Brief Summary Document

Overview

Product RIVOS™ EUS Access Device – IFU 51114127-01C

Rx Statement

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

RIVOS is to be used by physicians trained in interventional Endoscopic Ultrasound (EUS) and fluoroscopic procedures. A thorough understanding of technical principles, clinical applications, and risk associated with accessing the biliary tree is required before using this device. The intended use environment is an endoscopy suite or operating room at a hospital.
This device is intended for use in the adult patient population.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Content

INTENDED USE/INDICATIONS FOR USE

The device is used to access and electrosurgically puncture the transgastric or transduodenal wall into the following: the intra- or extra-hepatic bile ducts, or a pancreatic pseudocyst. The device is intended for use through the accessory channel of an ultrasound endoscope.

CONTRAINDICATIONS

- This procedure should not be attempted in any patient whose general medical condition and degree of respiratory failure would not allow the patient to tolerate endoscopy and/or the manipulation required to perform the procedure.
- Patients with an uncorrectable coagulopathy or who require ongoing complete anticoagulation at the time of procedure.
- Patients with contraindications to use of electrical devices.

WARNINGS

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

- Any electrocautery device constitutes a potential electrical hazard to the patient and/or the operator.
- Temporary EUS imaging artifact may occur due to electromagnetic interference of the electrocautery tip. Normal EUS operation will resume after deactivation of the electrocautery tip.
- When not using RIVOS, disconnect the device from the Electrosurgical Unit (ESU) and place in a clean, dry, highly visible area to avoid injury to patient or user.
- This device is not intended to be used in the presence of flammable liquid, in an oxygen enriched atmosphere, or in the presence of explosive gases.
- Fluids or flammable agents that may pool under the patient or in body depressions or cavities should be mopped prior to electrocautery.
- When the device is used simultaneously with other accessories compatible with electrosurgical current, do not activate output while the accessory is in contact with body cavity tissue or with this device. This may cause bleeding, or thermal injury of the non-target tissue.
- If at any point during the procedure deformation or malfunction of the device is detected discontinue the procedure and withdraw the device from the echoendoscope. Then continue the procedure with a new device. Failure to do so may result in patient injury.
- Do not press the electrocautery tip against tissue with excessive force while activating electrocautery. Otherwise, perforation, and bleeding may occur.
- Consult a qualified professional (e.g., cardiologist) prior to use in patients who have electronic implants such as cardiac pacemakers. A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- When using electrocardiograph or other physiological monitoring equipment simultaneously with RIVOS, monitoring electrodes should be placed as far away as possible from the electrodes used with the ESU.
- Be sure to check the output power of the ESU before use. If the unit is used without the proper output setting, perforation, bleeding or tissue damage may result. See Technical Specifications table for recommended settings.
- Ensure any and all patient leads are routed to prevent contact with any other leads.
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure in order to avoid thermal injuries to patients and/or users.
- Do not place devices near or in contact with flammable materials (such as gauze or surgical drapes). Devices that are activated or hot from use may cause a fire.
- When using RIVOS, do not activate the RF energy while the electrocautery tip is within the endoscope, as this could result in scope damage, burns or electrical shock to the user or patient.
- Do not activate the device when not in contact with target tissue, as this may cause injuries due to capacitive coupling.

- Inspect RIVOS, endoscope, and the active cable for damage prior to use and, especially, the insulation of endoscopic devices. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.
- The surface of the active electrode may remain hot enough to cause burns after the RF energy is deactivated.
- Connect cables and accessories to the ESU only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
- Prior to increasing the intensity, check the adherence of the neutral electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections.
- Take precautions to ensure that the sharp is handled properly. The sharp should be treated as infectious material after removal from the device and could create an infection risk.
- Possible safety hazards may result from gas embolism caused by over insufflation of air, inert gas prior to activating ESU, etc. Endogenous gases should be sucked away if possible, prior to procedure.
- Skin-to-skin contact should be avoided (for example between the patient's arms and body) by way of dry cloth or gauze in order to prevent a possible thermal/ electrical injury.
- Consult the neutral electrode manufacturer about proper grounding of the patient. It is recommended that a monitoring neutral electrode be used, if a contact quality monitor is available, or built into the generator. The entire area of the neutral electrode should be attached reliably to the patient's body, and as close to the operating field as possible. The patient should not come into contact with metal parts or objects that may be grounded to earth in order to avoid patient injury. The use of antistatic sheeting is recommended for this purpose.
- The lines to the surgical electrodes should be fitted so that they do not touch the patient or other lines. Any active electrodes not currently in use should be put to one side so that they cannot touch the patient in order to avoid patient injury.
- No modification of this equipment is allowed as it may cause patient or user injury.

