HOW TO CONNECT AND DISCONNECT

A Guide for Using the DELFLEX® Peritoneal Dialysis Solution with Attached stay•safe® Exchange Set without a stay•safe Organizer

Note: The following instructions should only be used in circumstances when a stay•safe organizer is not available. When available, a stay•safe organizer should always be used to assist with the stay•safe CAPD exchange procedure.

NxSTAGE® from FRESENIUS MEDICAL CARE

Note: This and all peritoneal dialysis procedures should be performed using aseptic technique during connections and disconnections.

Note: Do not heat PD solution in a microwave.

Note: For illustration purposes, the images here show the right hand to be the dominant hand.

STEP 1

Clean work surface and gather supplies:

- Masks (enough for everyone in the room)
- Warmed DELFLEX peritoneal dialysis solution bag with attached stay•safe exchange set
- Povidone iodine prefilled stay•safe cap, a stand-alone item provided separately
- Optional: IV pole (36-8335-0) or over-the-door hook (050-28255)
- Prescribed medication(s), if ordered by your healthcare provider

STEP 2

After removing the overwrap, check your DELFLEX solution bag(s) for strength, clarity, amount, leaks, and expiration date. Do not use DELFLEX solution if leaks are found, the solution bag is damaged, the solution is cloudy or discolored, and/or the product is expired. Color may vary from clear to slightly yellow but does not affect efficacy and may be used.

STEP 3

Prepare supplies:

i. Retrieve stay•safe catheter extension set and ensure clamp is closed.

ii. Tear the overwrap from the slit edge down the length of the inner bag to open.

iii. Wipe away any moisture from the solution bags. Some opacity may be observed in the plastic of the bag and/or tubing and is due to moisture absorption during the sterilization process. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

iv. Visually check that the solution bag tubing is free from kinks. If kinks are present, straighten tubing to allow the solution to flow freely.

Note: If any of the above defects are found, retain DELFLEX peritoneal dialysis bag sample for manufacturer evaluation and notify your healthcare provider.

v. Put on mask. Wash your hands per facility protocol.

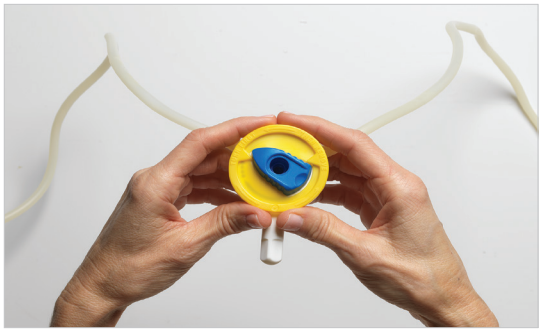
The following instructions will refer to the labeled dial positions and parts of the stay•safe DISC, as shown here.

STEP 4

Remove color-coded cover:

i. Turn the blue dial as directed by the arrow in the color-coded cover.

ii. Remove the color-coded cover from the stay•safe DISC. The blue dial will be in Position 1 (●) DRAIN.



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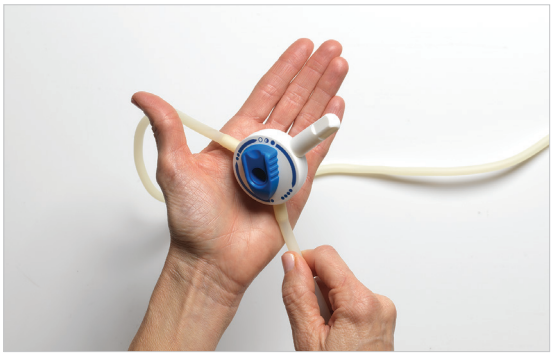
STEP 5

Remember to use aseptic technique throughout the procedure.

Place the stay•safe DISC in the palm on your non-dominant hand such that the protective cap is facing upward.

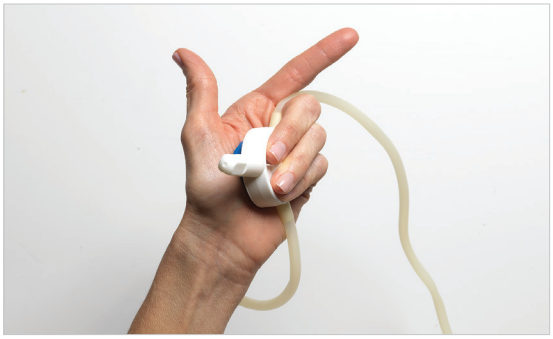


STEP 6

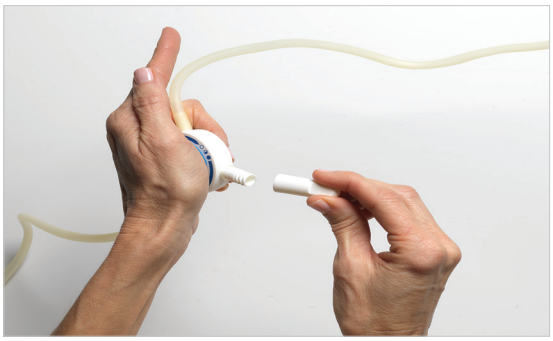
Connect catheter extension set to the stay•safe DISC:

i. Place the solution bag line between your index and middle finger with the DISC secured by the other fingers on your hand.

ii. Ensure your catheter extension set is accessible.

