BD | Caterpillar™
Arterial Embolization Device

BD | Caterpillar™ Micro
Arterial Embolization Device

INSTRUCTIONS FOR USE

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

A. Device Description

1. Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device Systems

The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices are self-expanding arterial occlusion plugs. The devices consist of the following components and are intended to be a permanent implant (**Figure 1**): cobalt-chrome stem, nickel-titanium fibers, platinum-iridium radiopaque marker bands, and a polyurethane and polyethylene occlusion membrane. These devices are intended for arterial vessel embolization in the peripheral vasculature.

The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device Systems are packaged as a single unit with the implant, loader, dispenser hoop, detachable delivery wire, and torque tool (**Figure 2**). The Caterpillar™ Micro delivery wire is coated with a hydrophilic coating while the Caterpillar™ delivery wire has a PTFE hydrophobic coating. The system is provided sterile and non-pyrogenic, and is intended for single use only.

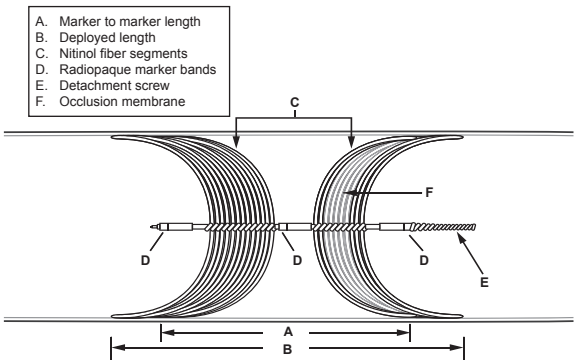

Figure 1: Caterpillar™ and Caterpillar™ Micro Device components

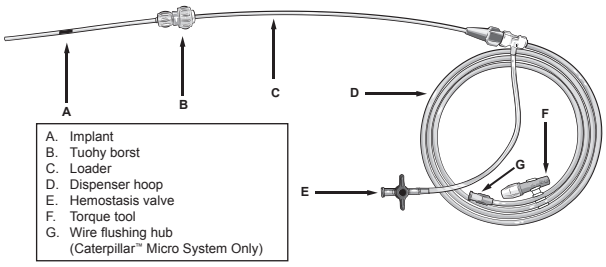

Figure 2: Caterpillar™ and Caterpillar™ Micro Delivery System

2. Implant Sizing and Lengths

The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices are intended for a specific arterial diameter range. The intended artery diameter range and required delivery catheter size (inner diameter (ID)) for deployment are provided in **Table 1**.

Table 1. Product Characteristics

Product Name	Product Reference	Target Artery Diameter (mm)	Delivery Catheter Compatibility: Inner Diameter (in/mm)	Marker to Marker Length (mm)[1]	Maximum Deployed Length (mm)[2]	Delivery Wire Length (cm)
Caterpillar™ Micro	027	1.5-4	0.027/0.686	7	16	170
Caterpillar™	038	3-6	0.038/0.965	17	26	155
	056	5-7	0.056/1.422	18	37	155

1. The Marker to Marker Length is the distance between the most distal radiopaque marker band to the most proximal radiopaque marker band (Figure 1, A).
2. The Maximum Deployed Length is the length from the distal fiber tips to the proximal fiber tips in the minimum target artery diameter (Figure 1, B).

B. 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.

C. 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 the artery diameters listed in Table 1. 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.**
- **The Caterpillar™ or Caterpillar™ Micro Arterial Embolization Devices are supplied sterile and non-pyrogenic. The device is sterilized using ethylene oxide (EtO) and is intended for single use only. Do not resterilize and/or reuse this device.**
- **Visually inspect the packaging to verify that the sterile barrier is intact. Do not use if the sterile barrier is opened or damaged.**
- **After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations.**
- **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.**

D. Precautions

- Check that the device has not been damaged prior to use. Do not use if any damage is visible or if any part of the implant is outside of the loader. If loader or wire kinks or becomes damaged during preparation, do not use the device.
- 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.
- Exercise care in handling the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices to reduce the potential of accidental damage.
- Do not advance the implant outside of the loader prior to insertion into the delivery catheter.
- Only use sterile saline to flush the device. Do not use a power injection syringe to inject contrast solution through the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices.
- Verify that the delivery catheter that is used is compatible with the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices prior to use (Section J).
- If excessive resistance beyond what would be expected is encountered at any point during advancement of the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices through the delivery catheter, stop and remove the device and delivery catheter as one unit/together.
- Do not advance or retract the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices from the loader without attaching the loader via the tuohy borst to the delivery catheter hub.
- Do not twist or rotate the delivery wire during advancement, because the implant may detach prematurely.

- The Caterpillar™ Arterial Embolization Device can only be re-positioned when the Detachment Zone is still in the delivery catheter (Figure 3). If the Detachment Zone is deployed, but re-positioning is required, retrieve and discard the device. A replacement device must then be used.
- Caterpillar™ Micro Arterial Embolization Device cannot be repositioned once the distal segment is deployed. If the distal segment is deployed, but repositioning is required, retrieve and discard the device. A replacement device must then be used.
- Following deployment, use caution to prevent deformation of the membrane or implant position, including with the use of adjunctive therapies.