PRECAUTIONS

- Follow instructions left by the electrosurgical unit manufacturer to ensure patient safety through proper placement and usage of the patient return electrode. Ensure a proper path from the patient return electrode to electrosurgical unit is maintained throughout the procedure.
- Access to the target structure should be performed under EUS and/or fluoroscopic guided visualization. Positioning the device distal end in an improper location may lead to patient injury.
- RIVOS must be used in conjunction with a Type BF generator, see Compatibility section. The active cable (sold separately) is connected to the device handle by a plug pushed onto the connector as far as possible so that none of the connecting pin is visible. The other end of the active cable is inserted into the generator. Always follow the manufacturer's suggestions for the operation of the generator unit to prevent unnecessary hazard to the operator and/or the patient.
- RIVOS should be used with caution and only after careful consideration in patients who are at risk for bleeding complications.

ADVERSE EVENTS

- Allergic Reaction
- Bleeding
- Bile Leak
- Biloma
- Cardiac Arrhythmia or Arrest
- Cholangitis
- Cholecystitis

- Embolism
- Extravasation
- Infection
- Inflammation
- Pancreatitis
- Perforation
- Peritonitis
- Pain
- Sepsis
- Tissue damage
- Unintended electrical shock, muscle stimulation or burns.

ADDITIONAL WARNINGS

Do not use a device that has unintended rough surfaces, sharp edges or protrusions which may cause harm. Cut, burned or damaged device insulation may cause unsafe currents in either patient or operator.

Ensure that the patient is properly grounded prior to use of the monopolar electrosurgical generator and RIVOS to avoid patient injury.

Do not use blended or coagulation ESU modes. Blended or coagulation modes may result in failure to access, prolonged time to access, tissue tenting or resistance. Using the incorrect ESU mode or setting may lead to patient injury.

Ensure sharp cap is fully seated prior to advancing the sharp. Failure to do so could result in tissue tenting, inability to puncture target tissue and may result in patient injury such as: hemorrhage, infection, inflammation, and perforation.

Please note that the device contains a sharp and should be handled with caution to prevent injury. The sharp will be removed from the device during the procedure and should be treated as infectious material and could create an infection risk.

To avoid patient injury, only advance device when it is visible in the ultrasound image.

Do not use a guidewire that has been cut, burned, or damaged. Damaged insulation may cause unsafe currents in either the patient or the operator. Leakage of current to the patient or user may increase at the site of the damaged insulation.

Only recommended insulated guidewires may be left in place during electrocautery. All other guidewires must be removed prior to energizing the catheter to prevent injury to the patient.

Do not activate RIVOS with sharp in place. After puncture is complete, remove the sharp before connecting RIVOS to the ESU and activating the device. Otherwise, flow of RF energy can be applied to the sharp and may cause an electric shock or burns to the patient, operator, and/or assistant.

Prior to advancing the electrocautery tip, ensure that the device is securely fastened to the echoendoscope and the catheter adjustment lock is secure. Failure to do so could result in damage to the echoendoscope or injury to the patient.

Failure to make contact with the tissue prior to ESU activation could result in unwanted tissue damage and patient injury.

Ensure that the patient is properly grounded prior to use of the monopolar electrosurgical generator to avoid patient injury.

It is recommended to maintain direct and constant contact with tissue when applying electrocautery current. Failure to do so may result in damage to the endoscope and/ or patient injury. Apply only enough energy to enter the target structure, prolonged energy delivery may cause unintended damage to tissues or perforation.

ADDITIONAL PRECAUTIONS

Do not use an instrument after the expiration date displayed on the sterile package.

Do not use the RIVOS if any defect is found during inspection. Please notify Boston Scientific and return for replacement.

Avoid injecting air in the target structure as it may lead to loss of visualization.

Failure to lower the elevator prior to insertion may cause damage to RIVOS.

If resistance is encountered, stop pushing and reposition the device or the echoendoscope. Pushing too hard could cause damage to the echoendoscope or device.

Do not over tighten the device to scope fitting connection as it may cause damage to the echoendoscope.

Failure to advance the device beyond the elevator could result in damage to the scope during puncture.

Prior to puncture, ensure that the device is secured to the echoendoscope and the catheter adjust lock is secure. Failure to do so could result in damage to the echoendoscope or loss of access to the desired target site.

To maintain access, the distal end of the access cannula should be in the target structure prior to sharp removal. Failure to do so could result in loss of access.

Maintain a stable scope position during sharp removal to reduce the chance of loss of access.

Once sharp removal is initiated, do not attempt to reinsert sharp while the echoendoscope elevator is engaged or the distal end is articulated. Doing so may cause damage to the device or scope.

Do not reinsert the sharp while the echoendoscope elevator is engaged or the distal end is articulated. Doing so may cause damage to the device or scope. Refer to Troubleshooting Due to Loss of Access: Preparation for Repuncture During Procedure section below.

Failure to properly handle the sharp could result in damage to the device.

Avoid injecting air into the target structure as it may lead to loss of visualization.

Depending on the scope position, target location and patient anatomy, guidewire passage may be more challenging. If resistance and/or excessive force is felt, adjust your position.

Failure to lower the elevator prior to withdrawal may cause damage to the device.

The device is not intended to create multiple fistula. If targeting multiple/ additional sites, replace device for each site to prevent damage to the device.

The device is intended to puncture up to three times. If additional punctures are required, replace device.

Reinserting the sharp while the echoendoscope elevator is engaged or the distal end is articulated could cause damage to the device or the scope.