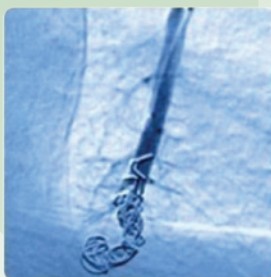
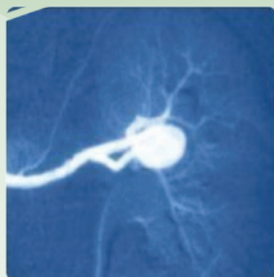
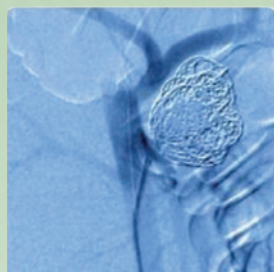
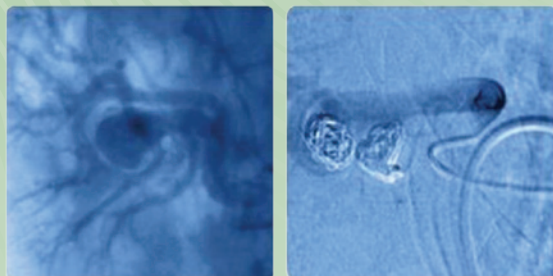


AZUR[®]

Peripheral HydroCoil Embolization System



THE POWER OF HYDROGEL

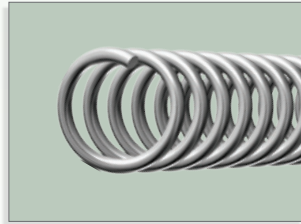
 **TERUMO**
INTERVENTIONAL
SYSTEMS

COIL CONSTRUCTION

There are many types of coils to choose from when preparing for an embolic procedure

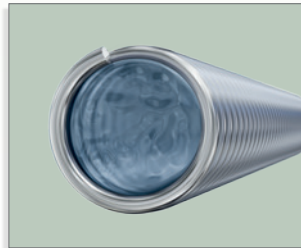
The construction of the coil may have an impact on the effectiveness of clinical outcomes.

0.020" Bare Platinum Coils



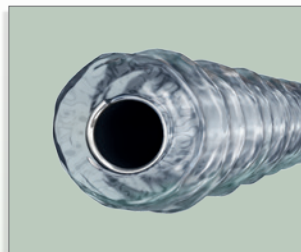
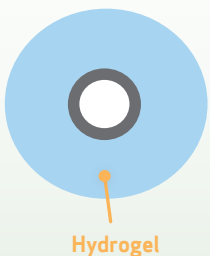
The majority of the coil core is **hollow**; this allows blood to flow through the coil, forming thrombus inside the core. Thrombus has the potential to break down over time, which may lead to coil mass instability.

AZUR[®] CX
Peripheral Coil System



AZUR[®] CX has a **solid** core upon Hydrogel expansion which, unlike thrombus, will not be absorbed by the body.^{1,2,3,4}

AZUR[®]
Peripheral HydroCoil Embolization System



AZUR[®] HydroCoil has expanding Hydrogel that provides a barrier around the outer diameter of the core to:

