INSTRUCTIONS

THUNDERBEAT 5 mm, 45 cm, Pistol Grip
TB-0545PC

THUNDERBEAT 5 mm, 35 cm, Pistol Grip
TB-0535PC

THUNDERBEAT 5 mm, 45 cm, Inline Grip
TB-0545IC

THUNDERBEAT 5 mm, 35 cm, Inline Grip
TB-0535IC

THUNDERBEAT 5 mm, 20 cm, Inline Grip
TB-0520IC

THUNDERBEAT 5 mm, 10 cm, Inline Grip
TB-0510IC

THUNDERBEAT 5 mm, 45 cm, Front-actuated Grip
TB-0545FC

THUNDERBEAT 5 mm, 35 cm, Front-actuated Grip
TB-0535FC

Labels and Symbols

Important Information — Please Read Before Use

Chapter 1 Checking the Package Contents

Chapter 2 Instrument Nomenclature and Specifications

Chapter 3 Preparation and Inspection

Chapter 4 Operation

Chapter 5 Storage and Disposal

Chapter 6 Troubleshooting

Appendix

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.
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Safety-related labels and symbols are attached to the instrument at the locations shown below. If labels and symbols are missing or illegible, contact Olympus.

- **THUNDERBEAT instrument (Pistol grip)**

- **THUNDERBEAT instrument (Inline grip)**

- **THUNDERBEAT instrument (Front-actuated grip)**
**Important Information — Please Read Before Use**

### Intended use

The THUNDERBEAT hand instruments are intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

**Seal & Cut mode:**
The THUNDERBEAT hand instruments when used in combination with the Seal & Cut mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc) and endoscopic surgery or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. These devices have been designed to seal and cut vessels up to and including 7 mm in diameter.

**Seal mode:**
The THUNDERBEAT hand instruments when used in combination with the Seal mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc), and endoscopic surgery or in any procedure in which vessel sealing, coagulation, grasping is performed. These devices have been designed to seal vessels up to and including 7 mm in diameter.

The THUNDERBEAT hand instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

### Application of high-frequency treatment

Before proceeding to high-frequency treatment, study well the diagnosis given and the expected prognosis, the properties and purpose of the treatment, its risks and effects, and the possible alternative treatments.

Particularly, balance the risks of the treatment with the potential benefits of a given procedure.
Instruction manual

This instruction manual contains essential information on using the THUNDERBEAT instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the equipment as instructed. Keep all instruction manuals in a safe, accessible location. If you have any questions and comments about any information in this manual, contact Olympus.

User qualification

This manual does not explain or discuss clinical surgical procedures. Therefore, the health care professional using the THUNDERBEAT instrument must be a licensed physician or medical personnel under the supervision of a licensed physician and must have received sufficient training in clinical procedures and the use of ultrasonic and electrosurgical energy.

Instrument compatibility

The THUNDERBEAT instrument should be used in combination with ancillary equipment listed in “System chart” on page 53. Using incompatible equipment could result in patient and/or operator injury, equipment damage and/or decreased product performance.

Reprocessing and storage

The THUNDERBEAT instrument is a sterile single use item. Do not reuse or attempt to sterilize. Reusing or using after re-sterilization, poses an infection control risk, a product performance risk, and can damage the THUNDERBEAT instrument. Store the instrument as instructed in this instruction manual. If not properly stored, the sterility of the instrument may be compromised. The transducer to be used in combination with the THUNDERBEAT instrument is not sterilized before shipment. Before using the transducer for the first time, reprocess it as described in Chapter 5, “Reprocessing: General Policy” and Chapter 6, “Cleaning, Disinfection, and Sterilization Procedures” in the instruction manual for the transducer.
Repair and modification

This THUNDERBEAT instrument contains no user-serviceable parts. Do not modify or attempt to repair; patient or surgeon, surgical staff injury and/or equipment damage can result.

Signal words

The following signal words are used throughout this manual:

<table>
<thead>
<tr>
<th>Signal word</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DANGER</strong></td>
<td>Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.</td>
</tr>
<tr>
<td><strong>WARNING</strong></td>
<td>Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.</td>
</tr>
<tr>
<td><strong>CAUTION</strong></td>
<td>Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.</td>
</tr>
<tr>
<td><strong>NOTE</strong></td>
<td>Indicates additional helpful information.</td>
</tr>
</tbody>
</table>
Dangers, warnings, and cautions

Follow the dangers, warnings and cautions described below when handling the THUNDERBEAT instrument. This information is supplemented by the dangers, warnings and cautions described in each chapter.

**DANGER**

- Avoid using the THUNDERBEAT instrument in a flammable atmosphere. Do not place flammable gas or liquid with the THUNDERBEAT instrument during use. The THUNDERBEAT instrument is not designed to be explosion-proof and a fire hazard may result.

- Before using high-frequency cauterization with a patient wearing a cardiac pacemaker, consult a cardiovascular specialist or the manufacturer of the cardiac pacemaker, and make sufficient preparation to ensure safety. The use of an electrosurgical generator may exert a serious effect on a patient due to malfunction or failure of the cardiac pacemaker.

- Do not bundle the transducer cords and the cords of another medical device (electrocardiograph, endoscopic video camera, etc.) during use. Otherwise, high-frequency signals and the spark discharge noise during coagulation may cause malfunction of the medical device and may harm the patient.

- When using the high flow insufflation unit, always use CO₂ gas. Do not use N₂O gas with the THUNDERBEAT instrument because this gas is flammable.

- Do not use the THUNDERBEAT instrument in combination with a product other than the compatible equipment shown in the “System chart” on page 53.

**WARNING**

- Do not set up or control the THUNDERBEAT instrument with wet hands. Otherwise, an electric shock of the user may result.

- Keep a defibrillator ready for use to prepare for possible medical emergencies. Be sure to withdraw the THUNDERBEAT instrument from the surgical field before using the defibrillator.

- Use the THUNDERBEAT instrument in an environment equipped to accommodate open surgery and have the hospitalization plan prepared in case any problem occurs that may not be resolved by form of endoscopic surgery.

- To ensure electrical safety, do not use the THUNDERBEAT instrument with equipment with which the safety of combined use is not ensured or with equipment with which the safety in regard to leakage current, etc. has not been confirmed.

- Exercise special care when electrosurgical output is applied in the vicinity of the heart. Current flowing through the heart, or the low-frequency current generated by rectification during spark discharge, may cause ventricular fibrillation.
Important Information — Please Read Before Use
Chapter 1  Checking the Package Contents

1.1 Checking the package contents

Confirm that there is a THUNDERBEAT instruction manual in the carton (both individual boxes and boxes of five have only one manual). Withdraw the sterile pack from the carton and confirm the “Use by” date has not passed. Next, check that the THUNDERBEAT instrument, torque wrench, and stabilizer are provided in the pack by referring to the following figure. If you drop the THUNDERBEAT instrument or torque wrench or stabilizer accidentally, be sure to replace it with a new device. If the sterile pack and/or the THUNDERBEAT instrument are damaged, a component is missing or you have any questions, do not use the THUNDERBEAT instrument; contact Olympus for assistance.

