

AZUR[®]

Embolization System

IN A CATEGORY OF ITS OWN

The AZUR Family of Products

Take control of your
embolization procedures
with the comprehensive
AZUR Embolization System.

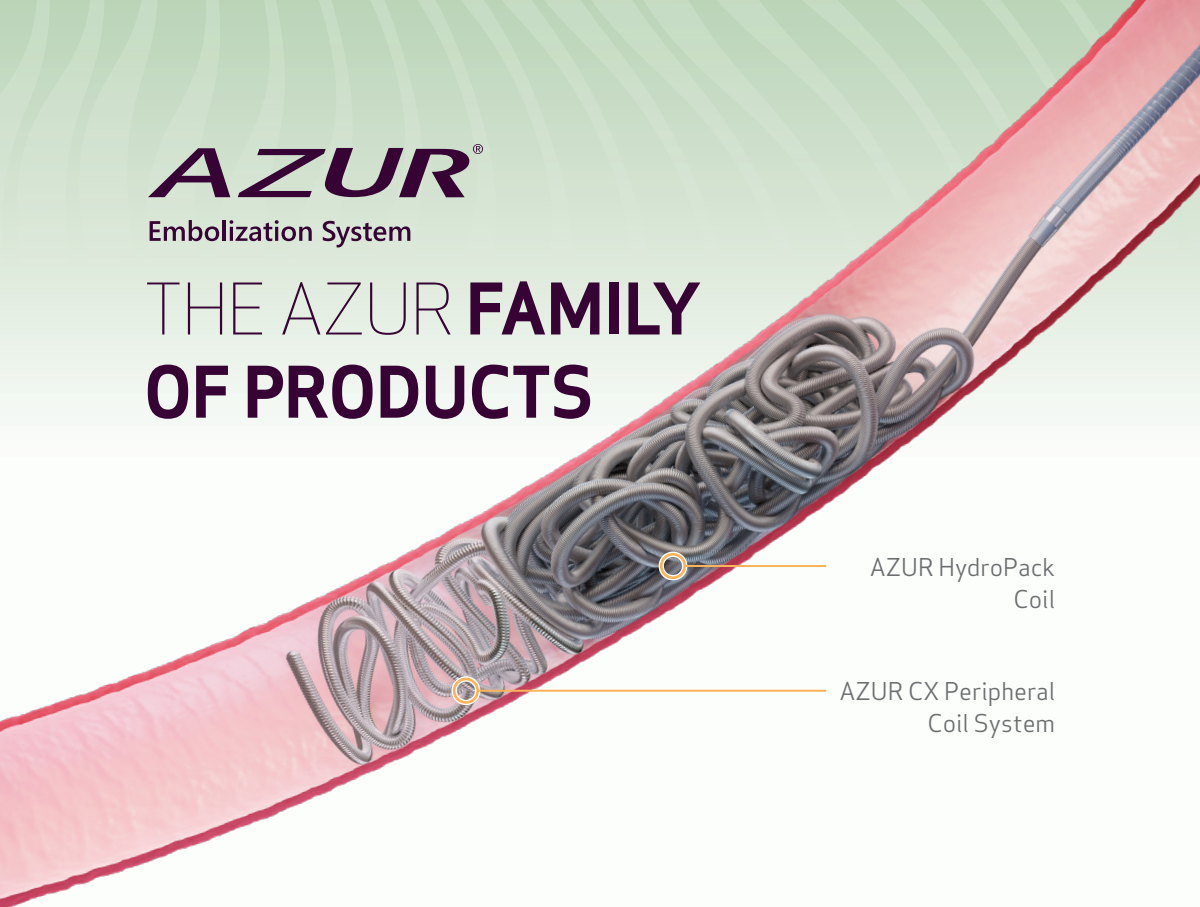


 **TERUMO**
INTERVENTIONAL
SYSTEMS

AZUR[®]

