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New Technology Focus: Smart Polymer in Vascular Surgery

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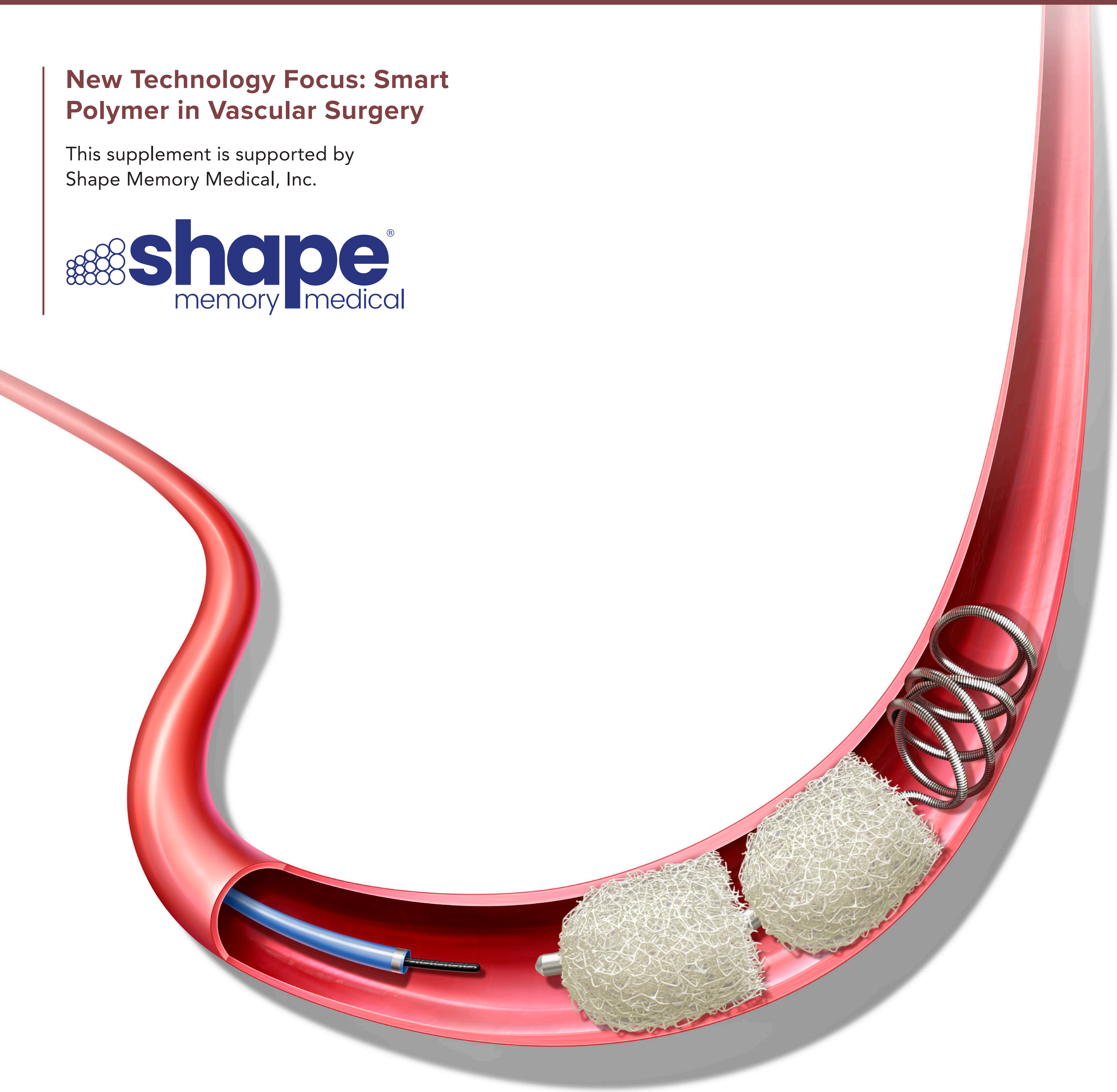

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New Technology Focus: Smart Polymer in Vascular Surgery

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Abstract

A new smart polymer technology developed by Shape Memory Medical is available to endovascular specialists. The shape memory polymer is incorporated into vascular plugs and coils. Dr Ross Milner, a vascular surgeon at University of Chicago Medicine, gives his perspective on the properties of the shape memory polymer and how smart polymer devices may be used in vascular surgery.

