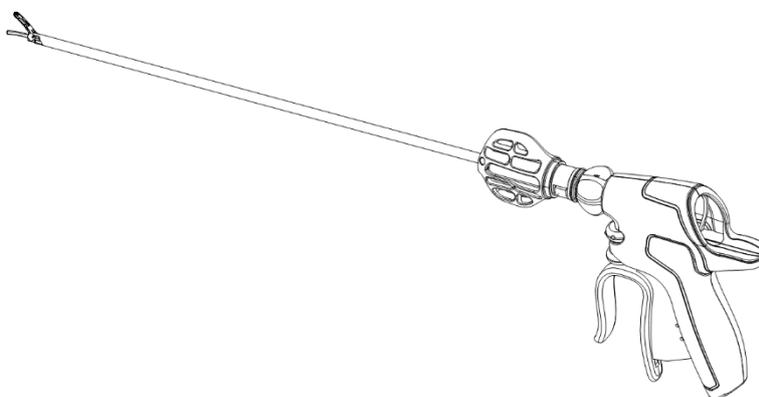


Ultrasound Activated Scalpel System

-- Shear

USE Series



Instruction for use

Hocer (Tianjin) Medical Technologies Co., Ltd.

Ultrasound Shears

Intended for use with the Ultrasound Activated Scalpel System

- USG10, USG10Plus Ultrasound Activated Scalpel System (Generator)

Please read all information carefully.

Failure to properly follow instructions may lead to serious surgical complications.

Important: This package insert is designed to provide instructions for use of the Ultrasound Shears with Torque Wrench. It's not a reference to surgical techniques.

Shears models covered by this Instructions list as follow:

Shears models	Shaft diameter	Shaft length
USE36	5.5mm	36cm
USE36-2	5.5mm	36cm
USE23	5.5mm	23cm
USE14	5.5mm	14cm

Indications for use

The Ultrasound Shears are intended to be used for soft tissue incisions when bleeding control and minimal thermal injury are desired.

Contraindication

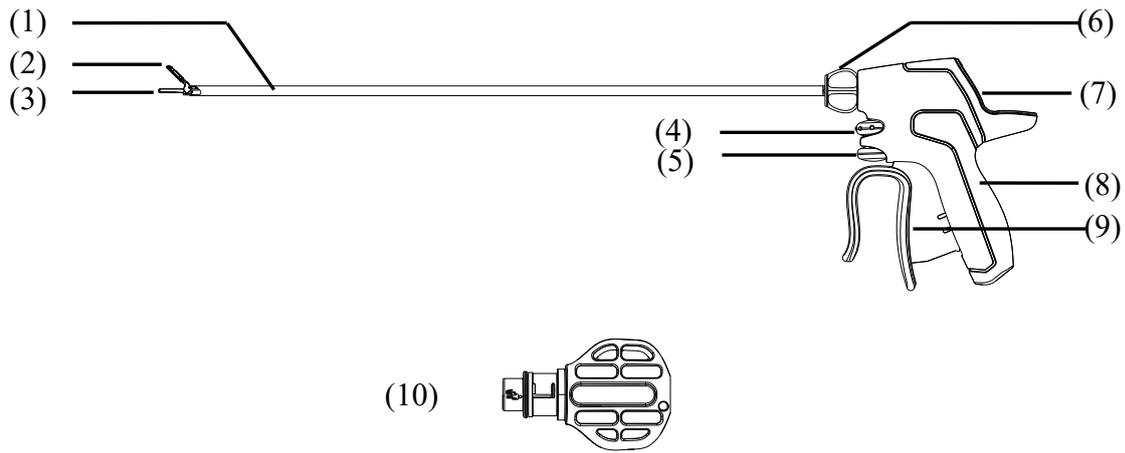
The instrument is not intended for incising bone.

The instrument is not intended for contraceptive tubal occlusion/ligation.

Device description

The Ultrasound Shears, with ergonomic handle, hand control and torque wrench, are a sterile single patient use instrument. Two hand control buttons (Coagulation Switch - MIN for minimum power level and Cutting Switch - MAX for maximum power level) are assembled into the grip housing that has an integrated audible and tactile mechanism for indicating full trigger closure. The instrument has a rotating shaft which is used to adjust the position of clamp arm and tissue pad.

