Diversatek™
Healthcare

SafeGuide® Single Disposable Over the Guidewire Esophageal Dilatation System

Instructions for Use

Read carefully prior to use.

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

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SAFEGUIDE® SINGLE DISPOSABLE OVER THE GUIDEWIRE DILATATION SYSTEM

Instructions for Use

Read carefully prior to use.

DESCRIPTION

THESE DEVICES ARE SUPPLIED CLEAN & READY FOR USE.

The SafeGuide® Single Disposable Over the Guidewire Esophageal Dilation System includes:

- Single-use flexible, tapered, polyvinylchloride (PVC) dilators that have a central, longitudinal lumen for over-the-guidewire placement.
- Single-use, marked, stainless steel spring tip guidewires (#1214-02D), 210cm long with a removable end cap.

THE ABOVE COMPONENTS ARE SOLD SEPARATELY.

INTENDED USE

For dilatation of upper esophageal webs, lower esophageal rings, caustic strictures, peptic esophageal strictures, and temporary ease of esophageal carcinoma.

The SafeGuide® Single Disposable Over the Guidewire Esophageal Dilators are single-use devices designed to be used over a pre-positioned, single-use SafeGuide® Guidewire, product number 1214-02D, or reusable SafeGuide® Guidewire, product number 1214-02.

INSPECTION – PRIOR TO USE

CAUTION: Remove protective end cap from new guidewire outside of procedure room and discard. Inspect dilators and guidewires for damage from shipping and handling. Visually inspect the guidewire for kinks, bends, or breaks. Damaged guidewires or dilators should NOT be used, as they may not perform as expected.

WARNINGS AND PRECAUTIONS

Products marked “single-use” are for single-use only. Do not reuse, reprocess, or resterilize single-use products. The materials used in the manufacture of the device may not withstand repeated reprocessing. The device may not perform as intended by the manufacturer if it is reused. This may lead to failure of the device to perform as intended and/or material degradation, which may result in patient injury, illness or death. Reuse, reprocessing, or resterilization may also increase the 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.

CONTRAINDICATIONS

Contraindications include those specific to upper GI endoscopy.

Contraindications to dilation include but are not limited to: uncooperative patient; asymptomatic strictures; inability to advance the dilator through the strictured area; coagulopathy; known or suspected perforation; severe inflammation or scarring near the dilation site, recent myocardial infarction, active ulcer and severe cervical arthritis.

POTENTIAL COMPLICATIONS

Potential complications associated with upper gastrointestinal endoscopy and esophageal dilation include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

INSTRUCTIONS FOR USE

1. Inspect all dilators and accessories before use. See INSPECTION - PRIOR TO USE section.
2. Perform screening endoscopy to identify strictured area.
3. Introduce the guidewire, spring tip end first, through the accessory channel of endoscope. A lubricant will help the guidewire glide through smoothly.
4. Advance the guidewire until the spring tip is endoscopically visualized well beyond tip of scope and beyond the strictured area. The guidewire can also be externally monitored using the marking bands. The guidewire is marked in 20cm increments to help determine the location of the spring tip. The markings are groups of bands, beginning distally with a group of two (2) bands 40 cm from the tip. Each band represents 20 cm of distance to the spring tip, ending in a grouping of seven (7) bands 140 cm from the tip.

   A simple formula to measure the distance from a specific group of bands to the spring tip is:

   - (number of bands) x 20 cm = distance in centimeters to the spring tip

- Measurements are taken from the most distal band in each group

CAUTION: When placing the guidewire, discontinue advancement of the wire if resistance is met.

5. When the guidewire is in position well beyond strictured area, slowly begin to withdraw endoscope in 5-10cm increments while simultaneously advancing guidewire in 5-10cm increments to ensure guidewire remains in position.
   CAUTION: Continuous monitoring (fluoroscopy may be used) of the guidewire is essential in order to ensure it remains in proper position.
6. When endoscope is removed completely, confirm (fluoroscopy may be used) that guidewire has not been displaced.
   Note: The guidewire position can be externally monitored using the marking bands (as described in 4 above) in reference to the dental arch, both before and during dilation.
7. Remove SafeGuide® Single from poly sleeve. Generously lubricate dilator and advance it over pre-positioned guidewire to strictured area. **Note:** SafeGuide® Single Dilators have a series of numbers (American Markings) printed on one side that measure the distance to the distal tip, identified as **"(from tip)"**. These printed distance markings can be used as a guide to avoid over-extending into the gastric cavity.
8. Proceed with esophageal dilation. Determine the SafeGuide® Single dilator to be used by the size of the stricture, starting with a smaller French sized dilator (sizes noted on dilator pouch) and gradually increasing the French size. Hold the dilator at the blunt, proximal end and place the lumen of the distal tapered tip over the end of the guidewire. Slide the dilator along the guidewire while continuing to monitor the guidewire location. Carefully remove dilator after completed dilation.
   Note: Successive dilations can be accomplished by repeating steps 7-8.
9. Upon completion of esophageal dilation, remove dilator and guidewire from patient and dispose.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of the product in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

STORAGE PRIOR TO USAGE

The SafeGuide® Single Dilators should be stored out of direct light, and at room temperature. SafeGuide® Single Dilators may be stored flat or vertically in any of the available Storage Solutions (part numbers 1214-70, 1214-71 or 1214-72) from Diversatek Healthcare. Product should remain in poly sleeve until used.

DESCRIPTION OF SYMBOLS USED ON LABELS

 Manufacturer

 Date of manufacture (YYYY-MM-DD)

Lot number

Part number

Non-sterile

 Do not re-use

 Consult instructions for use

 Caution, consult accompanying documents

Contains phthalates