



Bipolar Single-Use Sterile Resectoscopic Electrodes Instructions



Manufactured by
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Distributed by
Cook Medical LLC.
400 Daniels Way
Bloomington, In. 47404

REF

BTCL-2412-MD	Bipolar Transurethral Cutting Loop – 24Fr, 12° Medium
BTCL-2412-LG	Bipolar Transurethral Cutting Loop – 24Fr, 12° Large
BTCL-2430-MD	Bipolar Transurethral Cutting Loop – 24Fr, 30° Medium
BTCL-2430-LG	Bipolar Transurethral Cutting Loop – 24Fr, 30° Large
BTBL-2400	Bipolar Transurethral Bladder Loop – 24Fr.
BTPD-2400	Bipolar Transurethral Plasma Disc® – 24Fr.
BTNE-2400	Bipolar Transurethral Needle Electrode – 24Fr.

DEVICE DESCRIPTION

The resectoscopic electrode is a sterile packaged, bipolar electrode designed to deliver high frequency energy. Bipolar electrodes are single use only. The electrodes are designed to fit the Olympus bipolar WA22366A active and the WA22367A passive working elements. Use with the Olympus PK Superpulse, Olympus UES 40 or ESG 400 generator systems.



INDICATIONS FOR USE RESECTION ELECTRODES:

The HF Resection electrodes are a bipolar instrument series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation, or removal of soft tissue and where hemostasis is required. The specific urological indications include use in the prostate, bladder, and bladder neck. The procedures for which the devices can be used are: Transurethral resection in saline (TURis), Transurethral prostatectomy, transurethral resection of the prostate (TURP), for benign prostatic hyperplasia, Transurethral incision of the prostate (TUIP) or bladder neck, Transurethral resection of bladder tumors (TURBT) and cystodiathermy. These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

BTCL-2412-MD	Bipolar Transurethral Cutting Loop – 24Fr, 12° Medium
BTCL-2412-LG	Bipolar Transurethral Cutting Loop – 24Fr, 12° Large
BTCL-2430-MD	Bipolar Transurethral Cutting Loop – 24Fr, 30° Medium
BTCL-2430-LG	Bipolar Transurethral Cutting Loop – 24Fr, 30° Large
BTBL-2400	Bipolar Transurethral Bladder Loop – 24Fr.
BTNE-2400	Bipolar Transurethral Needle Electrode – 24Fr.

HF resection electrodes for bipolar endoscopic treatment in urological applications.

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INDICATIONS FOR USE VAPORIZATION ELECTRODE:

The HF Vaporization electrode for plasma vaporization is a bipolar instrument designed and intended for use in urological surgical procedures involving vaporization, ablation, coagulation, cutting, removal of soft tissue and coagulation where hemostasis is required. The specific soft tissue indications include: Use in the prostate, bladder, and bladder neck. The specific treatment indications include benign prostate hyperplasia (BPH), bladder cancer, tumors, lesions, and neoplasms. The specific urological indications include Transurethral Electro vaporization (TUEVP), (TVP), (TUEVP) also known as Transurethral Vapor Resection of the prostate (TUVRP), Transurethral Vaporization in Saline (TUVIS). These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

BTPD-2400 Bipolar Transurethral Plasma Disc® – 24Fr.

HF vaporization electrode for bipolar endoscopic treatment in urological applications.

CONTRAINDICATIONS

The use of this device is contraindicated in patients with the following conditions:

- Carcinoma of the bladder or prostate without tissue diagnosis.
- Patients with urinary tract infection.
- Patients with incipient renal failure.

It is advisable to monitor the input and output volumes of the irrigation fluid in all patients but especially those with cardiovascular insufficiency or poor renal function.

WARNINGS



1. Read and understand all device instructional material listed in this IFU as well as the instructions for the applicable Olympus generator and Olympus Endoscopy System Guide (Supplied separately).



2. Do not use if package is damaged or open. Doing so can lead to operator or patient injury.



3. This device is intended for single use only. Do not Re-Use this device as doing so may create a serious risk of contamination, injury to the operator or patient injury and device malfunction including:

- Geometry: Re-use may render the device geometry damaged and create injury risk.
- Durability: Device performance may seriously degrade after one use.
- Construction: Device materials may not withstand chemical or high temperature re-sterilization.



4. Do not re-sterilize. Re-use of a single use device may damage the device and make it unsafe for use.



5. Do not use the device if it has breaks or cracks in the insulation. Use of the device with damaged insulation may cause unintended electrosurgical burns.



6. Do not bend or change the angle or shape of the distal end of the device. Doing so may cause the device to malfunction and/or the tip to break which creates a risk of injury to the patient and the operator.



7. Only use 0.9% NaCl Saline for irrigation. If non-conductive irrigants are used, no cutting, coagulation, or vaporization will take place.



8. Immediately discontinue use if breaks or fractures appear on the electrode. These conditions may allow undirected emission of electrical energy rendering the device useless and potentially causing harm to surrounding tissues.



9. To avoid shock and/or burn, turn off the power to the generator before touching the electrode.



10. Risk of Death or serious Injury! Improper use of HF current can cause exogenous or endogenous burns and possibly explosions. Thoroughly review all HF current safety information from the manufacturer of the electrode as well as the generator system used.

PRECAUTIONS



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



2. To avoid damage to the device take care not to bend or crush the electrode.



3. This device should only be used by a physician who is familiar with the use of electrosurgical instruments, devices, and power generators. Consult the medical literature regarding techniques, complications, and hazards prior to any endoscopic procedure.