E. Potential Adverse Events

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

F. MR MRI Safety Information

Non-clinical testing demonstrated that the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices are MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or 1.5-Tesla.
- Spatial gradient magnetic field of 3,400-Gauss/cm or less.
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg (normal operating mode).

Under the scan conditions defined above, the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices are expected to produce a maximum temperature rise of less than 3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 16.45 mm from the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system.

G. How Supplied

The Caterpillar™ or Caterpillar™ Micro Arterial Embolization Devices are supplied sterile (by ethylene oxide gas) and intended for single use only.

H. Contents

Contents of one (1) Caterpillar™ or Caterpillar™ Micro Arterial Embolization Device package:

- One (1) Caterpillar™ or Caterpillar™ Micro Arterial Embolization Device system
- One (1) Patient Implant Card

I. Storage

Store in a cool, dry place. Keep away from sunlight. Rotate inventory so that the device and other dated products are used prior to the “Use By” date. Do not use if packaging is damaged or opened.

J. Materials Required For Use With The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device System

Delivery of the device requires the use of a compatible delivery catheter according to **Table 2**. The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices have been tested for compatibility with the following delivery catheters:

Table 2: Compatible Catheters

Product Name	Product Reference	Delivery Catheter Compatibility: Minimum Inner Diameter (in/mm)	Compatible Catheters (Outer Diameter)
Caterpillar™ Micro	027	0.027/0.686	Terumo Progreat™ (2.8F/3.0F)
			Boston Scientific Renegade™ Hi-Flo (2.8F/3.0F)
			Boston Scientific Direxion™ Hi-Flo (2.8F/3.0F)
			Merit EmboCath™ Plus (2.9F/3.0F)
			Stryker Excelsior™ (2.7F/2.9F)
			Codman Prowler™ (2.6F/3.0F)
			Medtronic Marksman™ (2.8F/3.2F)
			Medtronic Rebar™ (2.8F)
			Cook Cantata™ (2.9F)
Caterpillar™	038	0.038/0.965	Boston Scientific Imager™ II (5F)
			Cook Beacon™ Tip (5F)
			Cordis Tempo™ (4F or 5F)
	056	0.056/1.422	Cordis Vista Brite Tip™ (5F)
			Merit Concierge™ (5F)
			Codman Envoy™ (5F)

Caution: Physicians should exercise their clinical judgment in selection and use of catheters and tip shapes. Using imaging, track the implant through the catheter and catheter tip to the target delivery site. If at any point the Caterpillar™ or Caterpillar™ Micro Arterial Embolization Devices does not track, remove the device and catheter simultaneously from the body. Refer to the instructions for use for each product listed. Manufacturers may make changes to their catheters without notice which may impact their suitability for use with the Caterpillar™ and Caterpillar™ Micro Arterial Embolization systems.

- The use of other delivery catheters may result in an inability to deliver, deploy, or recapture the device.

Note: The delivery catheter length must be less than or equal to 140 cm (155 cm for Caterpillar™ Micro Arterial Embolization Device).

Note: Catheter availability may vary by region.

- A syringe (5cc/ml or l0cc/ml) with sterile saline should be used for flushing of the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices prior to use.

K. Directions For Use

Steps	Caterpillar™ Micro	Caterpillar™
1	Following target artery identification and evaluation, use Table 1 to ensure the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices have the appropriate diameter range for the treatment site.	
2	Per Table 1, ensure that the occlusion site is long enough to accommodate the deployed length of the device (fiber tip to fiber tip) to prevent non-target embolization.	
3	Per Section J, select an appropriate delivery catheter and prepare the catheter according to the manufacturer’s instructions for use.	
4	Prepare the device for use: Inspect the packaging and verify that it is unopened and undamaged. Do not use the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices if the packaging is open or damaged. **Caution:** Do not use if any damage is visible or if any part of the implant is outside of the loader. **Caution:** If loader or wire kinks or becomes damaged during preparation, do not use the device. Carefully open the sterile pouch and inspect the components for damage. Do not use the device if damage is evident.	
5	Using a 5cc/ml or 10cc/ml syringe of sterile saline, activate the hydrophilic delivery wire by flushing the dispenser hoop. Using a 5cc/ml or 10cc/ml syringe of sterile saline, flush the device until saline emerges from the distal tip of the loader. **Caution:** Ensure the hemostasis valve is closed after flushing the loader.	Using a 5cc/ml or 10cc/ml syringe of sterile saline, flush the device until saline emerges from the distal tip of the loader. **Caution:** Ensure the hemostasis valve is closed after flushing the loader.
6	Attach the tuohy borst to the hub of the delivery catheter.	