Embolization System

THE AZUR FAMILY OF PRODUCTS

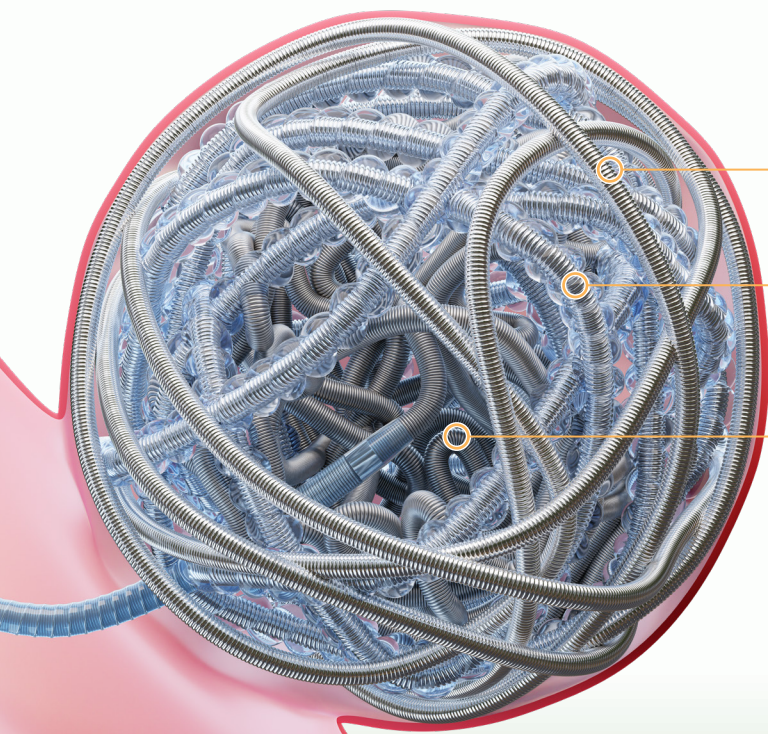


AZUR HydroPack
Coil

AZUR CX Peripheral
Coil System

In a category of its own

The AZUR Family of Products is the only system of coils that integrates soft, pliable Hydrogel, an expanding biologically inert scaffold that encourages regenerative neointimal tissue growth. For framing or filling aneurysms and vessel occlusions, AZUR coils provide the comprehensive suite of solutions you need.



AZUR Framing
Coil System

AZUR Peripheral
HydroCoil
Embolization System

AZUR HydroPack
Coil

AZUR[®]

Embolization System

THE AZUR TREATMENT ALGORITHM

1 Frame the base

Coils designed to provide the stability and coverage you need.



**AZUR CX
Peripheral
Coil System**



**AZUR
Framing
Coil System**

2 Fill the space

Coils designed to enable soft packing and superior density.



**AZUR
HydroCoil
Embolization
System**



**AZUR
HydroPack
Peripheral
Coil System**

The AZUR .035" advantage

- AZUR .035" coils provide more volume per cm than any other coil on the market¹
- More volume means fewer coils are needed
- If the target embolization site can be reached with an angiographic catheter, a .035" coil can be deployed instead of a .018" coil

Primary wind: .029"
Volume per cm: 4.26 mm³



AZUR CX

Primary wind: .020"
Volume per cm: 2.03 mm³



**Competitor's
product**

AZUR[®] CX

Peripheral Coil System

FRAME



Unique cross-sectional coverage²

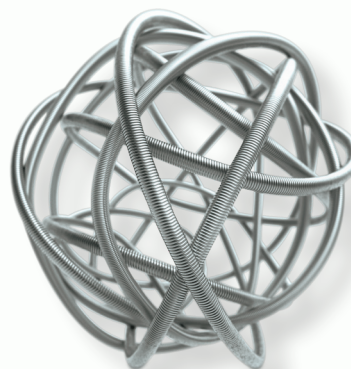
AZUR CX coils create a gel core with Hydrogel expansion for a stable, nonabsorbable mechanical occlusion.²

- Soft, flexible, and precise for controlled delivery
- Anchor coil provides precise placement for control in high-flow areas
- Coil design minimizes catheter manipulation and provides cross-sectional coverage
- Coil construction allows for Hydrogel to expand between the gaps

AZUR[®]

Framing Coil System

FRAME



Stability from the start

AZUR framing coils take a three-dimensional approach to aneurysms, providing an even distribution of coil loops at the treatment site to keep additional coils inside and prevent migration.

