Codman

MedStream™ Bolus Kit (Catalog No. 91-4284US)

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

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

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ENGLISH

IMPORTANT INFORMATION
Please Read Before Use

MedStream™ Bolus Kit (Catalog No. 91-4284US)

STERILE	EO

℞ Only

Become thoroughly familiar with the information contained in this user manual prior to administering a bolus into a MedStream Programmable Infusion System. Failure to adhere to these instructions can result in patient complications, such as a drug overdose.

For additional information, refer to the user manual packaged with the infusion pump.

Indications

The MedStream Bolus Kit is used to access the bolus port of a MedStream pump. The MedSteam Pump is indicated for the chronic intrathecal infusion of:

- Baclofen injection sterile solution (5.0 pH to7.0 pH) for treatment of severe spasticity

Use preservative-free sterile solution of 0.9% sodium chloride (4.5 pH to 7.0 pH) to achieve the physician-prescribed drug concentration.

WARNING: Use only the drug and diluent listed above with the MedStream 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

There are no known contraindications for the use of the Bolus Kit.

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

Warnings

Improper use of implanted infusion pumps could result in drug under- or overdose. Users must comply with product instructions for injecting into the bolus port of the pump. **Only qualified medical personnel must perform these procedures.**

Do not mix drugs. The effects of mixing drugs in the pump are not known.

Use only the drug and diluent listed in *Indications* with the MedStream pump.

The physician must consider the drug concentration, dose and flow rate relationships of the pump before selecting the pump volume and flow rate. Failure to consider these factors can lead to a drug under- or overdose.

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

Injection in the bolus port or into the pump pocket can result in drug overdose. To prevent injection errors:

- identify the location of the central port and the bolus port;
- use the bolus needle provided in the MedStream Bolus Kit for accessing the bolus port.

When the bolus channel has been rinsed, intrathecal delivery of the 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.

The Bolus Kit is for **single use only. Do not reuse.**

Use sterile technique in all phases of handling this product.

The catheter(s) of an implanted pump system are filled with infusion solution. During a bolus injection, the patient receives an additional bolus of the drug, which is approximately equal to the contents of the catheter(s). To prevent drug

overdose during injection through the bolus port, aspirate fluid to ensure drug removal. Use the MedStream Control Unit to access the catheter volume of the implanted pump (refer to the MedStream System Programming Guide).

Use only the needle provided with the MedStream Bolus Kit for accessing the bolus port of a MedStream pump. This needle is designed specifically for use with the pump. The use of other needles can damage the bolus port and/or result in a failure to administer solution appropriately.

If local or systemic infection is suspected, use extreme caution injecting a bolus. If infection is suspected, perform appropriate diagnostic procedures and intervention.

Do not overpressurize the bolus port when injecting fluids. Small syringes can generate very high fluid pressure. **Do not use syringes smaller than 10 mL for bolus port injections.**

Use only preservative-free solutions for intrathecal applications.

Adverse Events

Adverse events related to bolus injections include:

- contamination of the bolus channel resulting in infection, such as meningitis
- injection errors, which can lead to tissue damage or a drug under- or overdose

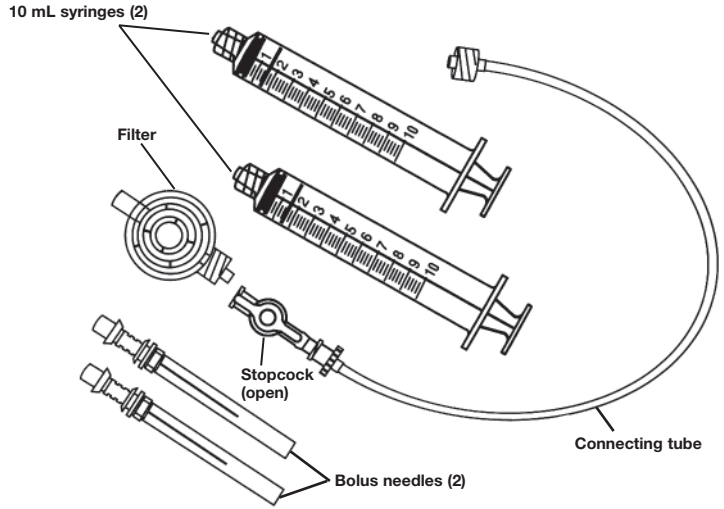
Complications relating to the drug therapy may arise, such as:

- drug toxicity (local and systemic) and its related side effects
- complications due to the use of a drug that is not approved for intrathecal administration
- complications due to the use of drugs that are not approved for use with the system
- complications due to use of an approved drug or diluent that is out of specification
- extravasation

Product Description

The MedStream Bolus Kit (Figure 1) contains a needle designed for use only with the MedStream infusion pump. The tip of the needle is closed; the drug solution exits the needle through an opening along the shaft of the needle. See Figure 2.