Steps	Caterpillar™ Micro	Caterpillar™
7	Advance the distal tip of the loader through the tuohy borst until seated against the hub of the delivery catheter and secure in place by tightening the tuohy borst valve. **Caution:** Do not advance or retract the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices from the loader without attaching the loader via the tuohy borst to the delivery catheter hub. Do not twist or rotate the delivery wire during advancement because the device may detach prematurely.	
8	Advance the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices using the delivery wire until the indicator band on the delivery wire is aligned with the end of the loader. At this point stop advancement and remove the loader. - The white band for Caterpillar™ Micro Arterial Embolization Device - The metal band for the Caterpillar™ Arterial Embolization Device **Note:** The indicator band only indicates that the loader may be safely removed. It is not an indicator for device position within the delivery catheter.	
9	Once the loader is removed, continue to use the delivery wire to advance the device into the catheter under fluoroscopic guidance until the distal radiopaque marker is at the distal tip of the catheter (Figure 3, C).	
10	Ensure the distal tip of the catheter is at the distal end of the target occlusion site.	
11	To deploy the device, hold the delivery wire stationary and slowly retract the delivery catheter to deploy the entire Caterpillar™ Micro Arterial Embolization Device.	To deploy the device, hold the delivery wire stationary and slowly retract the delivery catheter to deploy the **Positioning Zone** (Figure 3, A). **Caution:** Deployment beyond the medial marker may mean that repositioning is no longer possible.
12	**Caution:** Caterpillar™ Micro Arterial Embolization device cannot be recaptured for repositioning within the microcatheter once the distal segment is deployed.	If the device position is unsatisfactory after deployment of the **Positioning Zone** the device can be recaptured for repositioning: a. Stabilize the delivery wire and advance the delivery catheter until the **Positioning Zone** is recaptured within the catheter. **Note:** The safety of performing more than one re-positioning step has not been evaluated. b. If desired, reposition and redeploy the Caterpillar™ Arterial Embolization Device in accordance with steps 10 and 11. If the device position is satisfactory after deployment of the **Positioning Zone**, deploy the **Detachment Zone** (Figure 3,B) by holding the delivery wire stationary and slowly retracting the delivery catheter.
13	Confirm the Caterpillar™ or Caterpillar™ Micro Arterial Embolization Device position is satisfactory. If the position is satisfactory, follow steps 15-17 to complete the procedure. If the device position is unsatisfactory, complete step 14.	
14	**Caution:** If the position of the Caterpillar™ Micro Arterial Embolization Device is unsatisfactory after deployment of the device, perform the following: a. Stabilize the delivery wire and microcatheter and advance the guiding catheter over both the microcatheter and the implant. Or: b. Retract the implant and microcatheter into the guiding catheter. Then remove the device and catheters from the body. Discard the removed device.	**Caution:** If the Caterpillar™ device position is unsatisfactory after deployment of the **Detachment Zone** (Figure 3, B), perform the following: a. Stabilize the delivery wire and delivery catheter and advance the guiding sheath over both the delivery catheter and the implant. Or: b. Retract the implant and delivery catheter into the guiding sheath. Then remove the device and catheters from the body. Discard the removed device.
15	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. The torque tool should be attached to any portion of the remaining exposed delivery wire that is proximal to the indicator band. **Caution:** Do not advance the delivery wire after detaching it from the device as this may alter the position of the device.	
16	Retract the delivery wire into the catheter.	
17	Remove the delivery wire from the patient and complete the procedure following standard technique.	

A. Positioning zone
B. Detachment zone
C. Radiopaque marker bands

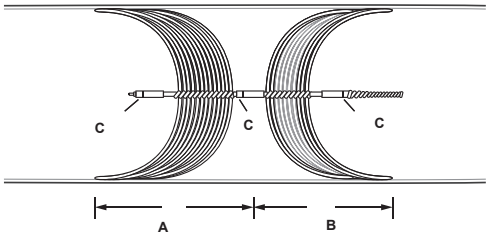

Figure 3: Position and Detachment Zones (Caterpillar™)

L. Disposal Instructions

After use, the delivery system is a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

M. Patient Implant Information Card

A Patient Implant Information Card is provided with this device. The Patient Data, Implant Data, and Hospital Data should be carefully recorded on the card and given to the patient.

Apply one of the peel-off stickers found on the product label on the pouch to the indicated area on the Patient Implant Information Card. This peel-off sticker contains important information about the patient's embolic implant. The patient should carry this card with them and provide to any medical personnel caring for the patient in the future.

N. Warranty

ClearStream Technologies Ltd warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in ClearStream's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL CLEARSTREAM BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact ClearStream Technologies Ltd to see if additional product information is available.

Use-By Date

Electronic Instructions for Use

Contents: (1)

Manufacturer

Catalogue Number

Do Not Resterilize

Single Use

Non-Pyrogenic

Keep Dry

Keep Away From Sunlight

Sterilized Using Ethylene Oxide

MR Conditional

Do Not Use if the Product Sterile Barrier System or its Packaging is Compromised

Not Made With Natural Rubber Latex

Distributed by:
Bard Peripheral Vascular, Inc.
www.bardpv.com/caterpillar-ifu.php
TEL: 1-800-321-4254

Manufacturer:
ClearStream Technologies Ltd.
Moyne Upper
Enniscorthy
Co. Wexford, Ireland

BD

BAW1444700 Rev. 2 08/20