English

SeaDragon 2™

TORQUE DEVICE

WIRE SIZES: 0.014"(0.36 MM) - 0.038"(0.97 MM)

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

A guide wire torque device designed with a cylindrical shape and a white cap grip mechanism that, when depressed, opens the lumen to allow passage of a guide wire. When the cap is released, the guide wire is gripped tightly to allow easy manipulation.

INTENDED USE

The SeaDragon2™ torque device is intended for facilitating guide wire manipulation during interventional procedures.

CLINICAL BENEFITS

Device can be used for both hydrophilic and standard guide wires. The easy grip ridges enhance steering and torque performance.

CONTRAINDICATIONS

There are no known contraindications for these devices.

PRECAUTIONS

None.

CAUTIONS

- Read instructions prior to use.
- **℞ Only - Caution**: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Store in a cool dry place.
- This device is intended for single use only . Do not reuse or resterilize.
- Prior to use, the device should be examined to verify functionality and ensure that its size and shape are suitable for the specific guide wire to be used.

REUSE PRECAUTION STATEMENT

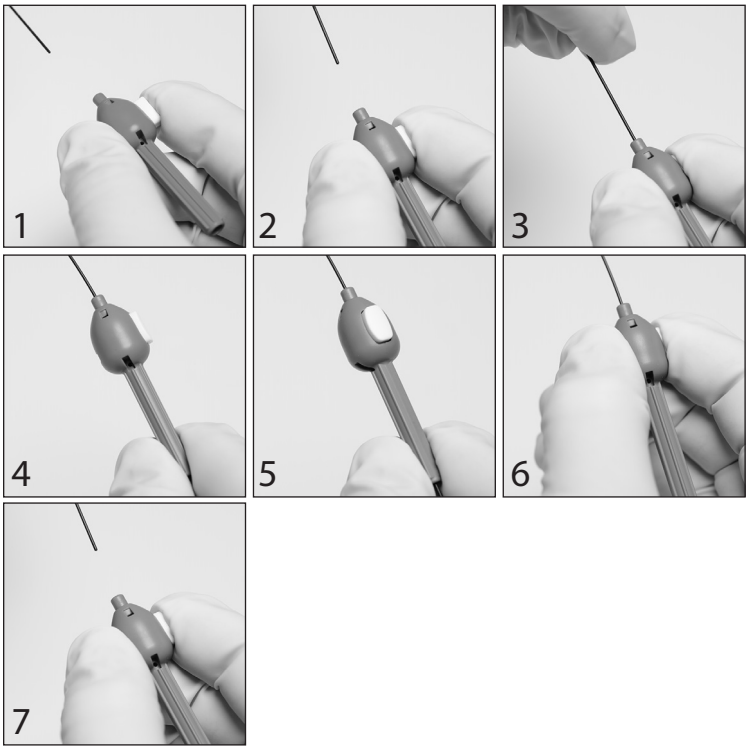
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also 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.

POTENTIAL COMPLICATIONS

Refer to the guide wire labeling for potential complications associated with the use of their device.

INSTRUCTIONS FOR USE

1. Squeeze white cap of the device toward the body to align lumens.
2. Once lumens are aligned, insert proximal tip of guide wire through device.
3. Continue squeezing white cap and slide device along guide wire until desired location is reached.
4. Release squeeze to activate locking mechanism.
5. Grasp and rotate device using ridges on back of the device to steer guide wire tip to desired position.
6. To move torque device to a new position, squeeze white cap and slide device along the guide wire to desired position, then release.
7. To remove torque device from guide wire, squeeze white cap and slide device off guide wire.



In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable member state.

WARNING: After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

	Use by date: YYYY-MM-DD
LOT	Lot Number
REF	Catalog Number
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single use
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
STERILE EO	Sterilized Using Ethylene Oxide
	Non-pyrogenic
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Manufacturer
MD	Medical Device
EC REP	Authorized Representative in the European Community/ European Union
	Caution
	Date of Manufacture: YYYY-MM-DD
UDI	Unique Device Manufacturer
	Single sterile barrier system

CE 2797

www.merit.com

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