EN For use with the Equil Ambulatory Insulin Infusion Pump and Equil Insulin Infusion Set

Insulin Infusion Set

HRN-S-60 / HRN-S-90, MTM-4

MicroTech Medical (Hangzhou) Co., Ltd.
No.108 Liuze St., Cangqian, Yuhang District,
Hangzhou, 311121 Zhejiang, P.R.China
www.microtechmd.com

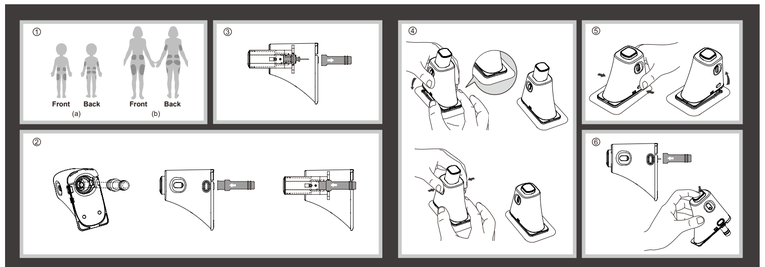
EU REP CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18 CP 29006,
Málaga-Spain
E-mail:info@cmcmedicaldevices.com

1001-PMTL-435:V03
Effective Date: 2025-12-23

MicroTech Medical

CE 0197

equil



English

Note

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

Product Name: Insulin Infusion Set
Components: Soft Cannula and Pump Base
HRN-S-60 / HRN-S-90, MTM-4
Shelf Life: 3 years
Use Life: 72 hours

1. Product

The infusion set consists of a Soft Cannula and a Pump Base. The Soft Cannula is a sterile, single-use component that is inserted into the subcutaneous tissue for short-term insulin infusion (typically up to 3 days). The Pump Base is a single-use component that is adhered to the skin surface and is used to secure the Cannula and connect to ambulatory insulin infusion pumps and insulin infusion pump reservoirs, with a use duration of up to 3 days.

Soft Cannula: HRN-S-60, HRN-S-90

Pump Base: MTM-4

Naming Convention: HRN-X-60

Cannula — Material: S - Soft/Flexible — Length: 60 - 6.0mm, 90 - 9.0mm

2. Components

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

The Pump Base contains Plastic Base and Medical Tape.

3. Intended Purpose

The insulin infusion set is intended for the subcutaneous delivery of insulin when using with insulin infusion pump reservoir and ambulatory insulin infusion pump.

4. Intended patient

Type 1 and Type 2 diabetes patients aged 3 and above requiring insulin pump therapy.

5. Intended user

From device operation perspective, this device is intended to be operated by professional users and lay users with age of 18 and above.

Requirement for professional users:
- Graduate from medical school or graduate with medical related major
- With normal touch, visual and hearing ability
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Requirement for Lay users:
- With elementary school or above education background
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Note

Learning to use your Equil patch insulin pump system and compatible supplies correctly is important for safe and effective use. Different training methods are available to match your learning needs. Your healthcare provider can help you to coordinate and set up appropriate training.
For pediatric patients, 'lay person'refers to caregiver, parent, or legal guardian.

6. Indications

① Patients with type 1 diabetes mellitus or type 2 diabetes mellitus who require insulin pump therapy.
② Patients with type 1 diabetes who are motivated to improve glycemic control following a trial of multiple daily insulin injection (MDI) therapy and who can show the level of self-care required for adherence.
③ Patients with type 2 diabetes on MDI who can use the device safely (either by them-selves or with a caregiver).

