

EMBOLIZATION COILS AND MICROCOILS*

Value Analysis

AND PRODUCT INFORMATION BROCHURE

2021



EMBOLIZE AND 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.

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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) study¹. The article is open access and can be found at <u>https://www.jvir.org/article/S1051-0443(18)31588-4/fulltext</u>.

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			

 $\label{eq:canbe} \mbox{Can be used in combination with other pushable and detachable embolization coils}$

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 ^{1,8}
Healthcare Physicians:	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 ⁸

*NOTE: References may be found on page $\underline{19}$ of this brochure.





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 mass¹, 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.⁸

3. The clinical impact:

• Fewer devices which are easy to use, can mean quicker procedures and less radiation exposure.⁹

Product information

Product intended use

Nester Embolization Coils are intended for arterial and venous vessel embolization procedures.

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.





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 coils¹ (Full Text Swine Article)

Healthcare Physicians:

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^{1,8}

Payers:

Potential cost savings by reducing the number of embolization coils needed to achieve acute occlusion compared to bare metal coils¹ and notably less expensive than detachable coils⁸

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





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 anatomies 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

• There is an increasing trend in the use of detachable coils¹². Cook Medical offer a broad range of pushable and detachable embolization coils which can help healthcare providers contain costs, by using these in combination.

For further information on the economic and clinical impact that could be achieved by using the Nester coil alone or in combination with other Cook or competitor coils please contact your local Cook Medical Representative.





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)





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 ^{1,8}
Healthcare Physicians:	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 ⁸

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. Specialists served:

- Vascular surgeons
- Interventional radiologists
- Interventional cardiologists

3. The financial impact:

Nester Embolization Coils are a potentially 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.⁸

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)





Materials management information

Order numbers and sizing

Order Number	Reference Part Number	Extended Embolus Length (cm)	Coiled Embolus Diameter (mm)
.018 inch MicroNes	ter [®] Embolization Microcoils		
G26986	MWCE-18-14-10-NESTER	14	10
G26987	MWCE-18-14-3-NESTER	14	3
G26988	MWCE-18-14-4-NESTER	14	4
G23522	MWCE-18-14-5-NESTER	14	5
G26989	MWCE-18-14-6-NESTER	14	6
G26990	MWCE-18-14-8-NESTER	14	8
G52731	MWCE-18-3-2-NESTER	3	2
G52732	MWCE-18-3-3-NESTER	3	3
G52733	MWCE-18-5-2-NESTER	5	2
G52734	MWCE-18-5-3-NESTER	5	3
G23520	MWCE-18-5-5-NESTER	5	5
G52741	MWCE-18-7-10-NESTER	7	10
G52735	MWCE-18-7-2-NESTER	7	2
G52736	MWCE-18-7-3-NESTER	7	3
G52737	MWCE-18-7-4-NESTER	7	4
G23521	MWCE-18-7-5-NESTER	7	5
G52738	MWCE-18-7-6-NESTER	7	6
G52739	MWCE-18-7-8-NESTER	7	8



Order Number	Reference Part Number	Extended Embolus Length (cm)	Coiled Embolus Diameter (mm)
.035 inch Nester Er	nbolization Coils		
G26991	MWCE-35-14-10-NESTER	14	10
G26992	MWCE-35-14-12-NESTER	14	12
G52751	MWCE-35-14-14-NESTER	14	14
G52752	MWCE-35-14-16-NESTER	14	16
G52753	MWCE-35-14-18-NESTER	14	18
G52754	MWCE-35-14-20-NESTER	14	20
G23525	MWCE-35-14-3-NESTER	14	3
G26993	MWCE-35-14-4-NESTER	14	4
G23526	MWCE-35-14-5-NESTER	14	5
G26994	MWCE-35-14-6-NESTER	14	6
G26995	MWCE-35-14-8-NESTER	14	8
G23530	MWCE-35-20-10-NESTER	20	10
G23531	MWCE-35-20-12-NESTER	20	12
G23532	MWCE-35-20-14-NESTER	20	14
G23533	MWCE-35-20-16-NESTER	20	16
G52755	MWCE-35-20-18-NESTER	20	18
G52756	MWCE-35-20-20-NESTER	20	20
G23527	MWCE-35-20-5-NESTER	20	5
G23528	MWCE-35-20-6-NESTER	20	6
G23529	MWCE-35-20-8-NESTER	20	8
G52745	MWCE-35-7-10-NESTER	7	10
G52746	MWCE-35-7-12-NESTER	7	12
G52747	MWCE-35-7-14-NESTER	7	14
G23523	MWCE-35-7-3-NESTER	7	3
G52742	MWCE-35-7-4-NESTER	7	4
G23524	MWCE-35-7-5-NESTER	7	5
G52743	MWCE-35-7-6-NESTER	7	6
G52744	MWCE-35-7-8-NESTER	7	8

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: <u>https://www.cookmedical.eu/products/</u>





Product specifications

Nester Embolization Coils are intended for arterial and venous vessel embolization procedures.

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 <u>https://www.cookmedical.eu/support/</u>reimbursement/.

^e Data on file with manufacturer. Reference document number: Design Dossier: 016-031 (Rev. 11)



CE Certification Notice

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Instructions for use (IFU)*

NESTER® EMBOLIZATION COILS

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

DEVICE DESCRIPTION

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.

INTENDED USE

Nester Embolization Coils are intended for arterial and venous vessel embolization procedures. 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.

CONTRAINDICATIONS

None known.

WARNINGS

- Positioning of Embolization Coils 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 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.

