A New Small to Medium Vessel Embolization Device
Shape Memory Medical First-in-Human IMPEDE Trial

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Disclosures and Disclaimers
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No other relevant disclosures

Background: The Need for Vascular Embolization Devices
- Vascular embolization devices have a wide range of applications
- Devices include microparticles, sclerosants, liquid embolics, coils and plugs
- Requirements for embolic devices used in small to medium sized vessels include accurate deployment, stable position, vessel conformability, rapid occlusion and freedom from recanalization

Shape Memory Polymer (SMP) Technology for Embolization
- The IMPEDE™ Embolization System with SMP Technology is indicated to obstruct blood flow in the peripheral vasculature
- The system provides:
  - Targeted deployment
  - Quick stable occlusion
  - High degree of space filling
  - Excellent vessel conformability

The IMPEDE device has a CE Mark. It does not have FDA Clearance and is not available in the US.

IMPEDE™ Embolization Plug with SMP Technology
- Length of SMP Technology (Plug) – expands when exposed to 37°C aqueous environment
- Proximal RO marker
- Distal platinum/iridium anchor coil

Shape Memory Polymer (SMP) Technology
- SMP Polymers are porous polymeric materials designed to exist in two stable states:
  - Primary Crimped State: for delivery
  - Secondary Expanded State: when exposed to blood and elevated temperature
- High surface area induces long fluid residence times and low shear rates which lead to thrombus formation

Cardiology Rev. 27 (2008): 56-70
J. Heart Valve Dis. 9 (2000): 379-388


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SMP Technology – Preclinical Experience

- At 90 days, SMP demonstrates significant healing with collagen (green) throughout the aneurysm and minimal red blood cell residual


Trichrome x-section of bisected aneurysm sac (1.3X mag)

Apex of aneurysm

SMP plug
Device-parent artery interface

IMPEDE™ Embolization Plug with SMP Technology

1. Crimped SMP Plug
2. Anchor Coil
3. Proximal Marker Band
4. Expanded SMP Plug

IMPEDE™ Embolization Plug – FIH Experience

- 7 cases performed to date
- Indications include:
  - Aortic branch artery embolization during EVAR
  - Trans-arterial tumour embolization
  - Varicocele embolization
- Devices successfully delivered and deployed in 100% cases
- Technical success 100% (all vessels completely occluded @ 5 minutes)
- No serious adverse events @ 30 days
- No recanalization on imaging @ 30 days (4/7 cases followed up to date)

IMPEDE™ Embolization Plug – Case # 1

- 76 year old male
- Unexplained sac expansion post-EVAR
- Possibly due to inadequate seal in RCIA (type 1B “endotension”)
- For right hypogastric artery embolization and limb extension

IMPEDE™ Embolization Plug – Case # 1

- 5F Terumo Destination sheath, RIIA 8mm diameter
- IMP – 10 (for 6 - 10mm vessels)

Sheath withdrawn to deploy plug
Angiogram after 5 minutes – completely occluded
Covered stent deployed
RIIA trunk remains occluded on CT @ 1 month

24 year old male with large left varicocele
IMP-10 (6-10mm vessel) via 5F Cook Shuttle sheath

IMPEDE™ Embolization Plug – Case # 1

IMPEDE™ Embolization Plug – Case # 2

Conclusions
• The IMPEDE™ Embolization System with SMP Technology is a new technology for small to medium vessel embolization
• Advantages include quick and stable occlusion, high degree of space filling and excellent vessel conformability
• Early clinical experience is promising