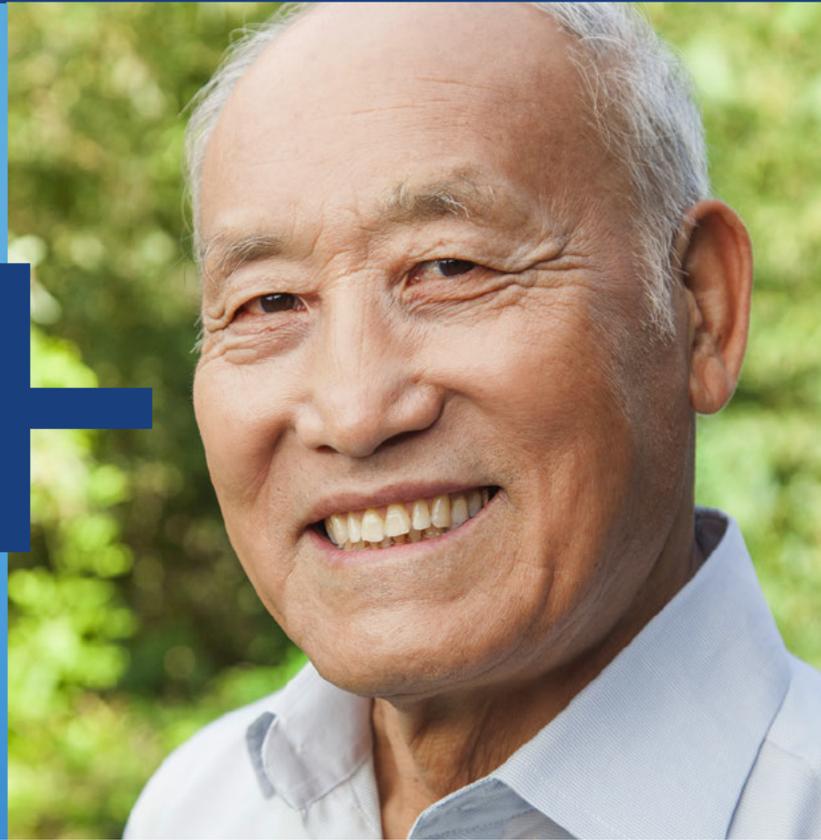


ARGYLE™*

PERITONEAL DIALYSIS CATHETERS



ARGYLE™* PERITONEAL DIALYSIS CATHETERS

Peritoneal dialysis catheters are intended to provide permanent access to the peritoneal cavity for patients to fill and drain their dialysate daily. Due to this daily, repetitive use, it's important to customize the catheter exit site for each patient to help facilitate easy patient and caregiver management. Optimized catheter placement and exit sites can help promote patient compliance for proper maintenance and may help reduce potential complications due to difficult to manage catheters. The Argyle™* peritoneal dialysis catheter line includes a variety of catheter configurations designed to enable patient customization to support long-term access preservation and patency.

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CATHETER & CATHETER KIT **ORDERING GUIDE**

CATHETER CONFIGURATION

The catheter products in this catalog can be ordered in either a catheter configuration or a catheter kit configuration.

Sterile Contents:

- Peritoneal Catheter (1)
 - Beta-Cap™* Adapter (1)
 - Beta-Cap™* Clamp (1)
-

When ordering a single catheter, you may also purchase the following accessories.

Single Catheter Accessories:

16Fr Pull-Apart Introducer Set with PTFE

8815544010	Includes:	5/case
	16Fr Pull-Apart Sheath†/Dilator (1)	
	18ga Introducer Needle (1)	
	12mL Syringe (1)	
	J/Straight 0.038 in Guide Wire (1)	
	†Made with PolyTetra FluoroEthylene (PTFE)	

Tunneling Stylet (Choose one tunneling stylet per catheter)

8817791001	Atraumatic Peritoneal Tunneling Stylet	5/case
8888415679	Faller Tunneling Stylet	1/case

Straightening Stylet, Non-sterile, Autoclavable (Choose one stylet per catheter)

8888415646	Insertion/Straightening Stylet, 44.5 cm	1/case
8888415661	Insertion/Straightening Stylet, 61 cm	1/case

Swan Neck Catheter Stencil (Choose one stencil if ordering the swan neck catheter)

8888412304	Swan Neck Tenckhoff Catheter Stencil, 2 Cuffs, Left/Right	1/case
8888412312	Swan Neck Missouri Catheter Stencil, 2 Cuffs, Left/Right	1/case

CATHETER KIT CONFIGURATION

Sterile Contents:

- Peritoneal Catheter (1)
- Beta-Cap™* Adapter, Cap and Clamp (1)
- 16Fr Pull-Apart Sheath†/Dilator (1)
- 18ga Introducer Needle (1)
- J/Straight Guide Wire (1)
- 12mL Syringe (1)
- #11 Scalpel (1)
- Tunneling Stylet (1)
- 4 in x 4 in Gauze Sponges (6)

Peritoneal catheter kits are convenient and cost-efficient. Kits simplify inventory and save staff time when assembling supplies needed for catheter insertion.

Peritoneal catheter kits are recommended for percutaneous placement of the catheter.

The Peritoneal catheter kit provides an ideal alternative to catheter placement by laparotomy. Each kit features a 16Fr pull-apart introducer used to insert the catheter percutaneously using modified Seldinger technique. This technique uses a smaller incision — helping minimize the risk of postoperative dialysate leakage.

†Made with PolyTetra FluoroEthylene (PTFE)

When ordering a catheter kit, you may also purchase the following accessories.