NOTE
Torque wrench and stabilizer are also available separately (MAJ-1983 Torque Wrench/Stabilizer Kit).
1.1 Checking the package contents
## Chapter 2  Instrument Nomenclature and Specifications

### 2.1 Symbols and descriptions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td>Refer to instructions.</td>
<td><img src="image2" alt="Symbol" /></td>
<td>Single use only</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>Use by (expiration date)</td>
<td><img src="image4" alt="Symbol" /></td>
<td>Sterilized using ethylene oxide</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>Sterilization lot number</td>
<td><img src="image6" alt="Symbol" /></td>
<td>Lot number</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>Keep away from sunlight</td>
<td><img src="image8" alt="Symbol" /></td>
<td>Keep dry</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>Do not resterilize</td>
<td><img src="image10" alt="Symbol" /></td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td><img src="image11" alt="Symbol" /></td>
<td>This Product Contains No Natural Rubber Latex.</td>
<td><img src="image12" alt="Symbol" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image13" alt="Symbol" /></td>
<td>Authorized representative in the European Community</td>
<td><img src="image14" alt="Symbol" /></td>
<td>Temperature limitation</td>
</tr>
</tbody>
</table>
### 2.2 Nomenclature

#### THUNDERBEAT instrument (Pistol grip)

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Probe tip</td>
<td>During output, ultrasonic vibration or bipolar output is activated.</td>
</tr>
<tr>
<td>2</td>
<td>Grasping section (jaw)</td>
<td>During output, bipolar output is activated.</td>
</tr>
<tr>
<td>3</td>
<td>Shaft</td>
<td>Shaft covered with insulated tube.</td>
</tr>
<tr>
<td>4</td>
<td>Rotation knob</td>
<td>Rotates the shaft.</td>
</tr>
<tr>
<td>5</td>
<td>Transducer connection</td>
<td>Connect the THUNDERBEAT Transducer.</td>
</tr>
<tr>
<td>6</td>
<td>Symbol for THUNDERBEAT</td>
<td>Indicates that this is a THUNDERBEAT instrument.</td>
</tr>
<tr>
<td>7</td>
<td>Control handle</td>
<td>By opening or closing the control handle, grasping section is opened or closed.</td>
</tr>
<tr>
<td>8</td>
<td>Grip handle</td>
<td>During using, it is held or operated.</td>
</tr>
<tr>
<td>9</td>
<td>Handswitch: Blue (SEAL)</td>
<td>Press the SEAL button to deliver the high-frequency (RF bipolar) energy for coagulation of tissue or sealing of vessels.</td>
</tr>
<tr>
<td>10</td>
<td>Handswitch: Purple (SEAL &amp; CUT)</td>
<td>Press the SEAL &amp; CUT button to deliver combined ultrasonic and high-frequency (RF Bipolar) energy for simultaneous coagulation and cutting of tissue or sealing and cutting of vessels.</td>
</tr>
</tbody>
</table>
2.2 Nomenclature

**THUNDERBEAT instrument (Inline grip)**

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Probe tip</td>
<td>During output, ultrasonic vibration or bipolar output is activated.</td>
</tr>
<tr>
<td>2</td>
<td>Grasping section (jaw)</td>
<td>During output, bipolar output is activated.</td>
</tr>
<tr>
<td>3</td>
<td>Shaft</td>
<td>Shaft covered with insulated tube.</td>
</tr>
<tr>
<td>4</td>
<td>Rotation knob</td>
<td>Rotates the shaft.</td>
</tr>
<tr>
<td>5</td>
<td>Control handle</td>
<td>By opening or closing the control handle, grasping section is opened or closed.</td>
</tr>
<tr>
<td>6</td>
<td>Transducer connection</td>
<td>Connect the THUNDERBEAT Transducer.</td>
</tr>
<tr>
<td>7</td>
<td>Symbol for THUNDERBEAT</td>
<td>Indicates that this is a THUNDERBEAT instrument.</td>
</tr>
<tr>
<td>8</td>
<td>Grip handle</td>
<td>During using, it is held or operated.</td>
</tr>
<tr>
<td>9</td>
<td>Handswitch: Blue (SEAL)</td>
<td>Press the SEAL button to deliver the high-frequency (RF bipolar) energy for coagulation of tissue or sealing of vessels.</td>
</tr>
<tr>
<td>10</td>
<td>Handswitch: Purple (SEAL &amp; CUT)</td>
<td>Press the SEAL &amp; CUT button to deliver the combined ultrasonic and high-frequency (RF Bipolar) energy for simultaneous coagulation and cutting of tissue or sealing and cutting of vessels.</td>
</tr>
</tbody>
</table>
### THUNDERBEAT instrument (Front-actuated grip)

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Probe tip</td>
<td>During output, ultrasonic vibration or bipolar output is activated.</td>
</tr>
<tr>
<td>2</td>
<td>Grasping section (jaw)</td>
<td>During output, bipolar output is activated.</td>
</tr>
<tr>
<td>3</td>
<td>Shaft</td>
<td>Is inserted into the abdominal cavity.</td>
</tr>
<tr>
<td>4</td>
<td>Rotation knob</td>
<td>Rotates the shaft.</td>
</tr>
<tr>
<td>5</td>
<td>Transducer connection</td>
<td>Is connected to the transducer.</td>
</tr>
<tr>
<td>6</td>
<td>Symbol 🟦 for THUNDERBEAT</td>
<td>Indicates that this is a THUNDERBEAT instrument.</td>
</tr>
<tr>
<td>7</td>
<td>Grip handle</td>
<td>During using, it is held or operated.</td>
</tr>
<tr>
<td>8</td>
<td>Control handle</td>
<td>By opening or closing the control handle, grasping section is opened or closed.</td>
</tr>
<tr>
<td>9</td>
<td>Handswitch: Blue (SEAL)</td>
<td>Press the SEAL button to deliver the high-frequency (RF bipolar) energy for coagulation of tissue or sealing of vessels. The button can be activated by depressing the front or the side.</td>
</tr>
<tr>
<td>10</td>
<td>Handswitch: Purple (SEAL &amp; CUT)</td>
<td>Press the SEAL &amp; CUT button to deliver combined ultrasonic and high-frequency (RF bipolar) energy for simultaneous sealing and cutting tissue. The button can be activated by depressing the front or the side.</td>
</tr>
</tbody>
</table>
### Closeup of the distal end of the shaft

![Closeup of the distal end of the shaft](image)

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Upper surface of the grasping section</td>
<td>Coated with insulating material excluding the gray area.</td>
</tr>
<tr>
<td>2</td>
<td>Non-insulated area</td>
<td>–</td>
</tr>
<tr>
<td>3</td>
<td>PTFE pad</td>
<td>–</td>
</tr>
</tbody>
</table>
2.2 Nomenclature

**Torque wrench (provided)**

For connecting the transducer (available separately) to the THUNDERBEAT instrument.

**NOTE**

The torque wrench is also available separately (MAJ-1983 Torque Wrench/Stabilizer Kit).

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Head</td>
<td>Mounts on the knob of the instrument.</td>
</tr>
<tr>
<td>2</td>
<td>Assembly index</td>
<td>THIS SIDE UP</td>
</tr>
<tr>
<td>3</td>
<td>Grip</td>
<td>During use, it is held.</td>
</tr>
<tr>
<td>4</td>
<td>Assembly index</td>
<td>Securing direction</td>
</tr>
</tbody>
</table>
### Stabilizer (provided)

For connecting the transducer (available separately) to the THUNDERBEAT instrument.

**NOTE**

The stabilizer is also available separately (MAJ-1983 Torque Wrench/Stabilizer Kit).

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Grip</td>
<td>During use, it is held.</td>
</tr>
</tbody>
</table>
2.2 Nomenclature

THUNDERBEAT Transducer (separately available)

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>THUNDERBEAT instrument connection</td>
<td>Is connected to the instrument.</td>
</tr>
<tr>
<td>2</td>
<td>Transducer cord</td>
<td>Electrical signal is output from the ultrasonic generator to the instrument.</td>
</tr>
<tr>
<td>3</td>
<td>Transducer plug</td>
<td>Connects to the THUNDERBEAT socket of the ultrasonic generator.</td>
</tr>
<tr>
<td>4</td>
<td>Symbol for THUNDERBEAT</td>
<td>Indicates that this is a THUNDERBEAT transducer.</td>
</tr>
<tr>
<td>5</td>
<td>Switch contacts</td>
<td>The switch contacts conduct the handswitch signal.</td>
</tr>
</tbody>
</table>
2.3 Specifications

Transportation, storage, and operating environments

<table>
<thead>
<tr>
<th>Operating environment</th>
<th>Ambient temperature</th>
<th>Relative humidity</th>
<th>Atmospheric pressure</th>
<th>Altitude</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 – 40°C (50 – 104°F)</td>
<td>30 – 85%</td>
<td>70 – 106 kPa</td>
<td>3000 m or less</td>
</tr>
</tbody>
</table>

Transportation and storage environment

<table>
<thead>
<tr>
<th>Ambient temperature</th>
<th>Relative humidity</th>
<th>Atmospheric pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>–40 to +60°C (–40 to +140°F)</td>
<td>10 – 90%</td>
<td>70 – 106 kPa</td>
</tr>
</tbody>
</table>

