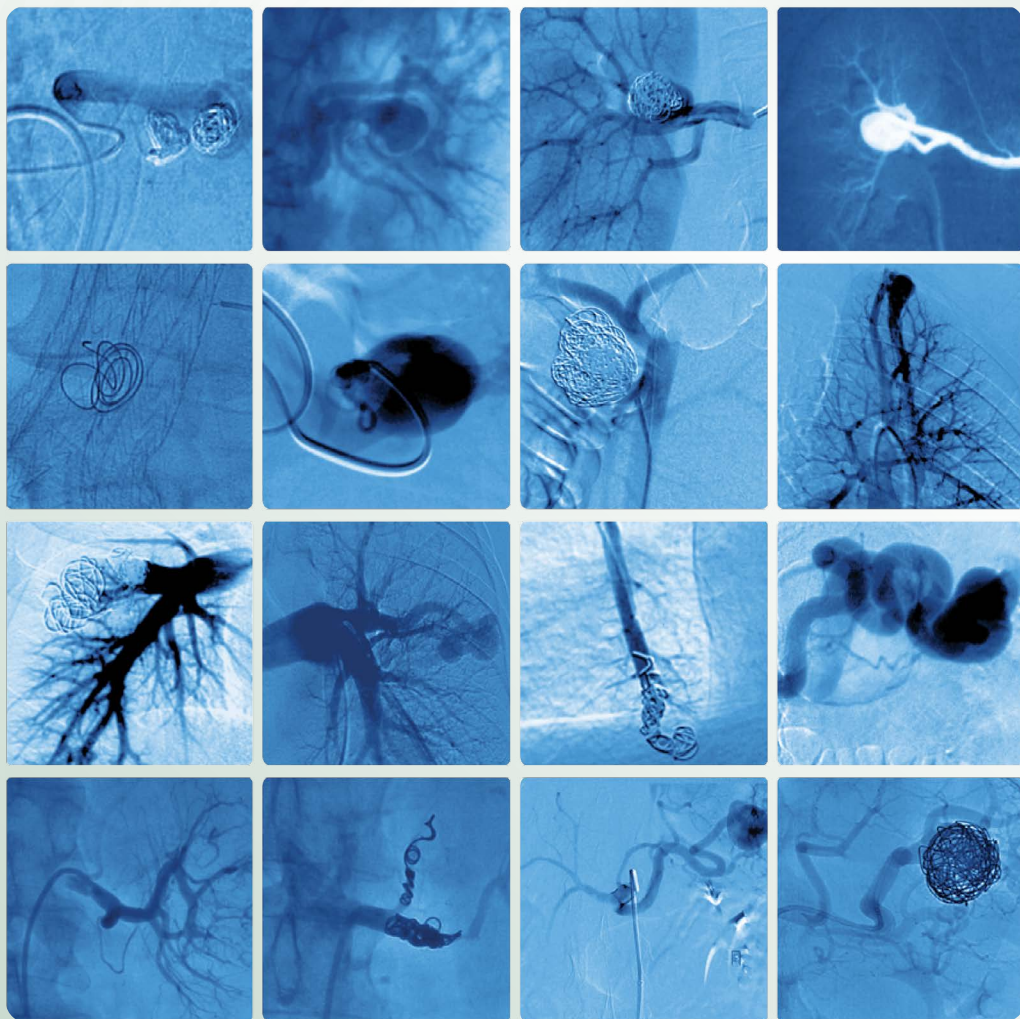


# AZUR<sup>®</sup>

Peripheral HydroCoil Embolization System



## TAKE CONTROL OF EMBOLIZATION

 **TERUMO**  
INTERVENTIONAL  
SYSTEMS

# EMBOLIZATION PROCEDURES POSE CHALLENGES ...

Every patient and every situation is different, prompting key questions:

- What is your goal for the procedure?
- What challenges or complications are you facing?
- What is the effect of a failed embolization?

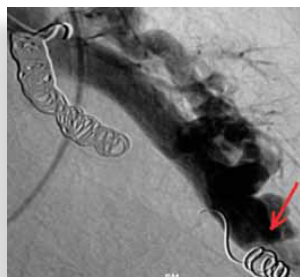
## COMMON CHALLENGES:



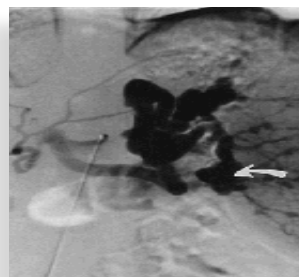
Occlusion of the vessel



Recanalization



Migration of the coil



Challenging anatomy



Patient considerations

TAKE CONTROL WITH THE  
AZUR® PERIPHERAL HYDROCOIL EMBOLIZATION SYSTEM



# THE POWER OF HYDROGEL

The only coil with patented Hydrogel technology.

