

Replacing a SynchroMed™ II pump

Priming option on table



SynchroMed™ II, Ascenda™, tablet and communicator

This document is aimed at describing the different steps enabling the replacement and programming of a SynchroMed™ II pump.

Before replacing a SynchroMed™ II pump, make sure you have all of the following elements:

- 1 CT900 tablet with SynchroMed™ II A810 application
- 1 8880T2 communicator and its cable
- 1 SynchroMed™ II pump, reference 8637-20 or 8637-40
- Potential Catheter Revision kit, reference 8782 or 8784

Material to prepare if a catheter change is required during the procedure (full or partial replacement or cutting of catheter):

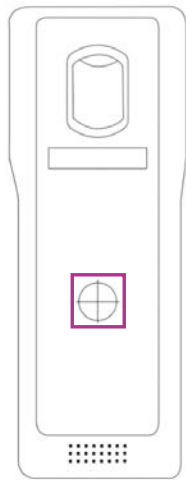
- 1 catheter, reference Ascenda™ 8781 or 8780
- 1 tunneler, reference 8583-38
- Potential Revision kit, reference 8596SC or 8598A

Note: Remember to keep the labels in the boxes to ensure traceability. Prepare the ID card present in the pump box for the patient.

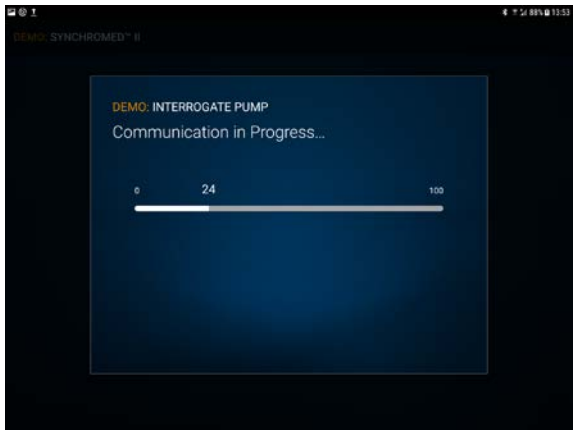
Steps preoperative

1 Interrogate the implanted SynchroMed™ II pump:

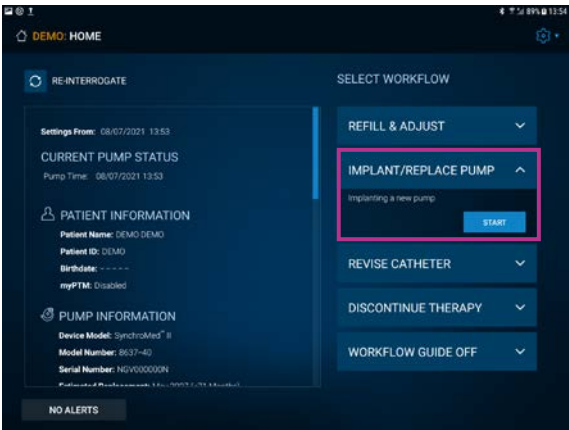
- Select the SynchroMed™ II application on the CT900 doctor's tablet.
- Turn on the communicator and place it above the pump (put the target located on the front of the communicator above the pump on the patient's abdomen). Select **CONNECT**. The programmer communicates with the pump. From the welcome screen, select workflow **IMPLANT/REPLACE PUMP** and click on **START**.



- Select the SynchroMed™ II application on the tablet. Place the communicator above the pump and select **CONNECT**.



- The communicator communicates with the pump.

