



AZUR HydroPack™ 18 Peripheral Coil System (Detachable) Instructions for Use

DEVICE DESCRIPTION

The Detachable AZUR HydroPack 18 Peripheral Coil System consists of a coil implant attached to a delivery system. The coils are platinum coils with an inner layer of hydrophilic polymer. The delivery pusher is powered by an AZUR Detachment Controller to selectively detach the coils. The AZUR Detachment Controller is provided separately.

The coil must be delivered only through a wire-reinforced microcatheter with the inner diameter specified.

Table 1

Coil Type	Microcatheter I.D.		Reposition Time
	inches	mm	
AZUR HydroPack 18 System	0.021 - 0.027	0.53 – 0.69	10 minutes

The implantable coil component that remains in the patient following detachment consists of:

Table 2

Implant Material		AZUR HydroPack 18* System
Metallic Substances	Platinum Alloys	≤ 0.58 g
Non-metallic substances	<ul style="list-style-type: none"> • Cross linked copolymer: acrylamide & acrylic acid • polyolefin, adhesive 	≤ 0.005 g
* Approximate content		

INDICATIONS FOR USE / INTENDED USE

The AZUR system is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

CONTRAINDICATIONS

Use of the AZUR system is contraindicated in any of the following circumstances:

- When superselective coil placement is not possible.
- When end arteries lead directly to nerves.
- When arteries supplying the lesion to be treated are not large enough to accept emboli.
- When the A-V shunt is larger than the coil.
- In the presence of severe atheromatous disease.
- In the presence of vasospasm (or likely onset of vasospasm).

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to: hematoma at the site of entry, vessel/aneurysm perforation, unintended parent artery occlusion, incomplete filling, vascular thrombosis, hemorrhage, ischemia, vasospasm, edema, coil migration or misplacement, premature or difficult coil detachment, clot formation, revascularization, post-embolization syndrome, and neurological deficits including stroke and possibly death.

The physician should be aware of these complications and instruct patients when indicated. Appropriate patient management should be considered.

REQUIRED ADDITIONAL ITEMS

- AZUR Detachment Controller
- Wire-reinforced microcatheter with distal tip RO marker, appropriately sized
- Guide catheter compatible with microcatheter
- Steerable guidewires compatible with microcatheter
- 2 rotating hemostatic Y valves (RHV)
- 1 three-way stopcock
- Pressurized sterile saline drip
- 1 one-way stopcock
- Stopwatch or timer

WARNINGS AND PRECAUTIONS

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

- This device should only be used by physicians who have received appropriate training in peripheral vascular embolization procedures
- The AZUR system is supplied sterile and non-pyrogenic unless package is opened or damaged.
- This device is intended for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Angiography is required for pre-embolization evaluation, operative control, and post-embolization follow up.
- Do not advance the delivery pusher with excessive force. Determine the cause of any unusual resistance, remove the AZUR system, and check for damage.
- Advance and retract the AZUR system slowly and smoothly. Remove the entire AZUR system if excessive friction is noted. If excessive friction is noted with a second AZUR system, check the microcatheter for damage or kinking.
- The coil must be properly positioned in the vessel or aneurysm within the specified reposition time from the time the device is first introduced into the microcatheter. If the coil cannot be positioned and detached within this time, simultaneously remove the device and the microcatheter. Positioning the device in a low-flow environment may increase the reposition time.
- If repositioning is necessary, take special care to retract the coil under fluoroscopy in a one-to-one motion with the delivery pusher. If the coil does not move in a one-to-one motion with the delivery pusher, or if repositioning is difficult, the coil may have become stretched and could possibly break. Gently remove and discard the entire device.
- Due to the delicate nature of the coils, the tortuous vascular pathways that lead to certain lesions, and the varying morphologies of the vasculature, a coil may occasionally stretch while being maneuvered. Stretching is a precursor to potential coil breakage and migration.
- If a coil must be retrieved from the vasculature after detachment, do not attempt to withdraw the coil with a retrieval device, such as a snare, into the delivery catheter. This could damage the coil and result in device separation. Remove the coil, microcatheter, and any retrieval device from the vasculature simultaneously.
- Delivery of multiple coils is usually required to achieve the desired occlusion of some vasculatures or lesions. The desired procedural endpoint is usually angiographic occlusion. The filling properties of the coils facilitate angiographic occlusion.
- Tortuosity or complex vessel anatomy may affect accurate placement of the coil.
- The long-term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.
- Always ensure that at least two AZUR Detachment Controllers are available before starting an AZUR system procedure.
- The coil cannot be detached with any power source other than an AZUR Detachment Controller.
- Do **NOT** place the delivery pusher on a bare metallic surface.
- Always handle the delivery pusher with surgical gloves.
- Do **NOT** use in conjunction with radio frequency (RF) devices.

