

Codman

**SureStream™ Intraspinal Catheter Kit  
(Catalog No. 70020US)  
For Use with CODMAN® 3000 Series  
and MedStream™ Implantable Pumps**



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# ENGLISH

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## IMPORTANT INFORMATION

Please Read Before Use

### SureStream™ Intraspinal Catheter Kit (REF 70020US) For Use with CODMAN® 3000 Series and MedStream™ Implantable Pumps

STERILE | EO

 Rx Only

#### Introduction

The SureStream Intraspinal Catheter Kit is an implantable catheter system that is designed to be connected to the outlet catheter of the CODMAN 3000 Series Implantable Pumps, or to the pump catheter connected to a MedStream Programmable Infusion Pump.

#### Indications

Use of the SureStream Intraspinal Catheter Kit and the implantable pump are indicated whenever patient therapy requires continuous intraspinal infusion of fluids.

#### Contraindications

- Known or suspected infections, such as bacteremia, septicemia, or peritonitis
- Allergic reaction or other signs of intolerance to implanted devices
- Spinal anomalies that might complicate the implantation and fixation of an intraspinal catheter

#### WARNINGS

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

After rinsing the bolus pathway or the drug reservoir, intraspinal delivery of the new drug solution from the reservoir will be delayed until the solution traverses the total catheter length. Carefully calculate the amount of the delay, based on the flow rate and the total volume contained in the bolus pathway and catheters before administering additional medication by another delivery method.

## Precautions

Thoroughly read these instructions for use and the pump instructions for use before using this device.

Inspect the sterile package carefully. Do not use if:

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

This device is **for single use only. Do not reuse.**

Use sterile technique in all phases of handling this product.

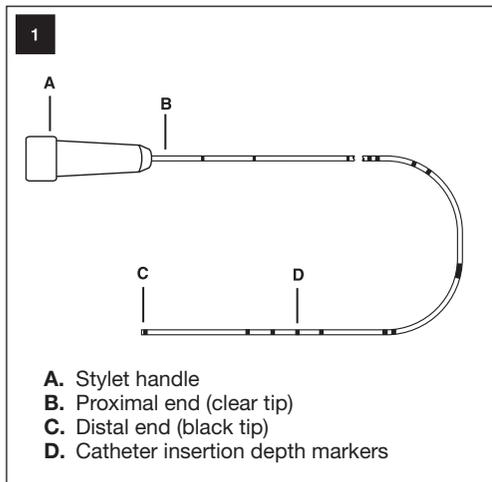
Use only the Tuohy needles provided in this kit with the SureStream Catheter. These needles have been designed specifically for use with the catheter.

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 pump septum
- cessation of therapy
- delivery of drug to the pump pocket or the subcutaneous tissue

## Product Description

The SureStream Intraspinal Catheter (Figure 1) is constructed of polyurethane with an internal titanium coil for strength, resistance to kinking, and ease of insertion.



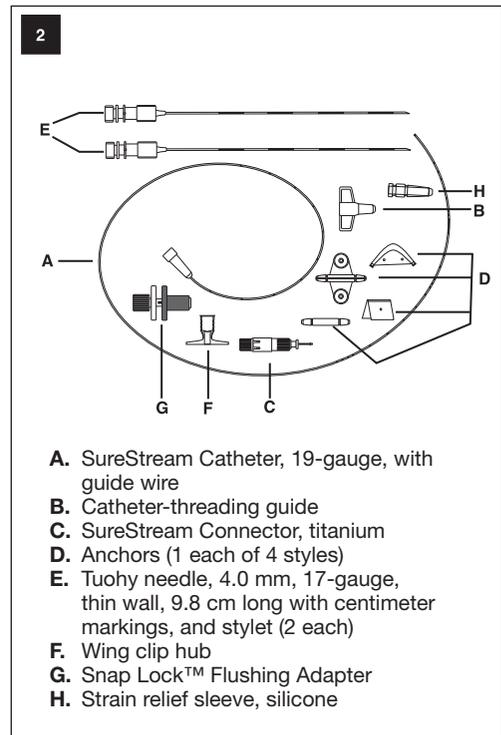
Nominal Catheter Specifications	
Length	105 cm
Inner Diameter	0.5 mm
Outer Diameter	1.0 mm
Volume	0.002 mL/cm

The SureStream Intraspinal Catheter Connector is specifically designed for use joining the SureStream Catheter with the silicone outlet catheter of the CODMAN 3000 Series Pumps or the CODMAN Pump Catheter (REF 60-2914US) that is used with the MedStream Programmable Infusion Pumps.

