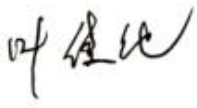
Device:	**Disposable Morcellator**				
Document No.:	QY-TD-IFU-F24	**Version No.:**	B/0	**Issue Date:**	2024.03.08

Disposable Morcellator

Instructions for Use

Document Approval

	Prepared by	**Reviewed by**	**Approval by**
Name	Ye Jiachun	Xu Yibo	Li Weiming
Department/Position	Technical Manager	Management Representative	General Manager
Signature/Date	 2024.03.08	 2024.03.08	 2024.03.08

Revision History

Version	**Date**	**Description of change**
B/0	2024.03.08	Initial version

CE 0051

Disposable Morcellator

【INTENDED PURPOSE】

This device is intended for cutting, coring and extracting tissue in laparoscopic gynecologic procedures such as hysterectomy and myomectomy.

【INTENDED PATIENT POPULATION AND MEDICAL CONDITIONS】

Age: no restrictions for age of the patients.

Gender: Women.

Weight: no restrictions for weight of the patients.

Health: patients who need to undergo laparoscopic gynecological surgery.

Nationality: multiple.

Patient status: PATIENT is not the OPERATOR.

【CONTRAINDICATIONS】

1) Contraindications for use on vascularised tissue (ovaries, fallopian tubes, myomas and other structures): tissue must be devascularised and dissected before morcellation.
2) Disposable morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

【POTENTIAL SIDE EFFECTS】

1) Infections;
2) Injury blood vessel;
3) Intestinal loops or injury the bladder.

【CAUTIONS】

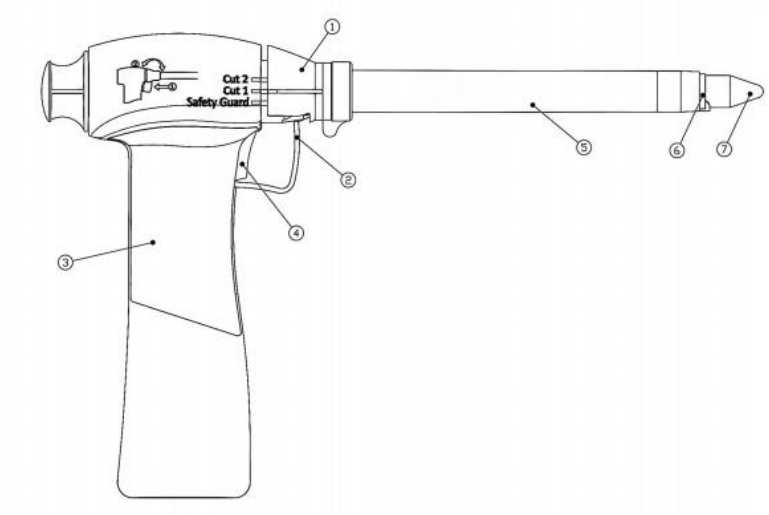
1) Disposable morcellator may lead to dissemination of benign or malignant tissue. Uterine tissue may contain unsuspected cancer. The use of Disposable morcellators during fibroid surgery may spread cancer, and decrease the long–term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.
2) The Disposable Morcellator is provided sterile. Carefully inspect the packaging for any damage prior to use. Do not attempt to use the device if sterile barrier is damaged. Do not use past expiration date.
3) For single use only. Do not reuse, reprocess or re-sterilize the Disposable Morcellator. Any reprocessing may impede the functions of this device. Reusing single use devices may also increase the risk of cross contamination. Attempts to clean the device results in risk of device malfunction and/or erroneous pathology specimen collection due to residual tissue in the Disposable Morcellator causing significant gas leakage through the morcellator.

4) In order to prevent injuries to surrounding viscera exercise caution while manipulating the Disposable Morcellator. Do not place the cutting tip nearby or in contact with tissue which is not intended to be morcellated.
5) When inserting the Obturator through the percutaneous access, there is risk of injury to blood vessels, intestinal loops or the bladder.
6) Be aware that the cutting tip of the Disposable Morcellator is not in contact with other instrument for example grasping forceps aiming to hold the tissue in place while morcellating the target tissue. It may cause knife dulling/chipping.
7) Do not activate the Disposable Morcellator if it is not possible to visualize the cutting tip.
8) Do not attempt to sharpen or modify the cutting tube. Modified or distorted cutting tube can result in patient, surgeon or equipment damage.
9) Do not use excessive force while using Disposable Morcellator. This could damage the product.
10) After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Be aware of sharp edges.

