NES EsoSure® Esophageal Retractor

REF # 100001

INSTRUCTIONS FOR USE

NOTE: Read all instructions carefully prior to using the Northeast Scientific, Inc. (NES) EsoSure® Esophageal Retractor. Observe all precautions, cautions and warnings stated in these instructions. Failure to do so may result in patient complications.

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Manufacturer:
Northeast Scientific, Inc.
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Northeast Scientific, Inc. EsoSure® Esophageal Retractor

INSTRUCTIONS FOR USE

SYMBOL GLOSSARY


Do Not Re-use


Manufacturer

Do Not Resterilize


Use-By Date


Caution

Catalogue/Reference Part Number

Sterilization Using Ethylene Oxide

Batch Code, Lot Number


Date of Manufacture


Do Not Use if Package is Damaged

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


Consult Instructions For Use


Keep Away From Sunlight


Keep Dry


Temperature Limit


Humidity Limitation

PACKAGE CONTENTS

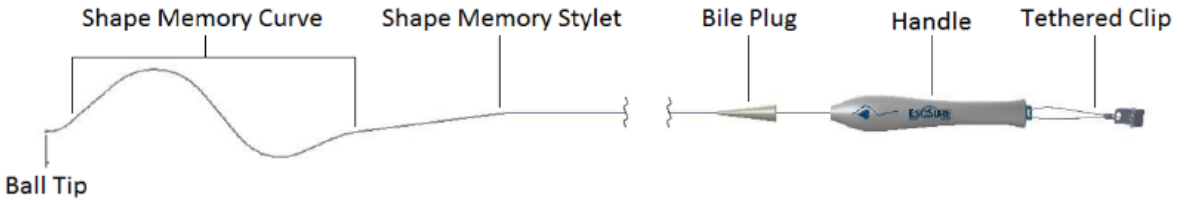
- One (1) NES EsoSure® Esophageal Retractor

INDICATIONS FOR USE

The Northeast Scientific, Inc. (NES) EsoSure® Esophageal Retractor is intended to move the esophagus in adults aged 18 years or older only.

DEVICE DESCRIPTION

The NES EsoSure® Esophageal Retractor device consists of four main components: The stylet (consisting of a Nitnol shape memory curve and ball tip), the handle, the bile plug and the tethered clip. The NES EsoSure® Esophageal Retractor is provided sterile and is a single-use disposable device. Its manner of construction does not permit it to be safely disinfected or sterilized for reuse. The device is designed to move the esophagus by using the stylet's shape memory curve to simulate the natural migration of the esophagus.



CONTRAINDICATIONS

- Patients who are not undergoing procedures that would benefit from moving the esophagus.
- Patients who do not have a proper orogastric (OG) tube entered through the mouth.
- Patients who have esophageal damage.

GENERAL WARNINGS & PRECAUTIONS

- Do not forcefully insert the device.
- Do not use the device except by insertion into an 18 Fr by 48 inch (122 cm) long orogastric (OG) tube.
- Do not insert the device through the nasal cavity.
- Do not fully insert the device. Insert as instructed.
- Use fluoroscopy while the device is inserted to determine the curve direction and device location. Do not use the figure on the handle as a direct reference of the inserted curve direction.
- To be used on adults only.

Single Use Only, Do Not Re-use

Do Not Resterilize

Contents are sterile unless package is opened or damaged.

U.S. Federal Law restricts this device to sale by or on the order of a physician.

RECOMMENDED PROCEDURE

USE ASEPTIC TECHNIQUE

ESOSURE® DEVICE INSPECTION

1. Inspect the device and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the package is damaged or if it is opened and the device not used, do not use the device. Return the device and packaging back to Northeast Scientific, Inc.
2. Do not attempt to disinfect or resterilize the EsoSure® as components cannot be safely disinfected, resterilized or re-used due to the shape memory properties of the stylet.
3. Remove the device from the package and place it in a sterile work area using aseptic technique.
4. Inspect the device for overall condition and physical integrity. **DO NOT USE** the device if any damage is noted. If such problems exist, return the device and packaging to Northeast Scientific, Inc.
5. Ensure the Bile Plug component is located at the proximal end of the wire near the handle.

PATIENT PREPARATION

1. Position the patient so they are lying flat.
2. Tilt the patient's head and adjust the neck so the upper airway and esophagus are linear prior to device insertion.
3. An orogastric (OG) tube, 18 Fr with a length of 48 inches (122 cm), **MUST** be entered into the patient's esophagus through the mouth prior to device insertion.
4. The patient **MUST** be under a fluoroscope and properly prepared to undergo fluoroscopy.
5. The position of the OG tube must be verified by fluoroscopy prior to insertion.

DEVICE INSERTION

Warning: Fluoroscopy **MUST** be used to determine curve location and direction while the device is inserted in the patient. Not locating the curve location and direction may result in esophageal injury.

1. While using fluoroscopy, hold the OG tube to keep it from advancing. Slowly, smoothly and continuously insert the distal tip (ball tip) of the device into the OG tube until the curve has passed the upper airway.

Warning: The device **MUST** be inserted into a proper OG tube. Inserting the device directly into the esophagus will result in esophageal injury.

Warning: Do not forcefully insert the device. Forceful insertion can cause injury to the esophagus.

Warning: The patient's head and neck must be adjusted so the upper airway and esophagus are linear prior to device insertion. Not adjusting the head and neck may cause esophageal injury.

Caution: Hold the OG tube to keep it in place while the device is being inserted. Not holding the OG tube may result in over insertion of the OG tube into the stomach.

2. While using fluoroscopy, slowly and smoothly insert the curve of the device into the patient so that the curve is in the intended direction of esophagus movement.
3. Once the curve of the device has been inserted, push the Bile Plug down and into the OG tube so a seal is created.

   Warning: Insert the Bile Plug into the OG tube. Not inserting the Bile Plug may result in stomach fluid reflux.

4. While using fluoroscopy, insert the device slowly and smoothly until the desired location of the esophagus is reached. Leave at least one inch of the device wire exposed, between the handle and the Bile Plug as inserted.

   Caution: Do not fully insert the device. Fully inserting the device may result in the tip of the wire exiting the OG tube resulting in injury.

5. Allow the device curve to transition fully by allowing the device to be inserted for at least five (5) minutes and verify the transition using fluoroscopy.

   Warning: Not allowing the device to transition fully will result in the esophagus not being moved completely and appropriately.

6. While using fluoroscopy, use the handle to turn the device slowly and smoothly until the esophagus is moved in the desired direction.

   Warning: Do not forcefully move the device. Forceful movement can cause injury to the esophagus.

DEVICE EXTRACTION

1. Prior to extracting the device, loosen the Bile Plug from the OG tube.
2. The device can either be removed simultaneously with the OG tube or individually without the OG tube.
   2.1. To extract the device and OG tube simultaneously, grip both the handle and OG tube so both can be pulled simultaneously. Slowly and smoothly extract the device and OG tube simultaneously from the patient while using fluoroscopy.
   2.2. To extract the device individually from the OG tube, grip the handle and hold on to the OG tube to keep it in place. Slowly and smoothly extract the device from the patient while using fluoroscopy.

TRANSPORT AND STORAGE ENVIRONMENTAL RANGES:

Temperature: -15˚ C to 40˚ C

Humidity: 10% to 85% RH

Store in a dry, cool place.

DISPOSAL

Used devices shall be disposed of as medical waste in accordance with all applicable local, state and federal laws and regulations.