BASHIR®+
endovascular catheter

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

Instructions for Use

BASHIR®+10
endovascular catheter

BASHIR®+20
endovascular catheter

BASHIR®+30
endovascular catheter

BASHIR®+40
endovascular catheter

WARNING

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

Manufactured for:
Thrombolex, Inc.
75 Britain Drive
New Britain, PA 18901
Tel: 267-898-3986 | 844-792-6300 (Toll-Free)
www.thrombolex.com

Not made with natural rubber latex.

International Symbols Glossary

Sterilized using ethylene oxide


Do not re-use

Do not resterilize


Consult instructions for use

Catalogue number


Keep dry


Keep away from sunlight


Use-by date indicated on label

Batch code


Non-pyrogenic

A. Device Description

The BASHIR® Plus Endovascular Catheter (Ref. No. 7210, 7220, 7230, 7240) is a device intended for the localized infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The catheter has a distal infusion segment consisting of an expandable basket with mini-infusion catheters, each with multiple infusion holes (hereafter referred to as “infusion basket”), and a second infusion segment on the catheter shaft, adjacent and proximal to the infusion basket and defined by length of the shaft infusion segment (+10cm,+ 20cm,+ 30cm, or + 40cm) between the proximal end of the infusion basket and a radiopaque marker located proximally on the shaft (Figure 1). The two infusion segments are independent from each other, each having a dedicated infusion line located on the catheter handle labeled BASKET or SHAFT. The infusion basket can be expanded using the red actuator located on the handle at the proximal end of the device (Figure 1B). 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 (Figure 1A). It is used for creating new open pathways through the clot for the immediate restoration of blood flow, thereby delivering endogenous lytics, and for the delivery of the physician-specified fluids at multiple cross-sectional points of the target vessel location (Figure 1).

Table 1. Key Dimensions, BASHIR® Plus Endovascular Catheter

Ref. No.	Infusion Basket Length	Infusion Basket Diameter	Shaft Infusion Segment Length
7210	12.5 cm (4.94 in)	45 mm max.	10 cm
7220			20 cm
7230			30 cm
7240			40 cm
French Size: 7 F (2.3 mm)			
Effective length 92.5 cm (36.44 in.)			

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

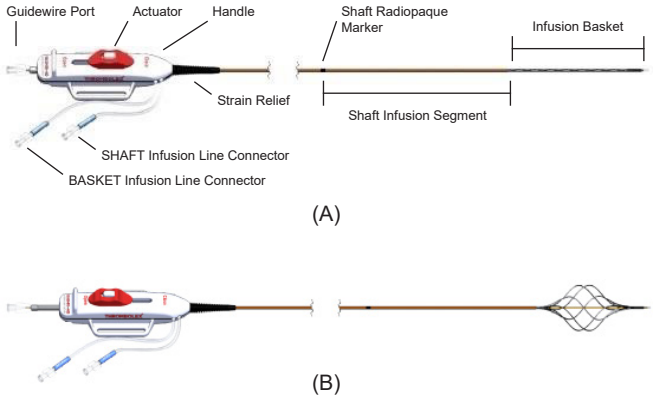

Figure 1. BASHIR® Plus Endovascular Catheter, shown with its infusion basket unexpanded (A) and expanded (B). There are four possible infusion segment lengths on the catheter shaft with infusion holes between the proximal end of the infusion basket and the radiopaque marker (10cm, 20cm, 30cm, or 40cm).

B. Intended Use / Indications for Use

The BASHIR® Plus Endovascular Catheters are intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature enabling the restoration of blood flow in patients with venous thrombus.

C. Contraindications

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

D. Precaution and Warnings

- The BASHIR® Plus Endovascular Catheter must only be used by physicians trained in interventional vascular procedures.
- Do not use the BASHIR® Plus 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® Plus Endovascular Catheter only with the sheath and guidewire sizes indicated in these instructions.
- The BASHIR® Plus 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 2, Page 5). Moving the actuator in the distal direction (away from the operator), while simultaneously pressing the actuator release button, reduces the infusion basket diameter (Figure 3, Page 5).
- 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.
- Verify that the infusion line connector selected corresponds to the desired catheter infusion segment. Select the connector labeled "BASKET" for infusion through the infusion basket. Select the connector labeled "SHAFT" for infusion through the shaft infusion segment.
- Ensure that the BASKET and SHAFT infusion connectors are each 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 and shaft infusion segment.
- 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® Plus 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
    - A 7F or greater dilator and sheath, of the desired length, not to cover the shaft infusion holes
    - Three three-way stopcocks
    - Three infusion pumps prepared with physician-specified fluids to be infused
    - Three 10 cc syringes

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

3. Inspect the entire BASHIR® Plus 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.

   Warning: The labels on the carton and sealed pouch that contains the sterile product must be read carefully to ensure that the desired infusion length is selected before proceeding any further. The infusion segment length is identified on the handle of the 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 2, Page 5). Moving the actuator in the distal direction (away from the operator), while simultaneously pressing the actuator release button, reduces the infusion basket diameter (Figure 3, Page 5).

