TERUMO®

Azur® Peripheral Coil System
Helical HydroCoil® Embolization System (Pushable)
Instructions for Use

DEVICE DESCRIPTION

The Pushable Azur Peripheral Coil System (Azur system) consists of a coil implant packaged in a coil introducer along with an introducer stylet. The coil is platinum-based with an outer layer of hydrogel polymer.

The Azur system is available in helical 18-system and helical 35-system configurations. Both configurations are available in a broad range of secondary diameters and lengths to meet the needs of the physician. Each system must be delivered through a microcatheter or catheter within the specified ID range, using a specified guidewire size.

System	Catheter/Microcatheter ID	
	inches	mm
18-system	0.021 – 0.022	0.53 – 0.56
35-system	0.041 – 0.047	1.04 – 1.19

System	Guidewire OD	
	inches	mm
18-system	0.018	0.46
35-system	0.035	0.89

INDICATIONS FOR 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.

This device should only be used by physicians who have undergone training in the use of the Azur system for embolization procedures as prescribed by a representative from Terumo or a Terumo-authorized distributor.

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, unintentional occlusion of the parent artery, incomplete filling, emboli, hemorrhage, ischemia, vasospasm, edema, coil migration or misplacement, clot formation, revascularization, post-embolization syndrome, and neurological deficits including stroke and possibly death.

REQUIRED ADDITIONAL ITEMS

- Appropriately-sized catheter/microcatheter (with wire reinforcement required for delivery through tortuous vasculature)
- Steerable guidewire compatible with coil system and delivery catheter/microcatheter
- Rotating hemostatic Y valve (RHV)
- Sterile saline
- Pressurized sterile saline drip
- One-way stopcock
- 1cc syringe

WARNINGS AND PRECAUTIONS

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

- The Azur system is sterile and non-pyrogenic unless the unit package is opened or damaged.
- The Azur system 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. Fluoroscopic roadmapping is recommended to achieve optimal device placement.
- Always inspect the Azur system prior to both preparation and insertion to ensure that the coil has not shifted within the introducer or migrated into the introducer caps. If the coil is not secure within the introducer prior to both the preparation and introduction processes, damage may result.
- Hydration of the Azur system prior to use is **mandatory**. A 3-minute hydration period is required to soften the coil. Failure to hydrate may result in the coil not taking its secondary shape, which can result in deployment away from the intended location, migration, or protrusion outside the delivery location.
- The coil must be delivered through a compatibly-sized catheter or microcatheter with a PTFE inner surface coating using a compatibly-sized guidewire. Failure to correctly size the delivery system may result in damage to the device and necessitate removal of both the device and delivery catheter from the patient.
- Always select a wire-reinforced delivery catheter/microcatheter when delivering the coil through highly tortuous vasculature. Non-reinforced catheters may ovalize under such circumstances, potentially resulting in coil damage and necessitating removal of both the device and delivery catheter from the patient.
- Do not use a syringe to deliver the coil. The coil is intended to be delivered using a compatible guidewire only. Delivery via syringe injection may result in the coil not taking its secondary shape, which can result in deployment away from the intended location, migration, or protrusion outside the delivery location.
- Do not advance the coil with excessive force. If unusual resistance is noted during advancement, determine its cause before proceeding by verifying the appropriate delivery catheter and guidewire are being used, and that both are free from damage and kinking. If necessary, replace the delivery catheter, coil, and/or guidewire before proceeding.
- The coil is not retractable or repositionable. If a coil must be retrieved from the vasculature after deployment, 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.
- If the coil and/or pushing guidewire get stuck within the delivery catheter lumen, do not continue advancing. Remove the catheter, and replace the catheter, coil, and/or guidewire when necessary.
- Delivery of multiple coils is generally required to achieve the desired occlusion of some vessels, aneurysms, and vascular lesions. The desired procedural endpoint is angiographic occlusion. The filling properties of the coil facilitate angiographic occlusion and reduce the need to tightly pack. Multiple embolization procedures may be required to achieve the desired occlusion of some vessels/vascular lesions.

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- 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. Care should be taken to retain the device in the intravascular space.
- Always advance an appropriately-sized guidewire through the delivery catheter after deployment to ensure that no part of the coil remains within the catheter prior to delivering the next coil or removing the catheter from the patient.