AZUR combines a platinum coil and an expandable, biocompatible hydrogel polymer. Together these elements provide a stable platform for blood stasis, thrombus organization and neointima formation.<sup>1,2,3</sup>



## PRE-EXPANSION

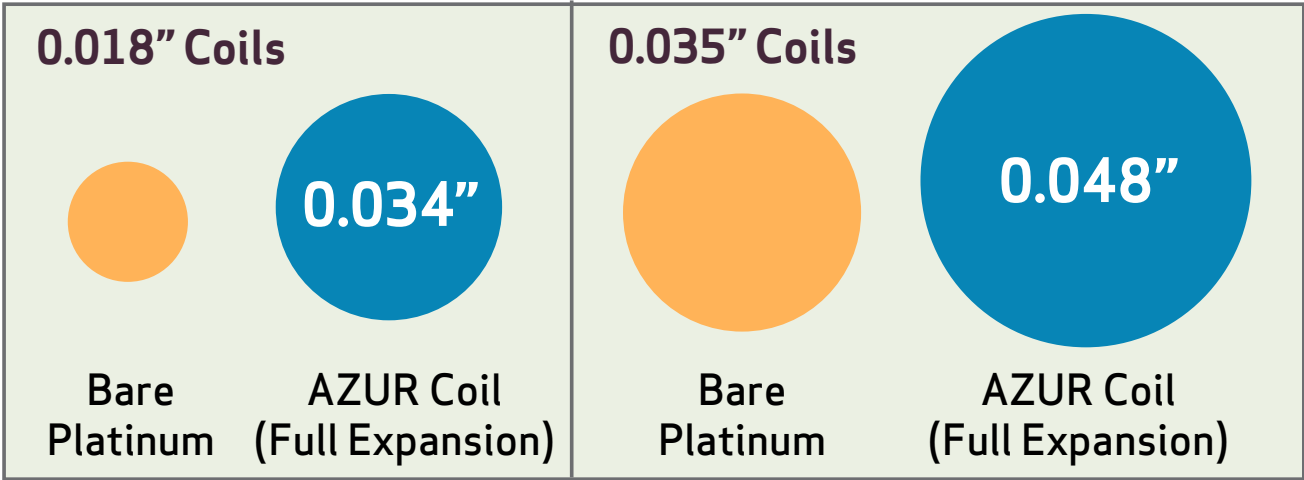


## POST-EXPANSION



**AZUR swells four to five times in size, once in contact with blood.\***  
Unlike any other peripheral coil, AZUR delivers superior filling volume and packing density.<sup>3,4</sup>

## CROSS-SECTIONAL COMPARISONS

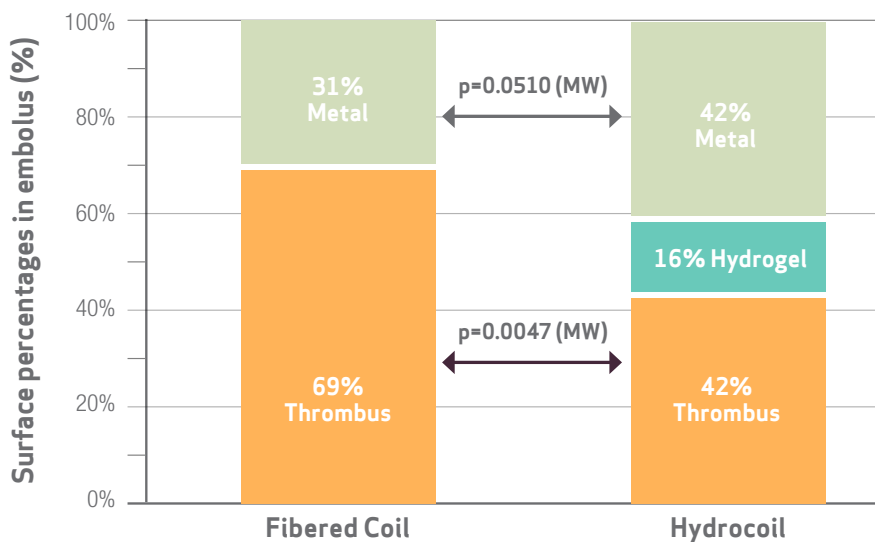


# CONTROL OCCLUSION WITH HYDROGEL

AZUR with hydrogel allows the body's own blood to expand the hydrocoil, creating a mechanical and sustainable occlusion.