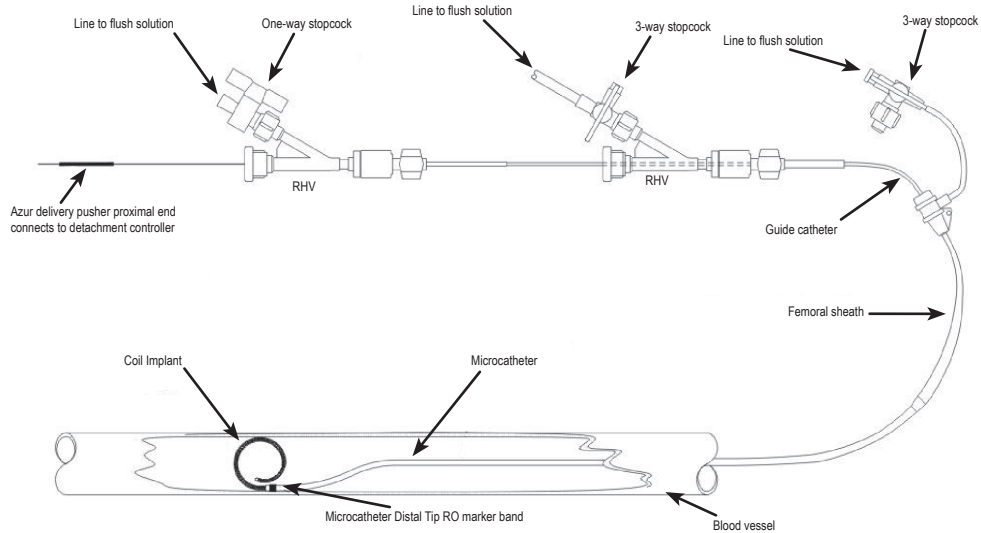


Figure 1 – Diagram of AZUR System Setup

PREPARATION FOR USE

1. Refer to Figure 1 for the set-up diagram.
2. Attach a rotating hemostatic valve (RHV) to the hub of the guiding catheter. Attach a 3-way stopcock to the side arm of the RHV and then connect a line for continuous infusion of flush solution.
3. Attach a second RHV to the hub of the microcatheter. Attach a 1-way stopcock to the sidearm of the second RHV and connect the flush solution line to the stopcock.
4. Open the stopcock and flush the microcatheter with sterile flush solution and then close the stopcock. To minimize the risk of thromboembolic complications, it is critical that a continuous infusion of appropriate sterile flush solution be maintained into the guide catheter, the femoral sheath and the microcatheter.

CATHETERIZATION OF THE LESION

5. Using standard interventional procedures, access the vessel with a guide catheter. The guide catheter should have an inner diameter (ID) large enough to allow for contrast injection while the microcatheter is in place. This will allow for fluoroscopic road mapping during the procedure.
6. Select a microcatheter with the appropriate inner diameter. After the microcatheter has been positioned inside the lesion, remove the guidewire.

COIL SIZE SELECTION

7. Perform fluoroscopic road mapping.
8. Measure and estimate the size of the lesion to be treated.
9. The diameter of the first coil should never be less than the width of the aneurysm neck or the diameter of the vessel.
10. For aneurysm occlusion, the diameter of the second coils should never be less than the width of the aneurysm neck or the propensity for the coils to migrate may be increased.
11. For vessel occlusion, select the second coil length to adequately fill at the target lesion.
12. Correct coil selection increases effectiveness and patient safety. Occlusive efficiency is, in part, a function of compaction and overall coil mass. In order to choose the optimum coil for any given lesion, examine the pre-treatment angiograms. The appropriate coil size should be chosen based upon angiographic assessment of the diameter of the target or parent vessel, aneurysm dome and aneurysm neck. Note: The coils include an inner layer of a hydrophilic polymer, which will expand to fill the internal space within the coil.

