

A Novel Device for Embolization in the Arterial Peripheral Vasculature: First-in-Human Update

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Disclosure

Speaker name: Andrew Holden

I have the following potential conflicts of interest to report:

- Receipt of grants/research support
Details: Clinical researcher for BD-BARD
- Receipt of honoraria and travel support
Details: Nil
- Employment in industry
Details: Nil
- Shareholder in a healthcare company
Details: Nil

Percutaneous Transcatheter Embolization

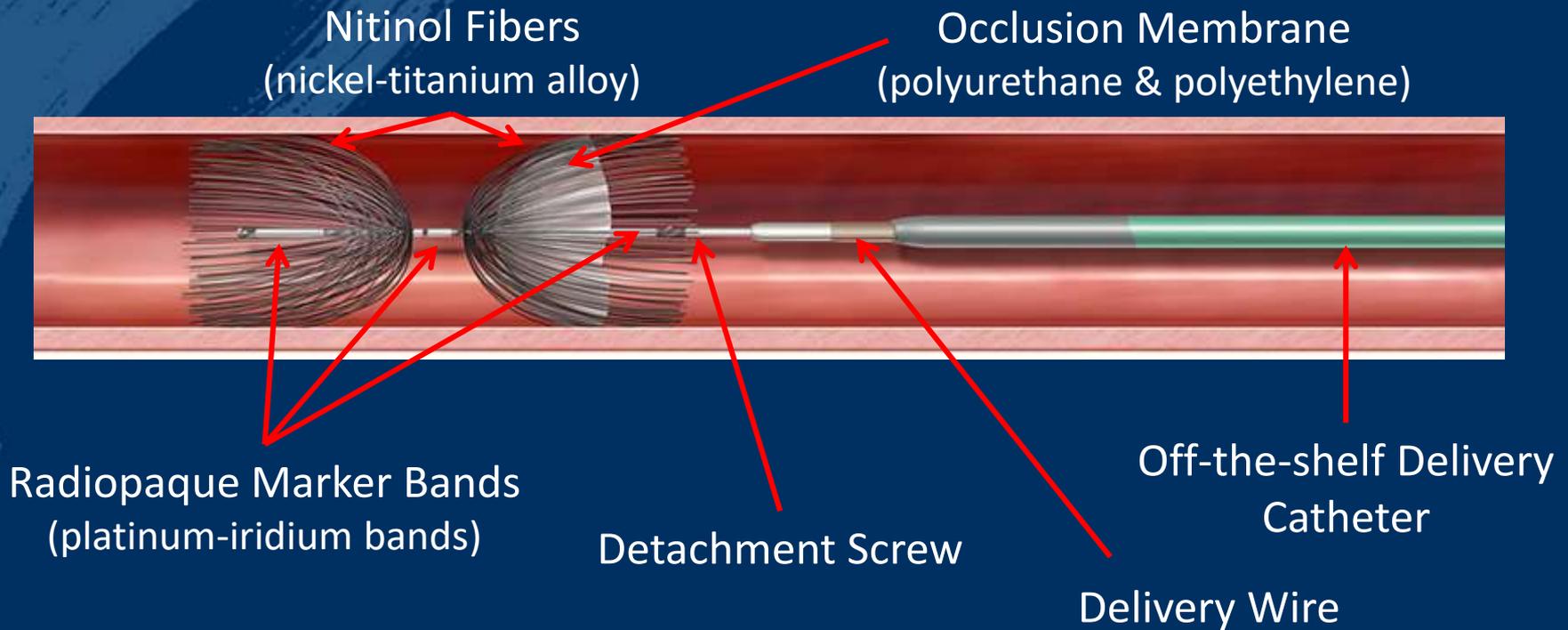
- Placement of an agent (solid or liquid) or device to produce temporary or permanent vessel occlusion (i.e., block flow)
- Used to treat a variety of conditions by de-vascularizing benign or malignant tissues

Types of Embolization Agents & Devices

Liquid Agents	Solid Agents	Particulates	Devices
Sclerosants	Autologous Clot	Polyvinyl Alcohol Particles (PVA)	Coils: <ul style="list-style-type: none">▪ Pushable▪ Detachable
Glues	Gelfoam: <ul style="list-style-type: none">▪ Slurry▪ Pledgets▪ Powder	Microspheres: <ul style="list-style-type: none">▪ Bland▪ Drug-Eluting▪ Radioactive	Plugs
Elastic Polymers			
Lipiodol	Microfibrillar Collagen		

