



Instructions For Use - EMP 400 ECO-T

! *Before using this product, please read the following information carefully*

IMPORTANT!

- 1) A 15mm Trocar is required for deployment.
- 2) This IFU is designed to assist using this product. It is not a reference for surgical techniques.
- 3) This device is designed, tested and manufactured for single use only. Reuse, reprocessing and/or re-sterilisation of this device, may lead to its failure and subsequent patient infection/injury.
- 4) All Espiner devices are latex free and sterilised using Ethylene Oxide.

CONTRAINDICATIONS

1) Do not use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy. Do not use for removal of uterine tissue containing suspected fibroids in patients who are: peri- or post-menopausal.

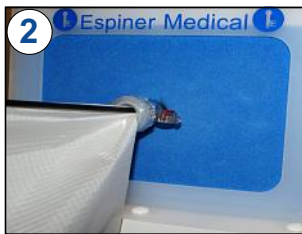
WARNINGS

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.

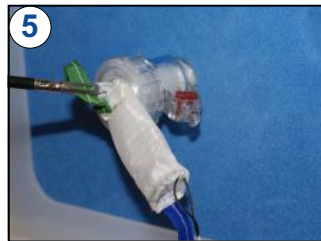
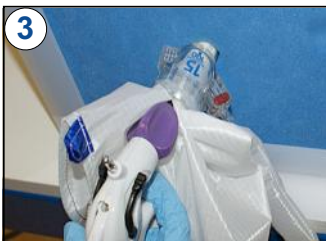
- 1) When using power morcellators, the Espiner Tissue Retrieval System should be used under direct laparoscopic vision.
- 2) Maintain adequate insufflation of the sac throughout the morcellation procedure, to reduce the risk of injury to internal structures.
- 3) When using the Espiner Tissue Retrieval System in conjunction with powered morcellators, cutting instruments or exposed blades, care must be taken to avoid damaging the sac.
- 4) Laparoscopic surgery should only be performed by physicians who are thoroughly trained in laparoscopic techniques, precautions and corrective actions in the event of a failure.
- 5) Dispose of all used products using standard hospital practices for biohazard control.
- 6) Do not use after expiration date shown on label.

CAUTION: Do not use if the sterile barrier is damaged or broken

Deployment



Using an Atraumatic Grasper, deploy sac base first, by grasping the white handling tab at the bottom of the sac.

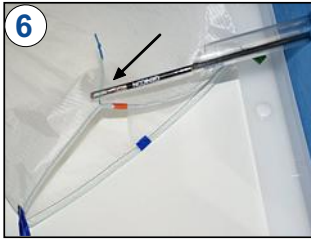


Use white tab to insert the sac as far as possible, into the pelvis. Next, grasp the coloured tab that is closest to the trocar lip and insert into the pelvis. Finally, grasp the blue sleeve locator and insert through the trocar.

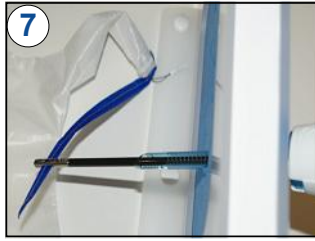
Comments

- The coloured tabs around the mouth of the sac can be used for orientation before placement of the specimen.
- The orange marker identifies the location of the drawstring.
- The green and blue tabs identify the lateral edges of the sac, with the green tab identifying the side with the sleeve.
- The black stitching around the mouth, indicates the inside of the sac.

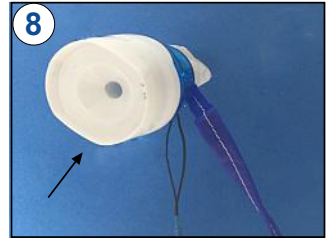
Use of camera sleeve



Once the specimen is securely within the sac - Pull drawstring to close sac mouth and continue to extract drawstring through trocar.



Locate the 'Blue camera sleeve locator' and extract the camera sleeve from the abdomen, through the port where the camera will be used.



A 5-10mm trocar can be placed inside the camera sleeve.

Morcellation

IMPORTANT: Direct vision should be on the morcellator blade at all times



The camera can then be placed through the 5-10mm trocar. Re-attach insufflation to this port

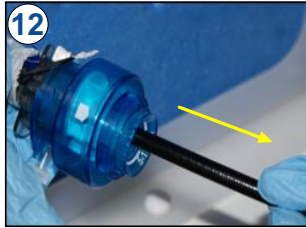


Extract and open the mouth of the sac just outside the abdomen.

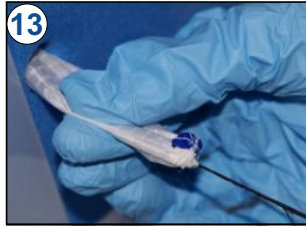


When insufflation is satisfactory, insert morcellator under direct vision and begin morcellation. *Note: An insufflation pressure of 25mmHg is recommended.*

Withdrawal of sac



After morcellation, insufflation can be turned off and camera removed.



Secure the sleeve using the suture drawstring.



Tie knot as close as possible to distal end of camera sleeve.










Important: Re-insert the camera to observe sac removal.