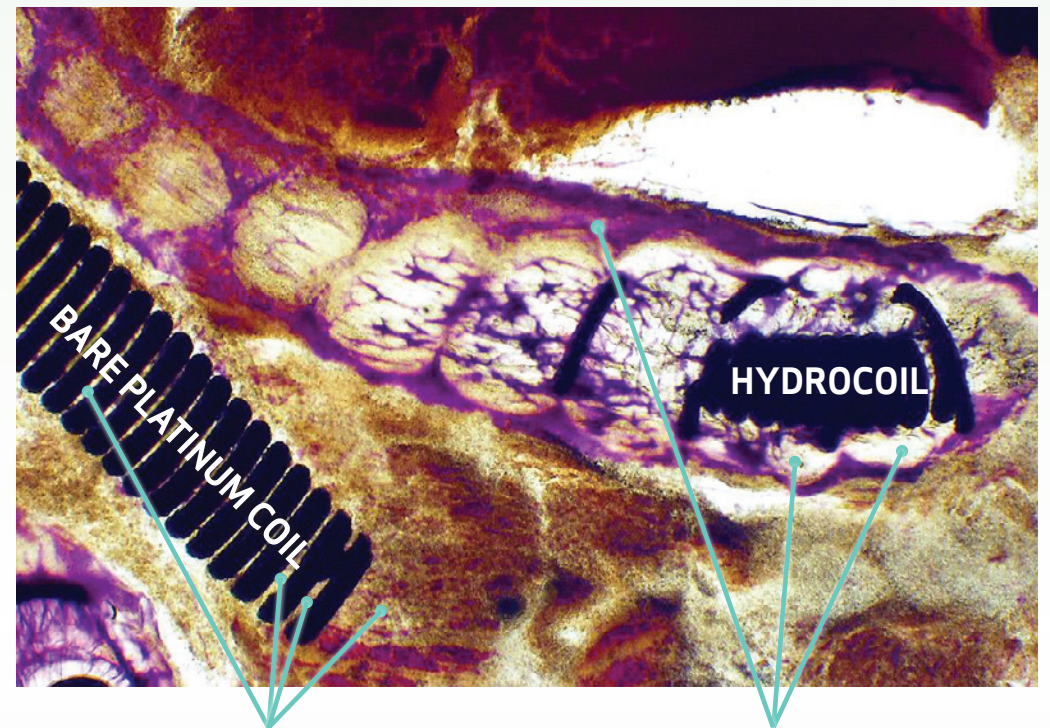
- Prevent blood flow through the coil
- Minimize microchannel formation

MECHANICAL OCCLUSION

Permanent long term occlusion is one of the primary goals of an embolic procedure

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.^{1,4}

Human explant three weeks post-treatment



Bare Platinum Coil

- Evidence of microchannels and unorganized thrombus within the core

AZUR[®] HydroCoil

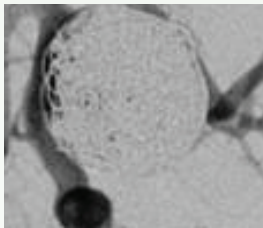
- Expanded Hydrogel with increased volume fill
- Evidence of organized neointima surrounding Hydrogel

RECANALIZATION DUE TO COIL COMPACTION

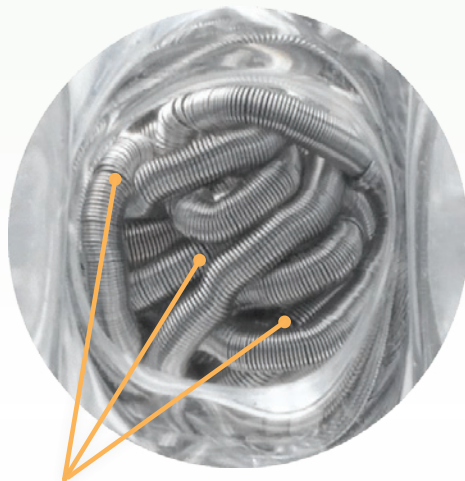
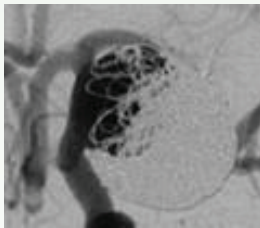
Compaction of the coil mesh is a decrease of interspaces between coil loops, which leads to a smaller coil mesh.

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.³

Before



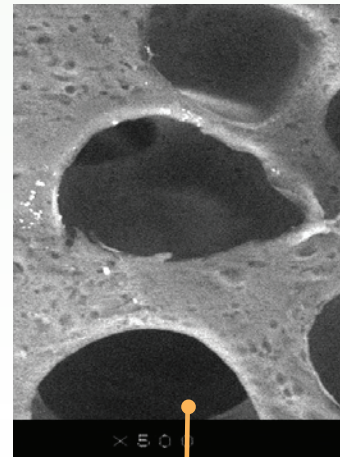
After



Microchannels

Bare platinum coils

Thrombus absorption within the embolic mass and microchannels between the interstices of the coils provide opportunities for blood to penetrate the coil mass, which may lead to instability and recanalization.



