Benesta® Tissue Removal Devices

Instructions for Use

Manufactured by:
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Symbol Glossary

The following is an explanation of symbols that may be used on Caldera Medical's products and packaging:

Symbol	Title/ Meaning/ Referent	Function/ Description	ISO 7000 Reg. no.	ISO 15223-1 or Other
Manufacture				
	**Manufacturer**	Indicates the medical device manufacturer.	3082	5.1.1
	**EU Authorized Representative**	Indicates the authorized representative in the European community.	N/A	5.1.2
	**Date of Manufacture**	Indicates the date when the medical device was manufactured.	2497	5.1.3
	**Use by Date**	Indicates the date after which the medical device is not to be used.	2607	5.1.4
	**Batch Code**	Indicates the manufacturer's batch code so that the batch or lot can be identified.	2492	5.1.5
	**Catalogue number**	Indicates the manufacturer's catalogue number so that the medical device can be identified.	2493	5.1.6
Sterility				
	**Sterilized Using Ethylene Oxide**	Indicates a medical device that has been sterilized using ethylene oxide.	2501	5.2.3
	**Do Not Re-sterilize**	Indicates a medical device that is not to be re-sterilized.	2608	5.2.6
	**Do Not Use If Package Is Damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.	2606	5.2.8
	**Non-sterile**	Indicates a medical device that has not been subjected to a sterilization process.	2609	5.2.7
Storage				
	**Keep Dry**	Indicates a medical device that needs to be protected from moisture.	0626	5.3.4
	**Temperature Limit**	Indicates the temperature limits to which the medical device can be safely exposed	0632	5.3.7
	**Humidity Limitation**	Indicates the range of humidity to which the medical device can be safely exposed	2620	5.3.8
Safe Use				
	**Do Not Re-use**	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	1051	5.4.2
	**Consult Instructions for Use**	Indicates the need for the user to consult the instructions for use.	1641	5.4.3
 [IFU URL]	**Consult Instructions for Use, or For Instructions for Use Refer to**	Indicates the need for the user to consult the instructions for use and where the electronic instructions for use (eIFU) and symbols glossary can be found.	1641	5.4.3
	**Follow Instructions for Use**	Refer to Instruction manual/booklet; on medical electrical equipment, Follow Instructions for Use	ISO 7010-M002	N/A
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	0434A	5.4.4
	**General Warning**	General Warning Sign	N/A	ISO 7010-W012
	**Type BF Applied Part**	Signifies Applied Part Type	N/A	IEC 60517-5840
	**Non-Ionizing Electromagnetic Radiation**	Indicates generally elevated, potentially hazardous levels of non-ionizing radiation, or to indicates equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	N/A	IEC 60417-5140
	**MR Unsafe**	Signifies that the device is not rated for us in an MR environment	N/A	ASTM F2503 Figure 8
Other				
	**Packaging Unit**	Indicates the number of pieces in the package.	2794	N/A
	**Prescription Only**	Requires prescription in the United States of America.	N/A	21 CFR 801.109

℞ **Caution: Federal law restricts the device to sale by or on the order of a physician.**

The brief operating instructions in this guide will make the system easier to use. As with any surgical instrument, there are important health and safety considerations.

Device Description

Benesta® Tissue Removal Devices are sterile, single-use hand-held devices that are used to hysteroscopically remove intrauterine tissue. Each device is battery-powered and primarily hand-operated through the use of a button that controls the motor inside the handle and the resulting cutting action of the blade of the device. Additionally, a safety switch is located above the activation button on the device handle that can be used to turn on or off the device.

Indications for Use

The Benesta® Tissue Removal Device is intended for intrauterine use by trained surgeons to hysteroscopically resect and remove tissue such as: submucosal myomas, endometrial polyps, and retained products of conception.

The Benesta Tissue Removal Device is only intended for use as defined in this section.

Contraindications

The Benesta Tissue Removal Device is contraindicated in pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

Use Environment

The Benesta Tissue Removal Device is designed to be used in the operating room, surgical center, and physician's office environments where surgical procedures are performed. The user (physician, surgeon, gynecologist, urogynecologist) should be trained in diagnostic and therapeutic hysteroscopy, resection and removal of pelvic or gynecologic tissue. The Benesta Tissue Removal Device is not indicated or intended for use in a residential environment.

