



PRECAUTIONS AND WARNINGS

- Device is not designed for reuse or reuse decontamination processes. Reuse of single-use devices creates a potential risk of patient or user infections, injury, illness or death.
- Do not use if instrument or cord is damaged.
- Do not use a scalpel or other sharp metal instrument to clean the TLS³. Do not grasp the tip boot and heater during cleaning as doing so may damage the tip and could prevent the TLS³ from functioning properly. Wipe only.
- Refrain from unnecessary activation of the heating elements while there is no tissue grasped between the jaws of the TLS³ as this activity may result in premature degradation of the TLS³.
- Do not immerse the TLS³ handle in liquids.
- Do not touch an electrosurgical (Bovie) electrode to any part of the TLS³.
- Use the TLS³ **only** with the UPS (Universal Power Supply). Use of any other power supply may damage the TLS³ and could prevent proper function during use.
- Device is not intended for continuous use. A typical duty cycle of approximately five (5) to ten (10) seconds on, ten (10) seconds off is recommended.
- Activating the device with excessive force or traction may result in an incomplete seal. If hemostasis is not present, use appropriate techniques to achieve hemostasis.
- Procedures using instruments for sealing and dividing of tissue during surgery should be performed only by persons having adequate training and familiarity with these surgical techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any procedure. Surgeons using this device should be familiar with the specific anatomy of the region in which they intend to perform the procedure.
- There are no unusual risks associated with the proper disposal of this equipment. Follow any local regulations regarding proper disposal of used surgical equipment.
- Store in a cool, dry place.

Warning

Do not use in the presence of flammable materials (e.g. alcohol, flammable anesthetics). Always disconnect the instrument before discarding; the UPS power supply is reusable.

Contraindications

The TLS³ is not to be used as a fallopian tube sterilization device.

Compliance with Standards

When used with the UPS, device complies with IEC60601-1 requirements for type CF applied part and meets electromagnetic compatibility requirements of IEC60601-1-2.



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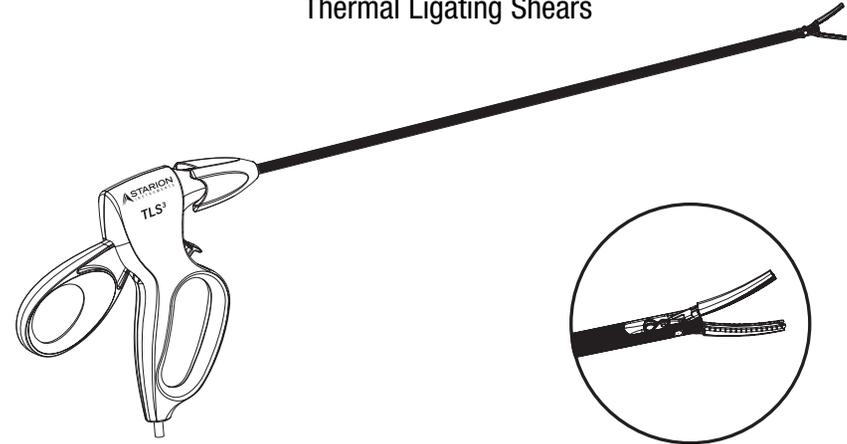
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TLS³ Thermal Ligating Shears



INSTRUCTIONS FOR USE

Only for use with

Starion UPS (Universal Power Supply) (REF 200-006R or REF 200-004R)

Device Description

The Starion TLS³ Thermal Ligating Shears are designed to provide thermal ligation and division in various endoscopic procedures. The TLS³ has heating elements at the distal tip which are activated by a finger switch located on the hand piece of the device. The TLS³ is designed to allow the surgeon to control the heating element power of the device in order to accommodate individual patient anatomy. A power cord extends from the hand piece of the TLS³ and connects to the UPS (Universal Power Supply).

For optimized performance, use with model 200-006R UPS (Universal Power Supply).

Note: See Instructions for Use for the Universal Power Supply.

Intended Use

The device is a single use device and is intended to be used once only for single patient. The TLS³ is intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting natural or synthetic, non-metallic sutures during surgery.

Symbol Definition



Means: Attention — Read and follow indicated Instructions For Use, Precautions, Warnings, etc.



Means: Type CF applied part.



Means: For single use only, do not reuse.



Means: Variable Power.



Means: Sterilized by gamma irradiation.



Means: Authorized Representative



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INSTRUCTIONS FOR USE

Connection to Power Source

1. Remove the TLS³ from packaging.
2. Uncoil the TLS³ power cord; pass the connector end of the power cord off the sterile field.
3. Align the key portion of the connector with the key portion of the instrument connector receptacle on the UPS. Insert the device connector firmly into the instrument connector receptacle (non-sterile) of the UPS.
4. Turn on UPS power switch.

Note: A light adjacent to the instrument connector receptacle of the UPS will illuminate to verify proper alignment of the connectors. If the light is not illuminated after turning ON the UPS, unplug the device connector and realign the key portion and reinsert into the instrument receptacle.

Note: The heating elements' output can be adjusted in the "Variable" mode if desired. (See the UPS Instructions for Use)

Note: The heating elements span the length of the jaws. Tissue grasped outside this region will not be subject to sealing and division by the TLS³.