PREPARATION OF THE AZUR SYSTEM FOR DELIVERY

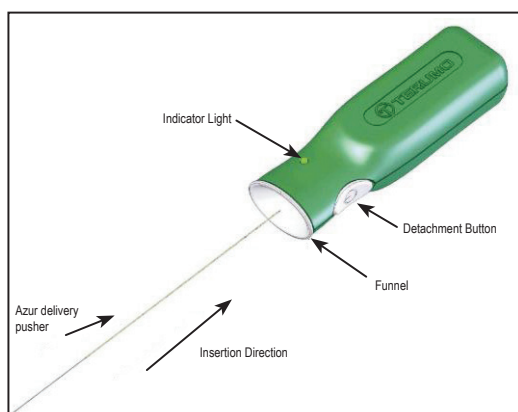


Figure 2 – Azur Detachment Controller

13. Remove the AZUR Detachment Controller from its protective packaging. Pull the white pull-tab from the side of the detachment controller. Discard the pull-tab and place the detachment controller in the sterile field. The AZUR Detachment Controller is packaged separately as a sterile device. **Do not use any power source other than the AZUR Detachment Controller to detach the coil. The AZUR Detachment Controller is intended to be used on one patient. Do not attempt to re-sterilize or otherwise re-use the AZUR Detachment Controller.**
14. Remove dispenser hoop from sterile packaging making sure not to contaminate the device. Attach a syringe to the flush port on the dispenser hoop and flush the hoop with a minimum of 3 cc of saline
15. Prior to using the device, remove the proximal end of the delivery pusher from the packaging hoop. Use care to avoid contaminating this end of the delivery pusher with foreign substances such as blood or contrast. Firmly insert the proximal end of the delivery pusher into the funnel section of the AZUR Detachment Controller. See Figure 2. **Do not push the detachment button at this time.**
16. Wait three seconds and observe the indicator light on the detachment controller.
 - If the green light does not appear or if a red light appears, replace the device.
 - If the light turns green, then turns off at any time during the three-second observation, replace the device.
 - If the green light remains solid green for the entire three-second observation, continue using the device.
17. Hold the device just distal to the shrink-lock and pull the shrink-lock proximally to expose the tab on introducer sheath. See Figure 3.

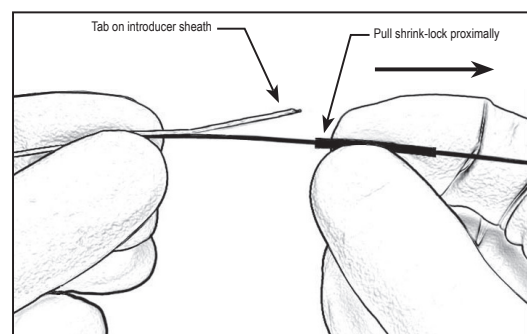


Figure 3 – Pull Shrink Lock Proximally

18. Slowly advance the coil out of the introducer sheath and inspect the coil for any irregularities or damage. **If any damage to the coil or delivery pusher is observed, DO NOT use the device.**
19. With the distal end of the introducer sheath pointed downward, gently retract the implant back completely into the introducer sheath about 1 to 2 cm.

INTRODUCTION AND DEPLOYMENT OF THE AZUR SYSTEM

20. Open the RHV on the microcatheter just enough to accept the introducer sheath of the AZUR system.
21. Insert the introducer sheath of the AZUR system through the RHV. Flush the introducer until it is completely purged of air and saline flush exits the proximal end.
22. Seat the distal tip of the introducer sheath at the distal end of the microcatheter hub and close the RHV **lightly** around the introducer sheath to secure the RHV to the introducer.

Do not over-tighten the RHV around the introducer sheath. Excessive tightening could damage the device.