1



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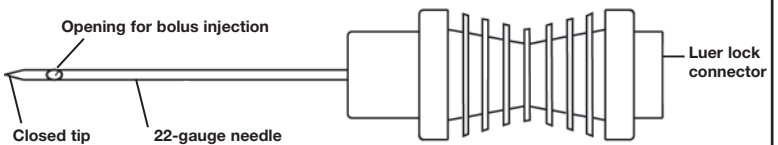


The Bolus Kit contains the following components, provided sterile:

- Two bolus needles with purple luer-lock
- Two 10 mL syringes
- Connecting tube with stopcock
- Fenestrated drape
- Filter, 0.2 micron

How Supplied

(2)

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 resterilization, after a single patient use. Reuse can potentially compromise device performance and any usage beyond the design intent of this single-use device may result in unpredictable loss of functionality.

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.

The following components have been tested and were determined to be nonpyrogenic:

Needles
Connecting tube with stopcock

The following components have been tested and were determined to have a nonpyrogenic fluid pathway:

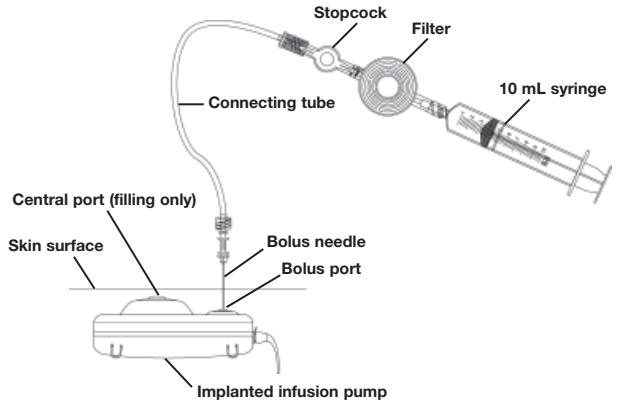
Filter
Syringes

INSTRUCTIONS FOR USE

These instructions do not address the procedure for priming the bolus channel in preparation for implantation. Follow the instructions for *Priming the Bolus Channel* in the user manual provided with the MedStream Pump.

Injecting a Bolus into an Implanted Pump (Refer To Figure 3)

3



PRECAUTIONS

Ensure that all luer-lock connections are secure.

Always ensure proper needle placement (needle held perpendicular to the pump and inserted completely to the needle stop) before injecting a bolus.

Use of excessive force when inserting the bolus needle into the bolus port can damage the needle tip. Never use a bolus needle if the tip is bent; use the second bolus needle provided. Using a bent bolus needle can damage the bolus port, and result in a failure to administer solution appropriately.

Gently flush the bolus channel with sterile 0.9% saline solution after each bolus injection.

Required materials:

- Aspiration needles
- MedStream Bolus Kit
- 5 mL of sterile 0.9% saline solution
- Drug solution
- Skin disinfectant
- Self-adhesive sterile bandage (optional)

1. Aspirate drug solution from the bolus channel and catheter(s)
   a. Use the MedStream Control Unit to interrogate the pump. Scroll to the catheter information section (the second page of the summary screens). If a one-piece catheter system was used, make note of the "Implanted Catheter Volume." If a two-piece catheter system was used, make note of the "Total Catheter Volume." Refer to the MedStream Infusion System Programming Guide for more information.
   b. Connect one 10 mL syringe to the stopcock at the end of the connecting tube. Connect the bolus needle to the other end of the connecting tube.
   c. Palpate the pump and locate the central port and the bolus port (next to the pump outlet). Fluoroscopy can be used to assist in locating the bolus port.
   d. Disinfect a wide area of skin over and around the **bolus port;** cover the prepared area with a sterile fenestrated drape.
   e. Holding the bolus needle perpendicular to the pump, puncture the bolus port. Insert the bolus needle until it contacts the needle stop; twist the needle to ensure it penetrates the silicone bolus channel beneath the bolus port.
   f. With gentle negative pressure, aspirate an amount of drug solution equal to the volume of the catheter(s).
   g. **Close the stopcock** of the connecting tube and remove the syringe, leaving the connecting tube and bolus needle in place.
   h. Dispose of the aspirated drug solution and syringe in an appropriate manner.

2. Set up for bolus administration
   a. Connect the unused 10 mL syringe to an aspiration needle.
   b. Using the aspiration needle, draw the prepared drug solution into the syringe. Expel the air from the syringe.
   c. **Remove the aspiration needle.** Connect the syringe to the filter.
   d. Expel the air from the filter.
   e. Connect the filter to the connecting tube.

3. Injecting the bolus
   a. **Open the stopcock** on the connecting tube and slowly inject the drug solution.
   WARNING: Do not exceed an injection speed of 5 mL/minute during bolus injection of drug solution or any fluid, including saline. Injection into the bolus port under high pressure may cause catheter disconnection or catheter damage and subsequent fluid leakage.
   b. Close the stopcock of the connecting tube and remove the syringe from the filter. Rinse the syringe with sterile water or sterile saline and retain for use in flushing the bolus channel (Step 4).

4. Gently flush the bolus channel
   a. Connect the syringe to an aspiration needle. Draw 5 mL of saline into the syringe; expel the air.
   b. **Remove the aspiration needle.** Connect the syringe to the filter on the connecting tube.
   c. **Open the stopcock** and slowly (over one full minute) inject the saline to gently flush the bolus channel.

