BASHIR® S-B
endovascular catheter

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

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:
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® S-B Endovascular Catheter (Ref. No. 7101) is a device intended for mechanical thrombolysis using a controlled expansion of a distal infusion basket and localized infusion of physician-specified fluids, including thrombolytics, into the peripheral or pulmonary vasculature. The distal infusion basket is 10.00 cm (3.94 in) long in its unexpanded state and consists of an expandable basket with six (6) mini-infusion catheters, each with multiple infusion holes (Table 1). It is used for the delivery of the physician-specified fluids at multiple cross-sectional points of the target vessel at the location of the thrombus (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 basket infusion line connector is also located on the handle.

Table 1. Key Dimensions, BASHIR® S-B Endovascular Catheter (Ref. No. 7101)

French size	7 F (2.3 mm)
Effective length	92.5 cm (36.44 in.)
Infusion basket length	10.00 cm (3.94 in.)
Infusion basket length	39 mm max.

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

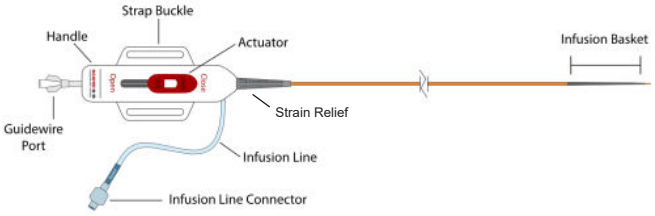

Figure 1. BASHIR® S-B Endovascular Catheter.

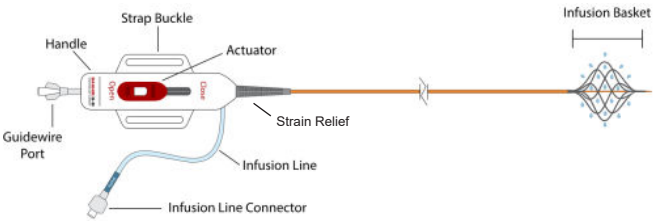

Figure 2. BASHIR® S-B Endovascular Catheter with infusion basket fully expanded.

B. Intended Use / Indications for Use

The BASHIR® Endovascular Catheters and BASHIR® S-B Endovascular Catheters are mechanical thrombolysis catheters indicated for the:

- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism.
- 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® S-B Endovascular Catheter is contraindicated for use in the coronary arteries and the neurovasculature.

D. Precaution and Warnings

- The BASHIR® S-B Endovascular Catheter must only be used by physicians trained in interventional vascular procedures.
- Do not use the BASHIR® S-B Endovascular Catheters with a power injector as catheter damage may occur.
- The 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.
- The 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® S-B Endovascular Catheter only with the sheath and guidewire sizes indicated in these instructions.
- The BASHIR® S-B 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 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 4, 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.
- Ensure that the basket infusion line connector 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 — Treatment of Pulmonary Embolism

Prior to using the device, prepare the BASHIR® S-B Endovascular Catheter appropriately for use in the pulmonary artery. Please refer to published literature for appropriate use of the BASHIR® S-B Endovascular Catheters in pulmonary endovascular cases.

1. Prepare the following additional items according to their manufacturer's instructions for use:
    - A micropuncture kit
    - A 0.035" guidewire, min. 260 cm long
    - An 0.018" guidewire, min. 260 cm long
    - A 7F or greater dilator and sheath, not to exceed 75 cm long but long enough to reach the treatment site.
    - Two 3-way stopcocks
    - Two infusion pumps prepared with physician-specified fluids to be infused
    - Two 10cc syringes
    - A Swan-Ganz or angled pigtail catheter, where pulmonary artery access is anticipated
2. Establish vascular access under ultrasound guidance using a standard micropuncture technique and place a short access sheath.

3. Introduce the 0.035” guidewire into the short sheath. A Swan Ganz or angled pigtail can be passed to the pulmonary artery over this wire. The guidewire is temporarily removed so that pressures can be measured through the lumen of the Swan or pigtail. The 0.035” guidewire is re-inserted and left in place in the desired location at the treatment site and the Swan Ganz or angled pigtail are removed.

4. Exchange the short sheath for a ≤75 cm long sheath and dilator. The 0.035” guidewire is still in place.

   Warning: Do not use a sheath greater than 75 cm long, not to impede opening of the infusion basket.

5. Pass the long sheath and dilator to the desired location over the 0.035” guidewire. Remove the dilator.

6. Inspect the entire BASHIR® S-B 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.

7. 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, 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 4, Page 5).

8. Attach one 3-way stopcock to the basket infusion line connector (Figure 5, Page 5).

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.

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

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

10. Under fluoroscopic guidance, introduce and advance an 0.018” guidewire through the in-place long sheath to beyond the treatment site using the 0.035” guidewire as a “buddy wire.” Then remove the 0.035” guidewire.

