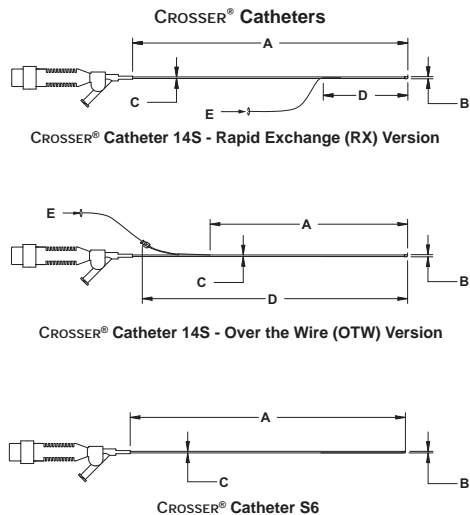


# CROSSER® CTO Recanalization Catheter High Frequency Mechanical Recanalization System

## Instructions for Use – CROSSER® Catheters 14S and S6

**Warning!** Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

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



|  | CROSSER® Catheter 14S       |                |                |                | CROSSER® Catheter S6        |       |
|--|-----------------------------|----------------|----------------|----------------|-----------------------------|-------|
|  | RX                          | OTW            | RX             | OTW            |                             |       |
| A- Working Length  | 146cm                       |                | 106cm          |                | 154cm                       | 106cm |
| B- Tip Outer Diameter  | 1.1mm (0.044")              |                |                |                | 0.6mm (0.025")              |       |
| C- Catheter Shaft Outer Diameter                                   | 1.3mm (0.052")              | 1.6mm (0.063") | 1.3mm (0.052") | 1.6mm (0.063") | 1.3mm (0.053")              |       |
| D- Guidewire Lumen Length (Rapid Exchange RX or Over the Wire OTW) | RX<br>20cm                  | OTW<br>152cm   | RX<br>20cm     | OTW<br>112cm   | n/a*                        |       |
| E- Guidewire Lumen Compatible                                      | 0.014" (0.36mm)             |                |                |                | n/a*                        |       |
| Guide Catheter Compatibility                                       | 6Fr (min ID 0.067" [1.7mm]) |                |                |                | 5Fr (min ID 0.055" [1.4mm]) |       |
| Sheath Compatibility   | 5Fr (min ID 0.067" [1.7mm]) |                |                |                | 5Fr (min ID 0.055" [1.4mm]) |       |

\* CROSSER® Catheter S6 does not use a guidewire for delivery

### Description

The CROSSER® Catheter is a high frequency mechanical recanalization system designed for recanalization of obstructed peripheral arteries. The system consists of an electronic CROSSER® Generator, Foot Switch, high frequency Transducer, the FLOWMATE® Injector (optional), and CROSSER® Catheter. The CROSSER® Catheter, which is intended for one procedure only, is connected to the CROSSER® Generator through the high frequency Transducer. The Foot Switch is used to activate the CROSSER® Recanalization System. The CROSSER® Generator and Transducer convert AC power into high frequency mechanical vibrations, which are propagated to the tip of the CROSSER® Catheter (Reference Figure 1 and 2).

Figure 1 – The CROSSER® Recanalization System

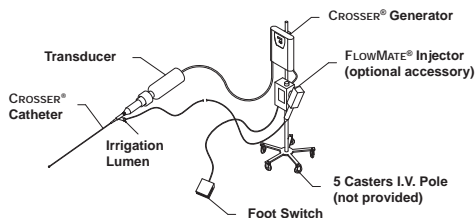
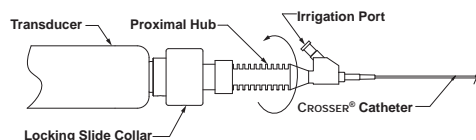


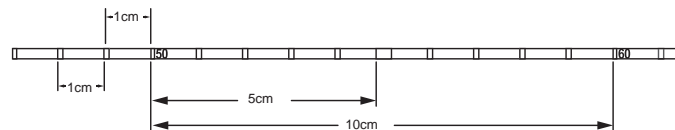
Figure 2 – Proximal Hub Connection to Transducer



The GEOALIGN® Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip. The GEOALIGN® markings are designated on the catheter shaft by 1cm increment bands with an accuracy within ±1mm. The distance from the distal catheter tip is labeled in 10cm increments. Thicker bands denote the midway point (5cm) between the labeled distances. The GEOALIGN® Marking System is designed to be used as a tool to externally measure the intravascular advancement and/or retraction of the catheter. This can provide an intravascular reference regarding the location of the distal tip of the catheter or an approximate intravascular length measurement between two points. The GEOALIGN® Marking System may also facilitate geographic alignment of an adjunctive therapy that includes the same GEOALIGN® Marking System.