Specifications

<table>
<thead>
<tr>
<th>Model</th>
<th>Pistol grip</th>
<th>Inline grip</th>
<th>Front-actuated grip</th>
<th>Frequency</th>
<th>Amplitude</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>–</td>
<td>TB-0510IC</td>
<td>–</td>
<td>47 kHz</td>
<td>80 µm</td>
<td>Shaft outer diameter: ø 5.5 mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TB-0520IC</td>
<td>–</td>
<td></td>
<td></td>
<td>Effective length: 100 mm, 200 mm, 350 mm, 450 mm</td>
</tr>
</tbody>
</table>

Rated high-frequency (RF bipolar) voltage: 229 Vp

Duty cycle (Normal cycle): ON: 5 s/OFF: 10 s

Level setting (SEAL&CUT mode)
Output levels for the energy of combined ultrasonic and high-frequency (RF Bipolar) (Time lag from the beginning of high-frequency to the beginning of ultrasonic)
- Level 1: 0 s
- Level 2: 0.5 s
- Level 3: 1 s

Level setting (SEAL mode)
Output levels for the energy of combined ultrasonic and high-frequency (RF Bipolar) (Minimum time of output)
- Level 1: 3 s
- Level 2: 4 s
- Level 3: 5 s
### 2.3 Specifications

<table>
<thead>
<tr>
<th>Medical Devices Directive</th>
<th>![CE logo] 0197</th>
</tr>
</thead>
<tbody>
<tr>
<td>This device complies with the requirements of Directive 93/42/EEC concerning medical devices.</td>
<td></td>
</tr>
<tr>
<td>Classification: Class II b</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EMC</th>
<th>Applied standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 60601-1-2: 2007</td>
<td></td>
</tr>
<tr>
<td>• This instrument complies with the EMC standard for medical electrical equipment; edition 3 (IEC 60601-1-2: 2007). However, when connecting to an instrument that complies with the EMC standard for medical electrical equipment, edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.</td>
<td></td>
</tr>
<tr>
<td>• CISPR 11 of emission: Group 1, Class A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year of manufacture</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>The last digit of the year of manufacture is the second digit of the lot number. In this example, the year is 2010. Ex. K0123 (lot number)</td>
<td></td>
</tr>
</tbody>
</table>

This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: TYPE CF applied part electromedical equipment. The degree of protection against electric shock of this instrument depends upon the electromedical equipment employed. Refer to the particular unit and its instruction manual.
Chapter 3  Preparation and Inspection

3.1 Warnings and cautions: preparation and inspection

**WARNING**

- As a precaution, prepare a secondary method for achieving hemostasis or desection, e.g. a spare of the THUNDERBEAT instrument, and a back-up of the transducer.

- The THUNDERBEAT instrument including the torque wrench and the stabilizer is a single-use product and is to be discarded after use. Do not attempt to resterilize or reuse it. Otherwise, infection or instrument damage may result and the THUNDERBEAT instrument may not function as intended.

- The transducer to be used in combination with this instrument was not sterilized before shipment. Before using the transducer for the first time, process it as described in chapter 5, “Reprocessing: General Policy” and Chapter 6, “Cleaning, Disinfection, and Sterilization Procedures” in the instruction manual for the transducer.

- Do not use the THUNDERBEAT instrument if the “Use by” date printed on the sterile pack has passed. Otherwise, inflammation of tissue and infection may result.

- Be sure to perform the preparation and inspection described in this chapter before use. Also inspect the ancillary equipment to be combined with the THUNDERBEAT instrument according to the instruction manuals for the equipment. Should any irregularity be observed with the THUNDERBEAT instrument, do not use it. Inspect it as described in Chapter 8, “Troubleshooting” in the instruction manual for the ultrasonic generator. If the irregularity is still not resolved after troubleshooting, contact Olympus. Using the THUNDERBEAT instrument while any irregularity is observed, may cause malfunction and may injure the surgeon, surgical staff and/or patient.

- To prevent injury to the surgeon, surgical staff and/or patient due to accidental activation, do not leave the THUNDERBEAT in contact with the patient or a flammable object, such as a drape, while not in use. Also do not leave the instrument in contact with a tissue, the patient or a flammable object, such as a drape, after the output has ceased. Otherwise, unintentional burns of the surgeon, surgical staff and/or patient or a fire hazard may result.
3.1 Warnings and cautions: preparation and inspection

**WARNING**

- To prevent malfunction or damage, be careful not to apply excessive force to the transducer connecting sections during assembly. If the connection is difficult, it is probable that a part is crushed, bent or otherwise deformed. Check the THUNDERBEAT instrument sufficiently and do not use it if an irregularity is observed.

- Avoid overtightening the rotate knob while holding the transducer. Always use the torque wrench and stabilizer provided when assembling or disassembling the THUNDERBEAT transducer. Overtightening may cause damage to the THUNDERBEAT instrument.

- Do not attempt to clean the contacts inside the transducer plug with a sharp object such as the tips of tweezers. Do not use metal brushes for cleaning. Otherwise, deformation or damage of the contact will cause conduction failure, making energy delivery impossible.

- Be sure to fully insert the transducer plug into the USG-400. Otherwise, an unsecure connection may result in unexpected disconnection of the transducer plug, resulting in no output which could lead to potential bleeding.

**CAUTION**

- When inspecting the transducer, do not touch the transducer plug contacts. Static electricity that was accumulated during autoclaving may cause an electric shock.

- Place the transducer on a level surface to prevent it from rolling and accidentally dropping to the floor.

- If the circumference of the contacts of the transducer plug or the switch contacts turn black, replace the transducer. Otherwise, the transducer could short-circuit and damage the ultrasonic generator.

- Use care when placing the THUNDERBEAT instrument on a hard surface to avoid unintentional damage to the THUNDERBEAT instrument.
3.2 Preparation of the equipment

Prepare the THUNDERBEAT instrument, the ultrasonic generator, compatible electrosurgical generator, the transducer compatible ancillary equipment (shown in the “System chart” in the Appendix) and other equipment to be used with the THUNDERBEAT instrument. The required personal protective equipment, such as eyewear, a face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly to prevent skin exposure. Refer to the respective instruction manuals for each piece of ancillary equipment.

3.3 Connection of the transducer

Connect the transducer to the THUNDERBEAT instrument to complete the THUNDERBEAT

**WARNING**

- Make sure that the THUNDERBEAT instrument and the transducer are connected firmly. If they are secured only with the hand, energy output may not be available and damage to the transducer or excessive heating of the exterior may also result. Even if output is available, performance may be compromised.

- Use the provided torque wrench and stabilizer for the connection and disconnection. If another tool or a hand is used for securing, incomplete connection, damage to the THUNDERBEAT instrument or the transducer, or impossibility of disconnection may result.

- If the rotation knob is not rotating freely upon attaching a transducer to the THUNDERBEAT instrument, loosen the rotation knob once and rotate it again. Rotating the rotation knob with excessive force or putting the transducer in a slanted angle may damage the threads.

- When using the torque wrench, securely hold only its grip section. Holding any other part of the wrench may cause the operator’s hand being pinched in the gap of the torque wrench injury and resulting in insufficient tightening or over-tightening of the transducer connection.

- Stop application of force to the torque wrench when an audible click is heard.

- Both torque wrench and stabilizer are single-use products after and are discarded after every procedure. Do not resterilize or reuse them.

- When mounting the stabilizer on the transducer, do not damage the transducer cord.
3.3 Connection of the transducer

- When attaching the head of the torque wrench to the rotation knob, do not damage the shaft insulation.

1. Confirm that the “Use by” date has not passed and the sterile pack shows no signs of damage such as a break, peeled stickers, contamination, or the presence of moisture. If any damage is detected to the package, the sterility may be compromised. Do not use the THUNDERBEAT instrument and replace it with a new THUNDERBEAT instrument.

2. Open the sterile pack and carefully take out the packaging spacer and the THUNDERBEAT instrument from the sterile pack using good sterile technique and check the appearance of the instrument, especially confirming the following:
   - The shaft is not torn, cut, peeled or rolled up.
   - The metallic section on the shaft and the grasping section is not corroded or discolored.
   - The appearance is free of bending, deformation, and other irregularity.

