

# Boston Scientific

## Peripheral Embolization Pushable Coil Portfolio

*Product Inservice*

**Prior to use, please refer to full DFU for indications, contraindications, warnings/precautions, adverse events and complete operating instructions.**

**IMPORTANT INFORMATION:** These materials are intended to describe common clinical considerations and procedural steps for the on-label use of referenced technologies as well as current standards of care for certain conditions. Of course, patients and their medical circumstances vary, so the clinical considerations and procedural steps described may not be appropriate for every patient or case. As always, decisions surrounding patient care depend on the physician's professional judgment in light of all available information for the case at hand.

**BSC does not promote or encourage the use of its devices outside their approved labeling.**

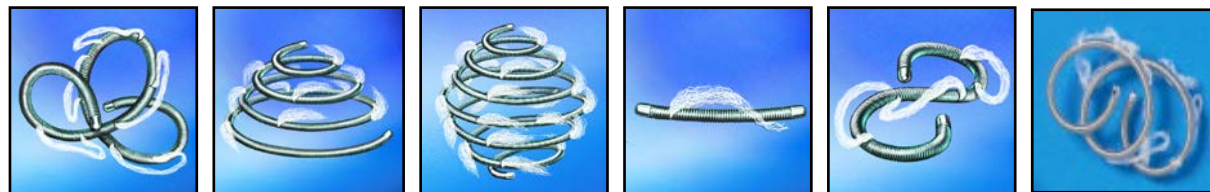
# Boston Scientific Pushable Coil Portfolio

*Versatile and Cost-Effective*

**Boston Scientific**

Advancing science for life™

**Six Shapes (L to R):** Complex Helical, VortX™, VortX Diamond, Straight, Figure 8, Multi-Loop (2D Helical)



**Coil Diameter**

Coil Length	2 mm	3 mm	4 mm	5 mm	6 mm	7 mm	8 mm	9 mm	10 mm	11 mm
0-3cm	0.018"	0.035"	0.035"	0.035"	0.018"					
4-6cm		0.035"	0.018"	0.035"	0.035"	0.018"	0.018"	0.035"	0.018"	
7-9cm					0.018"					0.018"



0.018" Pushable Coils



0.035" Pushable Coils

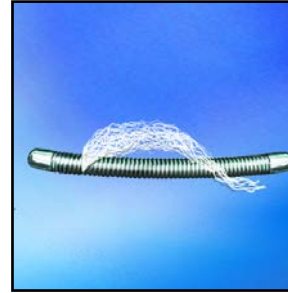
- Include highly thrombogenic, dense Dacron® fibers designed for fast and complete occlusion
- Have MRI conditional compatibility (up to 3.0 Tesla)
- Are recommended for use with continuous flush setup

# Boston Scientific Pushable Coil Portfolio

## Shape Comparisons & Benefits



Shape	Complex Helical
Coil Type	Framing
Benefit	Provide structure around the vessel wall
Best for	The first and last coil placed in a vessel



Shape	Straight
Coil Type	Straight
Benefit	Fill small accessory vessels prone to spasm
Best for	Tiny GI bleeds where vessel diameter < 2mm



Shape	Figure 8
Coil Type	Filling
Benefit	Short length fills small vessel area
Best for	Small vessels (2mm), such as the right gastric



Shape	Multi-Loop (2D Helical)
Coil Type	Framing
Benefit	Provide structure around the vessel wall
Best for	The first and last coil placed in a vessel