Catheter Kit Accessories

Straightening Stylet (Choose one stylet per catheter)

8888415646	Insertion/Straightening Stylet, 44.5 cm	1/case
8888415661	Insertion/Straightening Stylet, 61 cm	1/case

Swan Neck Catheter Stencil (Choose one stencil if ordering the swan neck catheter)

8888412304	Swan Neck Tenckhoff Catheter Stencil, 2 Cuffs, Left/Right	1/case
8888412312	Swan Neck Missouri Catheter Stencil, 2 Cuffs, Left/Right	1/case

TENCKHOFF
**PERITONEAL
CATHETERS**

ARGYLE™* TENCKHOFF PERITONEAL CATHETERS

Recommended for peritoneal dialysis or intraperitoneal chemotherapy

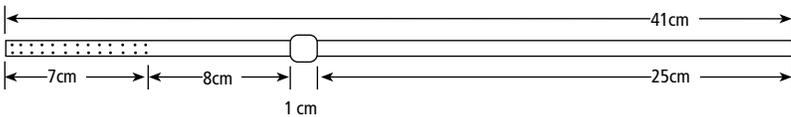
Broad Selection — Choose from a variety of catheter lengths and cuff placements and types. Or choose the Argyle™* Universal Tenckhoff catheter, a unique catheter that can be trimmed to fit most patient sizes. The Tenckhoff catheter is offered in the following cuff configurations:

- One attached cuff – in either the subcutaneous or preperitoneal position.
- Two attached cuffs – one subcutaneous and one preperitoneal.
- Two disks with one or two cuffs – Oreopoulos-Zellerman, Missouri catheter style helps keep catheter in place and prevent omental wrapping.

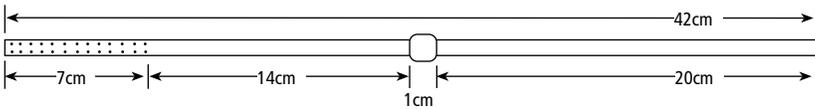
Cost Efficient — For your convenience, Tenckhoff catheters are packaged one per carton, enabling you to stock multiple configurations at minimal cost. Catheters are also available in time-saving, cost-efficient kits. They contain the basic items needed for percutaneous insertion, featuring the pull-apart sheath/dilator and tunneling stylet.

Complete System — Each Tenckhoff catheter comes with an adapter, cap and clamp. The Ultem™* adapter forms a tight closure with standard CAPD transfer sets.

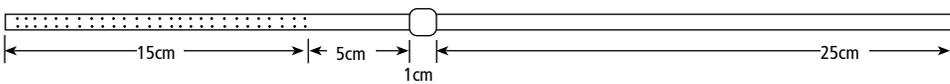
Tenckhoff Catheters — 1 Cuff



Catheter 8814843001 Tenckhoff Catheter, 1 Preperitoneal Cuff, 41 cm 1/case



Catheter 8810889003 Tenckhoff Catheter, 1 Subcutaneous Cuff, 42 cm 1/case

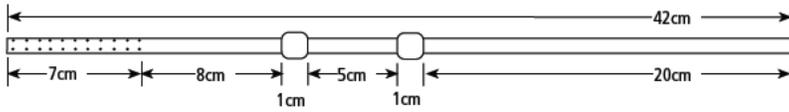


Catheter 8814843002 Tenckhoff Catheter, Universal, 1 Preperitoneal Cuff, 46 cm 1/case

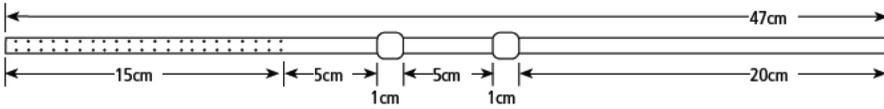
Kit 8817278001 Tenckhoff Catheter, Universal, 1 Preperitoneal Cuff Kit, 46 cm 5/case

ARGYLE™* TENCKHOFF PERITONEAL CATHETERS (CONTINUED)

Tenckhoff Catheters — 2 Cuffs

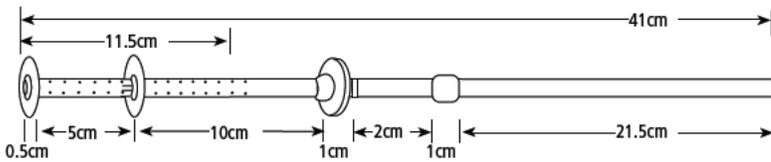


Catheter	8810888003	Tenckhoff Catheter, 2 Cuffs, 42 cm	1/case
Kit	8817278008	Tenckhoff Catheter, 2 Cuffs Kit, 42 cm	5/case



Catheter	8810888012	Tenckhoff Catheter, Universal, 2 Cuffs, 47 cm	1/case
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Oreopoulos-Zellerman Missouri Catheters



Catheter	8888411009	Oreopoulos-Zellerman Catheter, Missouri Catheter	1/case
		1 Bead, 2 Disks, 2 Cuffs, 41 cm	



SWAN NECK PERITONEAL CATHETERS

SWAN NECK SPECIALTY PERITONEAL CATHETERS

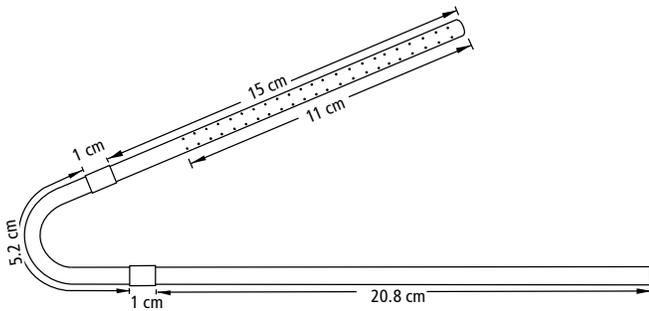
Swan neck specialty peritoneal catheters give you the options and features you need to simplify access for peritoneal dialysis.

Broad Selection — Choose from a variety of catheter options: Tenckhoff, Curl Cath, Missouri, Oreopoulos-Zellerman and Presternal. Pediatric catheters are also available.

