Surgical Systems Ltd
10mm Handpiece

USER GUIDE

CE 0120

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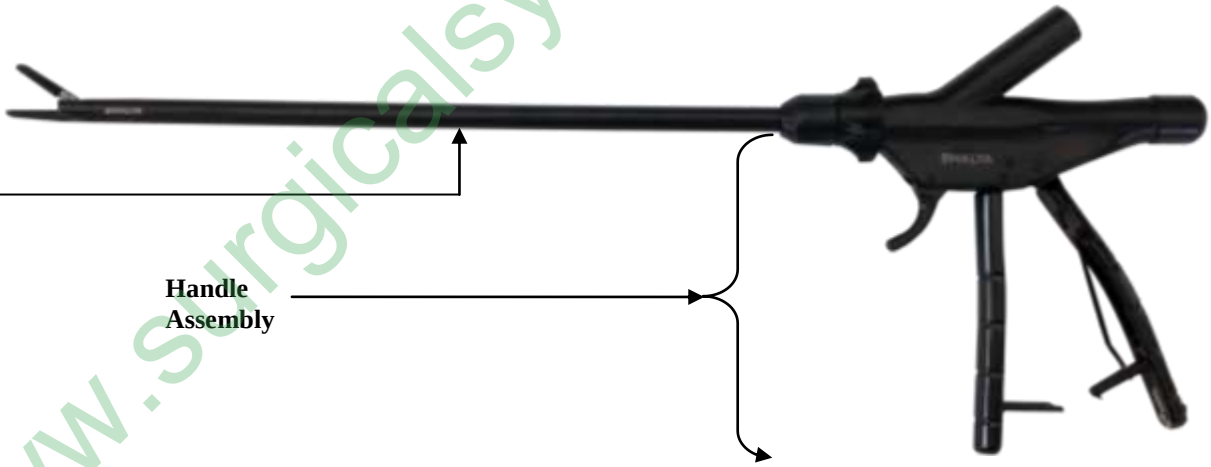
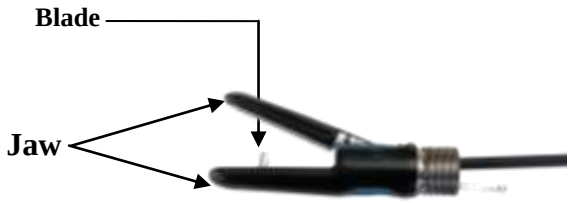


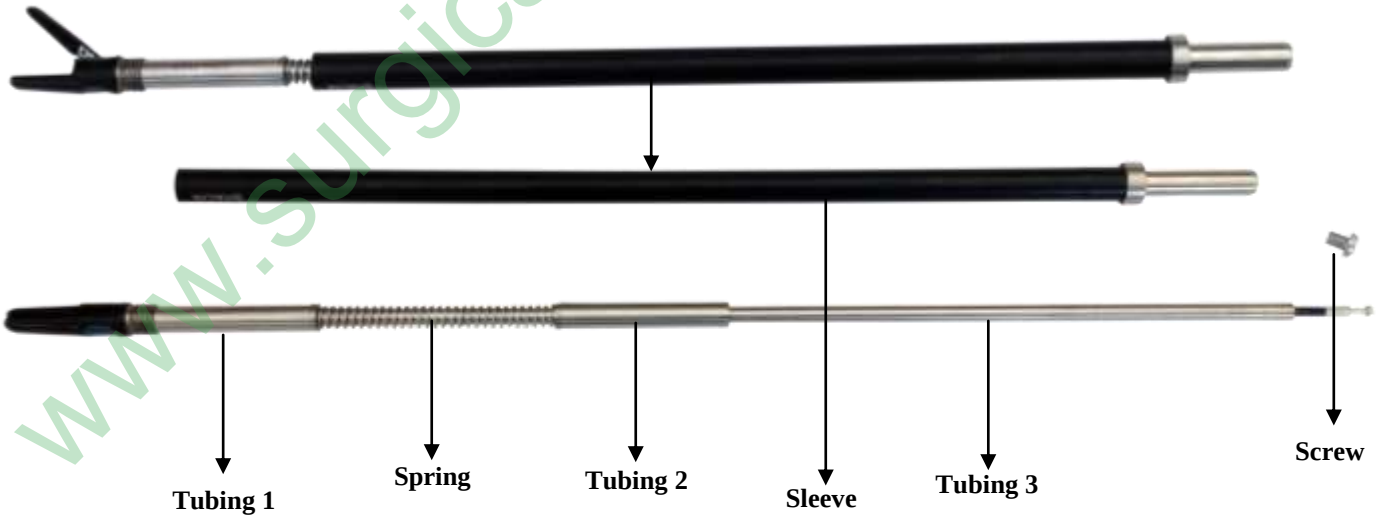
Following are the subparts of each of the above mentioned parts:

A. JAWS & BLADE ASSEMBLY



B. HANDLE ASSEMBLY

C. INSERT ASSEMBLY



The short insert (18 cm) is intended to be used for open abdominal and vaginal surgeries. The long insert (40 cm, 36 cm and 32 cm) are intended for laparoscopic and endoscopic surgeries.

Instructions for Use

GENERAL INSTRUCTIONS

- As this instrument is reusable device, the user has to always inspect the device for breakage & general wear and tear of the device before sending it for re-sterilization.
- Always check insulation of the jaws, outer tubing and inner tubing for breakages and damages. Do not use the damaged instrument for surgery.

INSTRUCTIONS BEFORE SURGERY

- Check all parts of Jaws & Blade assembly, Insert assembly and Handle for mechanical deformities and insulation breakages. Open the sleeve & Blade assembly to check proper cleaning of the instrument.
- Clean the Jaws & Hinge areas using H_2O_2 followed by any permissible disinfectant as per the Operations Theatre norms.
- Make sure that no tissue/ blood is left inside the hinge areas, blade assembly and insert assembly. This can damage/ contaminate the instrument during next usage.
- Ensure to assemble (refer **Instruction for Re-Assembly of Device** section) the instrument with blade before sending for sterilization.
- Wrap all the detached parts and assembly separately in a cloth to cover them completely as sterilization process may damage insulation of the open parts/ assembly.
- Pack all the covered assembly in one bunch before sending for sterilization.

INSTRUCTIONS DURING SURGERY

(A) FUNCTIONAL INSTRUCTIONS DURING SURGERY

- Make sure the instrument to be used for surgery is sterilized.
- Connect the instrument cord to the vessel sealing port of Shalya series of electrosurgical (ESU) generators, power on the generator and wait for the Ready indicator.
- Then, hold the tissue to be sealed in between the jaws of the instrument. Position the targeted tissue within the open jaws. Do not overstuff the jaws.
- Close the handle to apply the calibrated pressure over the held tissues.
- Activate the RF energy by pressing appropriate switches provided on the generators. Take care that the RF energy is activated only after the handle is completely closed.
- Allow the generator to complete the sealing cycle.
- Stop RF energy activation once the audio/visual alarm for sealing cycle competition is given by the generator.
- Press the blade trigger to cut the tissue. Do not activate the blade without completion of sealing cycle as this may cut the live arteries resulting in blood loss during surgery.

CAUTION

- Open the instrument gently. Do not pull the instrument from the tissue because this may damage the tissue seal.
- Do not give saline wash till procedure is completed as vessel sealing does not function in conductive medium
- Do not press the blade trigger in case of open re-Hold, close re-Hold or incomplete sealing alarm given by the ESU. Always refer the instruction manual provided by the ESU manufacturer for the details of these alarm condition..

