The MEDSTREAM Programmable Infusion System is intended for the intrathecal delivery of selected drugs for pain management or spasticity management. The implantable components of the system include the infusion pump, pump catheter, connector and strain-relief sleeve. The accessories needed to prepare the pump for implantation are included with the pump in the O.R. prep kit.

The pump must be connected to a suitable intraspinal catheter.

The following intraspinal catheters are designed for use with the MEDSTREAM pump:
- CODMAN® Intraspinal Catheter Kit
- SURESTREAM™ Intraspinal Catheter Kit

This guide covers the implantation of the SURESTREAM™ Intraspinal Catheter. For instructions on implantation of the CODMAN® Intraspinal Catheter, please refer to its instructions for use.

The MEDSTREAM Control Unit is an external part of the system that is required to prepare the pump for implantation, and to program the daily dosage postoperatively. The control unit uses radio frequency to create two-way communication with the pump. It is used to retrieve status information from and transmit programming changes to the pump. The control unit also must be used each time the reservoir is refilled.

**CAUTION:** Do not implant the MEDSTREAM Pump without ensuring a thorough familiarity with the information contained in this manual, the Control Unit instructions and the MEDSTREAM Programming Guide.
SUPPLIES NEEDED FROM CODMAN

- MEDSTREAM Implantable Pump (20 mL or 40 mL)
- MEDSTREAM OR Prep Kit
- CODMAN Pump Catheter
- MEDSTREAM Control Unit
- SURESTREAM™ Intraspinal Catheter
- CODMAN Tunneler

PREOPERATIVE PLANNING

- Identify pump location before surgery with patient.
- The pump is usually located between costal margin and iliac crest however optimal placement is patient specific.
- Draw position on skin while patient stands or sits upright.
- Avoid positioning the incision line directly over refill septum.
PATIENT POSITIONING

- Place patient in a right or left lateral decubitus position with the lumbar region slightly flexed.
- The skin should be prepared using an appropriate antimicrobial solution over the desired area in the back, flank, chest, and lower abdomen where the catheter will be tunneled to the pump.
- Sterile drapes should be applied.

PREOPERATIVE PUMP PREPARATION

- Follow the pump preparation procedure detailed in the MEDSTREAM Pump Instructions for Use.
- Using the MEDSTREAM Control Unit, perform the pump internal check and ensure that pump is deemed ready for implant.
STEP 1. Place the Intraspinal Catheter

POSITION THE SPINAL NEEDLE

- Under fluoroscopy, insert the 17 gauge Touhy needle using a shallow, oblique paramedian insertion technique.
- The skin entry point will be parallel to the vertebral pedicle, approximately ½ to 2 cm off of midline and ½ to 1 ½ vertebral levels below the targeted interlaminar space.

Note:
In patients with difficult spinal anatomy, the needle angle may need to be adjusted.

ALTERNATIVE TECHNIQUE:

- A small incision, centered around the desired needle entry point, may be made before needle insertion.
ENTER THE INTRATHECAL SPACE

- Advance the needle until the dura is penetrated.
- Remove the needle stylet to observe cerebrospinal fluid (CSF) backflow and confirm intrathecal location.
- Replace needle stylet to prevent CSF leakage.

Caution:
- If parathesia occurs, redirect the needle to avoid neural injury.
- If the patient develops neurological signs or symptoms, discontinue.
- If excessive bleeding is encountered, stop and reevaluate.

INSERT THE INTRASPINAL CATHETER

- When the needle position is properly located and confirmed by fluoroscopy, remove the stylet. Orient the needle bevel cephalad and thread the distal tip of catheter through the needle.
- When the wide marker band on the catheter is at the hub of the needle, the catheter tip is at the tip of the needle. A slight increase in advancement pressure may be noted.
- Advance the catheter with the guidewire to the desired location in the intrathecal space.
- Markers are provided on the SURESTREAM catheter in centimeter increments.

Caution:
- Pulling back on the guide wire while the catheter and guide wire are still inserted in the Touhy needle may damage the catheter.
MAKE A SKIN INCISION

- Make an incision centered at the needle insertion site.

- Expose an area of the fascia that is large enough to place the catheter anchor.
PLACE PURSE-STRING SUTURE

- Place a purse-string suture through the lumbo-dorsal fascia and around the catheter.
- The purse-string suture should be placed before removing the Touhy needle.
- The purse-string suture will help the surrounding tissue fibrose and may reduce the likelihood of CSF leakage, subcutaneous CSF collection and/or postoperative headache.

