

Safety Notification

Discontinuation of the IsoMed Accessory Kits IsoMed Model 8543 Catheter Access Port (CAP) Kit IsoMed Models 8553 and 8555 Refill Kit

Medtronic

7000 Central Ave NE
Minneapolis, MN 55432
www.medtronic.com

November 2019

Dear Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily issuing a safety notification related to availability of the IsoMed Catheter Access Port (CAP) and Refill Kits. According to Medtronic records, you have purchased at least one of the IsoMed Accessory Kits in the past 3 years.

Issue Description

In 2008, Medtronic communicated the discontinuance of the manufacture of the IsoMed Constant-Flow pump and our support for the implanted products throughout their useful life. As part of that product obsolescence communication, in November 2017 we notified customers of the accessory kit discontinuation for the Model 8543 CAP kit and Model 8553 Refill kit used for the IsoMed pump. Medtronic no longer has inventory for the Model 8543 CAP kit or the Model 8553 refill kit. The inventory for the Model 8555 Refill kit, also used with the IsoMed pump, is expected to be depleted in the next 3-5 months. In order ensure patients implanted with a Medtronic IsoMed drug infusion pump can continue to receive therapy, Medtronic is providing the attached instructions for performing CAP and Refill procedures.

Lack of ability to refill the pump or manage patient therapy due to the unavailability of accessory kits can result in sudden cessation of therapy. Sudden cessation of drug infusion therapy may result in the return of underlying symptoms and/or withdrawal symptoms, which can lead to a life-threatening condition. Medtronic is not aware of any report of an adverse event resulting from lack of the Model 8543, Model 8553, or Model 8555 kits.

Product Scope

This issue affects the IsoMed Accessory Kits:

- Model 8543 CAP Kit - Intended for use in accessing the catheter via the catheter access port of Medtronic IsoMed implantable drug infusion pump
- Models 8553 and 8555 Refill Kit - Intended for use in refilling the Medtronic IsoMed implantable drug infusion pump

Actions

Communicate this information to personnel in your facility that are:

- Responsible for purchasing drug refill kits for Medtronic IsoMed implantable drug infusion pumps
- Responsible for managing patients with a Medtronic IsoMed implantable drug infusion pump

Please complete the enclosed reply form and promptly respond to Medtronic confirming receipt of this notification.

Additional Information

Medtronic is providing notice of this communication to Regulatory Agencies as appropriate. The USFDA may describe this safety notification as a recall on their website. Adverse reactions or quality problems experienced may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by mail, or by fax.

We are committed to patient safety and appreciate your attention to this information. If you have questions regarding this material, please contact your Medtronic Field Representative or Technical Services at 1-800-707-0933 weekdays from 7am-6pm CT.

Sincerely,



Mike Ronningen
Vice President, Quality & Regulatory Affairs

enclosures: Alternative Procedure Information, Customer Confirmation Form

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Instructions for performing an IsoMed Catheter Access Port (CAP) Procedure when an IsoMed Model 8543 CAP Kit is not available

Due to discontinuation of the Model 8543 IsoMed CAP kit, a CAP procedure may be performed using a Medtronic Model 8540 SynchroMed II CAP Kit in conjunction with the noted differences below.

Primary difference: The **TEMPLATE** in the Medtronic Model 8540 SynchroMed II CAP Kit is **NOT compatible** with the IsoMed pump and cannot be used during the CAP procedure. The catheter access port of the IsoMed pump is in a different location than that of the SynchroMed II pump (see Figure 1).

- **Discard the SynchroMed II template provided with the kit.** The SynchroMed II template is not compatible with the IsoMed pump port layout for the Catheter Access Port Procedure.
- Palpate for the elevated side CAP of the IsoMed pump (Figures 1 and 2). The CAP is located on the edge of the pump and is approximately 2.5 cm away from the refill port.

Note: If you have difficulty identifying the pump features, x-ray or fluoroscopy can be used to assist in locating or determining the location of the IsoMed CAP.

