

Important Safety Information

Errata

Disregard any instructions in the catheter implant manual that refer to catheter connection to an IsoMed pump.

Component incompatibility – Do not use the following components with a Model 8472 IsoMed Implantable Constant-Flow Infusion Pump:

- Model 8731SC Intrathecal Catheter
- Model 8709SC Intrathecal Catheter
- Model 8596SC Pump Segment Revision Kit
- Model 8578 Sutureless Pump Connector Revision Kit

These components are not compatible with the IsoMed pump.



Medtronic

SUTURELESS PUMP CONNECTOR REVISION KIT

8578

for Model 8709 and Model 8709SC
intrathecal catheters

Implant manual

 Rx only



2006

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.



Open here



Do not reuse



Sterilization: ethylene-oxide gas



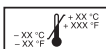
Caution: Consult accompanying documents



Use by



Manufacturing date



Storage temperature



Lot Number



Volume



Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive AIMD 90/385/EEC.



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Refer to the Indications, Drug Stability, and Emergency Procedures reference manual for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, and component disposal.

Refer to the appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.

Device description

The Medtronic Model 8578 Sutureless Pump Connector Revision Kit (Figure 1) is used when a pump connector for an Indura 1P Model 8709 or Model 8709SC Catheter is required. The catheter is part of an infusion system that stores and delivers parenteral drugs to the intrathecal space. The implanted infusion system components consist of a Medtronic pump and an Indura 1P Model 8709 or Model 8709SC catheter. The catheter connects to the pump with the Model 8578 sutureless pump connector at the catheter port.

Note: The Medtronic Model 8578 Sutureless Pump Connector Revision Kit is designed for use with Medtronic implantable infusion pumps, with the exception of Medtronic MiniMed infusion pumps.

Package contents

- Catheter interface with attached sutureless pump connector, catheter, connector pin, and strain-relief sleeve
- Strain-relief sleeves (2)
- Ruler (nonsterile)
- Product literature
- [REDACTED] Warranty card
- [REDACTED] Registration form

Registration form

[REDACTED] The implant registration form registers the device warranties and creates a record of the device in the Medtronic implant data system.

Device specifications

The Indura 1P catheter connects to the catheter interface with a connector pin and strain-relief sleeve. The catheter interface connects to the pump with a sutureless pump connector.

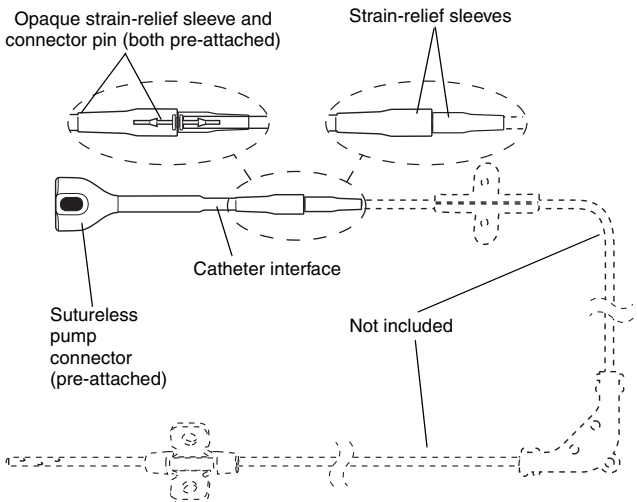


Figure 1. Model 8578 Sutureless Pump Connector Revision Kit.

Table 1. Device specifications for Model 8578 Sutureless Pump Connector Revision Kit^a

Description	Value
Catheter interface length	7.6 cm
Catheter	
Outer diameter	2.2 mm (6.5 French)
Inner diameter	0.53 mm
Catheter volume	0.0022 mL/cm
Connector pin inner diameter	0.41 mm
Strain-relief sleeves outer diameter (maximum)	4.1 mm
Catheter to catheter connection (catheter interface to catheter) separation force	>5.0 N
Pump connector to pump separation force	>10.0 N

^a All measurements are approximate

Table 2. Material of components in the Model 8578 sterile package

Component	Material	Material contacts human tissue?	Material contacts drug?
Catheter	Radiopaque silicone	Yes	Yes
Pump connector	Radiopaque silicone	Yes	Yes
	Titanium	Yes	No
	Silicone (external component)	Yes	No
	Nylon	Yes	No
Connector pin	Titanium	Yes	Yes
Strain-relief sleeves	Silicone	Yes	No

Instructions for use

Implanting physicians should be experienced in intrathecal-access procedures and should be thoroughly familiar with all product labeling.