## How Supplied



Each SureStream Intraspinal Catheter Kit (Figure 2) contains the following:



102 cm TYVEK® ruler (not shown)  
 Patient Data Stickers (not shown)

Replacement SureStream Intraspinal Catheter Connectors are also available. Contact your local Codman sales representative or Codman Customer Service for ordering information.

Catalog No.	Description
70029US	SureStream Intraspinal Catheter Connector with Strain Relief Sleeve

### Sterility

This product is for SINGLE USE ONLY; DO NOT RESTERILIZE. Codman Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminants such as Creutzfeldt-Jakob Disease. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

Codman & Shurtleff will not be responsible for product that is reesterilized, nor accept for credit or exchange product that has been opened but not used.

As long as the inner unit is not opened or damaged, the product is sterile. The following components have been tested and found to be nonpyrogenic:

Catheter with guide wire  
Catheter threading guide  
Connector  
Anchors  
Tuohy needles with stylets  
Snap Lock adapter

### Instructions for Use

The following instructions are intended as guidelines for the implantation and use of the catheter kit for intraspinal cannulation.

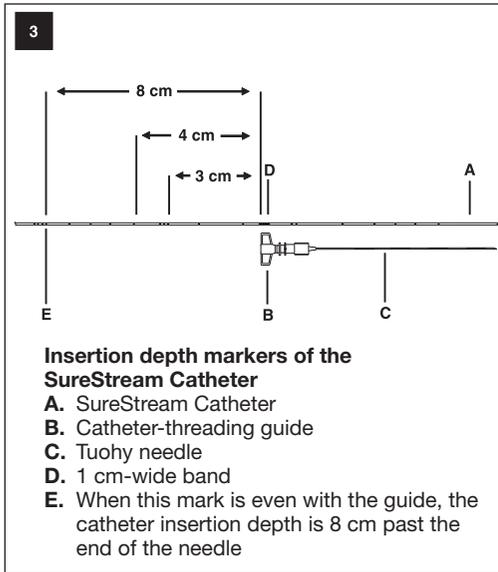
### Placing the Intraspinal Catheter

**CAUTION: Do not handle the SureStream Catheter with sharp or toothed instruments. Polyurethane is easily cut or torn. Use padded hemostats, vascular clamps, or tube-occluding forceps to handle the catheter. Grasp the catheter only at the end that will be trimmed before connection to the pump catheter.**

1. Identify the desired intraspinal space for catheter placement.
2. Make a small longitudinal incision between the spinous processes of the desired intravertebral space. This is done to:
  - a. Introduce the Tuohy needle
  - b. Facilitate anchoring of the catheter to a supporting structure, such as the supraspinous ligament
  - c. Permit introduction of the tunneling instrument.
3. Attach the wing clip hub, if desired, to the Tuohy needle by firmly pushing the wing clip hub onto the hub of the needle.
4. Insert the Tuohy needle with its stylet in place. If the intended catheter location is epidural, use a loss-of-resistance technique. If the intended catheter location is intrathecal, advance the needle until clear CSF flow is encountered.

**WARNING: If paresthesia ensues, remove and redirect the needle to avoid neural injury.**
5. Examine the catheter and preloaded guide wire to ascertain that the guide wire is fully movable within the catheter and that the guide wire hub is in contact with the proximal end of the catheter.

- With the point of the Tuohy needle properly positioned in the desired intraspinal location, remove the stylet from the needle. If desired, insert the catheter-threading guide into the hub of the Tuohy needle. Insert the distal end (black tip) of the catheter with the preloaded guide wire. Advance the catheter to the desired depth in the space. Depth markers are provided on the catheter for guidance during insertion (Figure 3).