7. Expected use environment

This device is intended to be used in Hospital setting and Home setting.
- Operating Temperature: 5-40°C (41-104°F)
- Operating Humidity: 10-93% (noncondensing)
- Operating Air Pressure: 70kPa-106kPa

8. Application

This infusion set is compatible only with MicroTech Medical ambulatory insulin infusion pump and insulin infusion pump reservoir. The compatible devices are as follows:

Compatible device	
Name	**Model**
Ambulatory Insulin Infusion Pump	MTM-1
	MTMT-H1
Insulin Infusion Pump Reservoir	MTM-3
	MTM-R10
	MTM-3WP
	MTM-10WP
Cannula Inserter	MTM-5

9. Contraindications

(1) Diabetic patients unwilling to perform insulin pump treatment
(2) Patients who do not want to or do not have access to self-monitoring of blood glucose levels
(3) Patients with alcohol addiction, drug abuse, or with severe mental disorders (e.g. depression, schizophrenia)
(4) Allergies, including insulin allergies and severe skin allergies
(5) People who are unconscious or disoriented
(6) People who are intellectually impaired and unable to understand or master the instructions for use
(7) People with severe visual or hearing impairments
(8) Elderly diabetics living alone
(9) Children with diabetes who are too young to take care of themselves
(10) The pump system has not been evaluated in:
- Pregnant woman
- Children below 3 years

(11) Diabetic patients who do not require insulin therapy
(12) Patients with granulomatous nodules, which are tiny lumps or nodules beneath the skin, should not use this product.
(13) Patients with any of the following conditions should not use this product:
- Blood albumin level lower than 90 g/L (may indicate poor nutrition or liver problems);
- White blood cell count lower than 4.0 × 10⁹/L (weakened immunity, higher risk of infection);
- Platelet count lower than 90 × 10⁹/L (reduced clotting ability, higher risk of bleeding).

(14) Patients in the acute phase of diabetic ketoacidosis or hyperosmolar coma.
(15) Hyperglycemic patients with severe circulatory disorders.
(16) Diabetic patients allergic to subcutaneous infusion sets or adhesive tapes.
(17) Patients and family members lacking relevant knowledge and still unable to use the device correctly after training.

10. Usage

① Firstly wash your hands. Then use an alcohol wipe to clean the infusion site area, removing any oils/dirt. Allow it to air 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), where Fig. 1(a) is a schematic diagram of application sites for children and Fig. 1(b) is for adults. It is important to choose a site with rich subcutaneous tissue. Avoid sites that may rub against other objects like belts, waistbands or tight clothing. Also, make sure that your infusion site is at least 2-3 cm away from your navel.
② Open the cannula pack as indicated on the packaging.Push the soft cannula assembly into the cannula inserter as shown in Figure. 2 until the soft cannula assembly is in the cocked position and you hear two "click"sounds. You should see that the soft cannula assembly is connected firmly to the cannula inserter and the inserter is held firmly in the cocked position.
③ Remove the protective sleeve as shown in Fig. 3.
④ Hold the cannula inserter and align the front end with the plastic base of the pump base as shown in Fig. 4. Press down, until you hear a "click" securing it in place. Press the release button on both sides of the cannula inserter at the same time, then the cannula will be inserted into the base and infusion site.

Note

When pressing the release button, the other hand must be pressed against the bottom of the cannula inserter and the pump base cannot be lifted.

Note

Do NOT press the button near the bottom of the inserter during this step.

⑤ Release the inserter from the pump base by pressing the button on the lower end of the cannula inserter as shown in Fig. 5. If the inserted needle or needle hub remains in the pump base, carefully remove it from the infusion site. Place the protective sleeve back onto the needle hub.
⑥ If the needle remains in the inserter, place the protective sleeve back onto the needle hub. Firmly push the top of the inserter to eject the needle hub (Fig. 6) and dispose of properly.

11. Potential Clinical Benefits

- Improved management of A1C, GMI and TIR for tighter glycemic control.
- Reduction in Hypoglycemia events.
- Reduction in Total Daily Dose of insulin.