CATERPILLAR Arterial Embolization Device

The CATERPILLAR™ Arterial Embolization Device is a self-expanding vascular occlusion plug (permanent implant) intended for arterial embolization in the peripheral vasculature



CATERPILLAR Device Selection

Diameter and maximum length of the embolization site must be measured to select the proper device:

CATERPILLAR Sizing Chart

Product Name	Product Reference	Marker to Marker Length (mm) ¹	Maximum Deployed Length (mm) ²	Target Artery Diameter (mm)
CATERPILLAR™ Micro	027	7	16	1.5 – 4
CATERPILLAR™	038	17	26	3 – 6
	056	18	37	5 – 7

¹Marker to Marker Length: distance between the most distal radiopaque marker band to the most proximal radiopaque marker band

² Maximum Deployed Length: length from the distal fiber tips to the proximal fiber tips in the minimum target vessel diameter

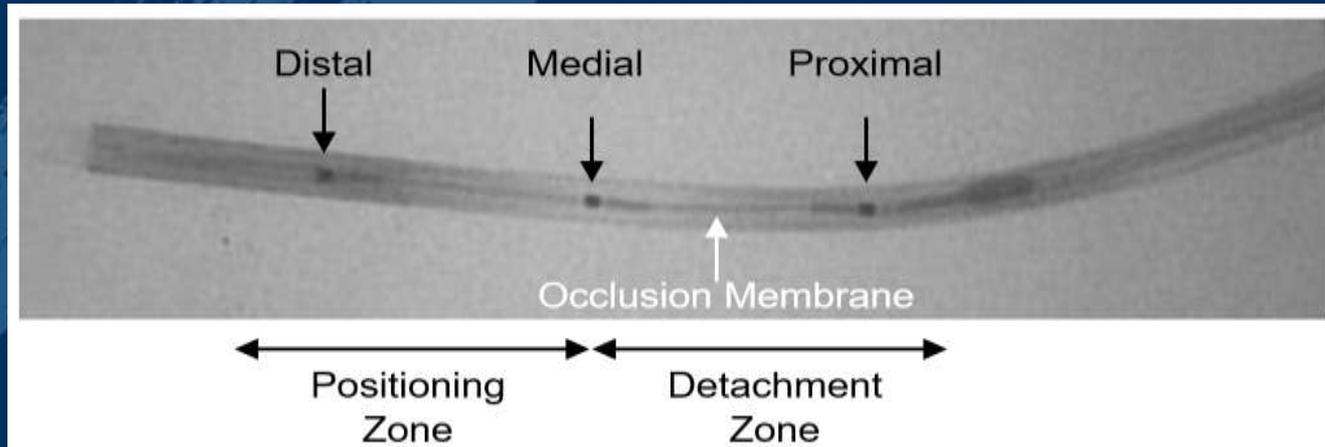
Delivery catheter minimum requirements:

(Full list of catheters and lengths found in the Instructions for Use)

- ≤155 cm for the CATERPILLAR™ Micro (027)
- ≤140 cm for CATERPILLAR™ (038 & 056)

CATERPILLAR Device Deployment

Visibility Under Fluoroscopy



- Slowly retract the delivery catheter to deploy the Positioning Zone
- Confirm position
- Slowly retract the delivery catheter to deploy the Detachment Zone



Positioning Zone



Detachment Zone

CHRYSALIS Study Design

Objective: First-in-man feasibility study designed to evaluate the CATERPILLAR™ Arterial Embolization Device used for peripheral arterial embolization

Study Type	Prospective, Multi-Center, Single-Arm
Countries	Australia & New Zealand
# of Sites	Up to 5
# of Subjects	Up to 20
Study Population	Male or non-pregnant female subjects ≥ 18 years of age requiring arterial embolization in the peripheral vascular.
Medical Monitor	Independent physician to identify potential safety issues or review needs for modification of the study
Follow-Up	30 (-7/+21) Days Post-Procedure

