Overview

Product **ORISE™ ProKnife Electrosurgical Knife – IFU # 51543383**

℞ ONLY

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

REUSE WARNING

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.

Indications for Use

The ORISE ProKnife has been designed to be used with endoscopes and electrosurgical units to cut tissue within the gastrointestinal tract using high-frequency current. The electrosurgical knife also has the capability of delivering saline/ submucosal lifting agent into submucosal tissue layers under direct visualization through an endoscope.

Contraindications

None known.

WARNINGS

- It is suggested that the operator and the assistant wear personal protective equipment to prevent accidental burns. Universal precautions should be used in all cases. While operating the device avoid contact with the patient.
- 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 as this may cause patient and/or operator injury.
- Any electrosurgical device constitutes a potential electrical hazard to the patient and/or the operator.

- No modification of this equipment is allowed.
- Fluids or flammable agents that may pool under the patient or in body depressions or cavities may lead to injuries such as electric shock or burns or other patient injuries. Any fluids on the procedure room floor should be mopped prior to electrosurgery.
- When using instrument in a two-channel endoscope, simultaneously with another instrument, the second instrument must be compatible with high-frequency current. Otherwise, flow of electrosurgical frequencies in an unexpected position may cause an electrification shock of the patient, operator, and/or assistant.
- When the instrument is used simultaneously with other accessories compatible with high-frequency current, do not activate output while the accessory is in contact with body cavity tissue or with this instrument. This may cause bleeding, or thermal injury of the non-target tissue.
- If at any point during the procedure deformation or malfunction of the knife is detected discontinue the procedure and withdraw the knife and endoscope. Then continue the procedure with a new knife. Failure to do so may result in patient injury.
- Do not press the cutting knife against tissue with excessive force while activating output. Otherwise, unintended resection, perforation, and bleeding may occur. When resecting tissue, always confirm the direction of resection and use the instrument without excessive force. Failure to do so may result in patient injury.
- If patient has an implanted pacemaker, serious harm may result. Instrument may cause implanted pace maker to malfunction. Confirm safety with cardiologist and manufacturer of pacemaker.
- When using electrocardiograph or other physiological monitoring equipment simultaneously with instrument on patient, monitoring electrodes should be placed as far away as possible from the electrodes used with the electrosurgical unit.
- Needle monitoring electrodes should not be used, as they may cause patient burns. Physiological monitoring equipment incorporating high-frequency current limiting devices is recommended.
- Be sure to check the output power of the electrosurgical unit before use. If the unit is used without the proper output setting, perforation, bleeding or mucous membrane damage may result. See below table Recommended Settings.
- Ensure any and all patient leads are routed to prevent contact with any other leads. Failure to do so may result in injury or electrical shock to the patient or user.
- Ensure any accessory or patient cleaning is done with non-flammable cleaning agents. Flammable agents used for cleaning or disinfecting along with solvents of adhesives should be allowed to evaporate before the procedure. Failure to do so may result in a fire and/or an electrical injury to the patient or user.
- Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
- Knife resection should be performed under direct endoscopic visualization to prevent patient injury.
- Check for the proper position of the device distal end using direct vision. Positioning the device distal end in an improper location may lead to patient injury.

