

Fixation Device

INSTRUCTIONS FOR USE

DESCRIPTION OF THE PRODUCT

The StayFIX Fixation Device is a sterile adhesive fastener.

INTENDED USE

The StayFIX Fixation Device is intended to secure non-vascular catheters and tubes.

INDICATIONS FOR USE

The StayFIX Fixation Device is indicated to adhere to the skin and secure a percutaneous non-vascular catheter or tube to help minimize movement and/or accidental removal.

CONTRAINDICATIONS

- Use on patients with known tape or adhesive allergies
- Use with vascular catheters

RESTRICTED DEVICE

Rx Only - Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device.

PRECAUTIONS:

- Read manufacturer's instructions prior to use.
- Contents are sterile.
- Do not use if packaging is opened, damaged, or broken.
- For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a 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.
- Do not use after expiration date.
- Store in a cool, dry place.
- After seven (7) days (sooner if the fixation device becomes loose for any reason) remove the old StayFIX Fixation Device and replace with a new StayFIX Fixation Device.
- When removing the old StayFIX Fixation Device, use care not to move or accidentally pull out catheter or tube.

INSTRUCTIONS FOR USE

To adhere effectively, the StayFIX Fixation Device must be applied to a clean, dry skin surface. Be sure to follow your healthcare provider's instructions for cleaning and managing the area where the catheter or tube exits your body. Application instructions are illustrated below (Reverse instructions for removal).

1. Remove the StayFIX Fixation Device from sterile packaging.
2. Align the StayFIX Fixation Device slit with catheter or tube. (Figure 1 B, Figure 2 B)
3. Slide the StayFIX Fixation Device slit around catheter or tube until catheter or tube is positioned in hole against the blue foam. (Figure 1 C, Figure 2 C)
4. Peel off paper backing and adhere the StayFIX Fixation Device to skin. (Figure 1 B & C, Figure 2 B & C)
5. Peel off paper backing from the blue foam. (Figure 1 D, Figure 2 D)
6. Gently bend catheter or tube into the blue foam channel. (Figure 1 D, Figure 2 D)
7. Peel off red tab to remove paper backing (685ME Large only). (Figure 2 E)
8. Fold adhesive tab over catheter or tube to secure catheter or tube (685ME Large only). (Figure 2 E)
9. Peel off large paper backing from second tab. (Figure 1 E, Figure 2 E)
10. Fold second tab over the catheter or tube. (Figure 1 F, Figure 2 F)

Daily management of your catheter and StayFIX Fixation Device

Your healthcare provider will tell you how to inspect your catheter or tube and exit site for possible problems. Contact your physician if you notice the following:

- excess leakage
- soreness around the catheter's exit site
- movement of the catheter or tube

Inspect the StayFIX Fixation Device daily to make sure that it:

- is still holding the catheter or tube securely
- continues to stick to your skin
- maintains its overall integrity

You may shower with the StayFIX Fixation Device on your body. Avoid soaking for long periods of time and refrain from touching the StayFIX Fixation Device until it has dried completely. Again, if you notice the StayFIX Fixation Device becoming loose, replace it with a new one.

FIGURE 1 SMALL

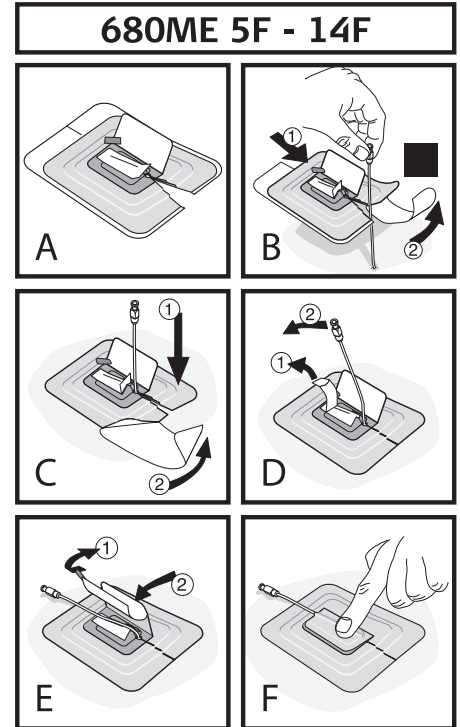
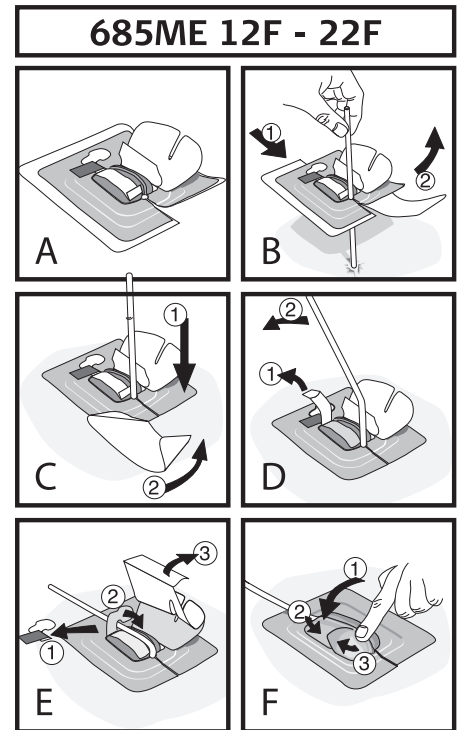


FIGURE 2 LARGE



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