



Lotus handpiece

Instructions for use



Instructions for use – handpiece

Before using the product, please read the following information thoroughly

Important

- This document provides instructions for using the Lotus Series 4 System. It is not a set of instructions for surgical technique.
- This document should be read in conjunction with the Lotus Series 4 User Manual.
- Failure to follow the instructions may lead to serious surgical consequences.
- The device is provided cleaned and sterile and is intended for use in single procedure only. Discard after use. Do not attempt to resterilize. Should the package be open or damaged, it must be discarded.
- Store packaged devices in a cool dry area.

Caution

Federal (USA) law restricts this device to sale and use by, or on the order of a physician.



Symbol meanings

Symbol	Meaning
	Consult instructions for use
CE 0120	Complies with Directive 93/42/EEC
	Catalogue Number
	Do not use if package damaged
	Lot No.
	Use By
	Single Use Only
	Caution - Carefully read the instructions
	Temperature Limit
	Humidity Limitation
	Manufactured By
	Sterilized By Ethylene Oxide



Intended use

The Series 4 Lotus Coagulation and Cutting System is indicated for soft tissue surgical incisions when bleeding control and thermal injury are important. Series 4 Lotus may be used as an adjunct to or substitute for electrosurgery, laser surgery, and traditional scalpels in general, plastic, urological, gynaecological, thoracic, exposure to orthopaedic structures (such as spine and joint space) and other endoscopic and open procedures.

Contraindications

The system is not indicated for cardiac surgery.

The handpiece is not indicated for coagulation and dissection of vessels larger than 5mm.

The device is not indicated for incising bone.

The device is not indicated for contraceptive tubal occlusion.



Steps for use

1. For handpiece, ensure that the trigger is in the forward position.
2. Ensure that the Transducer + Waveguide are disconnected from the Generator.
3. Slide the handpiece/sleeve over the end of the waveguide.
4. Align the red dot or white stripe on the transducer case with the orientation stripe on the rotation wheel of the handpiece.
5. Slide the handpiece/sleeve fully up against the transducer case and gently click into place.
6. Connect the transducer to the generator.
7. The white Power Select button on the front of the hand grip can be depressed to toggle the power level between high and low.
8. The coloured Activate button is used to activate the device.
9. The wheel on the front of the handpiece may be rotated to adjust the orientation of the jaw.
10. For operating technique of the full system refer to the Lotus Series 4 User Manual.



