The Abre stent system received CE Mark approval in April 2017 and is intended for use in the iliofemoral veins for treatment of symptomatic venous outflow obstruction. The stent is intended for permanent implant in the iliofemoral vein. It is premounted on a 9-F delivery system and features a nitinol stent with a triaxial catheter design. The stent utilizes an open-cell design with three connection points between the cells that enables flexibility and conformability. Upon deployment, the Abre stent uses an optimized balance of strength and flexibility to exert an outward force and open the vein.

The Abre stent is also part of a United States investigational device exemption study to evaluate its safety and effectiveness in patients with iliofemoral venous outflow obstruction. The multicenter, single-arm study intends to enroll 200 patients with deep venous disease from up to 35 sites throughout the United States and Europe. The primary efficacy endpoint will evaluate patency at 12 months, and the primary safety endpoint will evaluate the incidence of major adverse events at 30 days following stenting of an obstruction.

The Abre stent system is available for use in the European Union. It is not available for commercial use in the United States.

1. Test data on file at Medtronic, Inc. Bench test results may not be indicative of clinical performance.

IMPORTANT: Warnings, precautions, and instructions for use can be found in the product labeling.

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Indigo System CATD and SEPD

Penumbra, Inc. now offers a shorter-length 8-F catheter with the addition of Indigo System CATD and SEPD, which became commercially available in Europe following CE Mark approval in May 2018. Indigo is designed to extract clot from the peripheral arterial and venous systems using power aspiration with the Penumbra Pump Max. CATD features multiple material transitions for optimal tracking. The catheter is designed for situations in which the culprit thrombus lesion is close to the access site, such as fistula declots or thrombus in upper extremity arteries and veins. The Separator is an adjunctive device that is intended for use with the CATD to further aid in clot removal.

“CATD is an advancement in declotting technology designed to extract clot using high-power vacuum aspiration as opposed to conventional clot maceration and manual aspiration techniques, thereby potentially improving patency,” said Osman Ahmed, MD, an interventional radiologist at Rush University in Chicago, Illinois.

The Indigo System CATD and SEPD is commercially available in the United States, Europe, Chile, Hong Kong, and New Zealand.

Kanshas Drug-Coated Balloon

Terumo Corporation announced that it acquired European CE Mark approval for its Kanshas drug-coated balloon for the treatment of lower extremity peripheral artery disease. Terumo expects to launch the device in Europe, followed by launches in Latin America and Asia.

Kanshas can be expected to have an enhanced therapeutic effect due to Terumo’s proprietary uniform microcrystal coating named Unicoat, which is designed so that the coated drug is less likely to migrate before it reaches the lesion and then transfers swiftly to vascular tissue when the balloon is expanded. The product lineup includes a long balloon with a range up to 200 mm to treat long lesions that are common in the lower extremities, stated Terumo.

Penumbra, Inc.
(888) 272-4606

**KEY FEATURES**
- Power aspiration with general peripheral indication
- Continuous aspiration power for clot removal
- CATD has an 8-F declotting lumen for maximized aspiration
- Tip directionality for diseased, large vessels

Terumo Corporation
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**KEY FEATURES**
- Unicoat: Uniform coating with microcrystals
- Up to 200-mm balloon length available
- Metal core wire design for pushability