

CleanCision™ Wound Retraction and Protection System

Instructions for Use

SPECIFICATIONS

Model Number: FG 0001
Incision Size: 3 -9 cm

INDICATIONS

The CleanCision Wound Retraction and Protection System is intended for use by a surgeon during abdominal surgery to: retract the surgical incision, provide access to the abdominal cavity, and irrigate the surgical wound edge. The device may aid in the prevention of wound edge contamination. This device is intended to deliver a sterile irrigant solution and serve as a conduit for fluid removal from the surgical wound edge.

DESCRIPTION

The CleanCision Wound Retraction and Protection System is a sterile, single-use device, which integrates controlled fluid delivery, wound barrier protection and surgical retraction. The CleanCision Wound Retraction and Protection System consists of two components (Figure 1):

- A wound retraction assembly comprised of: a fixed-diameter bottom ring at the bottom of the sheath, designed to be inserted into the abdominal cavity; and a radially-adjustable upper retraction ring at the top of the sheath, designed to remain outside of the body and actuated to achieve wound retraction. The sheath and bottom ring include integrated fluid delivery and removal (suction) functions.
- A fluid tubing set with a universal spike connector at one end and a male Luer connector at the other end, designed to transfer fluid from a bag to the CleanCision Wound Retraction and Protection System.

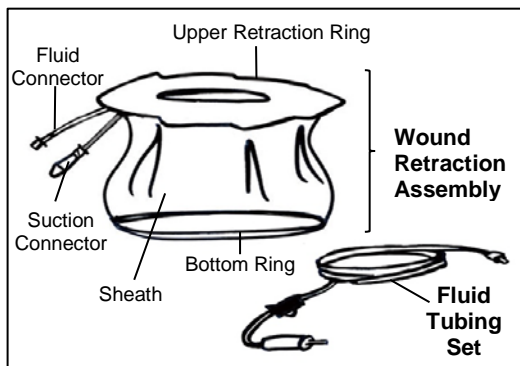


Figure 1. CleanCision Device Components

CONTRAINDICATIONS

Use of the CleanCision Wound Retraction and Protection System is contraindicated when, in the judgment of the physician, use of this device would be contrary to the best interest of the patient.

WARNINGS AND PRECAUTIONS

- Carefully read all instructions prior to use.
- Do not use if the product or sterile packing is damaged.
- Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia.
- This device was designed and tested for single patient use only. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing or resterilization may alter the structural and/or functional integrity of this device which may result in patient injury, infection, illness, or death. Risk of residual contamination and resterilization failure may lead to patient injury, infection, illness, or death.
- Device has been tested with a max hospital vacuum of 370mmHg.

CAUTIONS

Federal law restricts this device to sale by or on the order of a physician.

HOW SUPPLIED

This device is supplied sterile and for single patient use.

STORAGE AND HANDLING

Handle with care. Product should be stored in a clean, cool, dry area away from chemical fumes.

MANUFACTURED FOR:

Prescient Surgical, Inc.
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DISCLAIMER OF WARRANTY Note: Although the Prescient Surgical CleanCision Wound Retraction and Protection System hereafter referred to as "product," has been manufactured under carefully controlled conditions, Prescient Surgical, Inc. and its affiliates have no control over conditions under which this product is used. Prescient Surgical, Inc. therefore, disclaims all warranties, both expressed and implied with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Prescient Surgical, Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Prescient Surgical, Inc. to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected.

INSTRUCTIONS FOR USE

PREPARE SURGICAL SITE

- Prepare surgical site according to the hospital's standard procedures, making sure the skin is clean and dry.

MAKE AN INCISION

- Make an incision over the planned incision site. The CleanCision, small is intended for use with incisions ranging from 3cm to 9cm in length.

INSERT BOTTOM RING

- Insert the bottom fixed-diameter ring of the CleanCision device through the incision. (Figure 2)
- Adjust the orientation of the device as desired by rotating the upper retraction ring.
- Sweep area to ensure that tissue is not trapped between the bottom ring and abdominal wall.

DEPLOY UPPER RETRACTION RING

- Grasp the device with fingers around outside of the upper retraction ring and thumbs on inside edge of the handles, as shown in Figure 3.
- Pull the upper ring in a radially-expanding direction until the wound is retracted. The two locking ratchets will click and lock at incremental intervals as the upper ring is expanded.
- Sweep area again to ensure that tissue is not trapped between the bottom ring and abdominal wall.