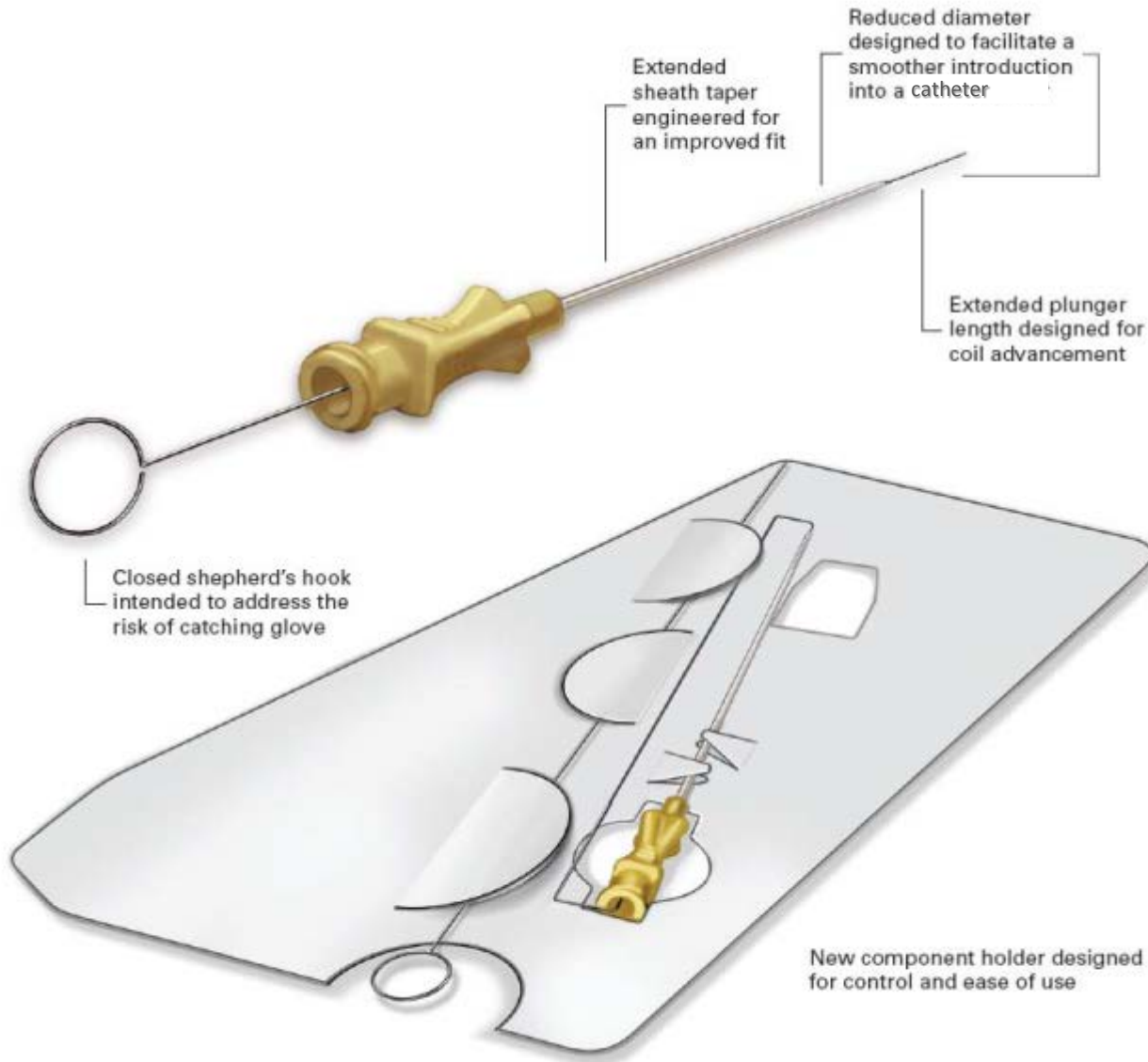
Shape	VortX
Coil Type	Filling
Benefit	Packable shape helps to fill vessels tightly
Best for	Filling a segment of a vessel proximal to a framing coil



Shape	VortX Diamond
Coil Type	Filling
Benefit	Center coil adheres to vessel wall while sides taper down and fill area
Best for	Filling a segment of a vessel proximal to a framing coil

# Boston Scientific Pushable Coil Portfolio

## Protective Packaging



- **Short sheath protects the coil in packaging**
- **Stylette is used to push coil from protective sheath into delivery catheter**
- **Compact cardboard tray carries both coil/sheath and stylette (on 0.018" pushables only)**

# Boston Scientific Pushable Coil Portfolio

## 0.018" Pushable Coil Offering

Name	UPN	Ordering No.	Total Length (cm)	Outer Diameter (in.)	Minimum Catheter Lumen Diameter (in.)	Units / Box
<b>Coil Pusher-16</b>	<b>M0014012160</b>	<b>401216</b>	<b>177</b>	<b>0.016</b>	<b>0.018</b>	<b>1</b>
Shape	UPN	Ordering No.	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)	Units / Box
VortX Diamond 18	M0013822031	382203	3	3.3	23	5
VortX Diamond 18	M0013822041	382204	4	3.7	41	5
VortX Diamond 18	M0013822051	382205	5	5.5	58	5
VortX Diamond 18	M0013822061	382206	6	6.7	80	5
VortX 18	M0013812031	381203	3	2.5	22	5
VortX 18	M0013812041	381204	4	4	42	5
VortX 18	M0013812051	381205	5	5.5	60	5
VortX 18	M0013812061	381206	6	6.5	85	5
Straight 18	M0013120021	312002	Straight	2	2	5
Straight 18	M0013120051	312005	Straight	5	5	5
Figure-8 18	M0013120211	312021	2	5	10	5
Multi-Loop 18	M0013120431	312043	4	7	30	5
Complex Helical 18	M0013120221	312022	4	4	20	5
Complex Helical 18	M0013120331	312033	6	6	30	5
Complex Helical 18	M0013120441	312044	7	10	40	5
Complex Helical 18	M0013120551	312055	8	12	50	5
Complex Helical 18	M0013120661	312066	10	14	60	5
Complex Helical 18	M0013120771	312077	11	17	70	5