12. Potential Risks

(1) Under delivery or excessive delivery of Insulin leading to severe hypoglycemia or diabetic ketoacidosis
(2) Infusion site problems
- Pruritus (Skin redness), Swelling and other skin allergies

(3) Hyperglycemia or hypoglycaemia
(4) Hardware defects
- Adhesion issues, difficulty peeling off the device, cannula deformation, etc.

(5) Failure to follow the instructions may lead to risks of hyperglycemia or hypoglycemia, and diabetic ketoacidosis (DKA). Both DKA and hypoglycemia can potentially lead to death.

13. Warnings

- Use only disposables that are manufactured by MicroTech Medical, or with the Equil brand name. The use of non-standard components may affect the safety of the device.
- Before continuing, please make sure you are familiar with the operation of the infusion set.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

14. Precautions

- Please be sure to operate in strict accordance with this instruction manual, because failure to follow the instructions may result in unsafe practices. Microtech Medical is not liable for any related legal obligations arising from misuse.
- This product can only be used to administer U-100 insulin.
- Select proper infusion site locations.
- Regular BG monitoring is essential to verify infusion effectiveness.
- Use only hypoallergenic tapes provided with pump base. Consult clinician if persistent dermatitis develops.
- This infusion set must be replaced every 72 hours after activation.
- Be careful of the exposed sharp introducer needle.

15. Sterilization Information

Sterilization method: ethylene oxide sterilization

16. Storage Condition

This product should be stored in a non corrosive gas, cool, dry, well ventilated area. Avoid storing with the chlorinated disinfectant.
- Temperature range: -40°C-50°C
- Relative humidity range: 5%-95%
- Atmospheric pressure range: 50kPa-106kPa

17. Electronic Manual

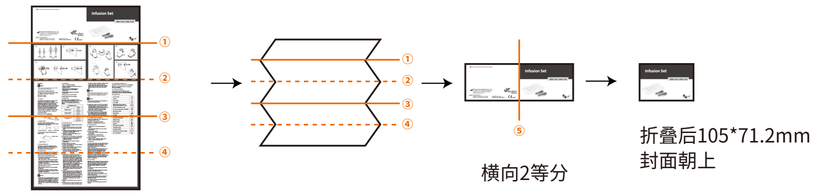
You can visit our website at any time to browse or download the latest electronic manual of this product:
https://microtechmd.com/support/download/83/148

18. Symbol List

Do not re-use	
Caution	
Use-by date	
Lot number	LOT
Single sterile barrier system. Sterilized using ethylene oxide	STERILE EO
Single sterile barrier system with protective packaging outside using ethylene oxide	STERILE EO
Sterilized using ethylene oxide	STERILE EO
Consult instructions for use	
Do not use if package is damaged	
Manufacture Date	
Manufacturer	
CE Mark	CE 0197
Authorised Representative in the European Community	EC REP
Medical device	MD
Model number	REF
Importer	
Unique device identifier	UDI
Operating temperature limitation	41 °F 104 °F 5 °C 40 °C
Operating humidity limitation	93% 10%
Operating atmospheric pressure limitation	106kPa 70kPa
Storage temperature limitation	-40 °C 50 °C -40 °F 122 °F
Storage humidity limitation	95% 5%
Storage atmospheric pressure limitation	106kPa 50kPa
Do not resterilize	

折叠方式

外折线
内折线



本图纸应与说明，产品状况，产品结构设计图及有关图纸协调使用，发现任何差异请立即通知设计师.