△ Cautions:

To prevent damage to the catheter, which may require additional surgery to repair or replace the catheter:

- Do not twist or stretch the catheter.
- Use only rubber-tipped forceps on the catheter and exercise care when using sharp surgical instruments near the catheter.
- Exercise care when using electrocautery near the catheter.

Positioning the patient

1. Position the patient for easy access to the pump pocket. Position the patient's hips, legs, and arms to avoid pressure points. Drape appropriately.
2. Administer the appropriate anesthesia.

Replacing the pump connector

Disconnecting the catheter from the pump

1. Open the pump pocket incision site.
2. Remove the pump from the pump pocket.
3. Disconnect a sutured connector using the following method:
 - a. Cut the sutures at the pump connector.
 - b. Disconnect the pump connector from the pump.
4. Disconnect a Medtronic sutureless pump connector using the following method:
 - a. If needed, slightly rotate the pump connector so one oval is flush with the front of the pump (Figure 2).

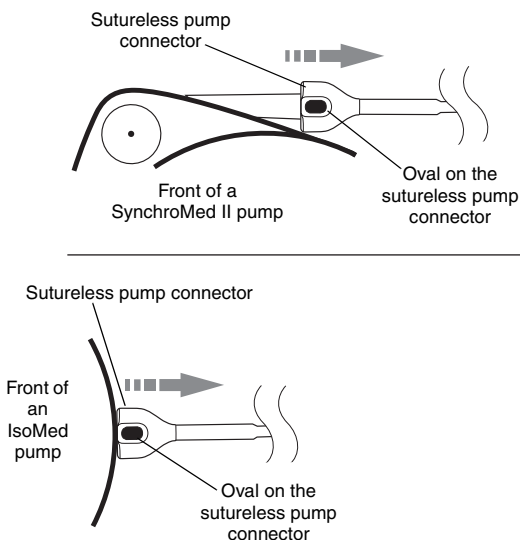


Figure 2. Removing the sutureless pump connector.

- b. Place a thumb and forefinger precisely on the oval marks located on the two flat portions of the connector (Figure 2).

- c. Firmly squeeze the connector to apply pressure precisely on the oval marks.
- d. While squeezing on the ovals, pull the connector off the catheter port.

Note: If the sutureless pump connector is difficult to remove, try one or both of the following methods:

- While squeezing on the ovals, gently rock the connector from side-to-side and slowly pull the connector off the catheter port.
- If finger pressure is inadequate, use a rubber-tipped forceps to carefully apply pressure precisely on the oval marks. While squeezing, pull the connector off the catheter port.

5. Using a rubber-tipped forceps, clamp the catheter to prevent CSF or drug loss. Clamp distal to the location at which the catheter will be cut.
6. Cut the catheter at the desired location to remove the pump connector or catheter interface from the catheter.
7. Save the trimmed catheter (including catheter interface, if applicable) for catheter length measurements and volume calculation.

Connecting the catheter

Warning: Firmly secure all connections. Failure to secure connections can allow drug or cerebrospinal fluid (CSF) leakage into surrounding tissue resulting in tissue damage or a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

1. Slide the strain-relief sleeve, small end first, onto the implanted catheter (Figure 3).

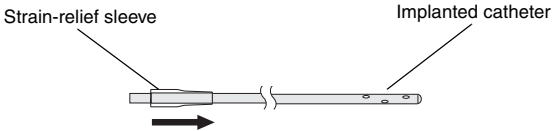


Figure 3. Sliding the strain-relief sleeve onto the implanted catheter.

2. On the catheter interface, grasp the pre-attached strain-relief sleeve near the connector pin and insert the connector pin into the implanted catheter until the catheter is against the connector pin large ring. Be careful not to disrupt the catheter placement in the spine (Figure 4).

