Habib 4X

Bipolar Resection Device

angiodynamics

Habib 4X Bipolar Resection Devices

The Habib 4X Device is a sterile, single use device that can be used in conjunction with the Angiodynamics 1500/1500X generator. The Habib 4X is used to assist in liver resection procedures by employing bi-polar Radio Frequency (RF) energy. Habib 4X consists of two pairs of opposing electrodes which are introduced perpendicularly into the liver along the intended transection line. It produces controlled RF energy between the electrodes, and the heat produced seals major biliary and blood vessels and enables resection of the liver parenchyma with a conventional scalpel without blood loss or biliary leak.[1]

HABIB 4X OPEN SURGERY BIPOLAR RESECTION DEVICE

Shaft: 6 cm Electrode Length
For surface or shallow coagulation fields

Push-off tool:
Plastic tool used to support tissue during electrode withdrawal and clean charred tissue off needles/electrodes

Shaft: 10 cm Electrode Length
For deeper coagulations during resection

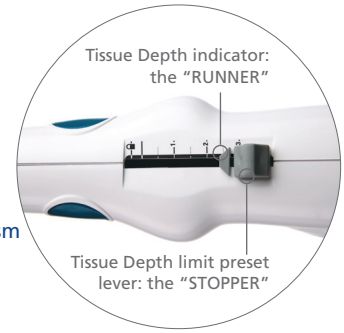
HABIB 4X LAPAROSCOPIC SURGERY BIPOLAR RESECTION DEVICE

RF ON/OFF button on the handle

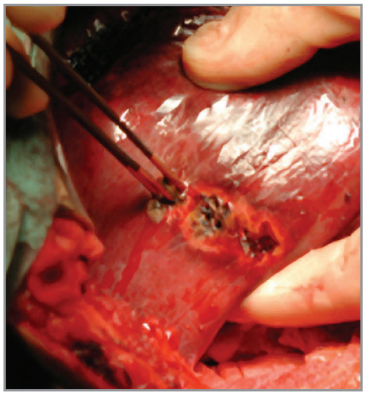
Electrode & Protective Plate:
3 cm length with a push-off, depth-controlling mechanism

Shaft:
38 cm length fits standard
10–12 mm laparoscopic access ports

Tissue Depth Mechanism

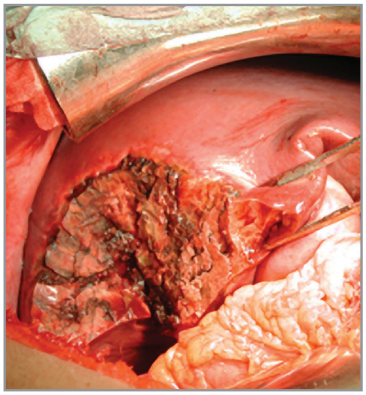


Procedure Simple as **C**oagulate, **C**ut and **E**xcise



COAGULATE

CUT



EXCISE

The intended use of the Habib 4X device is to assist in intraoperative coagulation of tissue during surgical procedures. The Habib 4X coagulates liver parenchyma with minimal blood loss to assist in liver resection procedures. Peer reviewed and published literature suggests the Habib 4X reduces the need for vessel clamping (Pringle Maneuver). Use of the Habib 4X in liver resections also resulted in low transfusion rates and low rates of patient ICU admissions.[1, 2]

Types of hepatic resection performed[2]

Resections	No. (%)
Major liver resections	*206/604 (34.1%)*
Right hepatectomy	118
Left hepatectomy	37
Extended right/left hepatectomy	13
Three or more segmentectomies	38
Minor liver resections	*398/604 (65.9%)*
One or two segmentectomies	325
Wedge resections	73

Postoperative morbidity and mortality following hepatic resection[2]

Post-operative outcome	
ITU Admission, No. (%)	26 (4.3)
Blood loss, median (range) mL	155 (0 – 4300)
Blood transfusion, No. (%)	76 (12.6)
Morbidities	
Symptomatic collection, No. (%)	69 (11.4)
Bile leak, No. (%)	25 (4.1)
Transient liver insufficiency, No. (%)	7 (1.2)
Pleural effusion needing intervention, No. (%)	17 (2.8)
Thoracic empyema, No. (%)	2 (0.3)
Hospital acquired pneumonia, No. (%)	11 (1.8)
30-Day mortality, No. (%)	11 (1.8)

