

# Habib™ EUS RFA

(Product Number: 6700)

## Step by Step Procedure Guide





## Endoscopic Approach

1. Remove the pouch from the outer carton. The Instructions for Use are between the inside of the outer carton and the pouch containing the sterile Habib™ EUS RFA and should be removed for consultation.

2. Switch on the generator and put into standby mode.

3. Connect the adaptor cable to the compatible generator. The adaptor cable should remain outside the sterile/clean field.



Ensure that the power output is set to a maximum of 10 Watts. Some generators default to a much higher power setting, which is not recommended for this device and its use.



Refer to the IFU for complete instructions.



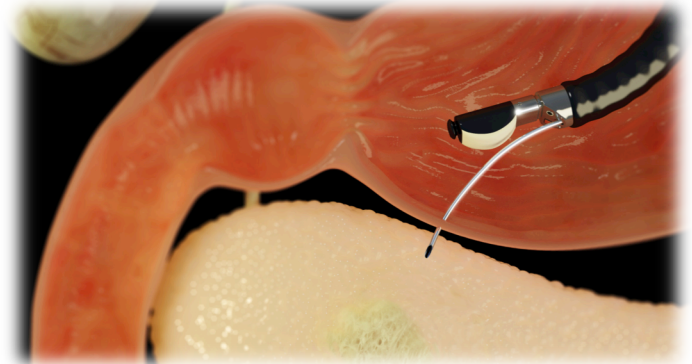
Apply a patient grounding / diathermy pad as close to the operating field as possible. The entire area of the grounding pad should be reliably attached to the patient's body.

4. Open the inner pouch and remove the dispensing coil.

Remove the Habib™ EUS RFA from the dispensing coil.

5. Introduce the echoendoscope using standard procedures and practices to ensure visualization of the target area.

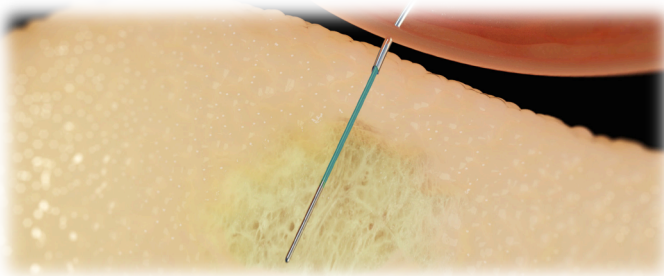
6. Introduce the introducer needle through the working channel of the echoendoscope and manoeuvre to the target area. Remove the stylet from the introducer needle.



The device must be used only by a qualified physician.



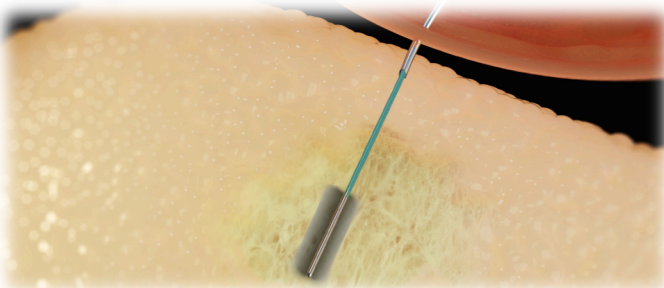
All metal instrumentation inside the introducer must be removed prior to advancing the Habib™ EUS RFA. This includes stylets, guidewires, needles, etc.



If the treatment is to a cyst then first aspirate the fluid to empty the cyst.



Between 5-10W, the ablation zone for this device is 20mm long x 8mm diameter, as obtained from porcine studies and lab testing.



Before removing or repositioning the device disable the generator by detaching the adaptor cable from the generator, placing into standby mode, or switching off.



It is inadvisable to perform any additional procedures near the treatment area immediately following ablation, including biopsy.



The patient should be recovered as per standard hospital practice for EUS procedures. It is advisable to administer IV antibiotics for pre EUS and for a further 48 hours.

7. Introduce the Habib™ EUS RFA through the introducer needle and advance the Habib™ EUS RFA to the target area which is to be treated targeting the most distal edge of the tissue first.

8. Carefully pull the introducer needle back 2 - 3cm leaving the Habib™ EUS RFA exposed directly at the treatment area.

9. Connect the Habib™ EUS RFA to the adaptor cable selected for the RF generator in use.

10. Set the generator power to 10 Watts and enable the power. The output power selected should be as low as possible for the intended purpose. Use Effect 4 on ERBE VIO generators.

11. Apply heat in 2 minute bursts. Allow a cool down period of 60 seconds prior to moving catheter to new position.

12. If further treatments are required retract the Habib™ EUS RFA into the introducer needle, reposition the introducer needle, retract the introducer needle by 2 - 3cm, reconnect to the generator and apply heat for a further 2 minutes at the recommended power settings.

13. Up to ten treatments can be given using the same device in a single procedure. When sufficient applications have been given disable the power, retract the Habib™ EUS RFA into the introducer needle before removing

any other equipment.

## Percutaneous Approach

1. Remove the pouch from the outer carton. The Instructions for Use are between the inside of the outer carton and the pouch containing the sterile Habib™ EUS RFA and should be removed for consultation.

2. Switch on the generator and put into standby mode.

3. Connect the adaptor cable to the compatible generator. The adaptor cable should remain outside the sterile/clean field.