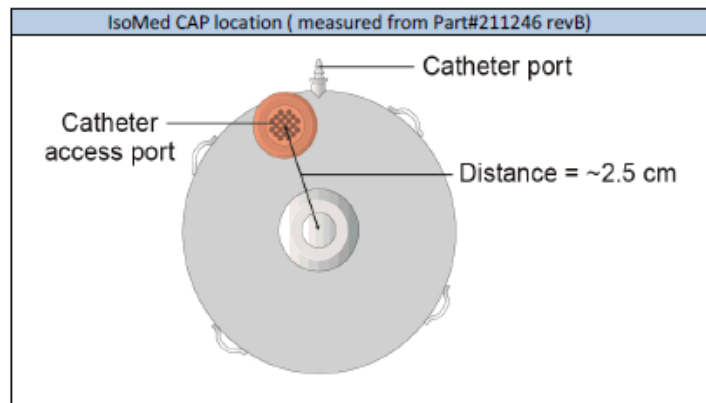


Figure 1: IsoMed Catheter Access Port location

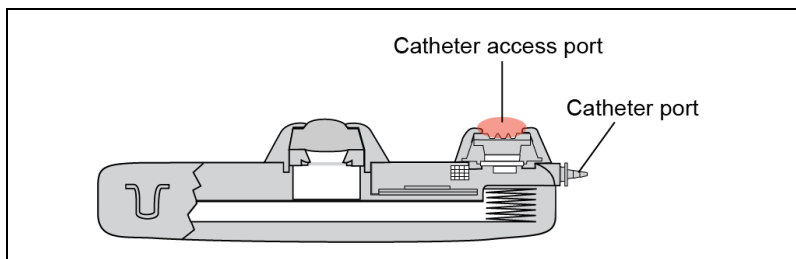


Figure 2: Side profile view – IsoMed pump

**Contact your Medtronic Representative for further information or
Medtronic Tech Services 1-800-707-0933 weekdays from 7am-6pm CT**

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Instructions for performing an IsoMed Refill Procedure when an IsoMed Model 8553 or 8555 Refill Kit is not available

Due to discontinuation of the Medtronic IsoMed Model 8533 and 8555 Refill kits, a refill procedure may be performed using a Medtronic Model 8551 SynchroMed II Refill Kit in conjunction with the noted differences below.

Preparation:

- Order a Medtronic Model 8551 SynchroMed II Refill Kit
- When ordering drug from the pharmacy or preparing the drug for refill, ensure it is contained in 10 mL syringes

Primary differences: The pump reservoir of IsoMed pump is under significant pressure compared to the SynchroMed II pump. The extension set in the Medtronic Model 8551 refill kit has a clamp, but does not have a Y-connector, and is not designed to prevent reservoir backflow. The clamp must be securely closed when changing refill syringes.

- When performing the refill procedure, use a 10-mL syringe. Use of a 20-mL syringe or larger is not recommended due to the increased pressure in the IsoMed reservoir.
- Place the template on the skin over the pump and align the refill template correctly (see picture below) . Align the rounded edges of the template with the edges of the pump. Use the center circle of the template to insert the needle into the reservoir fill port.
- During the procedure, ensure the clamp is properly aligned and engaged while changing syringes. Hold firm pressure on the syringe plunger when the clamp is not engaged. Confirm needle proper position before starting each injection.



See attached Supplemental Information for the IsoMed Refill procedure

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Supplemental Information IsoMed-Specific Warnings and Calculations when performing an IsoMed Refill Procedure when an IsoMed Model 8553 or 8555 Refill Kit is not available

This information is intended as a supplement for an IsoMed Refill Procedure while using a Medtronic Model 8551 SynchroMed II Refill Kit.

Warnings

During Refill: With IsoMed pumps, inserting the needle at the edge of the reservoir fill port may result in a pocket fill. Pocket fill can result in significant tissue damage or a loss of or change in symptom control, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose. Excessive resistance may indicate that the needle is improperly positioned. Do not force the needle excessively. Forcing the needle excessively may cause damage to the pump and needle, and cause injury to the patient.

Overpressurization (IsoMed Pumps): Do not overfill the pump reservoir. Overfilling the pump reservoir can result in overpressurization and overinfusion. Overinfusion can lead to a clinically significant or fatal drug overdose. Overpressurization can damage the pump. To prevent overfilling:

- Always identify the pump model and reservoir volume before filling or refilling;
- Always empty the pump reservoir completely before filling or refilling; and
- Do not exceed the maximum reservoir volume indicated in the pump labeling.

Note: When performing the refill procedure, use a 10-mL syringe. Use of a 20-mL syringe or larger is not recommended due to the increased pressure in the IsoMed reservoir.

Pump reservoir pressure (IsoMed Pumps): Do not use an open syringe when emptying the pump. The pump reservoir contents are under significant pressure and can eject through an open syringe when emptying the pump. Ejection of pump contents under pressure can result in procedural delays and a potential risk to the clinician or patient.

Note: When performing the refill procedure, use a 10-mL syringe. Use of a 20-mL syringe or larger is not recommended due to the increased pressure in the IsoMed reservoir.

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Calculations for IsoMed Pumps

Note: Flow rate is affected by changes in altitude and temperature. The viscosity of the infusion solution as well as the arterial pressure at the location of the catheter tip in vascular applications can also affect flow rate. Refer to “Calculating flow rate” on page 8, to determine the significance of the change.

