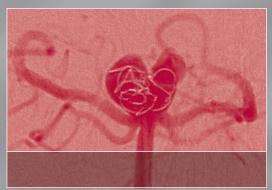


TRUFILL DCS ORBIT® Detachable Coil System Conforming to Your Complex Needs









Excellent Conformability and Concentric Filling for **Outstanding Packing Density**

TRUFILL DCS ORBIT®

Detachable Coil System

- Full range of Mini Complex and new Tight Distal Loop Technology coils
- Our Complex Standard coils are four times more stretch resistant than our Complex Fill Coils
- A customized fit for aneurysms: Random loops and breaks seek out the true aneurysm periphery

Mini Complex Fill Coils



- TRUFILL DCS ORBIT® Mini Complex Fill coils are designed for increased volumetric filling
- Extended offering of sizes including new
 2.5 mm and 3.5 mm coils and longer 3 mm x 6 cm coil

Tight Distal Loop Technology



- TRUFILL DCS ORBIT® Detachable Coils with Tight Distal Loop Technology
 First loop is 1/3 smaller than the coil diameter
- Avoids crossing the center of the aneurysm

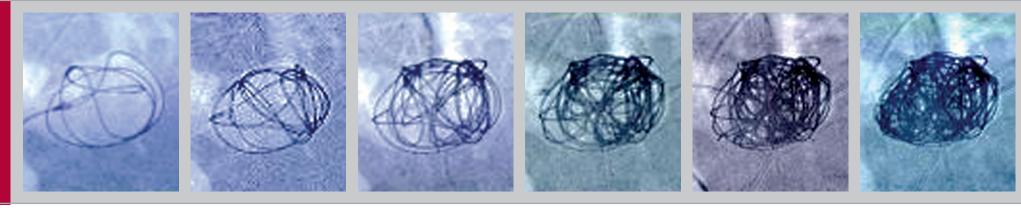


TRUFILL DCS ORBIT®

Detachable Coil System

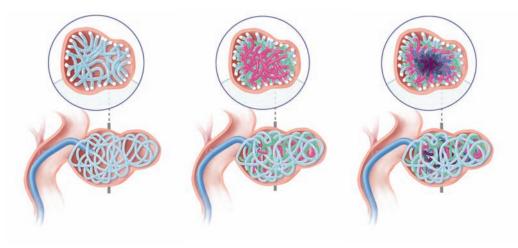
Conformability: The true complex structure of **TRUFILL DCS ORBIT®**Detachable Coils is designed to provide excellent conformability and concentric filling resulting in outstanding packing density.

Concentric Filling For Outstanding Packing Density



Complex random coil loop of TRUFILL DCS ORBIT® Detachable Coils

- Seek out free space and favor aneurysm periphery
- Fill from periphery to core without crossing the center of the aneurysm
- Helps to minimize compartmentalization



TRUFILL DCS ORBIT® Delivery System Advantages

- Soft gripper tube results in minimal microcatheter tip deflection while coiling
- Stable coil delivery

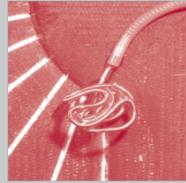
Gripper Tube: Transition from soft polymer delivery tube to coil **Microcatheter Deflection Test Setup**

TRUFILL DCS ORBIT® **Delivery System**

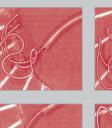
Competitive Wire Delivery Systems

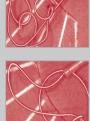


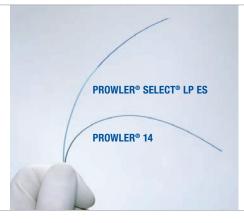












For your coiling needs, Codman Neurovascular offers two versions of the **PROWLER®** Microcatheter:

PROWLER® SELECT® Microcatheter

Offers more stability

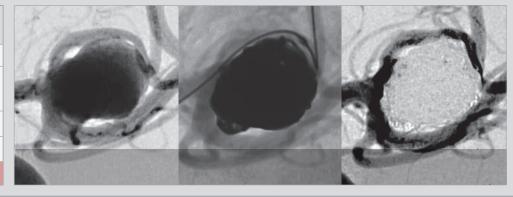
PROWLER® Microcatheter

Offers more flexibility for tortuous anatomy

Outstanding packing density: In a recent study, use of complex-shaped coils with a wire diameter of 0.012 in. to coil cerebral aneurysms, resulted in significantly better packing than was achieved with helical coils of 0.010 in. wire diameter.¹