- The Swan Neck catheter employs a preformed 180 degree angle designed to keep both the internal and external portions of the catheter positioned downward. The angled catheter is designed to keep the internal portion from migrating out of position and to decrease stress on the exit site, which often occurs when a straight catheter is manually curved.
- The felt cuffs anchor the catheter subcutaneously and help establish a natural infection barrier through tissue ingrowth.
- A radiopaque stripe on the front of each catheter makes it easy to differentiate under X-ray. During insertion and postplacement, this stripe helps identify catheter twisting.
- Stencils are available for skin markings before surgery. Each stencil reflects the exact shape of the catheter and is critical to ensure proper catheter implantation.

Swan Neck Tenckhoff Catheters

The Swan Neck Tenckhoff catheter is a standard Tenckhoff with a preformed 180 degree angle. The angled catheter keeps the internal portion from migrating out of position and decreases stress on the exit site, which often occurs when a straight catheter is manually curved. Indicated for any patient requiring peritoneal dialysis or intraperitoneal chemotherapy.



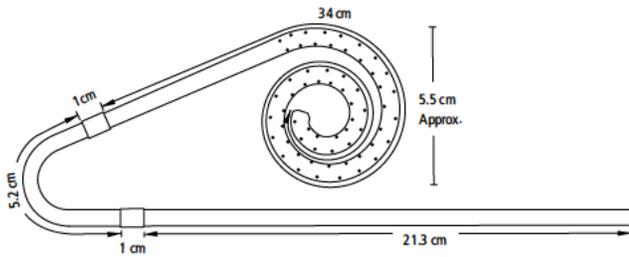
Catheter 8888412007 Swan Neck Tenckhoff Catheter, 2 Cuffs, Left, 43 cm 1/case

SWAN NECK PERITONEAL CATHETERS

Swan Neck Curl Cath Catheters

Swan Neck Curl Cath catheter employs the weight of the curl and the preformed bend to prevent internal catheter migration. The outside portion of the catheter is positioned downward, preventing cellular debris from collecting at the exit site.

Indicated for patients who have problems with catheter migration and inflow discomfort.

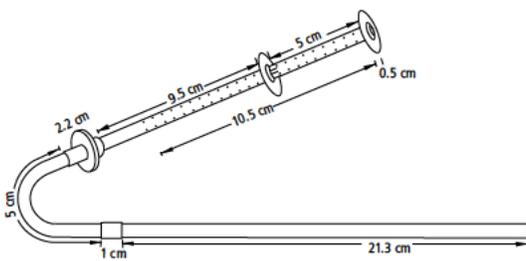


Catheter	8888413807	Swan Neck Curl Cath Catheter, 2 Cuffs, Left, 62.5 cm	1/case
Kit	8888413823	Swan Neck Curl Cath Catheter Kit, 2 Cuffs, Left, 62.5 cm	1/case
Catheter	8888413815	Swan Neck Curl Cath Catheter, 2 Cuffs, Right, 62.5 cm	1/case
Kit	8888413831	Swan Neck Curl Cath Catheter Kit, 2 Cuffs, Right, 62.5 cm	1/case

Swan Neck Oreopoulos-Zellerman Catheters

The Swan Neck Oreopoulos-Zellerman (also called Toronto Western) Catheter is available in Tenckhoff and Missouri configurations. These catheters are differentiated from other Swan Neck catheters by the two silicone disks added to the internal catheter segment. These disks are designed to prevent omental wrapping and to keep the catheter placed low in the pelvis.

Indicated for patients who have repeated problems with catheter migration and omental occlusion.



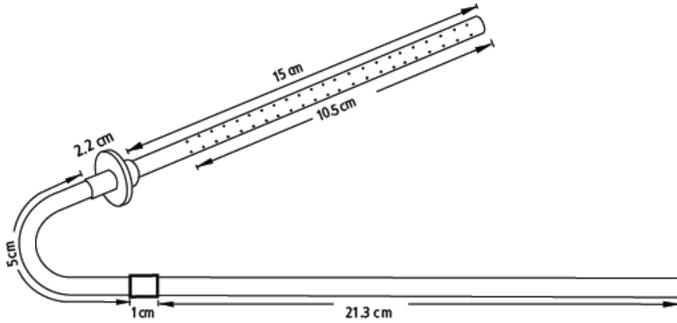
Catheter	8888413005	Swan Neck Oreopoulos-Zellerman Catheter, 2 Cuffs, Left, 44.5 cm	1/case
Catheter	8888413013	Swan Neck Oreopoulos-Zellerman Catheter, 2 Cuffs, Right, 44.5 cm	1/case

SWAN NECK SPECIALTY PERITONEAL CATHETERS (CONTINUED)

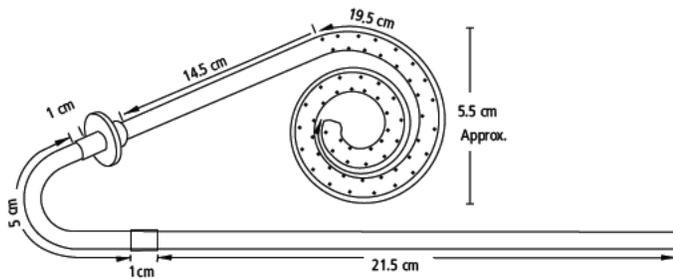
Swan Neck Missouri Catheters

The Swan Neck Missouri Catheter is the same basic design as the Swan Neck Tenckhoff and Curl Cath catheters with the addition of a silicone bead and a felt disk. The bead rests just inside the peritoneum to prevent dialysate leakage. The felt disk is placed just outside the peritoneum and is sutured to the rectus muscle. Fibroblasts grow into the fibers of the felt cuff to anchor the catheter. A second cuff in the subcutaneous tissue is designed to seal the exit site, helping to prevent bacteria from entering into the catheter tract.

Indicated for patients who experience dialysate leakage.