CHRYSALIS Investigators and Study Sites

Investigator	Site	City	Country
Andrew Holden*	Auckland Hospital	Auckland	
Thodur Vasudevan	Waikato District Health Board	Hamilton	
Steven Dubenec	Royal Prince Alfred Hospital	Sydney	
Gerard Goh	Alfred Health	Melbourne	

*National Principal Investigator

CHRYSALIS Study Criteria

Key Inclusion Criteria

- Peripheral arterial embolization site that can be treated according to the device Instructions for Use (IFU)
- Embolization site must be in a native peripheral artery or arteries
- Arterial diameter ranges: 1.5 to 7 mm (via visual estimate)
- Landing zone that can accommodate device lengths up to 37mm
- More than one target embolization site may be treated per patient

Key Exclusion Criteria

- Embolization site located in a vein, or head, neck, heart, or coronary vessels
- Embolization site across highly mobile joints or muscle beds (e.g. elbow, hip, knee, shoulder, thoracic inlet/outlet)
- Embolization site in a high-flow vessel with significant risk of device migration and unintended (non-target site) occlusion
- Known allergy or hypersensitivity to contrast media or any device materials (e.g., cobalt, chromium, nickel, titanium, platinum, iridium, polyurethane or polyethylene)
- Uncontrolled bleeding or coagulation disorders, or unresolved systemic infection

CHRYSALIS Primary Endpoints

Primary Performance Endpoint

Technical Success

- Periprocedural occlusion of the target embolization site(s) confirmed by angiographic assessment

Primary Safety Endpoint

30-Day Freedom from Device-Related Serious Adverse Events (SAEs)

CHRYSALIS Secondary Endpoints

Time of Occlusion

- % of sites with occlusion at ≤ 1 , ≤ 2 , ≤ 3 , ≤ 4 , ≤ 5 , ≤ 10 and >10 minutes post-procedure

Freedom from Recanalization

- 30-day freedom from clinically-relevant recanalization (i.e., flow through the device requiring re-intervention)

Freedom from Migration

- Freedom from clinically-relevant acute and 30-day migration of the device (i.e., device migration requiring intervention)

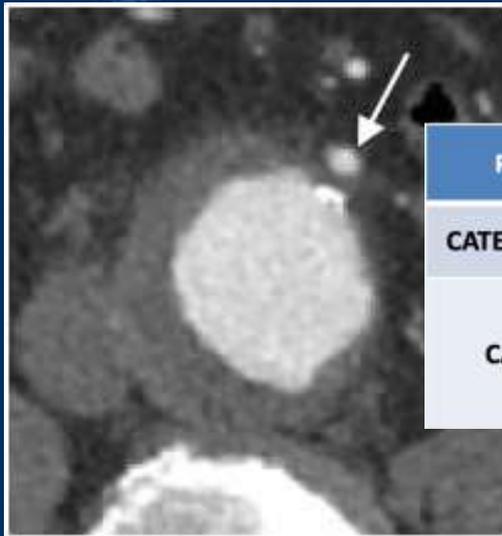
30-day Freedom from Device and/or Procedure-Related Adverse Events

Investigator Assessment/Satisfaction

- Qualitative assessment of the accuracy of device delivery, trackability and ease of delivery, and visibility under fluoroscopy

CASE 1

- A 69-year-old male presented for an elective repair of a 57 mm juxta-renal abdominal aortic aneurysm
- On pre-operative CT Angiography, a 5.5 mm diameter inferior mesenteric artery (IMA) was noted to arise from the lower aneurysm sac
- Planned for fenestrated endovascular aneurysm repair (FEVAR) with prophylactic embolization of the IMA trunk during the EVAR procedure