**Note:** The GEOALIGN® Marking System provides an approximation that may not be an exact representation of the actual distance traveled intravascularly and should be confirmed under fluoroscopy.

Figure 3 – Enhanced Graphic of CROSSER® Catheter Shaft from Figure 1



**Note:** The GEOALIGN® Marking System includes non-radiopaque white markings and are designed to be utilized outside the sheath.

### Indications

The CROSSER® Recanalization System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy.

The CROSSER® Catheter is only intended for use with the CROSSER® Generator. Refer to the CROSSER® Generator Manual of Operations for proper use.

### Contraindications

The device is contraindicated for use in carotid arteries.

### Warnings and Precautions

- The CROSSER® Recanalization System should only be used by individuals trained in percutaneous transluminal angioplasty (PTA or PTCA).
- Prior to use, the packaging and product should be inspected for signs of damage. Never use damaged product or product from a damaged package.
- DO NOT activate the CROSSER® Recanalization System without proper irrigation. Make sure to establish proper irrigation prior to introduction into guide catheter. Always use REFRIGERATED SALINE.
- The CROSSER® Recanalization System should be used in conjunction with proper anticoagulation agents.
- When exposed to the vascular system, never advance or withdraw the CROSSER® Catheter without proper fluoroscopic guidance.
- It is not recommended to use the CROSSER® Catheter over wires which have polymer-jacketed distal ends.
- Do not exceed 5 minutes of activation time as CROSSER® Catheter malfunction may occur. If 5 minutes of activation time is achieved exchange for a second CROSSER® Catheter before resetting the CROSSER® Generator.
- When using the CROSSER® Catheter 14S with the SIDEKICK® or MICRO SHEATH® XL Support Catheter Tapered, the CROSSER® Catheter can be advanced approximately 15cm from the tip of the support catheter before resistance is encountered due to the taper on the CROSSER® Catheter aligning with the taper on the support catheter. A taper lock-up marker (single black marker on the CROSSER® Catheter shaft) is located 127cm from the distal tip for the 146cm CROSSER® Catheter and 87cm from the distal tip for the 106cm CROSSER® Catheter. The taper lock-up marker can be used as an indicator that the tapers on the catheters are nearing alignment; advance the CROSSER® Catheter slowly. Do not continue to advance the CROSSER® Catheter if resistance is encountered.
- When manipulating the CROSSER® Catheter, the Catheter shaft may become warm to the touch. A warm feeling is normal, however, if the Catheter shaft becomes hot discontinue use immediately and withdraw from patient. Once removed from the patient confirm that irrigation is flowing.
- When using the CROSSER® Catheter in tortuous anatomy, the use of a support catheter is recommended to prevent kinking or prolapse of the CROSSER® Catheter tip. Kinking or prolapse of the tip could cause catheter breakage and/or malfunction.
- Position Foot Switch and cable to minimize potential tripping hazard.
- Ensure CROSSER® Generator is securely mounted to IV pole to reduce risk of falling.
- Should high frequency vibration fail to stop when foot switch is released, power off CROSSER® Generator or unplug from power receptacle.
- Never activate the CROSSER® Generator without a CROSSER® Catheter attached to the Transducer.

- Store in a cool, dry, dark place. Rotate inventory so that the catheters and other dated products are used prior to the "Use By" date.
- This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.
- Do not resterilize. After reesterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or reesterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations.
- GeoAlign® Marking System is designed to be used as an additional reference tool to accompany the interventionalist standard operation procedure. The use of fluoroscopic imaging is recommended following positioning of the catheter to the target lesion and prior to device activation.

#### Adverse Effects

As with most percutaneous interventions, potential adverse effects include: Bleeding which may require transfusion or surgical intervention, Hematoma, Perforation, Dissection, Guidewire entrapment and/or fracture, Hypertension / Hypotension, Infection or fever, Allergic reaction, Pseudoaneurysm or fistula Aneurysm, Acute occlusion, Thrombosis, Ischemic events, Distal embolization, Excessive contrast load resulting in renal insufficiency or failure, Excessive exposure to radiation, Stroke/CVA, Restenosis, Repeat catheterization / angioplasty, Peripheral artery bypass, Amputation, Death or other bleeding complications at access site.