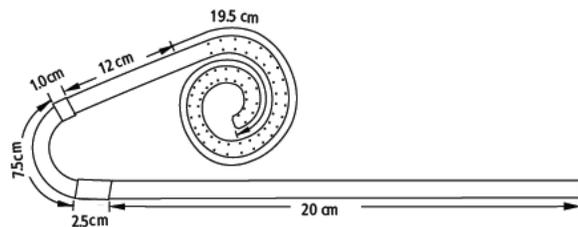


Catheter	8888412601	Swan Neck Missouri Catheter, 2 Cuffs, Left, 44.5 cm	1/case
Catheter	8888412619	Swan Neck Missouri Catheter, 2 Cuffs, Right, 44.5 cm	1/case



Catheter	8888413401	Swan Neck Curl Cath Missouri Catheter, 2 Cuffs, Left, 62.5 cm	1/case
Catheter	8888413419	Swan Neck Curl Cath Missouri Catheter, 2 Cuffs, Right, 62.5 cm	1/case

Moncrief-Popovich Swan Neck Curl Cath Catheters



Catheter	8888414029	Moncrief-Popovich Swan Neck Curl Cath Catheter, 2 Cuffs, 62.5 cm	5/case
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SWAN NECK PERITONEAL CATHETERS

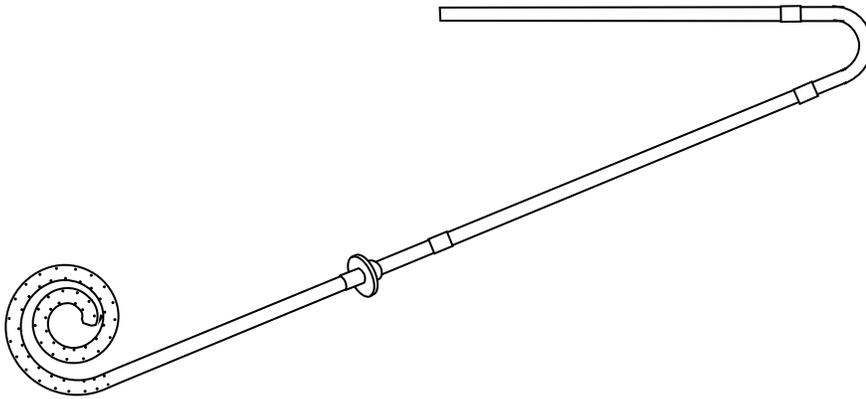
Swan Neck Presternal Catheters

The presteral (upper) segment of this catheter is tunneled into the subcutaneous tissue of the chest wall. The upper segment connects with the intraperitoneal (lower) segment by a double-barbed titanium connector. Both the presteral and intraperitoneal segments can be trimmed to custom fit the patient. The intraperitoneal segment is a variation of the Missouri catheter.

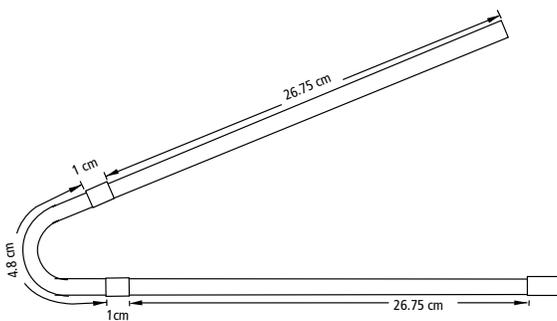
Indicated for:

- Patients with a more active lifestyle. As the exit site is located on the upper chest wall instead of at the belt line, this catheter is ideal for those patients who enjoy wading in a pool or soaking in a tub.
- Obese patients who may have difficulty manipulating a catheter at the belt line.
- Incontinent patients.

Assembled Presternal Catheter



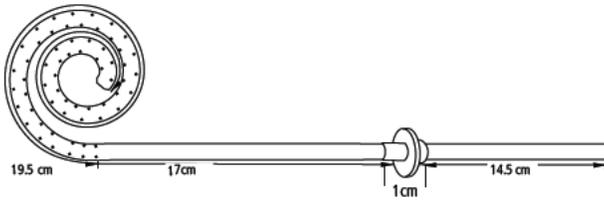
Presternal upper Segment 60.3 cm



SWAN NECK SPECIALTY PERITONEAL CATHETERS (CONTINUED)

Swan Neck Presternal Catheters

Intraperitoneal Lower Segment 52 cm



Catheter	8888414011	Swan Neck Presternal Catheter, 2 Cuffs, 112.3 cm (Swan Neck: 60.3 cm + 52 cm curl)	1/case
Catheter	8888111132	Swan Neck Pre-Sternal 2 Cuff, Curl Cath 1 Cuff, Tray	1/case
Catheter	8888121132	Presternal Peritoneal Dialysis Catheter Kit	5/case

When ordering the Swan Neck presternal catheter kit, also order the following procedural items:

8888412312	Swan Neck Missouri Catheter Stencil, 2 Cuffs, Left/Right	1/case
8888412304	Swan Neck Tenckhoff Catheter Stencil, 2 Cuffs, Left/Right	1/case
8888415679	Faller Tunneling Stylet	1/case
8888415661	Insertion/Straightening Stylet, 61 cm	1/case
8888415604	Titanium Two Part Adapter	1/case

Tunneler sold via Scanlaninternational.com.



CURL CATH **CATHETERS**

Recommended for peritoneal dialysis or intraperitoneal chemotherapy

The Curl Cath catheter, a modified Tenckhoff catheter, is suitable for acute or chronic peritoneal dialysis and intraperitoneal chemotherapy. It can be inserted either percutaneously or surgically.

The additional mass of the Curl Cath catheter keeps it low in the pelvic gutter, resulting in less catheter migration. The catheter's curled tubing and numerous inflow/outflow holes diffuse dialysate gently into the patient.

The Curl Cath catheter is made of translucent, medical-grade silicone rubber with a radiopaque stripe. It has a 4.9 mm OD and a 2.6 mm ID, and is available in adult or pediatric lengths. Unlike polyurethane catheters, the Curl Cath can be extended or repaired if necessary, eliminating the need for costly catheter replacement caused by external damage.

