DELFLEX® with attached stay•safe® CAPD Exchange Set Patient and Care Partner Learning Checklist

Instructions

Use this form to track and document patient and care partner training on DELFLEX with attached stay•safe CAPD Exchange Set. This checklist is designed as a resource to be used in conjunction with the DELFLEX with attached stay•safe CAPD Exchange Set Prescribing Information (PI).

Use a check mark to show steps performed during review and practice. Initials indicate all steps have been completed for each skill in that section. If the skill is not adequately demonstrated for a sub-topic, a follow-up plan of action is recommended. Do not leave fields blank. Enter N/A (not applicable) where appropriate.

CENTER NAME

TRAINING START DATE		TRAINING END DATE	

Signatures

PATIENT NAME

PRINTED NAME		DATE	
SIGNATURE			

CARE PARTNER NAME

PRINTED NAME		DATE	
SIGNATURE			

Hand Hygiene and Principles of Aseptic Technique

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Use aseptic technique to prepare treatment area.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Properly put on mask when called for during the procedure	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Clean hands according to center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

Proper Warming Up of the PD Solution Bag

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Demonstrate how to warm the PD solution according to center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Verbalize understanding on why the CAPD system should not be warmed by a microwave.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

Get Ready

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Close windows and doors, turn off fans, remove pets from the room.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Properly clean work surface.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Mask (verbalizes need for everyone in the room to mask).	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Cleans hands per center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

Gather Supplies

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Warmed DELFLEX PD solution bag with attached stay•safe exchange set.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
stay•safe organizer.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
stay•safe cap.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

Gather Supplies (cont'd)

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
IV pole (optional).	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
stay•safe organizer holder (optional).	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
stay•safe Handi-tool (optional).	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Spring scale.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Hand sanitizer.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
CAPD treatment log and pen.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Additional medication(s), if prescribed. • Clean hands (as per center's protocol). • Appropriately clean the medication port. • Add the medicine(s). • Turn the bag upside down several times to mix the medicine(s).	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

Prepare Supplies

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Retrieve stay•safe catheter extension set and ensure white clamp is closed.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Remove the overwrap.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Wipe away any moisture from the PD solution bag.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Check PD solution bag for strength, clarity, amount, leak, expiration date (SCALE).	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Understand when not to use the PD solution and/or exchange set.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Check that PD solution bag tubing is free from kinks. If kinks are present, straighten tubing to allow the solution to flow freely.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Clean hands per center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Position the stay•safe organizer at the edge of a clean work surface or insert with the stay•safe holder on the IV pole.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Remove color-coded cover from the stay•safe DISC by turning the blue dial counterclockwise to Position 1 (●) DRAIN.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

Prepare Organizer and Solution Bag

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Place stay•safe DISC and tubing into the organizer and tubing channels on the organizer.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Hang warmed PD solution bag on IV pole and place drain bag with clear side up on the floor.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Break cone of administration port. Use stay•safe Handi-tool, if needed.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Remove new stay•safe cap from its package and place into the organizer.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Place stay•safe catheter extension set into the other notch of the organizer.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Ensure white clamp on stay•safe catheter extension set is closed.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

Connection

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Clean hands per center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Remove protective cap from stay•safe DISC and set aside.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Unscrew stay•safe catheter extension set from its cap.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Immediately connect stay•safe catheter extension set to the stay•safe DISC.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Open white clamp of stay•safe catheter extension set and start to DRAIN.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Place protective cap from stay•safe DISC that was set aside onto the used stay•safe cap in the organizer and discard.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Remove mask per center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

When DRAIN Is Completed

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Turn blue dial to Position 2 (●●), FLUSH for about 5 seconds.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Make sure the line between solution bag and stay•safe DISC is fully primed.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

When FLUSH Is Completed

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Turn blue dial to Position 3 (○◐●), to FILL abdomen.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

When FILL Is Completed

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Turn blue dial as far as possible in Position 4 (●●●●), PIN/CLOSE until you feel and/or hear a “click.”	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

When PIN/Close Is Complete

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Close white clamp on stay•safe catheter extension set.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Mask and then clean hands per center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Unscrew protective cover from new stay•safe cap and set aside.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

Disconnection

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Unscrew stay•safe catheter extension set from stay•safe DISC.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Immediately attach stay•safe catheter extension set with a PIN to new stay•safe cap.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Remove capped stay•safe catheter extension set from stay•safe organizer and secure to abdomen.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

Completion of CAPD Exchange

SKILL	REVIEWED	PATIENT DEMONSTRATES SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Place protective cover from new stay•safe cap on stay•safe DISC connector to prevent drips.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Weigh drain bag and record exchange results according to center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Remove used stay•safe set from organizer and discard unused solution and effluent according to center's protocol.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Clean permanent supplies and prepare for next CAPD exchange.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Describe what to do if cloudiness is seen in the effluent.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

TRAINER INITIALS		PATIENT INITIALS		CARE PARTNER INITIALS		DATE	

TRAINER NAME

PRINTED NAME		INITIALS	
SIGNATURE			

TRAINER NAME

PRINTED NAME		INITIALS	
SIGNATURE			

MANAGER/ADMINISTRATOR NAME

PRINTED NAME		INITIALS	
SIGNATURE			

COMMENTS

FOLLOW-UP ACTION PLAN

Indications for Use: 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 1-800-FDA-1088 or www.fda.gov/medwatch. Visit MedWatch or call 1-800-FDA-1088.

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