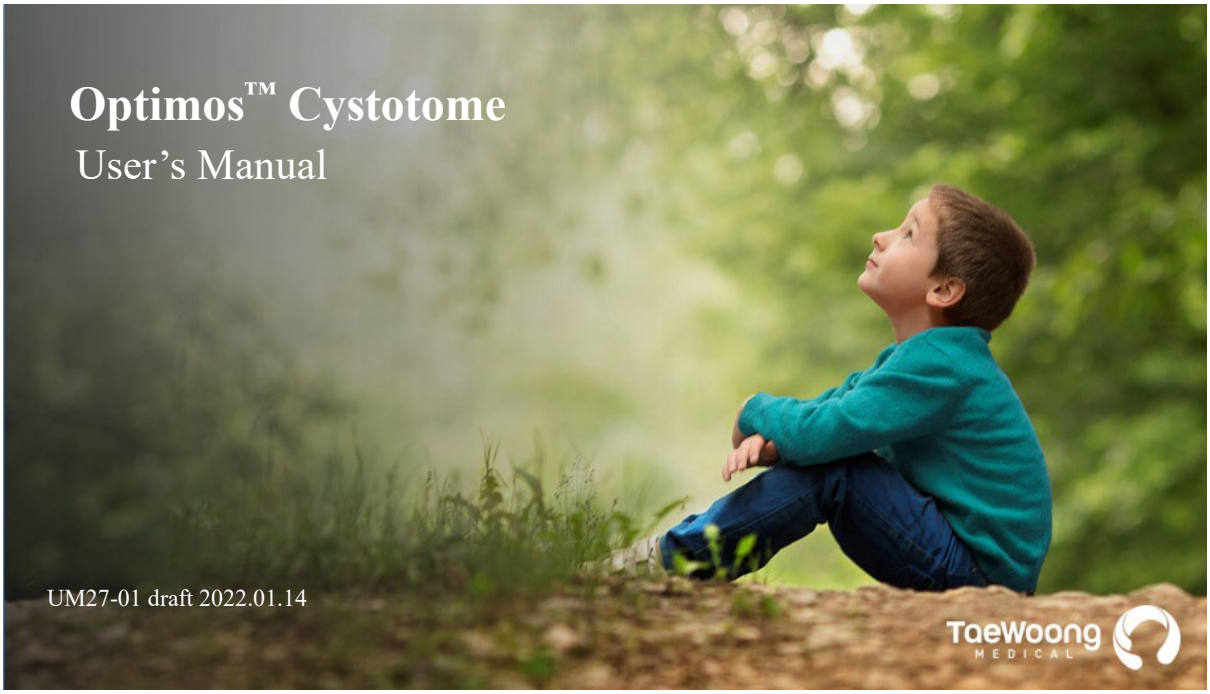
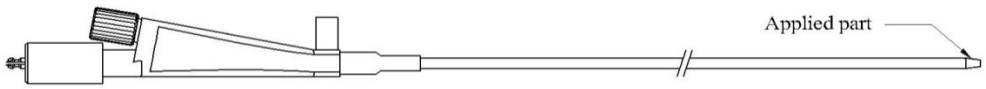


Description

The Optimos™ Cystotome is an electrode which uses heat generated from bio-electrical impedance between tissue and the electrode. It punctures a hole by using this heat energy when high frequency (RF) energy is applied to the electrode through the connector. Following a fine-needle aspiration (FNA) procedure, it is positioned over a guidewire so the applied part is located at the area of interest. After puncture of the target sit with 19G fine needle aspiration (FNA) procedure, The Optimos™ Cystotome can be inserted through-the-needle wire placement, or introduced to directly access the target lumen.

* Device Name: Optimos™ Cystotome



Indications for Use

The Optimos™ Cystotome is intended for use as an electrosurgical accessory to electrosurgically cannulate the transgastric or transduodenal wall and into pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract. It is supplied sterile and is intended for single use.

■ Patient Population
Not specialized for a particular population, but applicable to all patients over 18 years of age; however, the decision rests with the physicians.

Performance and Clinical Benefits

- Performance: Cyst puncture
- Clinical benefit: A passage for drainage

Contraindications

Contraindications include those specific to blood coagulation disease, interposing vessels between the pseudocyst wall and that of the stomach or the duodenum. If the pseudocyst is < 4 cm in diameter do not proceed.
Additional contraindications include:
• Patients that have allergies or are sensitive to drugs such as contrast media.

