System is provided sterile 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.

Contamination of the device may lead to injury, illness or death of the patient. Carefully inspect the sterile package and the FRED System prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components, or if the package is opened or damaged.

See the product label for shelf life. Do not use the FRED System beyond the labeled use by date.

Exercise caution when crossing the deployed/detached FRED System with adjunctive devices such as guidewires, catheters, microcatheters or balloon catheters to avoid disrupting the device geometry and device placement.

F. POTENTIAL COMPLICATIONS

Below is a list of the probable adverse effects (e.g., complications) associated with the use of the neurovascular flow diverters.

- Allergic reaction, including but not limited to: contrast dye, nitinol metal, and any other medications used during the procedure
- Blindness
- Complications of arterial puncture including pain, local bleeding, or injury to the artery, or adjacent nerves
- Cranial neuropathy
- Death
- Device fracture, migration or misplacement
- Dissection or perforation of the parent artery
- Headache
- Hemorrhage (i.e., intracranial hemorrhage (ICH), subarachnoid hemorrhage (SAH), retroperitoneal (or in other locations))
- Infection
- Mass effect
- Neurological deficits
- Reactions to anti-platelet/anti-coagulant agents
- Reactions due to radiation exposure (i.e., alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia)
- Reactions to anesthesia and related procedures
- Reactions to contrast agents including allergic reactions and kidney failure
- Rupture of the aneurysm
- Stenosis of stented segment
- Seizure
- Stent thrombosis
- Stroke or TIA (transient ischemic attack)
- Thromboembolic event
- Vasospasm
- Visual impairment

Potential Risks Associated with X-ray Exposure: The use of the FRED System requires fluoroscopy, which presents potential risks associated with X-ray exposure. The risks of angiographic and fluoroscopic X-ray radiation doses to the patient include risks such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase. The probability of adverse event occurrence increases as the procedure time and the number of procedures increase. Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.

G. MR ENVIRONMENT

Non-clinical testing has demonstrated that the FRED System is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,500-gauss/cm (25-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the FRED System is expected to produce a maximum temperature rise of 2.8 ºC at 1.5-Tesla or 3.6 ºC at 3-Tesla after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the device extends approximately 4-mm from the FRED System when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

MicroVention, Inc. recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation or equivalent organization. A FRED System patient implant card is included in the package, which should be completed and provided to the patient.

H. CLINICIAN USE INFORMATION

1. MATERIALS

The following parts are required to use the FRED System:
Note: Other accessories for performing a procedure are NOT supplied; should be selected based on the physician's experience and preferences

- Appropriate-sized guiding or intermediate catheter for use with selected

microcatheter

- Headway 27 microcatheter (FRED-27 system)
- Headway 21 microcatheter (FRED-21 system)
- Microcatheter-compatible guidewires
- Saline solution/heparin-saline solution continuous flush set
- Contrast solution
- Rotating Hemostatic Valve (RHV)
- Pressurized sterile Infusion solutions – IV stand
- Femoral arterial sheath, compatible with delivery guide catheter
- Femoral artery access device, sterile needle, guidewire

2. PACKAGING AND STORAGE

The FRED System is placed inside a protective, plastic dispenser coil and packaged in a pouch and unit carton. The FRED System and dispenser coil will remain sterile unless the package is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

3. SHELF LIFE

See the product label for the device shelf life. Do not use the device beyond the labeled use by date.

4. PREPARATION FOR USE

Device and Delivery System Selection

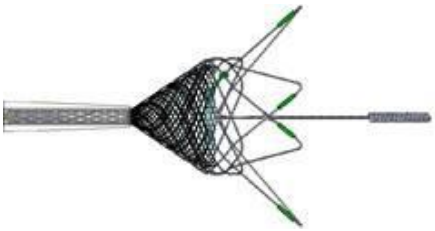
Appropriate selection of the FRED System is important for patient safety. In order to choose the optimal FRED System model size for any given lesion, examine pre-treatment angiograms for correct and accurate vessel measurements.

I. DIRECTIONS FOR USE

1. Gain vascular access according to standard angiographic practice and perform diagnostic angiogram to document target aneurysm and parent vessel to confirm vessel diameter.
2. Place appropriate size guide or intermediate catheter according to standard practice.
3. Per physician discretion, if embolization coils are going to be used along with the FRED System, position a suitable microcatheter to be utilized for coil embolization coaxially into the target aneurysm. If the FRED System is going to be used without embolization coils, disregard this step.
4. Coaxially navigate the appropriate sized microcatheter, Headway® 27 microcatheter (FRED- 27 system) or Headway® 21 microcatheter (FRED-21 system), over a guidewire distal to the aneurysm neck or target location. Remove the guidewire.
5. Maintain flush through the microcatheter(s) per standard endovascular practice.
6. Select an appropriate-sized FRED System according to the size of the parent

vessel/aneurysm neck.
Note: The FRED System implant foreshortens (up to 61%) as it expands to the diameter of the parent vessel. Take implant foreshortening into account when sizing and deploying the FRED System.
7. Carefully inspect the package for damage to the sterile barrier. Peel open the pouch using aseptic technique and place the dispenser coil into the sterile field.
8. a. Unclip the molded cap attached to the delivery wire from the dispenser coil. Pull on the proximal end of the delivery wire until the introducer exits the dispenser coil. Hold the delivery wire and introducer together while continuing to remove the entire device.
8. b. After removal from the dispenser coil, carefully push on the delivery wire and in a bowl of saline, only partially deploy the FRED implant up to 5 mm or 50% (whatever occurs first, being careful not to detach the implant) from the distal introducer tip.
Check for the following:

- Implant distal marker uniformity
- Implant distal end shows even displacement with no entanglement
- Implant tracks smoothly through introducer



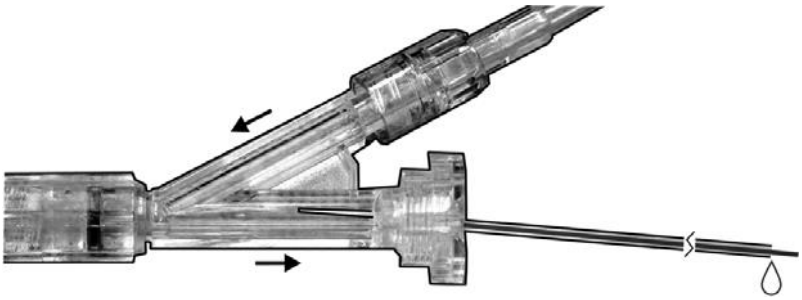
Warning: DO NOT FULLY DEPLOY FRED System.

8. c. With the FRED implant and introducer sheath positioned and hydrated within the bowlof saline, gently manipulate the FRED implant within the saline to hydrate the implant.Carefully pull back on the delivery wire to fully retrieve the FRED implant and delivery wire tip within the introducer.

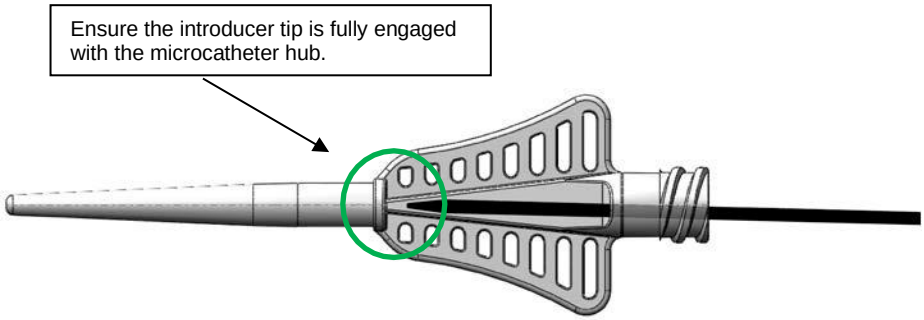
Warning: DO NOT CONTINUE if any defect is observed; return the unit to MicroVention, Inc.

9. Confirm that the device is entirely within the introducer, the tip of the delivery wire is not kinked, and the introducer tip is not damaged. DO NOT CONTINUE if either defect is observed; return the unit to MicroVention, Inc.
10. Partially insert the distal end of the introducer into the RHV connected to the compatible Headway® microcatheter. Tighten the RHV locking ring. Flush the RHV with sterile salineand verify that fluid exits the proximal end of the introducer, hydrating the introducer.

Warning: Purge the FRED System carefully to avoid the accidental introduction of air into the system.



11. Untighten the RHV locking ring and advance the introducer until it is fully engaged with the Headway® microcatheter hub, then tighten the RHV locking ring.
Caution: The introducer must be properly engaged with the microcatheter hub to enable FRED System to be introduced into the microcatheter.



12. Advance the delivery wire to transfer the FRED System from within the introducer into the microcatheter.
Warning: Do not torque the delivery wire while advancing or retracting the FRED System.
13. Continue advancing the delivery wire into the microcatheter until the proximal tip of the delivery wire enters the introducer. Loosen the RHV locking ring, remove the introducer, and set it aside.
Note: Fluoroscopy may be used up to this point at the physician's discretion**.**

Warning: Do not apply undue force. If resistance is encountered at any point during delivery or manipulation, withdraw the unit and select a new FRED System.

14. Carefully advance until the device exit marker on the proximal end of the delivery wire approaches the RHV. At this time, fluoroscopic guidance must be initiated.

15. Position the FRED System for deployment by aligning the FRED System implant distal radiopaque end markers past the aneurysm neck allowing for adequate distal and proximal device landing zones as shown in the following figures for FRED-27 system and FRED-21 system.