#### Required for Use

The CROSSER® Generator is required for use with this Catheter.

The following additional items not supplied with the CROSSER® Catheter are required for proper use:

- Heparinized saline (for flushing guidewire lumen)
- Normal Saline for Irrigation System
- Chilled saline (refrigerated to 45°F [7°C])
- Recommended flow rate of 0.3 ml/sec [18ml/min] and a back pressure of 200 psi [1378 KPa, 13.8 Bar]
- 0.014" (0.36mm) guidewire for CROSSER® Catheter 14S
- USHER® Support Catheter or other 5F guide catheter or equivalent sheath for use with the CROSSER® Catheter S6.

#### Instructions for Use

##### Set Up

1. Set up CROSSER® Generator according to the CROSSER® Generator Manual of Operations.

**Note:** Refer to CROSSER® Generator Manual of Operations for proper use and set up, cleaning and maintenance of the Generator, Transducer and Foot Switch.

2. Open the CROSSER® Catheter box and remove the pouch containing the sterile drape. Place the sterile drape over the High Frequency Transducer and transducer cable per normal hospital sterile draping procedures.
3. Remove the CROSSER® Catheter pouch from the box and introduce into the sterile field per normal hospital procedures.
4. Back the rigid portion of the catheter out of the end of the hoop, then carefully unsnap the catheter from the hoop with a gentle twisting motion.
5. Place the proximal hub of the CROSSER® Catheter through the opening in the sterile drape.
6. Attach the proximal end of the CROSSER® Catheter to the Transducer. Hold the proximal hub while rotating approximately two full turns clockwise. **Firmly tighten** by hand (Refer to Figure 2).

#### Warning! Allow CROSSER® Catheter tip to freely rotate during attachment.

7. Slide the locking slide collar on the Transducer distally over the proximal catheter hub. Secure the sterile drape around the Transducer / catheter connection using the attached adhesive tape.
8. Attach the irrigation system to the irrigation lumen (Refer to Figure 1) on the proximal end of the CROSSER® Catheter.
9. For the CROSSER® Catheter 14S, remove stylet from the tip of the CROSSER® Catheter.
10. Set the irrigation system to 0.3ml/sec (18 ml/min) and switch irrigation system 'ON'. Allow irrigation to flow for approximately 10-15 seconds to purge all air within the CROSSER® Catheter irrigation lumen.

**Note:** A constant flow should be observed at the tip of the CROSSER® Catheter. If irregular or no flow is observed, check irrigation system for proper function.

If irrigation system is not functioning properly discard CROSSER® Catheter and replace with another.

#### Warning! Do not use a CROSSER® Catheter without proper irrigation as device damage and/or patient injury may result.

11. For the CROSSER® Catheter 14S, flush the guidewire lumen of the CROSSER® Catheter using a standard 10ml syringe with heparinized saline.
12. Hold the CROSSER® Catheter at the distal tip in one hand and switch CROSSER® Generator 'ON'. Verify the CROSSER® Generator is 'ON' by observing front panel display. Once power to CROSSER® Generator has been confirmed, and the irrigation is flowing, depress foot switch for 3-5 seconds to test the function of system. Transmission of energy can be observed at the tip of the catheter.

#### Warning! Never activate the CROSSER® Generator without a catheter firmly attached.

13. Discontinue irrigation.
14. The CROSSER® Recanalization System is now prepped and ready for use.

**Caution! Be sure to position the Transducer in a secure location (e.g. between the patient's legs) to prevent the Transducer from falling off the table.**

