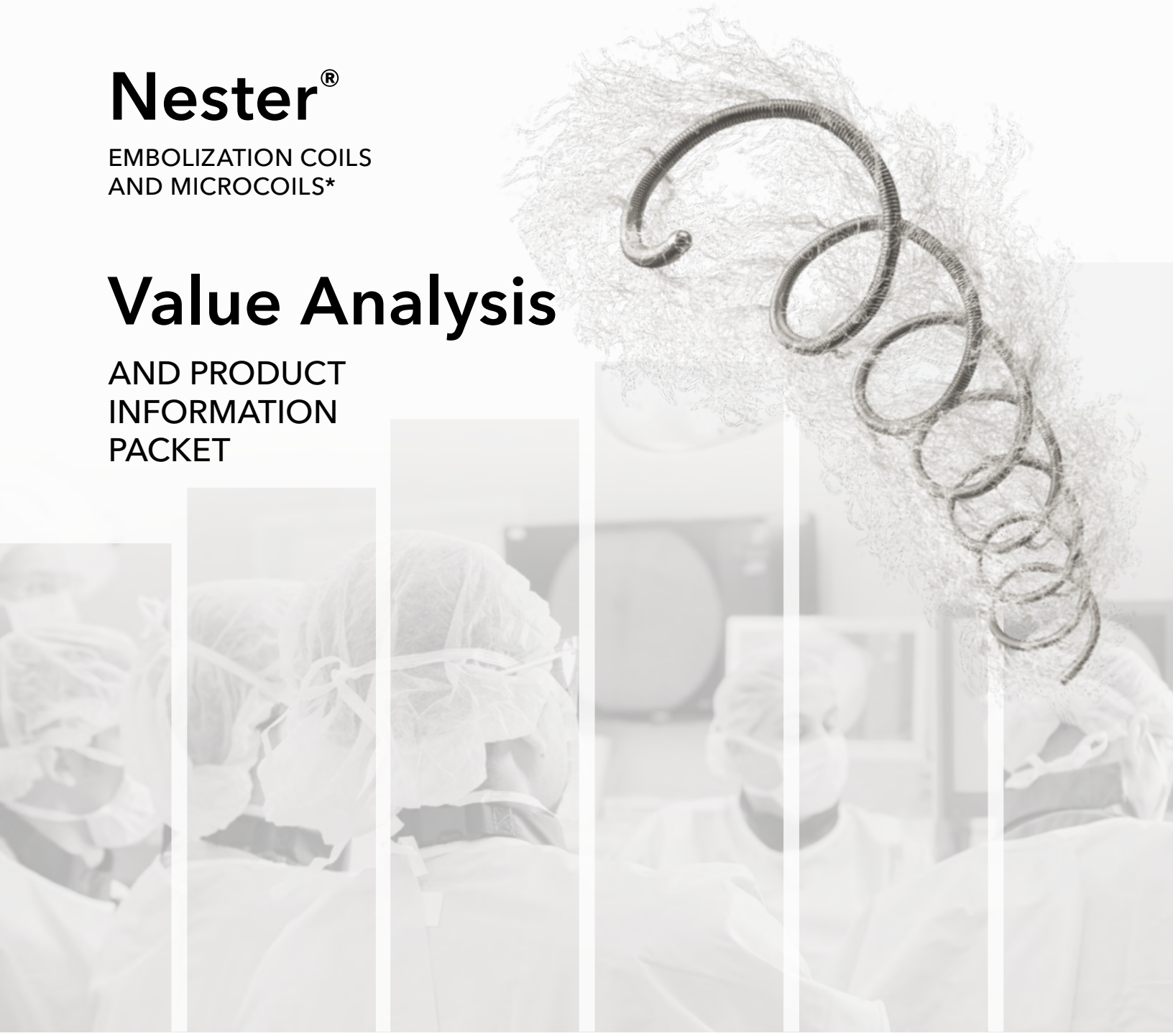
Nester®

EMBOLIZATION COILS
AND MICROCOILS*

Value Analysis

AND PRODUCT INFORMATION PACKET



COOK® MEDICAL

CONTAIN COSTS

BY USING NESTER COILS ALONE OR IN COMBINATION WITH OTHER COILS.

*For the purposes of this document, the reference to Nester coils includes both .035" coils and .018" microcoils. As of September 30, 2019, .038" Nester coils are no longer available in the U.S.A. market. The .035" Nester Embolization Coil and the .038" MReye® Embolization Coil are possible replacement options.

Disclaimer: The information provided herein reflects Cook's analysis of the procedure(s) and/or device(s), based upon the instructions for use (IFU), from sources that may include, but are not limited to, published journal articles, data on file with the manufacturer, physician and consultant input, the CPT coding system, and Medicare payment systems. This analysis is provided for general information purposes only, and Cook does not warrant or assume any liability or legal responsibility for this information. The entity assessing the product is solely responsible for determining the accurate cost of treatment at its site and the codes assigned to the services and items in the medical record. Each entity should use its own economic data to fully assess the assumptions and analysis stated herein.

Contents

Product overview

Cook Medical has manufactured embolization coils for over 35 years. Embolization coils are minimally invasive devices that are introduced percutaneously via a catheter. These devices are implantable, are supplied sterile and are intended for one-time use.

Nester Embolization Coils are commonly used in interventional procedures that include permanent vessel (arterial or venous) occlusion which are intended to treat various conditions.

Nester® Embolization Coils are specifically designed with synthetic fibers that have been shown to significantly reduce the number of coils required to occlude peripheral arteries in a published animal (swine) study[1]. The article is open access and can be found at https://www.jvir.org/article/S1051-0443(18)31588-4/fulltext.