Potential Complications

- Pneumoperitoneum - Abdominal pain - Fever - Bleeding
- Hemobilia

Warnings and Precautions

1. Like all other types of ESUs, do not use in the presence of flammable anesthetics nor oxidizing gases (such as nitrous oxide (N2O) and oxygen rich environment) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
2. Do not place the Optimos™ Cystotome near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
3. This product should be used by trained doctors only.
4. Before use, examine the outer surface of devices which are intended to be inserted into a patient or used during procedure. Do not use a device that has unintended rough surfaces, sharp edges or protrusions which may cause harm. Cut, burned or damaged device insulation may cause unsafe currents in either patient or operator.
5. Do not use this device for any purpose other than its stated intended use.
6. Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
7. Before use, compatibility with electrosurgical generators, accessories and other endoscopic equipment should be checked. Using incompatible equipment or equipment not specified by this Instruction for Use can result in patient injury or equipment damage. (see Specifications)
8. Select cables, patient return electrodes and other medical electrical equipment that are Type BF applied parts. Use of medical electrical equipment other than those specified may result in increased emissions or decreased immunity of generator. (see Specifications)
9. Use caution with endoscopic equipment, accessories, and other medical / non-medical electrical equipment to avoid risks caused by their use together. (see Specifications)
10. Avoid high frequency output settings where the maximum output voltage may exceed rated accessory voltage (Optimos™ Cystotome rated accessory voltage is 500 Vp or 1000 Vp-p).
11. Take precaution when the Optimos™ Cystotome is used under insufflation of air, inert gas prior to high frequency surgery or laser assist gas which may cause gas embolism. Keep vigilant monitoring of hemodynamic status if available, and visual inspection. If gas embolism is detected, immediate management should be treated such as if possible, prevention of further air entry or a reduction in the volume of air entrained.
12. When applying current, ensure the active tip of the Optimos™ Cystotome is completely outside the endoscope. Contact between the active element and the endoscope may cause grounding, which can result in injury to patient and operator or damage to the endoscope.
13. Do not activate the electrosurgical unit when device tip is not in contact with target tissue, as this may cause injuries due to capacitive coupling.

14. Unintended overtemperature may be measured at the tip of the device during the procedure. Do not use cautery for over 40 seconds without intermission to ensure patient safety.
15. Ensure proper placement of return electrode on patient and connection to generator. Failure to do so could result in harm to patient including burns. Avoid attaching a return electrode to the regions such as burned skin, inflammation, fat near the bone, ECG electrodes, metallic implants.
16. Use pure cut generator settings with Optimos™ Cystotome. Do not use blended or coagulation generator modes. Blended or coagulation modes may result in failure to access, prolonged time to access, tissue tenting or resistance.
17. Ensure correct generator installation. The generator must be installed and put into service according to the EMC information provided in the generator manufacturer's guidance and declaration for electromagnetic compatibility. Refer to the Specifications Table to confirm that this device is compatible with the equipment being used. (see Specifications)
18. Connect the Optimos™ Cystotome to the electrosurgical unit only when the unit is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
19. Prior to increasing the intensity, check the adherence of the return electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the return electrode or poor contact in its connections.
20. Device must be used in conjunction with a Type BF or CF generator, see compatible electrosurgical unit or generator information.
21. Those who experience allergic reactions to drugs such as contrast media may also show allergic reactions during the procedure.
22. Check if the device is damaged and notify Taewoong Medical for a return if an abnormality is detected.
23. Before using this device, follow recommendations provided by the manufacturer of the electrosurgical unit for the proper placement and utilization of the patient return electrode.
24. Do not touch the tip of the Optimos™ Cystotome with your finger or another tool (insulator or components can react to metal) when the product is connected to the ESU. It may cause electrical hazard to the patient or operator
25. Do not use Optimos™ Cystotome if its sterile package is opened or damaged.
26. This product is disposable and should therefore not be reused. If so, risks such as infection may occur.
27. Do not re-sterilize or reuse this product. If so, electrocautery function can deteriorate, which could pose a risk to a patient.
28. Use only the parts of this product whose shelf life has not expired.
29. Do not use this product when the patient has a severe fever, hemorrhaging, or difficulty breathing.
30. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
31. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
32. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
33. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Optimos™ Cystotome, including cables specified by the ESU manufacturer.

