INSTRUCTIONS FOR USE  LOTUS® Handpiece Single Use Device

Connection combinations

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Compatible with Transducer</th>
</tr>
</thead>
<tbody>
<tr>
<td>DS4-200SD</td>
<td>LOTUS Dissecting Shears Straight Handpiece Open 200</td>
<td>SV3-200</td>
</tr>
<tr>
<td>DS4-400CD</td>
<td>LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400</td>
<td>ES4-400CT Or CV3-400</td>
</tr>
<tr>
<td>DS4-500SD</td>
<td>LOTUS Dissecting Shears Straight Handpiece Bariatric 500</td>
<td>SV3-500</td>
</tr>
<tr>
<td>LR4-200SD</td>
<td>LOTUS Liver Resector Straight Handpiece Open 200</td>
<td>LR3-200</td>
</tr>
<tr>
<td>LR4-400SD</td>
<td>LOTUS Liver Resector Straight Handpiece Laparoscopic 400</td>
<td>LR3-400</td>
</tr>
<tr>
<td>VW4-200SD*</td>
<td>LOTUS Vessel Welder Straight Handpiece Open 200</td>
<td>W3-200</td>
</tr>
<tr>
<td>VW4-400SD*</td>
<td>LOTUS Vessel Welder Straight Handpiece Laparoscopic 400</td>
<td>W3-400</td>
</tr>
</tbody>
</table>

* Single items may not be available in your country

Medical Devices Directive

This device complies with Directive 93/42 EEC regarding medical devices.

STERILE FOR SINGLE USE

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

1 Important

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

2 Intended use

Indications

The single use Handpiece is only intended to be connected to approved LOTUS accessories and generators. The LOTUS Ultrasonic Surgical Systems & Accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. LOTUS Series 4 Ultrasonic Surgical System and Accessories may be used as an adjunct to or substitute for electrosurgery, laser surgery, and traditional scalpels in general, gynecological, thoracic surgery, and exposure to orthopedic structures (such as hip joint).

Contra-indications

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 intended for contraceptive tubal occlusion.

3 Device description

The LOTUS Handpiece Single Use Device is provided sterile having been sterilized using EO.

The LOTUS Handpiece Single Use Device is designed to be used with a LOTUS Transducer Reusable Device. When used in combination the Handpiece and Transducer form a scissor-like device enabling the user to perform soft tissue cutting of small vessels whilst controlling bleeding. The Handpiece has finger switches to allow the user to activate the device and also toggle between power levels. The wheel on the front of the Handpiece enables the user to alter the orientation of the jaw.

4 STEPS FOR USE

1. Ensure that the Handpiece trigger is in the forward position.
2. Ensure that the Transducer is disconnected from the Generator.
3. Slide the Handpiece over the end of the waveguide.
4. Align the red dot on the Transducer case with the orientation stripe on the rotation wheel of the Handpiece.
5. Slide the Handpiece 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 detailed information and operating technique of the full system refer to the LOTUS Series 4 Ultrasonic Surgical Systems & Accessories User Manual.

Symbols Glossary

<table>
<thead>
<tr>
<th>REF</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>QTY</td>
<td>Quantity</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot No.</td>
</tr>
</tbody>
</table>

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Straße 4-10
72810 Gomaringen | Germany
Phone: +49 (0) 7072-6002-0
Fax: +49 (0) 7072-6002-33
www.bowa-electronic.com
info@bowa-medical.com

SRA Developments Ltd
Bremridge House, Bremridge, Ashburton, Devon, TQ13 7AW, UK
a BOWA-electronic GmbH & Co. KG company

IFU10928 ISSUE09
BOWA-IFU-11914-LOTUS-HANDPIECE-50-EN 2017-05

**INSTRUCTION**

**STERILE FOR SINGLE USE**

**LOTUS DISSECTOR 4000 SERIES**

**Handpiece**

**LOTUS®®**

**Transducer**

**W3**

**Handpiece**

**LOTUS®®**

**Accessories**

**LOTUS®®**

**Wound**

**Wound**
5 Safety Instructions

5.1 Device specific

1. Replace the Handpiece if it becomes damaged or deformed in any way either prior to or during use.
2. 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.
3. 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.
4. 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.
5. Ensure the jaw is closed when inserting the device into, and removing from, a trocar.
6. Do not bend the jaw backwards. Take care when inserting the device into a quiver.
7. 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.
8. If the jaw becomes bent do not attempt to straighten it. Dispose of the device and open a new one.
9. 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.
10. If the waveguide touches anything metal or plastic while activated the device may become damaged.
11. Use only LOTUS accessories to assure compatibility.
12. Ensure that electrical insulation or grounding is not compromised.
13. After significant activation the distal end of the device may become hot. Do not allow the blade to contact tissue immediately following activation.
14. Do not allow the device to contact tissue while not in use in case accidental activation should occur.
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.
19. Avoid clamping the jaw too hard on incompressible "soft" tissue, bone or inorganic objects such as rubber gastric bands as the Handpiece can generate high forces in this state which could result in damage to the instrument or in extreme cases detachment of the jaw during use. Clamp lightly and let the ultrasound do the work.
20. Follow the user instructions for the LOTUS LG4.
21. Follow the user instructions for the Transducer.

5.2 Application specific

1. This device must only be used by surgeons who are - trained in the types of surgical procedures that are to be carried out and - trained in the specific use of ultrasonic surgical instruments.
2. The user must be trained and competent in the basics and the rules of application.
3. Instruments must only be used by trained medical staff.
4. Do not use for the preparation of metallic implants, such as stents.
5. Do not use on the heart, on the central circulatory system or on the central nervous system.
6. The operation area must be free of explosive gases or inflammable fluids and materials.
7. The instrument must not come into contact with any other uninsulated instruments or objects.
8. Perform coagulation only when the contact surfaces are visible.
9. Care should be taken when operating in the vicinity of nerves.
10. To avoid patient injury in the event of accidental activation, do not lay active instruments on the patient.

5.3 EMC instructions

For detailed EMC information refer to LOTUS Series 4 Ultrasonic Surgical System and Accessories User Manual.

6 Operation, storage and transport

Operating conditions: Temperature: +10 to +50°C; Relative humidity: 0 - 100%, non-condensing; Air pressure: 810 - 1060 hPa.
Store the Handpiece in a clean, dry place in accordance with the storage conditions.
Storage conditions: Temperature: -20 to +50°C; Relative humidity: 0 - 100%, non-condensing; Air pressure: 500 - 1060 hPa.
Protect the Handpieces from exposure to direct sunlight during storage.
It is recommended to keep the Handpieces in the original packaging until use.

7 Disposal

Please ensure that following use the Single Use Handpiece is removed from the Transducer and disposed of as clinical waste. The medical device, packaging material and accessories must be disposed of in accordance with any applicable country-specific regulations and laws.