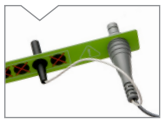
SUMMARY OF FINDINGS

- Seals major vessels
- Minimizes blood loss
- Reduces transfusion rates
- Lowers rate of ICU admissions[3]

HABIB 4X RESECTION DEVICES

Product Name	UPN
Habib 4X Kit 75 / 125 PG	H78744011
Habib 4X 6cm Device	H7874401S1
Habib 4X 10cm Device	H7874401L1
Habib 4X Laparoscopic Device	H7877001036591
1500 RF Generator Adapter Cable	700-103285
Software Module (Version 8.60)	700-103885

HABIB 4X ADAPTER CABLE



Habib 4X adapter cable is specifically designed for use with the AngioDynamics 1500X RF Generator and is a required accessory with the Habib 4X Open surgical device. The Habib 4X Laparoscopic device is packaged with a sterile pre-attached adapter cable.

MODEL 1500X RF GENERATOR

Designed specifically for use with AngioDynamics electrosurgical devices

1. Liver resection with bipolar radiofrequency device: Habib 4X. Madhava, P, et al. HPB (Oxford) 2008; 10(4): 256-260
2. Radiofrequency assisted liver resection: Analysis of 604 consecutive cases. Paj, M et al. ESJIO 38; 2012, 274-280
3. Is close monitoring in the intensive care unit necessary after elective liver resection? Kim, S.H, et al. JKSS 2012; 83:155-161
4. Factors associated with failure of enhanced recovery protocol in patients undergoing major hepatobiliary and pancreatic surgery: a retrospective cohort study. Lee, A et al. BMJ Open 2014; 4:e005330

IMPORTANT RISK INFORMATION

INDICATIONS FOR USE: The Habib® 4X Laparoscopic device is intended to be used to assist in coagulation of tissue during intraoperative and laparoscopic surgical procedures. The Habib 4X open device is intended to be used to assist in intraoperative coagulation of tissue during surgical procedures.

CONTRAINDICATIONS: Do not use on patients with cardiac pacemakers or other active implants.

SIDE EFFECTS: The potential side effects associated with liver surgery are: general problems related to general anesthetics, bleeding, liver abscess, bile leak, liver failure, subphrenic abscess, postoperative heart failure, chest infection, wound dehiscence, wound infection or incisional hernia.

WARNINGS AND PRECAUTIONS: Do not attach anything (i.e., clamps, etc.) to the device. This may damage the insulation, which could contribute to patient injury. Take care when handling as needles can cause injury. Do not use if needles are bent or damaged, as it could lead to patient injury. Please refer to the generator's user manual for warnings and precautions associated with the use of the generator. Do not use Dispersive Pad(s) with the Habib 4X device. Using dispersive pad(s) will reduce the effectiveness of the Habib 4X device and will create an unintended current path from the Habib 4X electrode to the dispersive pad(s). Do not use needle monitoring electrodes. The device cable should not contact the patient. Check the functioning of monitoring and other electronic equipment during and after use to identify any problems caused by interference. The Habib Device may interfere with the operation of other electronic equipment. Place any monitoring electrodes for physiological monitoring equipment as far as possible from the device. Monitoring systems incorporating high frequency current-limiting devices are recommended. Do not bend or kink the needles. This may cause damage and result in a non-functional device. RFA induces image changes with intraoperative ultrasound. Visualization of the tumor edge may become less clear. RFA hardens liver tissue. May not be able to palpate with the edge of the tumor. Burn hazard. Improper placement or handling of bipolar electrodes while RF is on may lead to burns due to the high levels of RF energy at the electrodes. It is recommended that ½ inch or 1 cm clearance be maintained from the electrodes. When holding a bipolar device during the procedure, keep hand and fingers ½ inch or 1 cm above the base of the handle (where the electrodes come out). Over ablation - Over ablation can cause the tissue to stick to the electrodes (charring). If over ablation occurs, the electrodes will need to be thoroughly cleaned and any tissue removed. Do not let the Needle electrodes of the Habib 4X device come in contact with each other, contact could result in damage to the Habib 4X device and/or RF generator. The Habib Adapter Cable has been validated for 50 usages. The Habib Adapter Cable may be cleaned with a damp disposable wipe moistened with 70/30 isopropyl alcohol and water. Check device for rough surfaces or sharp edges. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the device and / or lead to device failure.

For details regarding Indications, contraindications, warnings and instructions for use, please review the instructions for use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.

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