CONNECT FLUID TUBING SET AND SUCTION TUBING

- Connect the fluid connector to the fluid tubing set. (Figure 4, Panel A)
- Occlude the tubing with the roller clamp.
- Pass off the other end of the tubing set for connection to a bag of fluid, according to the hospital's standard procedures. Hang the bag on a standard IV pole at a height approximately 40 inches above the surgical wound.
- Connect the suction connector to the hospital's standard sterile surgical suction tube. (Figure 4, Panel B)
- Pass off the other end of the surgical suction tube for connection to the hospital's standard surgical suction canister and vacuum suction mechanism, according to the hospital's standard procedures.

ACTIVATE FLUID DELIVERY AND RETRIEVAL MECHANISM

- Release the roller clamp on the fluid tubing set to allow fluid to flow into the device and irrigate the surgical wound. Titrate the desired flow rate using the roller clamp. The flow rate is designed to be 5-16 mL/minute when the roller clamp is fully opened.
- Activate the hospital's suction mechanism with a maximum vacuum of 370mmHg.

Note: If pooling of fluid is observed, reduce the fluid flow rate using the roller clamp. Perform manual suction, as necessary to remove any excess fluid. If any unresolvable issues occur with the fluid delivery and retrieval mechanism, the fluid and suction tubing can be disconnected and the wound retractor can be used without the irrigation function.

REMOVE WOUND RETRACTOR

- Stop fluid delivery using the roller clamp.
- Grasp the bottom fixed-diameter ring and pull ring up and out of the incision. (Figure 5)
- Disconnect hospital's suction tube and the fluid tubing set from the CleanCision device.

RELEASE WOUND RETRACTION MECHANISM

(If needed, to release wound retraction)

- Grasp the two handles on the upper retraction ring, such that the thumbs are on the flat part of the handle and the index fingers are on the two blue buttons. (Figure 6)
- Push the two blue buttons with the index fingers and apply pressure toward the center of the ring (radially inward) to release the locking mechanism and release the retraction to the desired setting.

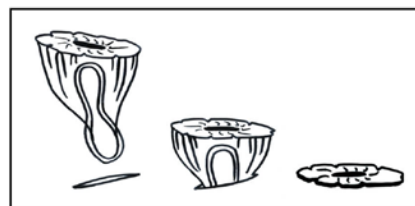


Figure 2. Insert Bottom Ring

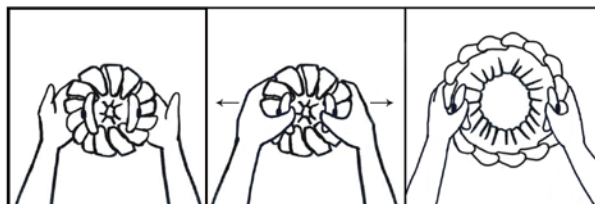


Figure 3. Deploy Upper Retraction Ring

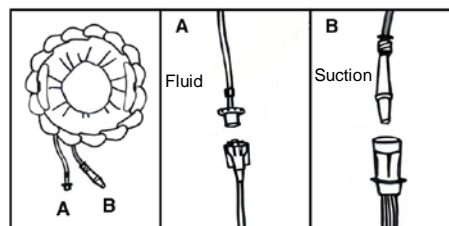


Figure 4. Connect Fluid Tubing Set and Suction Tubing (not provided)

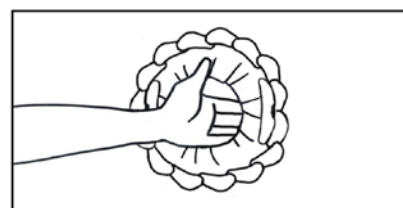


Figure 5. Remove Wound Retractor

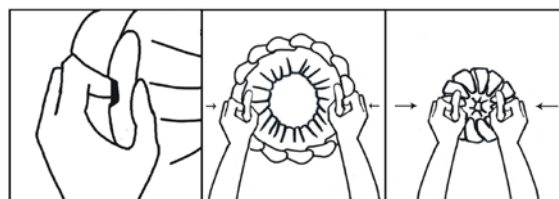


Figure 6. Release Wound Retraction Mechanism (if needed)