- Remove the Tuohy needle by sliding the needle up the catheter towards the proximal end. Apply counterforce on the catheter while sliding the needle over the catheter. When the needle is clear of the insertion site, continue to maintain gentle counterforce on the catheter while removing the needle and the guide wire from the catheter.  
**CAUTION: Always remove the Tuohy needle from the insertion site before removing the catheter guide wire. Withdrawing the catheter guide wire before removing the Tuohy needle can tear or shear the catheter.**

- Test the catheter for patency as follows. Insert the proximal end of the catheter into the Snap Lock flushing adapter until the catheter bottoms out. While maintaining the catheter position, tighten the adapter by squeezing the black collar towards the luer hub until the gap between the pieces is closed. Gently tug the catheter near the adapter to ensure that the connection is secure. Remove the blue cap from the adaptor. Attach a 10 mL syringe with preservative-free saline and gently flush the catheter. Observe the catheter for leakage.
- Using No. 0 silk suture, attach one of the catheter anchors to the catheter and suture it to a supporting structure, such as the supraspinous ligament. Retest the catheter for patency as in Step 8. Remove the 10 mL syringe and place the cap into the flushing adapter, if desired.

**CAUTION: Always use an anchor to secure the catheter to the surrounding tissue. This will help prevent dislodgment of the catheter.**  
**CAUTION: Do not suture the anchor too tightly to avoid cutting or tearing the silicone material of the anchor.**

### Pump Implantation

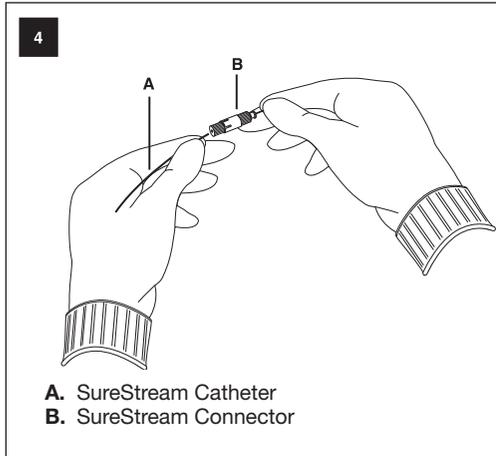
Prepare the pump and implant it into a subcutaneous pocket created for the purpose. Follow the instructions for use provided with the pump.

### Tunneling the Intraspinal Catheter

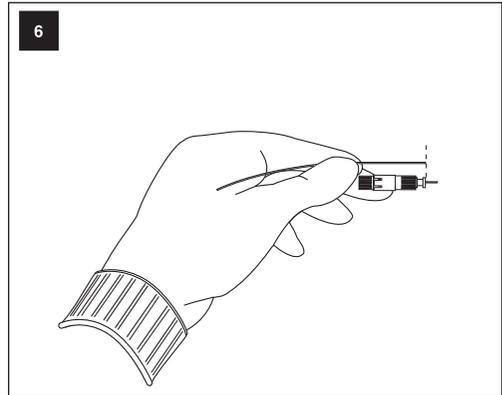
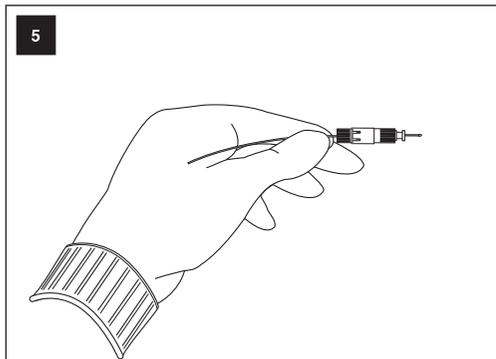
- Insert a tunneling instrument through the pocket wound and advance to the intraspinal catheter exit wound in the back. Attach the catheter to the tunneling instrument and tunnel to the pump pocket.
- Trim the intraspinal catheter to the desired length, making certain to provide sufficient slack in the catheter to allow for body movement; yet without leaving excessive length of catheter in the pump pocket.  
**Note:** When using the SureStream Connector, it is not necessary to trim the intraspinal catheter at a trim marker (dot). Trim at any appropriate point along the catheter length.  
**CAUTION: Trimming the intraspinal catheter a minimum of 10 mm is required to achieve a secure connection with the connector.**