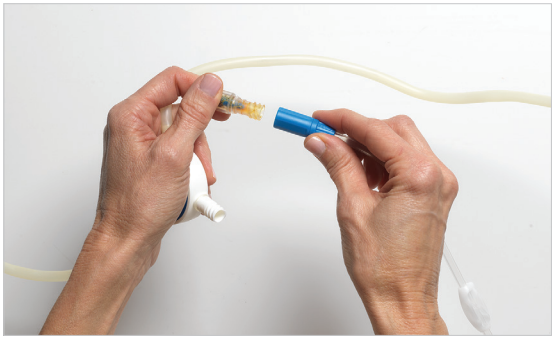


iii. Holding the dial tightly, remove the protective cap from the stay•safe DISC, and set aside.



iv. While continuing to securely hold the stay•safe DISC, pick up your catheter extension set with your dominant hand. Grasp the stay•safe cap between the index finger and thumb of your non-dominant hand.

v. Using your dominant hand, unscrew your catheter extension set from the stay•safe cap.



vi. Connect your catheter extension set to the stay•safe DISC.

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STEP 7

Hang the DELFLEX peritoneal dialysis solution bag on the IV pole (or over-the-door hook) and place the drain bag, with the clear side up, on the floor.

Break the cone on the administration port.

STEP 8

vii. With the dial still at Position 1 (●) DRAIN, open the white clamp on your catheter extension set to start the drain.

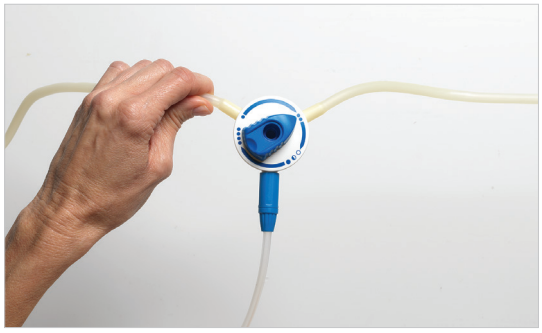
You may now remove your mask.

STEP 9

When DRAIN is complete:

i. Turn the blue dial to Position 2 (●●) FLUSH for about 5 seconds.

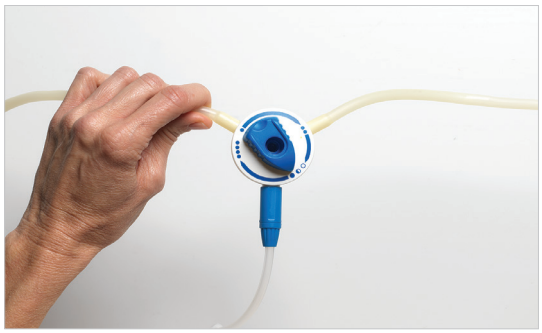
ii. Make sure the line between the solution bag and stay•safe DISC is fully primed.



STEP 10

When FLUSH is complete:

Turn blue dial to Position 3 (○◖●) FILL to begin the fill of solution to your abdomen. Flow rate can be adjusted from slow (○) to moderate (◖) to fast (●).

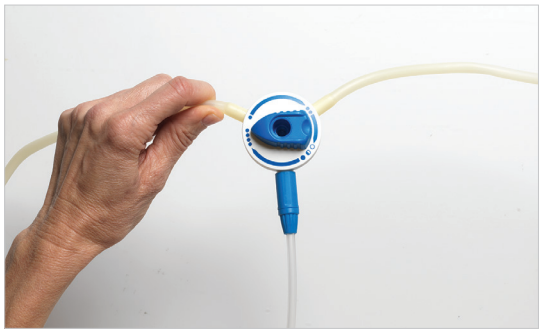


STEP 11

When FILL is complete:

i. Turn blue dial as far as possible in Position 4 (●●●●) PIN/CLOSE until you feel and/or hear a "click."

ii. The stay•safe PIN located in the stay•safe DISC will automatically be released into the end of the catheter extension set.