Felt cuffs anchor the catheter subcutaneously and help establish a natural infection barrier through tissue ingrowth. To meet the varying needs of patient and physician, two cuff configurations are offered:

- One attached cuff in the preperitoneal position
- Two attached cuffs, one subcutaneous and one preperitoneal

The Ultem™* adapter included in the packaging provides a tight closure with standard CAPD transfer sets. Titanium adapters are also available.

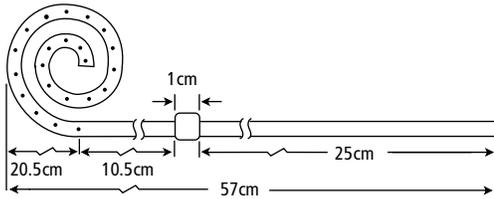
Curl Cath catheters are also available in convenient catheter kits, which provide the necessary components for inserting the catheter by modified Seldinger technique. Each Kit features a 16Fr Pull-Apart Introducer† and Peritoneal Catheter Tunneling Stylet.

†Made with PolyTetra FluoroEthylene (PTFE)

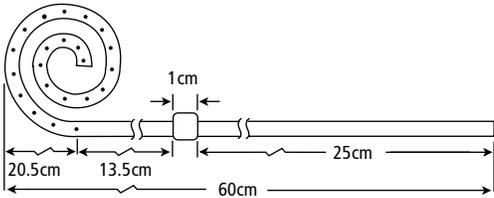
Product highlights include:

- Curled tubing with numerous inflow/outflow holes
- Can be inserted percutaneously or surgically
- Made of translucent, medical-grade silicone rubber
- Radiopaque stripe
- Can be extended or repaired if necessary
- Sterile

Curl Cath Catheters – 1 Cuff



Catheter 8811313014 Curled Catheter, 1 Cuff, 57 cm 1/case

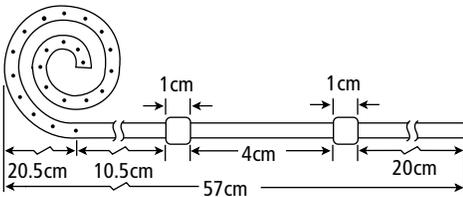


Catheter 8811313013 Curled Catheter, 1 Cuff, 60 cm 1/case

Catheter Kit 8817278010 Curled Catheter, 1 Cuff Kit, 60 cm 5/case

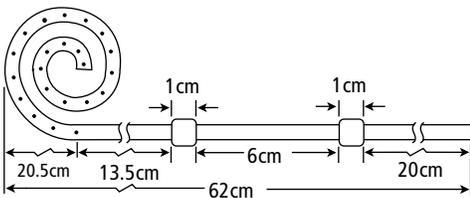
Catheter 8888411710 Curled Catheter, 1 Cuff, 62 cm 1/case

Curl Cath Catheters – 2 Cuffs



Catheter 8811313015 Curled Catheter, 2 Cuffs, 57 cm 1/case

Catheter Kit 8817278007 Curled Catheter, 2 Cuffs Kit, 57 cm 5/case



4 pozicija

Catheter 8811313010 Curled Catheter, 2 Cuffs, 62 cm 1/case

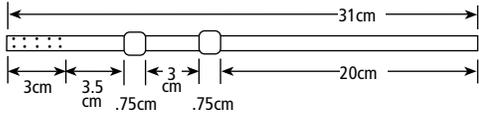
Catheter Kit 8817278006 Curled Catheter, 2 Cuffs Kit, 62 cm 5/case

Catheter 8888411702 Curled Catheter, 2 Cuffs, Curled, 62 cm, Sterile 1/case

PEDIATRIC
PERITONEAL
CATHETERS

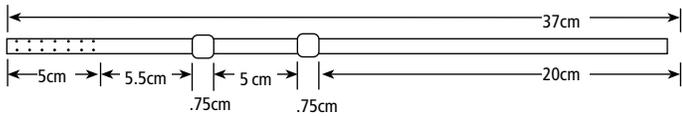
PEDIATRIC PERITONEAL CATHETERS

Pediatric Tenckhoff Catheters



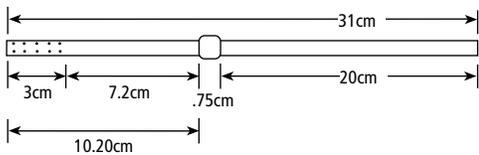
Catheter 8812329002 Pediatric Tenckhoff, 2 Cuffs, 31 cm 1/case

Catheter 8888414227 Infant Tenckhoff, 2 Cuff, 31 cm, Sterile 1/case

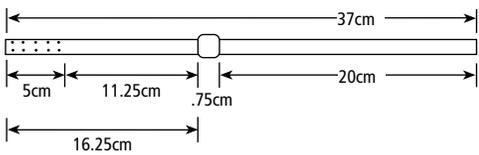


Catheter 8810890003 Pediatric Tenckhoff, 2 Cuffs, 37 cm 1/case

Catheter 8888414201 Pediatric Tenckhoff, 2 Cuff, 30 cm, Sterile 1/case

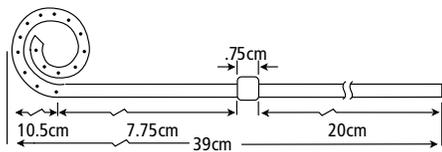


Catheter 8812329001 Pediatric Tenckhoff, 1 Subcutaneous Cuff, 31 cm 1/case



Catheter 8812321001 Pediatric Tenckhoff, 1 Subcutaneous Cuff, 37 cm 1/case

Pediatric Tenckhoff Curl Cath Catheter



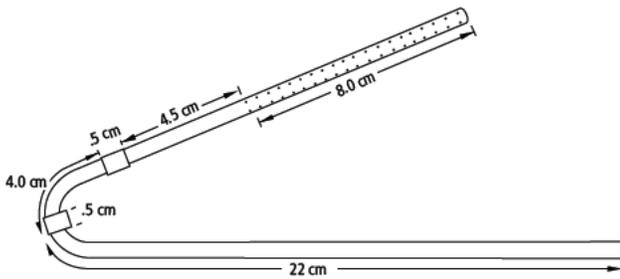
Catheter 8815677001 Pediatric Curl Cath Catheter, 1 Cuff, 39 cm 1/case