23. Push the coil into the lumen of the microcatheter. Use caution to avoid catching the coil on the junction between the introducer sheath and the hub of the microcatheter. **Initiate timing using a stopwatch or timer at the moment the device enters the microcatheter. Detachment must occur within the specified reposition time.**
24. Push the AZUR system through the microcatheter until the proximal end of the delivery pusher meets the proximal end of the introducer sheath. Loosen the RHV. Retract the introducer sheath just out of the RHV. Close the RHV around the delivery pusher. Slide the introducer sheath completely off of the delivery pusher. Use care not to kink the delivery system. To prevent premature hydration of the AZUR system, ensure that there is flow from the saline flush.
25. Discard the introducer sheath. The AZUR system cannot be re-sheathed after introduction into the microcatheter.
26. At this time, fluoroscopic guidance should be initiated. Depending on length of microcatheter used, fluoroscopy initiation may be delayed to minimize exposure.
27. Under fluoroscopic guidance, slowly advance the coil out the tip of the microcatheter. Continue to advance the coil into the lesion until optimal deployment is achieved. Reposition if necessary. If the coil size is not suitable, remove and replace with another device. If undesirable movement of the coil is observed under fluoroscopy following placement and prior to detachment, remove the coil and replace with another more appropriately sized coil. Movement of the coil may indicate that the coil could migrate once it is detached. **DO NOT** rotate the delivery pusher during or after delivery of the coil into the vasculature. Rotating the delivery pusher may result in a stretched coil or premature detachment of the coil from the delivery pusher, which could result in coil migration. Angiographic assessment should also be performed prior to detachment to ensure that the coil mass is not protruding into undesired vasculature.
28. Complete the deployment and any repositioning so that the coil will be detached within the reposition time specified in Table 1. After the specified time, the swelling of the hydrophilic polymer may prevent passage through the microcatheter and damage the coil. **If the coil cannot be properly positioned and detached within the specified time, simultaneously remove the device and the microcatheter.**
29. Advance the coil into the desired site until the radiopaque marker on the delivery pusher is aligned or slightly distal of microcatheter distal tip RO marker, positioning the detachment zone just outside the microcatheter tip. See Figure 4.
30. Tighten the RHV to prevent movement of the coil.
31. Verify repeatedly that the distal shaft of the delivery pusher is not under stress before coil detachment. Axial compression or tension could cause the tip of the microcatheter to move during coil delivery. Catheter tip movement could cause the aneurysm or vessel to perforate.

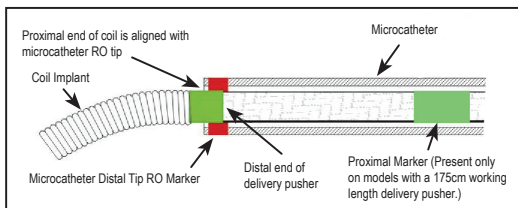


Figure 4 – Position of Marker Bands for Detachment

DETACHMENT OF THE COIL

32. The AZUR Detachment Controller is pre-loaded with battery power and will activate when a delivery pusher is properly connected. It is in a "power off" mode when no delivery pusher is attached. It is not necessary to push the button on the side of the AZUR Detachment Controller to activate it.
33. Verify that the RHV is firmly locked around the delivery pusher before attaching the AZUR Detachment Controller to ensure that the coil does not move during the connection process.
34. Although the delivery pusher's gold connectors are designed to be compatible with blood and contrast, every effort should be made to keep the connectors free of these items. If there appears to be blood or contrast on the connectors, wipe the connectors with sterile water or saline solution before connecting to the AZUR Detachment Controller.
35. Connect the proximal end of the delivery pusher to the AZUR Detachment Controller by firmly inserting the proximal end of the delivery pusher into the funnel section of the AZUR Detachment Controller. See Figure 2.
36. When the AZUR Detachment Controller is properly connected to the delivery pusher, a single audible tone will sound and the light will turn green to signal that it is ready to detach the coil. If the detachment button is not pushed within 30 seconds, the solid green light will slowly flash green. Both flashing green and solid green lights indicate that the device is ready to detach. If the green light does not appear, check to ensure that the connection has been made. If the connection is correct and no green light appears, replace the AZUR Detachment Controller.
37. Verify the coil position before pushing the detachment button.