Warnings and precautions

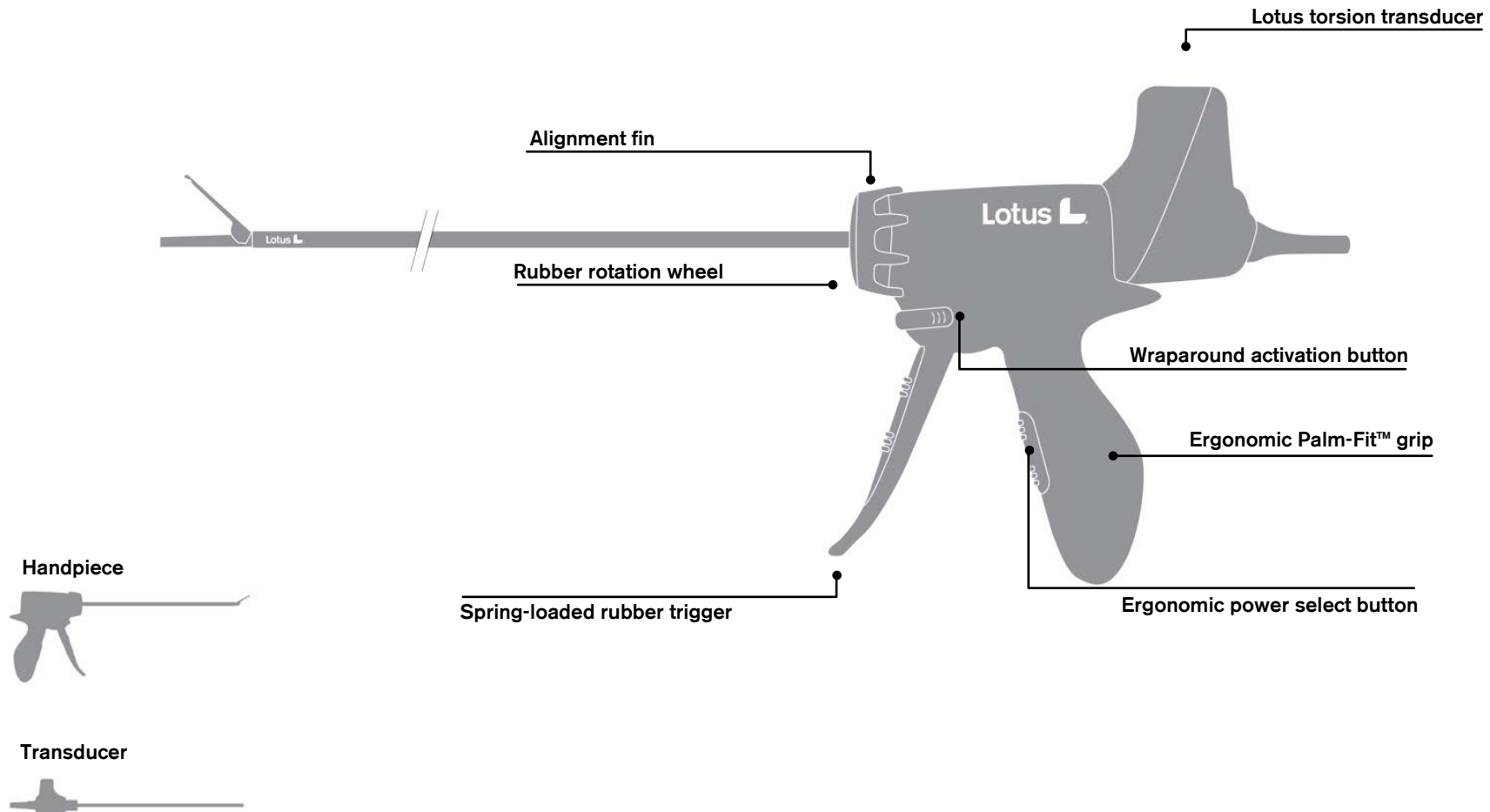
1. Minimally invasive devices can vary in dimension from one manufacturer to another. If combining devices from different manufacturers always ensure compatibility prior to commencing the procedure.
2. Handle the device with care. Do not attempt to modify the device. Damage or changes can affect the ability to attain resonance and reduce the effectiveness of the device. Do not use if damage is suspected.
3. Blood and tissue may build up between the jaw and waveguide during surgery. This can cause the tip of the device to become abnormally hot. Remove any visible tissue build up from the device to prevent the increased risk of burn injury.
4. Ensure the jaw is closed when inserting the device into, and removing from, a trocar.
5. Do not bend the jaw backwards. Take care when inserting the device into a quiver.
6. As with all energy sources (Electrosurgery, Laser or Ultrasound) there are concerns over carcinogenic and infectious potential of the procedure by-products e.g. tissue smoke plume and aerosols. Effective protective equipment should be used for both open and laparoscopic procedures.
7. If the jaw becomes bent do not attempt to straighten it. Dispose of the device and open a new one.
8. If the waveguide touches anything metal while activated, sparks may be produced. Therefore, use caution when using in the presence of flammable gases or liquids.