PRECAUTIONS

- 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 MicroNester[™] embolization coil, ensure that the delivery catheter has an internal diameter (ID) between .018 and .025 inch.

PRODUCT RECOMMENDATIONS

Appropriately sized diameter TFE-coated wire guides with flexible tapered tips are recommended for positioning Nester Embolization Coils. The following table offers specific recommendations.

INSTRUCTIONS FOR USE

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. 1)**

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 cm of the angiographic catheter. **(Fig. 2)** Remove the wire guide and loading cartridge.

NOTE: If you are placing a .018 inch embolization coil, you will advance the coil into the first few centimeters of the angiographic catheter with the loading stylet that is provided with the coils.

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.

*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.





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 onetime 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.





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. 1)
- 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. 2) 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. 3)

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.

Figure 2.



Coiling Techniques

Figure 1.

Guide catheter provides support or purchase for delivery of the coil into a densely packed coil mass.







Figure 3.

Weaving Guide Catheter 7 Fr Inner Catheter 5 Fr High Radial Force Coil High Radial Force Coil Deployed Weaving into Scaffold Weaving into Scaffold Soft Coil Soft Coil

Scaffold Technique

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 \leq 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.



SUPPORTING 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	CP-18-180
.035 inch	HNB[R]5.0-35	TSF-35 TSFB-35 TSFNA-35 TSFNB-35
.038 inch	HNB[R]5.0-38 HNB6.0-38	

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

European Reimbursement Support

Cook Medical's policy is to offer information that is complete, accurate, straightforward, and consistent with the statutes and regulations. If you are not sure what code to use for a procedure in which a Cook Medical device is used, we have a team of specialists covering several European countries that may be able to help. Contact us at <u>dnk-reimbursement@cookmedical.com</u>. We offer support in English, German, French, Italian, and Danish.

Purchasing

Digital catalog

Cook Medical can provide an image where available for each Cook product and supply this in a spreadsheet to the customer for upload into their cataloguing system. Product images allow end-users to view and validate their orders.

E-commerce

E-Commerce delivers many benefits. Cook Medical offers our customers a broad range of electronic data interchange (EDI) solutions in EMEA. This creates efficiency and supports cost reduction across the order-to-cash process. See <u>Appendix 1</u>.

GDSN

Cook Medical is now publishing to the Global Data Synchronization Network (GDSN) and has partnered with Atrify. For further information, refer to <u>Appendix 2</u>.





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 order value. 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 <u>https://www.cookmedical.eu/support/</u> 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 comparison exercises

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.

Customer Portal

Introducing a new self-service solution. View order status and shipment tracking. Real-time interaction with Customer Support. Find out what products are available to ship and what's currently on backorder. Access Cook Medical product notification in the Document Centre. Create your customer account at mycook.cookmedical.com. See <u>Appendix 3</u>.

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

Sustainable and environmental practices

Cook Medical is committed to responsible and sustainable business choices across our business:

- Our facilities: We are committed to making greener choices across our facilities by reducing emissions and waste, preventing pollution, and promoting the sustainable use of our natural resources.
- Our distribution channels: We seek the most efficient balance of technology, time, and transportation to get products to patients in a way that is mindful of our impact on the environment.
- Our products and packaging: We are always looking for ways to reduce excess waste in product design and packaging, while still ensuring our products are effective and protected during shipping and storage.



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E-Commerce EDI - Electronic Data Interchange

E-Commerce delivers many benefits. Cook Medical offers our customers a broad range of electronic data interchange (EDI) solutions in EMEA. This creates efficiency and supports cost reduction across the order-to-cash process.

What are the benefits of E-Commerce?

- Reduced processing and resource requirements for ordering and invoicing
- Immediate error recognition, which eliminates the need to re-key information
- Identification of the source of common ordering and invoicing errors
- Reduced environmental impact of a paperless process



We offer PEPPOL and Standard EDI solutions for document exchange.

EDI capabilities:

- E-Ordering
- Receiving advise message
- Dispatch advise
- E-Invoicing
- Order response

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Queries relating to onboarding?

Contact our EMEA Supply Chain Solutions team: SCS-EMEA@CookMedical.com



We're GDSN ready...are you?

Cook Medical is now publishing to the Global Data Synchronization Network (GDSN) and has partnered with atrify (formerly 1WorldSync). The GDSN is a subscription-based, warehouse of certified data that enables all members of the healthcare supply chain to share common, accurate GTIN and GLN information.

What are the benefits of GDSN to healthcare providers?

Providers can have visibility of products throughout the entire supply chain. This helps to improve inventory management. Providing accurate data improves ordering and invoicing quality. Additionally, maintenance of an item-crossreference database is no longer necessary

How GDSN works:

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GLNs

(Global location numbers) GLNs are 13-digit, globally unique num-

bers that identify physical locations and legal entities. Cook is now transacting via GLNs in these areas: **United Kingdom**, **Netherlands, Germany, Switzerland**

GTINs

(Global trade item numbers)

GTINs are globally unique product identification numbers. GTINs are usually accompanied by a barcode on product packaging. They identify the manufacturer, product and packaging unit of measure. Cook Medical uses 14-digit GTINs

Data Pool provider:

To access the data, please contact our Data Pool provider atrify (formerly 1WorldSync) as follows: +49 221 93373-333 saleseurope@1worldsync.com The Cook Medical Europe GLN is 0827002100084



Should you have any queries or require support, please contact our EMEA Supply Chain Solutions Team at SCS-EMEA@CookMedical.com



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