stay•safe® to Luer-Lock adapter, 4 inch

Cat. No. 050-95003

Storage: Store at room temperature Protect from excessive heat and freezing
Sterile single-use disposable

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The stay•safe to Luer-Lock adapter is indicated for use in patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The stay•safe to Luer-Lock adapter is used to connect a stay•safe catheter extension set to medical devices with a Luer-Lock connection.

WARNINGS: Do not use the Luer-Lock adapter if the package is damaged or caps are not in place. The use of a non-sterile device may increase the risk of infection.

For single patient use only.

Do not reuse, reprocess, or resterilize this product. The reuse of this product may increase the risk of infection.

PRECAUTIONS: Ensure connections are secure prior to use.

STERILE PRODUCT: EO STERILIZED

Package must be intact and caps in place to ensure sterility and a non-pyrogenic fluid pathway.

USE ASEPTIC TECHNIQUE

Replace product as directed; do not exceed 6 months of use.

The following agents do not impact the functionality of the device: Povidone Iodine 10%, Sodium Hypochlorite 0.55%, Hydrogen Peroxide 3%, Chlorhexidine 4% and Isopropyl Alcohol 70%.

This product and package are not made with natural rubber latex. Assembled in Mexico.

Patents apply, visit www.fmcna.com/patents

Fresenius Medical Care NA Waltham, MA 02451 1.800.323.5188 71-4453.A
Instructions for Use (IFU)

Components Referenced in IFU Steps

1. Gather all new supplies needed before initiating procedure. Check expiration date. Prepare work area per facility procedure.

2. Use aseptic technique: Mask, wash and dry hands per your facility procedure.

3. Prepare the catheter extension set per facility procedure. Ensure white clamp on patient’s catheter extension set is closed.

4. Unscrew sterility cap from square end of Luer-Lock adapter.

5. Remove stay-safe cap from patient’s catheter extension set.

6. Immediately connect square end of adapter to patient’s catheter extension set.

7. Remove protective cap from other end of adapter to connect to Luer-Lock device.

8. Open clamp on patient’s catheter extension set to proceed as directed by a physician.

9. Dispose used product as per local regulations.

Note: When the adapter is used with a transfer set, both devices should remain in place until returning to treatment with stay-safe technology.