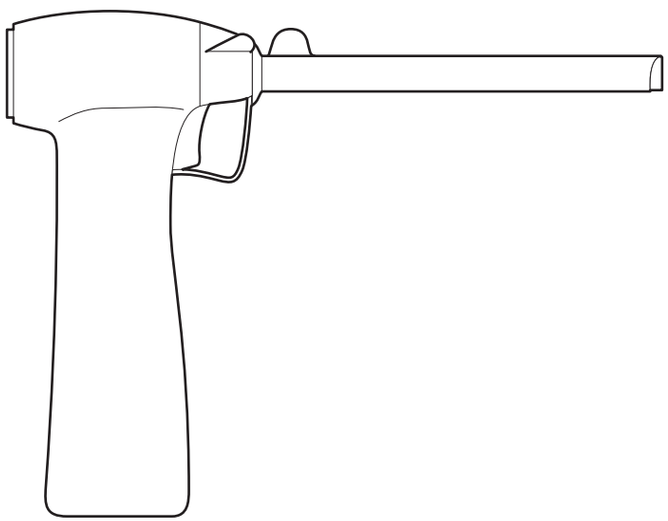
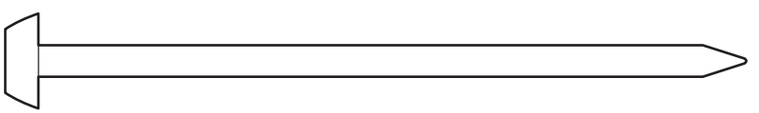
LiNA Xcise™

Laparoscopic Morcellator





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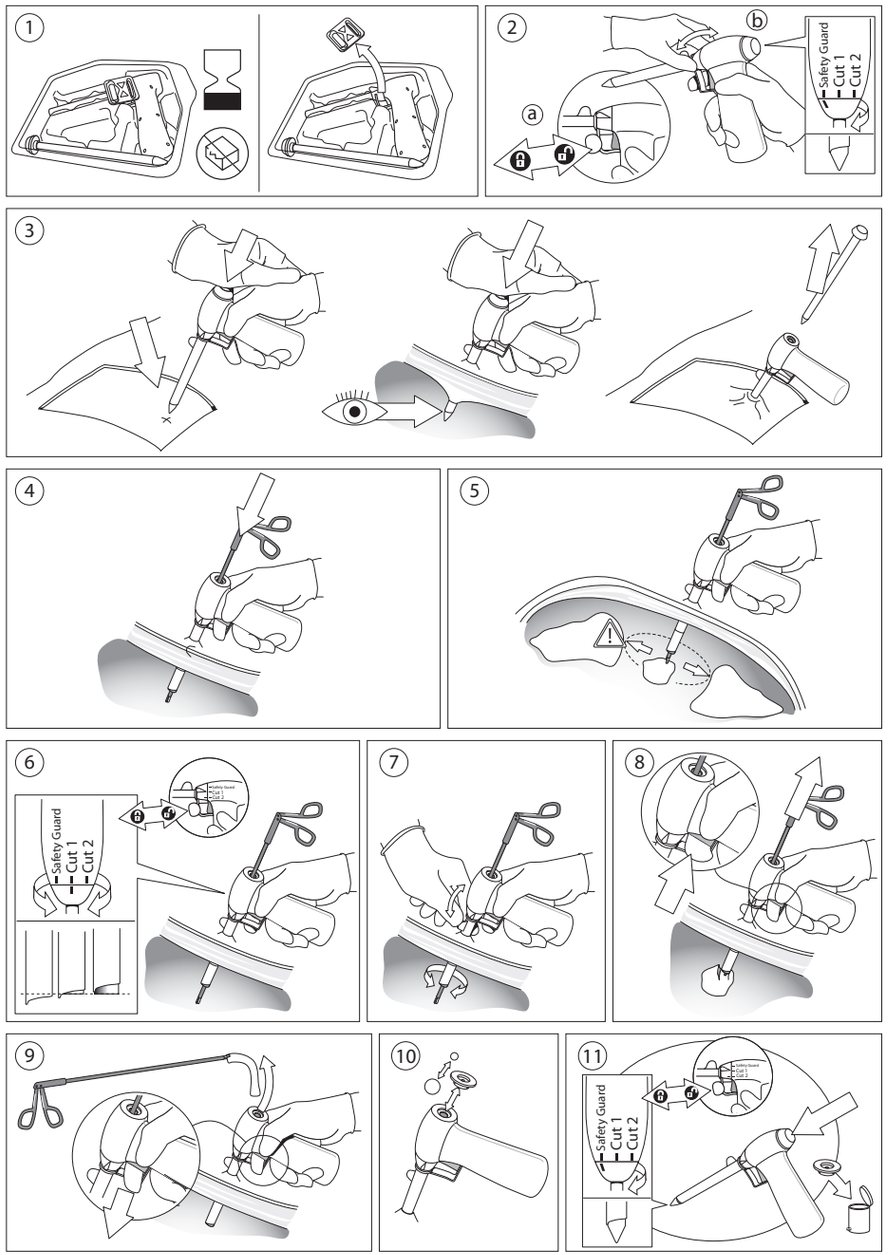