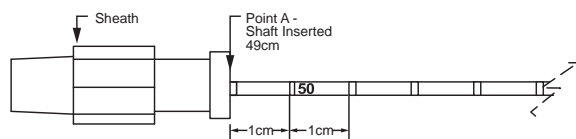
#### Interventional Use

|         | CROSSER® Catheter S6   | CROSSER® Catheter 14S  |
|---------|--|--|
| Step 1  | For the CROSSER® Catheter 14S and S6, access lesion with standard 0.014" (0.36 mm) guidewire.<br><b>Note:</b> Each CROSSER® Catheter is compatible for use with specific guiding catheter/sheath equipment. See chart for sizing for each CROSSER® Catheter version.   |  |
| Step 2  | Advance the USHER® Catheter over the guidewire to the lesion. Withdraw the guidewire and introduce the CROSSER® Catheter S6 through an RHV and irrigation line attached to the hub of the USHER® Catheter. Take care not to damage the tip of the CROSSER® Catheter S6 during introduction into the USHER® Catheter.   | Load the CROSSER® Catheter 14S over the wire and introduce through RHV. Take care not to damage the tip of the CROSSER® Catheter during introduction; no resistance should be encountered during this process.   |
| Step 3  | Gently advance CROSSER® Catheter to the tip of the guide catheter.<br><b>Caution! Never advance the CROSSER® Catheter without the aid of fluoroscopy.</b><br><b>Note:</b> An exit marker (double black marker on the CROSSER® Catheter shaft) is located on the CROSSER® Catheter shaft to denote when the CROSSER® Catheter exits the compatible support catheter.  |  |
|         | An exit marker is located:<br>132cm from the distal tip on the 154cm CROSSER® Catheter S6 to denote when exiting the 130cm USHER® Support catheter<br><br>85cm from the distal tip on the 106cm CROSSER® Catheter S6 to denote when exiting the 83cm USHER® Support catheter   | An exit marker is located:<br>112cm from the distal tip on the 146cm CROSSER® Catheter 14S to denote when exiting the 110cm SIDEKICK® or MICRO SHEATH® XL Support Catheter<br><br>72cm from the distal tip on the 106cm CROSSER® Catheter 14S to denote when exiting the 70cm SIDEKICK® or MICRO SHEATH® XL Support Catheter   |
| Step 4  | Advance the CROSSER® Catheter S6 through the USHER® Catheter to the lesion site.<br><br><b>Warning! The CROSSER® Catheter S6 delivers greater power intensity than the CROSSER® Catheter 14S due to its reduced tip profile. Never advance the CROSSER® Catheter S6 without proper fluoroscopic guidance. Movement of the product without fluoroscopic guidance may result in damage to the product or injury to the vasculature.</b><br><br><b>Warning! When using the 154cm CROSSER® Catheter S6 with the 83cm USHER® Support Catheter, the CROSSER® Catheter can only be advanced approximately 20cm from the tip before resistance is encountered due to the taper on the CROSSER® Catheter aligning with the taper on the 83cm USHER® Support Catheter.</b>                     | Advance the guidewire and CROSSER® Catheter 14S to the lesion site. Withdraw the guidewire approximately 1cm within the Catheter so that the tip of the CROSSER® Catheter is the leading edge.<br><br><b>Warning! When using the CROSSER® Catheter 14S with the SIDEKICK® or MICRO SHEATH® XL Support Catheter Tapered, the CROSSER® Catheter can only be advanced approximately 15cm from the tip before resistance is encountered due to the taper on the CROSSER® Catheter aligning with the taper on the SIDEKICK® or MICRO SHEATH® XL Support Catheter Tapered.</b> |
| Step 5  | Begin the irrigation and verify that the irrigation system is active. To ensure irrigation is flowing at the specified rate, it is recommended to allow at least 3 seconds before activating the CROSSER® Catheter.<br><br><b>Warning! Do not use a CROSSER® Catheter without proper irrigation as device damage and/or patient injury may result.</b>   |  |
| Step 6  | Activate the CROSSER® Catheter by activating the foot switch.<br><b>Note:</b> CROSSER® Generator will only deliver energy for a maximum of 30 seconds with one continuous depression of the foot switch and will not deliver more than 5 minutes total time without resetting the CROSSER® Generator. Only reset the CROSSER® Generator when a second CROSSER® Catheter is connected to the Transducer.  |  |
| Step 7  | Slowly advance the catheter tip through the lesion. Apply steady, constant pressure so the tip of the catheter is engaged to the lesion.<br><br><b>Warning! When manipulating the CROSSER® Catheter, the catheter shaft may become warm to the touch. A warm feeling is normal; however, if the catheter shaft becomes hot, discontinue use immediately and withdraw from patient. Once removed from the patient confirm that irrigation is flowing.</b><br><br><b>Warning! Do not exceed 5 minutes of activation time. If 5 minutes of activation time is achieved exchange for a second CROSSER® Catheter before resetting the CROSSER® Generator. Using a CROSSER® Catheter for more than 5 minutes of activation time may cause catheter malfunction and is NOT recommended.</b> |  |
|         | <b>Warning! The CROSSER® Catheter S6 delivers greater power intensity than the CROSSER® Catheter 14S due to its reduced tip profile. Never advance the CROSSER® Catheter S6 without proper fluoroscopic guidance. Movement of the product without fluoroscopic guidance may result in damage to the product or injury to the vasculature.</b>  | <b>Warning! When using the CROSSER® Catheter 14S with the SIDEKICK® or MICRO SHEATH® XL Support Catheter Tapered, the CROSSER® Catheter can only be advanced approximately 15cm from the tip before resistance is encountered due to the taper on the CROSSER® Catheter aligning with the taper on the SIDEKICK® or MICRO SHEATH® XL Support Catheter Tapered.</b>   |
| Step 8  | Upon successful recanalization of the lesion, withdraw the CROSSER® Catheter S6 from the body and advance a guidewire through the lesion.  | Upon successful recanalization of the lesion, advance the guidewire distal to the lesion and then withdraw the CROSSER® Catheter 14S.  |
| Step 9  | Turn CROSSER® Generator 'OFF'.   |  |
| Step 10 | When appropriate, carefully disconnect CROSSER® Catheter from Transducer hub by sliding the slide collar back and unsnap the CROSSER® Catheter completely. After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations. Remove sterile drape from Transducer, be careful not to drop transducer during this procedure.  |  |