   In addition, if the packaging spacer is enclosed in the sterile pack, carefully take it out from the sterile pack using good sterile technique. Should any damage and/or irregularity be observed, do not use the THUNDERBEAT instrument and replace with a new THUNDERBEAT instrument.

3. Check the appearance of the transducer for rust, disconnection, cracks, loosening, and transducer cord damage. Should any irregularity be observed, replace it with a new one.

4. Be sure to disconnect the transducer plug from the ultrasonic generator before connecting or disconnecting the transducer to/from the THUNDERBEAT instrument.

5. Insert the instrument connection of the transducer into the transducer connection of the THUNDERBEAT instrument.

Figure 3.1

Pistol grip | Inline grip | Front-actuated grip
6 Turn the rotation knob clockwise with a light force, holding the transducer by the other hand until the rotation knob stops.

7 Mount the stabilizer on the transducer.

8 Grasp the stabilizer grip mounted on the transducer and attach the head of the torque wrench to the proximal end of the shaft with the side marked "THIS SIDE UP" facing the distal end of the shaft.
3.3 Connection of the transducer

9 Grasp the stabilizer grip mounted on the transducer and attach the head of the torque wrench down onto the rotation knob.

![Figure 3.5](image)

Pistol grip  Inline grip  Front-actuated grip

10 Grasp both the grip of the torque wrench and the stabilizer mounted on the transducer and then rotate the rotation knob clockwise slowly with the torque wrench until the torque wrench clicks.

![Figure 3.6](image)

Pistol grip  Inline grip  Front-actuated grip

*Moving to next page*
3.3 Connection of the transducer

**CAUTION**

- In the case of the inline grip model, do not hold the grip handle and transducer together while rotating the rotation knob with the torque wrench.

![Inline grip](image)

Figure 3.7

- Do not dispose of the torque wrench and the stabilizer but keep them in a sterile condition, because they will be used for changing and withdrawing the transducer during the procedure and post-procedure.

11 Detach the torque wrench from the stabilizer.

12 Confirm the following:

- The grasping section at the distal end of the shaft can be opened and closed smoothly when you move the control handle until the control handle strikes the grip handle to stop.

- The rotation knob can be turned smoothly when the grasping section is open.

Should any irregularity be observed, replace the THUNDERBEAT instrument with a new one.
3.4 Preparation and inspection of compatible electrosurgical generator and ultrasonic generator

**WARNING**

Always use the THUNDERBEAT in combination with the compatible electrosurgical generator and the ultrasonic generator. The THUNDERBEAT cannot be combined with other generators.

<table>
<thead>
<tr>
<th>Ultrasonic Generator</th>
<th>Electrosurgical Generator</th>
</tr>
</thead>
<tbody>
<tr>
<td>USG-400</td>
<td>ESG-400</td>
</tr>
</tbody>
</table>

Table 3.1

Prepare and inspect the generators according to their instruction manuals. Should any irregularity be observed, do not use them; contact Olympus.

3.5 Connection to ultrasonic generator

- Connecting/disconnecting the transducer plug to/from the ultrasonic generator

**WARNING**

Do not connect the transducer plug to the ultrasonic generator while the transducer, transducer cord and/or transducer plug are wet. Otherwise, an electric shock and/or burns may result.

**CAUTION**

- Always hold the transducer plug when connecting or disconnecting the transducer plug to the ultrasonic generator. Holding a part other than the plug may unexpectedly bend, stretch, twist, or squeeze the transducer cord, and result in snapping of the wires.
- Do not touch the transducer plug contacts. Static electricity that was accumulated during autoclaving may cause an electric shock.
- If a liquid or foreign object gets inside the transducer plug, withdraw the object by referring to the instruction manual for the transducer. Otherwise, equipment malfunction may result.
3.5 Connection to ultrasonic generator

**CAUTION**

- Do not attempt to clean the contacts inside the transducer plug with a sharp object such as the tips of tweezers. Also, when cleaning the contacts with a brush, do not poke or rub the contacts with the metal tip on the bristles of the brush. Otherwise, deformation or damage of the contact will cause conduction failure, making energy delivery impossible.

- Be sure to fully insert the transducer plug securely. Otherwise, the unsecure connection may result in unexpected disconnection of the transducer plug, resulting in no output which could lead to potential bleeding.

---

**Connecting the THUNDERBEAT to the ultrasonic generator**

1. Confirm that the symbol 1 for THUNDERBEAT on the transducer plug and transducer socket are identical.

2. Fully insert the transducer plug into the transducer socket of the ultrasonic generator until it is fully seated.

---

**Disconnecting the THUNDERBEAT**

Hold the ultrasonic generator with one hand and the transducer plug in the other hand, pull out the transducer plug.
3.6 Inspection of ancillary equipment

Inspecting the system

**CAUTION**
- During the inspection, also refer to the instruction manual for THUNDERBEAT Transducer, ultrasonic generator, and compatible electrosurgical generator.
- After the transducer plug is connected to the generator and the ultrasonic generator is turned ON, the generator touch-screen should show the corresponding symbol that is identical to the symbol on the transducer plug. If these symbols are not identical, the ultrasonic generator or transducer may malfunction. If this occurs, immediately stop using the system and contact Olympus.

1. Prepare and connect ancillary equipment to be used with the THUNDERBEAT by referring to their respective instruction manuals.
2. Inspect the system by referring to the instruction manual for the ultrasonic generator.
3. Confirm that the selected output level is appropriate for the procedure to be performed.
   - If the selected output level is not appropriate, press the plus or minus button to set the appropriate output level.
   - When both the THUNDERBEAT and the SONICBEAT are connected, set the output level in the corresponding “Set screen” (referring to Section 5.4, “Output setting” in the instruction manual for the ultrasonic generator).
Output mode

<table>
<thead>
<tr>
<th>Output Mode</th>
<th>Energy</th>
<th>Output Level (Default Level)</th>
<th>Main Purpose</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEAL &amp; CUT</td>
<td>Ultrasonic + High frequency (RF bipolar output)</td>
<td>1 – 3 (1)</td>
<td>Tissue sealing/cutting Blood vessel sealing/cutting</td>
<td>• This mode is same as the setting 39 of FineCoag mode of the ESG-400. • The output setting that has been validated for vessel sealing is level 1. • The lower the output level setting is the faster the cutting speed will be. • The higher the output level setting is the longer the RF bipolar output time will be. • The sealing performance is not changed regardless of the output level.</td>
</tr>
<tr>
<td>SEAL</td>
<td>High frequency (RF bipolar output)</td>
<td>1 – 3 (3)</td>
<td>Tissue sealing/hemostasis Blood vessel sealing/hemostasis</td>
<td>• This mode is same as the setting 42 of HardCoag mode of the ESG-400. • The output setting that has been validated for vessel sealing is level 3. • The higher the output level setting is the longer the RF bipolar output time will be.</td>
</tr>
</tbody>
</table>

Table 3.2

* For the high-frequency (RF bipolar) output of SEAL & CUT and SEAL mode, refer to the instructions manual for the compatible electrosurgical generator.

Correlation between cutting speed and output level in SEAL & CUT mode

<table>
<thead>
<tr>
<th>Output level</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cutting speed indicator bars</td>
<td>3 (High/Fast)</td>
<td>2 (Middle/Median)</td>
<td>1 (Low/Slow)</td>
</tr>
</tbody>
</table>

Table 3.3
3.6 Inspection of ancillary equipment

Figure 3.9

The cutting speed indicator bars

THUNDERBEAT Set screen of the ultrasonic generator
### Verification of the high-frequency (RF bipolar) output

**WARNING**

- The output should always be verified outside the body cavity to avoid unintended tissue damage. Otherwise, tissues may be burnt.

- Verify the high-frequency (RF bipolar) energy delivery before surgery. Otherwise, the THUNDERBEAT may not function properly during the surgery.

- For inspecting the output in SEAL mode, do not press the SEAL & CUT button (purple) of handswitch or the SEAL & CUT pedal (left pedal: purple) of the footswitch accidentally. Otherwise, malfunction of the THUNDERBEAT instrument may not be detected correctly.

**CAUTION**

- Do not touch the probe tip during output. Otherwise, the high-frequency (RF bipolar) current may cause burns.