5. Remove the bolus needle from the bolus port and, if necessary, cover the injection site with a self-adhesive sterile bandage.

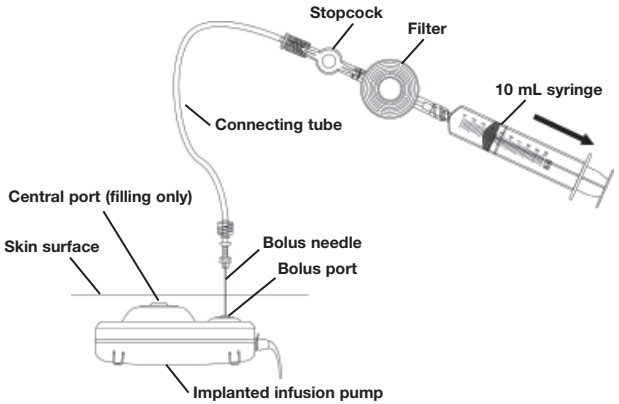
If you are unable to inject into the bolus port…

- **The bolus needle may not have been inserted completely.**
  Ensure that the bolus port is punctured and that the bolus needle is inserted perpendicularly until it contacts the needle stop; then twist the needle. Twisting the needle during insertion helps ensure that it penetrates the silicone bolus channel beneath the bolus port.
- **The bolus needle may be clogged.**
  Remove the bolus needle and check its function.
- **The catheter may be bent, kinked, or clogged.**
  Use radiography to ensure the catheter is not occluded due to being bent or kinked.

CAUTION: When injecting contrast media intrathecally, use only contrast medium indicated for intrathecal administration. Failure to do so may result in adverse events such as extreme pain, cramps, seizures, and death.

Aspirating Catheter Contents Via the Bolus Port (See Figure 4)

4



PRECAUTIONS

Ensure that all luer-lock connections are secure.

Always ensure proper bolus needle placement (needle held perpendicular to the pump and inserted completely to the needle stop) before injecting a bolus.

Use of excessive force when inserting the bolus needle into the bolus port can damage the needle tip. Never use a bolus needle if the tip is bent; use the second bolus needle provided. Using a bent bolus needle can cause damage to the bolus port, and result in a failure to administer solution appropriately.

Required materials:

- Aspiration needle
- MedStream Bolus Kit
- Skin disinfectant
- Self-adhesive sterile bandage (optional)

1. Use the MedStream Control Unit to interrogate the pump. Scroll to the catheter information section (the second page of the summary screens). If a one-piece catheter system was used, make note of the “Implanted Catheter Volume.” If a two-piece catheter system was used, make note of the “Total Catheter Volume.” Refer to the MedStream Infusion System Programming Guide for more information.
2. Connect one 10 mL syringe to the stopcock end of the connecting tube. Connect the female luer-lock end of the connecting tube to the bolus needle.
3. Palpate the pump and locate the central port and the bolus port (next to the pump outlet). Fluoroscopy can be used to assist in locating the bolus port.
4. Disinfect a wide area of skin over and around the **bolus port;** cover the prepared area with a sterile fenestrated drape.
5. Holding the bolus needle perpendicular to the pump, puncture the bolus port. Insert the bolus needle until it contacts the needle stop; twist the needle to ensure it penetrates the silicone bolus channel beneath the bolus port.
6. With gentle negative pressure, aspirate an amount of drug solution equal to the volume of the catheter(s).
7. Close the stopcock of the connecting tube and remove the syringe, leaving the connecting tube and bolus needle in place.
8. Dispose of the aspirated drug solution and syringe in an appropriate manner.
9. Remove the bolus needle from the bolus port and, if necessary, cover the injection site with a self-adhesive sterile bandage.

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.**

Appendix A: Emergency Procedures

Drug Overdose

WARNING: REFER TO THE APPROPRIATE DRUG LABELING FOR A COMPLETE LIST OF DRUG INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REATIONS, DOSAGE AND ADMINISTRATION INFORMATION, SCREENING PROCEDURES, AND OVERDOSE PROCEDURES CONTAINED IN THE PRESCRIBED DRUG LABELING.

Consult the patient's medical record or with the patient's physician to confirm the drug or drug concentration within the pump reservoir.

In the event of a suspected overdose:

1. Aspirate the catheter contents, if appropriate. (See *Aspirating Catheter Contents Via the Bolus Port.*)
2. Use a MedStream Refill Kit (catalog no. 91-4283US) to empty the reservoir of the remaining drug. Refer to *Emptying the Pump,* in the instructions for use provided with the Refill Kit.
3. After stabilizing the patient, rinse the reservoir. Refer to *Rinsing the Pump,* in the instructions for use provided with the Refill Kit.
4. Once the drug reservoir is rinsed, fill the reservoir with sterile preservative-free 0.9% saline solution to keep the pathway patent, or fill with the correct prescription.

Do not resterilize

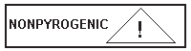

Do not use if package is damaged

Prescription device only (USA)


Manufacturer

Distributed in the USA by

Made in



Nonpyrogenic, see instructions for use

Latex free

Quantity