Scheduling a refill

A refill appointment should be scheduled with your patient. Before scheduling the appointment, calculate the number of days before the reservoir will need to be refilled (Refill Interval).

 **Caution:** At refill the pump should contain at least 2 mL of fluid. The flow rate of the pump decreases rapidly and stops as the volume in the reservoir decreases from 2 mL to 0 mL. This can result in the potential loss of therapeutic effect or drug withdrawal symptoms.

1. Calculate the refill interval.

$$\frac{\text{Fill Volume (mL)} - 2 \text{ mL}}{\text{Flow rate (mL/day)}} = \text{Refill interval (days)}$$

Example:

Fill Volume: 20 mL
Flow rate: 0.5 mL/day

$$\frac{20 \text{ mL} - 2 \text{ mL}}{0.5 \text{ mL/day}} = 36 \text{ days}$$

Note: The patient should be scheduled to return within 36 days.

2. Schedule the refill appointment with your patient.

Calculating the time required for the drug to advance to the catheter tip

When the pump is emptied and refilled with a change in concentration or a change in solution, it is important to calculate the time required for the new solution to advance to the catheter tip. The time required for the new solution to advance from the reservoir to the catheter tip is calculated based upon the volume of fluid in the implanted catheter and pump tubing. Four values are needed for the calculation: catheter volume per length, implanted catheter length, pump internal volume, and flow rate.

1. Calculate the flow rate in $\mu\text{L}/\text{hour}$.

$$\frac{\text{Flow Rate (mL/day)} \times 1000 \mu\text{L/mL}}{24 \text{ hours/day}} = \text{Flow Rate } (\mu\text{L}/\text{hour})$$

2. Calculate implanted catheter volume in μL .

$$\begin{array}{l} \text{Implanted} \\ \text{Catheter} \\ \text{Length} \\ \\ (\text{cm}) \end{array} \times \begin{array}{l} \text{Catheter} \\ \text{Volume per} \\ \text{Length} \\ \\ (\mu\text{L}/\text{cm}) \end{array} = \begin{array}{l} \text{Implanted} \\ \text{Catheter} \\ \text{Volume} \\ \\ (\mu\text{L}) \end{array}$$

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3. Calculate the time required for drug to advance to the catheter tip in hours.

$$\frac{\text{Implanted Catheter Volume } (\mu\text{L}) + \text{Pump Internal Volume } (\mu\text{L})}{\text{Flow Rate } (\mu\text{L}/\text{hour})} = \text{Time Required for Drug to Advance (Hours)}$$

Example:

Pump Model Number: 8472-20-10

Labeled Flow Rate: 1.0 mL/day

Pump Internal Volume: 300 μL

Implanted Catheter Length: 65 cm

Catheter Model Number: 8711

Catheter Volume: 2.22 $\mu\text{L}/\text{cm}$

- $\frac{1.0 \text{ mL/day} \times 1000 \mu\text{L/mL}}{24 \text{ hours/day}} = 42 \mu\text{L}/\text{hour}$
- $65 \text{ cm} \times 2.22 \mu\text{L}/\text{cm} = 144 \mu\text{L}$
- $\frac{144 \mu\text{L} + 300 \mu\text{L}}{42 \mu\text{L}/\text{hour}} = 10.5 \text{ hours}$

Note: The pump internal volume (internal tubing volume) for all models of the IsoMed pump is 300 μL .

Calculating flow rate

The actual flow rate of the IsoMed pump may vary from the labeled flow rate due to different environmental conditions, drug therapies, and routes of administration. The flow rate is affected by changes in altitude and temperature. The viscosity of the drug solution and the body fluid pressure at site of delivery also affect flow rate.

- For intrathecal applications, the average clinically measured flow rate accuracy was 99% of the labeled flow rate (90% confidence interval of 96-100%) for intrathecal delivery of analgesics (106 patients).
- For intravascular applications, the average clinically measured flow rate accuracy was 91% of the labeled flow rate (90% confidence interval of 88-91%) for intrahepatic arterial delivery of chemotherapy with 1000 units/mL of heparin (67 patients).

If the patient will be exposed to environmental conditions that differ from typical conditions of use, or if the patient or therapy requires precise knowledge of the labeled flow rate, refer to "Flow Rate Accuracy" in the pump technical manual to determine the impact of these variables on the flow rate.

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Calculating infusion solution

The infusion solution consists of the drug and sterile saline, mixed or diluted according to the procedure that follows.