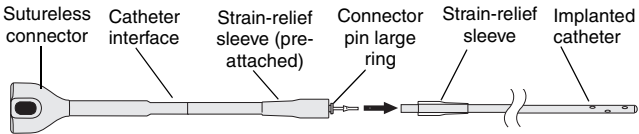


Figure 4. Inserting the connector pin.

3. Unclamp the catheter.
4. Confirm catheter patency by verifying CSF flow through the pump connector.
5. Using rubber-tipped forceps, re-clamp the catheter to prevent further CSF loss.

Note: If the catheter must be removed from the connector pin, grasp the implanted catheter next to the connector pin midsection. Then grasp the midsection of the connector pin with a rubber-tipped forceps and pull or twist the connector pin off of the implanted catheter. **DO NOT pull on the catheter.** Trim the implanted catheter before reconnecting. Save the trimmed catheter for catheter length measurements and volume calculations.

- Slide the catheter strain-relief sleeve onto the connector pin until the strain-relief sleeve snaps into place (Figure 5).

Note: Do not place sutures over the connector pin or strain-relief sleeves.

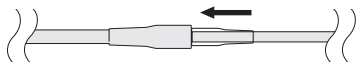


Figure 5. Sliding the strain-relief sleeve onto the connector pin.

Attaching the catheter interface to the pump

- With a thumb and forefinger, grasp the tapered portion of the sutureless pump connector (Figure 6).

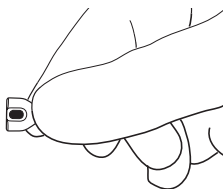


Figure 6. Grasping the tapered portion.

2. At the pump pocket site, position the catheter port of the pump in line with the opening of the sutureless pump connector.

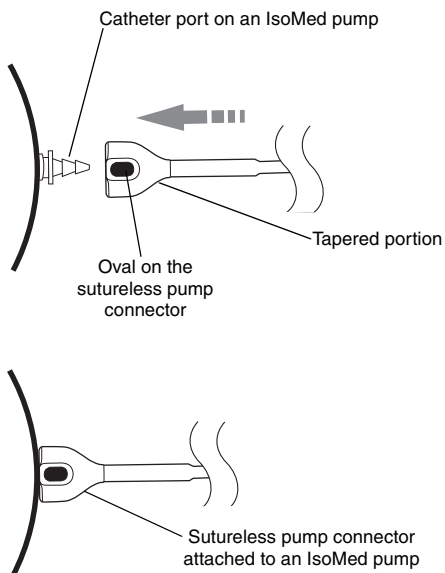
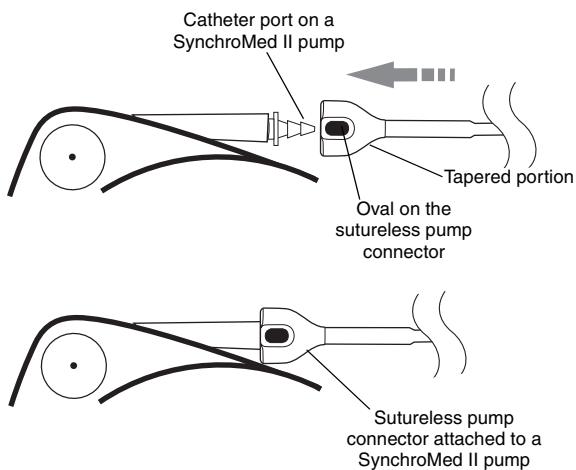


Figure 7. Attaching the sutureless pump connector to the pump.

3. Attach the sutureless pump connector using one of the following methods:

- Method 1

Firmly press the pump connector onto the catheter port until the connector fully covers the catheter port (Figure 7 on page 10). The connector snaps into place.

- Method 2

- a. Firmly squeeze precisely on the oval marks of the pump connector (Figure 7 on page 10).

- b. While squeezing, carefully press the pump connector onto the catheter port until the connector fully covers the catheter port (Figure 7 on page 10). The connector snaps into place.

