Disposable Passive Accessory – Dynamic Reference Frame for Medtronic StealthStation $^{\ensuremath{\$}}$ System

Intended Use

The Disposable Passive Accessory is intended to be used for anatomy palpation and registration in image guided surgeries with Medtronic StealthStation[®] system. The device is sterile and designed for single use.

Contraindications

There are no known contraindications for this device.

Warnings

Prior to use, examine the device for damage, deterioration and inspect sterile barrier for breach. Do not use any compromised device. This device is designed for single use and is supplied in sterile condition. Do not re-use or re-sterilize the product.

Precautions

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician. Do not re-use the devices Do re-sterilize the devices

Storage

Store in dry and clean conditions at ambient room temperature

Use

1. Remove the pouch from the carton; carefully peel open the pouch and drop the sterile tray onto the sterile field or alternatively peel open the pouch and present the sterile tray to sterile personal.

2. Verify the frame in the StealthStation interface.

- a. Attach frame to articulating arm.
- b. Select the Patient Reference Frame from the instruments list in the procedure software.
- b. Check that the frame has green status (it is being tracked by the StealthStation® system) on the screen.
- c. Face the tracker array toward the camera.
- d. Place the tip of the probe perpendicular in the reference frame divot.
- e. Press the footswitch or wait for the system to verify.



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