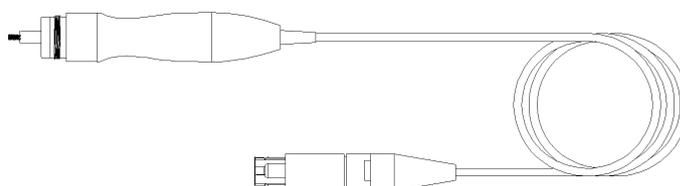


Ultrasound Activated Scalpel System

— Hand Piece

HP25



Instruction for use

Hocer (Tianjin) Medical Technologies Co., Ltd.

Hand piece (HP25)

Length: 13cm

Diameter: 2.5cm

Including the Hand piece cable

Intended for use with a compatible Ultrasonic Generator System

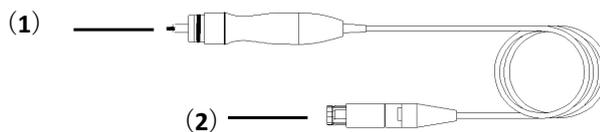
Technical Specifications:

Hand piece cable: 2.9m

Driving frequency: 55.5kHz

Resonant frequency: 55.5kHz

HP25



(1) Shears connection

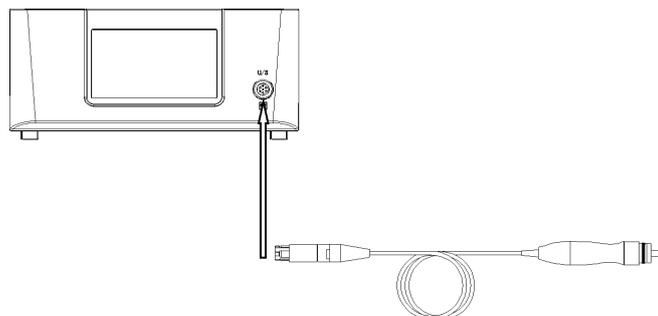
Used for connection to the shears.

(2) Generator connector

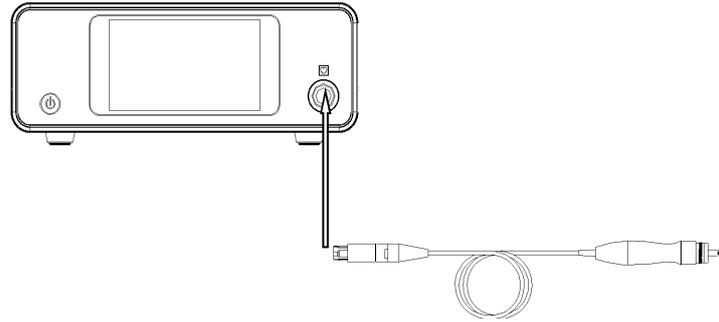
The connector is attached to the Hand Piece receptacle on the front panel of the Generator.

Connection:

The HP25 Hand piece is intended for use with a compatible Ultrasonic Generator System. Plug the Generator connector into the receptacle on the Compatible Ultrasonic Generator System, connect the Hand Piece connector, on the other end of the cable, to the Hand Piece receptacle.



(USG10)



Operation during surgery:

This product is an energy conversion device designed to be used together with HocerMed shears and a compatible Ultrasonic Generator System.

Surgeons will not need to operate it during procedures.

Note: The Hand Piece surface will become hot during prolonged use in procedures. Avoid contact with this surface.

Note: If the Hand Piece is not actively in use during a surgical procedure, place it on a level surface, otherwise the device may be dropped and sustain damage.

Cleaning after use:

After each use, perform cleaning and disinfection according to the procedures described in Chapter 4 (of the General IFU and below for Hand Piece): Cleaning, Disinfection, Periodical Inspection and Repair in the Use Instructions of Ultrasound Activated Scalpel.

Warning:

The products are delivered in a non-sterile condition and must be cleaned, disinfected and sterilized according to the Instructions for Cleaning and Disinfection prior to use.

If the contacts and pins inside the Hand Piece receptacle or the connection cable connector turn black, replace the Hand Piece and connection cable with new ones. Otherwise, a short circuit may occur, causing damage to the instrument and/or Generator.

Always ensure the availability of appropriate backup procedures and relevant equipment for the procedure, in the event of a system failure.

The disposable Ultrasound shears must be withdrawn from the patient's body when replacing the Hand Piece. After withdrawal, unplug the connector from the receptacle. Do not attempt to replace the Hand Piece while the shaft is still in the patient's abdominal cavity, as the rotating force used applied to attach it may cause the shaft to come in contact with tissue, thus injuring the patient.

