Caterpillar™ | Caterpillar™ Micro

Arterial Embolization Device | Arterial Embolization Device

ORDER CHART

Product code	Item name	Product reference	Target artery diameter	Marker to marker length[1]	Maximum deployed length[2]	Delivery wire length	Delivery catheter compatibility: inner diameter[3]
CTP027015U	Caterpillar™ Micro	027	1.5 – 4 mm	7 mm	16 mm	170 cm	0.027" / 0.686 mm
CTP038020U	Caterpillar™	038	3 – 6 mm	17 mm	26 mm	155 cm	0.038" / 0.965 mm
CTP056030U	Caterpillar™	056	5 – 7 mm	18 mm	37 mm	155 cm	0.056" / 1.422 mm

1. The marker to marker length is the distance between the most distal radiopaque marker band to the most proximal radiopaque marker band.
2. The maximum deployed length is the length from the distal fiber tips to the proximal fiber tips in the minimum target artery diameter.
3. Detailed list of compatible delivery catheters can be found in the product labels and inserts.

CONSTRAINED DIAMETERS AND LENGTHS

Caterpillar™ Micro Arterial Embolization Device (027)
Treats 1.5 – 4 mm diameter artery

Max deployed length – 16 mm

Caterpillar™ Arterial Embolization Device (038)
Treats 3 – 6 mm diameter artery

Max deployed length – 26 mm

Caterpillar™ Arterial Embolization Device (056)
Treats 5 – 7 mm diameter artery

Max deployed length – 37 mm

Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices

INDICATIONS FOR USE: The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices are indicated for arterial embolization in the peripheral vasculature. The devices are contraindicated for use in vessels subject to cyclic bending, such as locomotive joints or muscle beds. **WARNINGS:** Results of preclinical testing suggest that implant locations which expose the device to cyclic bending such as locomotive joints or muscle beds may increase the likelihood of device fracture or migration. • The safety and effectiveness of the use of the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices in veins, in the heart, in coronary vessels, and in the neurovasculature has not been established. • The Caterpillar™ or Caterpillar™ Micro Arterial Embolization Devices are only intended for use in specific artery diameter ranges that are listed in the IFU. Use in artery diameters other than those specified could result in poor occlusion and/or device migration. • The Caterpillar™ or Caterpillar™ Micro Arterial Embolization Devices should be advanced and/or manipulated under fluoroscopic guidance. If the device cannot be adequately visualized under fluoroscopy, remove and discard the device and use an alternative device. • Do not use this device in patients with a known hypersensitivity to the materials listed below as they may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as for allergy/hypersensitivity to these materials: Cobalt, Chromium, Nickel, Titanium, Platinum, Iridium, Polyurethane, Polyethylene. • The safety and effectiveness of this device has not been evaluated in children or pregnant women. **PRECAUTIONS:** The device should only be used by physicians who are trained in endovascular procedures and are familiar with the complications, side effects and hazards of peripheral vascular interventions. The physician should determine appropriate patient compatibility with the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices prior to use. In particular, the physician should determine that the product dimensions are appropriate for the implant area. • Physicians should exercise clinical judgment in situations that involve use of anticoagulants or antiplatelet drugs before, during and/or after use of the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices as their use may slow the rate of occlusion. **POTENTIAL COMPLICATIONS:** Potential patient/device adverse effects which can occur singularly or collectively and may include, but are not limited to, the following: Air embolism; allergic reaction/toxic effects; complications requiring surgical reintervention such as device or component retrieval; death; embolism; fracture and/or detachment of components; fever; foreign material embolic event; hemolysis; hemorrhage; implant malposition/misalignment; migration of the implant; nausea and vomiting; occlusion of unintended vessel; pain; recanalization; residual flow; sepsis, infection, and/or inflammation; stroke; tissue ischemia and infarction; vascular access site complication; vasospasm; vessel trauma including perforation, rupture, or extravasation. **Please consult product labels and inserts for complete indications, contraindications, hazards, warnings, precautions and directions for use.**

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Dual-action occlusion.

An innovative dual-action design with opposing nitinol fiber segments and an occlusion membrane to help support rapid embolization and provide a balance between placement accuracy and deliverability in tortuous anatomy.

