THROMBOLEX™

INNOVATIVE ENDOVASCULAR CATHETERS

BASHIR™

endovascular catheter

Instructions for Use

WARNING

Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.

Manufactured for:
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www.thrombolex.com

International Symbols Glossary

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Sterilized using ethylene oxide

Keep dry

Do not re-use

Keep away from sunlight

Do not resterilize

Use-by date indicated on label

Consult instructions for use

Batch code

Catalogue number

Non-pyrogenic

Not made with natural rubber latex.

A. Device Description

The Bashir Endovascular Catheter (Ref. No. 7201) is a device intended for the localized infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The distal infusion segment of the device is 12.50 cm (4.94 in) long and consists of an expandable basket with mini-infusion catheters, each with multiple infusion holes (hereafter referred to as “infusion basket” (Table 1). It is used for the delivery of the physician-specified fluids at multiple cross-sectional points of the target vessel location (Figure 1). The infusion basket can be expanded using the red actuator located on the handle at the proximal end of the device (Figure 2). After expansion, the mini-infusion catheters may be returned to their original closed positions by depressing the white button on the actuator and advancing the actuator toward the distal end of the device. The infusion line connector is also located on the handle.

Table 1. Key Dimensions, Bashir Endovascular Catheter (Ref. No. 7201)

French size	7 F (2.3 mm)
Effective length	92.5 cm (36.44 in)
Infusion basket length	12.50 cm (4.94 in)
Infusion basket diameter	45 mm max.

The catheter is advanced over a guidewire using standard endovascular interventional techniques and is compatible with standard infusion connectors, accessories and equipment.

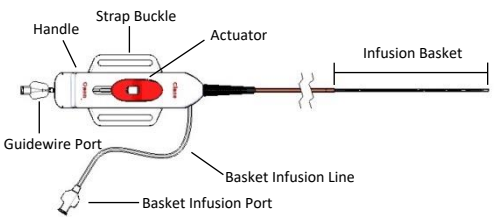

Figure 1. Bashir Endovascular Catheter.

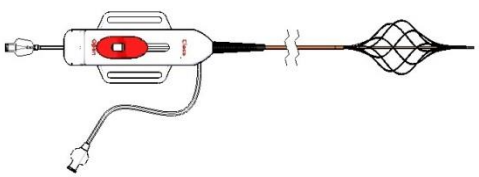

Figure 2. Bashir Endovascular Catheter with infusion basket fully expanded.

B. Intended Use / Indications for Use

The Bashir Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

C. Contraindications

The Bashir Endovascular Catheter is contraindicated for use in the coronary arteries, pulmonary arteries, and neurovasculature.

D. Precaution and Warnings

- The Bashir Endovascular Catheter must only be used by physicians trained in interventional vascular procedures.
- Do not use the Bashir Endovascular Catheter with a power injector as catheter damage may occur.
- This product is supplied STERILE using an ethylene oxide (EO) process. Carefully inspect the device packaging prior to use. Do not use if package appears open or damaged.
- Carefully inspect the device prior to use. Do not use the device if it appears damaged or if any of its components is missing.
- Use the device only prior to the “Use By” date listed on the package label.
- Store in a dry, cool place.
- This product is designed and intended for single use. Do not re-use.
- Do not re-sterilize.
- Re-using or re-sterilizing may be detrimental to the structural integrity and proper function of the product, resulting in patient injury or death. Reusing the product may also result in product contamination which may lead to infection and/or the transmission of infectious disease(s), resulting in patient injury, illness or death.
- Dispose of the product and package according to hospital and/or local government policies.
- Use the Bashir Endovascular Catheter only with the sheath and guidewire sizes indicated in these instructions.
- The Bashir Endovascular Catheter is designed to be used under standard fluoroscopic observation.
- Do not advance or manipulate the device in the vasculature if resistance is felt. Advancing or manipulating the device when resistance is felt may result in vessel trauma or device damage. If resistance is met, determine the cause of the resistance via fluoroscopy before proceeding.
- Do not apply excessive torque or rotation to the system.
- All physician-specified fluids to be infused must be used according to the manufacturer’s instructions for use.