Keywords

Smart polymer, endovascular, embolic technology, vascular surgery, thrombus remodelling, shape memory polymer

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Q: How would you describe shape memory polymer to your colleagues?

Dr Ross Milner: Shape Memory Medical's smart polymer is much more than a space filling embolic technology. Its biologically active healing mechanism is a unique feature that has the potential to produce better long-term outcomes when treating aneurysms and other cardiovascular conditions. Developing a novel material and incorporating it into medical devices is an arduous task and new materials do not come along often. It is important for us to assess this new technology with a curious and open mind.

Shape memory polymer is a biocompatible ultra-low-density polyurethane smart polymer that takes the form of an expanded porous structure when it is in the body (*Figure 1*). The expanded porous matrix is haemostatic and supports rapid formation of organised thrombus throughout its structure. Over time, the polymer stimulates thrombus remodelling and healthy tissue formation and gradually bioabsorbs (*Figure 2*). These micro-level properties have been observed during its development and in animal studies on vascular plugs and coils featuring the smart polymer.[1–3]

The smart polymer has shape memory properties which come into play during delivery of the devices as the material can switch between two stable shapes. The smart polymer in Shape Memory Medical's devices is manufactured in an expanded porous shape and is then – under specific conditions – crimped into another stable shape for storage and catheter delivery. When the smart polymer finds itself in an aqueous environment at body temperature – in a vessel, for example – it remembers its original shape and self-expands to the porous structure. The shape memory properties of the polymer have been created after years of work to understand and refine polymer chemistry, and the company has worked extensively to demonstrate the material's biocompatibility.

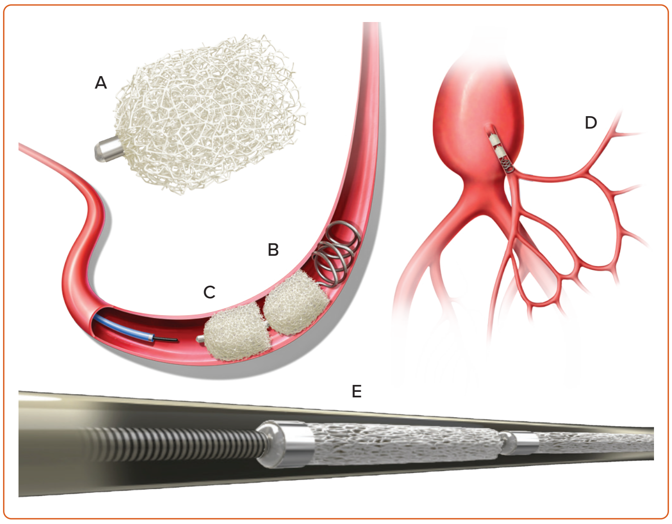
Q: What differentiates shape memory polymer from other embolisation device materials?

RM: Shape memory polymer is very different from other embolisation device materials, but it is natural to compare new things to more familiar materials, so we can compare it to two groups: metallic coils and vascular plugs; and liquid embolics.

When compared to metallic coils and plugs, the key differentiating feature of the shape memory polymer is its porous structure. Smart polymer devices are manufactured to fully-expanded diameters that fill the cross-section of a vessel, and the pores are approximately 1,000–2,000 microns (*Figure 2*). The porosity means that the mass and volume of implanted foreign material is low. The expanded matrix has a high surface area of biocompatible, embolic material, and the resulting polymer-supported thrombus embolus fills the diameter of the vessel. On the other hand, bare metal coils have a lower embolic surface area to volume ratio and numerous softer coils would be required to achieve the same high packing density of embolic material. Vascular plugs work by creating a physical barrier to achieve haemostasis and/or work in a similar fashion to coils. Therefore, to reiterate their unique mechanism of action, the porous smart polymer vascular plugs work by supporting acute thrombus formation throughout their structure across the entire vessel diameter and this thrombus then remodels to healthy tissue over time as the polymer gradually bioabsorbs (*Figure 2*).

