

# Sharp Medical

## Reactor™

Ref 100-36-01 ► Adult



Before using product, read the following information thoroughly.

### **Important!**

The instructions provided are intended to facilitate the use of the Reactor™ device. They are not intended to be an implication of chest tube placement techniques.

Properly following the instructions is essential to the safe and effective use of the product. Failure to do so may result in adverse surgical results. This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of the device may lead to its failure and subsequent patient injury. Reprocessing and/ or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

### **Description**

The Sharp Reactor™ is supplied with the Sharp Medical outer sleeve which provides for placement of a chest tube.

The Reactor™ consists of a pistol grip device with a trigger located at the proximal end and an enclosed crescent-shaped scalpel blade at the distal end. The scalpel blade extends approximately 1 mm and immediately retracts when the trigger is pulled. This action permits a controlled, sharp dissection of tissue.

### **Indications**

The Sharp Medical Reactor™ has indications in the creation of a port of entry into the thoracic cavity and allows the user to create and maintain limited access into the chest for the intention of chest tube placement.

### **Contraindications**

1. This device is not intended for use when endoscopic techniques generally are contraindicated.
2. This device is not indicated in a patient in whom pleural adhesions are suspected.
3. This device is not to be used if current chest tube placement techniques are not possible.

## **Warnings and Precautions**

1. Use of the Sharp Medical Reactor™ is not indicated unless at least a limited interpleural space exists (air or Fluid).
2. **DO NOT SQUEEZE THE TRIGGER IF THE DISTAL LOCATION OF THE REACTOR™ HAS NOT BEEN OR CANNOT BE DETERMINED.** Always take into consideration of adjacent tissue and anatomical structures prior to squeezing the trigger.
3. Do not apply excessive pressure to the Reactor™. Excessive pressure can diminish the user's control of insertion.
4. Monitor the depth of entry as the Reactor™ is introduced through the body wall. If the depth of entry suggests that entry should be complete, remove the Reactor™ leaving in place the outer sleeve and visualize location/depth of outer sleeve in body. Failure to monitor the depth of entry could result in continued dissection after the Reactor™ has reached the optimal location of entry and subsequent serious or lethal complications.
5. Use and placement of the Reactor™ should only be performed by professionals having adequate training and familiarity with chest tube placements as well as understanding and training of the usage, limitations and restrictions of the Reactor™. Medical literature should be consulted relative to techniques, complications and hazards prior to the performance of chest tube placement procedures.
6. A thorough understanding of the operating principals, risks versus benefits, and the hazards involved in performing a chest tube placement as well as usage and limitations of the Reactor™ is necessary to avoid possible injury to the user and/or patient.
7. Verify mechanical compatibility of devices from different manufacturers prior to using them together in a procedure.
8. This device is not intended for use except as indicated. **DISCARD AFTER USE. DO NOT RESTERILIZE.**
9. Do not fire the trigger of the device anywhere except the exact spot on the patient's chest wall that it is intended to be used on or bodily harm (lacerations and other injuries) can happen to the operator and/or patient.

## **Instructions for Use**

Confirm the compatibility of all instruments and accessories before using the Sharp Medical Reactor™. Prepare the patient in accordance with proper surgical techniques before insertion of the device.

1. Remove the device from the package using standard sterile technique. Care should be taken not to allow the device to fall to prevent damage to the device.
2. Following removal of the device from sterile packing, confirm that the outer sheath is in place over the distal end of the device.
3. Ensure that an adequate skin incision is made in the body wall to accommodate the device with the sleeve attached. Make an impression with the sleeve and then incise the diameter of the impression plus an appropriate additional amount.
4. Place the Reactor's distal end into the skin incision making direct contact with the tissue. Make sure that the longer oval cross section of the device is parallel with the ribs so that the incision by the device is made in parallel to the ribs not

- perpendicular. Make sure that the device is between the ribs so that the parallel incision is made ideally in the middle of the intercostal muscle between the ribs.
5. Sharp sequential dissection/incision is accomplished by maintaining continuous but controlled pressure and squeezing the trigger on the pistol grip multiple times until the thoracic cavity proper is entered; the knife blade advances approximately 1mm and immediately retracts.
  6. Once the thoracic cavity proper is entered, remove the inner device of the Reactor™ and leave the outer sleeve. Then gently insert a standard oval chest tube down the outer sleeve as deep and in the typical location you would normally for a standard open chest tube placement. If the chest tube does not enter the thoracic cavity easily do not force the chest tube into the thoracic cavity.

At any point during the introduction of the Reactor™ the surgeon may:

- (1) reposition the device to proceed with an alternative route of entry
  - (2) Blunt dissect gently using the device (without squeezing the trigger) through and around tissue structures
  - (3) Slightly withdraw the device relative to the incision for visual inspection of the instrument's entry point
  - (4) Completely remove the device to check the track to see if the thoracic cavity has been entered.
7. Prior to squeezing the trigger, verify the location of the distal tip of the device to ensure that sharp dissection will not injure adjacent structures.

**WARNING: DO NOT SQUEEZE THE TRIGGER IF THE LOCATION OF THE REACTOR™ HAS NOT OR CANNOT BE DETERMINED. FAILURE TO CONFIRM THE LOCATION OF THE TIP OF THE DEVICE MAY INCREASE THE RISK OF INJURY.**

Squeeze the trigger while applying downward pressure to sharply dissect with the Reactor™. Always identify the tissue to be dissected to avoid injury to adjacent structures prior to squeezing the trigger.

**WARNING: FAILURE TO IDENTIFY THE TISSUE TO BE DISSECTED WITH THE REACTOR™ CAN INCREASE THE RISK OF INJURY.**

The surgeon is able to control the speed and depth of entry by selecting between sharp and blunt dissection and by controlling the amount of pressure on the instrument.

**WARNING: DO NOT APPLY EXCESS PRESSURE TO THE REACTOR™. EXCESS PRESSURE MAY DIMINISH THE SURGEON'S CONTROL OF THE INSTRUMENT.**

8. The blade advances from the device and then immediately retracts each time the blade is squeezed. The surgeon should monitor the depth of entry. If the depth of

the device suggests that the entry is complete, remove the Reactor™ leaving the outer sheath in the patient.

**WARNING: FAILURE TO MONITOR THE DEPTH OF ENTRY OF THE REACTOR™ MAY RESULT IN CONTINUED BLUNT OR SHARP DISSECTION AFTER THE INSTRUMENT HAS ENTERED THE PLEURAL SPACE, INCREASING THE RISK OF INJURY TO INTERNAL STRUCTURES.**

9. Discontinue sharp and blunt dissection upon entry into the pleura space.

**WARNING: DO NOT SQUEEZE THE TRIGGER AFTER THE REACTOR™ HAS ENTERED THE PLEURAL SPACE; THE BLADE WILL EXTEND FROM THE TIP EXPOSING INTERNAL STRUCTURES TO INJURY.**

10. The Reactor™ outer sleeve will accept chest tubes in size up to 36Fr.

**STORE AT ROOM TEMPERATURE.  
AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.  
DO NOT RESTERILIZE.**