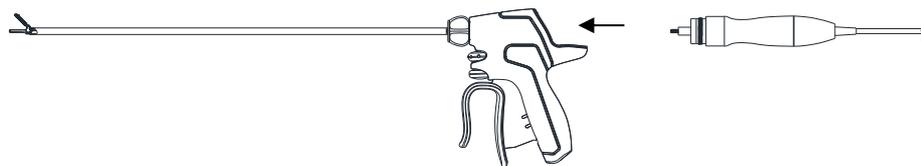
The instrument is shipped with one sterile, single patient use, disposable torque wrench. The torque wrench should not be discarded until the completion of the surgical case. In the event the torque wrench falls out of the sterile field, replace with a sterile torque wrench. Do not attempt to sterilize the disposable torque wrench.



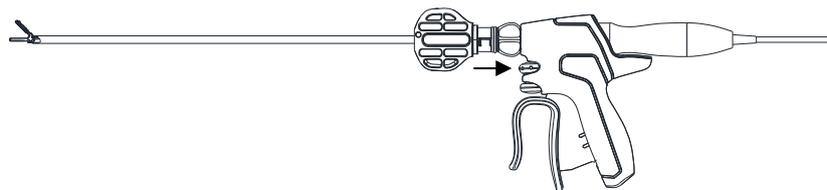
1	Outer tube	To protect the shaft
2	Clamp arm and tissue pad	Used to help clamp the tissue
3	Shaft	Output of the Ultrasound energy
4	MAX switch	Controls the output of the MAX energy
5	MIN switch	Controls the output of the MIN energy
6	Rotation knob	Adjust the position of the clamp arm and tissue pad
7	Hand piece connection	Connection between the hand piece and shears
8	Grip handle	Handle for operator to hold device
9	Control handle	Controls the opening/closing of the clamp arm and tissue pad
10	Torque wrench	Used for tightening the Shears to the Hand Piece .

Connection of the Hand Piece

1. Remove the Ultrasound Shears from the package.
2. Insert the hand piece into the rear receptacle of the Ultrasound Shears as indicated in the picture. Turn the Hand Piece counter clockwise until it is tightened (finger tight only).



3. Use the torque wrench (already mounted to rotation knob) to tighten the shaft onto the hand piece. Rotate the torque wrench slowly until it clicks three times.



Note: Do not use any other means than the torque wrench to attach or detach the instrument to/from the hand piece.

Note: Hold only the gray hand piece and not the shears handle when applying the torque wrench

4. Close the clamp arm by pushing the control handle (9). Remove the torque wrench by sliding it off the shear.

Note: Do not dispose of the torque wrench until the procedure is completed. The torque wrench is used to remove the instrument from the Hand Piece. Dispose of the torque wrench only after completing the procedure.

Note: Take care to avoid injury from the blade tip while sliding the torque wrench on or off the shear.

5. Connect the Hand Piece onto the Generator.

Note: The default power level of MAX is 5, and is not adjustable. The default power level of MIN is 3. It can be adjusted by pushing INCREASE button or DECREASE button.

Note: Do not turn on the Generator power before the hand piece and instrument are connected to the Generator.



(USG10)



(USG10Plus)

6. Test the instrument by activating the tip in saline by pushing the trigger or foot switch.



Operation during surgery

- **Rotation of the clamp arm and tissue pad**

The rotation knob (6) can be rotated 360 degrees to locate the clamp arm in the desired position.

Note: Do not rotate the rotation knob while grasping tissue otherwise the instrument may be damaged.

- **Tissue manipulating**

This instrument can be used to manipulate and dissect tissue.

- **Coagulation operation**

1. Push forward the control handle (9) to open the clamp arm.
2. Position the target vessel or tissue at the middle of the grasping section.
3. Close the clamp arm by squeezing the control handle (9) until it makes a click sound and you feel it stop once it contacts the plastic handle.

4. The instrument can be activated with following two methods:
 - a) Press the MIN switch (5)
 - b) Step on the blue pedal of the foot switchAfter activation, the USG10、 USG10 Plus Generator will sound an audio indication of “dudu” and the energy will be delivered at the set MIN energy level.
5. When the operation is finished, release the MIN activation button on the instrument or the pedal of the foot switch.

Warning: Tissue tension should be released prior to coagulation and cutting to ensure the instrument functions normally.

Warning: Do not try to perform coagulation on metal clips or staples; otherwise the clamp arm may not close properly.

