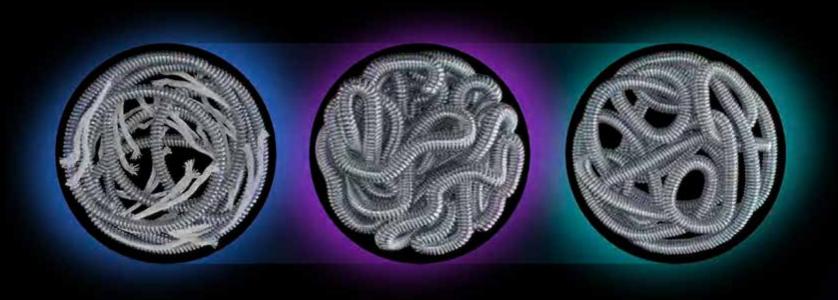


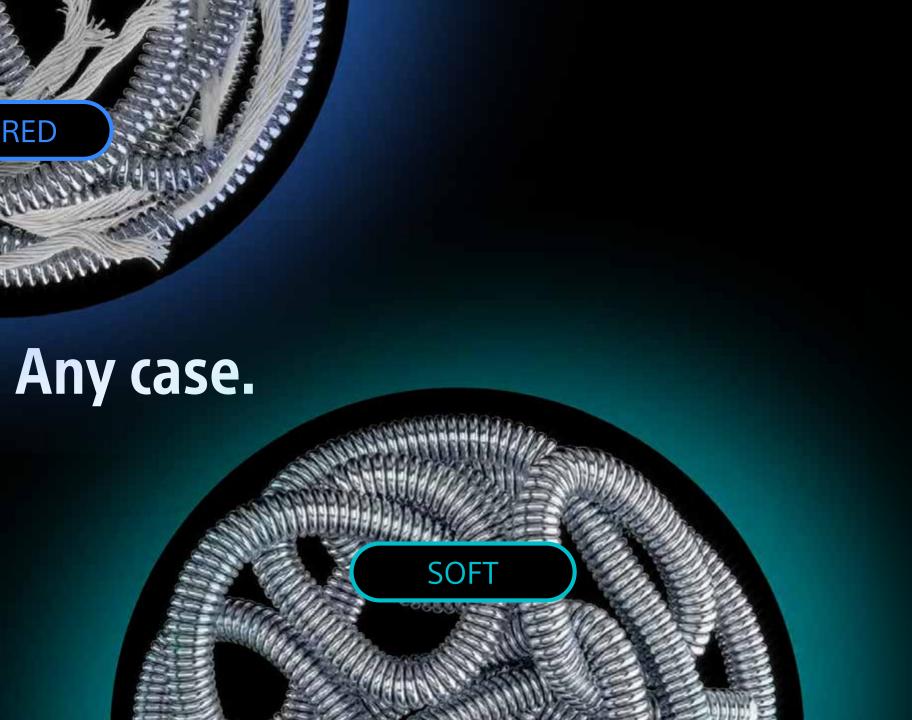


# **EMBOLD**<sup>™</sup> Detachable Coil System



SIMPLE BY DESIGN





#### **EMBOLD**<sup>™</sup> Detachable Coil System

All with handle-free detachment, kinkless performance, multi-catheter compatibility, and best-in-class occlusion power. Reduce coiling complexity and streamline inventory with one portfolio.



## MULTI-CATHETER COMPATIBILITY

Accomodates .021" to .027" ID microcatheters. Fewer exchanges. Fewer complications.



## HANDLE-FREE DETACHMENT

Provides complete control, reduces procedure steps and cost.



#### KINKLESS PERFORMANCE

Nitinol delivery system to ensure kinkless performance and resistance to premature detachment.



## BEST-IN-CLASS OCCLUSION POWER

Embold offers the best-in-class thrombogenicity, requiring less time and coils to achieve occlusion.

