English

Contents of unopened and undamaged package are STERILE and NON PYROGENIC

Disposable: This device is intended for one-use only. Do not clean or resterilize. Store at room temperature in a dry, dark area away from heat and chemical fluids.

Shelf life: The recommended shelf life is printed on each package. Storage beyond the expiration date may result in catheter deterioration.

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

Read all instructions prior to use.

Instructions for Use

Indications

The purpose and intended use of the Bentley InnoMed GmbH BeBack Crossing Catheter is to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires.

Contraindications

Contraindicated for use in the coronary, cerebral and carotid arteries.

Description

The Bentley InnoMed GmbH BeBack Crossing Catheter is a 4 F or 2.9 F catheter, 80 cm or 120 cm effective length, single lumen design catheter with rigid distal tip. A long needle pre-curved at its distal end is slightly slidable inside the catheter lumen to expose the needle tip. The needle protrusion is controlled from the catheter handle, and includes several discrete positions, a) about 1 - 3 mm straight protrusion; b) about 7 mm protrusion at an angle, and; c) about 11 mm protrusion at an angle (only for the 4 F catheter). The long needle inner through lumen permits the use of 0.018" guidewires for the 4 F catheter or 0.014" guidewires for the 2.9 F catheter, to facilitate the advancement of the catheter through and around the occlusion. The wire lumen is accessed through the proximal handle luer port. A radiopaque C-shape marker identifies the radial direction of the needle protrusion.

Warning

- Do not advance the BeBack Crossing Catheter, the guidewire or any other component, if resistance is met, without first determining the cause and taking corrective actions.
- Do not rotate the device inside the patient blood vessel for more than 3 full rotations.
- This device is intended for one-use only. Do not resterilize or reuse.

Precautions

- This catheter should only be used by physicians trained in peripheral percutaneous interventional techniques in a fully equipped catheterization laboratory.
- Procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- The sealed catheter container should be inspected prior to opening. If the seal is broken, or the container has been damaged, sterility cannot be assured.
- Excessive rotation, bending or kinking of the BeBack Crossing Catheter may affect its performance.
- Excessive calcification at the entry site may impair performance.
- A kinked or bent guidewire may become trapped within the catheter. Replace guidewire prior to catheter insertion if a kinked or bent guidewire is suspected.
- **Caution:** The catheter system should not be advanced against resistance. The cause of the resistance should be identified and corrective action should be taken. If resistance is felt upon catheter removal from an artery, check that the needle tip is retrieved into the catheter rigid distal tip. If resistance continues, then the catheter, needle, guidewire, and the sheath should be removed together as a unit.
- Damage may result from kinking, stretching, or forcefully wiping the catheter. Care should be used when handling.
- Do not rotate the catheter while needle is protruded and stuck inside hard plaque.
- Do not pull back the guidewire while the BeBack Crossing Catheter needle is protruded.

Potential Complications

- Potential adverse events include, but are not limited to vessel dissection, injury, pseudoaneurysm, hemorrhage, and ischemia.
- Potential complications related to percutaneous transluminal angioplasty include, but are not limited to clot formation and embolism, nerve damage, vascular perforation requiring surgical repair, damage to the vascular intima, or death.
- Potential complications related to introducing the catheter into the body include, but are not limited to infection, hematoma formation, and air embolism.

Operational Instructions

BeBack Crossing Catheter System Preparation

a) Use sterile technique to carefully remove the BeBack Crossing Catheter from its packaging. Inspect the catheter for damage.

b) Flush the long needle inner lumen thoroughly.