- The ORISE ProKnife must be used in conjunction with a Type BF generator, see Compatibility section. The active cord (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 cord 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.
- Consult the neutral electrode manufacturer about the proper grounding of the patient. Ensure proper placement of the neutral electrode on the patient and the connection to the generator. Failure to do so may result in harm to the patient including burns.
- The patient should not come into contact with metal parts or objects that may be grounded to earth. Failure to do so may result in patient injury such as electrical/thermal injury.
- ORISE ProKnife should be used with caution and only after careful consideration in patients who are at risk for bleeding complications in order to prevent patient harm.
- Attempting to push through saline/submucosal lifting agent when a clog is present may jeopardize the integrity of the ProKnife by damaging internal mechanisms which may cause injury to the patient.
- Visually inspect the device prior to use to ensure there is no damage to the outer catheter or insulation. Insulation failure may result in burns or other injuries to the patient or operator.
- Prior to insertion and during advancing of the ProKnife, ensure that the electrode is fully retracted in order to prevent injury.
- Prepare hemostasis devices in case of complication in order to prevent patient injury.
- When using in the gastrointestinal tract, ensure that flammable endogenous gases are removed prior to using the high-frequency current portion of the product.
- The ProKnife should never be connected to the Active Cord prior to inserting the ProKnife through the endoscope to avoid injury to the patient or equipment resulting from improper electrical circuit grounding.
- The electrosurgical generator should be placed in the OFF position prior to advancing the device through the endoscope to avoid injury to patient or equipment resulting from improper electrical circuit grounding.
- Ensure that the patient is properly grounded prior to use of the monopolar electrosurgical generator and ProKnife to avoid patient injury.
- Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
- The electrosurgical effect is greatly influenced by the size and configuration of the active electrode, one should set the unit at a power intensity as low as is necessary to achieve the desired effect in order to avoid patient harm.
- 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 and may result in patient injury.
- The surface of the active electrode may remain hot enough to cause burns after the high-frequency current is deactivated.

- 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.
- Prior to removal of the ProKnife from the endoscope, remove the active cord from the handle to avoid injury to the patient or equipment resulting from improper electrical circuit grounding.
- Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
- If bleeding does occur, remove the ProKnife and use a hemostasis device or agent to stop the bleeding.
- Maintain lift beneath the lesion as to avoid burning or perforation of tissue.
- It is recommended that physicians only press on the pedal when in contact with and intending to cut tissue. Failure to do so may result in patient injury.

PRECAUTIONS

- The active length information provided is intended to be used with the guidance from the Electrosurgical Generator manufacturer to determine if the overall length of an Electrosurgical Accessory remains within the maximum allowable length. The overall active length of this Electrosurgical Accessory is 263 cm. The overall active length includes the connector, handle, catheter shaft and electrode. The length of other connecting cords must be considered when used with ORISE ProKnife.
- 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.
- When using the ORISE™ ProKnife, the electrode must be fully retracted into the catheter prior to introduction, advancement, or withdrawal from endoscope to prevent damage to the endoscope.
- Cutting for long periods of time will increase the likelihood of charred tissue build up on the electrode tip.
- Failure to properly align the distal end with the cleaning tool prior to inserting the device may damage the cleaning stylet. Ensure proper alignment before inserting the distal end into the cleaning tool.
- Do not use an instrument after the expiration date displayed on the sterile package. Doing so may pose an infection control risk or cause tissue irritation.
- Kinks in the catheter will hinder injection capability. Do not use the ProKnife if any defect is found during inspection. Please notify Boston Scientific and return for replacement.
- Avoid electrode extension when inserting the catheter through the endoscope. Inserting catheter with extended electrode may cause damage to the scope, the electrode, or both.
- Ensure the injection syringe luer connection is secured before attempting to inject saline/submucosal lifting agent into the catheter.
- Any use of this device, other than those indicated in these instructions, is not recommended.

- The recommended maximum settings on the generator are the following: 2900 Vp (5800 Vp-p). Increasing the voltage past the maximum recommended generator settings may compromise the electrode.
- Ensure that the electrode is in the retracted position to avoid damage to the scope and/or the device.
- The ProKnife should be advanced through the endoscope using short, deliberate 2-3 cm movements to prevent inadvertent damage to the catheter shaft, such as kinking. Do not forcibly insert the instrument while the endoscope is angulated tightly. Otherwise, it may damage the endoscope and/or instrument.
- Ensure that the electrode is in the retracted position to avoid damage to the scope and/or the device.
- Do not use the ProKnife if unable to inject lifting agent. Use the cleaning tool to remove any tissue build up within the inner channel of the electrode.
- Ensure that the electrode has been fully retracted into the catheter before removing the ProKnife from the endoscope. Failure to do so may lead to damage within the endoscope. Power down the electrosurgical system.

ADVERSE EVENTS

Adverse events include, but are not limited to:

- Burns, including transmural burns characterized by abdominal pain, fever, and transient illeus
- Embolism
- Fulguration
- Immediate or delayed hemorrhages
- Infection/Inflammatory reaction
- Perforation
- Stricture formation (stenosis)