Key product features:

The coils are available in a wide range of configurations:	Lengths from 3 to 20 cm Diameters from 2 to 20 mm when coiled .035" and .018" platforms
Designed to form a tight occluding mass	Nester coils conform inside the vessel to create a tight occluding mass
Made of soft platinum for tight packing	Nester coils are suitable for use as starting, packing, and finishing coils
Fully fibered for thrombogenicity	The synthetic fibers promote clot formation
Easily visible under fluoroscopy	
MR conditionally safe at 3T and 1.5T	
Can be used in combination with other pushable and detachable embolization coils	

Nester coils are designed to provide value for:

Hospitals:	Provides positive clinical outcomes and help keep costs in check by using fewer, fibered pushable coils[1,9]
Healthcare providers:	Can be used alone or in combination with other Cook Medical or competitor coils to provide occlusion options for patients
Patients:	Results in potentially quicker occlusion times, which can shorten the procedure, leading to conceivably less radiation exposure compared to bare metal coils based on swine study results[1]
Payers:	Potential cost savings by reducing the number of embolization coils needed to achieve acute occlusion compared to bare metal coils[1] and notably less expensive than detachable coils[9]

The key considerations for your value analysis include:

1. **The product:**

- The incorporation of fibers in a metallic embolization coil design allows for the creation of a tight occluding mass[1], which can potentially reduce the number of coils required to achieve occlusion.

2. **The financial impact:**

- Nester Embolization Coils are a potential cost-effective option for acute occlusion; since they are notably less expensive than detachable coils, which means it may be less costly to treat patients.[9]

Product information

Product Intended Use

Nester Embolization Coils are intended for arterial and venous embolization in the peripheral vasculature.

Product design

Nester Embolization Coils are made of platinum with spaced synthetic fibers and are supplied preloaded in a loading cartridge. They are designed to be delivered to the target vessel using a soft, straight wire guide through a standard angiographic catheter. Nester coils are available in lengths from 3 cm to 20 cm and in diameters of 2 mm to 20 mm for .018" and .035" platforms.

Deployment method

The embolization coil is loaded into the catheter by inserting the cartridge through the catheter hub until it is seated in the flare of the catheter.

The coil is then pushed into the catheter using a loading stylet or wire guide. The cartridge can then be removed, and the coil can then be pushed through the catheter shaft with a flexible tipped wire guide.

The coil is deployed when the coil and wire pass the end of the catheter tip. See the IFU for step by step instructions for use, coil delivery techniques and coil size selection.

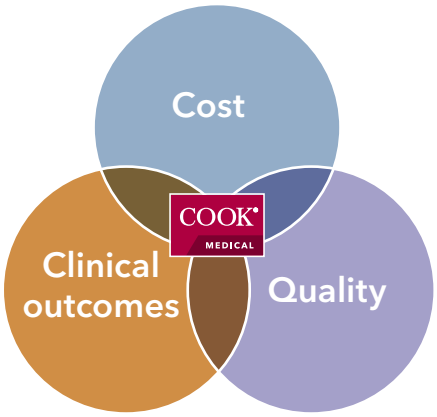
*NOTE: References may be found on page 24 of this packet.

Value analysis

Overview

Using Cost, Quality and Clinical Outcomes to make evidence-based decisions

Healthcare professionals understand the importance of a high-quality product and one that makes economic sense as well. In this ever-changing healthcare landscape, healthcare providers must not only focus on the best clinical option for their patients, but also the most cost-effective option. They can no longer focus solely on the individual procedure, but on the total care of that patient; including follow-up, return to work and a patient's overall quality of life.



The value analysis for the Nester Embolization Coils focuses on the variable that can be controlled—the choice of embolization coil—thus allowing healthcare providers to make evidence-based decisions to treat their patients.

Patients:

Results in potentially quicker occlusion times, which can shorten the procedure, leading to conceivably less radiation exposure compared to bare metal coils[1] (Full Text Swine Article)

Healthcare providers:

Can be used alone or in combination with other Cook Medical pushable and detachable coils, or competitor detachable coils, to provide occlusion options for patients.

Hospitals:

Provides positive clinical outcomes and keeps costs in check by using fewer, fibered pushable coils; thus it becomes potentially less costly to treat patients[1,9]

Payers:

Potential cost savings by reducing the number of embolization coils needed to achieve acute occlusion compared to bare metal coils[1] and notably less expensive than detachable coils[9]

Embolization coil placement and related procedures put the patient at additional risk. For the list of precautions and warnings associated with embolization coil procedures, please refer to the IFU.

*NOTE: References may be found on page 24 of this packet.

Economic value analysis

Economic value and device selection for acute vascular occlusions

Alternatives to the Nester Embolization Coils include vascular plugs and detachable coils. Vascular plugs can at times be difficult or impossible to place in tortuous arteries and therefore may make it necessary for the interventionalist to use coils. Additionally, use of a larger sheath to deliver the embolization device may result in an increased rate of access site complications.[2] Detachable coils may be an option as well, but the total cost of detachable coils compared to pushable coils is much higher.[3] The overall cost of care must be considered as part of the value analysis.

High cost detachable coils may increase the overall cost to treat the patient.

- The average mean cost of a **hospital outpatient** placement of embolization coils without complications is **approximately $11,631.94**. [a,4]
- Vascular embolization procedures are reimbursed on **average $9,907.37**[b] by Medicare. Thus, the total reimbursement rate per procedure is significantly less than the average hospital outpatient cost per procedure.