- If the output tone does not sound or the output screen is not displayed even when the handswitch or footswitch pedal is pressed, immediately stop using the system and turn the system OFF. The ultrasonic generator, the THUNDERBEAT or footswitch may be defective. Take proper measures as instructed in Chapter 8, “Troubleshooting” in the instruction manual for the ultrasonic generator. Continuing the use of the ultrasonic generator in this condition may result in burns of the surgeon, surgical staff and/or patient.

- If the output tone does not cease to sound even when the handswitch or footswitch pedal is released, immediately stop using the system and turn the system OFF. The ultrasonic generator, the THUNDERBEAT or footswitch may be defective. Take proper measures as instructed in Chapter 8, “Troubleshooting” in the instruction manual for the ultrasonic generator. Continuing the use of the ultrasonic generator in this condition may result in burns of the surgeon, surgical staff and/or patient.

- Do not touch the container with the probe tip or grasping section during activation. Also, do not fully submerge the grasping section in saline, otherwise an error window could be displayed along with an error tone.

- If an error window is displayed together with an error tone during the inspection of the output, wipe any remaining saline from the probe tip and the grasping section with dry, sterile gauze. Then, retry the verification submerging the probe tip and the grasping section in saline correctly.

- If you retry the verification correctly and the error window and error tone still persist, stop using the system and take remedial measures by referring to Chapter 8, “Troubleshooting”, in the instruction manual for the ultrasonic generator.
3.6 Inspection of ancillary equipment

**NOTE**

When the high frequency output activated for a long time (more than 15 seconds) the SEAL incomplete error is occur, but the THUNDERBEAT doesn't have any problem. Because it is normal.

1. Prepare a sterile container (like a bowl) with dimensions similar to those shown in Figure 3.10. Fill it with saline.

   ![Figure 3.10](image)

   **Figure 3.10**

   - Sterile container
   - Saline
   - Depth: more than 5 cm.
   - Diameter: more than 10 cm.

2. Open the grasping section completely and submerge only the distal half of the grasping section (different color area) and the probe tip in saline (see Figures 3.11).

   ![Figure 3.11](image)

   **Figure 3.11**

   - Different color area

3. Press and hold the SEAL button (blue) of the handswitch or the SEAL pedal (right pedal: blue) of the footswitch for the high-frequency (RF bipolar) output.
4 Confirm the following items during the SEAL mode output:
   • During activating, the activation in “All screen” or “Set screen” is displayed on the touch-screen of the ultrasonic generator, no error window (see Figure 3.12).
   • The output tone sounds from the compatible electrosurgical generator.

Output inspection when only the THUNDERBEAT is connected

Output inspection when both the THUNDERBEAT and the SONICBEAT are connected

5 After the confirmation, take the probe tip and the grasping section out of the saline and release the SEAL button of the handswitch or the SEAL pedal of the footswitch.

6 Wipe any remaining saline on the probe tip with dry, sterile gauze.
3.6 Inspection of ancillary equipment

**Inspecting the combination with the trocar**

**WARNING**

- The outer diameter of the shaft of the THUNDERBEAT instrument is 5.5 mm. Use a trocar with a corresponding size. Be sure to confirm the THUNDERBEAT instrument and trocar compatibility prior to use.

- When inserted through a trocar whose inner diameter has a sharp edge or tight fit, damage may occur to the shaft insulation. Prior to use, insert the THUNDERBEAT into the trocar and confirm that the insulation of the shaft is not damaged.

**CAUTION**

When inserting or withdrawing the THUNDERBEAT into or from the trocar, close the control handle by hand firmly. Do not open the control handle while inserting or withdrawing the THUNDERBEAT. This would put excessive stress on the grasping section and may cause the handle and trocar to be broken. There is a case where manipulation of the handle would not be relayed to the grasping section. This is because the internal mechanism of the handle is designed to break when excessive stress is applied to the grasping section during use.

1. Hold the control handle to close the grasping section of the THUNDERBEAT instrument, and carefully insert the THUNDERBEAT into the trocar.
2. Confirm that the grasping section and the probe tip of the THUNDERBEAT instrument are extending from the end of the trocar.
3. Make sure that the shaft moves smoothly in the trocar tube. If not, replace the trocar.
4. After confirming the compatibility, carefully withdraw the THUNDERBEAT from the trocar.
Chapter 4 Operation

4.1 Warnings and cautions

The surgeon and/or surgical staff using this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical surgical procedures. It only describes basic operation and important information related to the operation of this instrument.

**WARNING**

- When using any energy source (e.g., electrosurgical, laser, ultrasonic, etc.), be aware that the smoke or aerosols generated when energy is applied to the tissue may be carcinogenic or infectious. Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During operation, wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.

- Before use, be sure to read the instruction manuals for the compatible electrosurgical generator and ultrasonic generator that operate in conjunction with the THUNDERBEAT.

- Should any irregularity (error window, abnormal noise, abnormal output, abnormal operation, abnormal appearance, etc.) or malfunction be observed while using the THUNDERBEAT, stop the use and withdraw the instruments from the body cavity. Do not withdraw the transducer plug from the ultrasonic generator. Check the equipment by referring to Chapter 8, “Troubleshooting”, in the instruction manual for the ultrasonic generator. If the irregularity remains after troubleshooting, replace the transducer. If this does not resolve the issue, replace the THUNDERBEAT instrument. If the irregularity remains unresolved, contact Olympus.

- Use the THUNDERBEAT instrument properly. Improper use may cause the probe tip to fall off inside the body cavity, premature wear, partial separating, deformation, breakage, patient and/or operator injury, malfunction of the cardiac pacemaker, burns of the surgeon, surgical staff and/or patient, electric shock, abnormal output or malfunction, perforation, bleeding, postoperative bleeding, tissue damage and infection to the surgeon, surgical staff and/or patient.

- Should any crack, scratch, deformation, split, protrusion, or partial separating be observed on the probe tip, grasping section, PTFE pad, shaft, the surface of the transducer, transducer cord, or transducer plug, do not use them and replace the damaged instrument or the transducer with a spare. Using a damaged device may cause burns due to abnormal output or high-frequency (RF bipolar) current leakage or breakage of the probe tip, the PTFE pad, and the grasping section.
4.1 Warnings and cautions

**WARNING**

- The probe tip, the PTFE pad, and the grasping section of the THUNDERBEAT instrument wear due to ultrasonic vibrations. An excessive wear occurs depending on the way of use during the procedure, which may cause accidental destruction or deterioration of coagulating, coagulating/cutting, sealing, or sealing/cutting performances. To avoid such an event, be sure to prepare a spare THUNDERBEAT instrument, torque wrench, and stabilizer.

- Do not use the THUNDERBEAT to seal a blood vessel with a diameter over 7 mm. Otherwise, sufficient sealing may not be achieved.

- Even when using this instrument on blood vessel(s) with diameter of 7 mm or less, coagulation or sealing by the instrument could be insufficient, and patient bleeding may result. Depending on the condition of the patient or the blood vessel(s) and usage of THUNDERBEAT. When using this instrument on blood vessel(s) with a diameter over 4 mm, be careful to avoid rebleeding. The recommended output setting for the Seal & Cut mode is level 1, and/or the recommended output setting for the Seal mode is level 3.
4.1 Warnings and cautions

**WARNING**

- If the THUNDERBEAT is used to treat a patient with blood hypertension, coronary disease, arteriosclerosis, diabetes, and/or cirrhosis, or a patient with blood vessel irregularities such as calcification, sufficient sealing performance may not be possible. To ensure high sealing capability, use the THUNDERBEAT to seal healthy normal vessels.

- Coagulation may be incomplete due to thick vessels or certain blood characteristics. Study well using the other instruments such as, the metal clips and stapler at the same time.

- Confirm the state of tissue and/or vessel when using the THUNDERBEAT. After removing the instrument, be sure to examine the tissue for hemostasis. If bleeding is observed, conduct hemostasis with appropriate techniques.

- When treating a blood vessel and/or tissue, squeeze the control handle firmly until the control handle touches the grip handle to stop. Otherwise, incomplete sealing may cause bleeding.

- Always position a vessel in the middle of the grasping section. If the vessel extends beyond the distal tip of the grasping section, the coagulation may be incomplete and the THUNDERBEAT may wear out prematurely.

