CODMAN NEURO

DePuy Synthes

CODMAN® Pump Catheter (REF 60-2914US) For MedStream™ Pump

US DIST

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350 USA
☎ 800 225 0460
☎ +1 508 828 3000

24-Hour Technical Assistance:
☎ 800 660 2660

LCN 205788-001/E

♻ Revised 04/15

ENGLISH

IMPORTANT INFORMATION
Please Read Before Use

CODMAN® Pump Catheter (REF 60-2914US) for MedStream™ Pumps

STERILE	EO

℞ Only

Refer to the user's manual provided with the MedStream Pump for additional information.

Indications
The CODMAN Pump Catheter is indicated for use as part of an infusion system using a MedStream Programmable Pump.

Contraindications
Active or incompletely treated infection.

WARNINGS
The use of non-Codman accessories with the pump catheter can result in damage to the catheter or failure of the system to function as intended.

Improper use of implanted infusion pumps could result in drug under- or overdose. Users must comply with the product instructions for initial pump preparation, implantation, initial filling, refilling, and injecting into the bolus port of the pump. **Only qualified medical personnel must perform these tasks.**

Before closing the incisions, verify that the central port and bolus port of the implanted pump can be palpated, that the catheter(s) will not become twisted or contorted, and that the catheter(s) will not obstruct the central port or the bolus port.

Do not inject into the pump catheter; a drug under- or overdose or damage to the catheter can result.

Precautions

Inspect the sterile package carefully. Do not use if:

- the package or seal appears damaged;
- the contents appear damaged; or
- the expiry date has passed.

The pump catheter is for **single use only. Do not reuse.**

Use sterile technique in all phases of handling this product.

Exercise extreme care to prevent the silicone catheter(s) from coming in contact with towels, drapes, talc, or any linty or granular surfaces. Silicone is highly electrostatic and as a result, attracts airborne particles and surface contaminants that could produce tissue reactions.

Silicone has a low cut and tear resistance; therefore, do not tie ligatures too tightly on the strain relief sleeves or the connectors. Do not use stainless steel or chromium ligatures. Use only No. 0 silk suture for securing the catheters.

Do not handle catheters with sharp instruments. Use rubber shod forceps when handling catheters. Take care not to inadvertently cut or puncture catheters.

Make sure that catheter placement and connections are secure. Failure to adequately connect and secure catheters in place can result in:

- dislodgment or disconnection of the catheter;
- obstruction of the central port or bolus port;
- cessation of therapy; or
- delivery of drug to the pump pocket or the subcutaneous tissue.

Record the discarded length for each catheter implanted. The control unit requires this information for calculating the volume of the implanted catheter. There is no substitute for this information.

Trim catheters only after placement. When trimming catheters, leave an extra amount to help ensure that no tension is placed on the catheters when the patient moves.

During implantation, verify that catheter(s) will not become kinked or occluded due to knots, tight geometries, or a tortuous position. To prevent dislodgment or kinking, always use an anchor to secure the intraspinal catheter to the surrounding tissue.

Pass each catheter before connecting whenever possible. If passing a catheter that is already connected or implanted, ensure that the direction of tunneling and passing the catheter leads away from the site of connection or implantation.

Use only No. 0 silk suture for securing catheters and connectors. Smaller diameter suture and stainless steel suture may cut or tear silicone catheters.

Adverse Events

Catheter performance problems, such as kinking, disconnection, leakage, breakage, occlusion (complete or partial), dislodgment, migration, formation of fibrosis, hygroma, or granuloma can cause:

- delivery of the drug to an inappropriate site, such as the pump pocket or subcutaneous tissue
- drug withdrawal symptoms
- underinfusion of the drug
- a return of underlying symptoms
- free-floating catheter in the cerebrospinal fluid (CSF)
- CSF leakage, subcutaneous collection of CSF, or central nervous system (CNS) pressure changes
- damage to the spinal cord
- hemorrhage
- the need for surgical replacement of the catheter
- organ failure
- stroke
- death

Product Description

The CODMAN Pump Catheter is designed only for use in a system that includes a MedStream Pump. The pump catheter provides the pathway from the pump to the intraspinal catheter. The pump connector end of the pump catheter fits onto the outlet of the pump.

The pump catheter is made of medical-grade silicone elastomer impregnated with barium sulfate. **Note:** Although the catheter is X-ray detectable, on X-ray a gap of 1–2 mm appears between the catheter and the pump body. This gap does not represent a faulty connection. The catheter dimensions are as follows:

Inner diameter:	0.6 mm
Outer diameter:	2.4 mm
Length:	100 cm
Volume:	0. 283 mL (0.00283 mL per cm)

The pump catheter is compatible with the following intraspinal catheters and connectors:

Silicone Catheter System	
Intraspinal Catheter	**Replacement Connector**
CODMAN® Intraspinal Catheter (REF 60-2918US)	CODMAN Intraspinal Catheter Connector with Strain Relief Sleeve (REF 60-2950US)
Titanium-reinforced Catheter System	
Intraspinal Catheter	**Replacement Connector**
SureStream™ Intraspinal Catheter (REF 70020US)	SureStream Intraspinal Catheter Connector with Strain Relief Sleeve (REF 70029US)

How Supplied

This product is intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Codman & Shurtleff will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

As long as the inner unit is not opened or damaged, the product is sterile and nonpyrogenic.