- Volumetric filling with hydrogel reduces reliance on thrombus for embolization as shown in a recent animal study<sup>5</sup>
- Thrombus may be slow to form in coagulopathic patients
- Thrombolytic processes may cause recurrence [reperfusion] following coil therapy (as seen in in-vivo study)<sup>6</sup>

## PATHOLOGY OF THE OCCLUSION<sup>5</sup>



- Hydrogel provides a biologically inert scaffolding for natural tissue proliferation<sup>1</sup> including neointima formation and smooth muscle cell migration<sup>7</sup>

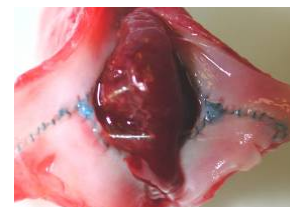
## WHY AZUR?

AZUR Hydrocoils provide volumetric filling with less reliance on thrombus, resulting in an occlusion that supports natural tissue proliferation.

## TIME LAPSE INTRALUMINAL VIEW OF A HYDROGEL OCCLUSION<sup>8</sup>



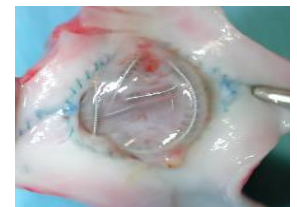
Day 0



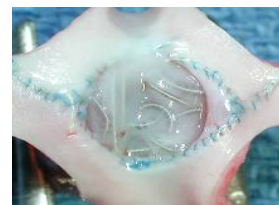
Day 7



2 Weeks



1 Month



2 Months



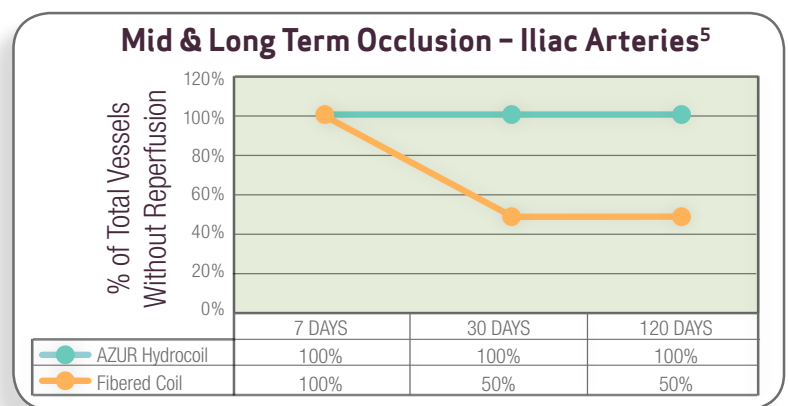
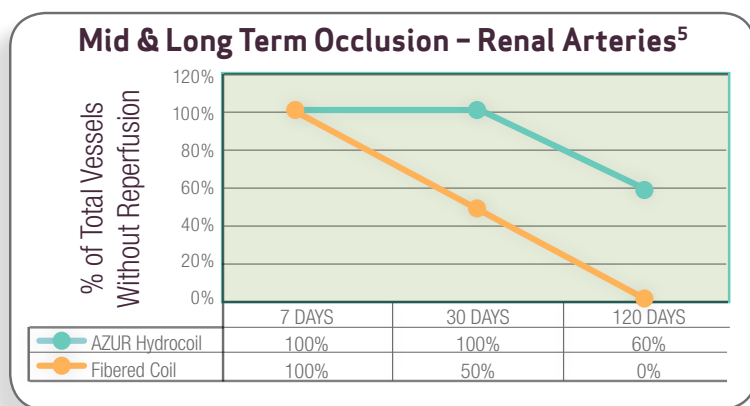
3 Months

Canine Bifurcation Model, Beth Israel. 6 aneurysms in genetically identical dogs were embolized using the HydroCoil. The picture shows the tissue growth in 6 different points of time.

