CODMAN NEURO

DePuy Synthes

CODMAN® Intraspinal Catheter Kit (REF 60-2918US) For CODMAN® 3000 Series and MedStream™ Pumps

US DIST

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ENGLISH

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IMPORTANT INFORMATION
Please Read Before Use

CODMAN® Intraspinal Catheter Kit (REF 60-2918US) for CODMAN® 3000 Series and MedStream™ Pumps

STERILE	EO

℞ Only

For additional information, refer to the user manual packaged with the CODMAN 3000 Series Pump or the MedStream Programmable Infusion System.

Indications
The CODMAN Intraspinal Catheter Kit is indicated for use as part of an infusion system using a CODMAN 3000 Series Pump or the MedStream Programmable Pump.

WARNING: Refer to the appropriate drug labeling for a complete list of drug indications, contraindications, warnings, precautions, adverse reactions, dosage and administration information, screening procedures, and overdose procedures.

Contraindications
- Cases of active or incompletely treated infection
- Spinal anomalies that might complicate the implantation and fixation of an intraspinal catheter

WARNINGS
Observe all contraindications relating to the use of the prescribed drug.

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

Be aware that after rinsing the bolus channel or the reservoir, intraspinal delivery of the new drug solution from the drug reservoir will be delayed until the solution traverses the total catheter length. Carefully calculate the amount of the delay, based on the total catheter length and the flow rate, before administering additional medication by another delivery method.

Precautions
- **Inspect** the sterile package carefully. Do not use if:
  - the package or seal appears damaged;
  - contents appear damaged; or
  - the expiry date has passed.
- **Do not reuse** the Intraspinal Catheter Kit. This product is for **single use only.**
- **Use sterile technique** in all phases of handling this product.
- **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 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.
- **Use only** No. 0 silk sutures for securing the catheter. Do not use stainless steel or chromium ligatures. Do not tie ligatures too tightly on the strain relief sleeves or the anchors. Silicone has a low cut and tear resistance.
- **Use** rubber-shod forceps when handling the catheter. Do not handle the catheter with sharp instruments. Take care not to inadvertently cut or puncture the catheter.
- **Make sure** that catheter connections and placement 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
  - delivery of drug to the pump pocket or the subcutaneous tissue
- **Measure and record** the length of catheter removed. Enter the total implanted catheter length and the catheter inner diameter in the patient's record. These dimensions are needed to calculate the catheter volume and the time required for drug to advance to the catheter tip. This information is necessary to help prevent a drug overdose when injecting into the bolus port, or when programming a bolus (MedStream Pump).
- **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.**
- **Do not trim** the intraspinal catheter when the guide wire is in place, or before the catheter is secured to the tissue with an anchor.
- **During implantation, verify** that the catheter 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 catheter to the surrounding tissue.

Adverse Events
Potential adverse events associated with the use of implantable infusion pumps include, but are not limited to the following. (Adverse events are alphabetized within each category.)

Inflammatory Mass
The development of a mass at the tip of the implanted intraspinal catheter. If the presence of an inflammatory mass is suspected, perform a full evaluation.

Presentations that require immediate diagnosis include bowel and/or bladder dysfunction, myelopathy, Conus Syndrome, gait disturbances or difficulty ambulating, and paraparesis or paralysis.

Catheter Performance Problems
Catheter performance problems, such as breakage, disconnection, dislodgment, formation of fibrosis or hygroma, kinking, leakage, migration, occlusion (complete or partial), can cause:
- damage to the spinal cord
- death
- drug delivery to an inappropriate site, such as the pump pocket or subcutaneous tissue
- drug withdrawal symptoms
- free-floating catheter in the cerebrospinal fluid (CSF)
- hemorrhage
- leakage of CSF, subcutaneous collection of CSF, or problems related to central nervous system (CNS) pressure
- need for surgical replacement of the catheter
- organ failure
- return of underlying symptoms
- stroke
- underinfusion of the drug

Drug Therapy Complications
- complications due to the use of a drug that is not approved for intraspinal administration
- complications due to the use of a drug that is not approved for use with the system
- drug toxicity (local and systemic) and its related side effects
- extravasation

Surgical Procedure Complications
- anesthesia complications
- arachnoiditis
- bleeding
- damage to the spinal cord
- fever

- headache
- infection
- leakage of CSF, subcutaneous collection of CSF, or problems related to CNS pressure
- meningitis
- radiculitis