图档中所有尺寸比例为1:1.
公差: L(长)*(宽): +1/-1mm,H(高): ±1mm

项目信息	
名称	留置针说明书(CE MDR版)
图纸号	
物料号	1001-PMTL-435
版本号	V03
版本变更描述	修改内容(详见附件)
发放范围	生产（ ）采购（ √ ）计划（ √ ）其他:

切刀 压线 开槽 半穿 粘合

备注 无印刷

尺寸:	210*356mm
印刷颜色:	黑白
材质:	70g轻涂纸
特种工艺:	
备注:	折叠，见图纸

设计审核		日期
设计		
审核		
批准		
生效日期		

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E-mail:info@cmcmedicaldevices.com

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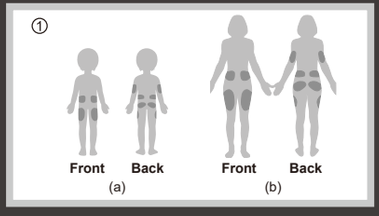
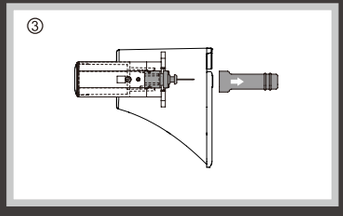
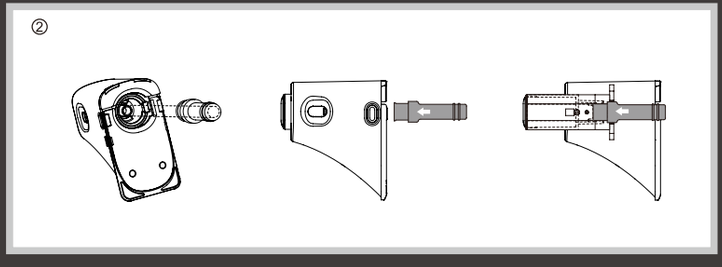
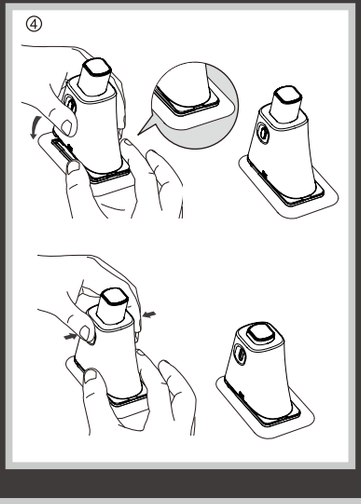
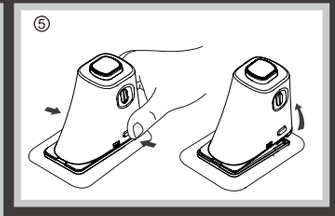
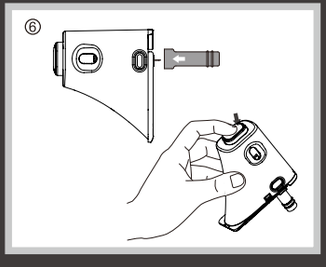












English

Note

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

Product Name: Insulin Infusion Set
Components: Soft Cannula and Pump Base
HRN-S-60 / HRN-S-90, MTM-4
Shelf Life: 3 years
Use Life: 72 hours

1. Product

The infusion set consists of a Soft Cannula and a Pump Base. The Soft Cannula is a sterile, single-use component that is inserted into the subcutaneous tissue for short-term insulin infusion (typically up to 3 days). The Pump Base is a single-use component that is adhered to the skin surface and is used to secure the Cannula and connect to ambulatory insulin infusion pumps and insulin infusion pump reservoirs, with a use duration of up to 3 days.

Soft Cannula: HRN-S-60, HRN-S-90

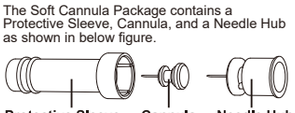
Pump Base: MTM-4

Naming Convention: HRN-X-60

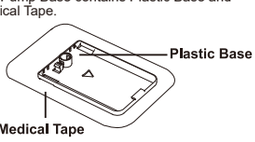
Cannula	Material	Length
	S - Soft/Flexible	60 - 6.0mm
		90 - 9.0mm

2. Components

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



The Pump Base contains Plastic Base and Medical Tape.



3. Intended Purpose

The insulin infusion set is intended for the subcutaneous delivery of insulin when using with insulin infusion pump reservoir and ambulatory insulin infusion pump.