   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. Identify the two separate infusion lines, one labeled “BASKET” and the other labeled “SHAFT”, attached to the device handle.

6. Attach three-way stopcocks to the BASKET infusion line connector and to the SHAFT infusion line connector. (Figure 4, Page 5).

7. Introduce a 7F 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 longer than 15 cm for general use, not to cover the shaft infusion holes.

8. Withdraw the dilator and the 0.035” guidewire used for sheath placement, leaving the sheath in place.

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

10. 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.

11. Connect the infusion pump lines for the physician-specified fluids to the stopcocks on the BASKET and SHAFT infusion line connectors of the BASHIR® Plus Endovascular Catheter. Start the infusion and verify that fluid exits the infusion holes of the infusion basket and shaft infusion segment.

12. 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® Plus Endovascular Catheter.

G. Instructions for Use

13. Backload the BASHIR® Plus Endovascular Catheter onto the proximal segment of the 0.018” guidewire.

14. Grasp the infusion basket gently between thumb and forefinger. Then insert the BASHIR® Plus Endovascular Catheter into the sheath and advance over the guidewire under fluoroscopic guidance until the infusion basket and shaft infusion segment are placed across the treatment site. The infusion basket is radiopaque and visible under fluoroscopy along its full length. The shaft infusion segment is the shaft section between the proximal end of the infusion basket and a radiopaque marker located proximally. The shaft infusion segment is 10cm to 40cm in length depending on the model selected. The radiopaque marker is located proximal to the infusion basket at 10cm, 20cm, 30cm or 40cm to delineate the shaft infusion segment.

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

15. Retract the sheath to a position proximal to the shaft radiopaque marker to fully expose the infusion basket and shaft infusion segment.

16. 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 2, Page 5). 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 3, Page 5).

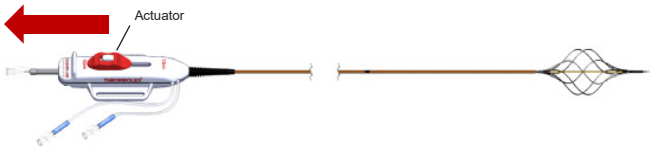

Figure 2. Move actuator in the proximal direction to expand the infusion basket to the desired diameter (diagram not to scale).

Figure 3. 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.

17. Pause the infusion of the physician-specified fluids. Turn the stopcock on the BASKET and SHAFT infusion line connectors closed to the infusion pump and open from the syringe to the catheter Ensure that the catheter and handle are aligned in a manner that does not kink or impede the forward flow of fluids. Perform manual pulse sprays of the physician-specified fluids using a 10 cc syringe via the BASKET and SHAFT infusion connectors as desired. Thereafter, turn the stopcock and continue IV infusion of the physician-specified fluids to maintain patency.
18. Remove the 0.018” guidewire from the body.
19. Attach a third three-way stopcock to the guidewire port and flush catheter with heparinized saline.

    Warning: Hold the Guidewire Port (not the handle) while attaching the three-way stop-cock.

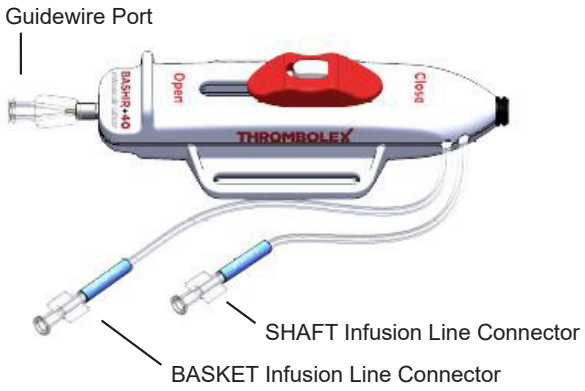

Figure 4. Basket infusion line connector, Shaft infusion line connector and guidewire port.

20. 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. Connect the guidewire port to an infusion pump and infuse heparinized saline at a TKO rate.
21. Set each infusion pump to the desired infusion rate and activate per standard practice. The infusion may continue for up to 24 hours.
22. Ensure that the catheter and handle are aligned in a manner that does not kink or impede the forward flow of fluids.Secure the BASHIR® Plus Endovascular Catheter handle and strain relief boot to the patient using Tegaderm or similar medical adhesive tape. Securely cover the actuator on the handle 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.
23. 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.
24. Retract the fully collapsed BASHIR® Plus Endovascular Catheter into the sheath and remove from the patient.
25. Discard the device after removal using standard methods for biological waste.
26. Withdraw and discard all applicable accessory devices using standard methods for biological waste.