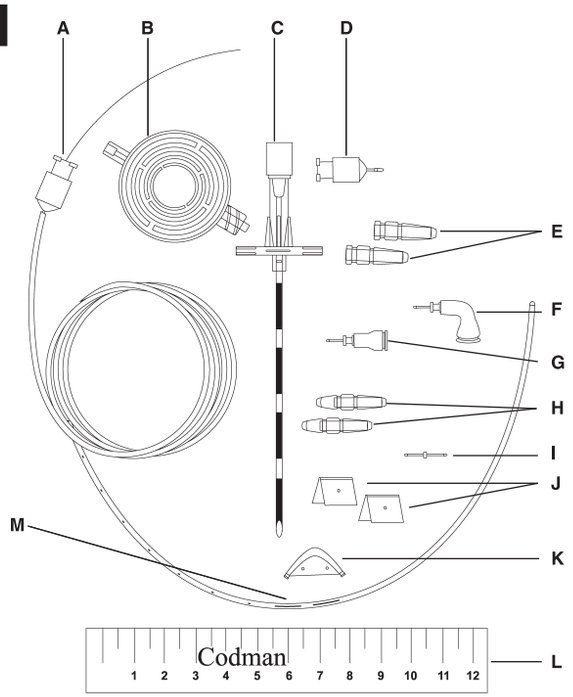
Other adverse events
- foreign body rejection phenomena
- postsurgical pain or discomfort
- skin erosion or wound dehiscence of the pocket

Product Description
The CODMAN Intraspinal Catheter Kit (see Figure 1) is for use with the CODMAN 3000 Series and MedStream Infusion Pumps. It can be used as follows:
- Joined to the outlet catheter of a CODMAN 3000 Series Pump
- Joined to the CODMAN Pump Catheter (REF 60-2914US) that is attached to a MedStream Pump
- Attached directly to the outlet of a MedStream Pump

The intraspinal catheter is a closed-end, fenestrated catheter made of medical grade silicone impregnated with barium sulfate. Markings are provided at each centimeter from 10 cm to 50 cm, with numerical markings at each 5-centimeter increment within that range. The guide wire assists with intraspinal placement.

Catheter Dimensions:
Length	100 cm
Inner diameter	0.6 mm
Outer diameter	1.5 mm
Volume	0.283 mL (0.00283 mL per cm)

1



The kit contains:
- **A.** Intraspinal catheter with female luer connector and guide wire
- **B.** Filter
- **C.** 14 G Tuohy needle
- **D.** Female luer connector
- **E.** Pump connector strain relief sleeves (2)
- **F.** 90-degree pump connector
- **G.** 0-degree pump connector
- **H.** Catheter connector strain relief sleeves (2)
- **I.** Catheter connector, titanium
- **J.** Winged anchors (2)
- **K.** 90-degree anchor
- **L.** Ruler
- **M.** Catheter marking: 11.5 cm

Replacement catheter connectors are also available:

Catalog No.	Description
60-2950US	CODMAN Intraspinal Catheter Connector with Strain Relief Sleeve

The CODMAN Disposable Tunneler (REF 60-2920) is available separately for use with the intraspinal catheter.

How Supplied
2

This product is 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.

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 contaminates 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. (THIS STATEMENT APPLIES TO NON-IMPLANTABLE COMPONENTS ONLY.)

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

Testing has shown that the following components are nonpyrogenic:
Intraspinal catheter with female luer connector and guide wire
Tuohy needle
Female luer connector
Pump connector strain relief sleeves
0-degree pump connector
90-degree pump connector
Catheter connector strain relief sleeves
Catheter connector, titanium
Winged anchors
90-degree anchor

Testing has shown that the filter has a nonpyrogenic fluid pathway.

Instructions for Use

A. Placing the Catheter Intraspinally

Precautions
Do not remove guide wire prior to use.

Do not bend or kink the guide wire. Do not trim the guide wire.

Do not insert the guide wire into the intraspinal catheter while the catheter is within the patient's body. This can cut or puncture the catheter. If the use of the guide wire is desired to verify or change catheter placement, remove the catheter together with the needle from the patient's body.

Do not use excessive force when reinserting the guide wire into the catheter. Excessive force can cut or puncture the catheter.