Clinical Evidence - Long-term Results

	TRUFILL DCS	TRUFILL DCS ORBIT® Coil ²	TRUFILL DCS ORBIT® Coil ³		
	Single Site Study	Complex Registry	Single Site Study		
Number of Centers	1	37	1		
Number of Aneurysms					
w/ Follow-up	95	99	31		
Recanalization	15.8%	16.2%	12.9%		
Retreatment	7.8%	5.1%	6.5%		



 These studies show TRUFILL DCS ORBIT® cases with relatively low recanalization and retreatment rates

- Efficient neck coverage
- Potential for shutdown of aneurysm in-flow zone

¹ Data on file.

² Slob, Neurol Res. 2005;27 Suppl 1:S116-9; 2

³ Hirsch, J Vasc Interv Radiol 2007; 18:1487-1494

TRUFILL DCS ORBIT® Detachable Coil System

CONSTRUCTION

PRODUCT COMPATIBILITY

- Coil Outer Diameter: 0.012 inches
- Usable Length: 175 cm
- Easy-to-Use Introducer Design
- and PROWLER® SELECT® Plus Microcatheters as well as PROWLER® 14 and PROWLER® Plus Microcatheters

• Compatible with Dual Markerband PROWLER® SELECT® LP ES

ORDERING INFORMATION:

	Catalog No.	Shape Diameter (mm)	Coil Length (cm)	Softness Type	Catalog No.	Shape Diameter (mm)	Coil Length (cm)	Softness Type	Catalog No.	Shape Diameter (mm)	Coil Length (cm)	Softness Type
Mini Complex Fill				Complex Standard			Complex Fill - Tight Distal Loop					
	637MF0201 637MF0202 637MF2525 637MF2535 637MF2545 637MF0303 637MF0304 637MF0306 637MF3505 637MF3505 637MF3509	2 2 2.5 2.5 2.5 3 3 3 3.5 3.5 3.5	1.5 2 2.5 3.5 4.5 3 4 6 5 7.5	FILL FILL FILL FILL FILL FILL FILL FILL	637CS0615 637CS0721 637CS0824 637CS0925 637CS1030 637CS1230 637CS1430 637CS1630 637CS1830 637CS2030	6 7 8 9 10 12 14 16 18 20	15 21 24 25 30 30 30 30 30 30 30	STANDARD	638MF0407 638MF0410 638CF0510 638CF0515 638CF0615 638CF0721 638CF0824 638CF0925 638CF1030 638CF1230	4 4 5 5 6 7 8 9 10	7 10 10 15 15 21 24 25 30 30	FILL FILL FILL FILL FILL FILL FILL FILL
•	637MF0403	4	3	FILL	Helical Fill			Complex Standard - Tight Distal Loop				
	637MF0407 637MF0410	4 4	7 10	FILL FILL	637HF0202 637HF0204	2 2	2	FILL FILL	638CS0615 638CS0721	6 7	15 21	STANDARD STANDARD
ם	638MF0407 638MF0410	4 4	7 10	FILL FILL	637HF0206 637HF0208 637HF0304	2 2 3	6 8 4	FILL FILL FILL	638CS0824 638CS0925 638CS1030	8 9 10	24 25 30	STANDARD STANDARD STANDARD
Complex Fill					637HF0306	3	6	FILL	638CS1230	12	30	STANDARD
-	637CF0505 637CF0510 637CF0515 637CF0609	5 5 5	5 10 15 9	FILL FILL FILL	637HF0308 637HF0310 637HF0406 637HF0408 637HF0410	3 3 4 4 4	8 10 6 8 10	FILL FILL FILL FILL FILL	638CS1430 638CS1630 638CS1830 638CS2030	14 16 18 20	30 30 30 30	STANDARD STANDARD STANDARD STANDARD
	637CF0615 637CF0713	6 7	15 13	FILL FILL	637HF0512	5	12	FILL	TRUFILL® DCS Syringe II / 635-002			
	637CF0721 637CF0815 637CF0824 637CF0915 637CF0925 637CF1030 637CF1230	7 8 8 9 9 10 12	21 15 24 15 25 30 30	FILL FILL FILL FILL FILL FILL FILL FILL	637HF0615 637HF0715 637HF0830 637HF0930 637HF1030 637HF1230	6 7 8 9 10 12	15 15 30 30 30 30 30	FILL FILL FILL FILL FILL				

USA

Codman & Shurtleff, Inc. 325 Paramount Drive

To place an order, call 1-800-255-2500.

