ImperativeCare™

TracStar LDP™
LARGE DISTAL PLATFORM

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The TracStar LDP™ Large Distal Platform™ (TracStar LDP) is a single lumen, braid and coil reinforced, variable stiffness catheter with a radiopaque marker and a lubricious hydrophilic coating on the distal 14 cm portion of the catheter. TheTracStar LDP has an outer diameter of 0.110" (2.79 mm) and is offered in working lengths of 80 cm, 90 cm, 95 cm and 105 cm. Additional dimensions are included on the device labels. The TracStar LDP has a luer hub on the proximal end. The TracStar LDP is compatible with 8F or greater introducer sheaths and 0.038" or smaller guidewires. A support catheter may also be used to assist in accessing the target vasculature.

The TracStar LDP is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is intended to be attached to the proximal hub of the TracStar LDP and used to control hemostasis during use with other devices.

INDICATIONS FOR USE

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The TracStar LDP should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- Extreme caution should be used if it is required that the TracStar LDP be advanced near or through any aneurysms or other vascular malformations.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per Step 7 with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Use prior to the "Use By" date specified on the product package.
- This device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Do not use if the labeling is incomplete or illegible.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the TracStar LDP and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
- Use the TracStar LDP in conjunction with fluoroscopic visualization.

  Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.
- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the TracStar LDP or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torqueing the device against resistance may result in damage to the vasculature or the device.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. The use of systematic heparinization and heparinized sterile solution should be considered.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.

- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Use of an introducer sheath is necessary to introduce the TracStar LDP into the patient's vasculature. Attempting to introduce the catheter without this introducer can result in kinking or other damage to the device.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Do not use automated high-pressure contrast injection equipment with the TracStar LDP as it may damage the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

- Acute occlusion, Ischemia
- Unstable angina
- Arrhythmia, including ventricular fibrillation
- Death
- Distal embolization
- Emboli
- False aneurysm formation
- Fever
- Access Site Complications(Hematoma or hemorrhage, sterile inflammation, granulomas)
- Infection, Sepsis
- Intracranial hemorrhage
- Hypotension/Hypertension
- Acute myocardial infarction
- Infarction/Necrosis
- Neurological defects including stroke
- Vessel spasm, thrombosis, dissection, perforation, rupture
- Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction)

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

DEVICE PREPARATION AND USE

1. Select an appropriate TracStar LDP based on the distance from the access site to the target anatomy. Ensure that the diameter of the TracStar LDP is appropriate for the vasculature.
2. Select an appropriate support catheter based on the dimensions of the TracStar LDP being used, the target vessel, and the surrounding anatomy to help aid in accessing the target vessel.
3. Open the product pouch and place the pouch card into the sterile field. Exercise care when removing the pouch card from the product pouch to prevent damage to the device and accessories.
4. Remove the Rotating Hemostasis Valve (RHV) from the pouch card by removing it from the card tabs before gently lifting the TracStar LDP luer from the pouch card tab and removing the catheter shaft from the protective tubing.
5. Inspect the TracStar LDP and accessories for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.

USE STEPS FOR THE TRACSTAR LDP LARGE DISTAL PLATFORM

6. Attach the provided RHV to the luer of the TracStar LDP.
7. Hydrate the outer surface of the TracStar LDP and flush the lumen of the catheter and RHV with heparinized saline.

   Note: To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
8. Open the RHV and advance support catheter + guidewire (≤0.038" diameter) into the TracStar LDP until the distal tip of the support catheter is well past the distal tip of the TracStar LDP and then tighten the RHV to secure the support catheter in place. Do not overtighten the RHV as it could deform the support catheter lumen and prevent passage of a guidewire.
9. Gently insert the TracStar LDP/support catheter/guidewire assembly (device assembly) into the 8F or larger introducer sheath.

   Note: Follow the introducer sheath manufacturer's instructions for use when performing this step.

10. Under fluoroscopy, advance the device assembly through the introducer sheath and into the patient's vasculature using conventional catheterization techniques.

    Note: If injection through the TracStar LDP is necessary, remove the support catheter and guidewire and aspirate the TracStar LDP lumen prior to injection.

11. After gaining access to the desired vessel with the support catheter and guidewire, advance the TracStar LDP over the support catheter to the desired position.
12. Once the desired position is achieved, remove the support catheter and, if necessary, the guidewire.
13. The TracStar LDP can be used as a conduit for other interventional and diagnostic agents to access the target vascular site and distal vessels.
14. After the procedure has been completed, remove the TracStar LDP through the introducer sheath per standard procedure.
15. Discard the TracStar LDP appropriately per facility procedure.

PACKAGING

The TracStar LDP is placed inside a protective HDPE tube and then secured to a HDPE packaging card. Accessories included in the TracStar LDP packaging include a Rotating Hemostasis Valve (RHV). The packaging card is placed into a Nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The TracStar LDP is sterilized using Ethylene Oxide (EtO).

The TracStar LDP will remain sterile unless the pouch is opened, damaged, or the "Use By" date has passed.

MATERIALS

The TracStar LDP is not made with natural rubber latex.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight. Store at room temperature.

SYMBOLS GLOSSARY

Except where indicated with an asterisk (*), Standard Reference: ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements, §5 Symbols

Symbol	Definition
	Manufacturer
	Lot number
	Use-by date
	Consult electronic instructions for use
	Catalogue number
	Sterilized using ethylene oxide and contained with single sterile barrier system
	Sterilized using ethylene oxide
	Sterilized using ethylene oxide and contained with single sterile barrier system with protective packaging outside
	Non-pyrogenic

Symbol	Definition
℞ Only	*Caution: Federal law restricts this device to sale by or on the order of a physician
	Do not use if package is damaged and consult instructions for use
	Do not resterilize
	Do not re-use
	*Contents (numeral indicates quantity of systems in package)
	Keep away from sunlight
	Keep dry
	Medical Device

WARRANTY

Imperative Care, Inc. (“Imperative Care”) 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 a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Imperative Care’s control directly affect the device and the results obtained from its use. Imperative Care’s obligation under this warranty is limited to the replacement of this device and Imperative Care shall not be liable for any incidental, consequential, or special loss, damage, or expense directly or indirectly arising from the use of this device. Imperative Care neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty is valid only if the device is used in accordance with the manufacturer’s instructions, and the warranty is limited to the original user. Any sale or other transfer or use of the device covered by this warranty to or by a user other than the original user shall cause this warranty to terminate immediately. Imperative Care assumes no liability with respect to devices reused, reprocessed, or resterilized, or serviced, repaired or modified by any party other than the original manufacturer, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.

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