- Flush the entire device with heparinized saline or suitable flush solution prior to placement to avoid accidental introduction of air into the system.
- Before placement, verify that the diameter of the infusion basket can be adjusted using the actuator on the handle. Moving the actuator in the proximal direction (towards the operator), increases the infusion basket diameter (Figure 3, Page 7). Moving the actuator in the distal direction (away from the operator), while simultaneously pressing the actuator release button, reduces the infusion basket diameter (Figure 4, Page 7).
- Do not move the handle actuator in the distal direction without simultaneously pressing the actuator release button.
- Before moving the device within a blood vessel, ensure that the infusion limbs are collapsed by moving the actuator handle in the distal direction.
- Ensure that the basket infusion port is attached to an infusion pump with the physician specified fluid at the rate prescribed by the physician prior to introducing the device into the vasculature and during insertion and placement. This will maintain patency of the infusion basket.
- Do not expand the infusion basket to touch the walls of the blood vessel; the infusion basket should remain within the vascular walls whether expanded or closed.

E. Potential Complications

- Intimal damage
- Vessel perforation
- Vessel spasm
- Hemorrhage
- Allergic reactions
- Vascular thrombosis
- Ischemia
- Pain and tenderness
- Hematoma at the site of entry

F. Preparations for Use

Prior to using the device, prepare the Bashir Endovascular Catheter appropriately.

1. Prepare the following additional items according to their manufacturer's instructions for use:
   - A micropuncture kit
   - A 0.035" guidewire, of the required length to fit the Sheath
   - An 0.018" guidewire, min. 300 cm long
   - A 7F or greater dilator and sheath, not to exceed 70cm in length, but long enough to reach the treatment site.
   - Two three-way stop-cocks
   - An infusion pump prepared with physician-specified fluids to be infused

- Two 10 cc syringes

2. Establish vascular access under ultrasound guidance using a micropuncture technique.

3. Inspect the entire Bashir Endovascular Catheter after it has been removed from its packaging to verify that it is undamaged.

   Warning: Do not use the product if it shows signs of damage. If damage is detected, replace with an undamaged device.

4. Verify that the diameter of the infusion basket can be adjusted using the red actuator on the handle. Moving the actuator in the proximal direction (towards the operator) increases the infusion basket diameter (Figure 3). Moving the actuator in the distal direction (away from the operator), while simultaneously pressing the actuator release button, reduces the infusion basket diameter (Figure 4).

   Warning: Do not use the product if it does not operate as described above and replace with another device.

   Warning: Do not move the red actuator in the distal direction without simultaneously pressing the actuator release button.

5. Attach one three-way stopcock to the basket infusion port connector.

6. Introduce a 7Fr or greater dilator and sheath of the appropriate length into the vasculature over a 0.035" guidewire. Advance the dilator, sheath and guidewire under fluoroscopic guidance to the treatment site.

   Warning: Do not use a sheath greater than 70cm in length.

7. Withdraw the dilator and the 0.035" guidewire used for sheath placement, leaving the sheath in place.

8. Under fluoroscopic guidance, introduce and advance an 0.018" guidewire through the in-place sheath to beyond the treatment site.

9. Prior to insertion of the device, flush the guidewire port verifying that the flush solution exits the distal end of the wire lumen of the catheter. Using the physician-specified infusion, connect the infusion line of the physician-specified infusion to the stopcock on the basket infusion port of the Bashir Endovascular Catheter. Start the infusion and verify that fluid exits the infusion holes of the infusion basket.

10. Ensure that the red handle actuator is fully positioned at the "Close" position and ensure that the infusion basket is completely closed to the original unexpanded position to facilitate the next step of inserting the Bashir Endovascular Catheter.