Specifications

Use:	Sterile, Single Use
Energy:	Monopolar
Maximum Rated Input:	1.0 kV peak-to-peak (500 Vp)
Recommended Generator Settings:	Pure cut mode, 80 – 120 Watts (400-500Vp)
Compatible Electrosurgical Unit or Generator:	Select an electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2: **ERBE VIO 300D** **Power off the generator when not in use.**
Electromagnetic Compatibility:	Refer to the generator manual for the manufacturer's guidance and declaration to electromagnetic compatibility.
Connectors:	Monopolar connecting cable, VIO, ICC, ACC, International Φ 8 mm (Bovie Jack), 4 m, with connection Φ 3 mm
Dispersive Pad:	Select pad or return electrode specified by generator manufacturer.
Needle Compatibility	19G (gauge) FNA needle
Guidewire Compatibility:	0.025 ~ 0.035 inches insulated
Endoscope Compatibility:	Working channel of 3.2mm diameter or larger.
Essential Performance:	Output accuracy : The output power of the Optimos™ Cystotome [OCT1906, OCT1908] shall not deviate from the setting of the Electrosurgical Unit (ESU) by more than ± 20%.

Instruction For Use

1. Upon removing from package, uncoil device.
2. Examine features of device.
Note: Do not use a device that has unintended rough surfaces, sharp edges or protrusions.
3. Confirm the location and size of the puncture site under endoscopic guidance.
4. Under endoscopic guidance, insert an endoscope until reaching the lesion. Then introduce needle through the working channel of the endoscope. Advance the needle until reaching the lesion and puncture it.
Recommendation: use a 19G FNA needle.
5. With the needle in the cyst, inject contrast to fill pseudocyst under fluoroscopic visualization.
6. After puncture of the lesion, insert a guide wire through the needle and advance it across the lesion. Remove the needle slowly and carefully.
Recommendation: use a 0.025" ~ 0.035" guide wire.
7. With the electrosurgical unit off, prepare equipment. Active cord fittings should fit snugly into both device handle and electrosurgical unit.
8. Connect the cable of the electrosurgical unit to the device.
Note: Pure Cut (Auto Cut) 80-120 Watts, 400-500 Vp.
9. Advance the metal tip to the puncture site and activate the electrosurgical unit by using the foot-switch.
10. Once the puncture is complete, turn the electrosurgical unit off and disconnect the active cable from device handle.
11. Remove the device from endoscopic accessory channel.
Note: The guide wire port should be closed when the saline or the contrast medium is injected.
12. Dispose of the device in accordance with the disposal procedure determined by hospital.

⚠ Warning: Avoid attaching the return electrode to the regions such as burned skin, inflammation, fat near the bone, ECG electrodes, metallic implants.
⚠ Warning: Follow the user's manual of the ESU when it comes to the attached return electrode.
⚠ Warning: Follow the user's manual of the ESU for detailed instructions and warnings of the electrosurgical unit.
⚠ Warning: Adhered blood, mucous and foreign bodies attached the device can result in infection of the patient or operator.
⚠ Warning: Follow the user's manual of the needle for detail instructions and warnings of the needle puncture procedure.

Application

· Environment
√ General: Operating room in a hospital
√ Physical condition: The user should maintain the below conditions during the procedure.

	Operation	Storage & Transportation
Range of temperature	10 ℃ to 40 ℃	-18 ℃ to 40 ℃
Range of humidity	10 % to 75 %	10 % to 90 %
Range of air pressure	70 kPa to 106 kPa	70 kPa to 106 kPa

Handling / Storage

The expiration period of this product is three (3) years. Store in a dry and cool place. Keep away from sunlight.

Reuse Precaution Statement

This product has been sterilized using ethylene oxide (E.O.) gas. Single use only. Do not re-sterilize or reuse this product. The company is not responsible for re-sterilized products.