4. Intended patient

Type 1 and Type 2 diabetes patients aged 3 and above requiring insulin pump therapy.

5. Intended user

From device operation perspective, this device is intended to be operated by professional users and lay users with age of 18 and above.

Requirement for professional users:

- Graduate from medical school or graduate with medical related major
- With normal touch, visual and hearing ability
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Requirement for Lay users:

- With elementary school or above education background
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Note

Learning to use your Equil patch insulin pump system and compatible supplies correctly is important for safe and effective use. Different training methods are available to match your leaning needs. Your healthcare provider can help you to coordinate and set up appropriate training.
For pediatric patients, 'lay person'refers to caregiver, parent, or legal guardian.

6. Indications

① Patients with type 1 diabetes mellitus or type 2 diabetes mellitus who require insulin pump therapy.
② Patients with type 1 diabetes who are motivated to improve glycemic control following a trial of multiple daily insulin injection (MDI) therapy and who can show the level of self-care required for adherence.
③ Patients with type 2 diabetes on MDI who can use the device safely (either by them-selves or with a caregiver).

7. Expected use environment

This device is intended to be used in Hospital setting and Home setting.

- Operating Temperature: 5-40°C (41-104°F)
- Operating Humidity: 10-93% (noncondensing)
- Operating Air Pressure: 70kPa-106kPa

8. Application

This infusion set is compatible only with MicroTech Medical ambulatory insulin infusion pump and insulin infusion pump reservoir. The compatible devices are as follows:

Compatible device	
Name	**Model**
Ambulatory Insulin Infusion Pump	MTM-1
	MTMT-H1
Insulin Infusion Pump Reservoir	MTM-3
	MTM-R10
	MTM-3WP
	MTM-10WP
Cannula Inserter	MTM-5

9. Contraindications

(1) Diabetic patients unwilling to perform insulin pump treatment
(2) Patients who do not want to or do not have access to self-monitoring of blood glucose levels
(3) Patients with alcohol addiction, drug abuse, or with severe mental disorders (e.g. depression, schizophrenia)
(4) Allergies, including insulin allergies and severe skin allergies
(5) People who are unconscious or disoriented
(6) People who are intellectually impaired and unable to understand or master the instructions for use
(7) People with severe visual or hearing impairments
(8) Elderly diabetics living alone
(9) Children with diabetes who are too young to take care of themselves
(10) The pump system has not been evaluated in:
- Pregnant woman
- Children below 3 years

(11) Diabetic patients who do not require insulin therapy
(12) Patients with granulomatous nodules, which are tiny lumps or nodules beneath the skin, should not use this product.
(13) Patients with any of the following conditions should not use this product:
- Blood albumin level lower than 90 g/L (may indicate poor nutrition or liver problems);
- White blood cell count lower than 4.0 × 10^9/L (weakened immunity, higher risk of infection);
- Platelet count lower than 90 × 10^9/L (reduced clotting ability, higher risk of bleeding).

(14) Patients in the acute phase of diabetic ketoacidosis or hyperosmolar coma.
(15) Hyperglycemic patients with severe circulatory disorders.
(16) Diabetic patients allergic to subcutaneous infusion sets or adhesive tapes.
(17) Patients and family members lacking relevant knowledge and still unable to use the device correctly after training.

10. Usage

① Firstly wash your hands. Then use an alcohol wipe to clean the infusion site area, removing any oils/dirt. Allow it to air 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), where Fig. 1(a) is a schematic diagram of application sites for children and Fig. 1(b) is for adults. It is important to choose a site with rich subcutaneous tissue. Avoid sites that may rub against other objects like belts, waistbands or tight clothing. Also, make sure that your infusion site is at least 2-3 cm away from your navel.
② Open the cannula pack as indicated on the packaging.Push the soft cannula assembly into the cannula inserter as shown in Figure. 2 until the soft cannula assembly is in the cocked position and you hear two "click"sounds. You should see that the soft cannula assembly is connected firmly to the cannula inserter and the inserter is held firmly in the cocked position.
③ Remove the protective sleeve as shown in Fig. 3.
④ Hold the cannula inserter and align the front end with the plastic base of the pump base as shown in Fig. 4. Press down, until you hear a "click" securing it in place. Press the release button on both sides of the cannula inserter at the same time, then the cannula will be inserted into the base and infusion site.