【PRODUCT MODEL】

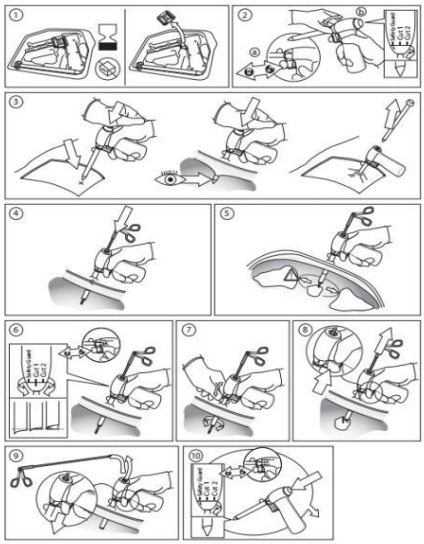
F240115150

【STRUCTURE AND SPECIFICATIONS】



No.	Description (Part/Component Name)
1.	Adjust cap
2.	Bracket
3.	Handle
4.	Trigger/Button
5.	Cutting sleeve
6.	Coreguard
7.	Obturator

【INSTRUCTION FOR USE】



1) Carefully inspect the packaging for any damage prior to use. Do not attempt to use the device if sterile barrier is damaged. Prior to removing the device from the tray take off the retainer.
2) Prior to using the trocar function of the Disposable Morcellator, insert the obturator fully into the device. Be sure that the trocar is placed in the “Safety Guard” position. If not, place the trocar in the “Safety Guard” position by holding in the bracket and then simultaneously turn the trocar (see illustration in picture 2).
3) The Disposable Morcellator with obturator should be placed into the abdomen using standard technique for laparoscopic trocar placement. It is recommended to insert the Disposable Morcellator with obturator through a 12-14mm incision under direct visualization.
4) In order to remove tissue use a 10-12 mm forceps or similar instrument inserted through the lumen of the Disposable Morcellatorand into the abdomen. To prevent injury to the abdominal wall, the tissue to be morcellated should be completely exposed before attempting to extract it through the morcellator.
5) It is recommended to use a second pair of grasping forceps to hold the tissue in place and reduce tissue movement during morcellation.
6) Place the trocar in the required position by turning the trocar into cutting position: “Cut 1” for peeling function or “Cut 2” for coring function. Prior to changing the required position hold the bracket and simultaneously turn the trocar.
7) Adjust the coreguard if needed.
8) To activate the cutting blade and begin morcellating, press the activation button on the hand piece while pulling pieces of tissue through the cutting tube.
9) Release the activation button as soon as the stripe of tissue is extracted from the Disposable Morcellator.
10) After surgery, remove the Disposable Morcellator from the abdominal cavity. For proper disposal, turn the trocar into the “Safety Guard” position.
11) The morcellator may now be safely disposed in accordance with local governing ordinances and recycling plans.

【PRECAUTIONS】

- For further clarification, the Disposable Morcellator should not be used without appropriate patient selection and pre-operative diagnostics.
- Note that certain types of cancer may not be detectable in such pre-operative diagnostics potentially leading to spreading cancer and thereby potentially decreasing the long–term survival of the patient. The trained

professional performing the surgery is responsible for obtaining the patient's written informed consent on this information.

- December 30, 2020, the US FDA recommended manufacturers of laparoscopic power morcellators to include the following contraindication in their IFU: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:
  - post-menopausal or over 50 years of age, or
  - candidates for en bloc tissue removal through the vagina or via a mini-laparotomy incision.
- Use of the Disposable Morcellator requires adequate training and experience in performing laparoscopic myomectomy and hysterectomy.
- Be careful when inserting or removing the device. Make sure that the cutting blade is retracted by putting the trocar in the "Safety Guard" position during insertion and removal and whenever the cutting blade is not in active use. Insertion and removal of the Disposable Morcellator should always be performed under direct visual control. Keep the rotating blade visible during the entire morcellation procedure.
- Failure to carefully follow all applicable instructions may result in significant injury to the patient, physician or attendants and may have an adverse effect on the outcome of procedures performed.
- The use of Disposable Morcellator does not pose any significant risk of reciprocal or electromagnetic interference. Disposable Morcellator RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. If interference is suspected, move the interfering equipment away or increase the distance between the devices.
- Do not use excessive axial force while changing the trocar position from safety guard to Cut 1 and/or Cut 2 and remember to hold the bracket prior to switching mode as not following these may result in detaching trocar from the rest of the device.

