CROSSER™ CTO Recanalization Catheter
High Frequency Mechanical Recanalization System

Instructions for Use – CROSSER™ Catheters 14P, 14S, 18, and 56

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 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.

Figure 1 – The CROSSER™ Recanalization System

Figure 2 – Proximal Hub Connection to Transducer

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.
• 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 or 14P with the MicroSheath® 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 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 markers on the catheter 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 resterilization, 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 resterilization 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.

Adverse Effects
As with most percutaneous interventions, potential adverse effects include: Bleeding which may require transfusion or surgical intervention, Hematoma,
Interventional Use (cont.)

Step 2  Advance the Uvascular Catheter over the guidewire to the lesion. Withdraw the guidewire and introduce the MiCrosheath® Catheter S6 through an RHW and irrigation line attached to the hub of the Uvascular Catheter. Take care not to damage the tip of the MiCrosheath® Catheter S6 during introduction into the Uvascular Catheter.

Step 3  Gently advance MiCrosheath® Catheter to the tip of the guide catheter.

Caution! Never advance the MiCrosheath® Catheter without the aid of fluoroscopy.

Note: An exterior marker (double marker on the MiCrosheath® Catheter shaft) is located on the MiCrosheath® Catheter shaft to denote when the MiCrosheath® Catheter exits the compatible support catheter.

Step 4  Advance the MiCrosheath® Catheter S6 through the Uvascular Catheter to the lesion site.

Warning! The MiCrosheath® Catheter S6 delivers greater power intensity than the MiCrosheath® Catheter 14P, 14S, and 18 due to its reduced tip profile. Never advance the MiCrosheath® Catheter S6 without proper fluoroscopically guided movement of the product without fluoroscopic guidance may result in damage to the product or injury to the vasculature.

Warning! When using the MiCrosheath® Catheter S6 with the Ecm Uvascular Support Catheter, the MiCrosheath® Catheter can only be advanced approximately 2cm from the tip before resistance is encountered due to the taper on the MiCrosheath® Catheter aligning with the taper on the Ecm Uvascular Support Catheter.

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 MiCrosheath® Catheter.

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

Step 6  Activate the MiCrosheath® Catheter by activating the foot switch.

Warning! When manipulating the MiCrosheath® 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. Warning! Do not exceed 5 minutes of activation time. If 5 minutes of activation time is achieved exchange for a second MiCrosheath® Catheter before activating the MiCrosheath® Generator. Using a MiCrosheath® Catheter for more than 5 minutes of activation time may cause catheter malfunction and is NOT recommended.

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.

Warning! When manipulating the MiCrosheath® 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. Warning! Do not exceed 5 minutes of activation time. If 5 minutes of activation time is achieved exchange for a second MiCrosheath® Catheter before activating the MiCrosheath® Generator. Using a MiCrosheath® Catheter for more than 5 minutes of activation time may cause catheter malfunction and is NOT recommended.

Warning! The MiCrosheath® Catheter S6 delivers greater power intensity than the MiCrosheath® Catheter 14P, 14S, and 18 due to its reduced tip profile. Never advance the MiCrosheath® Catheter S6 without proper fluoroscopically guided movement of the product without fluoroscopic guidance may result in damage to the product or injury to the vasculature.

Warning! When using the MiCrosheath® Catheter 14P or 14S with the MiCrosheath® XL Support Catheter Tapered, the MiCrosheath® Catheter can only be advanced approximately 15cm from the tip before resistance is encountered due to the taper on the MiCrosheath® Catheter aligning with the taper on the MiCrosheath® XL Support Catheter Tapered.

Upon successful recanalization of the lesion, withdraw the MiCrosheath® Catheter S6 from the body and advance a guidewire through the lesion.

Step 8  Upon successful recanalization of the lesion, advance the guidewire distal to the lesion and then withdraw the MiCrosheath® Catheter 14P, 14S, or 18.

Step 9  Turn MiCrosheath® Generator ‘OFF’.

Step 10  When appropriate, carefully disconnect MiCrosheath® Catheter from Transducer hub by sliding the slide collar back and unscrew the MiCrosheath® 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.

