SPINR™

English

High-Performance
Guidewire Controller

INSTRUCTIONS FOR USE

Description
Single-use high-performance controller and torque device for 0.014" to 0.038" guidewires.

- SPINR 3X rotates 3 times clockwise when the Front Grip is squeezed and 3 times counterclockwise when the Front Grip is released.
- SPINR 5X rotates 5 times clockwise when the Front Grip is squeezed and 5 times counterclockwise when the Front Grip is released.

Indications for Use
SPINR is used to maneuver guidewires in the coronary and peripheral vasculature during interventional or diagnostic procedures. SPINR is not intended for use in the neurovasculature.

Contraindications
None known

RX Only. Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device.

Precautions

- Store the packaged and sealed device in a dark, dry place.
- Do not expose the device to organic solvents.
- Confirm the compatibility of the guidewire with any brass collet torque device prior to use.
- Use prior to the "Use Before" date noted on the package.
- Prior to use, carefully inspect the package and device. Do not use if damaged or if damage is suspected.
- Do not over tighten the cap with a guide wire in place. Over tightening any torque device may damage guidewires.
- SPINR and guidewires should only be manipulated under x-ray, fluoroscopy, CT, or direct observation.
- Never advance or withdraw SPINR or guidewire against resistance until the cause of the resistance is determined.
- Movement of the SPINR or guidewire against resistance may result in medical device damage, vessel perforation, or other injury.

Warnings

- The system is supplied sterile for single-use only. Do not resterilize and/or reuse.
- Only physicians trained in percutaneous intravascular techniques and surgical procedures should use any torque device.
- Use care when handling and loading guidewires to avoid damage and kinking.
- Use x-ray, fluoroscopic, CT, or direct observation during use of any torque device.
- Do not advance, retract, or torque a guidewire with SPINR if resistance is met during manipulation.
- Determine the cause of any resistance before proceeding.

Adverse Reactions
Possible adverse effects during intravascular and surgical procedures include, but are not limited to, the following:

- Access site complication (i.e., AV fistula, dissection, hematoma, hemorrhage, pseudoaneurysm)
- Acute myocardial infarction
- Allergic, or other reactions, to contrast medium, procedure medications or device materials
- Arrhythmias (including life-threatening ventricular fibrillation)
- Bleeding requiring a surgical intervention or blood transfusion
- CVA/ stroke or transient ischemic attacks
- Damage or migration of implanted devices
- Death
- Device failure
- Embolization of air, tissue, thrombus or device
- Emergency surgical or percutaneous intervention
- Hemolysis, hemorrhage, and infection
- Ischemic infarction of tissue or organ
- No or slow reflow of blood in treated vessel
- Pain
- Pericardial tamponade, renal insufficiency and/or renal failure
- Severe hypotension or hypertension
- Total occlusion or thrombosis of the vessel
- Vessel perforation, dissection or injury

Instructions for use

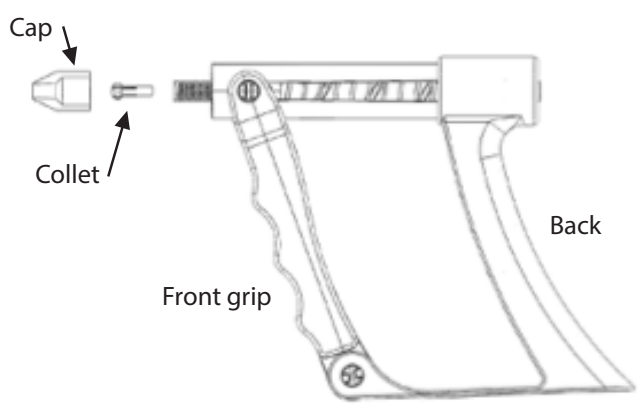
MATERIALS REQUIRED FOR USE
Vascular access sheaths, intravascular catheters, and 0.014" to 0.038" guidewires compatible with torque devices featuring brass collets.

PREPARATION

1. Remove SPINR from packaging.
2. Test squeeze Front Grip 1-2 times.
3. Loosen, but do not remove, the Cap 1 – 2 full counterclockwise turn(s) as needed to insert the guidewire.

CONNECT

1. Insert the guidewire's proximal end into distal tip of the Cap and through the Collet's center lumen.
2. Advance the SPINR over-the-wire and up to the access site.
3. Allow the proximal end of wire to exit the proximal end of the SPNR if necessary.
4. Tighten the Cap to secure to the guidewire. Over tightening any torque device may damage guidewires.



CONTROL

1. Straighten any portion of the guidewire located between the SPINR and the access site.
2. Straighten any portion of the guidewire located proximal, or behind, the SPINR.
3. Use under x-ray, fluoroscopy, CT or direct visualization.
4. Squeeze the top of Front Grip to rotate the guidewire clockwise.
5. Controllably release or manually open the Front Grip to return the guidewire to its original position. Never release the Front Grip in full when using the device.
6. Manually advance the guidewire proximal or distal per standard percutaneous, intravascular, and/or surgical techniques.
7. Loosen the Cap and move the SPINR as needed to re-position near the access site.
8. If rotation in the clockwise direction only is desired, squeeze and hold the Front Grip then loosen the Cap to release the wire and rotate the wire directly by hand.

	Single Use
	Do not use if package is damaged
REF	Catalog Number
LOT	Lot Number
	Use By
STERILE EO	Ethylene Oxide sterilized
	Caution: Consult accompanying document
	Manufacturer
EC REP	Authorized Representative

MERIT MEDICAL®

CE 2797

Manufacturer:
Merit Medical Systems, Inc.
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South Jordan, Utah 84095 U.S.A.
1-801-253-1600
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