- **Cutting operation**

1. Push forward the control handle (9) to open the clamp arm.
2. Position the target vessel or tissue at the middle of the grasping section.
3. Close the clamp arm by squeezing the control handle (9) until it makes a click sound and you feel it stop once it contacts the plastic handle.
4. The instrument can be activated with following two methods:
 - a) Press the MAX switch (4)
 - b) Step on the yellow pedal of the foot switchAfter activation, the USG10、 USG10 Plus generator will sound an audio indication of “dudu” and the energy will be delivered at the set MAX energy level.
5. When the operation is finished, release the MAX activation button on the instrument or the pedal of the foot switch.

Warning: Tissue tension should be released prior to coagulation and cutting to ensure the instrument functions normally.

Warning: Do not try to perform cutting on metal clips or staples; otherwise the clamp arm may not close properly.

Disassembly

1. Turn the generator OFF at the power switch or enter Lock mode.
2. Close the clamp arm and slide the torque wrench over the distal end and up the shaft until the wrench mounted to the rotation knob. Loosen the instrument by turning the wrench counterclockwise. Continue to loosen by turning the rotation knob manually to completely unscrew the instrument.

Note: Take care to avoid injury from the blade tip while sliding the torque wrench onto or off the shear.
3. Remove the torque wrench by pulling it straight back over the blade.
4. Dispose of the instrument in an appropriate container.

Warning and Precautions

- This instrument can be used only once and for a single patient since it cannot be adequately cleaned and/or sterilized to guarantee it can be safely used again. Any attempt to clean or sterilize it may lead to potential risks of biological incompatibility, infection to patient or instrument failure.
- The Ultrasound Shears can only be used with the USG10 、 USG10 Plus Ultrasound Activated Scalpel Generator. The use of this instrument with other models or generators from other manufacturers may lead to the following consequences: reduced performance, injury to the patient or surgical personnel, or damage to the instrument.
- This instrument can only be operated by qualified surgical personnel who have received adequate ultrasound surgery training. The improper use by untrained medical staff may cause dangerous conditions.
- There is no evidence that this instrument is effective in contraceptive tubal occlusion/ligation procedures. Do not use this instrument for such procedures.
- Confirm whether the power level set on the Ultrasound Activated Scalpel Generator is correct before operation.
- After withdrawal of the instrument from the patient's body, examine the tissue for hemostasis. Take appropriate measures to achieve hemostasis when the bleeding cannot be stopped.
- Ensure the availability of appropriate backup equipment for each specific procedure, in case of a system failure.
- Avoid accidentally touching the shears shaft.
- Check the clamp arm, tissue pad and serrations for wear, deformation, or any other damage that could lead to abnormal output or fracturing of the shears shaft.
- If there is gap between the clamp arm, tissue pad (white portion) and the metal part, do not use the Ultrasound Shears any longer.
- Ensure the clamp arm, tissue pad and the shears are not in contact with the surrounding tissue prior to activating the instrument. Otherwise, the Ultrasound output may cause perforation, bleeding, burns, or other tissue damage.
- Avoid contacting the outer tube of the Ultrasound Shears with tissue at any time. The temperature at the outer tube surface increases during prolonged activation and any tissue in contact with the outer tube may get burned.
- Avoid contacting the shears shaft with any hard object during activation (such as clips or other instruments). Never attempt to grasp the shaft with your hands.
- If cracks or scratches are observed on the shears shaft, do not use it any longer, otherwise abnormal output or fracturing of the shaft may occur.
- Avoid activating the energy delivery while applying the shaft tip to tissue with a strong force, grasping thick tissue, twisting the shaft, or rotating the rotation knob. Otherwise, the shears tip may be damaged or fall off due to interference with the other parts.
- Do not increase the ultrasound output level too high or too fast. Otherwise, it may lead to patient injury or a decrease in durability of the instrument.
- If the ultrasound output stops during the procedure, withdraw the Ultrasound Shears from the patient's body immediately with the hand piece and connection cable attached. Otherwise, the patient may be injured.
- If the clamp arm, tissue pad, or the shaft tip falls off, stop using the instrument immediately and retrieve it by appropriate means.