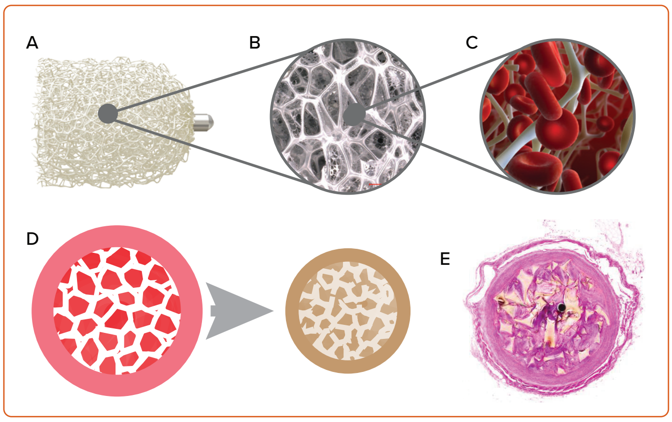
The porous, biologically active structure of the smart polymer sets it apart from the Onyx copolymer (Medtronic), which is the primary liquid embolic used in my vascular surgery practice. Furthermore, the shape memory polymer does not flow into a vessel; rather the polymer used in the IMPEDE Embolization Plug family of devices (Shape Memory Medical) simply self-expands to a discrete volume of ~1.25 ml for the 12 mm diameter devices. The discrete expanded volume means the smart

Figure 1. Smart Polymer Vascular Plug Devices



A: The expanded form of the IMPEDE-FX Embolization Plug with smart polymer and a proximal radiopaque marker; B: The IMPEDE Embolization Plug with a distal anchor coil deployed in a vessel; C: An IMPEDE-FX Embolization Plug deployed behind the IMPEDE Embolization Plug to increase the amount of embolic material in a vessel with minimal additional metal. D: The use of IMPEDE and IMPEDE-FX Embolization Plugs to embolise an inferior mesenteric artery prior to EVAR; E: The IMPEDE Embolization Plug family of devices are pushable. The IMPEDE-FX RapidFill device consists of five IMPEDE-FX Embolization Plugs preloaded in a cartridge. Source: Reproduced with permission from Shape Memory Medical, Inc.

Figure 2. IMPEDE-FX Embolization Plug with Smart Polymer



A: The expanded form of the IMPEDE-FX Embolization Plug with smart polymer and a proximal radiopaque marker; B: The pores of the smart polymer in the IMPEDE Embolization Plug family of devices are approximately ~1,000–2,000 microns; C: The expanded porous matrix is haemostatic and supports rapid formation of organised thrombus throughout its structure; D: The porous smart polymer matrix self-expands to and conforms to the surrounding anatomy. If appropriately sized, an IMPEDE-FX Embolization Plug will expand to fill the vessel diameter. Over time, the smart polymer stimulates thrombus remodelling and healthy tissue formation and the polymer gradually bioabsorbs; E: Histology of a porcine artery implanted with smart polymer device at 60 days post implantation, illustrating uniform extracellular matrix and collagen formation throughout the vessel diameter. Source: Reproduced with permission from Shape Memory Medical, Inc.

polymer devices fill the space in a predictable manner and the expanded form of the polymer has a low radial force which conforms to the surrounding anatomy.

A major differentiating factor for the shape memory polymer is its radiolucency. Delivery of the IMPEDE Embolization Plug family of devices is guided by a small proximal radiopaque marker (*Figure 3*) but the radiolucency of most of the volume of the device means that X-ray imaging of artefacts is minimal during follow-up imaging. This is particularly important if you are filling large spaces with these devices. The radiolucency can also be advantageous during a procedure if contrast is used to confirm exclusion of an aneurysm, for example, as it is easy to see the contrast around and behind the radiolucent device.

Q: How would you describe smart polymer devices to your patients?

RM: I try to avoid using 'doctor speak' when I talk to patients. I would tell them that smart polymer devices work with the blood to create the blockage in the vessel, which is how we plan to treat their condition. The polymer is soft and looks a bit like a sponge. The Swiss cheese structure of the polymer acts as a scaffold that supports the natural processes that occur when we implant something into a vessel. After a blockage is created, the polymer slowly absorbs into the body, which means there is very little foreign material left behind. The enclosing volume of the polymer portion in the largest of the IMPEDE Embolization Plug family of devices, when fully expanded, is about 1.25 ml – this is smaller than a quarter of a teaspoon or about the same size as the tip of a person's little finger.

