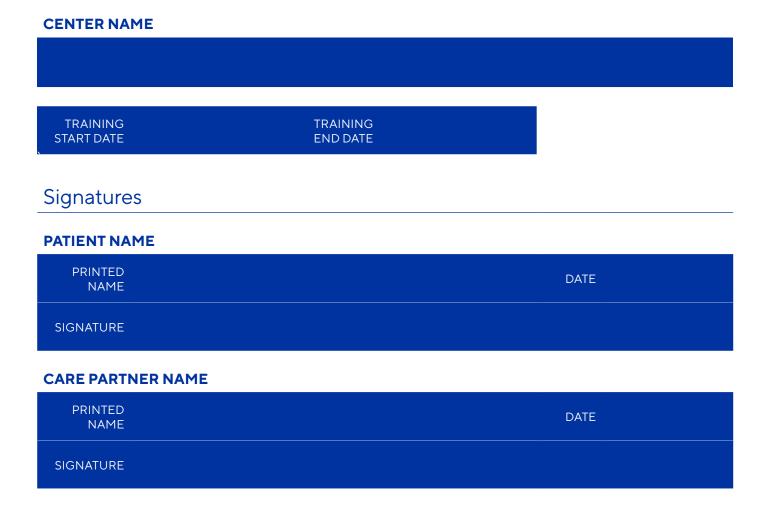


DELFLEX[®] with attached stay•safe[®] CAPD Exchange Set Patient and Care Partner Learning Checklist

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 | |
|--------------------------------------|-----------------------------|------|--|
|--------------------------------------|-----------------------------|------|--|

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 | |
|---------------------|---------------------|-----------------------------|------|--|
|---------------------|---------------------|-----------------------------|------|--|

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 |
| TRAINER PATIENT INITIALS INITIALS | | CARE RTNER D/ IITIALS | ATE |

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 | |
|---------------------|---------------------|-----------------------------|------|--|
|---------------------|---------------------|-----------------------------|------|--|

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 | |
|---------------------|---------------------|-----------------------------|------|--|
|---------------------|---------------------|-----------------------------|------|--|

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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