4. Read and follow all instructions for each piece of equipment used in conjunction with this device. Operating and maintenance manuals of corresponding equipment should be reviewed. Ensure all equipment used in conjunction with this device is certified for medical use.



5. Only use **0.9% NaCl Saline** for irrigation. If non-conductive irrigants are used, no cutting, coagulation, or vaporization will take place.



6. Patients with pacemakers: Use with caution in the presence of internal or external pacemakers. Interference from an electrosurgical current can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. For further information, consult the pacemaker manufacturer or hospital Cardiology Department.

DIRECTIONS FOR USE



1. Visually inspect the device for any signs of damage.



2. When attaching the device, use care as the electrode can be damaged while installing the device into the working element if device is pushed too forcefully into the working element.



3. Introduce the electrode's proximal end into the distal opening of the working elements guiding tube. Advance the working element until it comes to a stop and the electrode clicks into position. Make sure that the telescope is guided through the electrode's stabilizing tube.



4. Be sure not to pull too forcefully when checking the locking of the electrode. Otherwise the electrode stabilizer may be damaged.

Check locking of the electrode:

- Gently grasp the electrode at the stabilizer tube.
- Pull in distal direction.
- The electrode must be securely connected to the working element.



5. Check the position of the electrode tip.

- Make sure the non-insulated portion of the electrode tip is at least 2 mm from the end of the telescope.
- If there is not at least 2 mm distance, then replace with a new electrode.



6. To prevent burns caused by HF current, use only conductive irrigant fluid (0.9% NaCl) and conductive lubricant.

Applications:

HF resection and vaporization electrodes are classified according to their compatibility with each surgical function such as COAGULATION, CUTTING, and VAPORIZATION. Use HF electrodes only for compatible applications.

+ = Compatible
 _ = Not Compatible

MODEL NUMBER	COAGULATION	CUTTING	VAPORIZATION
BTCL-2412-MD	+	+	–
BTCL-2412-LG	+	+	–
BTCL2430-MD	+	+	–
BTCL2430-LG	+	+	–
BTBL-2400	+	+	–
BTNE-2400	+	+	–
BTPD-2400	+	–	+

RECOMMENDED TURis SETTINGS FOR ESG 400:

ELECTRODE		CUTTING (Saline Cut)	COAGULATION (Saline Coag)
BTCL-2412-MD	Bipolar Transurethral Cutting Loop – 24Fr, 12° Medium	200W EFFECT 2	120W EFFECT 2
BTCL-2412-LG	Bipolar Transurethral Cutting Loop – 24Fr, 12° Large	200W, EFFECT 2/3	120W EFFECT 2/3
BTCL-2430-MD	Bipolar Transurethral Cutting Loop – 24Fr, 30° Medium	200W EFFECT 2	120W EFFECT 2
BTCL-2430-LG	Bipolar Transurethral Cutting Loop – 24Fr, 30° Large	200W, EFFECT	120W EFFECT 2/3
BTBL-2400	Bipolar Transurethral Bladder Loop – 24Fr.	200W EFFECT 2	120W EFFECT 2
BTNE-2400	Bipolar Transurethral Needle Electrode – 24Fr.	140W EFFECT 2	40 W EFFECT 2
BTPD-2400	Bipolar Transurethral Plasma Disc® – 24Fr.	200W EFFECT 2/3	120W EFFECT 2/3

RECOMMENDED TURis SETTINGS FOR UES 40:

<u>ELECTRODE</u>	<u>CUTTING</u> (Pure Cut)	<u>COAGULATION</u> (Coag 1)
BTCL-2412-MD Bipolar Transurethral Cutting Loop – 24Fr, 12° Medium	280-320 W	120-140 W
BTCL-2412-LG Bipolar Transurethral Cutting Loop – 24Fr, 12° Large	290-320 W	120-140 W
BTCL-2430-MD Bipolar Transurethral Cutting Loop – 24Fr, 30° Medium	280-320 W	120-140 W
BTCL-2430-LG Bipolar Transurethral Cutting Loop – 24Fr, 30° Large	290-320 W	120-140 W
BTBL-2400 Bipolar Transurethral Medium Bladder Loop – 24Fr.	280-320 W	120-140 W
BTNE-2400 Bipolar Transurethral Needle Electrode – 24Fr.	200 W	60 W
BTPD-2400 Bipolar Plasma Disc® Vaporization Electrode – 24Fr.	290-320 W	150-180 W

RECOMMENDED TURis SETTINGS FOR OLYMPUS PK SUPERPULSE:

<u>SETTING:</u>	<u>TURis Electrodes</u>
TP1, TP2, TP3	Cut Modes
TP2	Default Cut Mode
180	Default Cut Power (W)
10-200	Cut Power Range (W)
DES	Default Coag Mode
100	Default Coag Power (W)
10-120	Coag Power Range (W)

- Default Setting is TP2, 180 Cut, 100 Coag
- TP3 is most optimal for Plasma Disc and Large Loop
- Physician should start on the Default Settings and adjust wattage and modes to achieve desired tissue effect.
- TP1 is the lowest mode, TP2 is the recommended and Default mode, and TP3 is the highest mode. Each mode has an increasingly aggressive effect on the tissue.

7. Vaporization of the prostate only (BTPD-2400 PLASMA DISC™)

- Adjust a cutting current setting at the minimum recommended wattage for vaporization. Start on the lowest setting and increase as necessary to obtain desired tissue effect.
- Move the electrode slowly. This will result in a smooth tissue effect.
- Place the patient's head in an elevated position to avoid the collection of air bubbles at the front end of the resectoscope.

8. Perform the procedure.

After use this product may be considered biohazard and must be disposed of properly.

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