Occlusion efficiency[1,2]

Pre-clinical results

Caterpillar™	MVP™	AVP 4 & AVP II
100% Occlusion efficiency with a single device	83% Occlusion efficiency with a single device	75% Occlusion efficiency with a single device

Rapid occlusion[1,2]

- Occlusion membrane designed to create a rapid cessation of blood flow
- Fiber segments assist in thrombis formation

Pre-clinical results

Caterpillar™	MVP™	AVP 4 & AVP II
2.29 Min. to full occlusion (n=14)	4.17 Min. to full occlusion (n=8)	5.63 Min. to full occlusion (n=8)

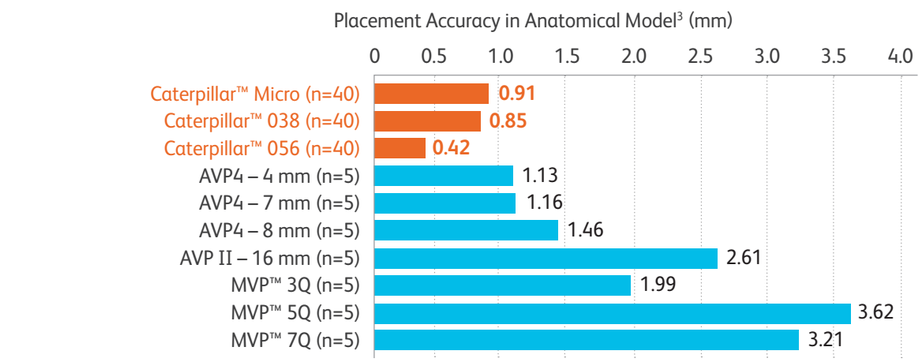
Average time to occlusion

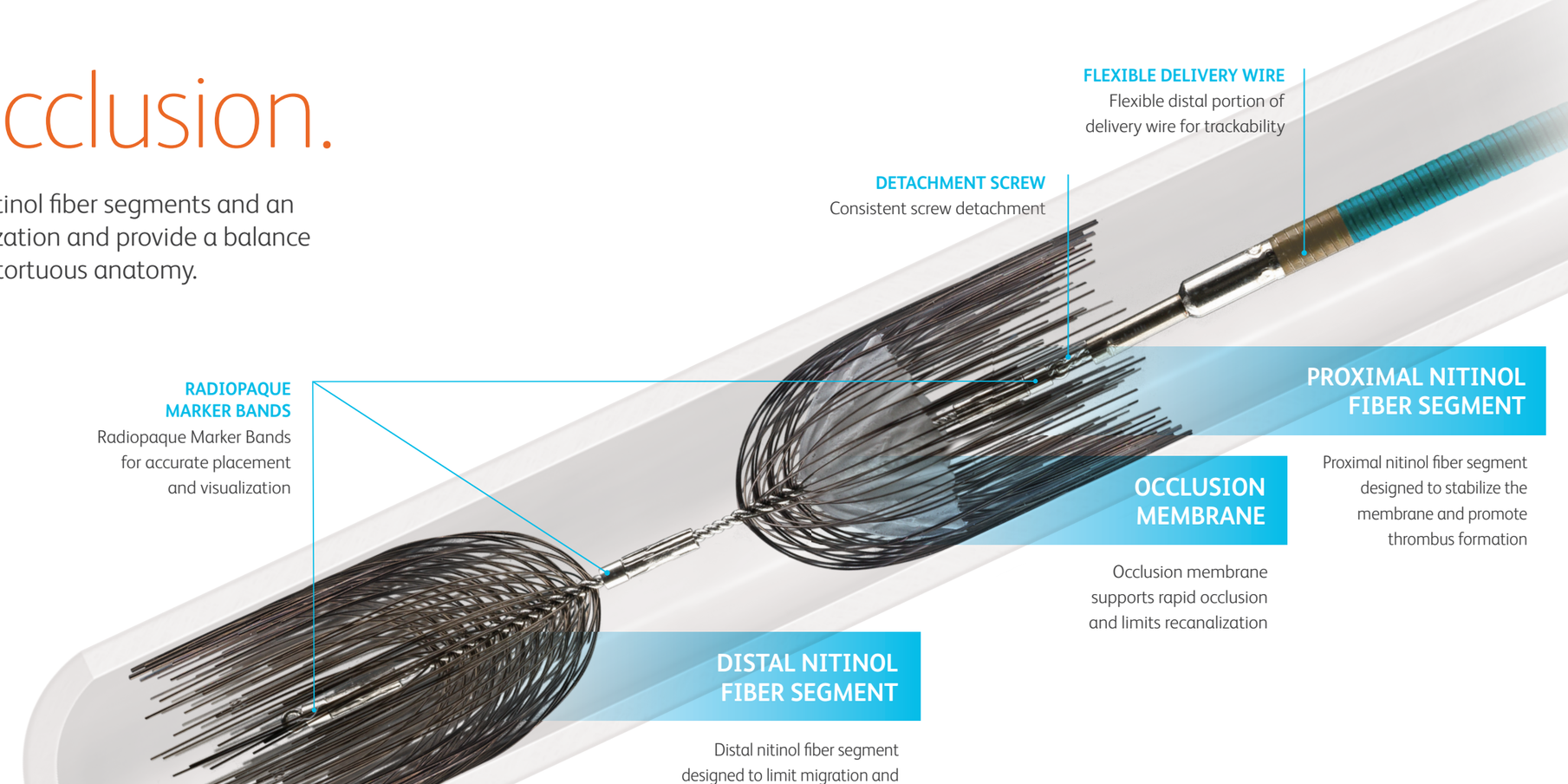
Deliverability in tortuous anatomy[3]