4. Open the inner pouch and remove the dispensing coil. Remove the Habib™ EUS RFA from the dispensing coil.

5. Introduce the laparoscope or Trocar using standard procedures and practices. Verify positioning using medical imaging.

6. Introduce the introducer needle through the working channel of the laparoscope or Trocar and manoeuvre to the target area. Remove the stylet from the introducer needle.



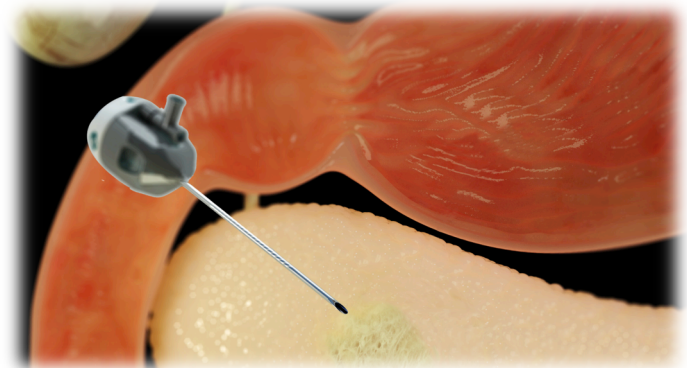
Ensure that the power output is set to a maximum of 10 Watts. Some generators default to a much higher power setting, which is not recommended for this device and its use.



Refer to the IFU for complete instructions.



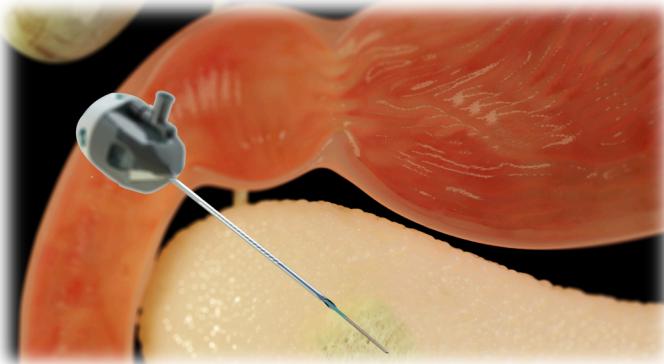
Apply a patient grounding / diathermy pad as close to the operating field as possible. The entire area of the grounding pad should be reliably attached to the patient's body.



The device must be used only by a qualified physician.



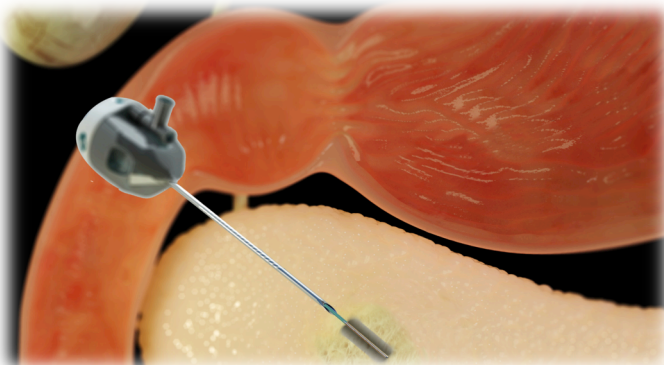
All metal instrumentation inside the introducer must be removed prior to advancing the Habib™ EUS RFA. This includes stylets, guidewires, needles, etc.



If the treatment is to a cyst then first aspirate the fluid to empty the cyst.



Between 5-10W, the ablation zone for this device is 20mm long x 8mm diameter, as obtained from porcine studies and lab testing.



Before removing or repositioning the device disable the generator by detaching the adaptor cable from the generator, placing into standby mode, or switching off.



It is inadvisable to perform any additional procedures near the treatment area immediately following ablation, including biopsy.



The patient should be recovered as per standard hospital practice for EUS procedures. It is advisable to administer IV antibiotics for pre EUS and for a further 48 hours.

7. Introduce the Habib™ EUS RFA through the introducer needle and advance the Habib™ EUS RFA to the target area which is to be treated targeting the most distal edge of the tissue first.

8. Carefully pull the introducer needle back 2 - 3cm leaving the Habib™ EUS RFA exposed directly at the treatment area.

9. Connect the Habib™ EUS RFA to the adaptor cable selected for the RF generator in use.

10. Set the generator power to 10 Watts and enable the power. The output power selected should be as low as possible for the intended purpose. Use Effect 4 on ERBE VIO generators

11. Apply heat in 2 minute bursts. Allow a cool down period of 60 seconds prior to moving catheter to new position.

12. If further treatments are required retract the Habib™ EUS RFA into the introducer needle, reposition the introducer needle, retract the introducer needle by 2 - 3cm, reconnect to the generator and apply heat for a further 2 minutes at the recommended power settings.

13. Up to ten treatments can be given using the same device in a single procedure. When sufficient applications have been given disable the power, retract the Habib™ EUS RFA into the introducer needle before removing any other equipment.

NOTES:

A large, empty rectangular box with a thin black border, occupying most of the page below the 'NOTES:' header. It is intended for handwritten or typed notes.

**Europe**

DuCane Road  
London W12 0HS  
United Kingdom  
Phone: +44 (0) 1462 423594

**North America**

300 Place D'Youville  
Suite C-33  
Montreal (QC), H2Y 2B6  
Canada  
Phone: 1-888-492-8168  
Email: [info@emcision.com](mailto:info@emcision.com)

[www.emcision.com](http://www.emcision.com)