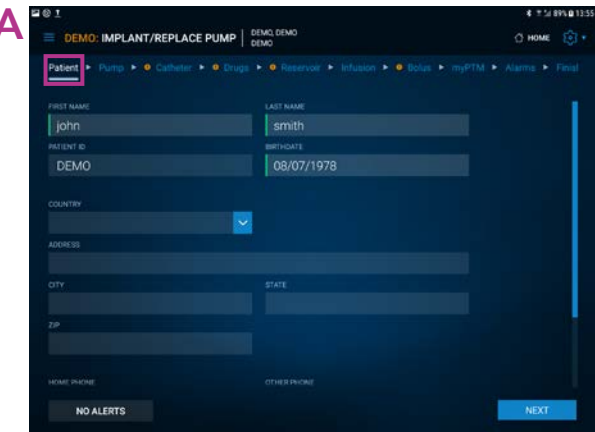


- Go to the **IMPLANT/REPLACE PUMP** workflow then click on **START**.

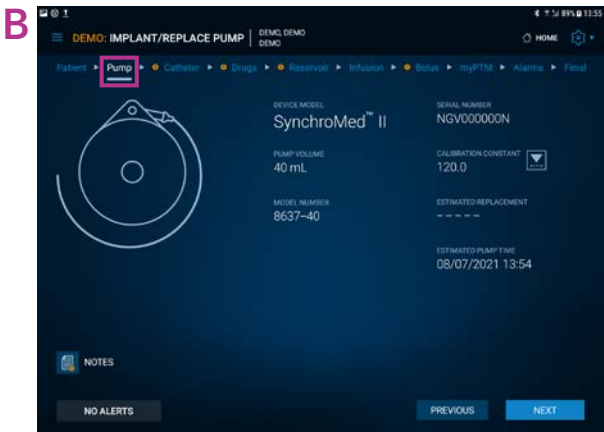
Steps preoperative (continued)

Workflow contents and information to be completed

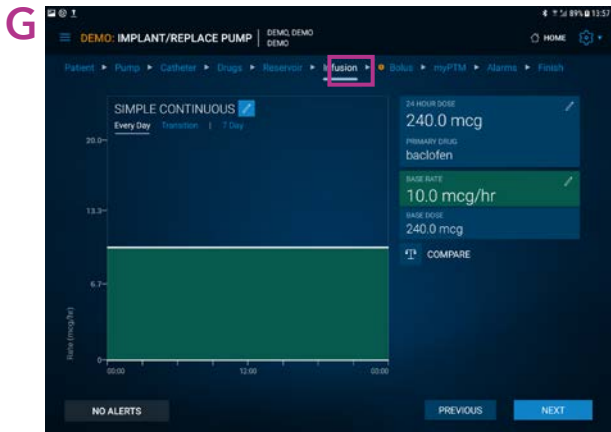
Recover all data present in the different tabs below (screencaps or tab content notes):