# MINIMIZE REPERFUSION WITH HYDROGEL

**AZUR Hydrocoils creates a mechanical occlusion that may be less susceptible to foreign body response when compared to natural thrombus alone.**

- A recent animal study shows an occlusion created with thrombus weakens over time as the body actively works to break it down<sup>5</sup>
- Reperfusion occurs in as many as 15% of PAVMs after initially successful [embolic] treatment<sup>9</sup>
- Patients with reperfusion continue to be at risk and require repeat embolotherapy<sup>9</sup>



## WHY AZUR?

**AZUR Hydrocoils show lower rates of mid and long-term recanalization than coils that rely on thrombus for occlusion as shown in an animal study<sup>5</sup>**

## ADDRESS THE PATIENT CONSIDERATION WITH HYDROGEL

**Different disease states present different challenges.**

- AZUR allows for mechanical occlusion to help address individual patient needs
  - PAVMS, Aneurysms, AV fistulas, Varicoceles, etc.
  - An option for patients on Anticoagulants



# CONTROL THE COIL

**AZUR offers true detachability especially in high flow vessels where catheter seating is tenuous.**

- Imprecise placement of the coil may be associated with reperfusion and potential coil migration<sup>9</sup>

## PRECISE PLACEMENT WITH MAXIMUM COIL MANIPULATION

- AZUR Controller allows for precise positioning & placement for consistent performance
- Allows repositioning with greater confidence<sup>†</sup>
- Design the compaction to maximize each coil
- Ability to extend well past tip of catheter before detaching and can reposition coil outside of the delivery catheter



### WHY AZUR?

**AZUR Hydrocoils provide the only truly detachable system to ensure patient safety, precise coil placement and coil compaction.**

## CATHETER COMPATIBILITY

- Compatible with large lumen catheters for maximum imaging quality

## CONTROL FROM ACCESS TO EMBOLIZATION

**Entry Site Management:** Reduce potential access site complications with PINNACLE® Access products.

**Lesion Access:** Navigate through the most tortuous anatomy with GLIDEWIRE®, GLIDECATH®, and PROGREAT®.

**Embolization:** AZUR Peripheral HydroCoils offer 0.018" and 0.035" platforms for every situation.

***Pinnacle***®

Introducer Sheaths

***Glidewire***®

Hydrophilic Coated Guidewire

***Glidecath***®

Hydrophilic Coated Catheter

***Progreat***®

Coaxial Microcatheter Systems





# ORDERING INFORMATION

Detachable 35 System / Pack of 1 (hydrogel coil)

Product Code	Loop Diameter	Length*
45-450405	4 mm	5 cm
45-450410	4 mm	10 cm
45-450610	6 mm	10 cm
45-450415	4 mm	15 cm
45-450615	6 mm	15 cm
45-450815	8 mm	15 cm
45-451015	10 mm	15 cm
45-451215	12 mm	15 cm
45-450620	6 mm	20 cm
45-450820	8 mm	20 cm
45-451020	10 mm	20 cm
45-451220	12 mm	20 cm
45-451520	15 mm	20 cm
45-452020	20 mm	20 cm
45-451230	12 mm	30 cm
45-451530	15 mm	30 cm
45-452030	20 mm	30 cm

Detachable 18 System / Pack of 1 (hydrogel coil)

Product Code	Loop Diameter	Length*
45-480202	2 mm	2 cm
45-480204	2 mm	4 cm
45-480302	3 mm	2 cm
45-480305	3 mm	5 cm
45-480405	4 mm	5 cm
45-480505	5 mm	5 cm
45-480310	3 mm	10 cm
45-480410	4 mm	10 cm
45-480510	5 mm	10 cm
45-480610	6 mm	10 cm
45-480810	8 mm	10 cm
45-481010	10 mm	10 cm
45-480415	4 mm	15 cm
45-480515	5 mm	15 cm
45-480615	6 mm	15 cm
45-480815	8 mm	15 cm
45-481015	10 mm	15 cm
45-481215	12 mm	15 cm
45-481515	15 mm	15 cm
45-480420	4 mm	20 cm
45-480520	5 mm	20 cm
45-480620	6 mm	20 cm
45-480820	8 mm	20 cm
45-481020	10 mm	20 cm
45-481220	12 mm	20 cm
45-481520	15 mm	20 cm
45-482020	20 mm	20 cm
45-481530	15 mm	30 cm
45-482030	20 mm	30 cm

Detachable 35 Framing Coil System / Pack of 1 (non-hydrogel coil)

Product Code	Loop Diameter	Length*
45-650820	8 mm	20 cm
45-651026	10 mm	26 cm
45-651434	14 mm	34 cm
45-652050	20 mm	50 cm