Rx only

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

Symbols

	Attention, consult instructions for use		Consult instructions for use		Manufacturer	REF	Catalog No.
STERILE EO	Sterilized using ethylene oxide		Do not re-sterilize		Use by(Expiration Date)	LOT	Lot Number
	Do not reuse		Type BF Applied Part		Do not use if package is damaged		Keep away from sunlight
	Keep dry		Date of Manufacture	MD	Medical device		Single sterile barrier system
	Minimum required working channel		Compatible guide wire diameter		Temperature limitation		

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Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The Optimos™ Cystotome is intended for use in the electromagnetic environment specified below. The customer or the user of the Optimos™ Cystotome should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF Emission CISPR 11	Group 1	The Optimos™ Cystotome uses RF 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.
RF Emission CISPR 11	Class A	The Optimos™ Cystotome is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is needed: Warning: This Optimos™ Cystotome is intended for used by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such a re-orienting or relocating the Optimos™ Cystotome or shielding the location.
Harmonic Emission IEC 61000-3-2	Class A	
Voltage fluctuation and flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Optimos™ Cystotome is intended for use in the electromagnetic environment specified below. The customer or the user of the Optimos™ Cystotome should assure that it is used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, a relative humidity of at least 30% is recommended.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV (for power supply lines) ±1 kV (for input/output lines)	±2 kV (for power supply lines) ±1 kV (for input/output lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power-supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dips in U_T) for 25/30 cycles[a] 0% U_T (100% dip in U_T) for 250/300 cycles[a]	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dips in U_T) for 25/30 cycles[a] 0% U_T (100% dip in U_T) for 250/300 cycles[a]	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz immunity IEC 61000-4-39	8 A/m 30 kHz CW Modulation 65A/m 134.2 kHz PM 2.1 kHz	8 A/m 30 kHz CW Modulation 65A/m 134.2 kHz PM 2.1 kHz	Resistance to magnetic fields was tested and applied only to surfaces of enclosures or accessories accessible during intended use.

	7.5 A/m 13.56 MHz PM 50 kHz	7.5 A/m 13.56 MHz PM 50 kHz	
NOTE: U_T is the main voltage (AC) prior to the application of the test level			
a For example, 10/12 means 10 cycles at 50 Hz or 12 cycles at 60 Hz			

Recommended separation distance between portable and mobile communication equipment and the Optimos™ Cystotome

The Optimos™ Cystotome is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Optimos™ Cystotome can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the Optimos™ Cystotome are recommended below, according to the maximum outer power of the communication equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]	
	IEC 60601-1-2: 2014	
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity

The Optimos™ Cystotome is intended for use in the electromagnetic environment specified below.
The customer or the user of the Optimos™ Cystotome should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should not be used closer to any part of the Ultrasound System, including cables, than the recommended separation distance. This is calculated using the equation applicable to the frequency of the transmitter. Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz – 80MHz Outside ISM Bands[c]	3 Vrms	$d = 1.2\sqrt{P}$
	6 Vrms 150 kHz – 80 MHz In ISM Bands[c]	6 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	IEC 60601-1-2:2014 $d = 2.0\sqrt{P}$ 80MHz to 2.7 GHz

			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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply all situations, Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and landmobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Optimos™ Cystotome is used exceeds the applicable RF compliance level above, the Optimos™ Cystotome should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Optimos™ Cystotome.

b In the frequency range exceeds 150 kHz ~ 80MHz, the electric field strength should be not higher than 3 V/m.

c The ISM (Industrial Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Guidance and manufacturer's declaration – electromagnetic immunity

The Optimos™ Cystotome is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the Optimos™ Cystotome. Otherwise, degradation of the performance of this equipment could result.

Immunity test	Band[a]	Service[a]	Modulation	IEC 60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC 61000-4-3	380 – 390 MHz	TETRA 400	Pulse[b] modulation 18 Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM[c] ± 5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band 13, 17	Pulse[b] modulation 217 Hz	9 V/m	9 V/m
	900 – 960 MHz	GSM 800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse[b] modulation 18 Hz	28 V/m	28 V/m
	1700 – 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse[b] modulation 217 Hz	28 V/m	28 V/m

	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse[b] modulation 217 Hz	28 V/m	28 V/m
	5100 – 5800 MHz	WLAN 802.11 a/n	Pulse[b] modulation 217 Hz	9 V/m	9 V/m
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.					
a For some services, only the uplink frequencies are included. b The carrier shall be modulated using a 50% duty cycle square wave signal. c As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.					