Catheter 8888417022 Pediatric Tenckhoff Curl Cath Catheter, 1 Cuff, 39 cm 1/case

PEDIATRIC PERITONEAL CATHETERS

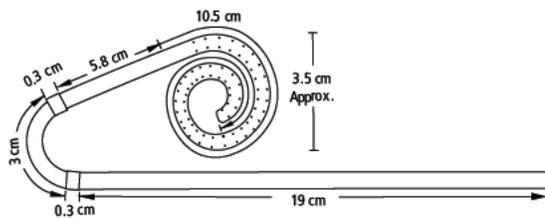
PEDIATRIC PERITONEAL CATHETERS (CONTINUED)

Pediatric Swan Neck Tenckhoff Catheter

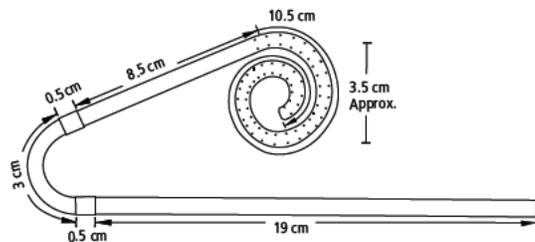


Catheter 8888410506 Pediatric Swan Neck Tenckhoff Catheter, 2 Cuffs, Left, 37.5 cm 1/case

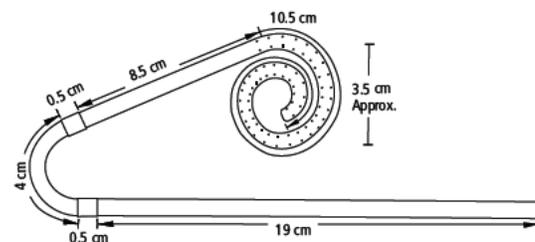
Pediatric Swan Neck Curl Cath Catheters



Catheter 8888413100 Infant Swan Neck Curl Cath Catheter, 2 Cuffs, 38.9 cm (Warady) 1/case



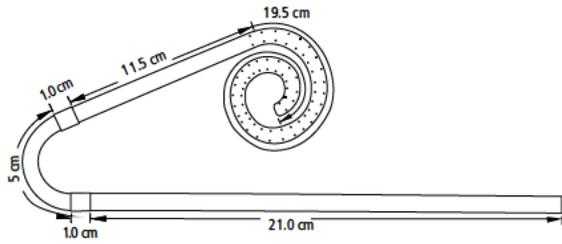
Catheter 8888414813 Pediatric Swan Neck Curl Cath Catheter, 2 Cuffs, Left, 42 cm 1/case



Catheter 8888413101 Pediatric Swan Neck Curl Cath Catheter, 2 Cuffs, 43 cm (Warady) 1/case

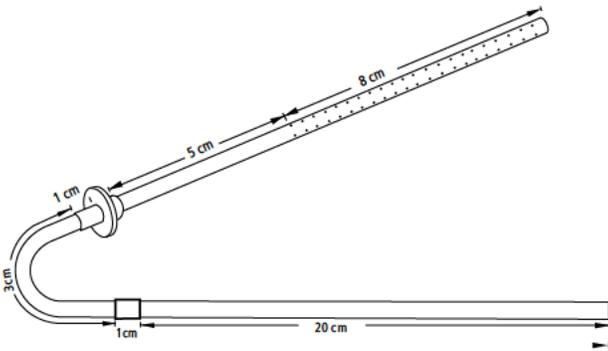
Catheter 8888414508 Pediatric, Tenckhoff, 1 Cuff, 34.25 cm 1/case

PEDIATRIC PERITONEAL CATHETERS



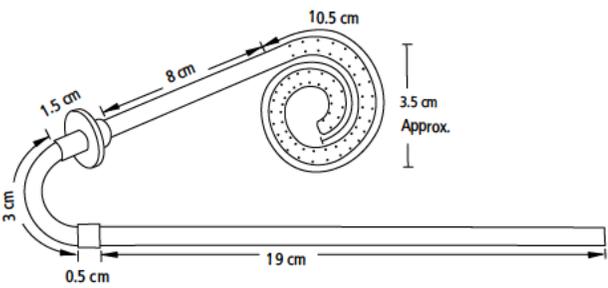
Catheter 8888413102 Adolescent Swan Neck Curl Cath Catheter, 2 Cuffs, 59 cm (Warady) 1/case

Pediatric Swan Neck Missouri Catheter



Catheter 8888412643 Pediatric Swan Neck Missouri Catheter, 2 Cuffs, Left, 38 cm 1/case

Pediatric Swan Neck Curl Cath Missouri Catheter



Catheter 8888415307 Pediatric Swan Neck Curl Cath Missouri Catheter, 2 Cuffs, Left, 42 cm 1/case

ACCESSORIES:
**PERITONEAL
CATHETERS**

ACCESSORIES — PERITONEAL CATHETERS

Peritoneal Catheter Straightening Stylet

Straightening stylets help keep the catheter straight for maneuvering during insertion into the peritoneum. Stylets come in a variety of sizes and can be used on all catheter types. Nonsterile. Autoclavable.

8888415646 Insertion/Straightening Stylet, 44.5 cm, for use with catheters 44.5 cm or shorter 1/case

8888415661 Insertion/Straightening Stylet, 61 cm, for use with catheters 61 cm or shorter 1/case

Atraumatic Peritoneal Tunneling Stylet

This atraumatic tunneling stylet penetrates tissue cleanly, creating a subcutaneous tunnel with minimal bleeding and tissue trauma. As the stylet dilates the tissue, the practitioner simultaneously pulls the catheter through the tunnel. Made of pliable stainless steel, it can be bent to create a customized, curved tunnel. The stylet is 5Fr X 23 cm (9"). Sterile. Single use only.