Q: Could you describe the smart polymer devices currently on the market?

RM: The IMPEDE-FX Embolization Plug consists of the shape memory polymer and a proximal radiopaque marker (*Figure 1*). The IMPEDE-FX RapidFill device is five 12 mm diameter IMPEDE-FX Embolization Plugs in a cartridge, which means all five are pushed into the vasculature at the same time. This is convenient if you want to embolise or fill a large volume, such as when treating an aneurysm, for example.

The IMPEDE Embolization Plug has an anchor coil (*Figure 1*) and this device should be used in situations where the low radial force of the smart polymer needs more stability – in high-flow situations, for example. Using the anchor coil means additional bare metal is implanted with consequent artefact. The smart polymer vascular plug devices have slightly differently indications under CE marking in Europe compared to the US; therefore, it is important to check local labelling.

The IMPEDE Embolization Plug family of devices are pushable rather than detachable. I performed my endovascular training in an era when pushable devices were commonplace. More recently, there has been an increase in the use of detachable coils and there is certainly a time and place for detachable embolisation devices. But when trying to fill space quickly, pushable devices are more than adequate and they can minimise the time and complexity of the procedure. I continue to train fellows to use pushable devices.

Finally, there is the TrelliX Embolic Coil with smart polymer (*Figure 4*). This detachable coil is indicated for use in the peripheral vasculature and neurovasculature. The volume of the embolic material of the coil increases approximately fourfold when the polymer is completely expanded. Therefore, the packing density of the embolic material is significantly increased upon expansion of the smart polymer, and coil packing density is an important factor in peripheral vascular aneurysm treatment.[4]

Q: What would be an ideal case for someone using smart polymer devices for the first time?

RM: Most of my endovascular embolisation work centres on the treatment of aortic aneurysms. Vascular surgeon and interventional radiology peers are using smart polymer devices to embolise peripheral vascular vessels contributing to post EVAR endoleaks, and smart polymer devices are being used to embolise iliac arteries during EVAR.

In the UK, Robert Morgan and colleagues have published a small case series using the technology, with the majority involving the treatment of common and internal iliac artery aneurysms.[5] Therefore, endoleak treatment or sac feeding vessel embolisation at the same time as EVAR appear to be ideal first cases for smart polymer devices.

In the Netherlands, Michel Reijnen and colleagues have published an article on false lumen embolisation as part of infrarenal post-dissection aneurysm treatment, which is also an interesting application of the space-filling and biologically active healing properties of the smart polymer.[6]

Q: What is important to know before using smart polymer devices for the first time?

RM: As mentioned previously, the IMPEDE Embolization Plug devices are pushable, which means delivery is likely to be intuitive. Smart polymer devices also have a working time for deployment, which means they must be delivered within a specific time after being pushed into the delivery catheter. This is because the shape memory effect is initiated immediately after the device enters the warm and aqueous environment of the catheter and the smart polymer starts to expand. If it takes too long to deliver the device, it is possible that the device would expand enough to encounter friction during delivery. But from initial literature reports, it appears that delivery within the working time is not really a challenge.

Dr Morgan and colleagues have reported that the landing zone required for the anchor coil of the IMPEDE Embolization Plug is 2–4.5 cm.[5] Getting a feel for the stability of the IMPEDE-FX Embolisation Plug in a vessel will be important and it was interesting to read about the technique used by Daniele Savio and colleagues in Italy when treating an ovarian vein with smart polymer devices when they were trying to minimise the amount of metal implanted. The authors reported holding the delivery catheter in place until they were sure haemostasis had occurred and the device was stable in the vein.[7]

Q: How do you see smart polymer technology being used to the greatest effect in vascular surgery?

