Benesta™ Tissue Removal Device

Instructions for Use

REF CAL-TR1511 (1 pack)

REF CAL-TR1513 (3 pack)

℞ ONLY

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
IPX2	**Ingress Rating**	Signifies that the device is rated to level 2 for water ingress protection, and that water splashing against the enclosure from any direction shall have no harmful effect.	N/A	N/A
	**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
	**NRTL Certification**	Signifies that the device meets regulatory and performance requirements verified by NRTL	N/A	N/A
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

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

The Benesta™ Tissue Removal Device is a sterile, single-use hand-held device that is used to hysteroscopically remove intrauterine tissue. It 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 on the proximal end of 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 gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retained products of conception.

Contraindications

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

Warnings

- Before using the Benesta™ Tissue Removal Device for the first time, please review all available product information.
- Before using the Benesta™ Tissue Removal Device, you 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.
- Careful pre-operative assessment, including preoperative imaging, should be performed on each patient prior to a hysteroscopic procedure to evaluate for conditions which 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.
- Ensure that a compatible vacuum system that can develop a pressure of at least 200 mm Hg is appropriately connected before commencing surgery.
- Uterine tissue containing suspected fibroids may harbor an occult malignancy. The safety of using mechanical tissue removal device 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 that have implants, assure that:
    - The Benesta™ Tissue Removal Device cutting window is facing away from (i.e., 180° opposite) the 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.
- 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 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 expiration date.
- 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.
- 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 may render any warranties null and void.
- Discard all opened, unused devices.

CAUTION: Premature unpacking of the device may result in additional and unacceptable risk

- 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 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 wear, degradation, and seizing of the inner assembly.
- 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 you find cracks, fractures, or dulling, or if you have 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 distal tip can cause the Benesta™ Tissue Removal Device cutter to come out of the cutting window. If such damage occurs, replace the device immediately.

Benesta™ Tissue Removal Device

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

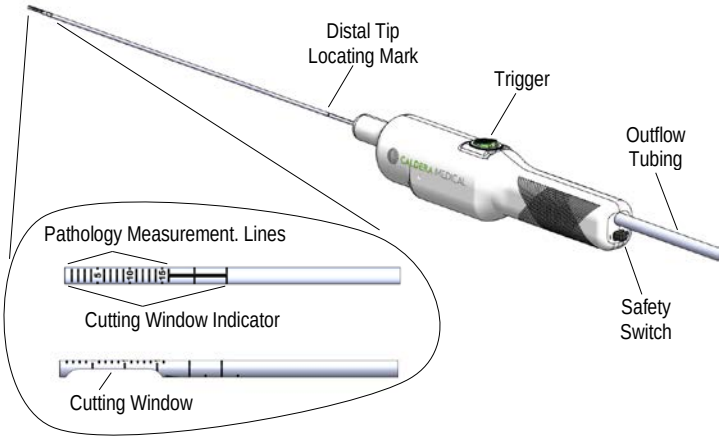

Figure 1. Benesta™ Tissue Removal Device

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.

Trigger: Depressing the trigger actuates cutting action. The device will continuously cut and allow the passage of fluid and tissue while the trigger is depressed and will stop as soon as the trigger is released. The cutting window will remain closed while cutting is not activated, but will still allow for some 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: side-facing cutting window at the distal tip

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

Distal Tip Locating Mark: Indicates depth relative to hysteroscope and can be used during 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
- Benesta™ Hysteroscope and outflow channel
- Inflow tubing
- Y-tubing
- Hysteroscope and outflow channel end cap seals