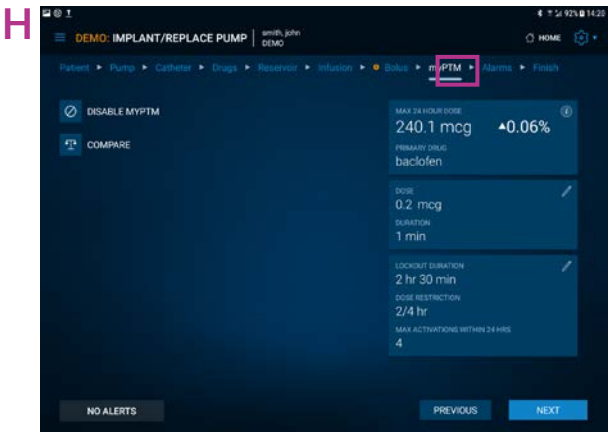
- Patient identity



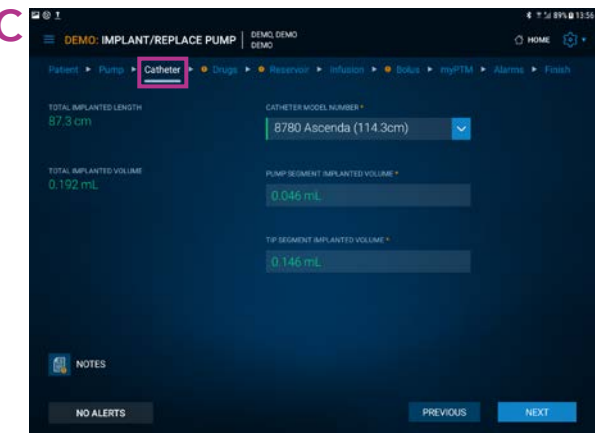
- Pump: volume 20 ml or 40 ml



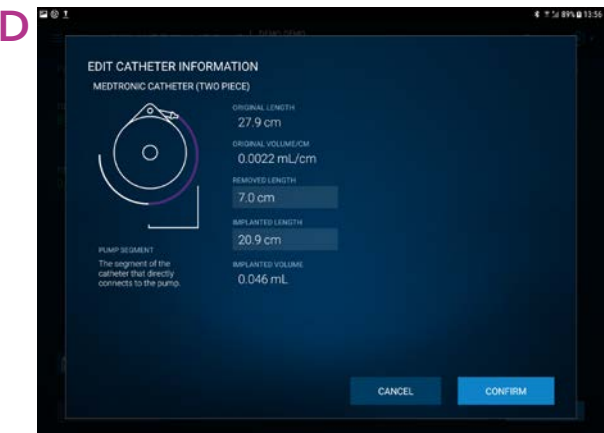
- Infusion: medication dose in single or modular continuous mode



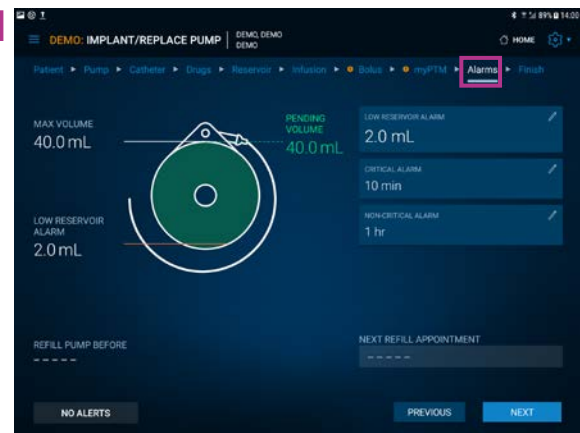
- If the myPTM™ patient remote control is activated, recover the myPTM™ tab information.