Required Materials:
10 mL syringe filled with preservative-free sterile saline

1. Attach the 10 mL syringe of sterile saline to the filter and flush to remove the air from the filter. Attach the free end of the filter to the luer connector of the catheter. Flush the catheter with saline until droplets exit from the fenestrations near the closed end. Remove the syringe and filter.
2. Remove the plastic protective tube from the Tuohy needle. If desired, remove the stabilizing wings from the needle. At the appropriate location along the spine, orient the needle with its bevel cephalad or parallel to the dural fibers. **Note:** The bevel of the needle is oriented to the tab on the stylet hub. Insert the needle. The centimeter markings on the needle assist in correct placement.
3. For epidural placement of the catheter, use a loss-of-resistance technique. For intrathecal placement of the catheter, advance the needle until it penetrates the dura. To confirm intrathecal location, slowly remove the needle stylet and observe CSF flow. If CSF does not appear, reinsert the stylet and reposition the needle.

   WARNING: If paresthesia ensues, remove and redirect to avoid neural injury.

   CAUTION: To minimize the loss of CSF during intrathecal placement, return the stylet to the needle until ready to insert the intraspinal catheter.

4. With the bevel of the needle cephalad, insert the distal tip of the catheter into the needle and advance the catheter. The 11.5 cm location on the catheter (see Item M in Figure 1) will be at the needle hub when the distal tip of the catheter reaches the distal tip of the needle. Continue advancing the catheter to the desired location.

5. Verify the position of the catheter with fluoroscopy.

   CAUTION: Do not pull back on the catheter or remove it through the needle; the catheter could be damaged by contact with the sharp inner edges of the needle tip. If the catheter must be removed, first remove the needle and the catheter together, then remove the needle from the proximal end of the catheter.

6. After catheter placement, make an incision at the needle site to facilitate securing of the catheter and the passage of the tunneler.

   CAUTION: Perform the incision with the needle still in place. This will protect the catheter from inadvertent damage.

7. Carefully remove the needle from the fascia until a sufficient amount of catheter is exposed; hold the catheter near the exit site.

   CAUTION: Hold the catheter securely at the exit site during needle and guide wire removal to prevent catheter dislodgment.

8. Remove the luer connector from the catheter. Carefully slide the needle to the proximal end of the catheter and remove the needle from the catheter.

   CAUTION: Always remove the Tuohy needle from the catheter before removing the guide wire. Withdrawing the guide wire before removing the Tuohy needle can tear or shear the catheter.

9. Slowly remove the guide wire from the catheter.

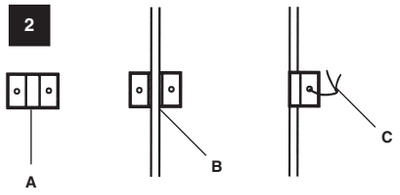
CAUTION: Follow these points to aid needle and guide wire removal and to prevent damaging the catheter.
- Hold the catheter securely at the exit site during needle and guide wire removal to prevent catheter dislodgment.
- Hold the entire length of the catheter straight during needle and guide wire removal.
- Do not squeeze the catheter. Excessive compression will increase the difficulty of guide wire removal.
- Withdraw the guide wire slowly.
- If the catheter becomes twisted or seizes the guide wire, stop. Allow the catheter to relax and return to its original shape. Slowly start again, being sure to hold the catheter at the exit site.

10. Test the catheter for patency as follows.
    For intrathecal placement: observe CSF flow exiting the proximal end of the catheter.
    For epidural placement: insert the female luer connector into the end of the catheter. Attach the filter and the 10 mL syringe of preservative-free sterile saline to the female luer connector. Gently flush the catheter. Observe the catheter for leakage.
    CAUTION: To minimize the loss of CSF during intrathecal placement, clamp the catheter with rubber shod forceps.

11. Place an anchor as close as possible to the spinal entry point. Suture the anchor to the surrounding tissue. Avoid angulation or kinking of the catheter as it exits the ligament.

    To place the winged anchor, see Figure 2 and follow the steps below:
    a. Open the tabs of the winged anchor.
    b. Wrap the anchor around the catheter in the desired position.
    c. Pass a suture through both wings of the anchor and suture to the surrounding tissue.

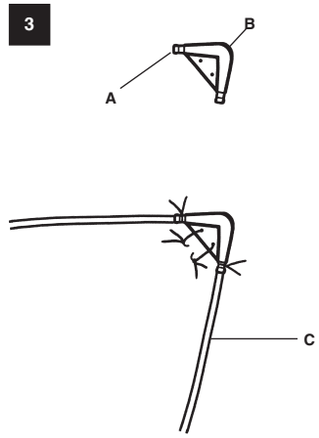
2



A. Winged anchor
B. Intraspinal catheter
C. Suture

To place the 90-degree anchor, see Figure 3 and follow the steps below:
a. Place the catheter into the slit of the anchor.
b. Place a suture loop in two places in the suture grooves at both ends of the anchor.
c. Pass a suture through the holes in the anchor and suture to the surrounding tissue.