(B) SAFETY INSTRUCTIONS DURING SURGERY

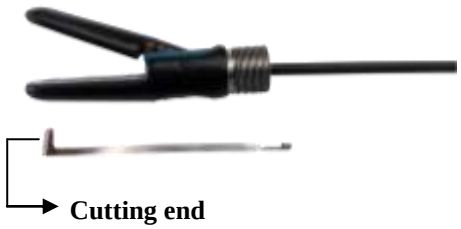
- Blade is a sharp element, it can operate even when the jaws are not closed which can prove to be fatal. Hence, it should be handled with utmost care during a surgery or while cleaning the instrument.
- **DO NOT USE NORMAL SALINE (NS) TO CLEAN THE INSTRUMENT AT ANY STAGE. USAGE OF SALINE COULD RESULT IN FAILURE OF THE INSTRUMENT.**
- Perform periodic cleaning of jaws using cleaning solution prepared with 50% H_2O_2 & 50% permissible disinfectant (like Betadine) for cleaning tissue and fat deposition on jaws during surgery.
- Open the sterilized bunch of the instrument only in the sterile zone of OT.
- Inspect all assembly for physical damage and insulation failure during sterilization.
- Assemble the instrument as per the re-assembly instructions and check functioning of the instrument before using for surgery.
- Sealing instrument may not be competent for sealing the arteries below 1mm due to functional behavior. Use other instrument in such case.
- Do not use the device in blood rich environment.
- In case of open re-hold (OP rEH Old) alarm, check instrument assembly and cable connection, also hold the tissue properly in the device to restart the sealing cycle. If this problem persists, please call for technical help.
- In case of close re-hold (CL rEH Old) alarm; check the instrument assembly for any metal object/ clips in the jaw during sealing or short circuit in jaws **or** usage of device in presence of blood rich environment **or** normal saline (NS). Rectify the condition & retry sealing cycle till completion alarm is received. If the problem persists, please call for technical help.
- When working in confined spaces, precautions should be taken to protect surrounding tissue from unintended thermal effects.
- Do not hold more than 7 mm tissue chunk for sealing as this may lead to increase in sealing cycle & lateral thermal spreading.

INSTRUCTIONS FOR DEVICE ASSEMBLY & DIS-ASSEMBLY

(A) DIRECTIONS FOR DEVICE ASSEMBLY

To begin assembly of VcUTer, first the insert assembly and blade assembly have to be assembled. Then, this combined assembly has to be attached to handle assembly.

STEP 1:
Hold the cutting end of the detached blade using a grasping clamp and insert the blade inside the slot provided between the jaws.



(a) Fix the blade between the jaws as shown below.

WARNING: Blade is a sharp element, it can operate even when the jaws are not closed which can prove to be fatal. Hence, it should be handled with utmost care during a surgery or while cleaning the instrument.

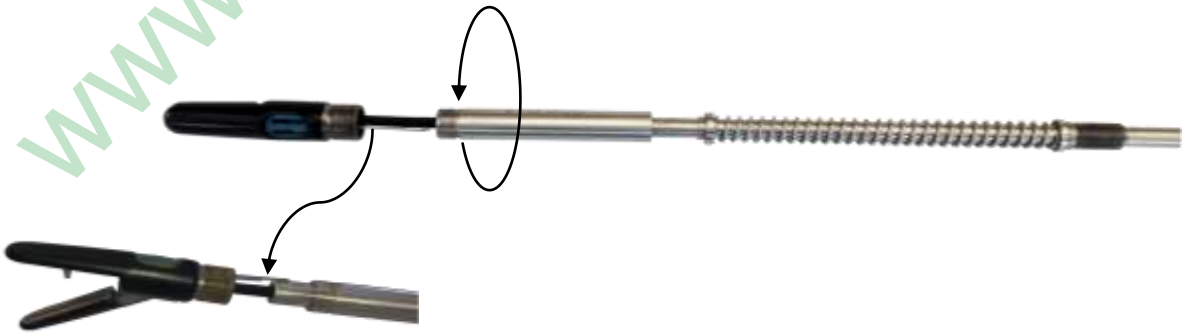
STEP 2:

(a) Bring on the tubing 1 over the tubing 3.

(b) Insert the jaw assembly into the tubing 3.