REMOVE NEEDLE AND GUIDE WIRE

- Carefully remove the needle tip from the fascia.
- Gently tighten the purse-string suture around the catheter taking care not to occlude or kink the catheter.
- Before removing the guide wire, grasp the catheter near the fascial exit site and carefully slide the needle to the end of the catheter.
- Remove the guide wire and needle from the catheter simultaneously.
TEST FOR INTRASPINAL CATHETER PATENCY.

- Catheter patency may be confirmed by observing continuous CSF backflow through the catheter. If CSF backflow is inadequate, patency may be tested via saline injection detailed in the alternative technique.

ALTERNATIVE TECHNIQUE:

- Insert the proximal end of the catheter into the SNAPLOCK™ Adaptor until the catheter bottoms out.
- While maintaining the catheter position, tighten the adaptor by squeezing the black collar toward the luer hub until the gap between the pieces is closed.
- To ensure that the connection is secure, gently tug the catheter near the adaptor.
- Attach a 10ml syringe filled with preservative free saline and flush the catheter to test for patency.
- Replace the SNAPLOCK™ cap to prevent CSF leakage.
ANCHOR INTRASPINAL CATHETER TO THE FASCIA

- Attach the silicone anchor to the catheter where the catheter enters the lumbo-dorsal fascia.
- Fasten the anchor to the fascia using heavy non-absorbable suture.
- Reconfirm catheter patency with saline flush or CSF backflow. Replace the SNAPLOCK™ cap to prevent CSF leakage.
- Verify and document catheter position using fluoroscopy.

ALTERNATIVE TECHNIQUE (DUAL ANCHOR):

- Attach the cylindrical silicone anchor to the catheter where the catheter enters the lumbo-dorsal fascia.
- Fasten the anchor to the fascia using heavy non-absorbable suture.
- Create a strain relief loop in the catheter of approximately 3 cm.
- Attach the right angle silicone anchor to the catheter and fasten to the fascia using heavy non-absorbable suture.
- Reconfirm catheter patency with saline flush or CSF backflow. Replace the SNAPLOCK™ cap to prevent CSF leakage.
- Verify and document catheter position using fluoroscopy.
STEP 2. Prepare the Pump

ATTACH THE PUMP CATHETER

- Aseptically deliver the pump and pump catheter to a sterile surface.
- Firmly press the catheter’s silicone connector onto the pump’s catheter port.
- Secure the connector with a heavy, non-absorbable suture placed in the suture groove at the base of the connector.
- Check the catheter for any tears.

ALTERNATIVE TECHNIQUE:

- The pump catheter may be attached to the intraspinal catheter before attaching to the pump.

FILL AND PRIME THE PUMP

- Using the OR Prep Kit, follow the MEDSTREAM Pump Instructions for Use to perform the following steps.
  1. Empty the reservoir
  2. Flush the reservoir
  3. Fill the reservoir
  4. Prime the bolus channel

Note:
Also refer to the MEDSTREAM OR Poster for detailed instructions and illustrations.
STEP 3. Prepare the Pump Pocket

CONSIDER THE FOLLOWING BEFORE PLACING THE PUMP

- The pump should be no more than 2.5 cm from the surface of the skin.
- Avoid positioning the incision line directly over the refill or bolus septum.
- The refill port should be accessible after implantation.

CREATE A SUBCUTANEOUS POCKET FOR THE PUMP.

- When possible, the incision should be along relaxed skin tension lines and not across skin creases.
- Care should be taken to apply meticulous hemostasis to avoid hematoma or seroma formation after surgery.
STEP 4. Tunnel the Intraspinal Catheter to the Pump Pocket

CREATE SUBCUTANEOUS TUNNEL

- Bend the tunneler to conform to the patient’s contour.
- Insert the tunneler through the pump pocket wound and advance to the intraspinal catheter exit wound in the back.
- Remove the plastic insert from the tunneler tube.

THREAD THE CATHETER TO THE PUMP POCKET

- Remove the SNAPLOCK Adapter from the SURESTREAM catheter and thread the catheter through the tunneler to the pump pocket.
**STEP 5. Prepare Catheter Connection**

**TRIM THE CATHETERS**

- Trim the MEDSTREAM pump catheter and the SURESTREAM catheter to the desired lengths.
- Provide sufficient slack in the pump catheter to allow the catheter to be coiled at least once under the pump.
- Document the length of the trimmed catheters to determine the implanted catheter volume.