Scenarios: Costs Comparing Pushable Nester Coils and Detachable Coils

Costs per procedure	Pushable Nester Embolization Coils	Detachable Coils
Estimated number of coils per procedure[13]	9	4
Total cost of coils per procedure [c]	$810	$3,148

Pushable and Detachable Coil Combination Comparisons		Pushable Nester Embolization Coils	Detachable Coils	$ Totals
All Detachable Coils	Estimated number of coils per procedure[13]	0	4	
	Total cost of coils per procedure[c]	0	$3,148	$3,148
Combination of Coils	Estimated number of coils per procedure[13]	3	2	
	Total cost of coils per procedure[c]	$270	$1,574	$1,844
All Pushable Coils	Estimated number of coils per procedure[13]	9	0	
	Total cost of coils per procedure[c]	$810	$0	$810

For more information on the clinical use and economic impact of Nester embolization coils, please contact your local Cook Medical Representative.

a The procedure cost is the average geometric mean cost of CPT codes 37241, 37242, 37243, and 37244 from the CY2020 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (Medicare program: changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. Centers for Medicare & Medicaid Services Web site. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC. Accessed January 7, 2020.

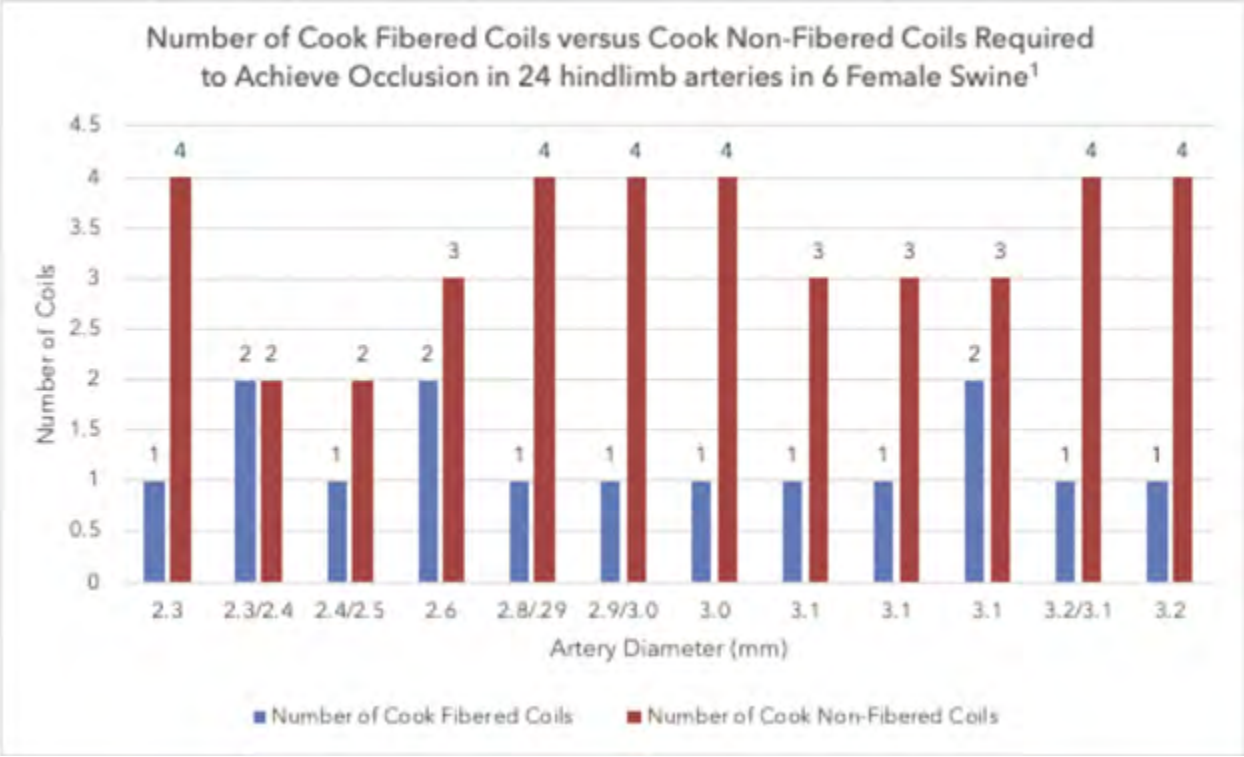
b The average Medicare reimbursement rate was calculated utilizing CPT codes 37241, 37242, 37243, and 37244.

c The estimated cost of each Nester Embolization Coil was $90 and the estimated cost of each Detachable coil was $787. Coil price estimates are averages from ECRI data.

Preclinical data analysis

Metallic coils are a mainstay of embolotherapy. Coils have evolved considerably over the past several decades with a transition of metal from stainless steel to platinum, from wool to polymer fibers (for fibered coils) and hydrogel, and with the development of detachable coils.

Nester Embolization Coils with nylon fibers allow significantly fewer embolization coils to achieve acute occlusion than Nester non-fibered coils.[1] Fewer coils required can lead to a potential cost savings, shorten procedure times, leading to conceivably less radiation exposure, and lessens the amount of metal left in the body when compared to bare metal coils.[1] (Full Text Swine Article)



*NOTE: References may be found on page 24 of this packet.

Summary

Embolization can be complicated, but embolization coil choice does not have to be. The data referenced throughout this document can help healthcare providers make evidence-based decisions. By using this information, providers can determine if Nester Embolization Coils are an ideal choice for their patients.

Nester coils are designed to provide value for:

Hospitals:	Provides positive clinical outcomes and keeps costs in check by using fewer, fibered pushable coils; thus it becomes potentially less costly to treat patients[1,9]
Healthcare Providers:	Can be used alone or in combination with other Cook Medical coils or competitor coils to provide occlusion options for patients
Patients:	Results in potentially quicker occlusion times, which can shorten the procedure, leading to conceivably less radiation exposure compared to bare metal coils[1] (Full Text Swine Article)
Payers:	Potential cost savings by reducing the number of embolization coils needed to achieve acute occlusion compared to bare metal coils[1] and notably less expensive than detachable coils[9]

Considerations for your value analysis include:

1. **The product:**

   The incorporation of fibers in a metallic embolization coil design allows for the creation of a tight occluding mass, which can potentially reduce the number of coils required to achieve occlusion.[1]

2. **Specialties served**

   - Vascular surgeons
   - Interventional radiologists
   - Interventional cardiologists

3. **The financial impact:**

   Nester Embolization Coils are a potential cost-effective option for acute occlusion since they are notably less expensive than detachable coils, which means it may be less costly to treat patients using Nester Embolization Coils.[9]

4. **Impact on patients**

   With a potentially quicker occlusion time and fewer coils required to achieve occlusion, patients will conceivably receive less radiation exposure with a smaller amount of metal left in the body, compared to bare metal coils.[1] (Full Text Swine Article)

*NOTE: References may be found on page 24 of this packet.