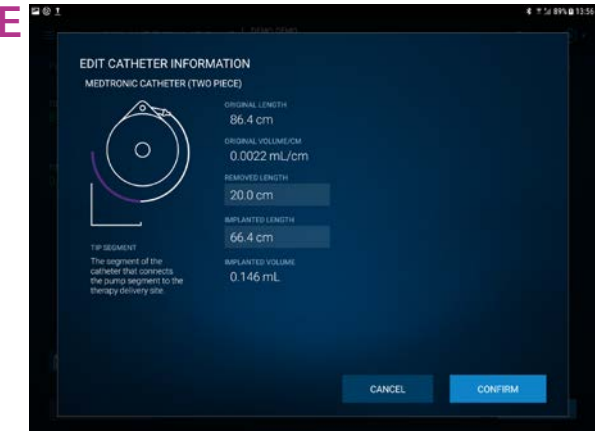
- Catheter: model



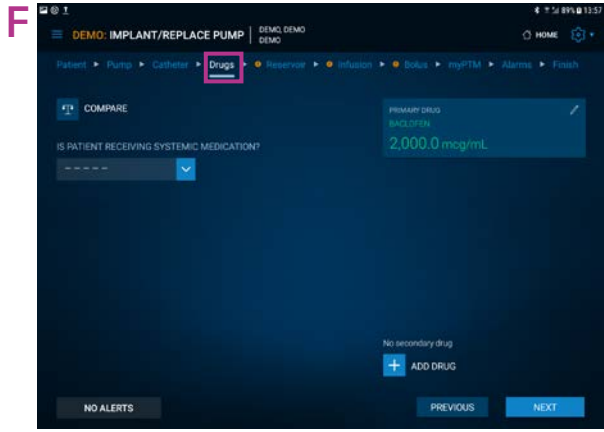
- Catheter: length of pump segment



- Alarms: Low reservoir alarm. Please click on next or on the HOME button



- Catheter: length of spinal segment

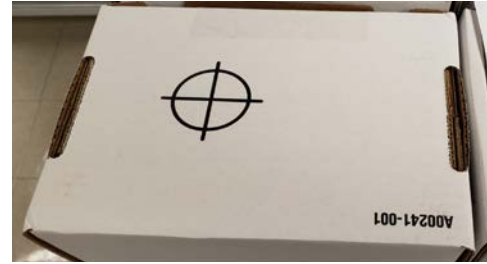


- Medication: name and concentration
- Save information and exit screen

Steps preimplant

2 Preparing the new SynchroMed™ II pump for implant:

- Interrogate the new pump while still packaged, by positioning the switched-on communicator on the target appearing on the pump packaging.
- Check an alert appears "**pump in Shelf Mode**".
- Select **IMPLANT/REPLACE PUMP**.
- Go to the PUMP tab and check:
 - The calibration constant, which must correspond to the one displayed on the pump packaging.
 - Pump volume: 20 ml or 40 ml.
 - The pump serial number: it must correspond to the serial number affixed to the one displayed on the pump packaging.
- Program the new pump with all data recovered (patient, pump, catheter, medications, infusion, alarm) and leave the programming session open.



Steps intraoperative

1 Preparing the new pump in a new sterile field

1. Open the sterile pump package and remove the pump.
2. Remove the protective cap from the catheter port (a small amount of water may be present in the protective cap).

A Emptying the pump

1. Assemble the 22 G (black) noncoring needle and the empty syringe.
2. Insert the needle into the reservoir filling port until the needle touches the metal needle stop.
3. Aspirate the sterile water from the pump into an empty syringe.
Note: if the volume of fluid in the reservoir is greater than the volume of the syringe used for emptying, remove the full syringe and the needle. Attach an empty syringe and a needle and repeat until the pump reservoir is empty.
4. Empty the pump reservoir until air bubbles no longer appear in the syringe, ensuring all water and air is removed from the pump reservoir. The volume to be emptied is approximately 17.5 ml for the 8637-20 model and 37.5 ml for the 8637-40 model.
5. Remove the syringe and needle from the reservoir filling port.

B Filling the pump

1. Attach the filter to the syringe containing the prescribed medication.
2. Attach the black 22 G needle to the syringe containing the prescribed medication and the filter, and empty the air from the fluid pathway.
3. Read the actual filling volume on the syringe.
4. Insert the needle in the reservoir filling port and slowly inject the prescribed liquid into the pump reservoir: 1 ml every 3 seconds.
5. When filling is complete, remove the needle from the reservoir filling port.

C Flushing the catheter access port

1. Flush the catheter access port using a 24 G (purple) noncoring needle and a syringe filled with 1 ml to 2 ml of saline solution until fluid can be seen at the catheter port.

Steps intraoperative (continued)

2 System priming options

There are two possible ways of replacing an implanted pump:

A The contents of the catheter in situ are aspirated or the catheter is replaced


The situation is similar to a first implantation. After the catheter has been aspirated, the new pump is implanted and you can program a post-operative priming bolus to advance the medication from the reservoir to the catheter tip.

If the catheter data is unknown, there is a risk of withdrawal or overdose. In this case it is preferable to prime the pump before implantation (see Step B).


B The catheter is left in place but its contents are not aspirated or the length data for this data is unknown

The pump internal tubing prime must be complete before attaching the catheter to the pump. If not, the medication present in the catheter is bolused into the intrathecal space, causing a risk of overdose.

Use a priming bolus of 0.300 ml to fill the pump tubing with the medication before connecting the catheter and implanting the pump. This step requires at least 19 minutes.

