[Bar Code]
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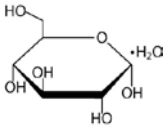
DELFLEX® Neutral pH
Peritoneal Dialysis Solutions
For Intraperitoneal Administration Only

No Latex

Description

DELFLEX® Neutral pH peritoneal dialysis solutions, (standard, low magnesium and low magnesium/low calcium) are sterile, non-pyrogenic formulations of dextrose and electrolytes in water for injection, USP, for use in peritoneal dialysis. These solutions do not contain antimicrobial agents or additional buffers. In comparison to conventional peritoneal dialysis solutions, DELFLEX® Neutral pH solutions are formulated to lower levels of glucose degradation products and provide a neutral pH of 7.0 ± 0.4, which is closer to physiologic pH. The osmotic and buffer solutions are stored separately and mixed by the patient prior to use. Composition, calculated osmolarity, pH and ionic concentrations of the mixed solutions are shown in Table 2.

Dextrose, USP, is chemically designated D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$) a hexose sugar freely soluble in water. The structural formula is shown here:



Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$) white fragments or granules freely soluble in water.

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$) colorless flakes or crystals very soluble in water.

Sodium lactate solution, USP, is chemically designated ($CH_3CH(OH)COONa$), a 60% aqueous solution miscible in water.

Sodium chloride, USP, is chemically designated (NaCl), a white, crystalline compound freely soluble in water.

Water for injection, USP, is chemically designated (H_2O).

Hydrochloric acid, and sodium hydroxide may be added for pH adjustment. pH is 7.0 ± 0.4.

Exposure to temperatures above 25°C (77°F) during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. Since the flexible inner bag is compounded from a specific polyvinyl chloride, water may permeate from the inner bag into the outerwrap in quantities insufficient to affect the solution significantly. Solutions in contact with the plastic inner bag can cause certain chemical components of the bag to leach out in very small amounts; however, the safety of the plastic formulation is supported by biological tests for plastic containers.

Nominal glucose degradation product (GDP) levels (immediately following sterilization) in DELFLEX® Neutral pH solution and DELFLEX® solution are reported in Table 1. The clinical relevance of these differences in GDP levels is unknown.

Table 1. Glucose Degradation Product Levels*

Dextrose Concentration	DELFLEX® Neutral pH	DELFLEX®
1.5%	55	175
2.5%	70	255
4.25%	95	420

*This is the sum [µmol/L] of the various component GDPs including: formaldehyde, acetaldehyde, furaldehyde, glyoxal, methylglyoxal 5-hydroxymethylfurfural (5-HMF), and 3 deoxyglucosone (3DG).

Table 2. Composition, Calculated Osmolarity, pH, and Ionic Concentration

5 Liter DELFLEX® Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
Composition / 100ml	Main Bag Contents									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.53 g	2.55 g	4.34 g	1.53 g	2.55 g	4.34 g	1.53 g	2.55 g	4.34 g
	Sodium Chloride, USP (NaCl)	578 mg	578 mg	578 mg	549 mg	549 mg	549 mg	549 mg	549 mg	549 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	26.2 mg	26.2 mg	26.2 mg	26.2 mg	26.2 mg	26.2 mg	18.8 mg	18.8 mg	18.8 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.5 mg	15.5 mg	15.5 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg
	Mini-Bag Contents									
	Sodium Lactate, USP ($C_3H_5NaO_3$)	18.0 g	18.0 g	18.0 g	20.9 g	20.9 g	20.9 g	20.9 g	20.9 g	20.9 g
	Sodium Bicarbonate, USP ($NaHCO_3$)	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g
	Sodium Chloride, USP (NaCl)	567 mg	567 mg	567 mg	538 mg	538 mg	538 mg	538 mg	538 mg	538 mg
	Sodium Lactate, USP ($C_3H_5NaO_3$)	353 mg	353 mg	353 mg	409 mg	409 mg	409 mg	409 mg	409 mg	409 mg
	Sodium Bicarbonate, USP ($NaHCO_3$)	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
	Osmolarity (mOsmoL/L)(calc)	347	398	486	346	396	484	344	395	483
	pH 7.0 ± 0.4	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0
Ionic Concentration(mEq/L)	Main Bag Contents									
	Sodium	98.9	98.9	98.9	93.9	93.9	93.9	93.9	93.9	93.9
	Calcium	3.56	3.56	3.56	3.56	3.56	3.56	2.56	2.56	2.56
	Magnesium	1.52	1.52	1.52	0.51	0.51	0.51	0.51	0.51	0.51
	Chloride	104	104	104	98.0	98.0	98.0	97.0	97.0	97.0
	Mini-Bag Contents									
	Sodium	1785	1785	1785	2044	2044	2044	2044	2044	2044
	Lactate	1606	1606	1606	1865	1865	1865	1865	1865	1865
	Bicarbonate	179	179	179	179	179	179	179	179	179
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Sodium	132	132	132	132	132	132	132	132	132
	Calcium	3.50	3.50	3.50	3.50	3.50	3.50	2.50	2.50	2.50
	Magnesium	1.50	1.50	1.50	0.50	0.50	0.50	0.50	0.50	0.50
	Chloride	102	102	102	96.0	96.0	96.0	95.0	95.0	95.0
	Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5
	Bicarbonate	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50

