**EN** For use with the Equil Patch Insulin Pump System

IT Da utilizzare con la pompa adesi per insulina Equil

FR Pour une utilization avec le système de pompe à insuline Equil Patch

GE Zur Verwendung mit dem Equil Patch Insulinpumpensystem

FI Käytä Equil-insuliinipumppujärjestelmän kanssa

SV För användning med Equil Patch Insulinpumpsystem

ES Para su uso con el Sistema Equil de Bomba de Parche de Insulina

# **Infusion Set**

Set infusione / Set de Perfusion / Infusionsset / Infusiosarja / Infusionsset / Conjunto de Infusión

HRN-S-60 / HRN-S-90



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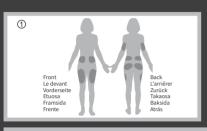
EC REP Lotus Global Co., Ltd. 1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG, United Kingdom

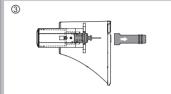






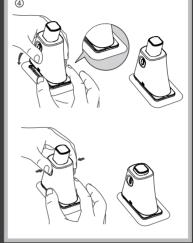


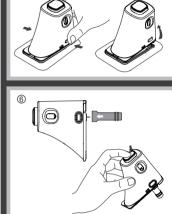




1001-PMTI-066 V02







#### **English**



#### O Note

This insert is only applies to the use of the soft cannula style infusion set.

Product Name: Insulin Infusion Set Type: Soft Cannula and Pump Base REF: MTM-4, HRN-S-60 / HRN-S-90

Shelf Life: 3 years

Manufacturer Date: Check label on box

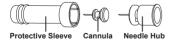
#### 1. Part Names

Cannula Package:HRN-S-60、HRN-S-90 Pump Base: MTM-4

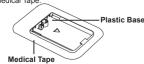
Naming Convention: HRN-X-60



The Soft Cannula Package contains a Protective Sleeve, Soft Cannula, and a Needle Hub as shown in below figure.



The Pump Base contains Plastic Base and Medical Tane



#### 3. Important Information Indications

This product is indicated for the subcutaneous infusion of insulin using the Equil Patch Insulin Pump (MTM-1).

This is a sterile disposable medical device

#### Expected use environment

This product may be used by the patient or a

family member who is familiar with infusion set application and operation. It may be used at home or in a hospital environment. Insulin delivery settings including bolus and basal rates should be recommended by the patient's physician.

#### Application

This disposable product is compatible with the Equil Patch Insulin Pump System and is suitable for treating diabetes requiring short-term or long-term insulin pump therapy.

#### Contraindications

- Use only with U-100 insulin.
- · Cannot be used for storage or infusion of blood or blood products

### 4. Usage

4. Usage

(i) First wash your hands and the infusion site and let everything dry. Remove the pump base from its packaging and place it on one of the suggested areas shown in Fig. 1 (abdomen, upper arm, thigh, lower back, etc.) Avoid sites that may rub against other objects like belts, waistbands or tight clothing. Also make sure that your infusion site is at least 2-3cm away from your navel. Do not use the abdomen if you are late in pregnancy.

are late in pregnancy.

② Open the cannula pack as indicated on the packaging. Push the cannula assembly into the cannula inserter as shown in Figure 2 until the cannula assembly is in the cocked position and you hear two "click" sounds. You should see that the cannula assembly is connected firmly to the cannula inserter and the inserter is held firmly in the cocked position.

Remove the protective sleeve as shown in

④ Align the front end of the inserter to the base as shown in Figure 4. Press down in the direction of the arrow until you hear a click. Now press the two opposing release buttons on inserter at the same time and the cannula will be inserted into the base

## O Note

When pressing the release button, the other hand must be pressed against the bottom of the cannula and the baseplate cannot be

© Release the inserter from the pump base by pressing the button near the bottom of the inserter as shown in Figure 5. If the introducer needle or needle hub remains on the cannula, carefully remove it from the infusion site. Place the protective sleeve back onto the cannula (i) If the needle remains in the inserter, place the protective sleeve back onto theneedle hub. Firmly push the top of theinserter to eject the needle hub (Fig6)and dispose of properly.

#### 5. Warnings

- Because the amount of subcutaneous fat is different in each person, please choose a cannula of appropriate length.
- Improper implantation of the needle or poor site selection may result in insulin infusion errors, infection and/or a tingling sensation at the infusion site.
- The infusion site should be cleaned with isopropyl alcohol before implantation.
- Because skin conditions can vary, the tape life will vary depending on the location chosen.
- If you are a new user, you should perform your first cannula insertion with professional help.
- The normal implanted position of the cannula should not cause pain, so check regularly to be sure it is in the correct position. The soft cannula must always be fully implanted to receive 100% of the injected insulin.
- If there is redness at the infusion site, please replace the pump base and the soft cannula.
   Before the original infusion site is healed, please find another site for infusion.
- If the adhesive tape is loose, or the soft cannula is completely or partially detached from the skin, please replace the pump base and the soft cannula.
- Replace the infusion set every 48-72 hours, as directed by your healthcare provider.
- Dispose of the insertion needle (needle hub) properly in a medical sharps container.
- This product is sterile unless the package is opened or damaged. Do not use if the package has been opened or damaged.
- nas been opened or damaged.

  If your blood glucose level is unusually high during insulin infusion, or if there is a blockage alarm, check for a blockage and/or leak. If there is any doubt, replace the infusion set, since the soft cannula may have dislodged, bent and/or partially blocked. If any of these problems appears, a plan should be developed with professional staff to quickly replace the insulin. Test blood glucose levels to ensure the plan was successful.
- Please be sure to use infusion sets that are produced by MicroTech.
- This product should be used under the guidance of doctors or other healthcare professionals.
- Please read this insert carefully before use and follow the directions.
- · Avoid strenuous exercise in order to prevent

damage to the infusion set and insulin pump.

- Check the status of all components often, pay attention to alarms, avoid leaks, blockages, bending etc.
- Check your blood glucose level regularly. Please contact your doctor or healthcare professionals in case of abnormal situations.

#### 6. Sterilization Information

Sterilization method: ethylene oxide sterilizationShelf life: 3 years (Please refer to expiration label on packaging)

#### 7. Storage Condition

This product should be stored in a non corrosive gas, cool, dry, well ventilated area. Avoid storing with the chlorinated disinfectant.

#### 8. Symbol List

| o. Symbol List |                                  |            |
|----------------|----------------------------------|------------|
|                | Single Use Only                  | 8          |
|                | Caution                          | <u>^</u>   |
|                | Expiration Date                  |            |
|                | Lot Number                       | LOT        |
|                | Sterilized by Ethylene Oxide     | STERILE EO |
|                | Read Instructions                | []i        |
|                | Do Not Use if Package is Damaged | 8          |
|                | Manufacture Date                 | ~          |
|                | Manufacturer                     |            |
|                |                                  |            |