- Do not pull or twist the blood vessel and/or tissue with a strong force during the procedure. Otherwise, the coagulation may be incomplete.

- Thermal denaturation of the proximal tissue may occur when treating the target tissue in SEAL & CUT mode. The higher the output level, the wider the range of thermal denaturation becomes. To select the proper output level considering the state of target tissue.

- In the SEAL mode, the lower output setting may cause degradation of seal performance.

- If the THUNDERBEAT is used with SEAL mode level 1 for sealing of blood vessel(s) with diameter over 2 mm or if the THUNDERBEAT is used with SEAL mode level 2 for sealing of blood vessel(s) with diameter over 4 mm, sufficient sealing performance may not be possible.

- Ultrasonic and high-frequency (RF bipolar) energy is delivered to the tissue through the probe tip and the grasping section during activation. The energy may change water into vapor and the thermal energy of vapor may cause unintended damage to the tissue which is in proximity to the probe tip and/or the grasping section. Be careful to the above situations during the surgery.

- To seal adjacent tissue, overlap the edge of the existing seal. The second seal should be distal to the first seal to increase seal margin. Otherwise, incomplete sealing may cause bleeding and/or the existing seal may be opened.

- Do not cut the existing seal performed with SEAL mode by using another instruments which cause thermal diffusion such as electrosurgical pencil or ultrasonic scalpel.
4.1 Warnings and cautions

**WARNING**

- When applying energy to a blood vessel, confirm that the distal end of the shaft is not submerged in fluids such as pooled blood or saline. Such conditions could potentially reduce the effectiveness of the THUNDERBEAT and could cause unintended tissue damage.

- Do not activate the THUNDERBEAT simultaneously during suctioning and/or irrigating the surgical site. Otherwise, an unexpected current path may cause unintended tissue burns or degradation of treatment performance.

- When a body fluid or tissue is present on the grasping section, probe tip or shaft surface during the procedure, immediately withdraw it by immersing the grasping section and probe tip in saline or wiping with sterile gauze. Otherwise, the performance may be degraded. Failure to maintain a clean grasping section may result in the grasping section becoming hard to open or close, and the load imposed on the distal end of the grasping section may cause vibration failure or other issues.

- The THUNDERBEAT gives priority to the function of a switch pushed earlier. During the procedure, be very careful not to accidentally activate the handswitch or footswitch as this may result in unintentional coagulation or cutting of tissue. Particularly, never mistake the SEAL & CUT button for the SEAL button because this may lead to unintentional cutting of tissue.

- During the seal mode, do not stop activation until the “SEAL Complete” tone is heard. Otherwise, the target tissue may not be coagulated and may bleed.

- If the grasping section, the PTFE pad, or the probe tip falls off, stop using the THUNDERBEAT immediately and retrieve it by appropriate means.
4.1 Warnings and cautions

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If the alarm tone sounds and an error window is displayed during the procedure, immediately stop the procedure. During surgical procedures, withdraw the THUNDERBEAT instrument from the body cavity. Do not remove the transducer plug from the ultrasonic generator. Follow Chapter 8, “Troubleshooting”, in the instruction manual for the ultrasonic generator. Otherwise, the probe tip may break and fall off inside the body cavity.</td>
</tr>
<tr>
<td>• Do not activate output in Seal &amp; Cut mode while the grasping section 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 probe tip and the grasping section may result in various forms of damage in the probe tip and/or the PTFE pad, such as premature wear, breakage, deformation, and/or falling off inside the body cavity and/or partial separating.</td>
</tr>
<tr>
<td>• If sparks are discharged frequently from the grasping section during output, the grasping surface (white PTFE pad surface) may be worn out. Continued use under this condition may result in a scratch on the probe tip. This could lead to the probe tip breaking and falling off into the body cavity during output.</td>
</tr>
<tr>
<td>• The THUNDERBEAT instrument should be used for soft tissue. Do not activate output while grasping hard tissue such as bone or highly calcified tissue, or hard objects such as metal clips, stapler, or other instruments (e.g., uterine manipulator, forceps, and others). Otherwise, it may cause the probe tip to be scratched or come into direct contact with the metal area of the grasping section as the heat generated by the friction between the hard object and the probe tip could cause wear/deforming/split/protruding/partial separating of the PTFE pad. In turn, the probe may break before displaying an error window or generating an alarm tone.</td>
</tr>
<tr>
<td>• Do not activate output while applying the probe tip to the tissue with a strong force, grasping thick tissue, or positioning the tissue, or twisting the shaft, or rotating the rotation knob. Manipulate and isolate the targeted tissue with another instrument, grasp the targeted tissue with the THUNDERBEAT instrument, and then activate. Otherwise, it may cause the deforming/split/protruding of PTFE pad or a scratch on the probe tip by interference with the other parts, which could result in the probe tip breaking and falling off inside the body cavity.</td>
</tr>
<tr>
<td>• Do not activate output while grasping thick, harder tissue, such as the uterine cervix, with the distal part of the probe tip and the grasping section. Otherwise, the grasping surface (white PTFE pad surface) may be worn out partially. Continued use under this condition may result in exposure of the metal area of the grasping section and a scratch on the probe tip. This could lead the probe tip to breaking and falling off into the body cavity during the output.</td>
</tr>
<tr>
<td>• When tissue or coagulum build-up, on the grasping section or the probe tip, use a piece of moistened, soft gauze to clean the grasping section or probe tip. Do not attempt to scrape it with a sharp object such as a scalpel. Otherwise, the grasping section, PTFE pad or the probe tip may be scratched, which leads the probe tip to break and fall off into the body cavity during treatment.</td>
</tr>
</tbody>
</table>
4.1 Warnings and cautions

**WARNING**

- During TLH colpotomy or LSH amputation, avoid inserting the probe tip vertically and deeply into the uterine cervix and activating the THUNDERBEAT instrument. Do not overfill the grasping section with a large bite of tissue. This may result in damage to the probe tip. Refer to Figure 4.3 on page 44 for an example of technique to avoid grasping a large bite of tissue.

- Do not use the THUNDERBEAT for treatment aiming at blockage of the bile duct or bowel. Successful hemostasis may require adjunct measures when THUNDERBEAT is used on solid organs. Due to the difficulty of visualizing internal structures, proceed slowly and do not attempt to transect large masses of tissue in one activation. Avoid the division of large vascular/biliary bundles when using the instrument under these conditions.

- This instrument is not indicated for female sterilization or circumcision.

- To prevent injury of the surgeon, surgical staff and/or patient due to accidental activation, do not leave the THUNDERBEAT in contact with the patient or a flammable object such as a drape while not in use. Also do not leave the THUNDERBEAT in contact with tissue, the patient or a flammable object such as a drape after output. Otherwise, burns of the surgeon, surgical staff or patient's tissue can be burnt or a fire hazard may result.

- The grasping section and probe tip become hot due to extended ultrasonic output. Do not let it come in contact with tissues other than the target tissue.

- Do not use a high-frequency therapeutic device or laser in the proximity of the area being treated with THUNDERBEAT at the same time. Otherwise, sparks transferred to the mist produced by ultrasonic vibrations may cause burns.

- Do not grasp or let the probe tip contact hard objects such as metal clips, stapler or other instruments (e.g., uterine manipulator). Also, be careful to avoid contacting the probe tip with those accidentally. Particularly during activation, a scratch on the probe tip could occur due to ultrasonic vibration, which leads the probe tip to break and fall off into the body cavity. In addition, the high-frequency (RF bipolar) current flows through the metal and generates spark discharge, which may cause burns and decrease functionalities.
4.1 Warnings and cautions

WARNING

• Whenever possible, avoid contacting the shaft other than the grasping section to the tissue as the temperature of the shaft can become elevated and could cause unintentional burns. Please refer to “Temperature of the shaft, grasping section and probe tip during activation” on page 61 for details of the temperature.

• Only the grasping section should come in contact with the tissue. If other parts (e.g., the metal area around the grasping section or shaft of the THUNDERBEAT instrument) come in contact with the tissue, they may cause burns due to current leakage.

• If releasing the switch does not stop energy delivery, immediately turn the ultrasonic generator off and withdraw the THUNDERBEAT instrument from the patient.