- Complex-shaped, bare platinum coil that provides framework for embolization
- Designed to reduce compartmentalization and provide greater coverage with a three-dimensional approach to embolization
- AZUR Framing Coil as your first coil can offer stability for your embolization procedures by providing lateral support and control
 - Each successive loop gently rotates course, changing direction as it is deployed

AZUR[™] Detachable System

Achieve immediate detachment at the push of a button.





AZUR®

Peripheral HydroCoil Embolization System

FILL

Superior filling **volume** and packing **density**

The AZUR HydroCoil combines a platinum coil and an expandable Hydrogel polymer to provide a uniquely stable and permanent platform for blood stasis, thrombus organization, and neointima formation.³

- Hydrogel expands 4-5 times the original size in the presence of blood to create a mechanical occlusion²
- Promotes natural tissue proliferation and may reduce rates of recanalization^{4,5}
- Offers the potential to use fewer coils per procedure and achieve cost savings with optimal filling volume¹
- Expanded Hydrogel is soft, compliant, and porous



AZUR HydroPack™

Peripheral Coil System

FILL

Soft packing. **Long lasting.**

Without the need to size the vessel diameter, HydroPack coils can be used in a variety of vessel sizes in the peripheral vasculature given prior placement of an anchor or framing coil.²

- Soft coil design allows for tight packing and smooth delivery
- Hydrogel expansion eliminates microchannels for reliable, long-lasting occlusion and helps avoid reintervention
- Versatile design means you can pack without compromise

THE POWER OF **HYDROGEL**

Only the **AZUR Embolization System** utilizes **Hydrogel**, an expanding bioinductive scaffold that encourages regenerative neointimal tissue growth.⁶

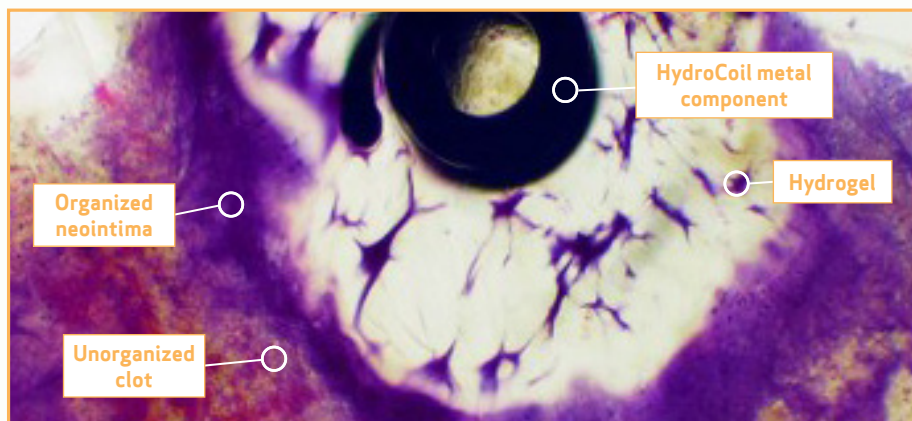
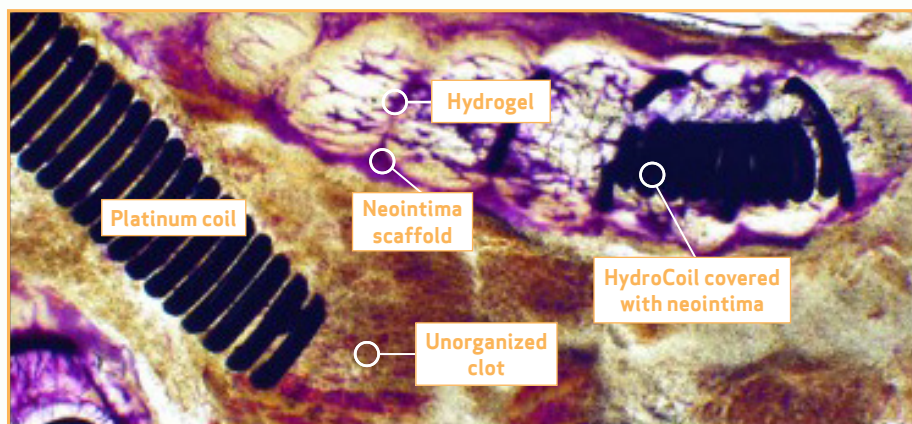
Effective occlusion for less reintervention