11. Using the physician-specified fluid, connect the infusion line of the physician-specified infusion to the stopcock on the basket infusion line connector of the BASHIR® S-B Endovascular Catheter. Start the infusion and verify that fluid exits the infusion holes of the infusion basket. This is to prevent blood clots from blocking the small holes in the infusion basket.

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® S-B Endovascular Catheter.

G. Instructions for BASHIR® S-B Catheter Insertion – Treatment of Pulmonary Embolism

13. Backload the BASHIR® S-B 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® S-B 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 10.0 cm (3.94 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.

15. Retract the long sheath to fully expose the infusion basket.

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 3, Page 5). To collapse the basket, move the actuator in the distal direction (away from the operator) while simultaneously pressing the white actuator release button (Figure 4, Page 5).

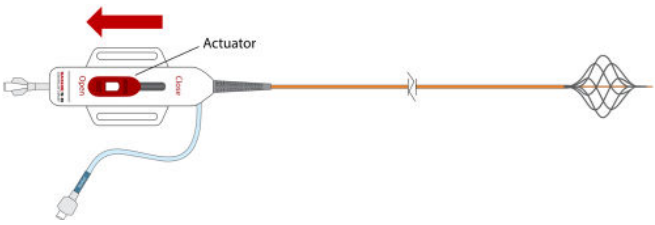

Figure 3. Move actuator in the proximal direction to expand the infusion basket to the desired diameter (diagram not to scale).

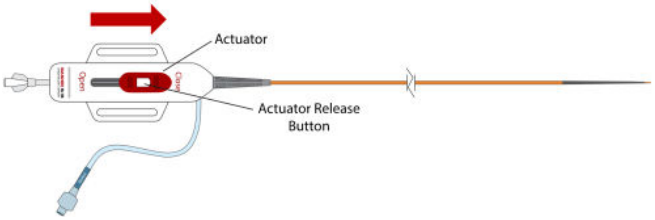

Figure 4. Move actuator in the distal direction while simultaneously pressing the actuator release button to reduce the diameter of the infusion basket. Move actuator fully in the distal direction to completely collapse the infusion basket.

17. **PULSE SPRAYS INTO BASKET:** Pause the infusion of the physician-specified fluid into the infusion basket. Turn the stopcock on the basket infusion line connector closed to the infusion pump and open from the syringe to the catheter. Pulse sprays of the physician-specified fluid may be administered through the stopcock while expanding and then collapsing the basket two times during pulse spray administration using a 10cc syringe. **Ensure that the catheter and handle are aligned in a manner that does not kink or impede the forward flow of fluids.**

18. Remove the 0.018" guidewire. Attach a second three-way stopcock to the guidewire port and flush the guidewire lumen with heparinized saline (Figure 5).

19. **INFUSION THROUGH BASKET:** Thereafter, turn the stopcock to open the infusion path and continue IV infusion of physician specified fluids at the desired rate for up to 8 hours.

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

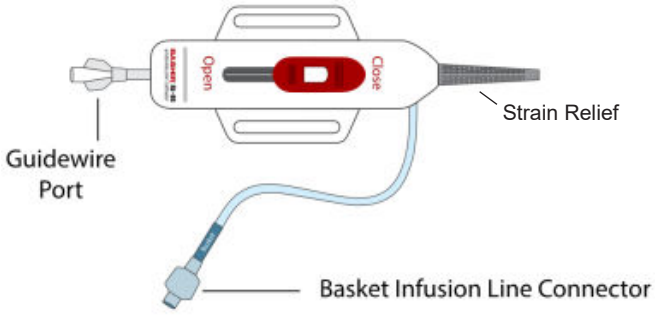

Figure 5. Basket infusion line connector and guidewire port.

20. Pressure and oxygen saturation can be measured from the distal end of the guidewire lumen via the proximal Luer hub on the guidewire port, in which case, connect an infusion pump (TKO) to the guidewire port. Alternatively, cap off the guidewire port.

21. **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® S-B Endovascular Catheter shaft, handle and strain relief 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.

22. Then, place a 4x4 gauze pad under the Luer hub of the guidewire port and stopcock and secure to the patient.

23. 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.

24. **AT THE END OF THE INFUSION:** After the infusion period 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 without simultaneously pressing the actuator release button.

25. Retract the fully collapsed BASHIR® S-B Endovascular Catheter into the sheath and remove from the patient.

26. Discard the device after removal using standard methods for biological waste. Thoroughly back-bleed the sheath and then flush it.

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

H. Preparations for Use — Treatment of Peripheral Thrombus

Prior to using the device, prepare the BASHIR® S-B Endovascular Catheter appropriately for use in the peripheral vasculature. Please refer to published literature for appropriate use of the BASHIR® S-B Endovascular Catheters in peripheral endovascular cases.