BeBack Crossing Catheter Steps for Use

c) Prior to catheter insertion, confirm using the appropriate guidewire for the size/length of the BeBack Crossing Catheter.

d) For the 4 F BeBack Crossing Catheter, confirm that at least 4 F sheath is used for percutaneous insertion. For cross-over (up and over) insertion, 6 F sheath is recommended.
For the 2.9 F BeBack Crossing Catheter, confirm that at least 2.9 F sheath is used for percutaneous insertion. For cross-over (up and over) insertion, 5 F sheath is recommended.

e) Enter the vessel percutaneously using clinically accepted techniques and desired guidewire.

f) Introduce the BeBack Crossing Catheter using accepted techniques over the guidewire already in the vessel by back loading the guidewire into the distal end of the BeBack Crossing Catheter.

g) **For crossing a stenosis/occlusion intra-luminal,** select the needle protrusion length for short (up to 3 mm) protrusion, using the handle protrusion length knob, retrieve the guidewire back inside the needle, and push through the occlusion using fluoroscopy imaging of the needle advancement.

h) If an angle up to 45 degrees needle protrusion is required, first select the needle protrusion length for up to 7 mm length, then rotate the catheter using the radiopaque C-shape marker at the tip of the catheter, to aim the needle curvature while protruded, to the required direction. The needle curve direction is indicated by the C opening direction (see marker picture below). Only then push the needle through the occlusion as much as needed, using fluoroscopy imaging of the needle advancement and location. Use same technique if full needle protrusion is required for crossing.

Fig. 1: Radiopaque C-shape marker

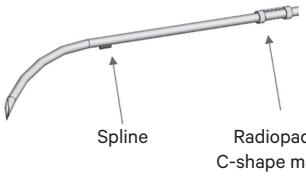

Fig. 2: Needle assembly

i) **For crossing large distance and at an angle and for sub-intimal reentry,** select the needle protrusion length to max protrusion length (up to 11 mm in the 4 F catheter and 7 mm in the 2.9 F catheter) using the handle protrusion length knob, then rotate the catheter using the radiopaque C-shape marker at the tip of the catheter, to aim the needle curvature while protruded, to the required direction. The needle curve direction is indicated by the C opening direction. Only then push the needle out as much as needed through the occlusion using fluoroscopy imaging of the needle advancement and location.

j) Advance the floppy guidewire through the BeBack Crossing Catheter while needle is protruded, to confirm penetration and location in the true lumen. If not in the true lumen, first pull back the needle then the guidewire, rotate and re-protrude the needle. Repeat steps (g) through (i) until gaining confirmation of true lumen entry.

Once satisfied that the guidewire has been placed beyond the lesion:

k) **Caution:** Retrieve the BeBack Crossing Catheter needle tip back inside the catheter rigid tip before any attempt to retrieve the BeBack Crossing Catheter.

l) **Caution:** Before retrieve the catheter, make sure the needle protrusion length knob is pushed to minimal length position, and the knob **red color side can't be seen from above.**

m) Gently withdraw the BeBack Crossing Catheter leaving the guidewire in place to complete the interventional procedure. Use a smooth, gentle, steady motion to remove the system from the vessel. If resistance is felt during removal, stop and obtain a fluoroscopic image.

n) Once the BeBack Crossing Catheter has been removed, inject contrast medium and ascertain a road map to confirm that the guidewire is in the true lumen. Then proceed with further percutaneous intervention such as balloon dilation and/or stent placement. If not in the true lumen, retract the guidewire into the subintimal space and repeat, using new system.

Warning, Warranty, and Limitations

- Bentley InnoMed GmbH Crossing Catheters may fail to function for a variety of reasons, including medical complications and/or catheter failure due to breakage.
- Catheters may be easily damaged before, during, or after insertion despite all efforts in design, manufacturing, and testing.
- No representation or warranty is made that the catheter will not fail or malfunction; that the body will not react adversely to the catheter and/or its placement; nor that medical complications will not arise during or after the use of catheters.
- Catheters are sold in an "as is" condition. All steps in the Instructions for Use are to aid the user in assessing the quality and performance of the catheter. The entire risk as to the performance of the catheter is borne by the buyer.
- Bentley InnoMed GmbH disclaims all warranties, expressed or implied, with respect to the catheters, including but not limited to any implied warranty of merchantability or fitness for a particular purpose. Bentley InnoMed GmbH shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any catheter or accessory or caused by any defect, failure, or malfunction of any catheter or accessory, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind Bentley InnoMed GmbH to any representation or warranty with respect to catheters and accessories.

	Caution
	Manufacturer
	Use-by date
	Single use
	Do not resterilize
	Sterilized using ethylene oxide
	Catalogue number
	Lot number
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

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