Warnings

- Before using the Benesta Tissue Removal Device for the first time, please review all available product information.
- It is the surgeon's responsibility to be familiar with appropriate surgical techniques prior to use of this device. Before using the Benesta Tissue Removal Device, the surgeon should be experienced in hysteroscopic surgery with powered instruments. Healthy uterine tissue can be injured by improper use of the tissue removal device. Use every available means to avoid such injury.
- Ensure that a compatible vacuum system that can develop a pressure of at least 200 mmHg is appropriately connected before commencing surgery. Do not exceed 450mmHg.
- Do not use the Benesta Tissue Removal Device in patients where anatomy does not support an endoscopic procedure, such as cervical stenosis, presence of an IUD, or in any condition that may limit access to the target pathology or tissue.
- Careful pre-operative assessment, including preoperative imaging, should be performed on each patient prior to a hysteroscopic procedure to evaluate for conditions that may, depending on their severity or extent, affect the appropriateness of hysteroscopy. These include but are not necessarily limited to: evidence and level of placental invasion of the myometrium, acute pelvic inflammatory disease, cervical or vaginal infection, known or possible viable pregnancy, carcinoma of the cervix, placental invasion of the myometrium, or previously diagnosed endometrial cancer.
- Removal of retained products of conception in the setting of known or suspected placenta accreta, placenta increta, or placenta percreta poses a risk of significant and potentially life-threatening bleeding with the highest risk occurring in the immediate postpartum phase.
- Uterine tissue containing suspected fibroids may harbor an occult malignancy. The safety of using mechanical tissue removal devices has not been evaluated in the potential presence of cancer cells.
- Exercise extreme caution when resecting tissue in patients who have implants that extend into the uterine cavity.
- Do not use the Benesta Tissue Removal Device to resect tissue that is adjacent to an implant. When resecting tissue in patients who have implants, ensure that:
    - The Benesta Tissue Removal Device cutting window is facing away from (i.e., 180° opposite) any implant;
        - The visual field is clear; and
        - The Benesta Tissue Removal Device cutting window is engaged in tissue and is moved away from the implant as tissue resection proceeds.
    - In the event, an implant becomes entangled with the Benesta cutter, cease cutting immediately. Maintain uterine distention (this may require the use of a kink in the outflow tubing). Carefully remove the implant from the cutting window.
- Use Resection and COAG with caution in the presence of any active implantable or body worn medical devices such as internal or external pacemakers or neurostimulators. Interference produced by the use of electrosurgical devices can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. The output of the Benesta device might also affect other types of active devices such as implanted neurostimulator devices. Consult the active implantable device manufacturer (for implanted pacemakers and ICDs the hospital cardiology department might also be helpful) for further information when use of myomectomy or tissue coagulation is planned in patients with active implantable devices such as cardiac pacemakers.
- If visualization is lost at any point during a procedure, stop cutting immediately.
- Periodically irrigate the device to prevent accumulation of excised tissue in the surgical site.
- Operating the device inside the uterine cavity with no tissue contact may result in the loss of uterine distension.
- Do not advance the hysteroscope forward in the uterine cavity when the device is activated.

- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1, and any equipment used with the Benesta Tissue Removal System should be Type BF.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment in the patient vicinity not complying with the equivalent medical safety requirements of this equipment may lead to a reduced level of safety of the resulting system. The use of accessory equipment outside the patient vicinity not complying with medical or otherwise appropriate safety requirements may lead to a reduced level of safety of the resulting system.
- Small electrical arcs between the resection electrode and the tissue being resected can produce low-frequency currents that may produce local neuromuscular stimulation. Per standard of care, ensure that the patient's legs are supported and secured appropriately.
- Do not lubricate the Resecting Device.
- Prior to use, examine all system components for possible damage and ensure proper function. If any of the system components are damaged, do not use the device.
- Do not use in the presence of flammable or explosive materials.
- Not for use in an oxygen-rich environment.
- No modification of this equipment is allowed.