1. Calculate the number of days until the pump is empty.

$$\frac{\text{Reservoir Volume (mL)}}{\text{Flow Rate (mL/day)}} = \text{Days Until Pump is Empty (days)}$$

2. Calculate the amount of drug required in mg.

$$\begin{array}{r} \text{Days Until} \\ \text{Pump is} \\ \text{Empty} \\ \text{(days)} \end{array} \times \begin{array}{r} \text{Prescribed} \\ \text{Daily Drug} \\ \text{Dose} \\ \text{(mg/day)} \end{array} = \begin{array}{r} \text{Amount of} \\ \text{Drug} \\ \text{Required} \\ \text{(mg)} \end{array}$$

3. Calculate volume of drug required in mL.

$$\frac{\text{Amount of Drug Required (mg)}}{\text{Drug Concentration (mg/mL)}} = \text{Volume of Drug Required (mL)}$$

4. Calculate the volume of sterile saline required in mL.

$$\begin{array}{r} \text{Reservoir} \\ \text{Volume} \\ \text{(mL)} \end{array} - \begin{array}{r} \text{Volume of} \\ \text{Drug} \\ \text{Required} \\ \text{(mL)} \end{array} = \begin{array}{r} \text{Volume of} \\ \text{Sterile Saline} \\ \text{Required} \\ \text{(mL)} \end{array}$$

Example:

Pump Model Number: 8472-20-10

Labeled Flow Rate: 1.0 mL/day

Reservoir Volume: 20 mL

Prescribed Drug: Morphine

Prescribed Daily Drug Dose: 4.0 mg/day

Drug Concentration: 10 mg/mL

$$1. \quad \frac{20 \text{ mL}}{1.0 \text{ mL/day}} = 20 \text{ days}$$

$$2. \quad 20 \text{ days} \times 4.0 \text{ mg/day} = 80 \text{ mg of morphine}$$

$$3. \quad \frac{80 \text{ mg}}{10 \text{ mg/mL}} = 8 \text{ mL of } 10 \text{ mg/mL morphine}$$

$$4. \quad 20 \text{ mL} - 8 \text{ mL} = 12 \text{ mL of sterile saline}$$

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Calculating IsoMed pump flow rate accuracy

If the actual volume withdrawn when emptying the pump varies significantly from the expected volume, verify that the Refill Interval has not been exceeded and calculate the flow rate accuracy. If the flow rate accuracy differs significantly from the expected (labeled) rate, taking into consideration the environmental and therapy factors that may affect the flow rate, contact your Medtronic Representative.

Calculate the flow rate accuracy according to the procedure that follows.

1. Calculate the expected dispensed volume in mL.

$$\begin{array}{rclcl} \text{Days} & & & & \text{Expected} \\ \text{Since} & \times & \text{Flow Rate} & = & \text{Dispensed} \\ \text{Refill} & & \text{(mL/day)} & & \text{Volume} \\ \text{(days)} & & & & \text{(mL)} \end{array}$$

2. Calculate the expected volume in mL.

$$\begin{array}{rclcl} \text{Refill} & & \text{Expected} & & \\ \text{Volume} & - & \text{Dispensed} & = & \text{Expected} \\ \text{(mL)} & & \text{Volume} & & \text{Volume} \\ & & \text{(mL)} & & \text{(mL)} \end{array}$$

3. Calculate the flow rate accuracy.

$$\begin{array}{rclcl} \text{Refill} & & \text{Actual} & & \text{Flow} \\ \text{Volume} & - & \text{Volume} & \times 100 & \text{Rate} \\ \text{(mL)} & & \text{(mL)} & & \text{Accuracy} \\ & & & & \text{(\%)} \\ \hline \text{Refill} & & \text{Expected} & & \\ \text{Volume} & - & \text{Volume} & & \\ \text{(mL)} & & \text{(mL)} & & \end{array}$$

Example: Underinfusion

Actual Volume: 12mL

Days Since Refill: 16 days

Refill Volume: 20 mL

Flow Rate: 1.0 mL/day

1. $16 \text{ days} \times 1.0 \text{ mL/day} = 16 \text{ mL}$
2. $20 \text{ mL} - 16 \text{ mL} = 4 \text{ mL}$
3. $\frac{20 \text{ mL} - 12 \text{ mL}}{20 \text{ mL} - 4 \text{ mL}} \times 100 = 50\%$

Example: Overinfusion

Actual Volume: 4mL

Days Since Refill: 10 days

Refill Volume: 20 mL

Flow Rate: 1.0 mL/day

1. $10 \text{ days} \times 1.0 \text{ mL/day} = 10 \text{ mL}$
2. $20 \text{ mL} - 10 \text{ mL} = 10 \text{ mL}$
3. $\frac{20 \text{ mL} - 4 \text{ mL}}{20 \text{ mL} - 10 \text{ mL}} \times 100 = 160\%$