Detachable 18 Framing Coil System / Pack of 1 (non-hydrogel coil)

Product Code	Loop Diameter	Length*
45-680820	8 mm	20 cm
45-681026	10 mm	26 cm
45-681434	14 mm	34 cm
45-682050	20 mm	50 cm

Detachment Controller For Use With Detachable Systems / Pack of 1

Product Code	Product Description
45-4001	AZUR Detachment Controller

Pushable 35 System / Pack of 3 (hydrogel coil)

Product Code	Loop Diameter	Length*
45-250404	4 mm	4 cm
45-250406	4 mm	6 cm
45-250506	5 mm	6 cm
45-250510	5 mm	10 cm
45-250610	6 mm	10 cm
45-250810	8 mm	10 cm
45-250614	6 mm	14 cm
45-250814	8 mm	14 cm
45-251014	10 mm	14 cm
45-251514	15 mm	14 cm
45-250820	8 mm	20 cm
45-251020	10 mm	20 cm
45-251520	15 mm	20 cm
45-251620	16 mm	20 cm

Pushable 18 System / Pack of 3 (hydrogel coil)

Product Code	Loop Diameter	Length*
45-280202	2 mm	2 cm
45-280302	3 mm	2 cm
45-280402	4 mm	2 cm
45-280304	3 mm	4 cm
45-280404	4 mm	4 cm
45-280504	5 mm	4 cm
45-280406	4 mm	6 cm
45-280506	5 mm	6 cm
45-280606	6 mm	6 cm
45-280510	5 mm	10 cm
45-280610	6 mm	10 cm
45-280810	8 mm	10 cm
45-280514	5 mm	14 cm
45-280614	6 mm	14 cm
45-280814	8 mm	14 cm
45-281014	10 mm	14 cm
45-280620	6 mm	20 cm
45-280820	8 mm	20 cm
45-281020	10 mm	20 cm

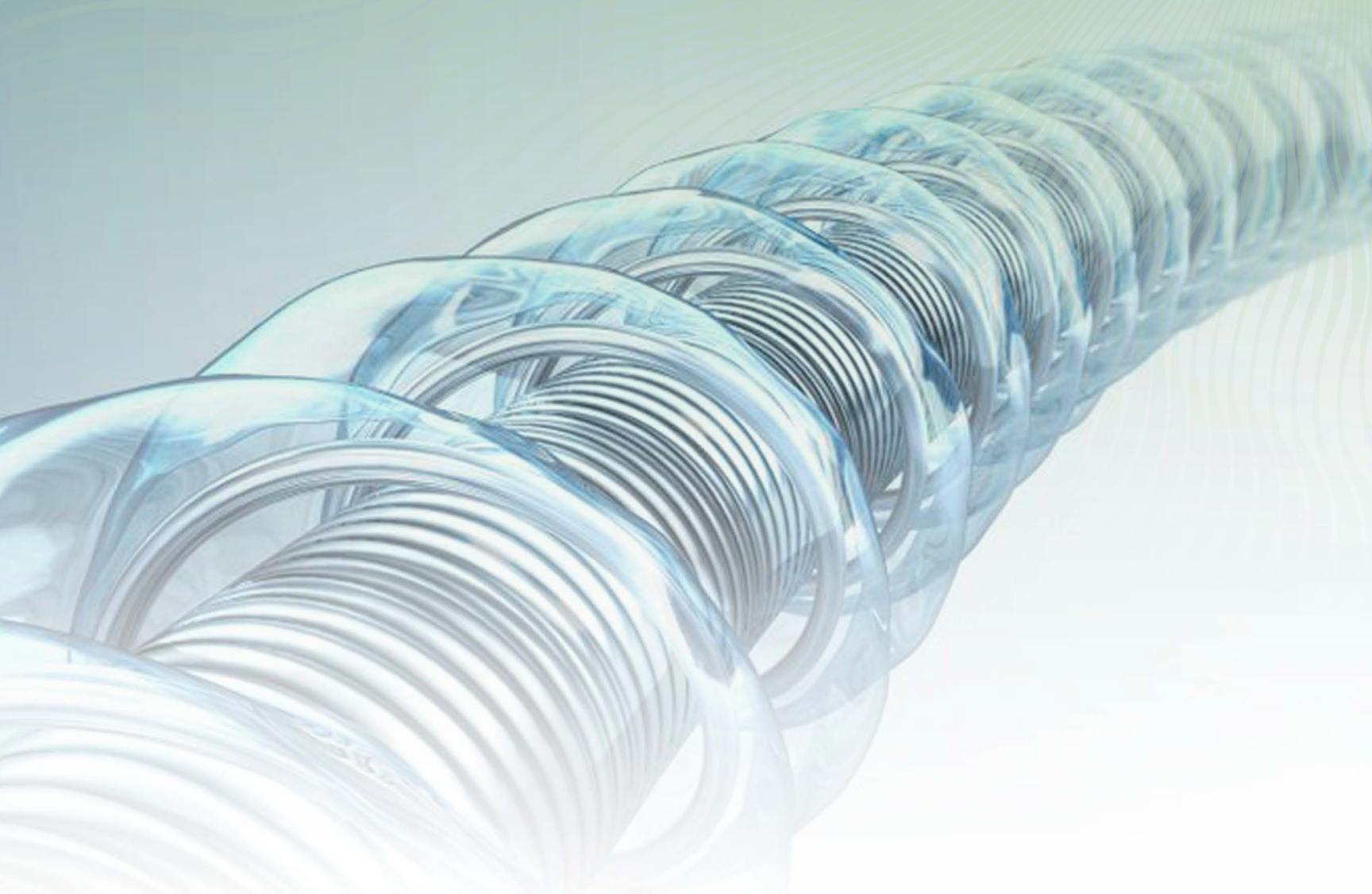
\*Length is calculated from the tip of the coil to the point of connection with the pusher wire when the coil is straight.