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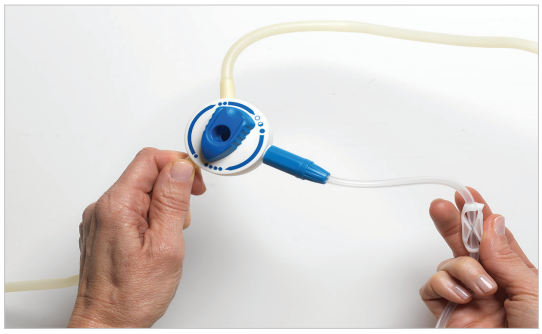
STEP 12

When PIN/CLOSE is complete:

i. Close the clamp of the catheter extension set.

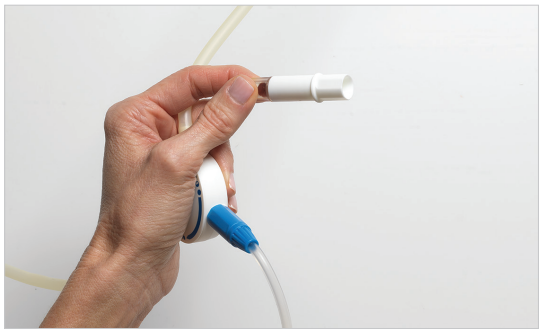
ii. Using aseptic technique, mask then clean hands as instructed by your healthcare provider.



STEP 13

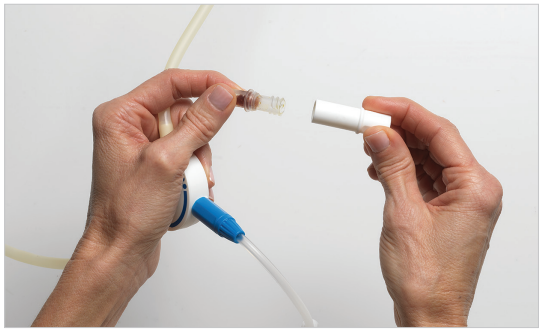
Disconnect from stay•safe DISC:

i. With the DISC in the palm of your non-dominant hand, hold the clear, betadine-filled end of the new stay•safe cap between your index finger and thumb.



STEP 14

ii. Unscrew the protective cover from the new stay•safe cap and set aside.

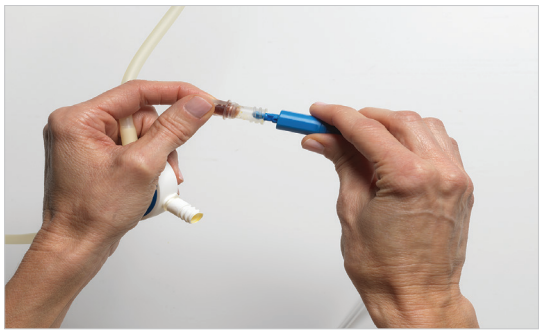


STEP 15

iii. Unscrew the catheter extension set from the stay•safe DISC.

iv. Immediately attach the stay•safe catheter extension set with a PIN to the new stay•safe cap.

v. Secure your catheter extension set to your abdomen.



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STEP 16

Complete treatment:

i. Place protective cover from the new stay•safe cap on the stay•safe DISC connector to prevent drips.

ii. Weigh drain bag (as per facility's protocol).

iii. Record exchange results on treatment log.

iv. If an effluent sample is required:

   a. Use aseptic technique and facility protocols throughout collection.

   b. Scrub the drain bag's sample port hub with friction and an Isopropyl Alcohol 70% swab/prep pad for 15 seconds and allow to dry for 30 seconds more.

   c. Withdraw the effluent sample directly from the sample port hub with a needle and syringe.

v. Discard the used tubing and solution (as per facility's protocol).

vi. Throw away the fluid and used exchange set as instructed by your healthcare provider. **In case of cloudiness, save the fluid and the used exchange set and immediately contact your healthcare provider.**

DELFLEX is indicated in the treatment of chronic kidney failure in patients being maintained on peritoneal dialysis.

DELFLEX is available by prescription only.

IMPORTANT SAFETY INFORMATION

- Intended for intraperitoneal administration only;
- Not for intravenous or intra-arterial administration;
- Use aseptic technique throughout the procedure;
- Monitor routinely for electrolyte, fluid, and nutrition imbalances;
- Monitor for signs of peritonitis or overfill;
- Inspect the drained fluid for fibrin or cloudiness;
- Ensure that there is no leakage around the catheter;
- Solution-related adverse reactions may include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, disequilibrium syndrome, muscle cramping, abdominal pain, abdominal distension, and abdominal discomfort.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Medical Care North America at 800-323-5188. You are encouraged to report negative side effects of prescription drugs to the FDA at 800-FDA-1088 or fda.gov/medwatch. Visit MedWatch or call 800-FDA-1088.

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