Materials management information

Order numbers and sizing

Order Number	Reference Part Number	Extended Embolus Length cm	Coiled Embolus Diameter mm
.018 inch Nester Embolization Microcoils			
G47331	**MWCE-18-3-2-NESTER-01**	3	2
G47332	**MWCE-18-3-3-NESTER-01**	3	3
G47333	**MWCE-18-5-2-NESTER-01**	5	2
G47334	**MWCE-18-5-3-NESTER-01**	5	3
G47335	**MWCE-18-5-5-NESTER-01**	5	5
G47337	**MWCE-18-7-2-NESTER-01**	7	2
G47338	**MWCE-18-7-3-NESTER-01**	7	3
G47339	**MWCE-18-7-4-NESTER-01**	7	4
G47340	**MWCE-18-7-5-NESTER-01**	7	5
G47341	**MWCE-18-7-6-NESTER-01**	7	6
G47342	**MWCE-18-7-8-NESTER-01**	7	8
G47326	**MWCE-18-14-3-NESTER-01**	14	3
G47327	**MWCE-18-14-4-NESTER-01**	14	4
G47328	**MWCE-18-14-5-NESTER-01**	14	5
G47329	**MWCE-18-14-6-NESTER-01**	14	6
G47330	**MWCE-18-14-8-NESTER-01**	14	8
G47325	**MWCE-18-14-10-NESTER-01**	14	10

Order Number	Reference Part Number	Extended Embolus Length cm	Coiled Embolus Diameter mm
.035 inch Nester Embolization Microcoils			
G47371	**MWCE-35-7-3-NESTER-01**	7	3
G47372	**MWCE-35-7-4-NESTER-01**	7	4
G47374	**MWCE-35-7-6-NESTER-01**	7	6
G47375	**MWCE-35-7-8-NESTER-01**	7	8
G47365	**MWCE-35-7-10-NESTER-01**	7	10
G47352	**MWCE-35-14-4-NESTER-01**	14	4
G47354	**MWCE-35-14-6-NESTER-01**	14	6
G47355	**MWCE-35-14-8-NESTER-01**	14	8
G47345	**MWCE-35-14-10-NESTER-01**	14	10
G47346	**MWCE-35-14-12-NESTER-01**	14	12
G47347	**MWCE-35-14-14-NESTER-01**	14	14
G47348	**MWCE-35-14-16-NESTER-01**	14	16
G47349	**MWCE-35-14-18-NESTER-01**	14	18
G47350	**MWCE-35-14-20-NESTER-01**	14	20
G47356	**MWCE-35-20-10-NESTER-01**	20	10
G47357	**MWCE-35-20-12-NESTER-01**	20	12
G47358	**MWCE-35-20-14-NESTER-01**	20	14
G47359	**MWCE-35-20-16-NESTER-01**	20	16
G47360	**MWCE-35-20-18-NESTER-01**	20	18
G47361	**MWCE-35-20-20-NESTER-01**	20	20

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

If you like Nester Embolization Coils, you may also be interested in the other coils in Cook Medical's embolization portfolio, as well as Cook Medical devices that support embolization and other vascular procedures: https://www.cookmedical.com/products/

Product specifications

Nester Embolization Coils and Microcoils are intended for arterial and venous embolization in the peripheral vasculature.

Material composition

Nester Embolization Coils are made of a platinum alloy (92% platinum, 8% tungsten) with equidistantly spaced nylon fibers between the coils and are supplied preloaded in a loading cartridge. They are designed to be delivered to the target vessel using a soft, straight wire guide through a standard angiographic catheter. Nester Embolization Coils are loaded onto an 19 or 21 gauge (depending upon coil diameter) hubbed stainless steel shipping cannula. The length of the cannula is based upon the coil length. A pusher stylet is provided with the .018 microcoils. The pusher is designed with a rounded ½ inch handle coiled in an offset manner for easy grip. Both ends of the pusher are rounded to a smooth finish.

Nester Embolization Coils are manufactured from platinum coiled wire and are recommended for use with TFE coated wire guides manufactured as a straight guide with a flexible distal tip. In addition, the deployment of platinum embolization coils is not recommended for use with polyurethane or polyvinylchloride catheters or any catheters with distal side ports since the material or side port may result in a jamming of the embolus within the catheter.[e]