Precautions

- Do not use after the expiration date.
- The Benesta Tissue Removal Device is supplied sterile. The Benesta Tissue Removal Device is sterilized by ethylene oxide. Verify that the Benesta Tissue Removal Device is sterile prior to use. Do not use the device if the sterile package is open or appears compromised. Do not use the device if damage is observed. Failure to maintain sterile technique could result in infection.
- The Benesta Tissue Removal Device is intended for single use only. Do not re-sterilize. Do not reuse. Use of a reprocessed, single-use tissue removal device may permanently damage, impede performance, or cause failure of the Benesta Tissue Removal Device. Use of such products renders any warranties null and void and may result in surgeon or patient injury.
- CAUTION: Premature unpacking of the device may result in additional and unacceptable risks.
- Do not use if moisture or condensation has penetrated the device.
- Discard all opened, unused devices. After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
- Exercise care when inserting or removing the device. Insertion and removal of the device should be performed under direct visualization at all times.
- To avoid perforation, keep the device tip under direct visualization and exercise care at all times when maneuvering it or cutting tissue close to the uterine wall. Avoid using the tip of the tissue removal device as a probe or dissecting tool.
- Excessive leverage on the Benesta Tissue Removal Device does not improve cutting performance and, in extreme cases, may result in tissue injury, including perforation or device damage, such as wear, degradation, and seizing of the inner assembly.
- No alterations or modification of this equipment is allowed. Modifications may cause serious injuries to both patient and/or user. Any modifications will void any warranty and the risk of use is transferred to the user.
- Do not allow the cutting window of the tissue removal device to touch any metallic object such as a hysteroscope. Damage to both instruments is likely. Damage to the Benesta Tissue Removal Device can range from a slight distortion or dulling of the cutting edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If any cracks, fractures, or dulling is found or if there is any other reason to suspect a tissue removal device is damaged, replace it immediately.
- Exercise care when inserting or removing the device. Excessive bending of the device's distal tip can cause the Benesta Tissue Removal Device cutter to come out of the cutting window. If such damage occurs, stop using the device and replace it immediately.
- Do not cool the tissue removal device by immersing it in water.

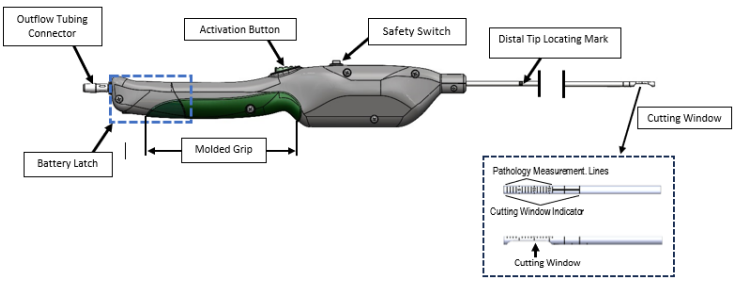
Benesta® Tissue Removal Device

	Pro	Plus	Max
Tissue recommended	Polyps up to 3cm	All Polyps + Fibroids up to 3cm	All Polyps + Fibroids up to 5cm
REF	**CAL-TR1711**	**CAL-TR1721**	**CAL-TR1731**
System consists of:			
REF	(1) CAL-1521* Benesta Pro	(1) CAL-1531* Benesta Plus	(1) CAL-1541* Benesta Max
REF	(1) CAL-TR1610 Benesta Outflow Tubing, 10 ft with universal connector, Each		

*Not sold individually

The hand-operated Benesta Tissue Removal Device is shown below in Figure 1. The parts of the device are listed below:

Figure 1. Benesta Tissue Removal Device



The parts of the hand-operated Benesta Tissue Removal Device are listed below:

Safety Switch: This switch turns power to the entire device on or off depending on the position of the switch. During shipment, the position is in the "off" (O) position to prevent any accidental activation. The safety switch must be turned to the "on" (I) during the preparation phase of an operative procedure for the device to function and resect tissue.

Activation Button: Depressing the activation button actuates cutting action. The device will continuously cut and allow the passage of fluid and tissue while the button is depressed and will stop as soon as the button is released. The cutting window will remain closed while the button is not depressed, but will still allow for some limited fluid outflow in this position.

