BASHIR® S-B.035 *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.
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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 .035 Endovascular Catheter (Ref. No. 8101) is 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 fluid 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 .035 Endovascular Catheter (Ref. No. 8101)

French size	8 F (2.67 mm)
Effective length	92.5 cm (36.44 in.)
Infusion basket length	10.0 cm (3.94 in.)
Infusion basket length	39 mm max.

The catheter is advanced over a .035” guidewire using standard endovascular interventional techniques and is compatible with standard infusion connectors, accessories and equipment.

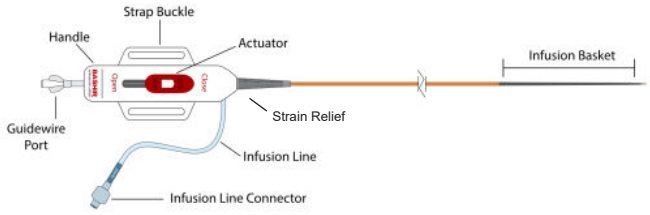

Figure 1. BASHIR® S-B .035 Endovascular Catheter.

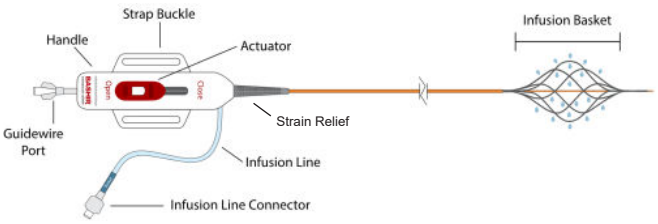

Figure 2. BASHIR® S-B .035 Endovascular Catheter with infusion basket fully expanded.

B. Intended Use / Indications for Use

The BASHIR® .035 Endovascular Catheters and BASHIR® S-B .035 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, including in patients with venous thrombus.

C. Contraindications

The BASHIR® S-B .035 Endovascular Catheter is contraindicated for use in the coronary arteries and the neurovasculature.

D. Precaution and Warnings

- The BASHIR® S-B .035 Endovascular Catheter must only be used by physicians trained in interventional vascular procedures.
- Do not use the BASHIR® S-B .035 Endovascular Catheter 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 .035 Endovascular Catheter only with the sheath and guidewire sizes indicated in these instructions.
- The BASHIR® S-B .035 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 .035 Endovascular Catheter appropriately for use in the pulmonary artery. Please refer to published literature for appropriate use of the BASHIR® S-B .035 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 8F or greater dilator and sheath, not to exceed 70 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
2. Establish vascular access under ultrasound guidance using a standard micropuncture technique and place a short access sheath.

3. Introduce the 8F short sheath over an 0.035” guidewire. A Swan Ganz or angled pigtail can be passed to the pulmonary artery over the .035” wire. The guidewire is temporarily removed so that pressures can be measured through the lumen of the Swan Ganz or pigtail catheter. 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 an 8F ≤70 cm long sheath and dilator.

   Warning: Do not use a sheath longer than 70 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 leaving the guidewire in place.

6. Inspect the entire BASHIR® S-B .035 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 0.035” 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 .035 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 .035 Endovascular Catheter.

G. Instructions for BASHIR® S-B .035 Catheter Insertion – Treatment of Pulmonary Embolism

13. Backload the BASHIR® S-B .035 Endovascular Catheter onto the proximal segment of the 0.035” guidewire.

14. Grasp the infusion basket gently between thumb and forefinger. Then insert the BASHIR® S-B .035 Endovascular Catheter into the sheath and advance over the .035” 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 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).

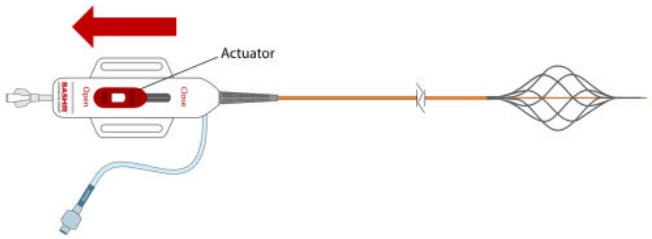

Figure 3. Move actuator in the proximal direction to expand the infusion basket to the desired diameter (diagram not to scale).

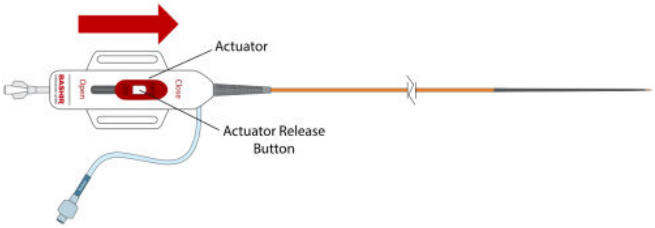

Figure 4. Move actuator in the distal direction while simultaneously pressing the actuator release button to reduce the diameter of the infusion basket. Move actuator fully in the distal direction to completely collapse the infusion basket.