Note

When pressing the release button, the other hand must be pressed against the bottom of the cannula inserter and the pump base cannot be lifted.

Note

Do NOT press the button near the bottom of the inserter during this step.

⑤ Release the inserter from the pump base by pressing the button on the lower end of the cannula inserter as shown in Fig. 5. If the inserted needle or needle hub remains in the pump base, carefully remove it from the infusion site. Place the protective sleeve back onto the needle hub.
⑥ If the needle remains in the inserter, place the protective sleeve back onto the needle hub. Firmly push the top of the inserter to eject the needle hub (Fig. 6) and dispose of properly.

11. Potential Clinical Benefits

- Improved management of A1C, GMI and TIR for tighter glycemic control.
- Reduction in Hypoglycemia events.
- Reduction in Total Daily Dose of insulin.

12. Potential Risks

(1) Under delivery or excessive delivery of Insulin leading to severe hypoglycemia or diabetic ketoacidosis
(2) Infusion site problems
- Pruritus (Skin redness), Swelling and other skin allergies

(3) Hyperglycemia or hypoglycaemia
(4) Hardware defects
- Adhesion issues, difficulty peeling off the device, cannula deformation, etc.

(5) Failure to follow the instructions may lead to risks of hyperglycemia or hypoglycemia, and diabetic ketoacidosis (DKA). Both DKA and hypoglycemia can potentially lead to death.

13. Warnings

- Use only disposables that are manufactured by MicroTech Medical, or with the Equil brand name. The use of non-standard components may affect the safety of the device.
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- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

14. Precautions

- Please be sure to operate in strict accordance with this instruction manual, because failure to follow the instructions may result in unsafe practices. Microtech Medical is not liable for any related legal obligations arising from misuse.
- This product can only be used to administer U-100 insulin.
- Select proper infusion site locations.
- Regular BG monitoring is essential to verify infusion effectiveness.
- Use only hypoallergenic tapes provided with pump base. Consult clinician if persistent dermatitis develops.
- This infusion set must be replaced every 72 hours after activation.
- Be careful of the exposed sharp introducer needle.

15. Sterilization Information

Sterilization method: ethylene oxide sterilization

16. Storage Condition

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

- Temperature range: -40°C-50°C
- Relative humidity range: 5%-95%
- Atmospheric pressure range: 50kPa-106kPa

17. Electronic Manual

You can visit our website at any time to browse or download the latest electronic manual of this product:
https://microtechmd.com/support/download/83/148

18. Symbol List

Do not re-use	
Caution	
Use-by date	
Lot number	LOT
Single sterile barrier system. Sterilized using ethylene oxide	STERILE EO
Single sterile barrier system with protective packaging outside using ethylene oxide	STERILE EO
Sterilized using ethylene oxide	STERILE EO
Consult instructions for use	
Do not use if package is damaged	
Manufacture Date	
Manufacturer	
CE Mark	CE 0197
Authorised Representative in the European Community	EU REP
Medical device	MD
Model number	#
Importer	
Unique device identifier	UDI
Operating temperature limitation	5°C 40°C
Operating humidity limitation	10% 93%
Operating atmospheric pressure limitation	70kPa 106kPa
Storage temperature limitation	-40°C 55°C
Storage humidity limitation	5% 93%
Storage atmospheric pressure limitation	50kPa 106kPa
Do not resterilize	