Studies have shown that an embolization that relies more on thrombus, and less on mechanical filling of the site, may lead to higher rates of recanalization.⁷

Hydrogel polymer expands to create a solid core for mechanical occlusion, eliminating microchannels and helping patients avoid reintervention.²

In a study of 13 human aneurysms retrieved at autopsy at 1-72 days post-treatment, Hydrogel-based devices occupied a large percentage of the aneurysm sac, provided a framework for thrombus organization to occur, and elicited less severe foreign body response than platinum coils.⁴

AZUR HydroCoil: Human explant 3 weeks post-treatment



Hydrogel provides substrate for neointima formation and smooth muscle cell migration^{4,6}

THE POWER OF **HYDROGEL**

Innovative technology for less recanalization

Compaction of the coil mass results in a smaller coil mesh. This compaction is the most important contributing factor in re-opening of the aneurysmal lumen, and it is believed that this phenomenon is caused by the water hammer effect of the pulsatile blood flow.⁸

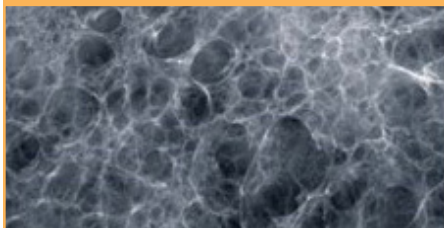
The porous surface of Hydrogel provides a biologically inert scaffolding for natural tissue proliferation,⁹ which may lead to less coil compaction and recanalization.⁵

After 24 months, patients receiving Hydrogel coils had

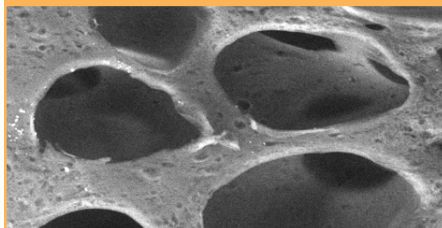
ZERO
RECANALIZATION¹⁰

150x and 500x magnification of Hydrogel surface using scanning electron microscope showing porous structure

150x



500x



Aneurysm necks depicting neointimal formation

Bare coil



First-generation Hydrogel



Second-generation Hydrogel



SUPERIOR VOLUME

Superior volume engineered for embolization

Patented TERUMO Hydrogel technology swells 4–5 times in size in the presence of blood and allows an increase in filling volume and packing density compared with competitive coils.^{1,2} Due to the volume achieved by the Hydrogel expansion, AZUR coils provide true volume compared to hollow-center coils.

- pH-sensitive Hydrogel expands once in contact with blood^{2,11}
- Does not degrade, break down over time, or get reabsorbed into the body²
- Does not contain or produce biologics and is not associated with any known toxicity or in-vivo material hypersensitivity²

Traditional vs Hydrogel coils



Traditional (Bare Platinum/Fibered)

- Hollow core design allows blood to flow through coil, forming thrombus inside the core
- Higher dependency on thrombus
- Thrombus has the potential to break down over time, which may lead to coil mass instability



First-generation Hydrogel

- Hydrogel on the exterior of the primary wind
- Engineered for mass expansion, swelling 4–5 times in size once in contact with blood¹
- Provides the most volume when compared to other coils that are longer in length²



Second-generation Hydrogel

- Hydrogel on the inside of primary wind for gel core construction
- Creates gel core upon expansion which, unlike thrombus, is not reabsorbed by the body²
- Pre-softened Hydrogel for a softer packing experience