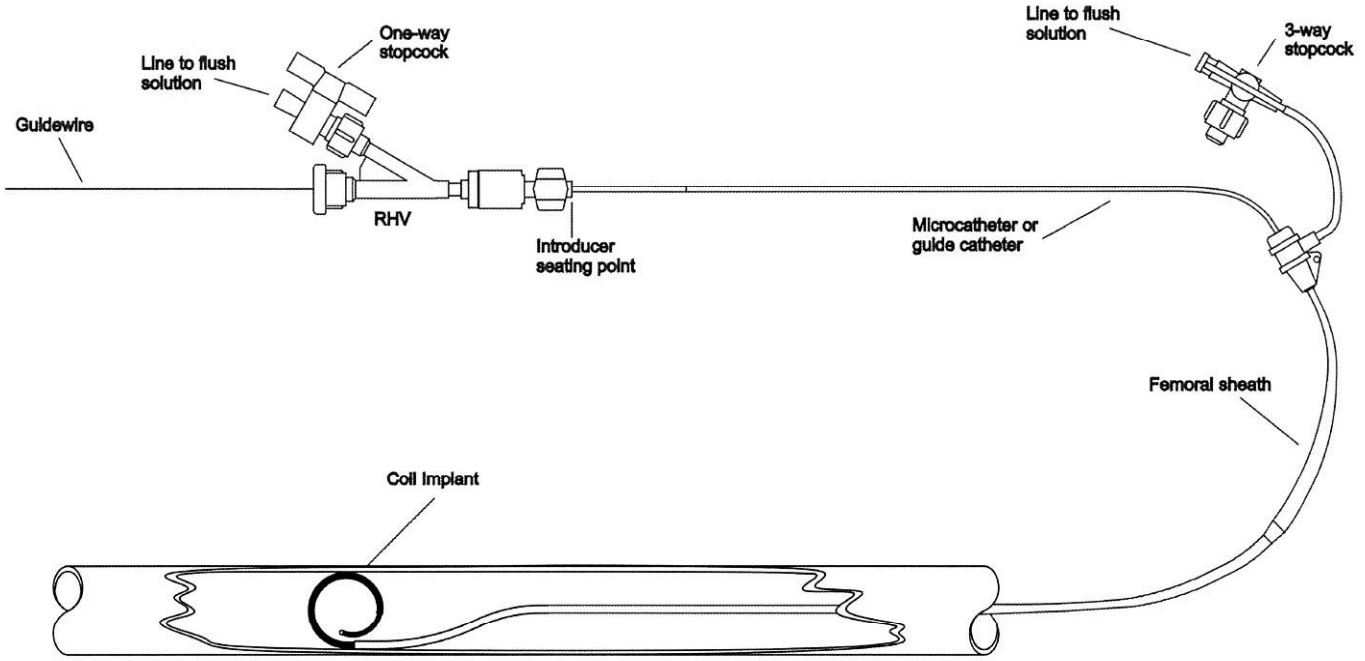


Diagram of Azur System Setup

PREPARATION FOR USE

1. Refer to the setup diagram.
2. Select the catheter or microcatheter to be used for coil delivery. Select a compatible pushing guidewire.
3. Attach an RHV to the hub of the delivery catheter/microcatheter. Attach a one-way stopcock to the side arm of the RHV and connect the flush solution line to the stopcock. (If fluoroscopic roadmapping is being used, an appropriate guide catheter with attached RHV and flush solution line must be incorporated as well.)
4. Open the stopcock and flush the delivery catheter with sterile flush solution. 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 delivery catheter (and femoral sheath, if present).

CATHETERIZATION OF THE LESION

5. Access the parent vessel or vascular structure using standard interventional procedures.
6. Position the delivery catheter for pushable coil deployment as close to the target lesions as possible, using standard technique. Remove the guidewire, if used.

COIL SIZE SELECTION

7. Measure or estimate the size of the vessel or lesion to be treated.
8. Select appropriately sized coils. The diameter of the first and second coils placed should never be less than the diameter of the vessel to be treated or less than the neck width of the aneurysm to be treated, or the propensity for the coils to migrate may be increased. For vessel occlusion, it is suggested that the diameter of the initial coil placed be slightly larger than the actual vessel diameter to prevent displacement or migration. For aneurysm treatment, coils placed within the aneurysm sac must not be larger than the dome size, or protrusion of the coil from the sac may result.
9. 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 treatment site. For vessel occlusion, the diameter of the vessel must be considered. In the case of aneurysms, diameter of the parent vessel, aneurysm dome size, and aneurysm neck width must be considered.

   NOTE: The coil has an outer layer consisting of a hydrophilic polymer. As a result, the secondary coil diameter (dimension 'A' on the package label) will increase by approximately 0.5 mm following full hydration (approx. 20 minutes).