- When the shaft is contaminated with carbonized tissue, remove the contaminants with wet, soft gauze. Do not scrape it with a sharp object, such as a scalpel. Otherwise, the shaft may be scratched or fractured and the tip of which may fall off into the body cavity during activation.
- Do not activate energy delivery while the clamp arm is closed without contacting tissue or vessel, or ensuring that tissue is transected. Otherwise, a local increase of the temperature due to a friction between the shaft tip and the clamp arm may result in damage to the shaft tip and/or the tissue pad, such as falling off inside the body cavity.
- Since continuous Ultrasound output will make the shaft become hot, do not let it come in contact with tissue other than the target one. Otherwise, the tissue could get burned. After the tissue is transected, stop the output immediately. Otherwise premature wear of the clamp arm, clamp pad and shaft may occur. Be careful to avoid injuries when the energy output level is high.
- If there is blood or saline solution inside the connector or receptacle, do not activate the Ultrasound output. Otherwise, the instrument may short circuit and the generator may be damaged.
- Do not use this instrument if you do not have a clear endoscopic view. This may result in unintended tissue damage.

Note:

- Do not use the instrument any longer if any part is deformed. Even if the original shape is recovered, its durability will be compromised. Continuing to use it in such condition may cause severe damage to the instrument or make it impossible to remove it through the trocar cannula.
- If the shears shaft's annular support member is damaged, it may result in an increase in temperature of the insertion part or the shaft's failure to deliver sufficient energy. When the annular support member is damaged, replace the Ultrasound Shears with a new one.
- Do not use the shears if any obvious damage is observed on the clamp arm or tissue pad. When the clamp arm and tissue pad are worn too thin, their gripping force and coagulation ability will be reduced. The clamp arm and tissue pad wear away gradually with use.
- Verify that the shears and the hand piece are connected securely. If the shears is tightened simply by hand, the Ultrasound energy may not be safely transmitted and the shears clamp arm may be damaged or cause a rise in temperature on the hand piece surface.
- Only loosen/tighten the Ultrasound Shears with the supplied torque wrench. Do not use other tools to tighten the shears. Otherwise the instrument or the hand piece will be damaged.
- If the clamp arm and tissue pad of the Ultrasound Shears does not rotate smoothly, remove the shears from the Hand Piece and attach it again, and then tighten them together. Over-tightening will cause damage to the Ultrasound Shears or hand piece.
- Turn the torque wrench until it snaps three times indicating that it has been tightened.
- Whenever inserting into or removing from the trocar, hold the shears gently and keep the clamp arm and tissue pad closed. If the clamp arm is kept open during insertion or removal, the instrument may be damaged or may become impossible to remove from the trocar.
- Operate the control handle and manipulate the instrument only with fingers or a single hand and do not apply excessive force.
- When the Ultrasound Shears are inserted into or removed from the trocar, do not apply excessive force. When it is difficult to insert into the trocar, withdraw it and check for damage. Using excessive force inserting or withdrawing may damage the instrument or make it impossible to remove from the trocar.
- When the Ultrasound Shears is used together with a trocar, handle it gently to avoid bending the trocar

cannula. If the shears come in contact with the opening of the cannula, it may cause the insulation part of the cannula to peel off or damage the instrument.

- This instrument can only be used on soft tissue and not on soft bone, bone, or other hard objects. This may result in damage to the instrument or make it impossible to remove the instrument from the trocar.
- If any body fluids or tissue debris are noted on the surface of the clamp arm, tissue pad, shears shaft or outer tube, clean the instrument with sterilized gauze or by activating the blade tip in the saline solution immediately.
- If any saline solution or blood residue is noted between the shaft and outer tube, use dry sterilized gauze to clean it. Otherwise, the remaining residuals will dry and harden, affecting the operation of the clamp arm and tissue pad or causing damage to the instrument.
- Do not rotate the instrument shaft unless necessary. Otherwise the cable of the hand piece will be twisted, possibly leading to instrument failure.
- Take care of the following conditions as soon as possible, otherwise damage to the instrument may occur:
 - Excessive force was applied to the shaft that is in contact with tissue;
 - Body fluid or tissue is present on the shaft surface during the procedure.
- Although this instrument is capable of delivering energy continuously, the delivery should be terminated after cutting cycle is complete. Basic test shall be conducted prior to the use of instrument. The optimal output level and activation time can be determined based on these test results.



Do not use the product if the package is opened or damaged.



Sterilized with epoxy ethane



Sterile



Do not sterilize again



Single use only



Refer to the Instructions for Use



CF type application parts



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