#### **EMBOLD**<sup>™</sup> Fibered Coil

#### Versatility in one coil.

Your go-to coil for a wide variety of vessels and cases. This highly thrombogenic coil is built to maximize procedural flexibility and reliability.



### **EMBOLD**<sup>™</sup> Packing Coil

#### High density. Low complexity.

With the highest metal volume of any 0.021" ID microcatheter compatible coil, easily achieve a high-density pack.



### **EMBOLD**<sup>™</sup> Soft Coil

#### Hard-to-reach anatomy? Easy.

Easily reach your target in tortuous anatomy and quickly embolize when you get there. Avoid catheter kickback and premature deployment. Designed in unique lengths for procedural flexibility.



## SIMPLE BY DESIGN

#### EMBOLD™ (SOFT/PACKING/FIBERED) DETACHABLE COIL SYSTEM

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions, INTENDED USE / INDICATIONS FOR USE: The EMBOLD (Soft/Packing/Fibered) Detachable Coil System is indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for coronary or neurovascular use. CONTRAINDICATIONS: There are no known contraindications. WARNINGS: The following warning statements provide important information for safe use of EMBOLD (Soft/Packing/Fibered) Detachable Coil System. Observe all warnings and precautions noted throughout these and other instructions relevant to the procedure. Failure to do so may result in patient injury or product damage. • Do not use the EMBOLD (Soft/Packing/ Fibered) Detachable Coil System if it is damaged. • To reduce the risk of thromboembolic complications, it is critical that a continuous flow of appropriate flush solution be maintained between a) the microcatheter and guide catheter, and b) the microcatheter and any intraluminal device. • Due to the delicate nature of coils and the tortuosity that can be present in vasculature pathways, as well as various morphologies of vasculature, the coil may become stretched during delivery and repositioning. If stretching is observed or suspected, carefully remove the coil and microcatheter from the vasculature simultaneously. • Do not rotate the delivery wire more than 1 turn (360 degrees) during delivery of the EMBOLD (Soft/Packing/Fibered) Detachable Coil System. Excessive rotation of the delivery wire may damage the EMBOLD (Soft/Packing/Fibered) Detachable Coil System or may result in premature detachment of the coil. PRECAUTIONS: The following precaution statements provide important information for safe use of EMBOLD (Soft/Packing/Fibered) Detachable Coil System. Observe all warnings and precautions noted throughout these and other instructions relevant to the procedure. Failure to do so may result in patient injury or product damage. • To ensure safe delivery, never make sudden movements, do not force in case of resistance, and operate gently and with caution. • Ensure the microcatheter in use has the appropriate ID and length for the selected coil. • Do not advance the EMBOLD (Soft/Packing/Fibered) Detachable Coil System if it becomes lodged within the microcatheter. Determine the cause of the resistance and replace the microcatheter and coil if necessary. See the "Operational Instructions - Full System Removal" section for further instructions. • No tools are required to detach the coil. Using a tool could result in damage to the inner wire causing the coil to be difficult or impossible to release. • When in highly tortuous anatomy, increased resistance may be felt when retracting the inner wire and a greater retraction distance may be required to detach the coil. • Multiple embolization coils may be required to achieve the desired occlusion. • Replace microcatheters periodically during delivery of multiple coils or if increased resistance is noted during coil delivery. ADVERSE EVENTS: Potential adverse events which may be associated with the use of a coil and/or the peripheral embolization procedure include, but are not limited to: • Allergic reaction (device, contrast, medications, or other) • Arrhythmia • Bleeding/hemorrhage • Cerebrovascular accident (CVA) • Death • Embolism (air, plaque, thrombus, device, tissue, or other) • Hematoma • Infection/sepsis • Ischemia • Necrosis • Need for additional intervention or surgery • Nerve injury • Pain/discomfort • Post-embolization syndrome (PES) • Recanalization • Thrombus/thrombosis • Transient ischemic attack (TIA) • Vasospasm • Vessel trauma (arteriovenous fistula, dissection, injury, perforation, pseudoaneurysm, rupture, or other) 97085821 A.1

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