- Nitinol fibers compress to allow for low track forces
- Flexible delivery wire designed to facilitate tracking across tortuous anatomy

Accurate placement[3]

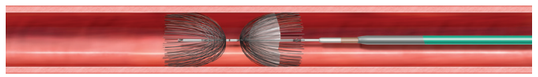
- Self-expansion of nitinol fibers designed for accurate placement
- Three radiopaque markers bands for visualization under fluoroscopy



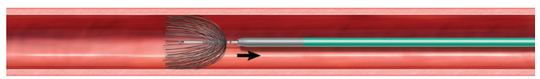


DEVICE DEPLOYMENT

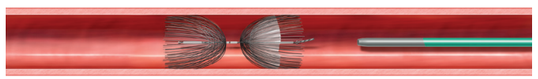
1. Ensure the distal tip of the catheter is at the distal end of the target occlusion site.



3. If the device position is satisfactory after deployment of the Positioning Zone, deploy the Detachment Zone by holding the delivery wire stationary and slowly retracting the delivery catheter.



2. Hold the delivery wire stationary and slowly retract the delivery catheter to deploy the Positioning Zone. Confirm the device position is satisfactory.*



4. To detach the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices, twist the delivery wire counterclockwise until it separates from the implant. To facilitate detachment, a torque tool is provided.

*Caution: Caterpillar™ Micro Arterial Embolization device cannot be recaptured for repositioning within the microcatheter once the distal segment is deployed.

1. In an arterial ovine Good Laboratory Practice (GLP) study with devices implanted according to labeled indicated vessel diameters, full occlusion at 10 minutes was achieved with all Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices (14/14). 5/6 Medtronic MVP™ control devices reached full occlusion at 10 minutes. 1 MVP™ 5Q device did not occlude at the 10-minute endpoint. 6/8 Abbott AMPLATZER™ (AVP) 4 and AVP II control devices reached full occlusion at 10 minutes. Two AVP 4 – 5 mm devices did not occlude at the 10-minute endpoint. Full occlusion defined as no perfusion – no antegrade flow beyond point of occlusion. Pre-clinical data may not be indicative of clinical performance. Data on file, Bard Peripheral Vascular, Inc.
2. Not all products have identical indications for use. Please refer to each manufacturer's respective Instructions for Use for product labeling information.
3. Placement accuracy and track forces were measured through pre-clinical bench studies using either an anatomical splenic artery or right gastric artery model. Placement accuracy values are averages of the absolute values of device placement to a target line. Bench tests may not be indicative of clinical performance. Different test methods may yield different results. Data on file, Bard Peripheral Vascular, Inc.