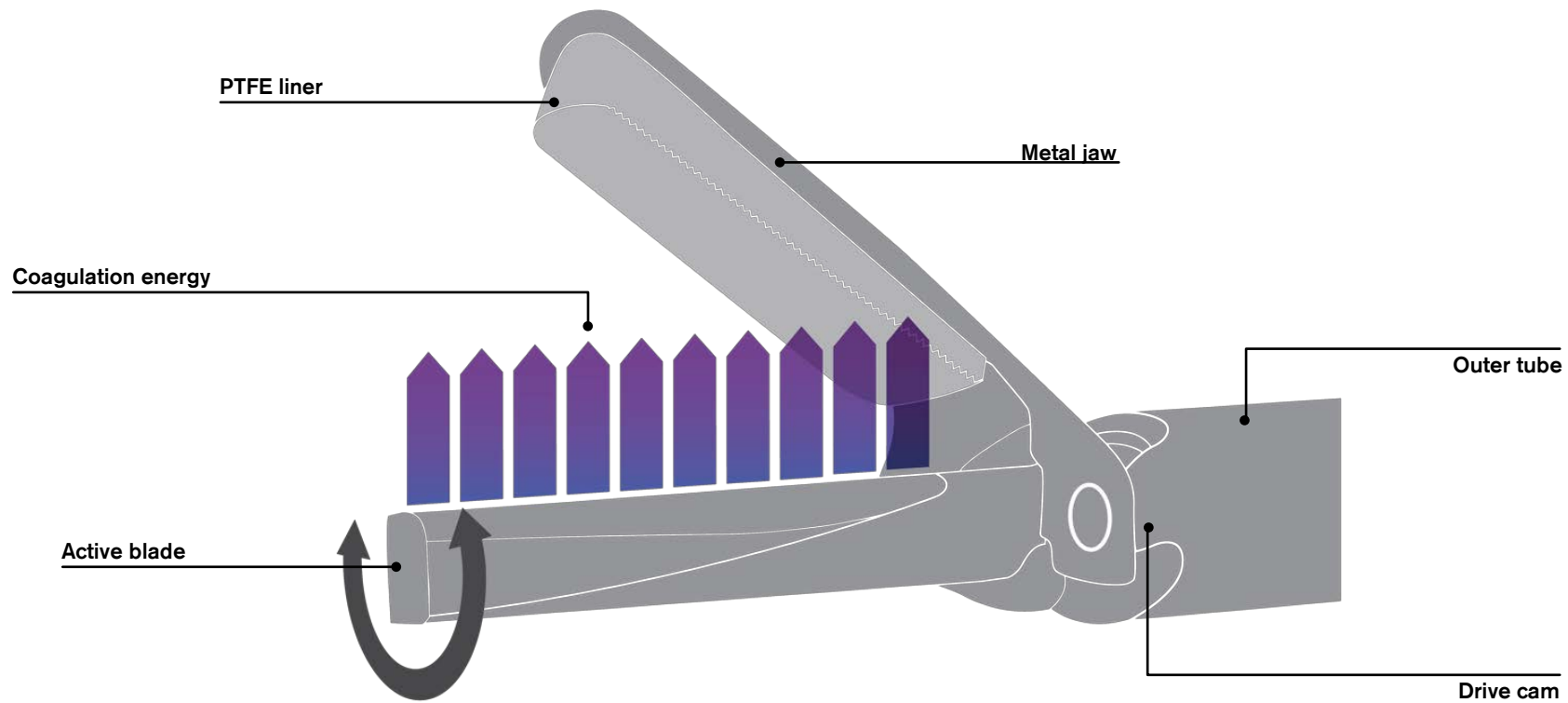
Warnings and precautions (continued)

9. If the waveguide touches anything metal or plastic while activated the device may become damaged.
10. This device should only be used by surgeons who are (1) trained in the types of surgical procedures that are to be carried out and (2) trained in the specific use of ultrasonic surgical instruments
11. Ensure that electrical insulation or grounding is not compromised.
12. After significant activation, the distal end of the device may become hot. Do not allow the blade to contact tissue immediately following activation.
13. Do not allow the device to contact tissue while not in use, in case accidental activation should occur.
14. Care should be taken when operating in the vicinity of nerves.
15. The jaw liner may be damaged if the jaw is closed against an activated waveguide without tissue between them.
16. In case of equipment failure always ensure adequate back up equipment is available.
17. Do not use the device if the expiration date has passed or its sterility is compromised.
18. Never reuse any components of the disposable instrument.

Transducer and handpiece



Distal tip schematic





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