Hydrogel Porous Surface

AZUR®

The porous surface of Hydrogel provides a biologically inert scaffolding for natural tissue proliferation,¹ which may lead to less coil compaction and recanalization.⁴

RECANALIZATION

Recanalization may lead to aneurysm rupture and repeat embolizations

However, if organized thrombus and fibrous tissue fills the aneurysm, and neointima forms at the neck of the aneurysm, then the risk of rupture and repeat embolization may be minimal.⁵

AZUR® Peripheral HydroCoil Embolization System & AZUR® CX Peripheral Coil System may provide:

- Greater packing density compared to bare platinum coils⁶
- A scaffold for neointimal growth and thicker neointimal tissue at the neck of the aneurysm¹
 - The ability to induce neointima formation⁶
- A lower rate of mid- and long-term recanalization⁴
- A good option for patients on anticoagulants / antiplatelet therapies due to the mechanical occlusion⁸

Aneurysm necks depicting neointimal formation^{5,7}



Bare platinum coils may:

- Show less coil packing density⁶
- Have a clot organization that seems to be delayed and/or incomplete due to the tiny open spaces between the coils³

Aneurysm neck depicting bare platinum coil technology⁵



VOLUMETRIC COMPARISON

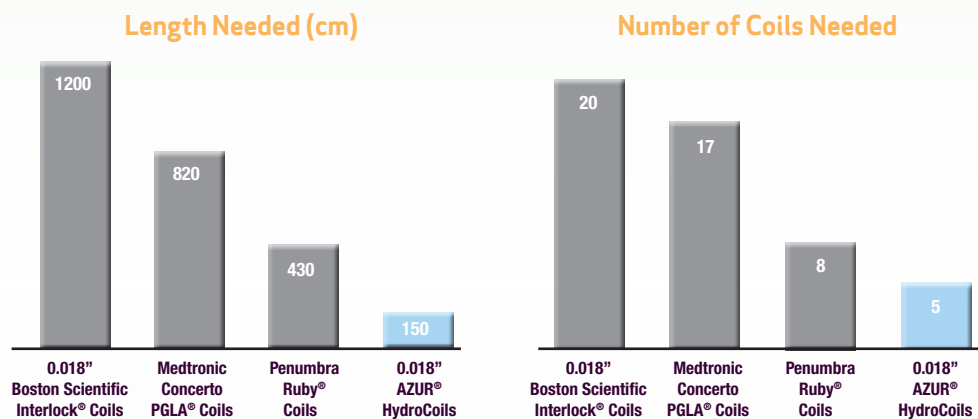
Patented TERUMO Hydrogel technology swells 4-5 times in size* in the presence of blood and allows an increase in filling volume and packing density compared with competitive coils.⁹



19mm spherical aneurysm
3,591.36 mm³ volume needed to achieve 24%

- There is a relationship between the percent of packing volume and aneurysm recanalization¹⁰
- Recanalization was significantly lower in aneurysms packed >25% in volume¹⁰
- Multiple studies show no compaction at six months in aneurysms that were packed less than 25% in volume^{11,12}

Volume to Achieve 24% Packing Density using AngioCalc.com⁹



*As described in the IFU: AZUR HydroCoil 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).

Conclusion

Due to the volumetric expansion of AZUR® HydroCoils, it would require a lower number of coils with less overall length to fill a 19 mm aneurysm compared to competitive coils.⁹



AZUR® Framing Coil

- Complex-shaped, bare platinum coil that provides framework for aneurysms as well as vessel embolization
- Designed to reduce compartmentalization and provide greater coverage with a three-dimensional approach to embolization
- Can be used with HydroCoils to frame the periphery of the space, leaving the center available for filling



AZUR® HydroCoil

- Patented Hydrogel technology swells at a defined rate in the presence of blood to provide additional filling and stabilization of the vascular space
- Provides a biologically inert scaffolding for natural tissue proliferation and shows lower rates of recanalization and repeat procedures¹
- AZUR® expanding Hydrogel and volume filling provides the potential to use fewer coils, which may provide cost saving per procedure¹³



AZUR® CX

- First and only peripheral embolization coil designed to provide cross-sectional coverage
- Coil with patented TERUMO Hydrogel technology on the interior provides a soft feel
- Coil design minimizes catheter manipulation




PUSHING BOUNDARIES



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

We're relentlessly seeking new ways to help you apply effective solutions and achieve **better outcomes for more patients.**



FIND OUT MORE  Phone: 800.862.4143  terumo.com  Fax: 800.411.5870

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For Rx only.

Before using refer to **Instructions for Use** for indications, contraindications as well as warnings and precautions at www.terumo.com.

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