PREPARATION FOR DELIVERY

10. Remove both the coil (in its introducer) and stylet from the protective pouch.
11. Verify the cap is present and secure on the distal end of the introducer and that the introducer is free from damage. **If any damage is observed, DO NOT use the system.**
12. Verify the coil is properly positioned in the introducer. If the coil has migrated proximally into the introducer hub, gently tap the distal end of the introducer onto a flat surface until the proximal end is no longer visible in the hub. If it has migrated distally into the cap, gently tap the proximal end of the introducer onto a flat surface until the distal end returns to the tube.
13. Remove the proximal cap from the introducer hub.
14. Fill a 1-cc syringe with saline. Connect the syringe to the introducer hub. Hold the introducer in a level position and slowly and gently inject saline until saline emerges from the vented distal cap. Allow the coil to remain in the introducer for 3 minutes, leaving the syringe attached. This helps

ensure coil hydration and softening, which allows the coil to quickly take its secondary shape upon delivery. Verify that the coil has not migrated into the hub or distal cap prior to proceeding.

NOTE: Do not overpressurize the introducer during hydration by holding the introducer upright or injecting too quickly. Doing so may result in migration of the coil into the distal cap or premature removal of the cap, which may result in coil damage.

INTRODUCTION AND DEPLOYMENT OF THE AZUR SYSTEM

NOTE: Do not proceed with coil introduction and deployment until after completion of the 3-minute saline hydration period.

15. Open the RHV on the delivery catheter just enough to accept the introducer.
16. Verify that the syringe is still attached to the introducer. Remove the distal cap and insert the introducer through the RHV. Seat the distal tip of the introducer in the ID of the delivery catheter hub and lightly close the RHV around the introducer to secure it in place. **The introducer must be seated in the hub prior to tightening the RHV. If the introducer is not seated, the coil may get caught in the resulting gap, potentially causing damage and inability to complete insertion.**
17. Remove the syringe from the introducer hub and immediately insert the stylet. Using the stylet, push the coil through the introducer, RHV, and catheter hub, into the lumen of the delivery catheter. Advance the stylet completely, until its shaped end seats on the introducer hub. This will ensure that the coil has been fully inserted into the catheter lumen. If the coil does not advance easily into the catheter lumen, rotate the introducer ½ turn while keeping it seated within the catheter hub, and advance the coil with the stylet. Use caution to avoid catching the coil on the junction between the introducer and the delivery catheter hub. Once the coil has been introduced into the delivery catheter lumen, **no more than 3 minutes must pass prior to coil delivery**.
18. Remove and discard the coil introducer and stylet. To prevent premature expansion of the coil, ensure that there is continuous intralumenal flow from the saline flush.
19. Insert an appropriately-sized pushing guidewire through the RHV. Using the guidewire, slowly advance the coil through the delivery catheter until it exits the catheter tip. Continue to slowly advance the coil into the lesion or vessel, adjusting catheter positioning as necessary, until optimal deployment is achieved. Complete the deployment within 3 minutes. After 3 minutes, swelling of the hydrophilic polymer may prevent passage through the delivery catheter and result in damage to the coil.

    NOTE: It is recommended to secure the catheter in place during coil advancement and delivery to prevent the catheter tip from moving away from the intended delivery location.
20. Once the coil has been deployed and prior to removing the delivery catheter, advance the guidewire through the catheter tip to verify that no part of the coil remains within the catheter lumen.

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.

PACKAGING AND STORAGE

The coil is provided in a capped coil introducer, and, together with a stylet, is packaged inside a protective pouch. There are three pouched devices in each unit carton. The coil, the coil introducer, and the stylet all remain sterile unless the package is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

SHELF LIFE

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

MR INFORMATION

The coil implant has been determined to be **MR conditional** according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08.

Non-clinical testing demonstrated that the coil implant is **MR conditional**. A patient can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient field of 720 Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the coil implant produced a maximum temperature rise of 1.7°C during MRI performed for 15 minutes of scanning in the 3 Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system.

Therefore, the MRI-related heating experiments for the coil implant at 3 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than 1.7°C.

Image Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the coil implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence: *Plane Orientation:*	*T1-SE* *Parallel*	*T1-SE* *Perpendicular*	*GRE* *Parallel*	*GRE* *Perpendicular*
Signal Void Size:	*511 mm^2*	*80 mm^2*	*633 mm^2*	*179 mm^2*

Terumo Corporation recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation or equivalent organization.

MATERIALS

The Azur system does not contain latex or PVC materials.

SYMBOLS

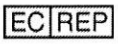
LOT	Lot Number
REF	Order Number
CONT	Content
STERILE R	Sterilized Using Irradiation
	Do Not Reuse
	Use-by Date


Date of Manufacture


Attention, Consult Accompanying Documents


CE Mark


Manufacturer


Authorized European Representative


MR Conditional


Non-pyrogenic


Upper limit of temperature

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.

Prices, specifications and model availability are subject to change without notice.

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