**Optional:** To ensure that the sheath does not move during the procedure, use a catheter stabilization device to stabilize the sheath at the access site.

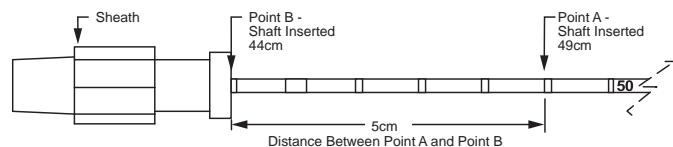
**Optional:** When used as a location reference tool, utilize the GEOALIGN® Marking System to assist with measuring how far the catheter has advanced. The GEOALIGN® Marking System provides an approximation that may not be an exact representation of the actual distance traveled intravascularly and should be confirmed under fluoroscopy (Reference Figure 4).

**Figure 4**



**Optional:** When used for intravascular length measurement, advance or retract the catheter between Points A and B utilizing the GEOALIGN® Marking System to measure the difference. The GEOALIGN® Marking System provides an approximation that may not be an exact representation of the actual distance traveled intravascularly and should be confirmed under fluoroscopy (Reference Figure 5).

**Figure 5**



**Optional:** To facilitate repeat catheter alignment with an additional device with the GEOALIGN® Marking System, ensure the GEOALIGN® Markings are at the same location outside the sheath as the initial device.

**Note:** Ensure the sheath does not move during the withdrawal of the initial device or the advancement of subsequent devices.

### Clinical Study Results

A prospective clinical study of 85 patients was conducted at 8 investigational sites to assess the safety and effectiveness of the CROSSER® Recanalization System in the treatment of chronically occluded infrainguinal arteries following demonstration of resistance to crossing with conventional guidewire techniques.

**Note:** This study was conducted using only the RX version of the CROSSER® Catheter.

### Inclusion Criteria:

Documentation from a previous attempt OR a concurrent attempt during this procedure is required to demonstrate resistance to conventional guidewire crossing; patient must have objective evidence of lower extremity ischemia; occluded artery must be the native infrainguinal arteries; patient must have a totally occlusive lesion in the infrainguinal arteries classified angiographically as absolute (100% occlusion with no flow), where no antegrade filling beyond the occlusion is visible; evidence must exist that demonstrates target occlusion has been in existence for 30 days or greater\*; patient's target vessel occlusion length is ≤ 30cm; patient's reference vessel diameter is ≥ 2.0mm; patient must be an acceptable candidate for PTA, peripheral artery bypass surgery or peripheral artery stent implantation; female patients of child bearing potential must have a negative pregnancy test within 48 hours prior to the study procedure; patient or guardian must have been informed of the nature of the study, agree to its provisions, and provide written informed consent; patient is ≥ 18 years of age.

### Exclusion Criteria:

Patient has hypersensitivity or contraindication to aspirin, heparin or radiographic contrast agents which cannot be adequately pre-medicated; the patient requires immediate treatment in more than one occluded vessel, in any combination of grafts or native vessels; patient has planned infrainguinal intervention scheduled within 30 days after index procedure; the patient is currently participating in another investigational drug or device trial that may conflict with study data collection and has not completed the entire follow-up period; patient's target lesion (CTO) is located in any of the following vessels: Iliac, Profunda (Deep Femoral), Dorsalis Pedis, Carotid, Renal, or Subclavian artery; patient has no collateral flow distal to the occlusion; patient's target occlusion has a dissection that occurred within the past 60 days caused by a guidewire attempt; patient has a history of bleeding diatheses, coagulopathy or will refuse blood transfusion in cases of emergency; patient suffered recent (within the past 6 months) stroke or transient ischemic neurological attack (TIA); patient suffered recent (within the past 6 months) significant gastrointestinal (GI) bleeding; patient's target lesion or the vessel proximal to the target lesion reveals significant ectasia, dissection, aneurysm or thrombus; patient has other medical illnesses (i.e., cancer or congestive heart failure) that may cause the patient to be non-compliant with the protocol, confound the data interpretation or is associated with life-expectancy less than 1 year.