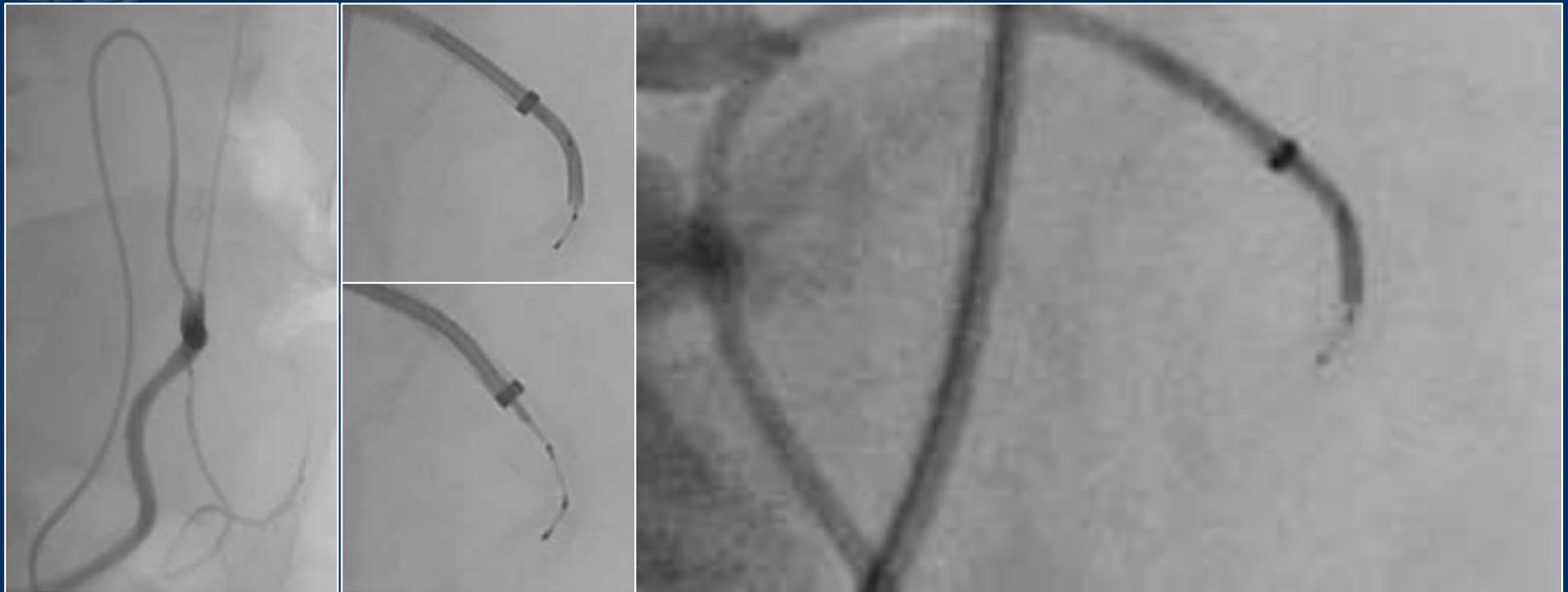


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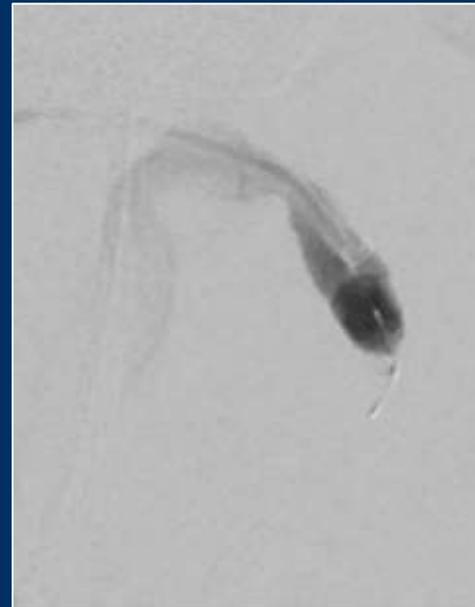
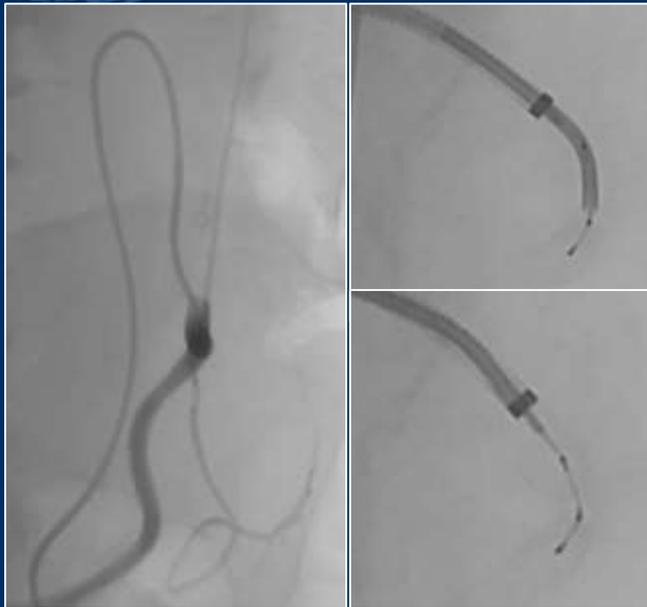
CASE 1