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Ref: MOR-1515-1, MOR-1515-6

Intended Use:
The LiNA Xcise™ laparoscopic morcellator is intended for gynecologic use by trained professionals in hospital and surgical environments.

Indications for use:
Indicated for cutting, coring and extracting tissue in laparoscopic gynecologic procedures such as hysterectomy and myomectomy.

Patient population:
Females requiring laparoscopic gynecologic procedures such as hysterectomy and myomectomy.

Product description:
The LiNA Xcise™ is a cordless, single use, fully disposable morcellator intended for tissue morcellation during laparoscopic gynecologic procedures. The LiNA Xcise™ contains a rotating cutting tube with built-in trocar function that also serves to protect the sharp end of the cutting tube. A grasper or a tenaculum forceps must be used to pull the stripes of tissue out through the lumen of the cutting tube. The LiNA Xcise™ cutting function is controlled by the activation button on the hand piece.

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

Warnings:

Uterine tissue may contain unsuspected cancer. The use of laparoscopic power 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.

- The LiNA Xcise™ 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.
- For single use only. Do not reuse, reprocess or re-sterilize the LiNA Xcise™. 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 LiNA Xcise™ causing significant gas leakage through the morcellator.
- In order to prevent injuries to surrounding viscera exercise caution while manipulating the LiNA Xcise™. Do not place the cutting tip nearby or in contact with tissue which is not intended to be morcellated.
- When inserting the Obturator through the percutaneous access, there is risk of injury to blood vessels, intestinal loops or the bladder.
- Be aware that the cutting tip of the LiNA Xcise™ 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.
- Do not activate the LiNA Xcise™ if it is not possible to visualize the cutting tip.
- Do not attempt to sharpen or modify the cutting tube. Modified or distorted cutting tube can result in patient, surgeon or equipment damage.
- Do not use excessive force while using LiNA Xcise™. This could damage the product.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Be aware of sharp edges.
- The risk of occult cancer, including uterine sarcoma, increases with age, particularly in women over 50 years of age. This information should be shared with patients when considering surgery with the use of these devices.
- Uncontained power morcellation has been associated with the spread of benign uterine tissue, i.e., parasitic myomas and disseminated peritoneal leiomyomatosis, potentially requiring additional surgeries.
- Laparoscopic power morcellators should only be used with a containment system. The containment system should be compatible with the laparoscopic power morcellator.

Precautions:
- Use of the LiNA Xcise™ 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 LiNA Xcise™ 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 LiNA Xcise™ does not pose any significant risk of reciprocal or electromagnetic interference. LiNA Xcise™ 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.

Instructions for use:
The surgeon should read the Instructions for use carefully before using this device.

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 LiNA Xcise™, 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 LiNA Xcise™ with obturator should be placed into the abdomen using standard technique for laparoscopic trocar placement. It is recommended to insert the LiNA Xcise™ 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 LiNA Xcise™ and 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 LiNA Xcise™.
10. For use with a 5 mm instrument: Mount the reducer cap onto the back of the morcellator with a pressing and turning motion.
11. After surgery, remove the LiNA Xcise™ from the abdominal cavity. For proper disposal, turn the trocar into the "Safety Guard" position, remove the reducer cap and insert the obturator. The morcellator may now be safely disposed in accordance with local governing ordinances and recycling plans.

Reporting:
Any serious incident that has occurred in relation to the device should be reported to the LiNA Medical ApS and the competent regulatory authority of the country in which the user and/or patient is established.

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

Country of origin: Poland.
IP class: IPX0.

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