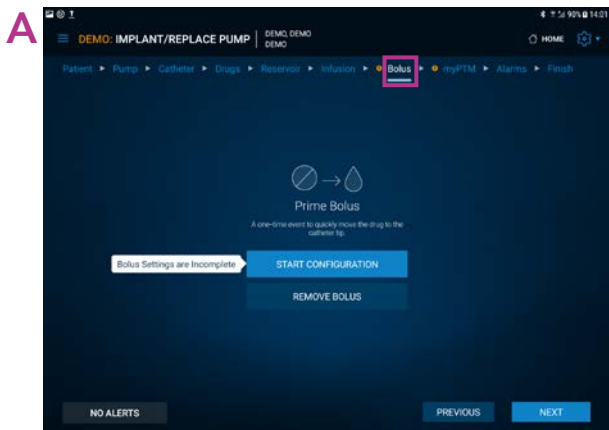
 For this procedure (content not aspirated) please refer to the document "Replacing SynchroMed™ II pump priming option following catheter aspiration"

3 Priming the pump if "the catheter has not been replaced or aspirated"

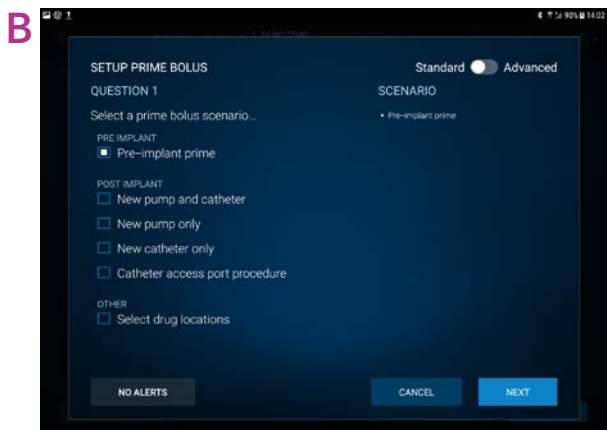
 The tubing of the new pump must be primed on the table before connecting the catheter and implanting the pump.
Do not program a post-operative priming bolus after connecting the catheter to the pump.
Programming a post-operative priming bolus in these conditions may cause a clinically severe or even fatal overdose.

Priming the new pump on the table:

- Position the communicator over the new filled pump on the table.
- Start programming with the data collected from the old pump and complete the tabs (patients, pump, catheter, medication, reservoir, infusion), then go to the BOLUS tab and follow the steps below:

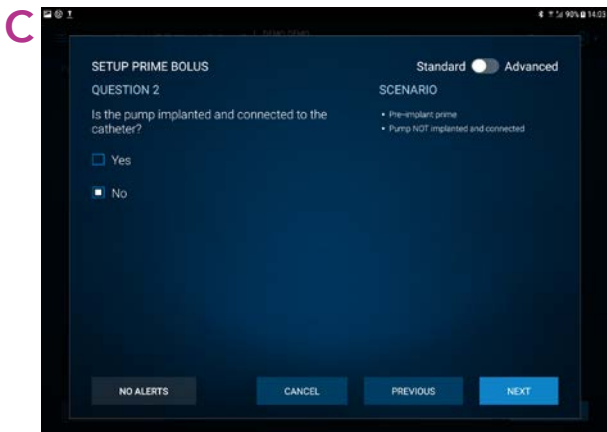


- Start the configuration of the priming bolus.



- Answer the question on the screen and click on **NEXT**.