If there is blood or saline solution observed inside the receptacle or connector, do not activate the Ultrasound output. Otherwise, the instrument may short circuit and the Generator could be damaged.

If the Hand Piece cable is damaged or broken, the leakage current may cause burns to the operator or patient. Replace the cable when damage is observed.

Note:

Keep the Hand Piece on a level surface. Otherwise, the Hand Piece may be dropped and sustain damage.

Confirm that the shears and the Hand Piece are connected securely together. If the shears are tightened by hand, rather than with a torque wrench, the energy created by the Ultrasound may not be transmitted in a safe manner, thus resulting in damage to the tip of the shaft or a rise in temperature of the Hand Piece surface.

Do not clean the inside of the connector or receptacle with gauze wetted with saline solution. If the saline solution comes in contact with the contacts inside the connector or receptacle, do not activate the Ultrasound output, as this may damage the Generator.

If blood or tissue debris is observed inside the connector or receptacle after performing surgery, rinse it with sterile water and wipe it with dry gauze.

Straighten the connection cable out if it becomes twisted during removal from the Hand Piece.

Avoid contact with the pins or contacts of the connector and receptacle. The buildup of static electricity may cause electric shock.

Hand piece

Cleaning

Please follow the below steps to wipe and clean the instrument:

1. Prepare the PH neutral detergent or pH neutral detergent containing enzyme according to the instruction from manufacturer.
2. Please use detergent to wet slightly the clean soft cloth to clean manually all the surfaces. Pay special attention to the cracks and crevices.
3. Then use lukewarm sterile water to slightly wet a clean soft cloth and wipe it thoroughly.
4. Finally use clean dry soft cloth to wipe it dry.

Sterilization

Following the cleaning and disinfection steps above, the Hand Piece must be sterilized by one of the methods listed below. Drying times post-sterilization of 273°F (134°C) or less for a maximum of 30 minutes is allowable. Handling of the Hand Piece should follow hospital protocol throughout the cleaning and sterilization process

Steam

The following steam sterilization cycle parameters are approved for use.

| Sterilizer Type | Method | Cycle Time (at temperature) | Temperature Set Points | Preconditioning Pulses |
|------------------------|-------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Prevacuum | Wrapped | 3–18 minutes | 270°F / 273°F (132°C / 134°C) | 3 |
| Prevacuum | Unwrapped | 3–5 minutes | 270°F / 273°F (132°C / 134°C) | 3 |
| Prevacuum | Wrapped | 20 minutes | 250°F (121°C) | 3 |
| Gravity | Unwrapped | 10 minutes | 270°F / 273°F (132°C / 134°C) | Not applicable |
| Gravity | Wrapped OR Unwrapped | 30 minutes | 250°F (121°C) | Not applicable |
| Gravity | Wrapped | 15 minutes | 270°F / 273°F (132°C / 134°C) | Not applicable |

Minimum dry time for each method above is 0 minutes.

Note:

1. The above table includes the minimum temperature and time validated to assure sterility.
2. Based on steam autoclave tolerances, the actual autoclave temperature can exceed the set point temperature by a maximum of +5°F (+3°C).
3. Health Authorities in some regulated regions do not accept unwrapped sterilization methods. Please review the appropriate guidelines, standards and national Health Authorities' guidelines when determining acceptable steam sterilization process parameters for use in each respective country.

Low-Temperature Plasma

Please use low-temperature plasma sterilization in standard cycle. (Such as “Sterrad” or other Equivalent) in accordance with manufacturer’s instructions

EO

Packaging

EO breathable pouch, sterilization tray wrapped in CSR wrap, or enclosed in an EO breathable pouch.

EO Concentration

750mg/liter minimum

Preconditioning Time

Sufficient to allow temperature and relative humidity to rise to specified targets.

Sterilizer Set Temperature

130°F (54°C)

EO Dwell Period

2 Hours

Relative Humidity

50%

Aeration

12 Hours minimum

EO Residuals Dissipation

24 Hours minimum

EO sterilization equipment

- 1 Clean and dry the Hand Piece following the steps listed in the Hand Piece Cleaning section.
- 2 Carefully place the Hand Piece within the appropriately sized packaging and wrap the tray according to hospital procedure.
- 3 Sterilize the Hand Piece within the EO sterilization equipment Sterilizer according to the instructions provided in the Operator’s Manual.

NON-STERILE

Non-sterile



Refer to Instructions for use for reference



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