FRED-27 Positioning

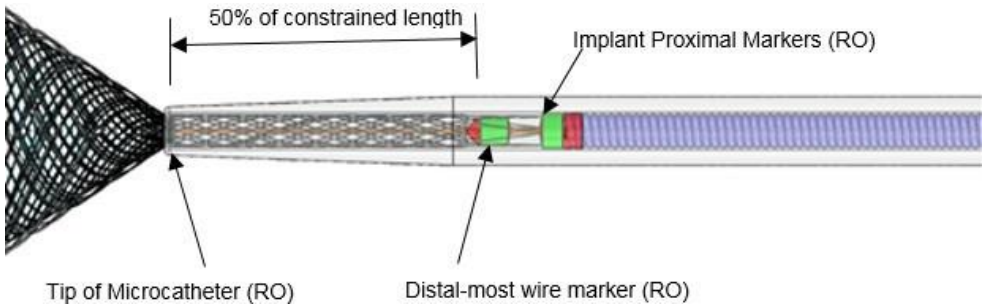
FRED-21 Positioning

Note: A slow, proper push/pull technique, encompassing sufficient delivery wire push force, in addition to an opposing microcatheter withdrawal force, to remove excess microcatheter slack while maintaining the microcatheter tip within the center of the parent vessel, will facilitate properly deploying the FRED System at the proper location, to achieve full expansion and good vessel apposition.

Note: If applicable, verify microcatheter placed into aneurysm in step 3 is still properly positioned for coil delivery.

Caution: Using a rapid microcatheter withdrawal technique to deploy the FRED System is not recommended and may result in device elongation or improper deployment. Be aware of delivery wire tip position during deployment.

16. If the FRED System positioning is not satisfactory, the implant may be recaptured and repositioned if it is not fully deployed. The implant may be recaptured until the point where the distal-most wire marker, collocated distal to the implant proximal markers, is aligned approximately 50% of length proximal to the microcatheter distal marker band.



Caution: If resistance is felt while recapturing the device, do not continue to recapture. Withdraw the microcatheter slightly to unsheathe the device (without exceeding the recapture limit), and then attempt to recapture again.

Caution: The FRED System must not be re-deployed more than three times.

17. If FRED System positioning is satisfactory, carefully advance the delivery wire while retracting the microcatheter as needed to minimize slack, maintaining the microcatheter around the center of the parent vessel, to allow the implant to deploy across the neck of the aneurysm. Ensure the implant proximal radiopaque end markers are in the advised position (see step 15) proximal to the aneurysm neck for adequate coverage.

Note: The FRED System will expand and may foreshorten up to 61% from its undeployed length. Visually verify opening of the proximal end, ensuring that the microcatheter distal tip marker is pulled back, adequately away from the implant proximal end, to allow the proximal end to freely open. Push forward on the delivery wire to assist in maintaining access within the implant as needed.

Note: Visualize and refer to implant radiopaque end markers to maintain adequate implant length of on each side of the aneurysm neck/target location to ensure appropriate coverage.

Warning: Do not fully deploy the FRED System if positioning in the parent vessel is not satisfactory.

Warning: If applicable, observe FRED System marker position during coiling procedure to ensure that the device does not migrate.

18. If necessary to maintain access through the implanted device, advance the microcatheter distal to the implanted device. Remove and discard the delivery wire.

Caution: The FRED System delivery wire should not be utilized as a guidewire. Do not torque the FRED System. A torque device should not be used.

19. Carefully inspect the deployed FRED implant under fluoroscopy to confirm that it is completely open and opposed to the vessel wall and not kinked. If the implant is not fully open and apposed or is kinked, consider utilizing a suitable micro guidewire and/or occlusion balloon catheter to fully open the implant.

20. If applicable, detachable coils may be delivered into the aneurysm sac following conventional methods, utilizing the jailed microcatheter from step 3. Verify that the implant remains patent and properly positioned.

Note: The jailed microcatheter should be carefully removed to avoid dislodging the FRED implant.

21. After completing the procedure, withdraw and discard all applicable accessory devices.

Caution: Carefully watch the FRED implant distal and proximal markers when passing through the implanted device with other devices to avoid displacing the implant.

J. HOW SUPPLIED

Sterile: This device is sterilized with E-Beam irradiation. Non-pyrogenic
Contents: One (1) FRED System
Storage: Store product in a dry, cool place.

WARRANTY DISCLAIMER

MicroVention warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for particular purpose. Handling, storage, cleaning, and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure, and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device through its expiration date.

MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

Prices, specifications, and model availability are subject to change without notice.

IFU100043B

SYMBOLS

	Consult instructions for use
	Caution
	Lot Number
	Catalog Number
	Contents
	Sterilized Using Irradiation
	Do Not Reuse
	Use-by Date
	Date of Manufacture
	Manufacturer
	MR Conditional
	Non-pyrogenic
	Do not use if package is damaged

Manufacturer:
MicroVention, Inc.
35 Enterprise
Aliso Viejo, CA 92656 USA
Tel: 714.247.8000
www.microvention.com