(c) Fix the free end of the blade into the notch provided on the tubing 3.

(d) Now fix tubing 1 & 3 assembly to the jaws via the threading on the tubing 1.



CAUTION: *Hold jaws in one hand and tighten the tubing 1. Do not hold other parts while fixing this assembly as this could damage the blade.*

(e) Jaws & blade assembly fixed to the tubings 1 & 3 assembly.

STEP 3:

(a) Introduce tubing 2 from the end opposite to the jaws.

(b) Bring the tubing 2 closer to the threading on tubing 3 and rotate clockwise over the threading to fix it to the tubing 2.

CAUTION: *Do not hold other parts while fixing this assembly as this could damage the blade.*

(c) Jaws & blade assembly attached to tubings 1, 2 and 3.

STEP 4:

(a) Introduce sleeve over the tubing from behind.

(b) Bring the sleeve closer to the jaw assembly. Rotate the sleeve clockwise over along the threading on the jaws to tighten the assembly.

(c) Sleeve fixed to the jaws & blade assembly.

STEP 5:

(a) Bring the screw from the end opposite to the jaws.

(b) Rotate the screw clockwise to engage the sleeve and inner tubing by the tightening the screw as shown below.

CAUTION: *Hold the tubing 3 and tighten the screw over it. Do not hold the jaw portion while fixing this assembly as this could damage the blade.*

(c) Joint assembly of jaws & blade assembly and insert assembly are ready.

STEP 6: Gather insert assembly and handle assembly for final assembly of the device.

STEP 7: Advance the handle cap form the jaw end.

STEP 8: Introduce the handle from the screwed end and thread the cap to the handle as shown below.

STEP 9: Below is a fully assembled vessel sealing device.

(B) DIRECTIONS FOR DEVICE DIS-ASSEMBLY

To dis-assemble the device, please follow the reverse steps of assembling procedure.

Read all the warnings, cautions provided with this product before using.....

(A) WARNINGS

- This instrument should be sterilized before use and its use without sterilization is strictly prohibited.
- The instrument must be used by qualified medical person only.
- Do not connect wet accessories to the electrosurgical generator.
- Hazardous Surgical Instrument: This instrument is to be handled by trained technician.
- Improper handling of the blades can be dangerous to the Assembler.
- Blade is sharp element. Always handle the blade with proper care.
- Do not handle the instrument without reading the instructions.
- Proper inspection of the instrument is necessary before use. In case of any insulation failure or damage or improper assembly of instrument, do not use it on the patient as this could be dangerous for Operator and the Patient.
- Do not use Normal Saline (NS) to clean the instrument at any stage. Usage of Saline could result in failure of the instrument.
- Vessel sealing devices will not work in blood rich environment; get the tissue clean before sealing.
- Do not use vessel sealer with the tissue washed with Normal Saline (NS). Do not give saline wash till vessel sealing procedure complete. Use sterile water in case of requirement.
- Do not activate the blade without completion of sealing cycle as this may cut the live arteries resulting to blood loss during surgery.
- The product is meant only for the sealing of blood vessels and tissue bundles and should not be in areas that are devoid of collagen and elastin.
- When disconnecting cables from the generator or instrument, always grasp the cables by the connector only. Never pull the cable by the cord. Do not use instruments or cables if the insulation is not fully intact.

(B) COMPLICATIONS

The following potential risks or discomforts may be associated with electrosurgical procedures.

- Allergic reaction, Arrhythmias, Cardiac or respiratory arrest, Cardiac valve damage, Chest pain, Damage to vessel intima or cardiac ultrastructures, Death, Hematoma / ecchymosis, Hemorrhage, Infarction, Infection, Perforation, Pericardial effusion, Pericarditis / pleuritis, Pseudoaneurysm, Pulmonary edema, Sinus or AV node injury, Stroke, Tamponade, Thrombosis, Vasovagal reaction.

The frequency and severity of these events can vary and may necessitate additional medical ing surgery. Strict adherence to the instruction manual/ IFUs before u