AZUR®

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DIMENSION REFERENCE

AZUR® CX Detachable .018"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-780202	2	2	.014"	.015"	.019" - .027"	30 min
45-780204	2	4	.014"	.015"	.019" - .027"	30 min
45-780304	3	4	.014"	.015"	.019" - .027"	30 min
45-780308	3	8	.014"	.015"	.019" - .027"	30 min
45-780413	4	13	.014"	.015"	.019" - .027"	30 min
45-780516	5	16	.014"	.015"	.019" - .027"	30 min
45-780620	6	20	.014"	.015"	.019" - .027"	30 min
45-780724	7	24	.014"	.015"	.019" - .027"	30 min
45-780828	8	28	.014"	.015"	.019" - .027"	30 min
45-780928	9	28	.014"	.015"	.019" - .027"	30 min
45-781032	10	32	.014"	.015"	.019" - .027"	30 min
45-781238	12	38	.014"	.015"	.019" - .027"	30 min
45-781434	14	34	.014"	.015"	.019" - .027"	30 min
45-781639	16	39	.014"	.015"	.019" - .027"	30 min
45-781836	18	36	.014"	.015"	.019" - .027"	30 min
45-782040	20	40	.014"	.015"	.019" - .027"	30 min
AZUR® Framing Coil Detachable .018"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-680820	8	20	.014"	N/A	.021" - .027"	N/A
45-681026	10	26	.014"	N/A	.021" - .027"	N/A
45-681434	14	34	.015"	N/A	.021" - .027"	N/A
45-682050	20	50	.015"	N/A	.021" - .027"	N/A
AZUR® HydroCoil Detachable .018"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-480202	2	2	.014"	.034"	.021" - .027"	3 min
45-480204	2	4	.014"	.034"	.021" - .027"	3 min
45-480302	3	2	.014"	.034"	.021" - .027"	3 min
45-480305	3	5	.014"	.034"	.021" - .027"	3 min
45-480310	3	10	.014"	.034"	.021" - .027"	3 min
45-480405	4	5	.014"	.034"	.021" - .027"	3 min
45-480410	4	10	.014"	.034"	.021" - .027"	3 min
45-480415	4	15	.014"	.034"	.021" - .027"	3 min
45-480420	4	20	.014"	.034"	.021" - .027"	3 min
45-480505	5	5	.014"	.034"	.021" - .027"	3 min
45-480510	5	10	.014"	.034"	.021" - .027"	3 min
45-480515	5	15	.014"	.034"	.021" - .027"	3 min
45-480520	5	20	.014"	.034"	.021" - .027"	3 min
45-480610	6	10	.014"	.034"	.021" - .027"	3 min
45-480615	6	15	.014"	.034"	.021" - .027"	3 min
45-480620	6	20	.014"	.034"	.021" - .027"	3 min
45-480810	8	10	.014"	.034"	.021" - .027"	3 min
45-480815	8	15	.014"	.034"	.021" - .027"	3 min
45-480820	8	20	.014"	.034"	.021" - .027"	3 min
45-481010	10	10	.014"	.034"	.021" - .027"	3 min
45-481015	10	15	.014"	.034"	.021" - .027"	3 min