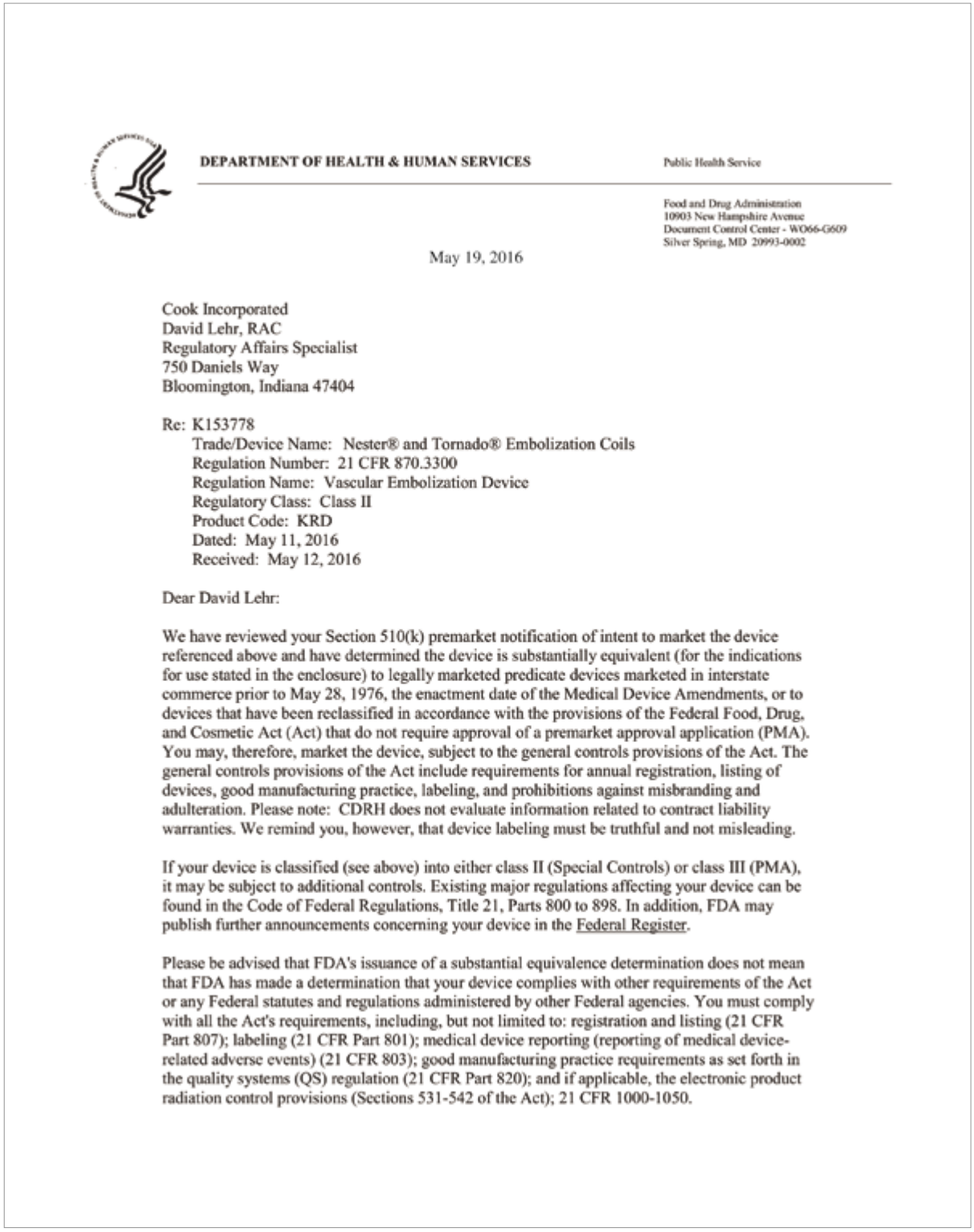
Coding and reimbursement

For the most up-to-date information, please visit https://www.cookmedical.com/support/reimbursement/ and click on the Interventional Radiology tab under "Coding and Reimbursement Guides", then click on "Transcatheter Peripheral Embolization or Occlusion Services".

[e] Data on file with manufacturer. Reference document number: Design Dossier: 016-031 (Rev. 8)

FDA 510(k) clearance letter

(This document is also available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K153778)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 19, 2016

Cook Incorporated
David Lehr, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K153778
Trade/Device Name: Nester® and Tornado® Embolization Coils
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: May 11, 2016
Received: May 12, 2016

Dear David Lehr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153778

Device Name
Nester® and Tornado® Embolization Coils

Indications for Use *(Describe)*
The Nester® and Tornado® Embolization Coils are intended for arterial and venous embolization in the peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (8/14) Page 1 of 1

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K153778

2.0 510(k) SUMMARY

As required by 21 CFR §807.92
Date Prepared: April 1, 2016

I. SUBMITTER

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	David Lehr, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 ext. 102309
Contact Fax Number:	(812) 332-0281

II. DEVICE

Trade Name:	Nester® and Tornado® Embolization Coils
Common Name:	Vascular Embolization Device
Classification Name:	Device, Vascular, For Promoting Embolization
Regulation/Class:	21 CFR §870.3300/Class II
Product Code	KRD

III. PREDICATE DEVICE

The device subject of this submission is considered substantially equivalent to the predicate device, the Cook Retracta® Detachable Embolization Coil (K123712/K151676). This predicate has never been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Nester® and Tornado® Embolization Coils are constructed from coiled platinum wire and synthetic fibers. The wire forms primary coil diameters that can be delivered through catheters with end hole diameters of 0.018, 0.035, and 0.038 inch. For the Nester® Embolization Coils, the extended embolus lengths range from 3 to 20 cm, and upon deployment the coiled embolus diameters range from 2 to 20 mm. For the Tornado® Embolization Coils, the extended embolus lengths range from 2 to 14.2 cm, and upon deployment the coiled embolus tapering diameters range from 3/2 to 10/5 mm.

V. INDICATIONS FOR USE

The Nester® and Tornado® Embolization Coils are intended for arterial and venous embolization in the peripheral vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject devices, the Nester® and Tornado® Embolization Coils, and the predicate device, the Retracta® Detachable Embolization Coil (K123712/151676), are substantially equivalent in that these devices have identical intended uses and similar technological characteristics. The predicate device is a combined embolization coil and delivery wire. Its embolization coil (made of platinum wire and nylon fibers) is delivered by a detachment mechanism. The subject devices are pushable embolization coils (also made of platinum wire and nylon fibers) delivered with a wire guide through a delivery catheter. The predicate coils (intended for delivery through catheters with an end hole size of 0.035 inch) have a helical shape, and are available in lengths of 7 cm or 14 cm and diameters ranging from 4 to 20 mm. The subject Nester coils (intended for delivery through catheters with end hole sizes of 0.018, 0.035, and 0.038 inch) also have a helical shape and are available in lengths ranging from 2 to 20 cm and in diameters ranging from 2 to 20 mm. The subject Tornado coils (also intended for delivery through catheters with end hole sizes of 0.018, 0.035, and 0.038 inch) have a tapered vortex (or tornado) shape and are available in lengths ranging from 2.0 to 14.2 cm and tapering diameters ranging from 3/2 to 10/5 mm. Additionally, the subject devices, like the predicate device, are labeled as MR Conditional. However, there are differences in the MR scanning conditions to reflect the testing performed on the subject devices. Based on the comparison of the design, intended use, materials, fundamental technology, and principle of operation, the subject devices are considered to be substantially equivalent to the currently marketed predicate device.