8817791001 Atraumatic Peritoneal Tunneling Stylet 5/case

Faller Tunneling Stylet

This stylet is an alternative to the atraumatic tunneling stylet. It has a cutting edge on the portion leading into the tunnel and a barbed portion on the opposite end, which connects to the catheter. Sterile.

8888415679 Faller Tunneling Stylet 1/case

Catheter Stencils

These stencils are used to provide a clear outline for the Swan Neck or Swan Neck Missouri catheters before implantation. Details include proper position on the abdominal wall and position of the silicone bead (Missouri) and also include two choices of exit sites so the physician can select the exit site most appropriate for each patient. Each stencil can be turned over to select left- or right-sided placement. Nonsterile.

8888412304 Swan Neck Tenckhoff Catheter Stencil, 2 Cuffs, Left/Right 1/case

8888412312 Swan Neck Missouri Catheter Stencil, 2 Cuffs, Left/Right 1/case

Titanium Adapter

An alternative to the Beta-Cap™ Adapter. Can be used on all Argyle™ peritoneal catheters. Sterile.

8888415604 Titanium Two Part Adapter 1/case

Scanlan™ Tunneler

Sold by Scanlaninternational.com.

Medical Grade Silicone Adhesive

This sterile adhesive is used to:

- Bond felt cuffs to the catheter
- Repair damaged catheters
- Extend the length of existing catheters

8810807001 Medical Grade Silicone Adhesive‡ 1/case

‡Must be ordered separately for any of the above uses.

ACCESSORIES — PERITONEAL CATHETERS (CONTINUED)

Injection Sealing Caps

Used to close off the end of any Argyle™ Catheter. Universal luer fitting. Sterile. Latex-free.

8813791001 Injection Sealing Cap 50/case

Beta-Cap™ Adapter

These adapters form a tight closure with standard CAPD transfer sets, or connect to a sealing cap. The Beta-Cap™ adapter is made of Ultem™ resin. Can be used with all Argyle™ Peritoneal Catheters. Sterile.

8814661001 Beta-Cap™ Adapter 25/case

Beta-Cap™ Clamp

Used to clamp the peritoneal catheter tubing when not in use. Sterile.

8810805001 Beta-Cap™ Clamp 25/case

Catheter Extender

Provides 6 inches of silicone tubing with a titanium connector. Not attached. Sterile.

8888415612 Adult Titanium Catheter Extender 1/case

Peri-Patch™ Repair Kit

Use an Argyle™ Peritoneal Catheter Repair Kit to replace the external portion of a damaged catheter and eliminate the need for catheter replacement. All components are sterile. Kits are double packaged; the inner package can be placed directly on a sterile field.

NOTE: To repair an indwelling catheter, there must be at least 3 cm undamaged tubing at the exit site.

8888285001 Peri-Patch™ Repair Kit 1/case

NOTE: Also order glue using code # **8810807001**

Sterile contents include:

- 1 15 cm Silicone Rubber Catheter Extension (2.6 mm ID, 4.9 mm OD) with Double-Barbed Connector
- 1 Beta-Cap™ Adapter, Cap and Clamp
- 1 Glue Mold

Introducer Set

Introducer sets are used when placing peritoneal catheters percutaneously.

8815544010 16Fr Pull-Apart Introducer Set 5/case

Sterile contents include:

- 1 16Fr Pull-Apart Sheath†/Dilator
- 1 18 ga Introducer Needle
- 1 12 mL Syringe
- 1 J/Straight 0.038" Guide Wire

†Made with PolyTetra FluoroEthylene (PTFE)



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15 Hampshire Street
Mansfield, MA 02048

800.962.9888
508.261.8000

[medtronic.com/covidien](https://www.medtronic.com/covidien)

Medtronic



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 003280 0006 Rev. 01

Manufacturer: **Covidien Ilc**
15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies): Hemodialysis / Peritoneal / Central Venous / PTA Balloon Catheters and Related Accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10032800006Rev.01

Report No.: ITA1527293

Valid from: 2021-01-29

Valid until: 2024-05-26

Date, 2021-01-29





**Add value.
Inspire trust.**

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

Covidien LLC
15 Hampshire Street
02048 MANSFIELD
USA

Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
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**TÜV SÜD Product Service GmbH
Confirmation Letter**

CL 003280 0026 Rev. 00

Reference: 713234292 | GA713217822

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: US-MF-000028763

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification Body for Medical Devices
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747





If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL_003280_0026_Rev._00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-23

Conformity Assessment Responsible (CARE)

Application Reviewer



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p>Ritus™ Peritoneal Dialysis Catheters 0763000B00008618A</p> <p>8810887003 8810888003 8810888012 8810889003 8811313009 8811313010 8811313013 8811313014 8811313015 8814843001 8814843002 8817278001 8817278006 8817278007 8817278008 8817278010 8888111132 8888121132 8888411009 8888411405 8888411421 8888411447 8888411702 8888411710 8888412007 8888412015 8888412601 8888412619 8888413005 8888413013 8888413401 8888413419 8888413807 8888413815 8888413823 8888413831 8888414011 8888414029</p>	<p><input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 003280 0006 Rev. 01; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
8888422170 8888423103 8888425702 8888425710 8888425728 8888425744			
Ritus™ Peritoneal Dialysis Catheters (Neonatal, Infant, Adolescent, Pediatric) 0763000B00008618A 8810890003 8810890014 8812321001 8812329001 8812329002 8815677001 8888410506 8888413100 8888413101 8888413102 8888414201 8888414219 8888414227 8888414235 8888414508 8888414813 8888415307 8888423111 8888425785	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 003280 0006 Rev. 01; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-23	713234292 GA713217822	Initial issue

Declaration of Conformity (DoC)

Manufacturer:	Covidien llc 15 Hampshire Street Mansfield, MA 02048 USA
Authorized Representative:	Covidien Ireland Limited IDA Business and Technology Park Tullamore, Ireland
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
Conformity Assessment Certificate(s):	G1 003280 0006 Rev. 01 expires 31-December-2028
Conformity Assessment Route:	Directive 93/42/ECC on Medical Devices (MDD), Annex II excluding (4)
Risk Class:	Refer to products listed in the table below
Classification rule:	Refer to products listed in the table below
Standard List:	Located in the Essential Requirements Checklist
Intended purpose:	Peritoneal Dialysis Catheters are intended for acute and chronic peritoneal dialysis treatment.

