

CAUTION: READ ALL INSTRUCTIONS AND WARNINGS CAREFULLY BEFORE USE.

DESCRIPTION

Wire WatchTM is a sterile, single-use device designed to hold and secure guidewires 0.014" to 0.035" during interventional procedures. Its plastic shell contains an adhesive on one side that can be attached to a surgical drape and a writing surface on the other side to allow physicians or technicians to label and distinguish which guidewire is being held. The device is removable and allows the physician or technician to move and re-attach the device in different positions as needed.

INTENDED USE

The Wire Watch device is intended to hold wires with diameters 0.014" to 0.035" during interventional procedures on surgical drapes.

PACKAGING AND DISTRIBUTION

Wire Watch is packaged and distributed as a kit in a carton box with a peel pouch, including a marker, a wipe, and two Wire Watch devices.

STORAGE

Store in a dry, dark place.

| ENVIRONMENT SPECIFICATIONS | | | |
|--------------------------------|-------------------------------------------------|--|--|
| Storage, Transportation, & Use | Temperature: -18 to 60°C Humidity: 30 to 85% | | |

WARNINGS

- 1. The Wire Watch Kit is intended for single use. DO NOT REUSE. Device is sterilized via gamma irradiation. DO NOT RESTERILIZE.
- 2. The Wire Watch Kit is supplied sterile and should not be used if the sterile packaging is opened, damaged, or exposed to the environmental conditions outside of those specified.
- 3. Report any serious incident related to Wire Watch to the manufacturer, Biotex, Inc., and the FDA (United States Food and Drug Administration).

PRODUCT DISPOSAL INFORMATION

After Wire Watch use is complete, follow facility and local regulations to properly dispose of used medical devices.



Manufactured By: Biotex, Inc. 114 Holmes Rd. Houston, TX 77045 Phone: (713) 741-0111 www.wirewatch.co

INSTRUCTIONS FOR USE

- 1. Using the aseptic technique, open the Wire Watch peel pouch in a manner that maintains sterility of contents.
- 2. Carefully remove the Wire Watch devices from the packaging card by taking one side out at a time.
- 3. Remove the adhesive liner located on the bottom of a Wire Watch device.
- 4. Place the adhesive side of the Wire Watch device on a surgical drape.
- 5. Slide a guidewire into the device.

 Note: The top of the device can be used to indicate what guide

wire size or any other type of identification using the pen provided in the peel pouch.

6. Dispose of the Wire Watch Kit per proper local regulations and guidelines.



| SYMBOLS WITH DESCRIPTIONS | | | |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------|----------|----------------------------------|
| ~~ | Manufacturer | س | Date of Manufacture |
| \subseteq | Use by Date | REF | Catalogue Number |
| LOT | Lot Number | | Packaging Unit |
| STERILE R | Sterilized via Gamma Irradiation | 紫 | Keep away from direct sunlight |
| STERNIZE | Do not resterilize | | Single sterile barrier system |
| | Keep dry | 2 | Do not reuse |
| 1 | Temperature Limit | Æ | Humidity Limit |
| []i | Refer to User Guide | ® | Do not use if package is damaged |
| Rx Only | Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner. | | |