VII. PERFORMANCE DATA

The subject devices underwent the applicable testing listed below to ensure reliable design and performance under the testing parameters. Performance (bench, MRI, and animal) and biocompatibility testing was conducted in accordance with applicable FDA guidance documents to confirm the reliable performance of critical device characteristics.

- Biocompatibility Testing – Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Subchronic Toxicity, Genotoxicity, Implantation, Hemocompatibility, and Pyrogenicity tests were performed on the implantable embolization coils. Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, and Hemocompatibility tests were performed on the device's

loading stylet and loading cartridge. All tests results met the acceptance criteria, where applicable, or demonstrated that the device is biocompatible.

- Wire Tensile Testing – Testing shows the raw wire has a peak load value greater than or equal to the minimum tensile strength requirements. The predetermined acceptance criteria were met.
- Coil Tensile Testing – Testing characterized the embolization coils' uniaxial tensile strength.
- Rotations to Failure Testing – Testing characterized the embolization coils' torque strength.
- Delivery Friction Testing – Testing shows that the embolization coils fully deploy into the portion of the target artery in an anatomical model. The predetermined acceptance criteria were met.
- Delivery Fatigue Testing – Testing shows that the embolization coils do not have any visual defect after delivery. The predetermined acceptance criteria were met.
- Fiber Security Testing – Testing shows that an entire fiber is not released from the coils during simulated delivery conditions. The predetermined acceptance criteria were met.
- MRI Testing – MRI compatibility was assessed by evaluating magnetic field interactions (displacement force and torque), artifact, and RF-induced heating in accordance with FDA guidance titled, *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*.
- Animal Testing – One-month, three-month, and six-month safety evaluations in swine were performed on platinum embolization coils. Testing shows that the target arteries do not indicate a substantially adverse biological response. The predetermined acceptance criteria were met.

VIII. CONCLUSIONS

The data included in this submission indicate that the subject devices do not raise new questions of safety or effectiveness compared to the predicate device. This supports a determination of substantial equivalence.

Instructions for use (IFU)*

NESTER® EMBOLIZATION COILS
AND MICROCOILS

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner)

DEVICE DESCRIPTION

Nester Embolization Coils (0.035" and 0.038") and 0.018" Microcoils are made of platinum with spaced synthetic fibers, and are supplied preloaded in a loading cartridge. They are designed to be delivered to the target vessel using a soft, straight wire guide through a standard angiographic catheter.

INTENDED USE

Nester Embolization Coils and Microcoils are intended for arterial and venous embolization in the peripheral vasculature.

MRI SAFETY INFORMATION

Nonclinical testing has demonstrated that single and multiple Nester Embolization Coils and Microcoils are MR Conditional according to ASTM F2503. A patient with this device may be safely scanned after placement under the following conditions:

- Static magnetic field of 3.0 tesla or 1.5 tesla only
- Maximum magnetic field spatial gradient of 1700 gauss/cm (17 T/m)or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of ≤ 2.0 W/kg (Normal Operating Mode)

Under the scan conditions provided above, the Nester Embolization Coils and Microcoils are not expected to result in a temperature rise of more than 3.0° C after 15 minutes of continuous scanning.

The image artifact extends approximately 5.7 mm from the Nester Embolization Coils and Microcoils as found during nonclinical testing when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

None known

WARNINGS

- Positioning of Embolization Coils and Microcoils should be done with particular care. Coils should not be left too close to the inlets of arteries and should be intermeshed with previously placed coils if possible. A minimal but sufficient arterial blood flow should remain to hold the coils against the previously placed coils until a solid clot ensures permanent fixation. The purpose of these suggestions is to minimize the possibility of loose coils becoming dislodged and obstructing a normal and essential arterial channel.
- Nester Embolization Coils and Microcoils are not recommended for use with polyurethane catheters or catheters with sideports. If a catheter with sideports is used, the embolus may lodge in the sideport or pass inadvertently through it. Use of a polyurethane catheter may also result in lodging of the embolus within the catheter.
- If difficulties occur when deploying the embolization coil, withdraw the wire guide, coil and angiographic catheter simultaneously as a unit.

*The Nester Embolization Coil IFU references the .038", .035" and .018" size coils. Please note that as of September 30, 2019, .038" size Nester coils are no longer available in the U.S.A. market. The .035" Nester Embolization Coil and the .038" MReye Embolization Coil are possible replacement options.

PRECAUTIONS

- The product is intended for use by physicians trained and experienced in embolization techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.
- Perform an angiogram prior to embolization to determine correct catheter position.
- Prior to introduction of the embolization coil, flush the angiographic catheter with saline.
- If using a .018 inch Nester Embolization Microcoil, ensure that the delivery catheter has an internal diameter (ID) of .018 to .025 inch.

PRODUCT RECOMMENDATIONS

The following table offers specific recommendations.