# Boston Scientific Pushable Coil Portfolio

## 0.035" Pushable Coil Offering

Shape	UPN	Ordering No.	Maximum Diameter (mm)	Unrestrained Coil Length (mm)	Length in Introducer (mm)	Units / Box
2D Helical 35	M0013723021	372302	3	2.6	20	5
2D Helical 35	M0013723041	372304	3	5.2	40	5
2D Helical 35	M0013724031	372403	4	2.9	30	5
2D Helical 35	M0013725031	372503	5	2.4	30	5
2D Helical 35	M0013725051	372505	5	4	50	5
2D Helical 35	M0013726041	372604	6	2.6	40	5
2D Helical 35	M0013727041	372704	7	2.3	40	5
2D Helical 35	M0013729061	372906	9	2.7	60	5
VortX 35	M0013732041	373204	4	4	30	5
VortX 35	M0013733051	373305	5	4.5	35	5
VortX 35	M0013733061	373306	6	5	53	5
VortX 35	M0013733071	373307	7	5.5	67	5

**Per the Directions for Use (DFU), the 0.035" pushable coils:**

- A. Require a catheter with minimum inner lumen of 0.038" (0.97mm)**
- B. Utilize a standard 0.035" (0.89mm) guidewire for coil delivery**

# Pushable-18 Coils

## *Brief Summary Statement*

### **Pushable-18 Coils: VortX™ Diamond, Straight, Figure-8, Multi-Loop, Complex Helical**

**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 “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

**INTENDED USE/INDICATIONS FOR USE:** Boston Scientific’s 0.018 Fibered Platinum Coils are intended for arterial and venous embolizations in the peripheral vasculature.

The Coil Pusher-16 is intended to be used in conjunction with a microcatheter to deliver and deploy 0.018 pushable occlusion coils.

**CONTRAINDICATIONS:** None known.

**PRECAUTIONS:** The long-term effect of this product on extravascular tissues has not been established, so care should be taken to retain this device in the intravascular space. Do not advance the coil with force if the coil becomes lodged within the microcatheter. Determine the cause of resistance and replace the microcatheter and the coil when necessary. Replace the microcatheter if increased resistance is noted during coil delivery.

#### **ADVERSE EVENTS:**

The complications that may result from a peripheral embolization procedure include, but are not limited to: • Complications related to catheterization (e.g., hematoma at the site of entry, vessel injury, etc.) • Death • Emboli • Foreign body reactions necessitating medical intervention • Hemorrhage • Infection necessitating medical intervention • Ischemia • Pain • Recanalization • Temporary neurological deficit • Tissue necrosis • Undesirable clot formation of the vasculature • Vasospasm



# Pushable-35 Coils

## *Brief Summary Statement*

### **Pushable-35 Coils: VortX™, 2D Helical**

**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 “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

**INTENDED USE/INDICATIONS FOR USE:** VortX - 35 and 2D Helical - 35 Fibered Platinum Coils are intended for arterial and venous embolizations in the peripheral vasculature.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** Never advance the guidewire after coil has been deposited. Advancing the guidewire after the coil has been deposited risks damaging the vessel.

**PRECAUTIONS:** In preclinical studies, the use of this device has been associated with a minor chronic inflammation of a giant cell foreign body reaction. Although inflammation of this type has not been observed in humans, the long term clinical significance of this type of inflammatory response, if any, is unknown. The long term effect of this product on extravascular tissues has not been established, so care should be taken to retain this device in the intravascular space. Do not advance the coil with force if the coil becomes lodged within the catheter. Determine the cause of resistance and replace the catheter and the coil when necessary. Replace catheter frequently if increased resistance is noted during coil delivery.

#### **ADVERSE EVENTS:**

The complications that may result from a peripheral embolization procedure include, but are not limited to: • Complications related to catheterization (e.g., hematoma at the site of entry, vessel injury, etc.) • Death • Emboli • Foreign body reactions necessitating medical intervention • Hemorrhage • Infection necessitating medical intervention • Ischemia • Pain • Recanalization • Temporary neurological deficit • Tissue necrosis • Undesirable clot formation of the vasculature • Vasospasm