【WORKING, TRANSPORT and STORAGE CONDITIONS】

Relative humidity is not greater than RH80 %

The range of temperature is between -10° C -+50° C.

【OPERATION MODE】

Non-continuous operation

【NOMIMCAL PARAMETER】

Nominal voltage: 15.0V

Nominal capacity: 1500mAh

Cutting tool tube parameters

Maximum speed: 1000 rpm (RPM)

Waterproof: IPX0

【STERILIZATION】

EO sterilization.

【SHELF LIFE】

3 years.

【INSPECTION AND FUNCTIONAL CHECK】

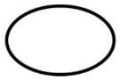
It is very important to examine carefully each surgical instrument for breaks, cracks or malfunctions before use. Do not use damaged instruments. Do not use the instrument when the package is damaged. Never attempt to make repairs yourself. Any repairs made by the customer may void the warranty.

【RETURNED GOODS POLICY】

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Products will not be accepted for replacement if they have been in the possession of the customer for more than 120 days.

【SIGNS AND SYMBOLS】

Symbol	Title of symbol	Symbol	Title of symbol
front	Company logo	MD	Medical device
	Manufacturer		Type BF
EC REP	Authorized representative in the European Community		Consult accompanying documents
REF	Catalogue number		Do not re-use
LOT	Batch code		Do not resterilize
	Date of manufacture		Do not use if package is damaged
	Use-by date	LATEX	Latex Free
STERILE EO	Sterilized using ethylene oxide		Keep away from sunlight
UDI	Unique device identifier		Keep dry
	Caution	Rx Only	RX Only
	Non-ionizing electromagnetic radiation	SBS	Sterile barrier system

CE 0051	CE marking of conformity, and Notified Body Code		Sterile barrier system
	Single sterile barrier system with protective packaging outside		

【EMC】

ATTENRION：

- The Disposable Morcellator comply with the electromagnetic compatibility requirements of IEC 60601-1-2: 2014+AMD1: 2020 standards;
- The user shall install and use according to the electromagnetic compatibility information provided in the delivered documents;
- Portable and mobile RF communication devices may affect the performance of Disposable morcellator. Avoid strong electromagnetic interference when used, such as near mobile phones, microwave ovens, etc;
- Guidelines and manufacturer's statements can be found in the attached file.

WARNING:

- Disposable Morcellator should not be used in close proximity or stacked with other devices, and if they must be used in close proximity or stacked, they should be observed to verify that they operate properly in the configuration they are used in；
- Class A devices are intended for use in industrial Settings where it may be potentially difficult to ensure electromagnetic compatibility in other environments due to radiation interference from disposable morcellator.
- The use of accessories and cables other than those sold as spare parts for internal components by manufacturers of Disposable morcellator may result in increased emission or reduced immunity from Disposable morcellator.

NAME	Mask or Not
CABLE	N

【APPENDIX】

Guidance and manufacturer's statement – Radiated emission.

Disposable Morcellator is expected to be used in the radiated environment specified bellow, and the buyer or user shall guarantee that it is used in this radiated environment.		
Launching experiment	Conformance	Radiated emission - Guidelines
RF emission	Class A Class B	Disposable Morcellator uses RF energy only for its internal functions. Therefore, its radio frequency emission is very low, and the possibility of interference to nearby electronic equipment is very small.
Harmonic current EN 61000-3-2	Not applicable	Disposable Morcellator is suitable for use in non-domestic and all facilities that are not directly connected to the public low-voltage power supply network of domestic houses.
Voltage fluctuation/flicker emission EN 61000-3-3	Not applicable	

Guidance and manufacturer's statement - Electromagnetic Immunity.