For product availability, please contact your Codman Neurovascular representative.

For technical/product questions, call 1-800-225-0460.

Ravnham, MA 02767 www.codman.com

TRUFILL DCS ORBIT® Detachable Coil Essential Prescribing Information (EPI)

INTENDED USE: The TRUFILL DCS ORBIT® Detachable Coil is indicated for embolizing certain intracranial aneurysms that, because of their morphology, location, or the patient's general medical condition, are considered by the treating neurosurgical team to be: 1. Very high-risk for management by traditional operative techniques; 2. Inoperable and for embolizing other vascular malformations such as arteriovenous malformations such as arteriovenous malformations and arteriovenous malformations and arteriovenous fistulae of the neurovasculature. The TRUFILL DCS ORBIT® Detachable Coil is contraindicated when: superselective placement is not cossible; the arteries supplying the lesion are not large enough to accept embolic material; patent extra-to-intracranial anastomoses are present; end arteries lead directly to cranial nerves; the A-V shunt is bigoer than the size of the coil; there is severe atheromatous disease; in the presence or likely onset of vasospasm. WARNINGS. Therapeutic embolizations to occlude blood vessels are high-risk procedures. The procedure should be carried out under the direction of personnel with the requisite interventional training and thorough knowledge of angiographic techniques, especially coil embolization techniques. Appropriate facilities should be available for managing the potential complications of the procedure. Contaminants found in the angiography room may cause foreign body reactions or infection. The physician must use the utmost caution to avoid introducing contaminants. Incomplete occlusion of vascular bed or territories may give rise to hemorrhage, ischemia, infarction, development of alternative vascular pathways, or recurrence of symptoms. Do not use any other syringes other than the specified TRUFILL® DCS Syringe for operation of the TRUFILL DCS ORBIT® Detachable Coil. The introduction of air emboli may occur during detachment if one of the following is not performed properly: saline purge of the syringe to remove all air prior to connecting to the delivery tube hub; saline purge of the delivery tube with visual confirmation at the hub; saline flush of the delivery tube hub prior to any system reconnections. Do not use the distal tip of the infusion catheter to manipulate or reposition embolic coils previously detached in the patient's vasculature. Do not reuse. Discard after one procedure. Failure to open the second RHV sufficiently prior to slow and careful removal of the delivery tube from the patient could result in damage to the distal portion of the delivery tube. PRECAUTIONS: TRUFILL DCS ORBIT® Detachable Coils are delicate devices and should be handled carefully. Prior to use and when possible during the procedure, inspect the system for bends or kinks. Do not use a coil system that shows signs of damage. Do not expose the product to granic solvents. The long-term effects of this product on extravascular tissues have not been established, so care should be taken to retain this device in the intravascular space. Multiple embolization procedures may be required to achieve the desired occlusion of some vessels or aneurosms. The TRUFILL DCS ORBIT® Detachable Coil is intended for one use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital, administrative and/or local government policy. Store in a cool, dark, dry place. Do not use if package is open or damaged. Use prior to the "Use By" date. Angiography is necessary for the pre-embolization evaluation, operative control, and post-embolization follow up. Ensure proper detachable coil selection according to vascular territory and measurements taken from a baseline angiogram. ADVERSE EVENTS: Complications specific to embolization procedures may occur at any time during or after the procedure and may include, but are not limited to, the following: ischemia at an undesired location; stroke or cerebral infarction; coil migration into normal vessels adjacent to the lesion; pulmonary embolism; vessel dissection, perforation, rupture and hemorrhage; neurological deficits; injury to normal vessels or tissue; infection; allergic reaction; vasospasm; and/or death.

Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Prior to use, please read the more detailed information in the "Instructions for Use."

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