### Primary Safety Endpoint:

Freedom from clinical perforation (any perforation requiring treatment) of the index lesion through the 30 day follow-up.

### Primary Effectiveness Endpoint:

Advancement of the CROSSER® Catheter into or through total occlusions in native infrainguinal arteries and achievement of distal vessel guidewire position with any conventional guidewire following demonstration of resistance to crossing with conventional guidewire techniques.

### Patient Demographics:

| Demographics and History               | Value +/- Stdev | N Reporting | (Min, Max)   | 95% CI       |
|--|-----------------|-------------|--------------|--------------|
| Average Age (yrs)                      | 72.5 ± 10.6     | 85          | (46.8, 95.4) | [70.2, 74.8] |
| Gender (Male)                          | 61.2%           | (52/85)     |              | [50.6, 70.8] |
| History of Coronary Artery Disease     | 65.9%           | (56/85)     |              | [55.3, 75.1] |
| History of Diabetes                    | 49.4%           | (42/85)     |              | [39.0, 59.8] |
| History of Chronic Renal Insufficiency | 14.1%           | (12/85)     |              | [8.3, 23.1]  |
| History of Hyperlipidemia (req Tx)     | 81.2%           | (69/85)     |              | [71.6, 88.1] |
| History of Hypertension (req Tx)       | 87.1%           | (74/85)     |              | [78.3, 92.6] |
| History of Obesity                     | 10.6%           | (9/85)      |              | [5.7, 18.9]  |
| History of Cigarette Smoking           | 54.1%           | (46/85)     |              | [43.6, 64.3] |
| Signs and Symptoms                     |                 |             |              |              |
| Claudication                           | 97.6%           | (83/85)     |              | [91.8, 99.4] |
| Edema                                  | 34.1%           | (29/85)     |              | [24.9, 44.7] |
| Rest Pain                              | 58.8%           | (50/85)     |              | [48.2, 68.7] |
| Sensory Deficit                        | 25.9%           | (22/85)     |              | [17.8, 36.1] |
| Skin Discoloration                     | 37.7%           | (32/85)     |              | [28.1, 48.3] |
| Skin Changes / Necrosis                | 15.3%           | (13/85)     |              | [9.2, 24.4]  |
| Ulcers                                 | 24.7%           | (21/85)     |              | [16.8, 34.8] |
| Rutherford Class                       |                 |             |              |              |
| 1                                      | 1.2%            | (1/85)      |              | [0.2, 6.4]   |
| 2                                      | 7.1%            | (6/85)      |              | [3.3, 14.6]  |
| 3                                      | 42.4%           | (36/85)     |              | [32.4, 53.0] |
| 4                                      | 30.6%           | (26/85)     |              | [21.8, 41.1] |
| 5                                      | 16.5%           | (14/85)     |              | [10.1, 25.8] |
| 6                                      | 2.4%            | (2/85)      |              | [0.7, 8.2]   |