- A During the procedure, the IMA was cannulated with a Simmons 2 catheter, subsequently exchanged for a 6F Terumo Destination sheath with a Cordis Tempo™ catheter
- Through this a 3-6 mm Caterpillar™ Arterial Embolization Device was introduced and deployed with the device carefully positioned in the IMA trunk above its bifurcation into left colic and superior rectal branches



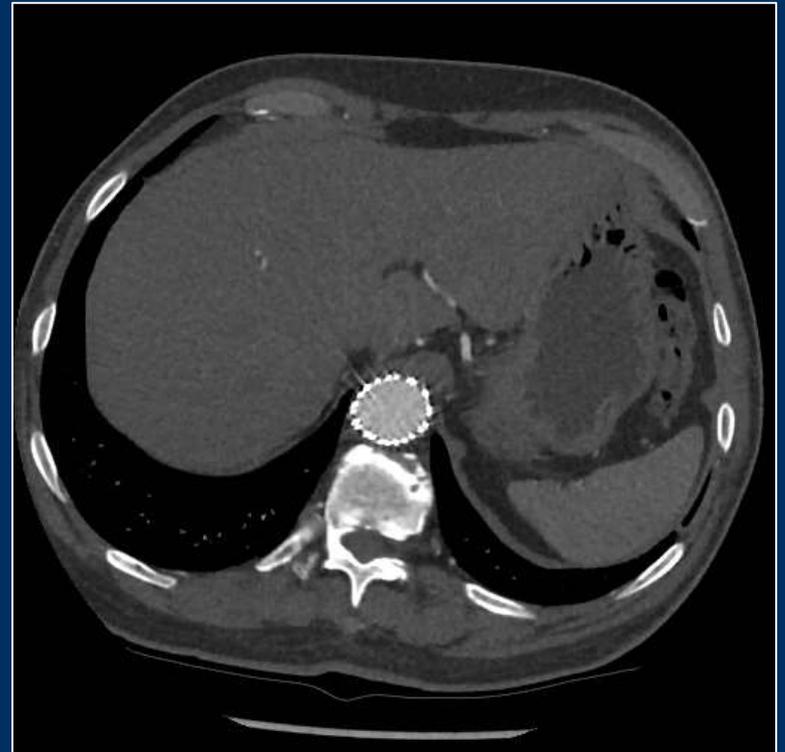
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- **Angiogram at 5 minutes post-deployment showed complete occlusion of the IMA trunk**
- **The remainder of the procedure was uneventful**



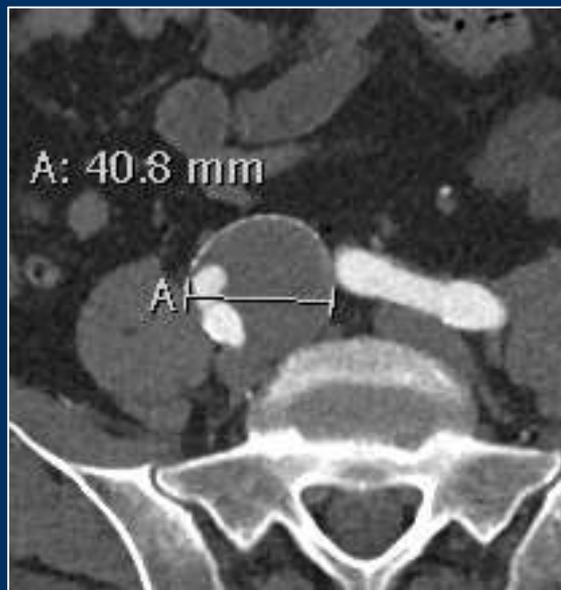
CASE 1

- A post-operative CT at 1 month showed complete aneurysm exclusion and no endoleak
- The trunk of the IMA was occluded above the Caterpillar™ device, but the superior rectal artery remained patent



