1. Remove all slack from the catheter prior to stent deployment. Excessive slack may result in stent jumping or the stent length being reduced.

2. Remove the safety lock positioned on the rack by pulling vertically to the axis of the stent delivery system. Confirm that the radiopaque markers and are still properly positioned across the target lesion.

3. Keep the entire length of the delivery system as straight as possible, and maintain slight backward tension on the delivery system during deployment.

4. Stent deployment: Start deploying the stent by slowly rotating the thumb wheel. Allow the stent to contact and anchor to the vessel wall.

5. Continue to deploy the stent with one of the following methods:
   - Roll the thumb wheel of the deployment handle in a proximal direction. Continue to roll thumb wheel until the radiopaque marker of the exterior shaft passes the proximal radiopaque markers of the stent resulting in full deployment.
   - Grasp the manual pull grip and pull toward the deployment handle. Continue to pull back until the radiopaque marker of the exterior shaft passes the proximal radiopaque markers of the stent resulting in full deployment.

Prior to use, please see complete ‘Directions for Use’
**Epic™ Vascular Self-Expanding Stent System**

Prior to use, see the complete ‘Directions for Use’ for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

**INDICATIONS FOR USE:** Epic™ Vascular Self-Expanding Stent System is indicated for the improvement of luminal diameter in patients with de novo or restenotic symptomatic atherosclerotic lesions up to 120 mm in length in the common and/or external iliac arteries, with a reference vessel diameter between 5 mm and 11 mm.

**CONTRAINDICATIONS:** There are no known contraindications.

**WARNINGS:**
- Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures.
- Persons allergic to nickel-titanium may suffer an allergic response to this implant.
- Improper stent size selection may lead to stent migration or stent jumping.
- As with any type of intravascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm, or rupture into a neighboring organ or into the retroperitoneum.
- The stent may cause thrombus or distal emboli to migrate from the site of the implant down the arterial lumen.
- The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- In patients with poor kidney function, contrast agents may precipitate kidney failure.

**PRECAUTIONS:** Safety and effectiveness has not been demonstrated in patients with the following characteristics:
- Highly calcified lesions resistant to PTA.
- Persistent, intraluminal thrombus at the target lesion.
- Uncorrected bleeding disorders or patients who cannot receive anticoagulation or anti-platelet aggregation therapy.
- Perforated vessels evidenced by extravasation of contrast media.
- Lesions that are within or adjacent to an aneurysm.
- Vessels with excessive tortuosity.

The delivery system is not designed for use with power injection systems. Always use an introducer or guide sheath for the implant procedure, to protect the access site. Only advance the stent delivery system over a guidewire. Never dilate the stent using a balloon that is larger in diameter than the labeled diameter of the stent. The stent delivery system is not intended for arterial blood monitoring. In the event of complications such as infection, pseudoaneurysms or fistula formation, surgical removal of the stent may be required.

**ADVERSE EVENTS:** Potential adverse events that may occur following intravascular stent implantation include, but are not limited to: Abscess; Allergic reaction (to drug, contrast, device or other); Amputation; Aneurysm; Angina/coronary ischemia; Arrhythmia; Arteriovenous fistula; Death; Drug reactions; Embolization (air, plaque, thrombus, device, or other); Entanglement of delivery system in deployed stent; Fever; GI bleeding; Hemorrhage/hematoma; Hypertension/hypertension; Myocardial Infarction (MI); Need for urgent intervention or surgery; Pseudoaneurysm; Renal insufficiency or failure; Restenosis of stented artery; Sepsis/infection; Stent fracture; Stent migration; Stent misplacement/jumping; Stent thrombosis with possible neurological injury; Stroke; Thrombosis/thrombus; Tissue ischemia/necrosis; Vasospasm; Vessel injury, examples include perforation, dissection, intimal tear, rupture; Vessel occlusion.

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