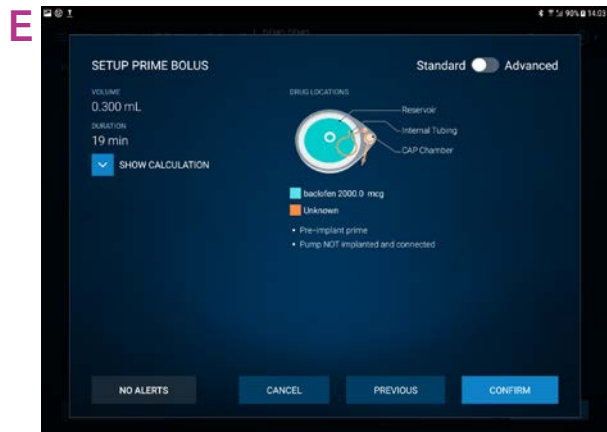
Steps intraoperative (continued)



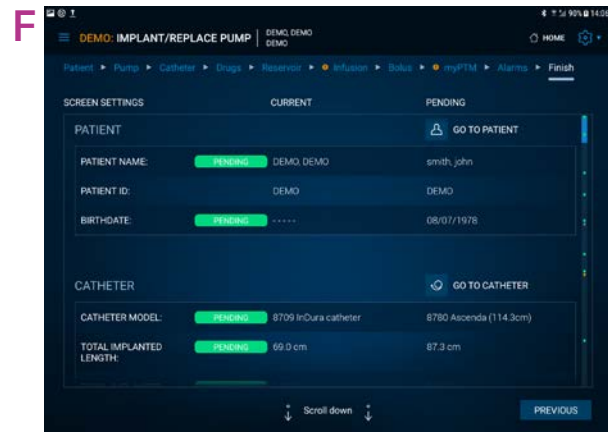
- Answer the question on the screen and click on **NEXT**.



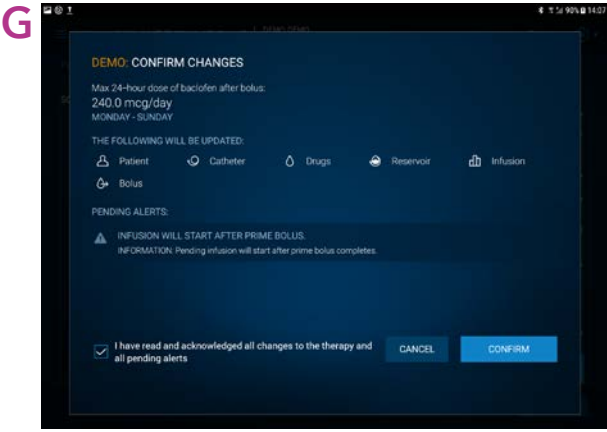
- Check medication location, then click on **NEXT**.



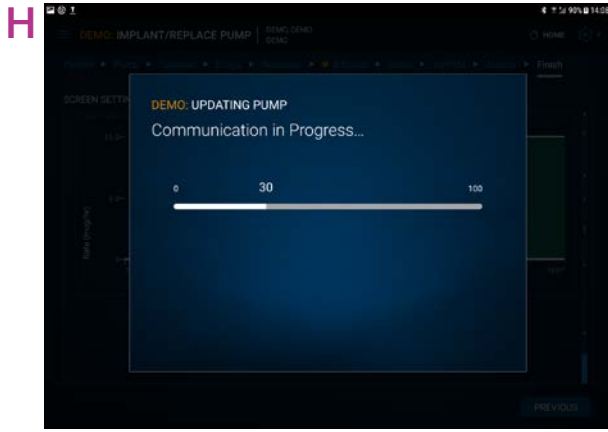
- Check the calculated values for the priming bolus, then click on **CONFIRM**.



- Go to the "Finish" tab and check the prescription and programming data.



- Confirm changes. Select and update

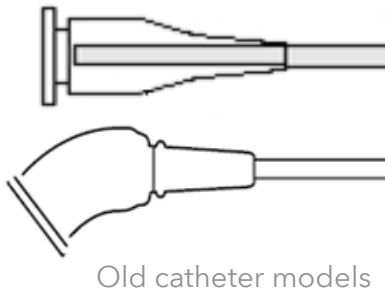


- Wait for 19 minutes, the end of the priming bolus on the table, before connecting the new pump to the catheter.