AZUR®

Embolization System

DIMENSION REFERENCE

AZUR® HydroCoil Detachable .018"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-481020	10	20	.014"	.034"	.021" - .027"	3 min
45-481215	12	15	.014"	.034"	.021" - .027"	3 min
45-481220	12	20	.014"	.034"	.021" - .027"	3 min
45-481515	15	15	.014"	.034"	.021" - .027"	3 min
45-481520	15	20	.014"	.034"	.021" - .027"	3 min
45-481530	15	30	.014"	.034"	.021" - .027"	3 min
45-482020	20	20	.014"	.034"	.021" - .027"	3 min
45-482030	20	30	.014"	.034"	.021" - .027"	3 min
AZUR® HydroCoil Pushable .018"						*Packed 3 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-280202	2	2	.014"	.034"	.021" - .027"	N/A
45-280302	3	2	.014"	.034"	.021" - .027"	N/A
45-280304	3	4	.014"	.034"	.021" - .027"	N/A
45-280402	4	2	.014"	.034"	.021" - .027"	N/A
45-280404	4	4	.014"	.034"	.021" - .027"	N/A
45-280406	4	6	.014"	.034"	.021" - .027"	N/A
45-280504	5	4	.014"	.034"	.021" - .027"	N/A
45-280506	5	6	.014"	.034"	.021" - .027"	N/A
45-280510	5	10	.014"	.034"	.021" - .027"	N/A
45-280514	5	14	.014"	.034"	.021" - .027"	N/A
45-280606	6	6	.014"	.034"	.021" - .027"	N/A
45-280610	6	10	.014"	.034"	.021" - .027"	N/A
45-280614	6	14	.014"	.034"	.021" - .027"	N/A
45-280620	6	20	.014"	.034"	.021" - .027"	N/A
45-280810	8	10	.014"	.034"	.021" - .027"	N/A
45-280814	8	14	.014"	.034"	.021" - .027"	N/A
45-280820	8	20	.014"	.034"	.021" - .027"	N/A
45-281014	10	14	.014"	.034"	.021" - .027"	N/A
45-281020	10	20	.014"	.034"	.021" - .027"	N/A
AZUR HydroPack™ Detachable .018"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-880005	N/A	5	.018"	.018"	.021" - .027"	10 min
45-880010	N/A	10	.018"	.018"	.021" - .027"	10 min
45-880020	N/A	20	.018"	.018"	.021" - .027"	10 min
45-880035	N/A	35	.018"	.018"	.021" - .027"	10 min
45-880050	N/A	50	.018"	.018"	.021" - .027"	10 min
45-880060	N/A	60	.018"	.018"	.021" - .027"	10 min
AZUR® Detachment Controller						*Packed 5 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-4001	N/A	N/A	N/A	N/A	N/A	N/A

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AZUR®

Embolization System

DIMENSION REFERENCE

AZUR® CX Detachable .035"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-750407	4	7	.029"	.029"	.041" - .047"	20 min
45-750511	5	11	.029"	.029"	.041" - .047"	20 min
45-750609	6	9	.029"	.029"	.041" - .047"	20 min
45-750617	6	17	.029"	.029"	.041" - .047"	20 min
45-750812	8	12	.029"	.029"	.041" - .047"	20 min
45-750824	8	24	.029"	.029"	.041" - .047"	20 min
45-751019	10	19	.029"	.029"	.041" - .047"	20 min
45-751324	13	24	.029"	.029"	.041" - .047"	20 min
45-751632	16	32	.029"	.029"	.041" - .047"	20 min
45-752039	20	39	.029"	.029"	.041" - .047"	20 min
AZUR® Framing Coil Detachable .035"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-650820	8	20	.022"	N/A	.038" - .047"	N/A
45-651026	10	26	.022"	N/A	.038" - .047"	N/A
45-651434	14	34	.022"	N/A	.038" - .047"	N/A
45-652050	20	50	.022"	N/A	.038" - .047"	N/A
AZUR® HydroCoil Detachable .035"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-450405	4	5	.024"	.048"	.038" - .047"	3 min
45-450410	4	10	.024"	.048"	.038" - .047"	3 min
45-450415	4	15	.024"	.048"	.038" - .047"	3 min
45-450610	6	10	.024"	.048"	.038" - .047"	3 min
45-450615	6	15	.024"	.048"	.038" - .047"	3 min
45-450620	6	20	.024"	.048"	.038" - .047"	3 min
45-450815	8	15	.024"	.048"	.038" - .047"	3 min
45-450820	8	20	.024"	.048"	.038" - .047"	3 min
45-451015	10	15	.024"	.048"	.038" - .047"	3 min
45-451020	10	20	.024"	.048"	.038" - .047"	3 min
45-451215	12	15	.024"	.048"	.038" - .047"	3 min
45-451220	12	20	.024"	.048"	.038" - .047"	3 min
45-451230	12	30	.024"	.048"	.038" - .047"	3 min
45-451520	15	20	.024"	.048"	.038" - .047"	3 min
45-451530	15	30	.024"	.048"	.038" - .047"	3 min
45-452020	20	20	.024"	.048"	.038" - .047"	3 min
45-452030	20	30	.024"	.048"	.038" - .047"	3 min
AZUR® HydroCoil Pushable .035"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-250404	4	4	.024"	.048"	.038" - .047"	N/A
45-250406	4	6	.024"	.048"	.038" - .047"	N/A
45-250506	5	6	.024"	.048"	.038" - .047"	N/A
45-250510	5	10	.024"	.048"	.038" - .047"	N/A
45-250610	6	10	.024"	.048"	.038" - .047"	N/A
45-250614	6	14	.024"	.048"	.038" - .047"	N/A
45-250810	8	10	.024"	.048"	.038" - .047"	N/A