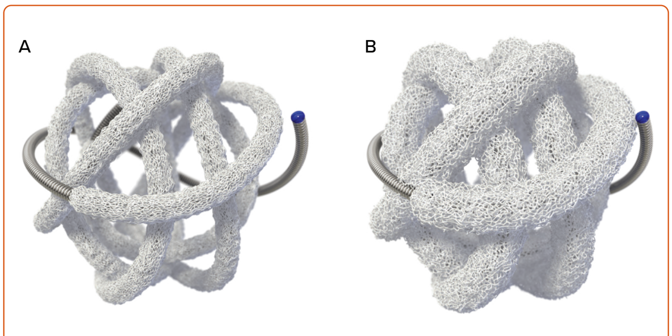
RM: There is encouraging initial news coming from the AAA-SHAPE studies looking at the use of smart polymer devices to treat abdominal aortic aneurysm (AAA) in New Zealand (AAA-SHAPE; NCT04227054) and the Netherlands (AAA-SHAPE_NLD; NCT04751578). The studies are nearing complete enrolment and we must wait for 12-month follow-up, but early presentations are reporting large reductions in sac size after filling AAA sacs with smart polymer devices at the same time as EVAR.

It has been demonstrated that the volume of embolic material implanted in an AAA sac may be related to the extent of sac shrinkage, and that the failure of an AAA sac to regress is associated with lower long-term survival.[8,9] The AAA-SHAPE studies are building on these observations. We have learned that 'filling the space' alone in aneurysm care is not wholly effective and comprehensive aneurysm care requires a different mechanism. A soft and conformable device material that supports thrombus formation throughout its structure and supports tissue remodelling over time is an exciting prospect for the active treatment of aortic aneurysm sacs at the same time as EVAR. Time will tell if we have a revolutionary material in our hands. ❑

Figure 3. Smart Polymer is Radiolucent

The smart polymer (white arrow) of an IMPEDE Embolization Plug with an anchor coil and the smart polymer (black arrow) of an IMPEDE-FX Embolization Plug implanted into an inferior mesenteric artery. The smart polymer (yellow arrow) of an IMPEDE Embolization Plug with an anchor coil and the smart polymer (blue arrow) of an IMPEDE-FX Embolization Plug implanted into a left renal accessory artery. Arrows indicate the location of the radiolucent smart polymer. Source: Angiographic image from a type II endoleak case courtesy of Alexander Maßmann, Saarland University Medical Center, Homburg/Saar, Germany. Reproduced with permission from Shape Memory Medical, inc.

Figure 4. The Detachable TrelliX Embolic Coil with Smart Polymer



The Detachable TrelliX Embolic Coil with smart polymer in its crimped form for catheter delivery (A) and in its expanded form (B). The volume of the embolic material of the coil increases approximately fourfold on complete polymer expansion. Source: Reproduced with permission from Shape Memory Medical, Inc.

Indications

In countries that recognise CE marking, the IMPEDE® Embolization Plug, the IMPEDE-FX Embolization Plug, and IMPEDE-FX RapidFill® are indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature. In the US, the IMPEDE Embolization Plug is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature and the IMPEDE-FX Embolization Plug is indicated for use with the IMPEDE Embolization Plug to obstruct or reduce the rate of blood flow in the peripheral vasculature. The IMPEDE-FX RapidFill device is not approved for sale in the US.

In countries that recognise CE marking, the TrelliX Embolic Coil System is intended to obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels. Indications include intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and arterial and venous embolisations in the peripheral vasculature. The TrelliX Embolic Coil is not approved for sale in the US.