3



A. 90-degree anchor
B. Slit
C. Intraspinal catheter

12 Retest the catheter for patency as in Step 10. Remove the 10 mL syringe, the female luer connector, and the filter.

13. Use appropriate instruments to pass the catheter to the connection site. If using the CODMAN Disposable Tunneler, follow the procedure outlined in the instructions packaged with that device.

    CAUTION: To minimize the loss of CSF during intrathecal placement, clamp the catheter with rubber-shod forceps.

14. Follow the steps in *Section B* or *Section C* to connect the catheter to the infusion pump.

B. Connecting the Intraspinal Catheter to a Pump Catheter or an Outlet Catheter

CAUTION: Follow the instructions packaged with the pump to prepare the pump and pump/outlet catheter for implantation.

Required materials:

For the MedStream pump: MedStream Bolus Kit (REF 91-4284US) (**Note:** If implanting the catheter with a new MedStream Pump, use the bolus needle and other components packaged with the pump.)
For the CODMAN 3000 Series pump: Special Bolus Needle (REF AP-04013)
5 mL of preservative-free sterile saline

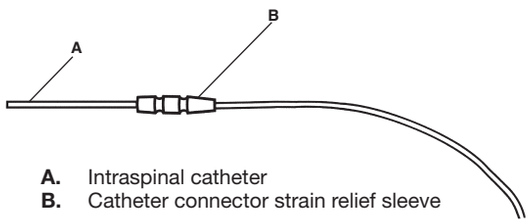
1. At the catheter connection site, trim the intraspinal catheter, if necessary. Record the length of catheter removed.

2. Orient the pump in the pump pocket so that the pump outlet is positioned laterally, towards the intraspinal catheter. Suture the pump as outlined in the instructions provided with the pump. Position the excess pump catheter in a loose loop underneath the pump.

3. Pass the pump/outlet catheter to the connection site. Trim the pump/outlet catheter, if necessary. Record the length of catheter removed.

4. Select the pump connector strain relief sleeve (Item H in Figure 1). Slide the white-ringed (smaller diameter) end of the catheter connector strain relief sleeve approximately 4 cm over the intraspinal catheter (Figure 4).

4



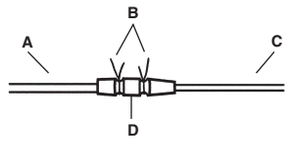
A. Intraspinal catheter
B. Catheter connector strain relief sleeve

5. Insert either end of the catheter connector into the lumen of the intraspinal catheter. Insert the opposite end of the catheter connector into the pump/outlet catheter. Both catheter ends must touch the center step of the connector.

6. Slide the strain relief sleeve over the junction of the catheters until it bottoms out on the connector step.

7. Secure the strain relief sleeve to both catheters by tying ligatures of No. 0 silk suture in the suture grooves (Figure 5).

5



A. Pump/outlet catheter
B. Ligatures (No. 0 silk suture)
C. Intraspinal catheter
D. Catheter connector strain relief sleeve

8. Test the patency of the catheters and connections by administering a bolus injection of saline through the bolus port. Use 3 mL of saline for the CODMAN 3000 Series pumps or 5 mL of saline for the MedStream pump. Refer to the instructions for priming the bolus channel in the instructions that are packaged with the pump. Resistance might be a sign of occlusion; take appropriate measures. Inspect the pump/catheter connection for signs of leakage.

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

C. Connecting the Intraspinal Catheter Directly to the Pump (MedStream Pump only)

CAUTION: When connecting the catheter directly to the MedStream pump outlet, DO NOT USE the pump catheter packaged with the pump. Follow the instructions packaged with the pump to prepare the pump for implantation, excluding steps to attach the pump catheter.

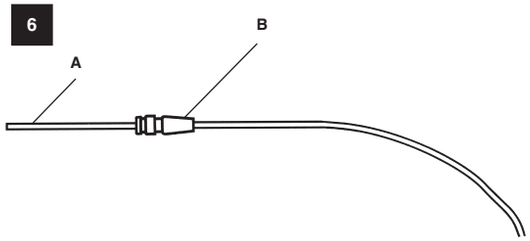
Required materials:

MedStream Bolus Kit (REF 91-4284US)
(**Note:** If implanting the catheter with a new MedStream Pump, use the bolus needle and other components packaged with the pump.)
5 mL of preservative-free sterile saline

1. At the pump implantation site, trim the catheter, if necessary, leaving excess catheter to loop under the pump. Record the length of catheter removed.