### Lesion Characteristics:

| Lesion Characteristics             | Value +/- Stdev        | N Reporting        | (Min, Max)        | 95% CI        |
|------------------------------------|------------------------|--------------------|-------------------|---------------|
| <b>Vessel Location†</b>            |                        |                    |                   |               |
| Common Femoral                     | 2.4%                   | (2/85)             |                   | [0.7, 8.2]    |
| Superficial Femoral                | 61.2%                  | (52/85)            |                   | [50.6, 70.8]  |
| Popliteal                          | 20.0%                  | (17/85)            |                   | [12.9, 29.7]  |
| Anterior Tibial                    | 5.9%                   | (5/85)             |                   | [2.5, 13.0]   |
| Posterior Tibial                   | 4.7%                   | (4/85)             |                   | [1.9, 11.5]   |
| Peroneal                           | 2.4%                   | (2/85)             |                   | [0.7, 8.2]    |
| Tibioperoneal Trunk                | 3.5%                   | (3/85)             |                   | [1.2, 9.9]    |
| Approximate Age of Lesion (months) | 16.0±23.0              | 85                 | (1.0, 142.0)      | [11.0, 20.9]  |
| Average Length of Occlusion (mm)†  | 117.5±84.0             | 85                 | (15.0, 354.0)     | [99.4, 135.6] |
| Average Vessel Diameter (mm)†      | 4.5±1.0                | 85                 | (2.0, 5.9)        | [4.3, 4.7]    |
| Target Occlusion Involved Stent†   | 5.9%                   | (5/85)             |                   | [2.5, 13.0]   |
| Previous Bypass at Occlusion       | 6.0%                   | (5/84)             |                   | [2.6, 13.2]   |
| Number of Distal Run-Off Vessels†  |                        |                    |                   |               |
| 1                                  | 37.7%                  | (32/85)            |                   | [28.1, 48.3]  |
| 2                                  | 27.1%                  | (23/85)            |                   | [18.8, 37.3]  |
| 3                                  | 35.3%                  | (30/85)            |                   | [26.0, 45.9]  |
| <b>Calcification†</b>              |                        |                    |                   |               |
| None / Mild                        | 25.0%                  | (21/84)            |                   | [17.0, 35.2]  |
| Moderate                           | 20.2%                  | (17/84)            |                   | [13.0, 30.0]  |
| Severe                             | 54.8%                  | (46/84)            |                   | [44.1, 65.0]  |
| <b>Lesion Characteristics</b>      | <b>Value +/- Stdev</b> | <b>N Reporting</b> | <b>(Min, Max)</b> | <b>95% CI</b> |
| <b>Total Occlusion Shape†</b>      |                        |                    |                   |               |
| Blunt                              | 35.4%                  | (28/79)            |                   | [25.8, 46.4]  |
| Central                            | 44.3%                  | (35/79)            |                   | [33.9, 55.3]  |
| Eccentric                          | 20.3%                  | (16/79)            |                   | [12.9, 30.4]  |
| Major Side Branch at Occlusion†    | 19.0%                  | (16/84)            |                   | [12.9, 29.7]  |
| <b>Vascular Access</b>             |                        |                    |                   |               |
| Femoral                            | 98.8%                  | (84/85)            |                   | [93.6, 99.8]  |
| Brachial                           | 1.2%                   | (1/85)             |                   | [0.2, 6.4]    |

† Core lab audited

### Study Results:

| Endpoint  | Value +/- Stdev | N Reporting    | (Min, Max) | 95% CI              |
|---|-----------------|----------------|------------|---------------------|
| <b>Primary Safety Endpoint†</b>                                     | <b>98.8%</b>    | <b>(84/85)</b> |            | <b>[93.6, 99.8]</b> |
| Clinical Perforation Related to CROSSER® Catheter                   | 0.0%            | (0/85)         |            | [0.0, 4.3]          |
| Clinical Perforation Related to device other than CROSSER® Catheter | 1.2%            | (1/85)         |            | [0.2, 6.4]          |
| <b>Primary Efficacy Endpoint†</b>                                   | <b>83.5%</b>    | <b>(71/85)</b> |            | <b>[74.2, 89.9]</b> |
| <b>Secondary Endpoints (hierarchical)</b>                           |                 |                |            |                     |
| Technical Success†  | 83.5%           | (71/85)        |            | [74.2, 89.9]        |
| Procedural Success†   | 75.3%           | (64/85)        |            | [65.2, 83.2]        |
| Clinical Success  | 74.1%           | (63/85)        |            | [63.9, 82.2]        |
| Angiographic Perforation (any time during procedure) †              |                 |                |            |                     |
| Type 1 – wire exit  | 4.7%            | (4/85)         |            | [1.9, 11.5]         |

| Endpoint  | Value +/- Stdev | N Reporting    | (Min, Max) | 95% CI              |
|---|-----------------|----------------|------------|---------------------|
| Type 2 – blush  | 0.0%            | (0/85)         |            | [0, 4.3]            |
| Type 3 – staining   | 3.5%            | (3/85)         |            | [1.2, 9.9]          |
| Type 4 – extravasation  | 8.2%            | (7/85)         |            | [4.1, 16.0]         |
| Related to the CROSSER® Catheter  | 2.4%            | (2/85)         |            | [0.7, 8.2]          |
| Related to other than the CROSSER® Catheter   | 5.9%            | (5/85)         |            | [2.5, 13.0]         |
| <b>Other Endpoints</b>  |                 |                |            |                     |
| Freedom from Limb Loss, Clinical Perforation and Repeat Revascularization (through 30 days) | <b>94.1%</b>    | <b>(80/85)</b> |            | <b>[87.0, 97.5]</b> |
| Clinical Perforation†   | 1.2%            | (1/85)         |            | [0.2, 6.4]          |
| Limb Loss   | 2.4%            | (2/85)         |            | [0.7, 8.2]          |
| Repeat Revascularization  | 2.4%            | (2/85)         |            | [0.7, 8.2]          |
| Surgery   | 1.2%            | (1/85)         |            | [0.2, 6.4]          |
| PTA   | 1.2%            | (1/85)         |            | [0.2, 6.4]          |