Statement:

I, the undersigned declare that the Medical Device(s) specified [above/below/in Appendix X](#) comply with Article 120 of the Regulation (EU) 2017/745 as amended by Regulation (EU) 2023/607 and 93/42/EEC (MDD) or 90/385/EEC (AIMD). This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of 93/42/EEC (MDD) or 90/385/EEC (AIMD), and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607.

The validity of the certificate listed on this DoC is valid through [31 December 2028](#).

Peritoneal Dialysis Catheters: Declaration of Conformity

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We, Covidien llc, declare under our sole responsibility that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, and the Essential Principles and classification rules according to Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

Each kind of medical device which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules at each stage, from the design of the device until its final inspection before being supplied, in accordance with clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

If this Declaration of Conformity contains Class I, non-sterile, non-measurement devices, it is noted that they are not regulated by TÜV SÜD P.S and follow conformity assessment procedures set out in Annex VII, in accordance with clause 6.6 of Schedule 3 Australian Therapeutic Goods (Medical Devices) Regulation 2002.

Place: Mansfield, MA USA

Name:



Title: Regulatory Affairs Manager

Signature:



Date: 30 October 2024

Peritoneal Dialysis Catheters: Declaration of Conformity

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Products Covered

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8810887003	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Loose Cuffs 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810888003	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810888012	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Universal Tenckhoff, 2 Cuff 47 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810890003	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 37 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810890014	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 32 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8811313009	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Loose Cuffs 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8811313010	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8811313013	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 1 Preperitoneal Cuff 60 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8811313014	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 1 Preperitoneal Cuff 57 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

Peritoneal Dialysis Catheters: Declaration of Conformity

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CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8811313015	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 57 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8812321001	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Tenckhoff, 1 Subcutaneous Cuff 37 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8812329001	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 1 Subcutaneous Cuff 31 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8812329002	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 31 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8814843001	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 1 Preperitoneal Cuff 41 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8814843002	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Universal Tenckhoff, 1 Preperitoneal Cuff 46 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8815677001	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Curl Cath, 1 Preperitoneal Cuff 39 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8817278001	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Universal Tenckhoff, 1 Preperitoneal Cuff 46 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

Peritoneal Dialysis Catheters: Declaration of Conformity

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CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8817278006	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Curl Cath, 2 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8817278007	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Curl Cath, 2 Cuff 57cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8817278008	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Tenckhoff, 2 Cuff 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8817278010	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Curl Cath, 1 Preperitoneal Cuff 60 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888111132	Argyle™ (or Ritus™) Presternal Peritoneal Dialysis Catheter Tray, Swan Neck, Curl Cath, 1 Cuff, 122.3 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	6/12/2014
8888121132	Argyle™ (or Ritus™) Presternal Peritoneal Dialysis Catheter Kit, Swan Neck, Curl Cath, 1 Cuff, 122.3 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	6/12/2014
8888410506	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Swan Neck Tenckhoff, 2 Cuff Left 37.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411009	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, Missouri Oreopoulos-Zellerman 2 Cuff, 2 Disk, 1 Bead, 41 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411405	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Cuffs 41 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

Peritoneal Dialysis Catheters: Declaration of Conformity

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CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8888411421	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 1 Cuff 47 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411447	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 47 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411702	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411710	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 1 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888412007	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Tenckhoff, 2 Cuff Left 43 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888412015	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck 2 Cuff Right 43 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888412601	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri, 2 Cuff Left 44.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888412619	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri, 2 Cuff Right 44.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413005	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Oreopolulos-Zellerman, 2 Cuff Left 44.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

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8888413013	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Oreopolulos-Zellerman, 2 Cuff Right 44.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413100	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff 38.9 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413101	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff 43 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413102	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff 59 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413401	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri Curl Cath, 2 Cuff Left 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413419	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri Curl Cath, 2 Cuff Right 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413807	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff Left 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413815	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff Right 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

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8888413823	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Swan Neck Curl Cath, 2 Cuff Left 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413831	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Swan Neck Curl Cath, 2 Cuff Right 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414011	Argyle™ (or Ritus™) Presternal Peritoneal Dialysis Catheter Swan Neck Missouri 112.8 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414029	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Moncrief-Popovich Swan Neck Curl Cath, 2 Cuff 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414201	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 30 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414219	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff 1 Cuff 30 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414227	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 31 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414235	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff 1 Cuff 31 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414508	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Curl Cath, 1 Cuff 39.25 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

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8888414813	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff Left 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888415307	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri Curl Cath, 2 Cuff Left 42.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888422170	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888423103	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 41 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888423111	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 2 Cuffs 30 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888425702	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Oreopoulos-Zellerman Curl Cath, 1 Cuff, 1 Bubble 63 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888425710	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Oreopoulos-Zellerman Curl Cath, 2 Cuff, 1 Bubble 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888425728	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck, Tenckhoff, Special Left 20 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888425744	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Teckhoff, Left, 2 Cuffs, 53 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

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8888425785	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Curl Cath, 2 Loose Cuffs 39.25 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810889003	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 1 Subcutaneous Cuff 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998