Coil Size Diameter	Catheter Type & Size	Wire Guide Type & Size
.018 inch	MCS-2.5 MCS-2.8 SCR3.0B	STF-18 TSF-18 TSFB-18
.035 inch	HNB4.0-35 HNB4.1-35 HNB[R]5.0-35 SCBR4.0-35 SCBR5.0-35	TSF-35 TSFB-35 TSFBP-35 TSFNA-35 TSFNB-35
.038 inch	HNB[R]5.0-38 HNB[R]6.0-38 SCBR4.0-38 SCBR5.0-38	TSF-38 TSFB-38 TSFNA-38 TSFNB-38

Coil Delivery Technique and Coil Size Selection

Long-term occlusion depends on achieving cross-sectional occlusion of the blood vessel, and coaxial catheters provide the ability to control placement of coils and permanent occlusion. The combination of the coaxial technique and either the anchor or scaffold technique significantly enhances stability of coil deployment.

- Coaxial technique: The use of an outer guiding sheath/catheter is the most important step in preventing coil elongation and uncertain long-term occlusion. The outer guiding sheath/catheter provides support, and the inner catheter provides finer selective maneuvers. (Fig. 7)
- Anchor technique: The anchor technique provides safe and distal occlusion when there is a question about instability of coils. At least 2 cm of a coil is advanced into the side branch, which is normally sacrificed. The rest of the coil is then deployed just proximal to that side branch, and additional coils are packed. (Fig. 8) NOTE: Use a coil longer than 10 cm for anchor technique.
- Scaffold technique: The scaffold technique is used for high-flow vessels when there is concern about migration of a softer coil. A high radial force coil is placed initially. Then, several Inconel coils or platinum coils (soft coils) may be packed within the scaffold. (Fig. 9)

In general, the first coil selected should have a diameter that is 20% larger, or at least 2 mm oversized, than the vessel that is being occluded.

INSTRUCTIONS FOR USE

For .018 Inch Microcoils:

1. Perform an angiogram prior to embolization to determine optimal catheter position.

2. Push the loading cartridge completely into the delivery catheter. (Fig. 1)

3. Advance the Luer lock connector fitting toward the catheter hub and lock into place. (Fig. 2)

4. Use the pusher stylet to load the Nester Embolization Microcoil into the delivery catheter. (Fig. 3) NOTE: The stylet must be pushed as far as possible into the loading cartridge to ensure proper loading. Remove the pusher stylet and loading cartridge.

5. To obtain secure placement of the Nester Embolization Microcoil, we recommend the use of the pusher stylet to push the Microcoil further into the delivery catheter. (Fig. 4)

6. Once coil is positioned into delivery catheter, verify position of catheter tip prior to deployment. Coil design permits delivery into the target vessel by saline/contrast flush or by push technique using an appropriately sized wire guide or pusher.

7. Perform final angiogram to confirm coil position within target vessel.

For .035 and .038 Inch Coils:

1. Perform an angiogram prior to embolization to determine optimal catheter position.

2. Firmly grasp the loading cartridge between thumb and forefinger. Introduce the metal end of the loading cartridge into the base of the catheter hub. Lock loading cartridge onto catheter hub by turning Luer lock adapter clockwise. (Fig. 5)

3. Maintaining position of the cartridge, advance the stiff portion of the wire guide into the loading cannula. Push the coil into the first 20 to 30 centimeters of the angiographic catheter. (Fig. 6) Remove the wire guide and loading cartridge.

4. With the flexible tip of the wire guide, advance the embolization coil to the tip of the catheter. Verify position of the angiographic catheter prior to deployment.

5. Deploy the coil by advancing the wire guide past the tip of the catheter.

6. Perform final angiogram to confirm coil position within target vessel.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature

Figure 1.

Figure 2.

Figure 3.

Figure 4.

Figure 5.

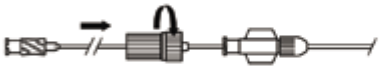


Figure 6.

Figure 7.

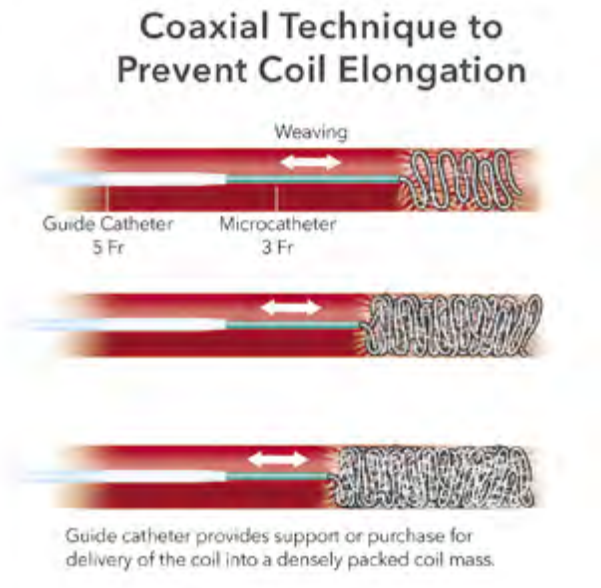


Figure 8.

