EN

Thala SubQ Pump
Instructions for Use

Thala SubQ Pump is a mechanical infusion pump that works independently from main power supplies or batteries, enabling Thalassemia therapy to be carried out in an ambulatory manner. Any Luer Lock tip syringe regardless of the manufacturer could be used with the pump. The flow rate is determined by the Flobot Flow Regulator provided in the packaging.

Indications for Use:
The Thala SubQ Pump is intended for subcutaneous delivery of medications indicated for the treatment of Thalassemia.

Warnings:
- For subcutaneous use only.
- Discard if packaging is not intact.
- Use only Luer Lock tip plastic syringe of size indicated on the pump.
- Do not fill the syringe with medications exceeding the volume indicated on the pump.
- Only use Flobot Flow Regulator provided in the package. Do not use other means of flow regulation.
- Before inserting the syringe into Thala SubQ Pump, ensure that
  - Flobot Flow Regulator and subcutaneous infusion set are properly connected to the syringe.
  - On/Off clamps on subcutaneous infusion set are closed.
- Do not remove syringe from pump or disconnect tubing after use.
- Do not re-use to avoid contamination.
- Discard the device in accordance with local regulations.

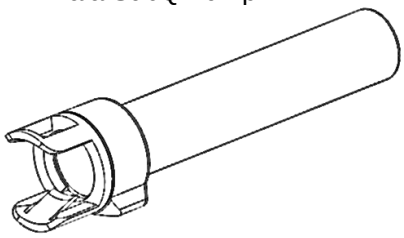
Cautions:
- U.S. Federal Law restricts this device to sale by or on the order of a physician.
- The subcutaneous infusion set (not provided with the pump) should be used as per manufacturer's instruction.
- Follow your healthcare provider's instruction for the location and number of infusion sites.
- Always follow infusion instructions found in labeling of medications.
- The system has a flow rate accuracy of ±15% from labeled flow rate.
- The accuracy of the system is calibrated at room temperature 22.5°C using normal saline 0.9% NaCl. Factors that can influence the flow rate accuracy are:
  - Medication viscosity. Higher medication viscosity will result in slower flow rate and vice versa.
  - Temperature. Higher environment temperature will result in faster flow rate and vice versa.
- The priming volume of subcutaneous infusion set affects priming time. In general, smaller needle gauge, less infusion sites, and shorter tubing length will result faster priming time and vice versa.

Contraindications:
- Delivery of insulin.
- Infusion through routes other than subcutaneous.
- Medication to be prepared is contraindicated to ABS, PVC, and silicone.

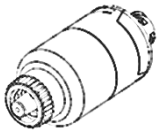
Complications:
Common complications associated with the use Thala SubQ Pump are:
- Subcutaneous needle related complications. (Skin irritation, tissue redness or swelling)

Each package contains:

1x Thala SubQ Pump

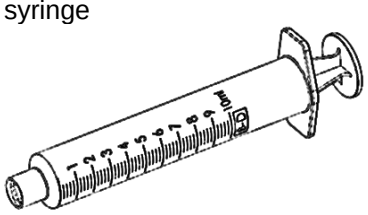


1x Flobot Flow Regulator

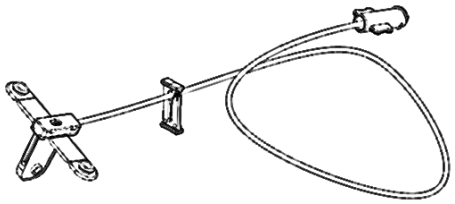


You will need the following devices: (Not provided with the pump)

1x Single use Luer Lock tip plastic syringe



1x Subcutaneous Infusion Set



780108 Rev.01 / Date of issue: 2021-05-06

Step-by-Step Instructions:

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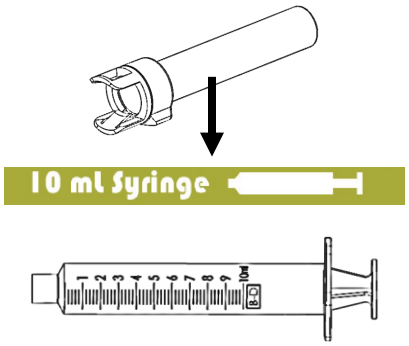
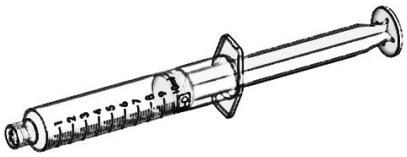
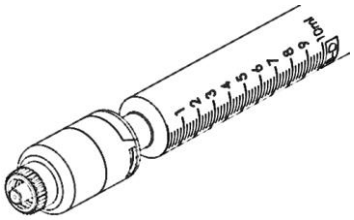
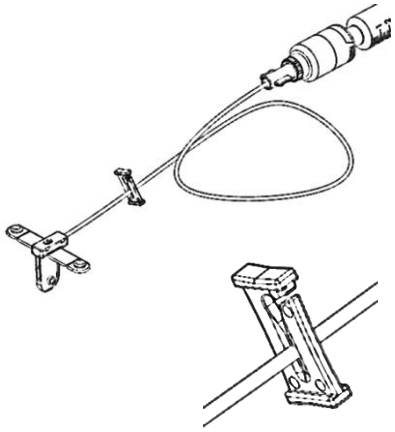
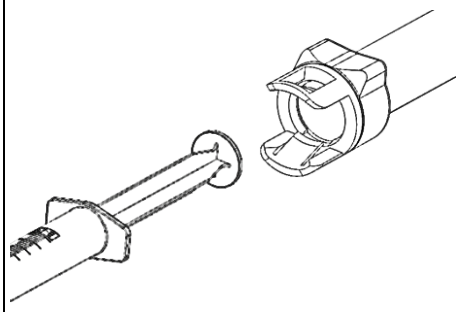
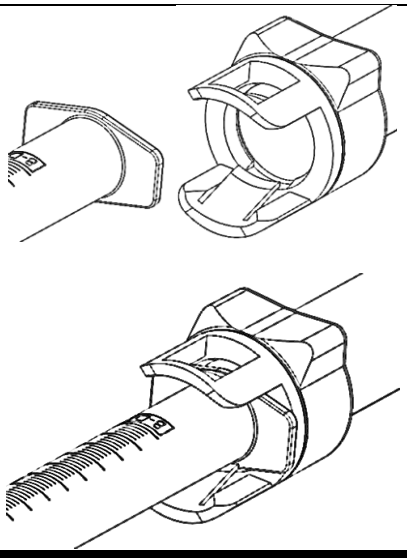
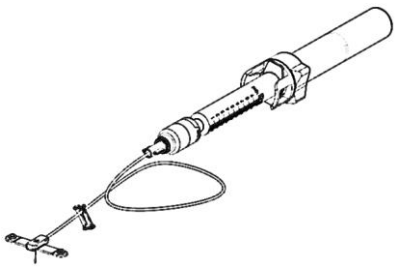
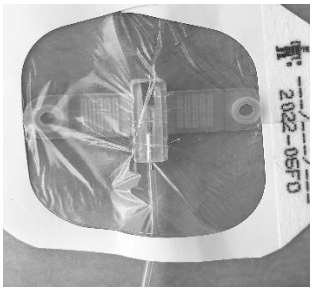
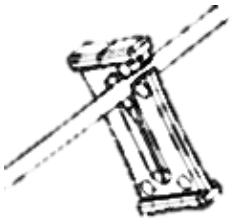
<tr><td> 
</td><td>  </td><td>  </td></tr>
<tr><td>STEP 1</td><td>STEP 2</td><td>STEP 3</td></tr>
<tr><td>Select a single-use Luer Lock tip syringe of correct size indicated on the pump.</td><td>Fill the syringe with medication to be infused.
Do not fill exceeding the maximum scale on syringe.</td><td>Connect the Flobot Flow Regulator to the syringe.</td></tr>
<tr><td>  </td><td>  </td><td>  </td></tr>
<tr><td>STEP 4</td><td>STEP 5</td><td>STEP 6</td></tr>
<tr><td>Connect the subcutaneous infusion set to the Flobot Flow Regulator.
Close the ON/OFF clamp on subcutaneous infusion set.</td><td>Push the plunger of the syringe against the opening of Thala SubQ Pump.</td><td>Ensure the syringe flange is oriented according to the indication on the pump.
Keep pushing the syringe plunger into the pump until a click sound indicates that the flange is locked securely with the pump.</td></tr>
<tr><td>  </td><td>  </td><td>  </td></tr>
<tr><td>STEP 7</td><td>STEP 8</td><td>STEP 9</td></tr>
<tr><td>Follow your healthcare provider’s instruction for priming.</td><td>Follow your healthcare provider’s instruction for the preparation of infusion sites.
Refer to the subcutaneous infusion set’s instruction manual for the proper use.</td><td>Open the On/Off clamp on subcutaneous infusion set to start the infusion.
Place the device on a flat surface or use an appropriate carrying means during infusion.</td></tr>
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