SENTREHEART®

FINDRWIRZ®
GUIDE WIRE SYSTEM

40-05

Carefully Read All Instructions Prior to Use.

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

PACKAGING & STORAGE

The FindrWIRZ are sterile (using ethylene oxide gas) and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouches have been opened or damaged.

Handle with care. Do not store in excessive heat. After use, this product may be a potential biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

INDICATIONS

The FindrWIRZ Guide Wire System is intended for use in the cardiovascular system for introduction and positioning of over-the-wire catheters and therapeutic devices during interventional procedures. A FindrWIRZ may also be used to manipulate and or reposition another FindrWIRZ.

The FindrWIRZ System is not intended for use in the coronary or cerebral vasculature. The device is not intended for use in crossing chronic total occlusions.

Contraindications: The FindrWIRZ system is contraindicated for use with rotational atherectomy devices, ferromagnetic interventional devices and Inferior Vena Cava (IVC) filters. The FindrWIRZ system is also contraindicated for use in MRI.

DESCRIPTION

The FindrWIRZ System consists of the following components:

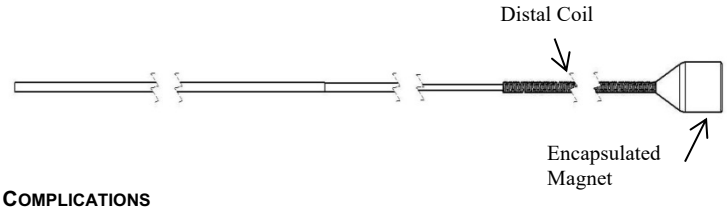
A 0.035" x 150 cm FindrWIRZ

A 0.025" x 220 cm FindrWIRZ

Guide wire introducer

Each FindrWIRZ Guide Wire System is intended for use in the cardiovascular system for introduction and positioning of over-the-wire catheters and therapeutic devices during Interventional procedures. A FindrWIRZ may also be used to manipulate and or reposition another FindrWIRZ.

The FindrWIRZ System is not intended for use in the coronary or cerebral vasculature. The device is not intended for use in crossing chronic total occlusions.



COMPLICATIONS

Potential complications associated with percutaneous catheter/guide wire procedures include but are not limited to:

- Air embolism
- Vessel or tissue damage, including perforation
- Vessel spasm
- Wound infection
- Local and/or systemic infection
- Hematoma

WARNINGS

- Never advance, torque, or retract a guide wire which meets significant resistance.
- Do not attempt to perform FindrWIRZ guide wire exchanges through O-T-W catheters or other therapeutic devices.
- Do not place FindrWIRZ near ferromagnetic materials or instruments during the procedure.
- Do not withdraw or manipulate the FindrWIRZ in a metal cannula or sharp edged object.
- 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.

PRECAUTIONS

Always use the FindrWIRZ introducers to advance the FindrWIRZ into the hemostatic valves of the appropriate-sized sheath.

INSTRUCTIONS FOR USE

1. Carefully inspect all devices and their packaging prior to use to verify size, shape, and condition. Do not use a device that is damaged in any way or if its packaging is damaged.

2. Reference Table 1 for recommended introducer sheaths.

Table 1 – Recommended Introducer Sheath

FindrWIRZ Size	Introducer Sheath
.025" FindrWIRZ	8F
.035" FindrWIRZ	11F

3. Remove the desired FindrWIRZ from its individual pouch and inspect for any damage.

NOTE: Ensure there are no non-sterile ferromagnetic objects near the magnetic tips of the FindrWIRZ.

4. Remove the protective guide wire tip cover from the dispenser coil.

5. Flush the FindrWIRZ with sterile normal saline or a similar isotonic solution by connecting a syringe to the Luer hub of the guide wire dispenser.

<u>FindrWIRZ Introduction and Placement</u>

6. Load and position the guide wire introducer packaged with the device onto the FindrWIRZ until the introducer is flush with the distal tip of the FindrWIRZ.

7. Insert the introducer and the FindrWIRZ, as a unit, into the introducer sheath and slowly advance the FindrWIRZ to the desired location under fluoroscopy. Withdraw the introducer from the introducer sheath and remove from the FindrWIRZ.

8. Ensure that the tip of the FindrWIRZ is rotating freely and no resistance is felt when torque is applied. Torque is approximately a one-to-one ratio.

NOTE: If resistance is met while advancing the FindrWIRZ determine the cause prior to proceeding.

<u>FindrWIRZ Repositioning and Removal</u>

NOTE: It may be necessary or desirable to reposition a FindrWIRZ on occasion. To do so, the other FindrWIRZ included in the package may be used to manipulate the first FindrWIRZ into a more optimum position.

9. Repeat steps 1-8 for the placement of the other FindrWIRZ through a second insertion site.

10. Advance the guide wire tip of the first FindrWIRZ to the proximity of the desired location.

11. Advance the guide wire tip of the second FindrWIRZ to the proximity of the first FindrWIRZ.

12. Under fluoroscopic guidance slowly advance the second FindrWIRZ towards the distal (magnetic) tip of the first FindrWIRZ under fluoroscopy until the two FindrWIRZ attach.

NOTE: For optimal performance of the FindrWIRZ, an end-to-end connection is desirable. If the FindrWIRZ magnet tips connect side-to-side versus end-to-end, detach the two FindrWIRZ and re-position.

13. With the two FindrWIRZ attached gently pull, push, and maneuver the FindrWIRZ to the desired location under fluoroscopy.

14. To uncouple and remove the FindrWIRZ, the first FindrWIRZ is grasped and held in position while the second FindrWIRZ is retracted and removed through its respective introducer sheath. The remaining FindrWIRZ is then retracted and removed from its respective introducer sheath.

15. When the procedure is completed, remove any catheters or components on the proximal end of the FindrWIRZ prior to removing the FindrWIRZ.

16. Alternatively, the FindrWIRZ and catheters or other components on the proximal end may be removed together as a unit. DO NOT attempt to withdraw the FindrWIRZ through catheters or other components over the proximal end of the FindrWIRZ.

Note: If resistance is met while advancing the FindrWIRZ determine the cause prior to proceeding.

Catalog Number:	
Batch Code:	
Use By:	
Contents of the package:	
Do Not Reuse:	
Do Not Resterilize:	
Do not use if packaging is damaged:	
Keep Away From Sunlight:	
Keep Dry:	
CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician:	
Caution, consult accompanying documents:	
Consult Instructions For Use:	
Sterilized using ethylene oxide:	
Manufactured By: **SentreHEART, Inc**. 300 Saginaw Drive Redwood City, CA 94063 Tel: 650. 354. 1200 Fax: 650. 354. 1204 www.sentreheart.com	
Authorized European Representative: Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	
CE Mark: Indicates conformance with European Council Directive 93/42/EEC	

All rights reserved