## Connecting the Catheters to the SureStream Connector

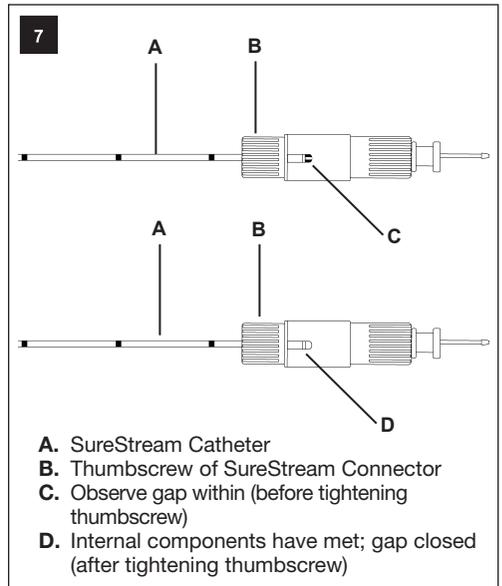
1. Insert the trimmed end of the SureStream Catheter into the opening in the connector thumbscrew until it is bottomed out or cannot be advanced any farther into the connector housing (Figure 4).



**IMPORTANT:** Confirm that the catheter is fully inserted. Hold the catheter at the point where it exits the connector, with fingers against the connector (Figure 5). **Without changing the position of the fingers**, withdraw the catheter and compare the length of catheter to the exterior of the connector as shown in Figure 6. Perform this step again, if necessary, until the length of catheter inserted equals the segment of the connector shown. Reinsert the catheter until fingers contact the connector.

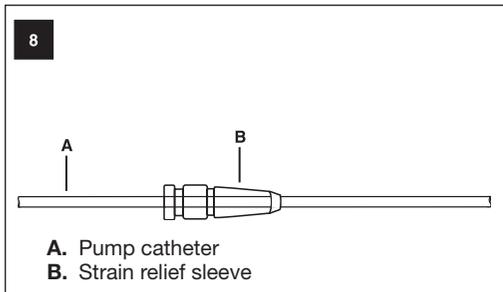


2. Tighten the thumbscrew until it bottoms out against the connector body and there is no visible gap between the thumbscrew internal components (see Figure 7). Use an instrument, such as a Kelly clamp, for tightening, if needed.

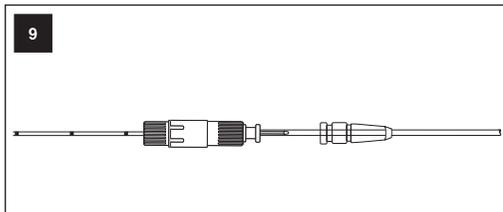


3. Test the security of the connection by gently tugging the SureStream Catheter.
4. If slippage occurs, loosen the thumbscrew and repeat Steps 1 through 3.
5. Trim the outlet catheter/pump catheter to the required length.

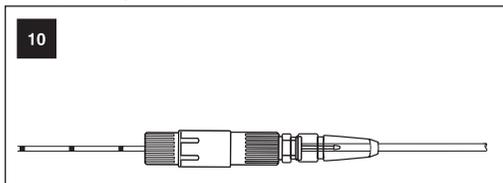
6. Slide the white-ringed (smaller diameter) end of the strain relief sleeve approximately 4 cm onto the outlet catheter/pump catheter (see Figure 8).



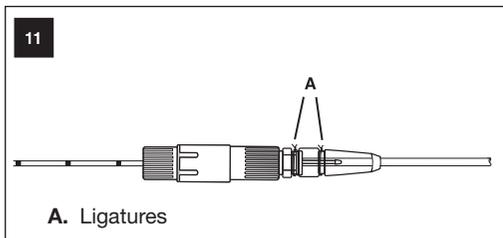
7. Slide the end of the outlet catheter/pump catheter onto the pin connector with a slight twisting motion (see Figure 9).



