

EMBOLD™ Fibered Coil



**Built on the radical idea
that simpler is better.**



MULTI-CATHETER COMPATIBILITY

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



KINKLESS PERFORMANCE

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



BEST-IN-CLASS OCCLUSION POWER

The most occlusion power in its class,
Embold offers the greatest volume of any
.021" ID microcatheter compatible coil and is
purpose built for exceptional deliverability.*

*The testing was performed by or on behalf of BSC. Data on file.

**SIMPLE
BY
DESIGN**

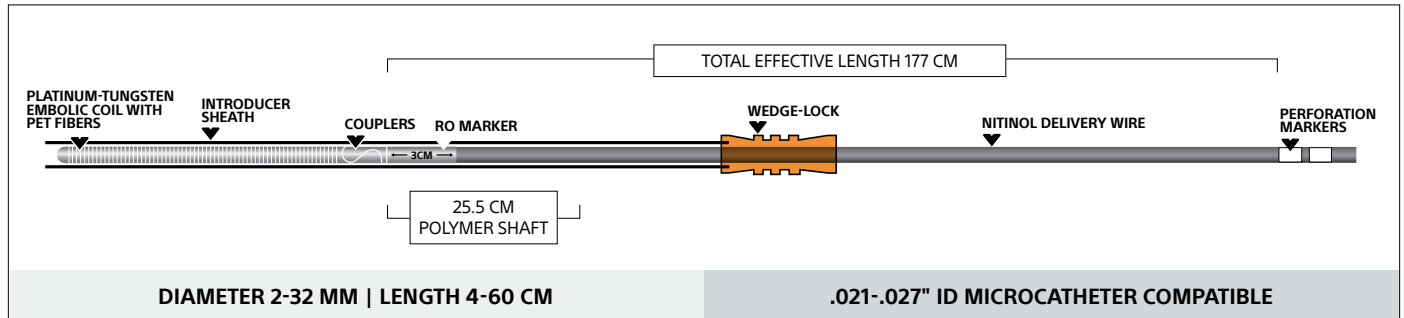




Innovation deliberately designed to simplify the complex.

A single utility coil designed to do the job of many. Designed to reduce coil complexity, simplify decision-making, reduce complications and streamline inventory. Your new go-to has arrived.

EMBOLD FIBERED PRODUCT SPECIFICATIONS



Ref Catalog Number	Material Description	GTIN
M001394240020040	EMBOLD FIBERED 2X4	08714729983521
M001394240020060	EMBOLD FIBERED 2X6	08714729983538
M001394240030060	EMBOLD FIBERED 3X6	08714729983545
M001394240030120	EMBOLD FIBERED 3X12	08714729983552
M001394240040080	EMBOLD FIBERED 4X8	08714729983569
M001394240040150	EMBOLD FIBERED 4X15	08714729983576
M001394240050080	EMBOLD FIBERED 5X8	08714729983583
M001394240050150	EMBOLD FIBERED 5X15	08714729983590
M001394240060100	EMBOLD FIBERED 6X10	08714729983606
M001394240060200	EMBOLD FIBERED 6X20	08714729983613
M001394240080200	EMBOLD FIBERED 8X20	08714729983620
M001394240100200	EMBOLD FIBERED 10X20	08714729983637

Ref Catalog Number	Material Description	GTIN
M001394240100300	EMBOLD FIBERED 10X30	08714729983644
M001394240100500	EMBOLD FIBERED 10X50	08714729983651
M001394240120200	EMBOLD FIBERED 12X20	08714729983668
M001394240120300	EMBOLD FIBERED 12X30	08714729983675
M001394240120500	EMBOLD FIBERED 12X50	08714729983682
M001394240140200	EMBOLD FIBERED 14X20	08714729983699
M001394240140300	EMBOLD FIBERED 14X30	08714729983705
M001394240140500	EMBOLD FIBERED 14X50	08714729983712
M001394240180500	EMBOLD FIBERED 18X50	08714729983729
M001394240200500	EMBOLD FIBERED 20X50	08714729983736
M001394240220600	EMBOLD FIBERED 22X60	08714729983743
M001394240320600	EMBOLD FIBERED 32X60	00191506010485

EMBOLD™ 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 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 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 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 Fibered Detachable Coil System. Excessive rotation of the delivery wire may damage the EMBOLD 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 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 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) • 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) **92825903 A.1**



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