2. Select the pump connector strain relief sleeve (Item E in Figure 1). Slide the white-ringed (smaller diameter) end of the pump connector strain relief sleeve onto the catheter, approximately 4 cm (see Figure 6).

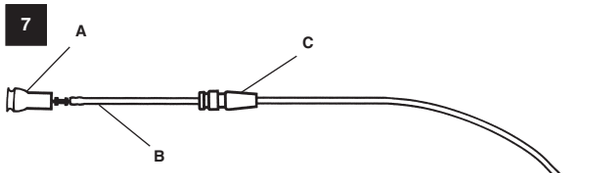
6



A. Intraspinal catheter
B. Pump connector strain relief sleeve

3. Select the 90-degree or 0-degree pump connector. Slide the end of the catheter onto the pump connector with a slight rotating motion (see Figure 7).

7

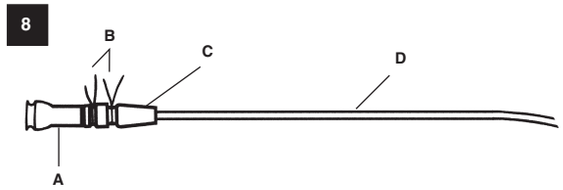


A. Pump connector (0-degree)
B. Intraspinal catheter
C. Pump connector strain relief sleeve

4. Slide the strain relief sleeve over the pump connector until it contacts the stop.

5. Secure the strain relief sleeve onto the catheter by tying ligatures of No. 0 silk suture (see Figure 8).

8



A. Pump connector (0-degree)
B. Ligatures (No. 0 silk suture)
C. Pump connector strain relief sleeve
D. Intraspinal catheter

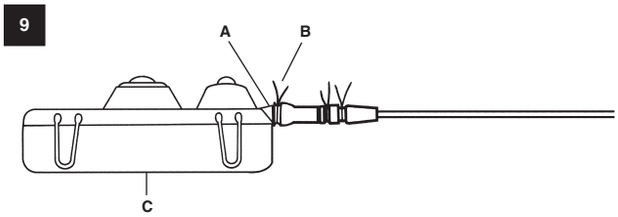
6. If placed intrathecally, remove any occluding clamps from the catheter and allow a few drops of CSF to exit the pump connector, to confirm patency and purge air.

7. Gently push the pump connector onto the pump outlet with a twisting motion.

8. Ensure that the groove of the connector is completely seated in the groove of the pump outlet.

9. Secure the pump connector to the pump outlet with a ligature of No. 0 silk suture. The suture must lie in the groove of the connector (see Figure 9).

9



A. Pump outlet
B. Ligature (No. 0 silk suture)
C. Pump

10. Test the patency of the catheters and connections by administering a bolus injection of saline through the bolus port. Refer to the instructions for priming the bolus channel provided with the pump. Resistance may be a sign of occlusion; take appropriate measures. Inspect the pump connection for signs of leakage.

11. Orient the pump so that the pump outlet is positioned laterally, towards the intraspinal catheter. Suture the pump as outlined in the instructions provided with the pump. Position excess catheter in a loose loop underneath the pump.

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

D. Calculating the Catheter Volume

MedStream Pump

CAUTION: It is important to note the discarded catheter length in the patient's record. This measurement 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 total bolus pathway and catheter volumes.

CODMAN 3000 Pump

CAUTION: It is important to note the total catheter length and the catheter inner diameter in the patient's record. The total implanted catheter length and inner diameter are 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.

1. Determine volume of CODMAN Intraspinal Catheter:
   Multiply the length of implanted segment by 0.003mL/cm = _____mL
2. Determine volume of pump catheter: multiply the length of implanted segment by 0.003mL/cm = _____mL
3. Enter bolus pathway volume of pump (choose one from below)
   Check one:

	Pump Model	**Bolus Pathway Volume**	
☐	CODMAN 3000-16 (16mL)	0.2 mL	
☐	CODMAN 3000-30 (30mL)	0.3 mL	
☐	CODMAN 3000-50 (50mL)	0.4 mL	= _____mL

4. Add 1, 2 and 3 above

TOTAL BOLUS PATHWAY AND CATHETER VOLUME = _____mL

Note: Patient Data Stickers are provided for your records.

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.**

Do not resterilize

Do not use if package is damaged

Prescription device only (USA)

Manufacturer

Distributed in the USA by

Made in

Nonpyrogenic, see instructions for use

Quantity

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*

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*For recognized manufacturer, refer to product label