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 the basket is expanded. Then collapse the basket and re-expand it for the second pulse spray 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 0.035" 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.

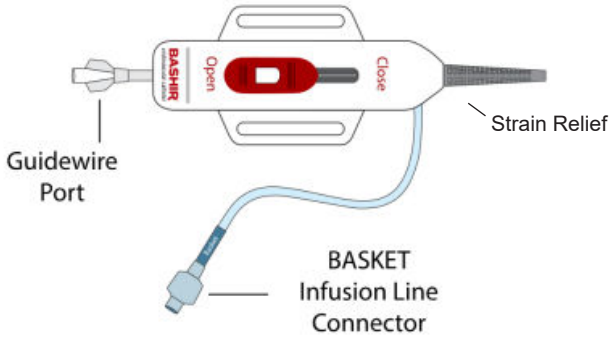

Figure 5. Basket infusion line connector and guidewire port.

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 Keep Open) 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 .035 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 .035 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 .035 Endovascular Catheter appropriately for use in the peripheral vasculature. Please refer to published literature for appropriate use of the BASHIR® S-B .035 Endovascular Catheter 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
   - A 8F or longer dilator and sheath, long enough to reach the treatment site
   - Two 3-way stopcocks
   - One infusion pump 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 longer than 70 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 .035 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. 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 .035 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.

9. 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 .035 Endovascular Catheter.

I. Instructions for BASHIR® S-B .035 Catheter Insertion – Treatment of Peripheral Thrombus

10. Backload the BASHIR® S-B .035 Endovascular Catheter onto the proximal segment of the 0.035" guidewire.

11. Grasp the infusion basket gently between thumb and forefinger. Then insert the BASHIR® S-B .035 Endovascular Catheter into the sheath and advance over the .035" 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.

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

13. 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).

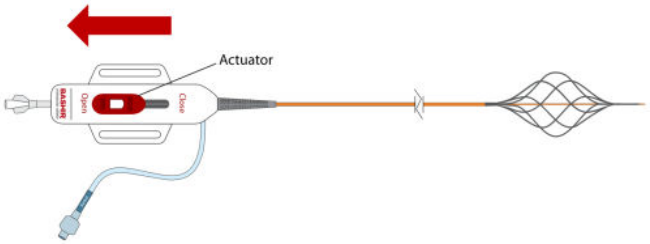

Figure 6. Move actuator in the proximal direction to expand the infusion basket to the desired diameter (diagram not to scale).

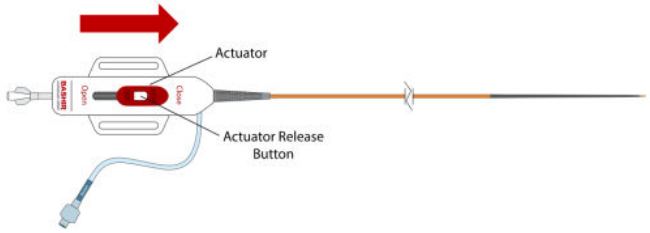

Figure 7. Move actuator in the distal direction while simultaneously pressing the actuator release button to reduce the diameter of the infusion basket. Move actuator fully in the distal direction to completely collapse the infusion basket.

14. **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.**

15. **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.

16. Remove the 0.035” guidewire. Attach a second three-way stopcock to the guidewire port and flush the guidewire lumen with heparinized saline (Figure 8).

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

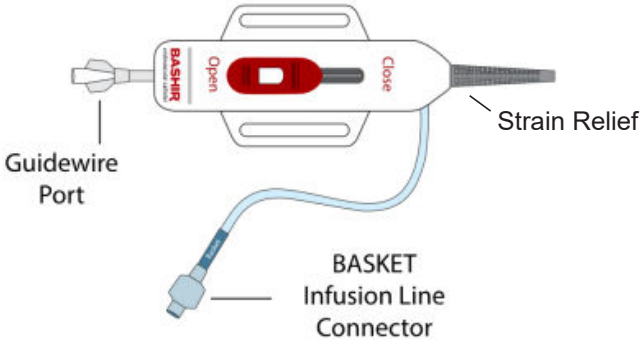

Figure 8. Basket infusion line connector and guidewire port.

17. The guidewire port should be capped off.

18. **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® .035 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.

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

20. 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. **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.

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

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