**CONNECT THE SURESTREAM INTRASPINAL CATHETER TO THE SURESTREAM CONNECTOR**

- Insert the trimmed end of the SURESTREAM Catheter into the opening in the connector thumbscrew until it cannot be advanced any further into the housing.
- Tighten the thumbscrew until there is no visible gap in the viewing window.
- If needed, use an instrument, such as a Kelly clamp, for tightening.
CONNECT THE MEDSTREAM PUMP CATHETER TO THE SURESTREAM CONNECTOR

- Slide the small diameter end of the strain relief sleeve approximately 4 cm over the pump catheter.
- Slide the end of the pump catheter onto the pin connector with a slight twisting motion.
- Slide the strain relief sleeve over the pin connector until it contacts the stop.
- Secure the strain relief sleeve onto the catheter and the connector by tying 2 ligatures of heavy non-absorbable suture.
- Test for leaks and catheter patency by administering a bolus injection of preservative free saline through the bolus port.

Note:
Refer to the MEDSTREAM OR Poster for detailed bolus instructions and illustrations.
**STEP 6. Place and Secure Pump**

**SECURE THE PUMP WITH SUTURE LOOPS**

- Firmly secure the pump using heavy non-absorbable suture in a minimum of three of the four available suture loops.
- The sutures should be deep into the fascia and not in the fatty tissue.
- Place the SURESTREAM Connector and at least one loop of pump catheter under the pump.
- Re-test for catheter patency and leaks at the connection site via the bolus port and MEDSTREAM Bolus Needle.

**CLOSE INCISIONS**

- Irrigate the pump pocket and spinal incision site thoroughly.
- Close the incisions using subcutaneous and skin sutures and apply dressing.
- Care should be taken to avoid having skin sutures directly overlying the refill port or the bolus port.
Step 7. Post Operative Programming

- Refer to the MEDSTREAM Pump Instructions for Use and the MEDSTREAM Programming Guide for detailed programming instructions.
Essential Prescribing Information

MEDSTREAM™ Programmable Infusion System
Essential Prescribing Information:
Product instructions for use and appropriate drug labeling must be reviewed prior to use for detailed disclosure.

INDICATIONS:
The MEDSTREAM™ Programmable Infusion System is indicated for the chronic intrathecal infusion of preservative-free morphine sulfate sterile solution (4.0 pH to 7.0 pH) in the treatment of chronic, intractable pain (benign or malignant), and Baclofen injection sterile solution (5.0 pH to 7.0 pH) in the treatment of severe spasticity.

CONTRAINDICATIONS:
The pump is contraindicated under the following conditions: in the presence of active or incompletely treated infection; if the top surface of the implanted pump will be more than 2.5 cm from the surface of the skin; if the patient's body size is insufficient to accept the bulk and weight of the pump; when conservative treatment is appropriate; and in the presence of spinal anomalies that might complicate the implantation and fixation of an intraspinal catheter. In addition, observe all contraindications relating to the use of the prescribed drug.

Thoroughly review product instructions for use for a detailed listing of Indications, Contraindications, Warnings, Precautions and Adverse Events.

LIMITED WARRANTY AND DISCLAIMER:
CODMAN products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

CAUTION:
This device is restricted to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training or experience.
CONTACT INFORMATION

Germany
Johnson & Johnson MEDICAL GmbH
Geschäftsbereich Codman
Oststrasse I
D-22844 Norderstedt
e-Mail: codinfo@its.jnj.com
Marketing and Vertrieb:
Telefon: +49 040-5297 4614
Telefax: +49 040-5297 4617
Auftragsbearbeitung:
Telefon: +49 01801-000 829
Telefax: +49 0800-1016 138

Italy
Johnson & Johnson Medical SPA
Via Del Mare, 56
00040 Pratica Di Mare RM
+39-06-911.94.500 fax +39-06-911.94.505

United Kingdom
Johnson & Johnson Medical Ltd
Pinewood Campus, Nine Mile Ride
Wokingham
RG40 3EW
United Kingdom
Office Contact Information:
Telephone: +44 (0) 1344 871000
Fax: +44 (0) 1344 871120
Customer Services Contact Information:
Telephone: +44 (0) 800 864 060
Fax: +44 (0) 1344 864 018
Email: contact@medgb.jnj.com

USA
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767
(800) 225-0460