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AZUR® HydroCoil Pushable .035"						*Packed 1 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-250814	8	14	.024"	.048"	.038" - .047"	N/A
45-250820	8	20	.024"	.048"	.038" - .047"	N/A
45-251014	10	14	.024"	.048"	.038" - .047"	N/A
45-251020	10	20	.024"	.048"	.038" - .047"	N/A
45-251514	15	14	.024"	.048"	.038" - .047"	N/A
45-251520	15	20	.024"	.048"	.038" - .047"	N/A
45-251620	16	20	.024"	.048"	.038" - .047"	N/A
AZUR® Detachment Controller						*Packed 5 per box
PRODUCT CODE	LOOP DIAMETER (mm)	LENGTH (cm)	PRE-EXPANDED OD (in)	EXPANDED OD (in)	CATHETER ID REQ. (in)	REPOSITIONING TIME
45-4001	N/A	N/A	N/A	N/A	N/A	N/A

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TERUMO
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Terumo Interventional Systems is **committed to your success** with innovative procedural solutions and ongoing support for your most challenging cases.

We are relentlessly seeking new ways to help you achieve **better outcomes for more patients.**

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References: **1.** Coil volume was calculated assuming a cylindrical coil shape using the formula: coil volume = $\pi \times (\text{coil radius})^2 \times (\text{coil length})$ for each coil. In this calculation, the volume of the hydrogel-coated coils was calculated assuming full hydrogel expansion. **2.** Data on File **3.** 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;101(6):996-1003. doi:10.3171/jns.2004.101.6.0996 **4.** 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;94(2):486-492. doi:10.1002/jbm.b.31660 **5.** Shimohira M, Kawai T, Hashizume T, Muto M, Kitase M, Shibamoto Y. Usefulness of Hydrogel-Coated Coils in Embolization of Pulmonary Arteriovenous Malformations [published correction appears in *Cardiovasc Intervent Radiol.* 2018 Jul;41(7):1140. doi: 10.1007/s00270-018-1928-x.]. *Cardiovasc Intervent Radiol.* 2018;41(6):848-855. doi:10.1007/s00270-018-1876-5 **6.** El-Sherbiny IM, Yacoub MH. Hydrogel scaffolds for tissue engineering: Progress and challenges. *Glob Cardiol Sci Pract.* 2013;2013(3):316-342. Published 2013 Nov 1. doi:10.5339/gcsp.2013.38 **7.** Fohlen A, Namur J, Ghegediban H, Laurent A, Wassef M, Pelage JP. Peripheral embolization using hydrogel-coated coils versus fibered coils: short-term results in an animal model. *Cardiovasc Intervent Radiol.* 2018;41(2):305-312. doi:10.1007/s00270-017-1834-7. **8.** Bavzinski G, Talazoglu V, Killer M, et al. Gross and microscopic histopathological findings in aneurysms of the human brain treated with Guglielmi detachable coils. *J Neurosurg.* 1999;91(2):284-293. (in-vivo study) **9.** 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) **10.** Shimohira M, Kawai T, Hashizume T, et al. Reperfusion rates of pulmonary arteriovenous malformations after coil embolization: evaluation with time-resolved MR angiography or pulmonary angiography. *J Vasc Interv Radiol.* 2015;26(6):856-864.e1. doi:10.1016/j.jvir.2015.02.016 **11.** Maleux G, Deroose C, Fieuws S, et al. Prospective Comparison of Hydrogel-coated Microcoils versus Fibered Platinum Microcoils in the Prophylactic Embolization of the Gastroduodenal Artery before Yttrium-90 Radioembolization. *J Vasc Interv Radiol.* 2013;24(6):797-804. doi:10.1016/j.jvir.2013.01.503

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