4 Explantation of the old pump

1. Disconnect the implanted catheter from the pump.

- **If the catheter connector has stitching** (old catheter models), see photos opposite: Remove the stitching of the catheter connector and disconnect the implanted catheter pump. Check the condition of the connector.



Old catheter models

- **If the catheter connection does not have stitching** (more recent catheter models), see photo opposite: Grip the tapered part of the pump connector without stitching (oval metal parts) with your thumb and index finger, and disconnect the catheter.



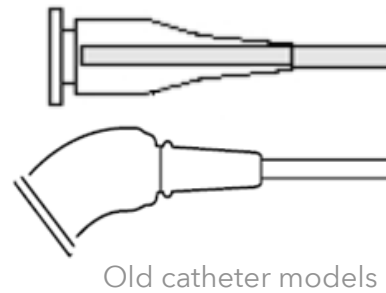
Catheter Ascenda

Steps intraoperative (continued)

5 Attaching the new pump to the catheter

Connect the new pump to the catheter.

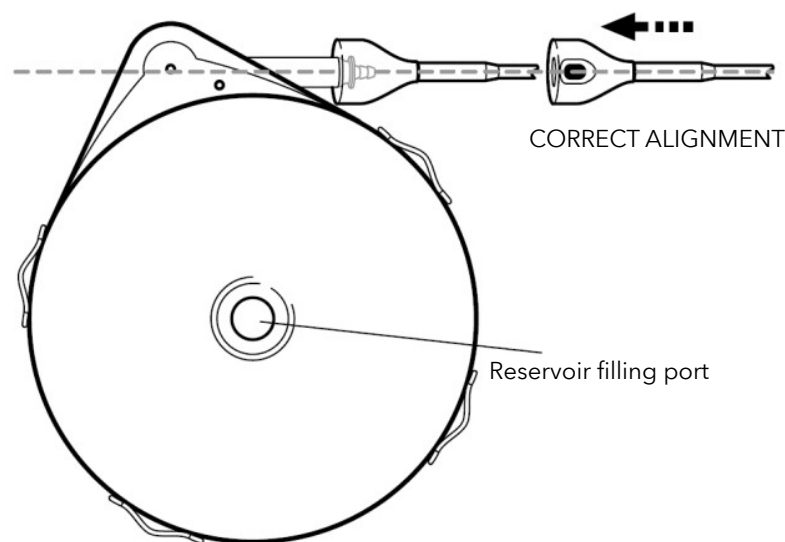
- **If the connector has stitching**
(old catheter models, see photos opposite) :
Reposition the connector on the port of the new pump.
Follow the non-reabsorbable solid stitching in the groove located at the base of the pump connector.
- **If the connector does not have stitching**
(more recent catheter models, see photo opposite) :
Connect the catheter to the new pump by placing your thumb and index finger on the gray oval marks.
Check that the pump connector is attached correctly: by pulling and detaching the pump connector by rotating the pump connector at least 90° to the right and to the left.



Old catheter models



Catheter Ascenda



6 Placing the new pump:

1. Place the pump in the pocket so that:

- the reservoir filling port is oriented towards the front, and this filling port and the catheter access port will be easy to palpate after implantation.
- no skin sutures are made directly over the reservoir filling port or the catheter access port.
- the catheter is not kinked or twisted and is well away from the pump ports.

2. Suture the pump in the subcutaneous pocket using the following steps:

- Suture first to the fascia in the bottom of the subcutaneous pocket.
- Use these two sutures and the lower suture loops on the pump to draw the pump into the pocket.
- Tie the sutures.
- Suture the remaining two loops at the top of the pump pocket.
- Tie the sutures, securing the pump into the pocket.

3. Interrogate the pump pocket.

4. Close the incision per normal procedure and apply dressing.

i Do not reprogram at the end of the procedure

Notes

Notes

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu. For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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