• Before pressing a hand switch or footswitch pedal, make sure that it is the target switch for the desired application. Otherwise, burns of the surgeon, surgical staff and/or patient may result.
4.1 Warnings and cautions

**WARNING**

- Do not pinch or contact the transducer cord with sharp object. Otherwise the cord may break and malfunction, which could cause burns due to a possible leakage of RF Bipolar current.

- Before activating the output, be sure that neither the grasping section nor the probe tip comes into contact with the surrounding tissue. Do not use the THUNDERBEAT if you do not have a sufficient view to confirm the above or if the grasping section and probe tip are penetrating into the tissues. Otherwise, perforation, bleeding or burns may result. Do not use the THUNDERBEAT if you do not have a sufficient view of the grasping section and probe tip to ensure that only the intended tissue is in contact with the grasping section.

- The probe tip of the THUNDERBEAT instrument is sharp. Do not activate the THUNDERBEAT instrument if you do not have a sufficient view to confirm the probe tip. Such condition could cause unintended tissue damage.

- Incomplete or partial cutting tends to occur with thin membranous tissues. Even if a tissue or vessel (especially thin membranous tissue) cannot be cut completely, do not continue output for a longer period. Otherwise, this may cause patient injury and/or deterioration of the equipment. In addition, if the distal end of the shaft is stuck to desiccated tissue, bleeding may also result if you attempt to withdraw it by force.

- If dessicated tissue or coagulum is present on the probe tip in the SEAL mode output, activate the SEAL & CUT mode with the grasping section open. This will assist in the cleaning of the probe tip via ultrasonic vibrations. While doing so, do not touch tissue with the probe tip accidentally.

- Do not hold the transducer surface for an extended period of time. Otherwise, the rise of the surface temperature may result in burns.

- When cutting, or vessel sealing is performed in SEAL & CUT mode, apply light tension on the tissue so that users can confirm that they are transected. Also, stop activation immediately after tissue is transected. Otherwise, the grasping section, the PTFE pad, or the probe tip may break and fall off, and partial separating of the PTFE pad may occur due to a local increase of temperature caused by the friction between PTFE pad and the probe tip during activation.

- If an irregular noise is generated during output, the THUNDERBEAT instrument or the transducer may be damaged. Continuing to use them may cause the probe tip to break and fall off inside the body cavity. Replace the damaged THUNDERBEAT instrument or transducer with a spare one.

- Take care not to drop the transducer or not to subject the transducer to strong impacts. Even if the transducer appears undamaged, do not use it and replace it with a new transducer. Its durability and capability may have been impaired.

- This system will only allow the activation of one instrument at a time. Confirm that other instruments are not being activated before activating a selected instrument.
4.1 Warnings and cautions

**WARNING**

- For hemostasis in the SEAL mode, grasp a bleeding point with the grasping section and the probe tip. Do not use the outside surface of the grasping section for hemostasis because that surface coated with insulating material is not conductive so as not to stop bleeding.
- Do not apply excessive bending, straining, or squeezing force to the cords. It may cause malfunction.
- Do not submerge the handle in any liquid.
- Be careful not to break the probe tip or separate the PTFE pad by the load imposed on the probe tip and the PTFE pad when the instruments are withdrawn from the body cavity and/or the instruments are cleaned.

**CAUTION**

- Activation for extended period of time may cause malfunction.
- Treatment of hard or thick tissue in the SEAL & CUT mode may result in failure to cut/coagulate because of the overload imposed on the probe tip.
- If the SEAL & CUT mode is activated for a long time (3-5 seconds) with the grasping section open, an error could occur.
- When inserting the THUNDERBEAT into or withdrawing it from the trocar tube, gently hold the control handle and make sure that the grasping section is closed. If the THUNDERBEAT is inserted or withdraw with the grasping section open, the probe tip/grasping section may become damaged, or it may become impossible to withdraw it from the trocar.
- When inserting the THUNDERBEAT into or withdrawing it from the trocar, do not apply excessive force. If the THUNDERBEAT is difficult to insert into or difficult to withdraw it from the trocar, make sure that it is not damaged. Attempting to insert or withdraw the THUNDERBEAT with excessive force may cause the insulation on the THUNDERBEAT instrument’s shaft to be peeled and/or make it impossible to withdraw the THUNDERBEAT from the trocar.
- When using the THUNDERBEAT in combination with the trocar, do not apply strong bending pressure to the shaft. If the THUNDERBEAT instrument comes in strongly contact with the opening of the trocar, it could cause the insulation on the THUNDERBEAT instrument’s shaft to be peeled and/or cause other damage to the THUNDERBEAT instrument.
- Do not turn the shaft more than necessary. Doing so will twist the transducer cord, which can cause a malfunction. Also, do not apply excessive force to the transducer cord by bending, straining, or twisting it too much. Otherwise, the damaged cord may cause malfunction.
4.2 Operation

**NOTE**

- When the THUNDERBEAT instrument is withdrawn from the patient due to the occurrence of an error display or other irregularities, the probe tip may break and fall off due to friction between the trocar and the instrument or due to the stress caused by cleaning the probe tip.

- The material of the probe tip is titanium alloy. It is radio-opaque.

- Use a plastic uterine manipulator.

- The following technique, drilling with small biting, is just one example for TLH colpotomy or LSH amputation to avoid grasping a large bite of tissue, and tips/techniques are not limited to this. Details on clinical surgical technique are the responsibility of trained specialists. Patient safety in surgical examinations and surgical treatment can be ensured through appropriate handling by the physician and the medical facility.
  
  - Narrowly open the grasping section and use the probe tip to drill in laterally at a shallow angle while activating the Seal & Cut mode. Close the grasping section slowly and cut through tissue using the distal half of the grasping section to achieve a slow cut and shallow bites around the cervix.

![Figure 4.3](image)

**4.2 Operation**

- **Turning power ON**

  Confirm that the components are appropriately connected for the procedure to be performed as described in Chapter 3, “Preparation and Inspection”. Then turn the compatible electrosurgical generator and ultrasonic generator ON.
4.2 Operation

Setting the output level

1. Confirm that the output level displayed on the touchscreen is appropriate for the procedure.

2. Press the plus or minus button to change the output level, if desired. Set the appropriate output level by referring to “Output mode” on page 29.

3. When both the THUNDERBEAT and SONICBEAT are connected to the ultrasonic generator, press the “THUNDERBEAT” or “SONICBEAT” button on the touch-screen of the ultrasonic generator as described in the generator’s instruction manual to display the set screen for each output mode, and then set the output level as desired for the procedure.

Coagulating and cutting tissues and vessels

NOTE

When SEAL mode is selected and the device detects a change in the state of tissue and/or the vessel during activation, a short tone different from the output tone sounds and the output automatically stops.

1. For a laparoscopic surgery, close the grasping section and carefully insert the THUNDERBEAT into the trocar.

2. When exfoliating tissue, use the tip of grasping section.

3. Grasp the tissue or vessel to be coagulated/cut or sealed by manipulating the control handle. Squeeze the control handle until the control handle strikes the grip handle to stop, and confirm that the grasping section and probe tip are not in contact with surrounding tissues.
4.2 Operation

4 Output mode

**SEAL & CUT mode**
- In the SEAL & CUT mode, stop the output after finding that the vessel or tissue is transected.
- Always grasp a blood vessel in the middle of the grasping section.
- While coagulating and cutting tissue in the SEAL & CUT mode, put light tension on tissue until it separates, and immediately stop the activation after the tissue is separated.

Press and hold the SEAL & CUT button (purple) or the SEAL & CUT pedal (left pedal: purple) of the footswitch to activate the output for coagulation/sealing and cutting. The compatible electrosurgical generator produces the output tone during activation.

**SEAL mode**
- In the SEAL mode, SEAL output is automatically stopped following the SEAL complete tone.
- For hemostasis only, apply the SEAL mode output.
- In the SEAL mode, grasp a bleeding tissue with the grasping section and the probe tip.
- Always grasp a blood vessel in the middle of the grasping section.
- If desiccated tissue is present on the probe tip in the SEAL mode output, activate the SEAL & CUT mode output with the grasping section open so that the desiccated tissue falls caused by the ultrasonic vibration.

Press and hold the SEAL button (blue) of the handswitch or SEAL pedal (right pedal: blue) of the footswitch to activate the output for coagulation/sealing. The compatible electrosurgical generator produces the output tone during activation.

