



**FRESENIUS
MEDICAL CARE**

stay•safe[®] catheter extension set with Safe-Lock[®], 12 inch



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Cat. No. 050-95001

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 catheter extension set with Safe-Lock 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 catheter extension set with Safe-Lock is used to connect a PD catheter with Safe-Lock compatible catheter adapter to PD systems that use stay•safe PIN technology.

WARNINGS: Do not use the catheter extension set 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 STERILE 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% and Isopropyl Alcohol 70%. Do not use Chlorhexidine 4%. The use of Chlorhexidine 4% may impact device functionality.

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

Patents apply, visit www.fmcna.com/patents

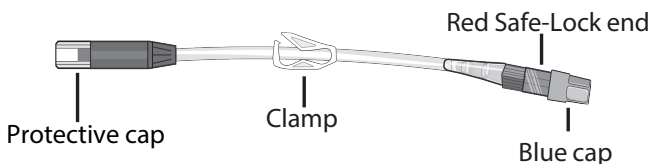
Fresenius Medical Care NA Waltham, MA 02451 1.800.323.5188

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Instructions for Use (IFU)

Components Referenced in IFU Steps



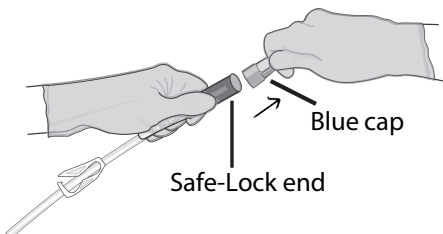
1 Gather all new supplies needed before initiating procedure. Check expiration date.

2 Prepare work area (sterile field) per facility procedure. Maintain sterile technique.

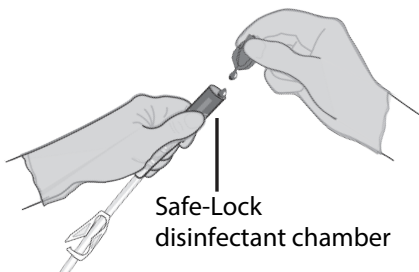
3 Make PD catheter with Safe-Lock compatible catheter adapter accessible. Place a clamp on PD catheter near exit site.

4 Prepare the Safe-Lock compatible catheter adapter per facility procedure.

5 Remove blue cap from red Safe-Lock end on new catheter extension set.

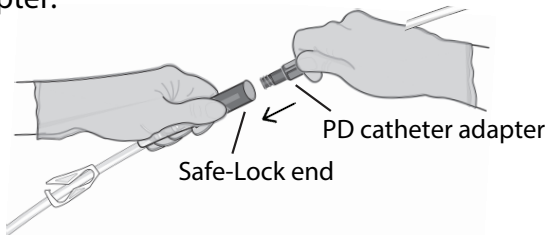


6 Instill Povidone-Iodine into the red Safe-Lock disinfectant chamber to cover the chamber threads.



7 Remove cap from PD catheter adapter or remove existing catheter extension set.

8 Immediately connect red Safe-Lock end of new catheter extension set to PD catheter adapter.



9 Close clamp on new catheter extension set.

10 Remove clamp on PD catheter near exit site.

11 Follow procedure to insert PIN (from Drain Set, Multiple Tubing Segment (MTS) Set or perform an exchange) prior to capping catheter extension set with new stay-safe cap.

Note: The protective cap should remain in place until the patient receives a new stay-safe cap.

12 Dispose used product as per local regulations.