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

Note: This study was conducted using only the RX version of the MiCrosheath® 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 lesion 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 arterial 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: Advance ment 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:

<table>
<thead>
<tr>
<th>Demographics and History</th>
<th>Value ± Stdev</th>
<th>N Reporting</th>
<th>(Min, Max)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Age (yrs)</td>
<td>72.3 ± 10.6</td>
<td>(46.8, 90.4)</td>
<td>(70.2, 74.6)</td>
<td></td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>61.2%</td>
<td>(53/85)</td>
<td>(56.7, 70.9)</td>
<td></td>
</tr>
<tr>
<td>History of Coronary Artery Disease</td>
<td>59.9%</td>
<td>(56/85)</td>
<td>(55.3, 75.1)</td>
<td></td>
</tr>
<tr>
<td>History of Diabetes</td>
<td>49.9%</td>
<td>(42/85)</td>
<td>(39.8, 59.8)</td>
<td></td>
</tr>
<tr>
<td>History of Chronic Renal Insufficiency</td>
<td>14.1%</td>
<td>(13/85)</td>
<td>(8.3, 25.3)</td>
<td></td>
</tr>
<tr>
<td>History of Hypertension (yes/ no)</td>
<td>81.2%</td>
<td>(69/85)</td>
<td>(71.6, 88.1)</td>
<td></td>
</tr>
<tr>
<td>History of Hyperlipidemia (yes/ no)</td>
<td>87.1%</td>
<td>(74/85)</td>
<td>(76.8, 92.6)</td>
<td></td>
</tr>
<tr>
<td>History of Obesity</td>
<td>10.0%</td>
<td>(14/85)</td>
<td>(5.7, 18.9)</td>
<td></td>
</tr>
<tr>
<td>History of Cigarette Smoking</td>
<td>54.1%</td>
<td>(45/85)</td>
<td>(43.6, 64.3)</td>
<td></td>
</tr>
<tr>
<td>History of Diabetes</td>
<td>49.4%</td>
<td>(42/85)</td>
<td>(39.8, 59.8)</td>
<td></td>
</tr>
<tr>
<td>History of Chronic Renal Insufficiency</td>
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<td>(13/85)</td>
<td>(8.3, 25.3)</td>
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</tr>
<tr>
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<td>54.1%</td>
<td>(45/85)</td>
<td>(43.6, 64.3)</td>
<td></td>
</tr>
<tr>
<td>Claudication</td>
<td>97.0%</td>
<td>(83/85)</td>
<td>(91.9, 99.4)</td>
<td></td>
</tr>
<tr>
<td>Edema</td>
<td>34.1%</td>
<td>(29/85)</td>
<td>(24.9, 44.7)</td>
<td></td>
</tr>
<tr>
<td>Rest Pain</td>
<td>58.8%</td>
<td>(30/85)</td>
<td>(46.2, 68.7)</td>
<td></td>
</tr>
<tr>
<td>Sensory Deficit</td>
<td>25.3%</td>
<td>(23/85)</td>
<td>(17.3, 36.1)</td>
<td></td>
</tr>
<tr>
<td>Skin Discoloration</td>
<td>37.7%</td>
<td>(33/85)</td>
<td>(28.1, 48.7)</td>
<td></td>
</tr>
<tr>
<td>Skin Changes / Necrosis</td>
<td>15.3%</td>
<td>(13/85)</td>
<td>(9.2, 24.9)</td>
<td></td>
</tr>
<tr>
<td>Ulcers</td>
<td>24.7%</td>
<td>(21/85)</td>
<td>(16.3, 34.8)</td>
<td></td>
</tr>
<tr>
<td>Rutherford Class</td>
<td>1.2%</td>
<td>(1/85)</td>
<td>[0.2, 4.4]</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>7.1%</td>
<td>(6/85)</td>
<td>[3.3, 14.4]</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>42.4%</td>
<td>(30/85)</td>
<td>(32.4, 53.0)</td>
<td></td>
</tr>
</tbody>
</table>

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

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

## 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.

**TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.**

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 Number

Keep Dry

Consult Instructions For Use

Manufacturer

Non-Pyrogenic

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

Rapid Exchange

Recommended Support Catheter

BARD, CROSSER, FLOWMATE, MICROSHED and USHER are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.
OTW  Over The Wire

WL  Working Length

Recommended
Guidewire

Recommended
Guide Catheter

Do Not Re-use

Sterilized Using
Irradiation

Does Not Contain Natural
Rubber Latex

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