## Terumo Product Code Nomenclature:

45-XYYABB  
 45 = Terumo Interventional Systems  
 X = 2 for Pushable; 4 for Detachable; 6 for Framing Coil  
 Y = 8 for 0.018"; 5 for 0.035"  
 AA = Loop diameter in mm  
 BB = Coil length in cm

## Examples:

45-250510 stands for a pushable coil 0.035" with a loop diameter of 5 mm and a length of 10 cm.  
 45-480815 stands for a detachable coil 0.018" with a loop diameter of 8 mm and a length of 15 cm.



For more information, call 800.862.4143 to speak to an Inside Sales Specialist or visit [www.terumo.com](http://www.terumo.com)  
Terumo Interventional Systems • 2101 Cottontail Lane • Somerset, NJ 08873 • Fax: 800.411.5870

1. Plenk H, Killer M, Richling B. Pathophysiologic considerations on HydroCoil- and platinum coil-occluded retrieved human cerebral aneurysms. Presented at ASITN MicroVention Symposium. 2005. (in-vivo study)
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  3. Ding YH, Dai D, Lewis DA, Cloft HJ, Kallmes DF. Angiographic and histologic analysis of experimental aneurysms embolized with platinum coils, Matrix, and HydroCoil. *AJNR Am J Neuroradiol*. 2005 Aug;26(7):1757-63. (animal study)
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  5. Pelage JP. Angiographic and Pathologic Comparison of HydroCoils vs. Fibred Coils Mechanisms of Occlusion and Mid-Term Recanalization in an Animal Model. *GEST* 2012. (animal study)
  6. Cloft HJ, Kallmes DF. Aneurysm packing with HydroCoil Embolic System versus platinum coils: Initial clinical experience. *AJNR Am J Neuroradiol*. 2004; 25(1): 60-62. (in-vivo study)
  7. Killer M, Arthur AS, Barr JD, Richling B, Cruise GM. Histomorphology of thrombus organization, neointima formation, and foreign body response in retrieved human aneurysms treated with hydrocoil devices. *J Biomed Mater Res B Appl Biomater*. 2010 Aug;94(2):486-92. doi: 10.1002/jbm.b.31660. (in-vivo study)
  8. Yoshino Y, Niimi Y, Song JK, Silane M, Berenstein A. Endovascular treatment of intracranial aneurysms: comparative evaluation in a terminal bifurcation aneurysm model in dogs. *J Neurosurg*. 2004 Dec;101(6):996-1003<tel:996-1003>. (animal study)
  9. Milic A, Chan RP, Cohen JH, Faughnan ME. Reperfusion of pulmonary arteriovenous malformations after embolotherapy. *J Vasc Interv Radiol*. 2005 Dec;16(12):1675-83. (in-vivo study)
- \* As described in the IFU: The AZUR 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).
- † As described in the IFU: The coil must be properly positioned in the vessel or aneurysm within three minutes from the time the device is first introduced into the microcatheter.
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INTERVENTIONAL  
SYSTEMS

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