Pre-Check

The TLS³ has two power options accessible from the finger switch of the hand piece; a variable mode (manually set at the UPS) and a high mode. The following sequence will verify electrical functions: (**Caution:** Do not touch the device tips while performing the pre-check as this may cause injury.)

1. Adjust the knob setting to #1 on the UPS to activate the heat output to minimum power (See the UPS Instructions for Use).
2. Soak a sterile 4x4 gauze pad in saline.
3. Place the gauze pad between the jaws of the device and close the jaws using the thumb trigger.
4. There should be no steam generated from the gauze pad nor tones emitted from the UPS when the jaws are closed but the finger switch is not depressed.

Variable Power Check

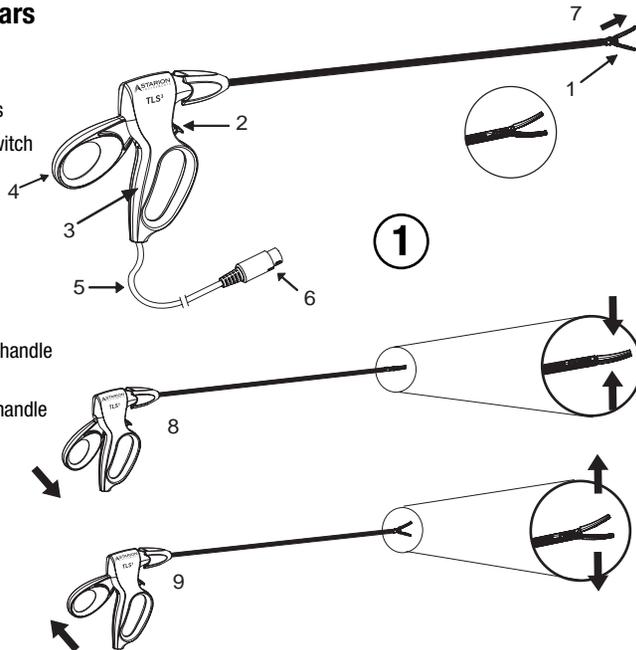
5. Depress the finger switch partially. This allows the user to adjust the heat output (via the power supply). A hissing sound from the gauze pad and a pulsing tone indicates the device is active in the "Variable" mode of the UPS. If a constant tone is emitted and steam generated, the finger switch was depressed too far. Release the finger switch and try again.

High Power Check

6. Continue to depress the finger switch until it is fully depressed. This engages the high power option in the TLS³ activating the heat output to maximum power. Generation of steam with a hissing sound from the gauze pad and a continuous higher pitched tone indicate the device is active in the "High" mode of the UPS. This mode is utilized in avascular tissue or where sealing of vessels is not a primary concern.

1 Thermal Ligating Shears (sterile)

- 1 - Jaws with Heating Elements
- 2 - Two Power Range Finger Switch
- 3 - Handle
- 4 - Thumb Trigger
- 5 - Power Cord
- 6 - Connector
- 7 - Tip Cleaning Direction
- 8 - Squeeze thumb trigger and handle to close jaws
- 9 - Release thumb trigger and handle to open jaws



INSTRUCTIONS FOR USE

Troubleshooting

- If there is no audible tone: Check the electrical connections and ensure the power switch is in the "ON" position. An indicator light located at the receptacle of the UPS for the device should be illuminated, in addition to the power indicator light on the UPS.
- Generation of steam during variable power check: Verify power supply setting of #1.
- Absence of steam during high power check: Add more saline to the gauze pad.
- If there is hissing sound and/or steam generation with no audible tone: DO NOT use the device or power supply and contact Starion Customer Service.

Using the Device

Note: Individual patient anatomy and physician technique can influence the performance of the device. The following steps are recommendations only.

1. Grasp desired tissue between the jaws of the TLS³ and gently squeeze the thumb trigger and handle to close the jaws. Depress the finger switch to achieve the desired power output. Do not squeeze the handle with excessive force. Hemostasis is best achieved with gentle pressure. Generally, lower heat ranges increase the sealing capabilities and the time required to divide tissue. Higher heat ranges decrease the time to divide and may compromise seal integrity.

Note: Depressing the finger switch activates the heating elements. This is not recommended when the jaws are open or no tissue is present between the jaws of the TLS³.

2. After the desired sealing and division of tissue is accomplished, release the finger switch and open the jaws. This deactivates the heating elements.

Note: After removing the TLS³, examine tissue for hemostasis. If hemostasis is not present, use appropriate techniques to achieve hemostasis.

3. If desired, progress to a new region of tissue to be sealed and divided.

Note: It may be desirable to occasionally clean the tip of the TLS³ during the surgical procedure. A saline-moistened surgical gauze or sponge may be applied gently to the jaws to remove buildup of coagulated blood and tissue debris by cleaning in a linear motion along the heating elements. After cleaning the tip, it may also be desirable to open and close the jaws several times by squeezing and releasing the handle to ensure optimal performance.

4. At the end of the surgical procedure, disconnect and discard the TLS³.

2 Universal Power Supply (non sterile)



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Label graphics may vary