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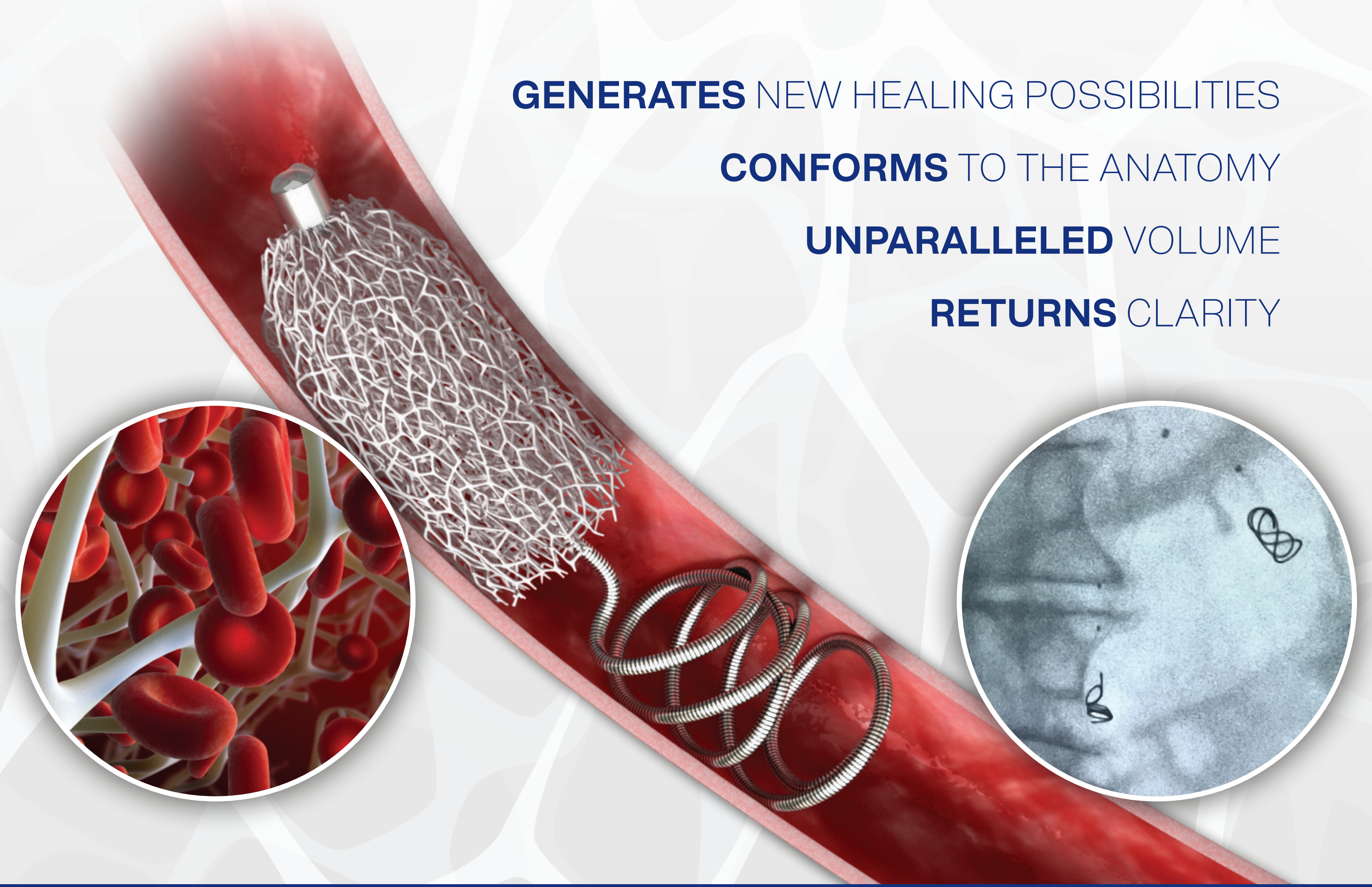

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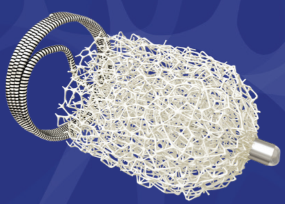

IMPEDE®
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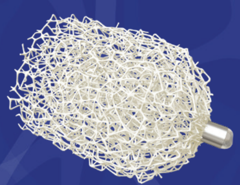

IMPEDE-FX
Embolization Plug

Indications: The IMPEDE Embolization Plug is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature. The IMPEDE-FX Embolization Plug is indicated for use with the IMPEDE Embolization Plug to obstruct or reduce the rate of blood flow in the peripheral vasculature. Refer to the IFU – supplied with each device – for a complete statement of the indications, contraindications, warnings, and instructions for use.

Inferior Mesenteric (IMA) and Renal Accessory Artery angiographic image courtesy of Alexander Maβmann, MD, Saarland University Medical Center, Homburg/Saar, Germany.
The images are illustrative and do not represent the actual size of any products.

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