△ **Cautions:**

- Exercise care when connecting the catheter or pump connector to metal connectors or fittings. These can cut or puncture the catheter or pump connector, requiring additional surgery to repair or replace the damaged component.
- When connecting the catheter to the pump, do not introduce air bubbles into the catheter, which can lead to spinal headache or affect infusion accuracy.

⚠ **Warning:** Firmly secure all connections. Failure to secure connections can allow drug or cerebrospinal fluid (CSF) leakage into surrounding tissue resulting in tissue damage or a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

4. Release the thumb and forefinger.

5. Check that the sutureless pump connector is properly attached by using the following method:

- a. Grasp the tapered portion of the connector (Figure 8).

- b. Tug as if to remove the connector from the pump. The connector should feel firmly attached.

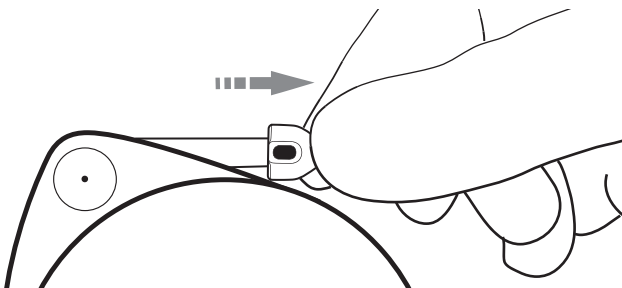


Figure 8. Checking for proper attachment to a SynchroMed II pump.

Notes:

- If the sutureless pump connector does not feel firmly attached:
 - a. Place a thumb and forefinger precisely on the oval marks located on the two flat portions of the connector (Figure 7 on page 10).
 - b. Firmly squeeze the connector to apply pressure precisely on the oval marks.
 - c. While squeezing on the ovals, pull the connector off the catheter port.
 - d. Repeat steps 1-5 of “Attaching the catheter interface to the pump” beginning on page 9.
 - If the sutureless pump connector is difficult to remove, try one or both of the following methods:
 - While squeezing on the ovals, gently rock the connector from side-to-side and slowly pull the connector off the catheter port.
 - If the finger pressure is inadequate, use a rubber-tipped forceps to carefully apply pressure precisely on the oval marks. While squeezing, pull the connector off the catheter port. Be careful not to damage the connector.
 - Do not use additional methods to secure this sutureless pump connector.
6. Unclamp the catheter.
 7. Coil the excess catheter behind the pump and place the pump in the pocket.
 8. Refer to the pump implant manual for additional pump implant instructions.



Caution: Do not coil excess catheter in front of the pump. Coil excess catheter behind the pump to:

- minimize potential damage during pump replacement surgery.
- minimize potential kinking of the catheter.
- prevent damage to the catheter during refill and catheter access procedures.

Calculating catheter length and volume



Warning: Record the exact implanted catheter length, the catheter model number, and the calculated catheter volume in the patient's medical record. In the event of a catheter revision, record the changes made to the catheter length and the calculated catheter volume in the patient's medical records. Catheter measurement information will be required in later calculations. **A universal value does not exist that can be used as a substitute for this knowledge.** Attempting to estimate catheter volume in later calculations can result in a clinically significant or fatal drug underdose or overdose.

Note: If this is a partial catheter replacement, take into consideration the remaining implanted catheter volume when calculating total catheter volume.

1. Measure the removed length of catheter.
2. Record this removed length in the patient's record.
3. Subtract the removed length from the total catheter length.

**(Previously implanted catheter length + newly implanted 7.6 cm catheter interface length)
- trimmed (discarded) length
= total newly implanted catheter length**

4. Multiply the new implanted catheter length by the catheter volume per cm.
5. Record this information in the patient's record.

Example	
Previously implanted catheter length:	89.0 cm
Newly implanted catheter interface length:	7.6 cm
Removed catheter length from patient:	8.0 cm (smaller number)
Catheter volume per cm:	0.0022 mL/cm
Total implanted catheter volume:	
$[(89.0 + 7.6 \text{ cm}) - 8.0 \text{ cm}] \times 0.0022 \text{ mL/cm} =$	0.19492 mL

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