5 After the SEAL & CUT output is stopped or the SEAL output is stopped automatically with the SEAL complete tone, visually confirm that the tissue is completely coagulated.
4.3 Procedure after use

**CAUTION**

- Do not withdraw the trocar and the THUNDERBEAT simultaneously. Otherwise, the grasping section or the probe tip may damage the surrounding tissue, or the THUNDERBEAT itself may be damaged.

- Do not pull the transducer cord when disconnecting the transducer from the THUNDERBEAT instrument. Otherwise, the transducer cord may be damaged.

1. While holding the trocar tube, close the grasping section of the THUNDERBEAT instrument and withdraw it from the trocar slowly and carefully.

2. Turn the compatible electrosurgical generator and ultrasonic generator OFF.

3. Turn OFF any accessories being used with the instruments as described in their respective instruction manuals.
4.3 Procedure after use

4 Disassemble the THUNDERBEAT instrument and transducer with the torque wrench and the stabilizer.

As well as the connection of the transducer, mount the stabilizer on the transducer, and attach the head of the torque wrench to the proximal end of the shaft with the side marked “THIS SIDE UP” facing the distal end of the shaft. Slide the head of the torque wrench down onto the rotation knob.

Grasp both the grip section of the torque wrench and the stabilizer on the transducer and then rotate the rotation knob counterclockwise with the torque wrench until the rotation knob is loosened.

If a THUNDERBEAT instrument cannot be disconnected from the transducer, contact Olympus.

5 Dispose of the THUNDERBEAT instrument, torque wrench, and stabilizer, and clean and sterilize the transducer as described in Chapter 5, “Reprocessing: General Policy” and Chapter 6, “Cleaning, Disinfection, and Sterilization Procedures” of the instruction manual for the transducer.
Chapter 5  Storage and Disposal

5.1 Storage

**WARNING**

- Do not store the sterile instrument packs in a place where they may be damaged, the stickers may be peeled off or they may be exposed to moisture. Otherwise, sterility of the THUNDERBEAT instrument may be compromised and inflammation of tissue and infection may result.

- Do not store this instrument in a place that is exposed to direct sunlight, X-rays, radioactivity or strong electromagnetic waves (e.g., the vicinity of a microwave therapeutic device, short-wave therapeutic device, MRI, wireless set, cellular phone, etc.) or to high temperatures, high humidity or water/moisture. Otherwise, the instrument may be damaged and/or could present an infection control risk.

- Do not store this instrument in the box in which it was shipped. This may present an infection control risk.

- Do not subject this instrument to strong impacts during transportation and storage. Doing so may damage the instrument.

Store this instrument in a clean place under normal temperature and humidity where it will not be exposed to direct sunlight.

5.2 Disposal

**WARNING**

- After use, dispose of the instrument in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.

- Do not reuse this instrument. Otherwise, infection or instrument damage may result and the instrument may become unable to achieve the expected performance.

When disposing of this instrument or any of its components, follow all applicable local laws and guidelines.
5.2 Disposal
Chapter 6  Troubleshooting

6.1 Troubleshooting

If any irregularity is observed, take proper remedial actions by referring to Chapter 8, “Troubleshooting” in the instruction manual for the ultrasonic generator.

**WARNING**

Do not use the THUNDERBEAT instrument on the patient if any irregularity is observed with the equipment. Otherwise, the system may not work properly and serious injury to the surgeon, surgical staff, and/or the patient may result.
6.1 Troubleshooting
Appendix

System chart

The recommended combinations of equipment and accessories that can be used with this instrument are listed below. New products released after the introduction of this instrument may also be compatible for use in combination with this instrument. For further details, contact Olympus.

**WARNING**

If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.
When the ultrasonic generator is combined with the compatible electrosurgical generator, the EMC information shall comply with the compatible electrosurgical generator.
THUNDERBEAT series

Instrument

TB-0535PC

TB-0545PC

TB-0510IC

TB-0520IC

TB-0535IC

TB-0545IC

TB-0535FC

TB-0545FC
System chart

- Torque wrench

- Stabilizer
This model is intended for use in the electromagnetic environments specified below. The user and the medical staff should ensure that it is used only in these environments.

**Magnetic emission compliance information and recommended electromagnetic environments**

<table>
<thead>
<tr>
<th>Emission standard</th>
<th>Compliance</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>Radiated emissions</td>
<td>Class A</td>
<td>This instrument is suitable for use in all establishments other than domestic establishments and those directly connected to a low voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Main terminal conducted emissions</td>
<td>Class A</td>
<td>This instrument’s harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions</td>
<td>Complies</td>
<td>This instrument stabilizes its own radio variability and has no effect such as flicker in lighting apparatus.</td>
</tr>
</tbody>
</table>
## Electromagnetic immunity compliance information and recommended electromagnetic environments

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601-1-2 test level</th>
<th>Compliance level</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>Contact: ±2, ±4, ±6 kV</td>
<td>Same as left</td>
<td>Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>Air: ±2, ±4, ±8 kV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines</td>
<td>Same as left</td>
<td>Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1 kV for input/output lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>Differential mode: ±0.5, ±1 kV</td>
<td>Same as left</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>Common mode: ±0.5, ±1, ±2 kV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IEC 61000-4-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions, and voltage variations on power supply input lines</td>
<td>&lt; 5% $U_T$ ($&gt;95%$ dip in $U_T$) for 0.5 cycle</td>
<td>Same as left</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td></td>
<td>40% $U_T$ ($60%$ dip in $U_T$) for 5 cycle</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% $U_T$ ($30%$ dip in $U_T$) for 25 cycle</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5% $U_T$ ($&gt;95%$ dip in $U_T$) for 5 seconds</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IEC 61000-4-11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>Same as left</td>
<td>It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.</td>
</tr>
<tr>
<td></td>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE**

$U_T$ is the AC mains power supply prior to application of the test level.
Cautions and recommended electromagnetic environment regarding portable and mobile RF communications equipment, such as cellular phones

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601-1-2 test level</th>
<th>Compliance level</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms (150 kHz – 80 MHz)</td>
<td>3 V (V₁)</td>
<td>Formula for recommended separation distance (V₁=3 according to the compliance level)</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td></td>
<td></td>
<td>[ d = \left( \frac{3.5}{V₁} \right) \sqrt{P} ]</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m (80 MHz – 2.5 GHz)</td>
<td>3 V/m (E₁)</td>
<td>Formula for recommended separation distance (E₁=3 according to the compliance level)</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td></td>
<td></td>
<td>[ d = \left( \frac{3.5}{E₁} \right) \sqrt{P} ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80 MHz – 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[ d = \left( \frac{7}{E₁} \right) \sqrt{P} ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>800 MHz – 2.5 GHz</td>
</tr>
</tbody>
</table>

**NOTE**

- Where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and “d” is the recommended separation distance in meters (m).
- This instrument complies with the requirements of IEC 60601-1-2: 2001. However, under an electromagnetic environment that exceeds its noise level, electromagnetic interference may occur on this instrument.
- Electromagnetic interference may occur on this instrument near a high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:
## Recommended separation distance between portable and mobile RF communications equipment and this instrument

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter P (W)</th>
<th>Separation distance according to frequency of transmitter (m) (calculated as $V_1=3$ and $E_1=3$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz – 80 MHz</td>
</tr>
<tr>
<td></td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

**NOTE**

The guidance may not apply in some situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. Portable and mobile RF communications equipment such as cellular phones should be used no closer to any part of this instrument, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
### Temperature of the shaft, grasping section and probe tip during activation

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Grasping section and probe tip</td>
<td>Over 200°C</td>
</tr>
<tr>
<td>2</td>
<td>Distal end of the shaft</td>
<td>Over 135°C by the continuous activation.</td>
</tr>
<tr>
<td>3</td>
<td>Shaft up to 60 mm from the distal end</td>
<td>Over 60°C by the continuous activation.</td>
</tr>
<tr>
<td>4</td>
<td>Rest of the shaft</td>
<td>60°C or less. It can be more than 60°C depending on situation.</td>
</tr>
</tbody>
</table>

(The method of measurement is in accordance with our standard.)
Temperature of the shaft, grasping section and probe tip during activation