G. Instructions for Use

11. Backload the Bashir Endovascular Catheter onto the proximal segment of the 0.018" guidewire.

12. Grasp the infusion basket gently between thumb and forefinger. Then insert the Bashir Endovascular Catheter into the sheath and advance over the guidewire under fluoroscopic guidance until the infusion basket is placed across the treatment site. The distal 12.50 cm (4.94 in) infusion basket is radiopaque and visible under fluoroscopy along its full length.

    Warning: Do not advance the device if resistance is felt. Determine the cause of resistance via fluoroscopy before proceeding.

13. Retract the sheath to fully expose the infusion basket.

14. Under fluoroscopic visualization, use the red actuator on the handle to expand the infusion basket to a diameter less than that of the vessel in which it is situated, to minimize the chance of occluding any infusion holes. Moving the actuator in the proximal direction (towards the operator) expands the infusion basket (Figure 3). Moving it in the distal direction (away from the operator), while simultaneously pressing the white actuator release button, collapses the infusion basket to reduce its diameter (Figure 4).

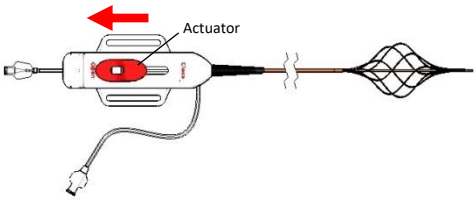

Figure 3. Move actuator in the proximal direction to expand the infusion basket to the desired diameter (diagram not to scale).

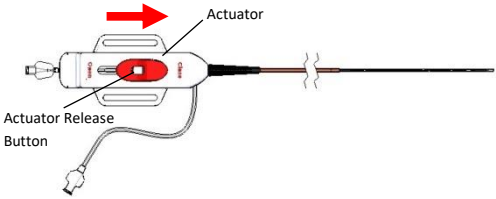

Figure 4. Move actuator in the distal direction while simultaneously pressing the actuator release button to reduce the diameter of the infusion basket. Move actuator fully in the distal direction to completely collapse the infusion basket.

15. Pause the infusion of the physician-specified fluid. Turn the stopcock on the basket infusion port closed to the infusion pump and open

from the syringe to the catheter and perform manual pulse sprays of the physician-specified fluid using a 10 cc syringe via the basket infusion port as desired. Thereafter, turn the stopcock and continue IV infusion of physician specified fluids

16. Remove the 0.018" guidewire from the body.

17. Attach a second three-way stopcock to the guidewire port.

    Warning: For the guidewire port, hold the luer hub (not the handle) while attaching the three-way stop-cock.

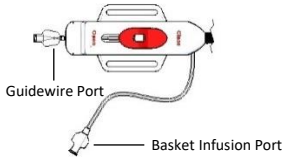

Figure 5. Basket infusion port and guidewire port.

18. Pressure and oxygen saturation can be measured from the distal end of the catheter via the proximal luer hub on the guidewire port, as required by the operator.

19. Set the infusion pump to the desired infusion rate and activate per standard practice. The infusion may continue for up to 24 hours.

20. Finally, secure the Bashir Endovascular Catheter handle to the patient per standard operating procedures of the hospital and securely cover the actuator so that it cannot be moved forward or backward. A knee brace is recommended to immobilize the patient's knee and to prevent the possible kinking of the catheter. The patient can now be moved to the appropriate care unit for the duration of the infusion therapy.

    Warning: Failure to properly secure the handle strap and catheter shaft may result in inadvertently pulling the catheter away from the treatment location or out of the patient or damaging the catheter.

21. After the infusion procedure has been completed, completely collapse the infusion basket to its smallest diameter by moving the red actuator fully in the distal direction (away from the operator) while simultaneously pressing the white actuator release button.

    Warning: Do not move the handle actuator in the distal direction without simultaneously pressing the actuator release button.

22. Retract the fully collapsed Bashir Endovascular Catheter into the sheath and remove from the patient.

23. Discard the device after removal using standard methods for biological waste.

24. Withdraw and discard all applicable accessory devices using standard methods for biological waste.

PK07IN00 Rev. C