The Disposable Morcellator is expected to be used in the electromagnetic environment specified below, and the buyer or user shall guarantee that it is used in this electromagnetic environment.			
Anti-interference measurement	EN 60601 test level	Coincidence level	The electromagnetic environment.
(Electrostatic discharge) IEC 60601-1-2: 2014+AMD1: 2020	± 2kV, ± 4kV , ± 8kV,±15kV for air discharge and ± 8kV for contact discharge	± 2kV, ± 4kV , ± 8kV,±15kV for air discharge and ± 8kV for contact discharge	30% The floor shall be wood, concrete or tile, and if the floor is covered with synthetic material, the relative humidity shall be at least 30%
(Electrical fast transient) IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-4: 2012	Not applicable		
Electrical surge IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-5:2014+AMD1:2017	Not applicable		

Voltage Dips and Interruptions IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-11: 2020	Not applicable		
Power frequency magnetic field (80~2700MHz) IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-3: 2020	3 V/m	3 V/m	The power frequency magnetic field shall have the horizontal characteristics of power frequency magnetic field in typical places in typical commercial or hospital environments.
Note: UT refers to the AC network voltage before the test voltage is applied			

Guidelines and Manufacturer's Statement-Electromagnetic Immunity.

Disposable Morcellator is expected to be used in the electromagnetic environment specified below, and the buyer or user shall guarantee that it is used in this electromagnetic environment.

Immunity test	EN 60601 test level	Coincidence level	The electromagnetic environment.
radio frequence EN 61000-4-6	Level 1 Level 2 Level 3	1V/m 3V/m 10V/m	Portable and mobile RF communication devices should not be used closer to any part of the Disposable Morcellator, including cables, than the recommended isolation distance, which should be determined by a distance corresponding to the transmitter frequency Formula calculation.
(Radio frequency radiation) EN 61000-4-3	3V/m 80MHz-2700MHz	3V/m 80MHz-2700MHz	 Recommended separation distance d= $1.2\sqrt{P}$ d= $1.2\sqrt{P}$ 80MHz-800MHz d= $2.3\sqrt{P}$ 800MHz-2.5GHz Formula: p - according to the maximum rated output power of transmitter provided by transmitter manufacturer, unit: Watt (W); d------ recommended isolation distance, unit: m The field strength of the fixed transmitter is determined by the electromagnetic field survey. In each frequency range, it should be lower than the compliance level. Interference may occur near equipment marked with the following symbols. 

Note 1: on the frequency points of 80MHz and 2700MHz, the formula of higher frequency band is adopted.

Note 2: these guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and emission of buildings, objects and human body.

a. Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, etc., cannot have their field strengths predicted accurately in theory. In order to evaluate the electromagnetic environment of fixed RF transmitters, the survey of electromagnetic sites should be considered.

If the measured field strength in the place where the Disposable Morcellator is located is higher than the above applicable RF compliance level, the Disposable Morcellator shall be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary and the orientation or position of the Disposable Morcellator need to be readjusted.

b. In the whole frequency range of 80MHz-2700MHz, the field strength should be lower than 3v/m.

Recommended Isolation Distance between Portable and Mobile RF Communication Equipment and Disposable Morcellator.

Recommended Isolation Distance between Portable and Mobile RF Communication Equipment and Disposable Morcellator

Disposable Morcellator is expected to be used in an electromagnetic environment where radio frequency radiation disturbance is controlled. According to the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the Disposable Morcellator as recommended below.

Maximum rated output power of transmitter W	Isolation distance corresponding to different frequencies of transmitter/m		
	150kHz-80MHz $d = 1.2\sqrt{P}$	80MHz-800MHz $d = 1.2\sqrt{P}$	800MHz-2.5GHz $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, it is recommended to isolate the distance d in meters (m), which can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer in watts (W).

Note 1: At the frequency points of 80MHz and 800MHz, the formula of higher frequency band is adopted.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic transmission is affected by absorption and emission by buildings, objects and human bodies.

EC REP Name: Eunitor GmbH

Address: Kennedydamm 5, 40476 Düsseldorf Germany

Tonglu Qianyan Medtech Co., Ltd.

Address: Room 101, Building 6, Medical Device Industry Park, No. 1688, Chunjiang East Road, Fengchuan Street, Tonglu County, Hangzhou, Zhejiang Province,311501,China

Zip Code: 311509

Tel: 0086-571-69873666

Fax: 0086-571-69873888

Website: http:// www.frontmedtech.com

Email: qianyan@qymedtech.com