Outflow Tubing: The outflow tube removes waste fluid and resected tissue through a compatible suction canister and tissue trap.

Cutting Window: Partial opening near the distal tip of the device through which fluid and tissue are evacuated from the uterus

Cutting Window Indicator: Indicates the orientation of cutting window when cutting window is not under direct visualization

Distal Tip Locating Mark: Indicates depth relative to the hysteroscope and can be used during the initial insertion of the tissue removal device into the hysteroscope.

Pathology Measurement Lines: contains markings spaced 1mm apart to help estimate pathology size under direct visualization

Components not included with the Benesta Tissue Removal Device:

- Under-buttocks drape
- IV Pole, pressure cuff or fluid management system (FMS)
- Distending media
- Vacuum source, suction canister and tissue trap
- Inflow tubing
- Hysteroscope with a working channel to accommodate the Benesta Tissue Removal Device.

SET-UP

Please review the system configuration diagram in Figure 2 for a diagram of the system setup.

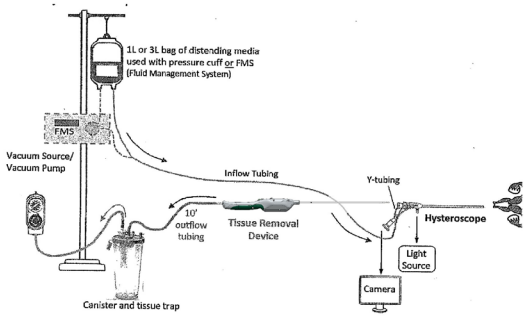


Figure 2. System configuration diagram

Distending Media Set-Up

- It is strongly recommended that isotonic media such as 0.9% Normal Saline or Lactated Ringer's be the media used for distending the endometrial cavity.
- Either a purpose-built hysteroscopic fluid management system or a bag of distending media and a pressure cuff should be utilized.
- For purpose-built fluid management systems, carefully follow the manufacturer's instructions.
- Connect the inflow tubing to the appropriate attachment on the hysteroscope.
- Position an under-buttocks drape with an integrated fluid reservoir or similar fluid collection system that allows estimation of fluid volume.
- Connect the outflow tubing to a tissue trap in line with tubing that attaches to an appropriate suction canister.
- Attach the suction canister to a regulated vacuum or fluid management system.
- Start the procedure with the vacuum pressure set to 250 mm Hg.
- Make sure the lid is securely attached to the canister prior to using.
- Connect the outflow vacuum tubing to the tissue trap connection on the canister lid.

OPERATION

1. Prior to opening the device, inspect the package for any signs of damage. If damage is found, do not use the device and contact Technical Support.
2. Open the device by peeling back the corner of the tray lid completely.
3. Remove the inner tray lid to expose the device.
4. Holding the tray securely, grasp the handle of the device firmly and pull up to release the device from the tray.
5. Remove the outflow tubing from the package. Connect the open end of the outflow tubing to the Benesta Tissue Removal Device, then connect the opposite end to the vacuum canister.
6. Turn the safety switch from the "off" (O) position to the "on" (I) position. Confirm the LED light illuminates the activation button.
7. Temporarily actuate the Benesta Tissue Removal Device activation button prior to introducing into the working channel of the hysteroscope to ensure that the power is on and functioning correctly.
    - Do not operate the Benesta Tissue Removal Device in a non-irrigated, open-air environment for an extended period of time as this may cause damage to the device.
8. Introduce the inactivated Benesta Tissue Removal Device through the working channel of the hysteroscope until the distal tip of the tissue removal device is visible under clear visualization.
9. Actuate the Benesta Tissue Removal Device activation button for 2-3 seconds while under clear visualization and away from any patient tissues to prime the device with the distending media or retract the tissue removal device into the hysteroscope until the cutting window is within the hysteroscope working channel to prime the device.
    - If the system is turned off for any reason or the treatment is interrupted for any reason, remove the device from any tissue, wait 15 seconds, and repeat steps 5 through 8 before continuing.
10. Rotate to align the cutting window with the target pathology. Rotating the hysteroscope may be necessary to achieve the desired visualization of the cutting window and target tissue pathology.
11. Bring the cutting window in proximity with the target tissue pathology.
12. Press the activation button to actuate cutting action.
    - The suction pressure and/or media infusion pressure can be adjusted to optimize visualization and cutting performance.
    - Optimal function may be achieved by resecting the tissue in bursts of a few seconds each. This may aid in the maintenance of distension of the endometrial cavity and facilitate monitoring of the cutting progress as well as device orientation or position.
13. Do not apply excessive leverage on the device by pushing hard into the target pathology. Excessive leverage on the device does not improve cutting performance and may result in decreased performance and/or unintended excision of tissue pathology.
14. Excised tissue is collected in the tissue trap.

