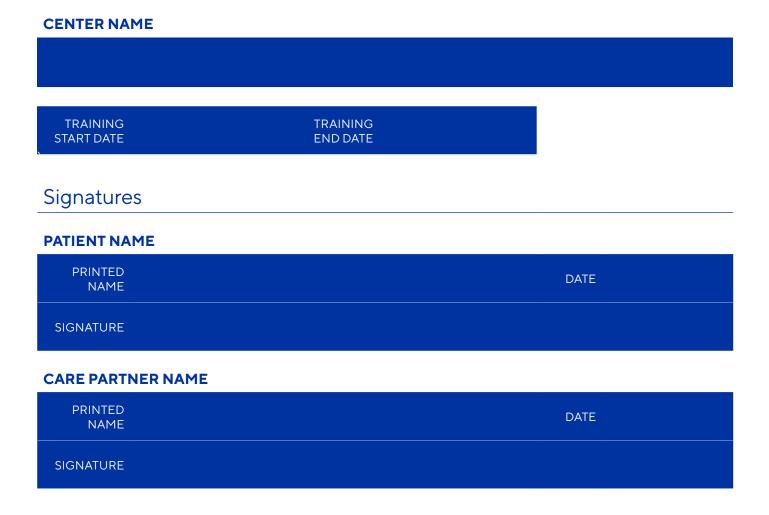


DELFLEX[®] with attached stay•safe[®] CAPD Exchange Set Patient and Care Partner Learning Checklist

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.



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	Νο	Yes	No	Yes	No

TRAINER PATIENT INITIALS INITIALS	CARE PARTNER INITIALS	DATE	
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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	REVIEWE	PATIENT DEMONSTRA SKILL	CARE PARTNER DEMONSTRATES SKILL (if applicable)
Warmed DELFLEX PD solution bag with attached stay•safe exchange set.	Yes No	o 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	
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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 PATIENT INITIALS INITIALS	CARE PARTNER INITIALS	DATE	
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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
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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 PAR DEMONST SKILL (if ap	RATES
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

When DRAIN Is Completed

SKILL	REVIE	WED	PATIENT DEMONS SKILL	TRATES	CARE PAR DEMONST SKILL (if ap	RATES
Turn blue dial to Position 2 (●●), FLUSH for about 5 seconds.	Yes	Νο	Yes	No	Yes	No
Make sure the line between solution bag and stay•safe DISC is fully primed.	Yes	Νο	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 (O❶●), 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	
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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	REVIEWE	ED	PATIENT DEMONS SKILL	TRATES	CARE PAR DEMONST SKILL (if ap	RATES
Unscrew stay•safe catheter extension set from stay•safe DISC.	Yes N	No	Yes	No	Yes	No
Immediately attach stay•safe catheter extension set with a PIN to new stay•safe cap.	Yes N	No	Yes	No	Yes	No
Remove capped stay•safe catheter extension set from stay•safe Organizer and secure to abdomen.	Yes N	No	Yes	No	Yes	No

TRAINER INITIALS	PATIENT INITIALS	CARE PARTNER INITIALS	DATE	
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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	
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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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