#### Definitions:

**Technical Success** - the ability to facilitate crossing a CTO into the true distal lumen with the CROSSER® Catheter and/or any conventional guidewire after use of the CROSSER® Catheter.

**Procedural Success** - achievement of Technical Success plus a residual stenosis <50% and improved flow verified angiographically, following the procedure.

**Clinical Success** - achievement of Procedural Success, and freedom from limb loss and repeat revascularization (bypass surgery, or PTA) from index hospitalization through 30 day follow-up.

**Angiographic Perforation Classification and Rate** - tabulation of the formal classification (using the standard Type 1-4 classification) of any extravasation of contrast detected by the physician performing the procedure or the Angiographic Core Laboratory at any point during the procedure.

**Clinical Perforation** - Any perforation requiring treatment (ie. long balloon inflation, covered stent, surgical intervention).

#### How Supplied

Sterile, non-pyrogenic, intended for single use only.

#### Troubleshooting

| Symptom  | Cause  | Solution   |
|--|--|--|
| Excessive vibration noise coming from Transducer | Transducer/Catheter connection loose   | Loosen and re-tighten connection   |
|  | Energy transmission wire fracture  | Dispose of catheter, get a new catheter, notify manufacturer                                     |
| No energy observed at the tip of the catheter    | Loose catheter/transducer connection   | Loosen and re-tighten connection   |
|  | Energy transmission wire fracture  | Dispose of catheter, get a new catheter, notify manufacturer                                     |
| Excessive heat felt by operator                  | Blocked irrigation lumen   | Dispose of catheter, get a new catheter, notify manufacturer                                     |
|  | Irrigation equipment not turned 'ON'   | Check irrigation system  |
|  | Irrigation equipment not set properly or malfunctioning irrigation equipment | Check irrigation system  |
|  | Leak in irrigation system  | Check all luer connections   |
| Irrigation leak (other than from tip)            | Improper hand/finger placement   | Avoid creating a focal bend on the catheter shaft. Use only two fingers to advance the CROSSER®. |
|  | Irrigation equipment not set properly or malfunctioning irrigation equipment | Check irrigation system  |
|  | Blocked irrigation lumen   | Dispose of catheter, get a new catheter, notify manufacturer                                     |
| Guidewire fails to exit from the Guidewire Lumen | Defective catheter   | Dispose of catheter, get a new catheter, notify manufacturer                                     |
|  | Sharp back end of guidewire pierced guidewire lumen of CROSSER® Catheter     | Dispose of catheter, get a new catheter, notify manufacturer                                     |
|  | Defective catheter   | Dispose of catheter, get a new catheter, notify manufacturer                                     |

#### Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product, that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited, to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion, or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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Some countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your country.

An issue or revision date and revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.





Recanalization Catheter

**ID**

Minimum Inner Diameter

**LOT**

LOT Number



Keep Dry



Consult Instructions For Use



Manufacturer



Non-Pyrogenic

**REF**

Catalogue Number



Keep Away From Sunlight



Use By



Do not use if the product sterile barrier system or its packaging is compromised



Do Not Resterilize



Contents

**RX**

Rapid Exchange



Recommended Support Catheter



Bard, Crosser, GeoAlign, MicroSheath, Sidekick, and Usher are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

**OTW** Over The Wire



Recommended Guidewire

**WL**

Working Length



Recommended Introducer



Do Not Re-use

**STERILE R**

Sterilized Using Irradiation



Not Made With Natural Rubber Latex



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**Manufacturer:**  
**Bard Peripheral Vascular, Inc**

1625 West 3<sup>rd</sup> Street  
Tempe, AZ 85281 USA  
Tel.: 1-480-894-9515 / 1-800-321-4254  
Fax: 1-480-966-7062 / 1-800-440-5376  
[www.bardpv.com](http://www.bardpv.com)

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