SET-UP

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

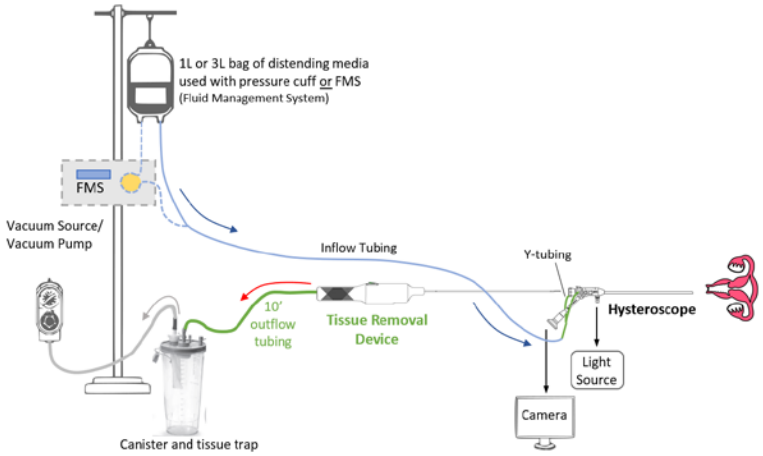

Figure 2. System configuration diagram

Distending Media Set-Up

- It is strongly recommended that isotonic media such as 0.9% Normal Saline or Ringer's Lactate be the media used for distending the endometrial cavity.
- Either a purpose-built hysteroscopic fluid management system or a protocol for manual estimation of systemic absorption should be in place.
- For purpose-built fluid management systems, carefully follow the manufacturer's instructions.
- If using a manual fluid management system:
  - Procure an intravenous (IV) pole from which to hang either a 1L or 3L bag of distending media at least 40 inches above the patient's uterus
  - A pressure sleeve may be placed around the fluid bag to increase inflow and uterine pressure and improve visualization during the procedure.
  - When using the Benesta™ Hysteroscope, open the packaging for the Y-tubing and connect it to the hysteroscope inflow ports. Connect the Y-tubing to the fluid bag containing distention media using compatible inflow tubing.
  - When using with the Benesta™ Hysteroscope (and/or outflow channel), make sure the single-use seal is installed in the hysteroscope (and/or outflow channel).
- 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 the regulated vacuum source which is set to approximately 250 mmHg.
  - Make sure the lid is securely attached to the cannister prior to using.

– Connect the outflow vacuum tubing to the tissue trap connection on the cannister 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 Tyvek® lid completely to expose the device.
3. Holding the tray securely, grasp the handle of the device firmly and pull up to release the device from the tray.
4. Remove connected outflow tubing and, leaving the end of the tubing free, straighten out the tubing so that it is completely unwound.
5. Turn the safety switch from the “off” (O) position to the “on” (I) position.
6. Temporarily actuate the Benesta™ Tissue Removal Device trigger prior to introducing into the working channel of the hysteroscope to ensure that the power is on.
   – 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.
7. 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.
   – When used with the Benesta™ Hysteroscope, the tip of the Benesta™ Tissue Removal Device will extend approximately 3.2 cm from the end of the hysteroscope.
8. Actuate the Benesta™ Tissue Removal Device trigger for 2-3 seconds while under clear visualization and away from any patient tissues to prime the device with the distending media. You can also 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
9. Rotate to align the cutting window with the target pathology. Rotating the hysteroscope may be necessary to achieve desired visualization of the cutting window and target tissue pathology.
10. Bring the cutting window in proximity with the target tissue pathology.
11. Press the trigger to actuate cutting action in a fashion that allows for excision of the excised tissue.
    – 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 maintenance of distension of the endometrial cavity and facilitate monitoring of the cutting progress as well as device orientation or position.
12. Do not apply excessive leverage on the device by pushing hard into 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.
13. 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 trigger 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.

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 trigger 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 vacuum tubing is connected and functioning and vacuum is set to 250mmHg minimum.
  – 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, 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 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 7.7V – 9.0V, and the operating current is ~0.2A.

- 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 1-4.

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 assure 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

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 assure 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.

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.			

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.
  - No 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.
  - 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 866-422-5337.

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 818.879.6555, fax 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 866.422.5337 or visit our website at www.calderamedical.com.