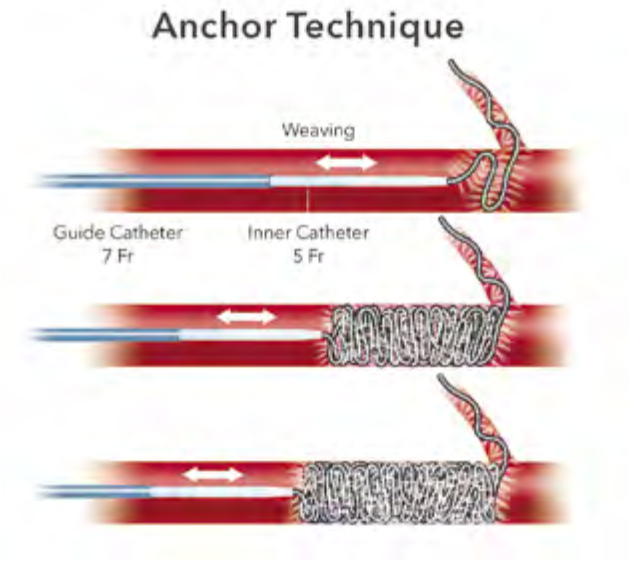
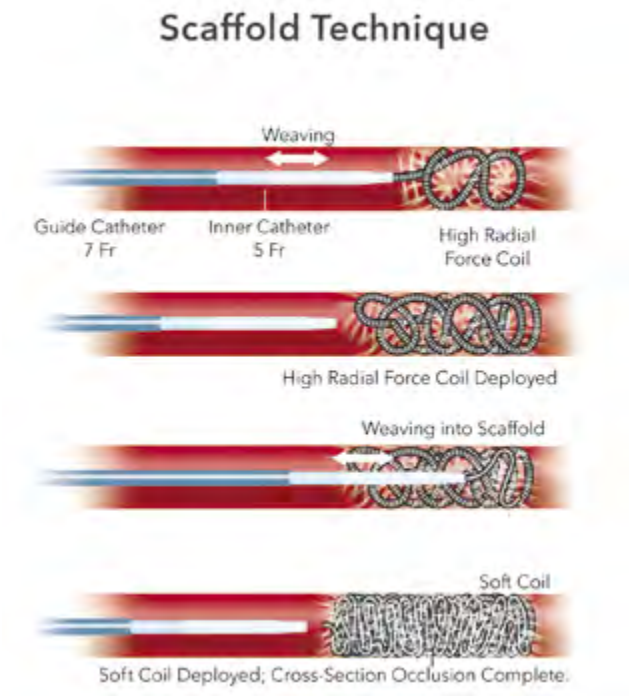


Figure 9



Solutions portfolio

Clinical

Vista and educational programs

Cook Medical's Vista Education and Training programs set a high standard for product education via peer-to-peer interaction. These programs incorporate Cook-selected qualified faculty with Cook-specific content training, and peer-to-peer interaction in every session. These programs are designed to focus on product education.

Visit https://vista.cookmedical.com for more information, or speak to your local Cook sales representative for upcoming events in your area.

Reimbursement

Cook's policy is to offer information that is complete, accurate, straightforward, and consistent with the statutes and regulations of the federal government and well-accepted coding guidelines as established by the Centers for Medicare and Medicaid Services (CMS), the American Medical Association (AMA), the American Hospital Association (AHA), and other relevant professional societies. Cook's reimbursement assistance team can provide Medicare reimbursement rates, assessment of Medicare and commercial insurance coverage policies, and coverage appeals support.

Purchasing

Digital catalog

Cook can provide a URL to an image for each product in the Cook Medical catalog. These URLs are delivered to a customer in a spreadsheet that can be uploaded to display the images in customer's purchasing platform (ERP) or clinical information system. Product images allow end users to view and validate the items.

E-commerce

We have the ability to help you order electronically. E-commerce is an automated, paper-free method of transacting purchase orders, acknowledgments, invoices, and dispatch and receiving notifications. Cook offers value-added-network (VAN), direct EDI, XML, and web-based methods of e-commerce transactions and ordering.

GS1

GS1 is an international, not-for-profit association that creates and implements standards to bring efficiency and visibility to supply chains across multiple industries. The GS1 standards for healthcare focus on improving patient safety and supply-chain efficiency. They do this by providing unique product identification (GTINs), clean data (GDSN), and location information (GLNs) numbers.

All Cook Medical products are GS1 compliant. Having GS1-compliant products gives systems improved visibility in the supply chain.

Customer support and delivery

Distribution support

At Cook Medical, we partner with health systems to identify the distribution model that best fits their needs. We're glad to engage in a discussion regarding the desire to ship Cook Medical items through a third-party distributor or customer's self-distribution center.

Shipping

Standard shipping is included for most orders, although Cook Medical may require a minimum order quantity or dollar amount. Expedited shipping may be available and subject to an additional cost which will be prepaid by Cook Medical and invoiced to the customer. Cook Medical's shipping policy is subject to change and may be updated from time to time. Please refer to www.cookmedical.com/support/ordering-returns for current order requirements and further information about shipping options.

Item master clean-up

Cook Medical can perform an item master clean-up for its customers. This includes, but is not limited to, helping customers correct pricing discrepancies, discover unit of measure discrepancies, locate unavailable or invalid part numbers, provide GTINs, and offer contract information. This will ensure that the ordering process between the customer and Cook Medical is seamless.

Product use and SKU reduction

Cook Medical can provide cross-referencing to all customers who request it. This includes cross-referencing between a competitor and Cook Medical and between Cook Medical's stock and nonstock items.

Consolidated packaging

Cook Medical's consolidated packaging program combines separate product orders in clear, heat-sealed plastic bags that will ensure that the integrity of each purchase order (PO) is maintained. A packing slip with scannable barcode is included in each heat-sealed pack. Our process includes placing individually bagged POs into as few boxes as possible by using a mutually agreed-upon order cutoff time. Fewer boxes received means a more streamlined receiving process, reduced shipping and freight costs, and reduced cardboard recycling waste and expense.

Embolization Services

- Personalized and customized attention
- Sales representatives that can offer case and product support when requested
- Devices for access, navigation, and treatment that support embolization procedures from start to finish
- Patient specific solutions
- Fulfillment options and business solutions assistance

Sustainability

At Cook Medical, we strive to perform in an environmentally responsible manner by incorporating the best management practices, fostering the sustainable use of natural resources, promoting pollution prevention, reducing waste generation, and recycling and reusing materials where possible within our operations. Cook Medical has a corporate sustainability team responsible for finding new ways to reduce waste for our customers and for us. Currently, our sustainability strategy is focused mainly on improving the environmental performance of our facilities, packaging, and recycling.

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