1. Prepare the following additional items according to their manufacturer's instructions for use:

    - A micropuncture kit
    - An 0.035" guidewire
    - An 0.018" guidewire
    - A 7F or greater dilator and sheath, not to exceed 75 cm in length but long enough to reach the treatment site
    - Two 3-way stopcocks
    - Two infusion pumps prepared with physician-specified fluids to be infused
    - Two 10cc syringes

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

    Warning: Do not use a sheath greater than 75 cm long, not to impede opening of the infusion basket.

3. Pass the sheath and dilator to the desired location over the 0.035" guidewire. Remove the dilator.

4. Inspect the entire BASHIR® S-B 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.

5. 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 6, 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 7, Page 7).

6. Attach one 3-way stopcock to the basket infusion line connector (Figure 8, Page 7).

7. 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.

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

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

8. 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.

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

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

11. Using the physician-specified fluid, connect the infusion line of the physician-specified infusion to the stopcock on the basket infusion line connector of the BASHIR® S-B Endovascular Catheter. Start the infusion and verify that fluid exits the infusion holes of the infusion basket. This is to prevent blood clots from blocking the small holes in the infusion basket.

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® S-B Endovascular Catheter.

I. Instructions for BASHIR® S-B Catheter Insertion – Treatment of Peripheral Thrombus

13. Backload the BASHIR® S-B 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® S-B 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 10.00 cm (3.94 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.

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

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 6). To collapse the basket, move the actuator in the distal direction (away from the operator) while simultaneously pressing the white actuator release button (Figure 7).

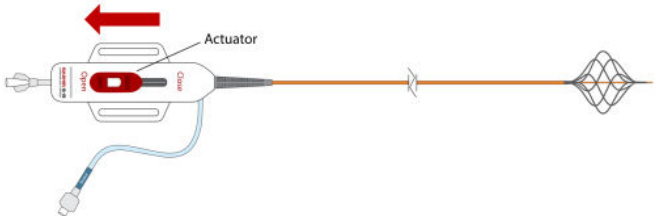

Figure 6. Move actuator in the proximal direction to expand the infusion basket to the desired diameter (diagram not to scale).

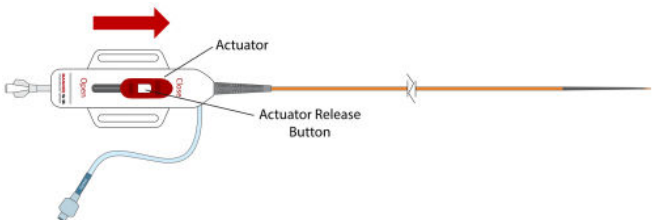

Figure 7. Move actuator in the distal direction while simultaneously pressing the actuator release button to reduce the diameter of the infusion basket. Move actuator fully in the distal direction to completely collapse the infusion basket.

17. **PULSE SPRAYS INTO BASKET:** Pause the infusion of the physician-specified fluid into the infusion basket. Turn the stopcock on the basket infusion line connector closed to the infusion pump and open from the syringe to the catheter. Pulse sprays of the physician-specified fluid may be administered through the stopcock while expanding and then collapsing the basket several times, as determined by the physician, using a 10cc syringe along the length of the vessel being treated. **Ensure that the catheter and handle are aligned in a manner that does not kink or impede the forward flow of fluids.**

18. Remove the 0.018" guidewire. Attach a second three-way stopcock to the guidewire port and flush the guidewire lumen with heparinized saline. (Figure 8).

19. The guidewire port should be capped off.

20. **INFUSION THROUGH BASKET:** Thereafter, turn the stopcock to open the infusion path and continue IV infusion of physician specified fluids at the desired rate for up to 24 hours.

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

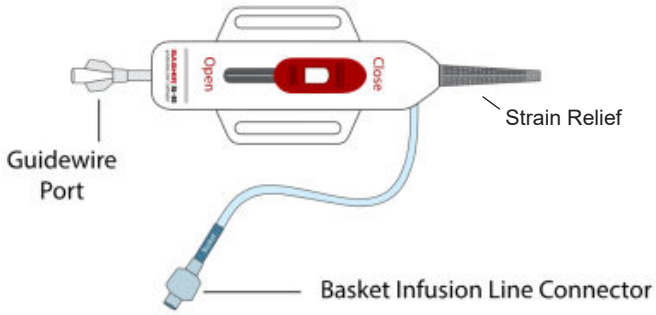

Figure 8. Basket infusion line connector and guidewire port.

21. **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® S-B Endovascular Catheter shaft, handle and strain relief 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.

22. Then, place a 4x4 gauze pad under the Luer hub of the guidewire port and stopcock and secure to the patient.

23. 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.

24. **AT THE END OF THE INFUSION:** After the infusion period 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 without simultaneously pressing the actuator release button.

25. Retract the fully collapsed BASHIR® S-B Endovascular Catheter into the sheath and remove from the patient.

26. Discard the device after removal using standard methods for biological waste. Thoroughly back-bleed the sheath and then flush it.

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