Remove the sac and remaining contents: Under direct visualization, insert camera through alternate 5mm trocar, pull mouth using a 'rocking motion' to dispel air. Continue to pull under direct vision until sac and contents are clear of patient.



The drawstring is designed for sac closure. Do not exceed the breaking strain of 8kg

Caution: Federal (USA) and European Union law restricts this device to sale, distribution and use by or on the order of a physician

 Single Use Only	 Store in a cool place	 Not made with latex	 0120	 Do not use after expiry date shown on unit label	 Fannin UK Ltd. Yeo Bank 3, Clevedon BS21 6TH UK +44 (0)1275 878801	 STERILE EO Part no. E268/3
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Instructions For Use - EMP 200 ECO-TMF

! Before using this product, please read the following information carefully

IMPORTANT!

- 1) A 12mm Trocar is required for deployment.
- 2) This IFU is designed to assist using this product. It is not a reference for surgical techniques.
- 3) This device is designed, tested and manufactured for single use only. Reuse, reprocessing and/or re-sterilisation of this device may lead to its failure and subsequent patient infection/injury.
- 4) All Espiner devices are latex free and sterilised using Ethylene Oxide.

CONTRAINDICATIONS

- 1) Do not use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
- Do not use for removal of uterine tissue containing suspected fibroids in patients who are: peri- or post-menopausal.

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.

- 1) When using power morcellators, the Espiner Tissue Retrieval System should be used under direct laparoscopic vision.
- 2) Maintain adequate insufflation of the sac throughout the morcellation procedure, to reduce the risk of injury to internal structures.
- 3) When using the Espiner Tissue Retrieval System in conjunction with powered morcellators, cutting instruments or exposed blades, care must be taken to avoid damaging the sac.
- 4) Laparoscopic surgery should only be performed by physicians who are thoroughly trained in laparoscopic techniques, precautions and corrective actions in the event of a failure.
- 5) Dispose of all used products using standard hospital practices for biohazard control.
- 6) Do not use after expiration date shown on label.

CAUTION: Do not use if the sterile barrier is damaged or broken

Deployment



Deploy sac base first, using the white handling tab provided.

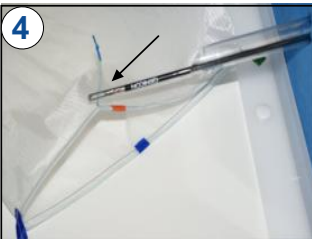


Use the blue looped tab to continue loading. *Note: The green looped tab may also be used if appropriate.*

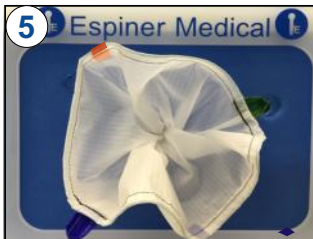


Finally push sleeve through.

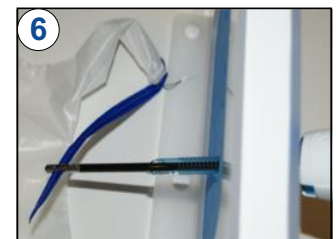
Use of camera sleeve



Post tissue capture - Pull drawstring to close sac mouth and continue to extract through trocar.



Open sac mouth just outside of the abdomen.

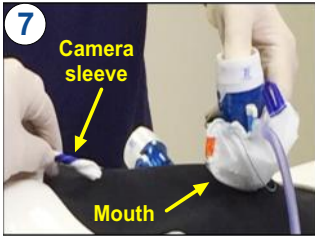


Use the 'blue camera sleeve locator' to extract the camera sleeve.

Tips

- The coloured tabs around the mouth of the sac, can be used to orientate the sac before capture of the specimen.
- The orange marker is recommended to be anterior as it depicts where the drawstring is.
- The green tab should be on the right hand side and portrays which side of the bag the sleeve is.

Morcellation



TIP: If the camera sleeve is twisted, insufflate through the mouth of the sac first.



Insert 5-10mm trocar and camera within sleeve. Re-attach insufflation to this port.



When insufflation is satisfactory, morcellation can begin.

IMPORTANT: Direct vision should be on the morcellator blade at all times

Withdrawal of sac



After morcellation, insufflation can be turned off and camera removed.



The 'blue camera sleeve locator' may now be cut away.



Secure the sleeve using the suture drawstring.



Tie knot as close as possible to distal end of camera sleeve.

Important: Re-insert the camera to observe sac removal.



To remove the sac and remaining contents, pull mouth using a 'rocking motion' to dispel air.



Continue to pull under direct vision until sac and contents are clear of patient.

The drawstring is designed for sac closure. Do not exceed the breaking strain of 8kg

Caution: Federal (USA) and European Union law restricts this device to sale, distribution and use by or on the order of a physician

This device is only to be used by surgeons experienced in the specific techniques required by these medical devices.



0120



Do not re-use



Not made with Natural Rubber Latex



Store in a cool place



Catalogue Number



Batch Code



Date of manufacture



Use-by date



Sterilized using ethylene oxide



Manufacturer

Fannik UK Ltd, T/a Espiner Medical
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Part no.
E315/2

! Do not use after expiry
date shown on unit label