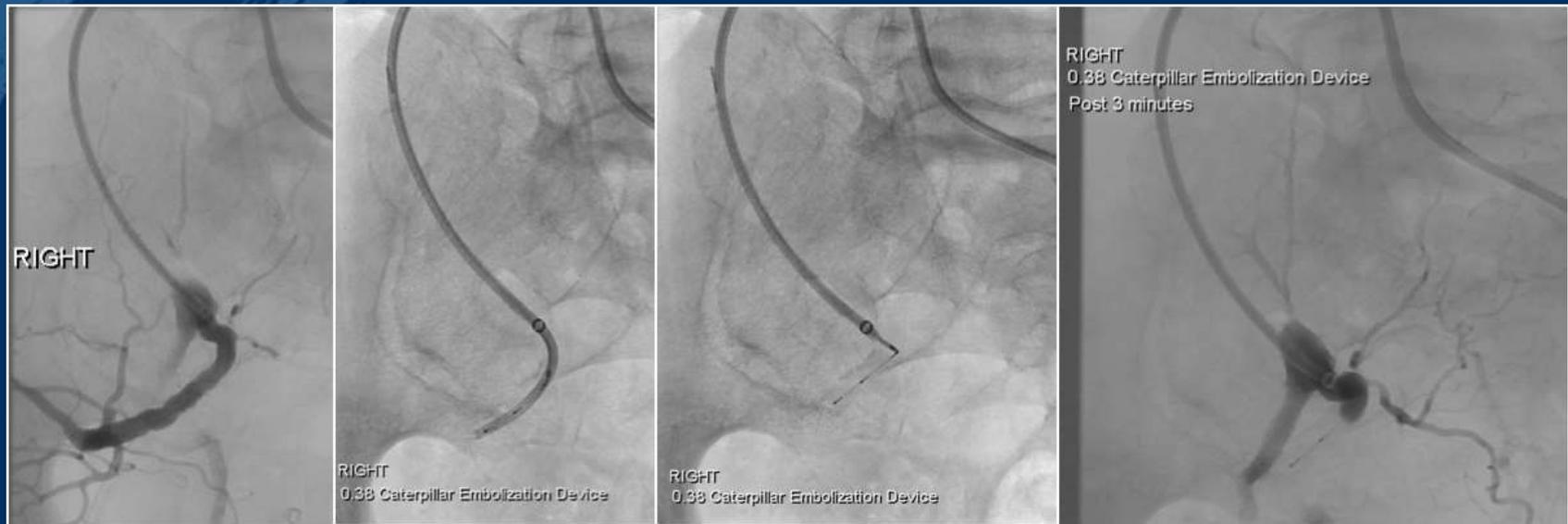
CASE 2

- A 77-year old male had a past history of open repair of a ruptured abdominal aortic aneurysm in 2016. The right common iliac artery aneurysm (RCIAA) was not treated at that time and had progressively dilated, measuring 41 mm in diameter
- This aneurysm was treated with prophylactic embolization of the anterior and posterior divisions of the right internal iliac artery (RIIA) followed by deployment of an endograft (Gore Exclude limb) from the proximal RCIA to the mid right external iliac artery



CASE 2

- The posterior division of the RIA was embolized with a 3-6 mm Caterpillar™ Arterial Embolization Device deployed from the contralateral groin via a 6F sheath and 5F Boston Scientific Imager™ Cobra 2 co-axial catheter
- Complete occlusion was achieved at 3-minutes post-deployment



CASE 2

- The anterior division RIIA was embolized and the iliac endograft deployed
- A post-operative CT at 1-month showed the RCIAA was satisfactorily occluded and the anterior and posterior divisions proximally occluded but distally reconstituted
- The patient made an uneventful recovery apart from mild right buttock claudication when walking > 500 metres



Summary

- The CATERPILLAR™ Arterial Embolization Device is a new self-expanding vascular occlusion plug intended as a permanent implant for arterial embolization in the peripheral vasculature



- CHRYSALIS is a prospective feasibility study being conducted at 5 sites in Australia and New Zealand to evaluate the safety and performance of the device when used for peripheral arterial embolization
- Two initial cases from the trial were presented today. Enrollment is ongoing with early results expected later this year

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