Ending the Procedure

1. Retract the Benesta Tissue Removal Device into the hysteroscope until the cutting window is within the hysteroscope working channel.
2. Actuate the activation button for a few seconds to ensure that all tissue is transferred into the tissue trap.
3. Remove the Benesta Tissue Removal Device from the hysteroscope.

Device Disposal

Dispose of the Benesta Tissue Removal Device according to your facility's policies and local, state or Federal procedures for biohazardous materials, sharp waste, and battery disposal. In order to facilitate removal, the batteries can be accessed using the battery latch located on the underside of the device handle.

Storage

- The Benesta Tissue Removal Device should be stored at room temperature, away from moisture and direct heat.
- The device should not be stored at temperatures below 40°F or above 120°F, or in conditions where the humidity is below 40% or above 60%.

Troubleshooting

- If the device does not actuate, remove the device from the hysteroscope. Turn the safety switch from the "off" (O) position to the "on" (I) position. Temporarily actuate the activation button to ensure that the power is on before reintroducing into the hysteroscope.
- If the distal tip of the tissue removal device is not visible after insertion, remove the device completely from the hysteroscope. Reintroduce the inactivated device through the working channel of the hysteroscope until the distal tip of the device is visible under clear visualization. If the issue does not resolve, please check the hysteroscope for obstructions and/or field of view. Ensure the vacuum tubing is connected and the vacuum is functioning. The vacuum pressure should be set to a minimum of 250 mm Hg.
    - Note: If troubleshooting steps do not resolve the issue, please contact Technical Support.

Electrical and Electromagnetic Safety

- All equipment performance is considered to be safety-related performance, including any degradation of performance caused by reciprocal interference. If the product is not put into service in accordance with the electromagnetic safety requirements in this manual and fails to perform as specified, e.g. continuous operation for 30 minutes resecting pathology, the procedure should be aborted immediately, and biomedical engineering staff should be alerted to the observed issues.
- The Benesta Tissue Removal Device is an applied part Type BF device, meaning that it complies with a specific requirement for protection against electric shock. This device is not suitable for direct cardiac application.
- The Type F applied part status of energized hysteroscopes intended for use with a multiplicity of supply units and/or light guide cables is ensured by, for instance, using only supply units having isolated light guide output sockets.

- The standard operating voltage of the Benesta Tissue Removal Device is 9.0V, and the operating current is ~1.5A.
- Interconnections conditions require the applied parts of other medical electrical equipment used within the configuration for hysteroscopic application to be type BF applied parts or type CF applied parts.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment, it may be corrected by one or more of the following measures:
    1. Reorient or relocate this equipment, the other equipment, or both.
    2. Increase the separation between the pieces of equipment.
    3. Connect the pieces of equipment into different outlets or circuits.
    4. Consult a biomedical engineer. Electrical safety testing should be performed by a trained biomedical engineer or other qualified person.
- It is the responsibility of the person(s) installing, utilizing, and decommissioning the Benesta Tissue Removal Device to ensure that the electromagnetic environment does not exceed or deviate from the specifications listed in Tables 1-6.

WARNING: 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.

The following tables provide information on the electromagnetic environment that the Benesta Tissue Removal Device is capable of operating in safely.

Table 1. Declaration of Electromagnetic Emissions

The Benesta Tissue Removal Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Benesta Tissue Removal Device should ensure that it is used in such an environment.