8. Slide the strain relief sleeve over the pin connector until it contacts the stop (see Figure 10).



9. Secure the strain relief sleeve onto the catheter and the connector by tying 2 ligatures of No. 0 silk suture (see Figure 11).



**CAUTION: Do not tie ligatures too tightly to avoid cutting or tearing the silicone material of the strain relief sleeve.**

10. Test for leaks of the connections and patency of the catheters by administering a bolus injection. Follow the instructions that apply to the implanted pump.

#### 10.1 CODMAN 3000 Series Pumps

Using a 10 mL syringe of preservative-free sterile saline and the Special Bolus Needle (REF AP-04013) enter the pump septum and slowly inject 3 mL of fluid through the system and observe for any leakage. **Refer to the instructions for use that accompany the CODMAN 3000 Pump for more detail on the bolus procedure.**

**CAUTION: Use only the Special Bolus Needle (REF AP-04013) that is appropriate for the CODMAN 3000 Pump.**

#### 10.2 MedStream Pump

Using the MedStream Bolus Kit (REF 91-4284US), and a 10 mL syringe filled with preservative-free sterile saline, enter the bolus septum and slowly inject 5 mL of fluid through the system and observe for any leakage. **Refer to the instructions for use that accompany the bolus kit for more detail on the bolus procedure. (Note: If implanting the catheter with a new MedStream Pump, use the bolus needle and other components packaged with the pump.)**

**CAUTION: Use only the bolus needle that is appropriate for the MedStream Pump.**

#### Calculating the Catheter Volume – MedStream Pump

**CAUTION: It is important to note the total catheter length in the patient's record. The total implanted catheter length is used to calculate the volume of a bridge bolus and the duration of a single bolus.**

Refer to the MedStream Infusion System Programming Guide for using the MedStream Control Unit after the surgery to compute the catheter volume.

## Calculating the Catheter Volume — CODMAN 3000 Series Pumps

**CAUTION:** It is important to note the total implanted catheter length, the catheter inner diameter, and the catheter volume per centimeter in the patient's record. This information is used to calculate the time required for drug to advance to the catheter tip, as well as to help prevent a drug overdose when injecting a bolus into the pump.

- Determine volume of SureStream Intraspinal Catheter:  
Multiply the length of implanted segment by 0.002 mL/cm = \_\_\_\_ mL
- Determine volume of pump catheter:  
multiply the length of implanted segment by 0.003 mL/cm = \_\_\_\_ mL
- Enter bolus pathway volume of pump (choose one from below)

**Check one:**

Pump Model	Bolus Pathway Volume
<input type="checkbox"/> CODMAN 3000-16 (16 mL)	0.2 mL
<input type="checkbox"/> CODMAN 3000-30 (30 mL)	0.3 mL
<input type="checkbox"/> CODMAN 3000-50 (50 mL)	0.4 mL = ____ mL

- Add 1, 2 and 3 above  
TOTAL BOLUS PATHWAY  
AND CATHETER VOLUME = \_\_\_\_ mL

**Note: Patient Data Stickers are provided for your records.**

## Wound Closure

Close and dress the back and the pump pocket wounds per desired routines.

## Technical Assistance

For 24-hour technical assistance, please contact us by telephone:

(800) 660-2660

## 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.**

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® CODMAN is a registered trademark of Codman & Shurtleff, Inc.

<sup>TM</sup> MedStream is a trademark of Codman & Shurtleff, Inc.

<sup>TM</sup> Snap Lock is a trademark of Arrow International, Inc., used under license

® TYVEK is a registered trademark of E.I. du Pont de Nemours and Company

**DO NOT RESTERILIZE** 

**Do not resterilize**



**Do not use if package is damaged**



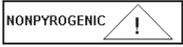
**Prescription device only (USA)**



**Manufacturer**

**MADE IN**

**Made in**



**Nonpyrogenic, see instructions for use**



**PVC Free**

**LATEX FREE**

**Latex free**

**QTY**

**Quantity**