38. Push the detachment button. When the button is pushed, an audible tone will sound and the light will flash green.
39. At the end of the detachment cycle, three audible tones will sound and the light will flash yellow three times. This indicates that the detachment cycle is complete. If the coil does not detach during the detachment cycle, leave the AZUR Detachment Controller attached to the delivery pusher and attempt another detachment cycle when the light turns green.
40. The light will turn red after the number of detachment cycles specified on the AZUR Detachment Controller labeling. **DO NOT** use the AZUR Detachment Controller if the light is red. Discard the AZUR Detachment Controller and replace it with a new one when the light is red.
41. Verify detachment of the coil by first loosening the RHV valve, then pulling back slowly on the delivery system and verifying that there is no coil movement. If the implant did not detach, do not attempt to detach it more than two additional times. If it does not detach after the third attempt, remove the delivery system.
42. After detachment has been confirmed, slowly retract and remove the delivery pusher. **Advancing the delivery pusher once the coil has been detached involves the risk of aneurysm or vessel rupture. Do NOT advance the delivery pusher once the coil has been detached.**
43. Verify the position of the coil angiographically through the guide catheter.
44. Additional coils may be deployed into the lesion as described above. Prior to removing the microcatheter from the treatment site, place an appropriately sized guidewire completely through the microcatheter lumen to ensure that no part of the last coil remains within the microcatheter.

The physician has the discretion to modify the coil deployment technique to accommodate the complexity and variation in embolization procedures. Any technique modifications must be consistent with the previously described procedures, warnings, precautions and patient safety information.

SPECIFICATIONS FOR AZUR DETACHMENT CONTROLLER

- Output voltage: 8 ± 1 VDC
- Cleaning, preventative inspection, and maintenance: The AZUR Detachment Controller is a single use device, preloaded with battery power, and packaged sterile. No cleaning, inspection, or maintenance is required. If the device does not perform as described in the Detachment section of these Instructions, discard the AZUR Detachment Controller and replace it with a new unit.
- The AZUR Detachment Controller is a single use device. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Batteries are pre-loaded into the AZUR Detachment Controllers. Do not attempt to remove or replace the batteries prior to use.
- After use, dispose of the AZUR Detachment Controller in a manner consistent with local regulations.

PACKAGING AND STORAGE

The AZUR system is placed inside a protective, plastic dispenser hoop and packaged in a pouch and unit carton. The AZUR system and dispenser hoop will remain sterile unless the package is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

Visually inspect all the sterile barrier systems, that are labeled as sterile, immediately prior to use. Do not use if breaches in sterile barrier system integrity are evident, such as pouch is damaged or open.

The AZUR Detachment Controller is packaged separately in a protective pouch and carton. The AZUR Detachment Controller has been sterilized; it will remain sterile unless the pouch is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

After use, dispose of the delivery system and detachment controller in accordance with hospital, administrative and/or local government policy

SHELF LIFE

See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

MRI SAFETY INFORMATION



Non-clinical testing has demonstrated that the AZUR Peripheral Embolization Coil System implant is **MR conditional**. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined above, the AZUR Peripheral Embolization Coil System implant is expected to produce a maximum temperature rise of 2.3°C after 15-minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the AZUR Peripheral Embolization Coil System implant extends approximately 5-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. MicroVention, Inc. recommends that the patient register the MR conditions disclosed in this IFU with the Medialert Foundation or equivalent organization.

MATERIALS

The AZUR system does not contain latex or PVC materials.

ADDITIONAL NOTICE TO USER

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established
- *Permanent implant. Follow-up required at the discretion of the physician*

SYMBOLS

	Batch code
	Catalogue Number
	Content
	Sterilized Using Irradiation
	Do Not Re-use
	Do Not Resterilize
	Use-by Date
	Date of Manufacture
	Country of Manufacture
	Consult instructions for use
	Manufacturer
	Authorized representative in the European Community/European Union
	MR Conditional
	Non-pyrogenic
	For Prescription Use Only
	Medical Device
	Unique Device Identifier
	Do not use if package is damaged and consult instructions for use
	Importer
	Distributor
	Single sterile barrier system with protective packaging outside
	Patient Identification
	Health care center or doctor
	Date
	Patient Information Website

WARRANTY

Terumo warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for particular purpose. Handling, storage, cleaning, and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure, and other matters beyond Terumo's control directly affect the device and the results obtained from its use. Terumo's obligation under this warranty is limited to the repair or replacement of this device through its expiration date. Terumo shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. Terumo neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Terumo assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

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