Emissions test	Test Level/ Limits	Electromagnetic Environment / Recommendations
RF emissions CISPR 11	Class A	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
Harmonic distortion IEC 61000-3-2 IEC 61000-3-2	Class A	Not Applicable - device is battery operated
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Pst ≤1.0 Plt ≤ 0.65 dc ≤ 3.3% dmax ≤4.0%	Not Applicable - device is battery operated

NOTE 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.

CAUTION: The Benesta Tissue Removal Device is not indicated or intended for use in a residential environment.

Table 2. Declaration of Electromagnetic Immunity

Immunity Test	Test Level / Limits	Electromagnetic Environment / Recommendations
Electrostatic Discharge (ESD) IEC 61000-4-2	8 kV (±) Contact 15 kV (±) Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transients IEC 61000-4-4	±2 kV AC/DC power supply ±1 kV input/output lines	Not Applicable – device is battery-operated
Surge IEC 61000-4-5	±1 kV to line(s) ±2 kV to line(s) to earth	Not Applicable – device is battery-operated
Radio Frequency (RF) Common Mode IEC 61000-4-6	3 Vms 150kHz to 80MHz	Not Applicable – device is battery-operated
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels typical commercial or hospital environments.
Voltage Dips and Interruptions IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not Applicable – device is battery-operated

U_T is the A.C. mains voltage prior to application test level

Table 3. Guidance and Manufacturer's Declaration of Electromagnetic Immunity

The Benesta Tissue Removal Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Benesta Tissue Removal Device should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted Radiated RF IEC 61000-4-3	3 Vrms 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Benesta Tissue Removal Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance (in meters) $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, 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.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess 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 Benesta Tissue Removal Device is used exceeds the applicable RF compliance level above, the Benesta Tissue Removal Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Benesta Tissue Removal Device.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE: Electromagnetic disturbances may cause the Benesta Tissue Removal Device performance to degrade or stop functioning. If these symptoms are experienced, immediately, turn the safety switch "off" by depressing the (O) position on the handle and remove the device from the hysteroscope.

Table 4. Recommended separation distance between potable and mobile RF communications equipment and the Benesta Tissue Removal Device

The Benesta Tissue Removal Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Benesta Tissue Removal Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Benesta Tissue Removal Device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (in meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80MHzto800 MHz $d=1.2\sqrt{P}$	800MHzto2.5 GHz $d=2.3\sqrt{P}$
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 transmitters 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.

WARNING: 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 Benesta Tissue Removal Device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 5. Immunity to RF wireless communications equipment (Table 9 of IEC 60601-1-2)

Test Frequency (MHz)	Band (MHz)	Service [a]	Modulation	Immunity Test Level (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25, UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				

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 6100-4-3.

[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, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

Table 6. Enclosure Port Immunity to Proximity magnetic fields

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz [a]	CW	8
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	7,5 [c]

a) Not applicable.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal

c) r.m.s., before modulation is applied

Warranty

- Caldera Medical products are warrantied to be free from defects in material and workmanship for the warranty period beginning from the date of invoice.
- This limited warranty is restricted to replacement by Caldera Medical, at its option, of any product found to be defective during the warranty period.
- Damage inflicted to a product by the user will result in additional charges and may void the warranty.
- There are no serviceable components of the Benesta Tissue Removal Device.
- This includes but is not limited to normal use related damage, any attempted repairs by unauthorized service providers, use of a sterilization method not approved by Caldera Medical, and use of the product in a way that is not intended by Caldera Medical.
- All warranties apply to the original buyer only and are not transferable.
- In no event shall Caldera Medical be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.
- Refer to the current Caldera Medical Terms and Conditions for full warranty details or contact Customer Service for specific warranty information.
- NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

Technical Support

For technical support and product return information, please contact Caldera Medical via email (info@calderamedical.com) or telephone, at 1.818.879.6555.

All Caldera Medical Instruction for Use (IFU) documents are available in print form at no additional cost upon request. If you would like to request a copy, please contact us at 1.818.879.6555, fax 1.818.879.6556, or email info@calderamedical.com.

To learn more about Caldera Medical, other products for incontinence, product evaluations, and training opportunities, contact Caldera Medical at 1.818.879.6555 or visit our website at www.calderamedical.com.