Instructions for Use

A. Attaching the pump catheter to the pump before implantation

Refer to the MedStream Infusion System IFU and to the MedStream Infusion System Programming Guide to perform the pump preparation and implantation steps.

Refer to the instructions provided with the intraspinal catheter to implant it and join it with the pump catheter.

1. Gently push the pump connector end of the catheter onto the pump outlet with a twisting motion.
2. Make sure the groove of the connector is completely seated in the groove of the pump outlet.
3. Use No. 0 silk suture material to tie the catheter securely to the pump outlet. The suture must lie in the groove of the connector. See Figure 1.
4. Trim the pump catheter as appropriate. Record the amount of pump catheter removed.
5. Follow the instructions packaged with the intraspinal catheter kit to join the two catheters.

B. Replacing an implanted pump catheter

Required materials:

- MedStream Control Unit
- MedStream Bolus Kit (REF 91-4284US)
- No. 0 silk suture

- 10 mL preservative-free sterile 0.9% saline solution
- Appropriate replacement catheter connector:
  CODMAN Intraspinal Catheter Connector with Strain Relief Sleeve (REF 60-2950US)
  -- OR –
  SureStream Intraspinal Catheter Connector with Strain Relief Sleeve (REF 70029US)

1. Use the MedStream Control Unit to interrogate the MedStream pump and scroll to the catheter information section (refer to the MedStream Infusion System Programming Guide for more information). Make note of the "Total Catheter Volume" of the current catheters.
2. **IMPORTANT: Referring to the instructions provided with the bolus kit, use the bolus needle to aspirate the contents of the catheters.**
3. Take steps to minimize leakage of CSF. Cut the intraspinal catheter just distal to the catheter connector. Record the length of intraspinal catheter removed.
4. Remove and discard the old pump catheter.
5. Gently push the pump connector end of the new pump catheter onto the pump outlet with a twisting motion.
6. Make sure the groove of the connector is completely seated in the groove of the pump outlet.
7. Use No. 0 silk suture material to tie the catheter securely to the pump outlet. The suture must lie in the groove of the connector. See Figure 1.
8. To test patency of the catheter and connection and to prime the pump catheter, administer a 5 mL bolus injection of saline through the bolus port. Refer to the instructions for administering a bolus in the instructions provided with the bolus kit. Resistance may be a sign of occlusion; take appropriate measures. Inspect the pump connection for signs of leakage.

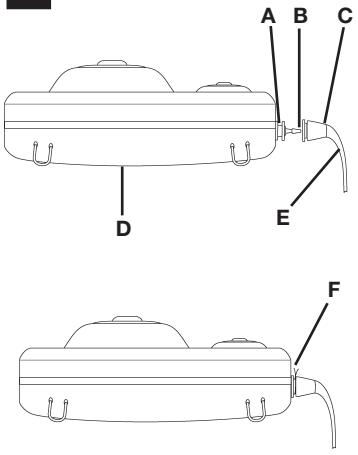
9. Trim the pump catheter as appropriate. Use the appropriate catheter connector and strain relief sleeve to join the pump catheter to the intraspinal catheter. Follow the instructions packaged with the catheter connector. Record the amount of pump catheter removed.
10. Administer another 5 mL bolus injection of saline to test the connection of the catheters. Resistance may be a sign of occlusion; take appropriate measures. Inspect the connection of the catheters for signs of leakage.
11. Use the Control Unit to update the catheter length information. Refer to the Programming Guide for additional information.

WARNING: This procedure results in the catheters being filled with saline solution. Intraspinal delivery of the drug solution from the drug reservoir will be delayed until the saline solution exits the intraspinal catheter.

Warranty

Codman & Shurtleff, Inc. warrants that this medical device is free from defects in both materials and workmanship. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.**

1



A. Pump outlet
B. Connector groove
C. Catheter connector
D. MedStream pump
E. Catheter
F. Ligature

US REP **US Representative**

Do not resterilize

Do not use if package is damaged

℞ Only **Prescription device only (USA)**

Manufacturer

US DIST **Distributed in the USA by**

MADE IN **Made in**

NONPYROGENIC **Nonpyrogenic**

QTY **Quantity**

*

Codman Neuro Sciences Sàrl
Rue Girardet 29
CH 2400 Le Locle, Switzerland
☎ +41 32 934 80 00

*

Medos International SÀRL
Chemin-Blanc 38, 2400
Le Locle, Switzerland

*For recognized manufacturer, refer to product label