6 Liter DELFLEX® Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
Composition / 100ml	Main Bag Contents									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.52 g	2.54 g	4.32 g	1.52 g	2.54 g	4.32 g	1.52 g	2.54 g	4.32 g
	Sodium Chloride, USP (NaCl)	576 mg	576 mg	576 mg	547 mg	547 mg	547 mg	547 mg	547 mg	547 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	26.1 mg	26.1 mg	26.1 mg	26.1 mg	26.1 mg	26.1 mg	18.7 mg	18.7 mg	18.7 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.5 mg	15.5 mg	15.5 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg
	Mini-Bag Contents									
	Sodium Lactate, USP ($C_3H_5NaO_3$)	21.6 g	21.6 g	21.6 g	25.0 g	25.0 g	25.0 g	25.0 g	25.0 g	25.0 g
	Sodium Bicarbonate, USP ($NaHCO_3$)	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g
	Sodium Chloride, USP (NaCl)	567 mg	567 mg	567 mg	538 mg	538 mg	538 mg	538 mg	538 mg	538 mg
	Sodium Lactate, USP ($C_3H_5NaO_3$)	353 mg	353 mg	353 mg	409 mg	409 mg	409 mg	409 mg	409 mg	409 mg
	Sodium Bicarbonate, USP ($NaHCO_3$)	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
	Osmolarity (mOsmoL/L)(calc)	347	398	486	346	396	484	344	395	483
	pH 7.0 ± 0.4	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0
Ionic Concentration(mEq/L)	Main Bag Contents									
	Sodium	98.6	98.6	98.6	93.6	93.6	93.6	93.6	93.6	93.6
	Calcium	3.55	3.55	3.55	3.55	3.55	3.55	2.54	2.54	2.54
	Magnesium	1.52	1.52	1.52	0.51	0.51	0.51	0.51	0.51	0.51
	Chloride	104	104	104	97.7	97.7	97.7	96.7	96.7	96.7
	Mini-Bag Contents									
	Sodium	2142	2142	2142	2445	2445	2445	2445	2445	2445
	Lactate	1928	1928	1928	2231	2231	2231	2231	2231	2231
	Bicarbonate	214	214	214	214	214	214	214	214	214
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Sodium	132	132	132	132	132	132	132	132	132
	Calcium	3.50	3.50	3.50	3.50	3.50	3.50	2.50	2.50	2.50
	Magnesium	1.50	1.50	1.50	0.50	0.50	0.50	0.50	0.50	0.50
	Chloride	102	102	102	96.0	96.0	96.0	95.0	95.0	95.0
	Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5
	Bicarbonate	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50

Clinical Pharmacology

Peritoneal dialysis is the process of filtering excess water and toxins from the bloodstream through a semi-permeable membrane. This process does not cure the disease, but prevents progression of symptoms. Dialysis for chronic kidney failure is essential to maintain life, unless the patient receives a kidney transplant. A peritoneal dialysis procedure utilizes the peritoneum (lining of the abdomen) as the semi-permeable membrane. The procedure is conducted by instilling peritoneal dialysis solution through a catheter in the abdomen into the peritoneal cavity. Since the peritoneum is heavily supplied with blood vessels, the contact of the solution with the peritoneum causes excess water and toxins in the bloodstream to be drawn across the membrane into the solution. This osmosis and diffusion occurs between the plasma of the patient and the peritoneal dialysis solution. After a period of time called "dwell time," the solution is then drained from the patient.

This solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

Clinical studies have demonstrated that the use of low magnesium solutions resulted in significant increases in serum CO_2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications and Usage

DELFLEX® peritoneal dialysis solutions are indicated in the treatment of chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

Contraindications

None known.

Warnings

Not for Intravenous Injection.

Use Aseptic Technique.

It is important to mix the buffer (Mini-Bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, other prescribed medication(s) may be added prior to administration.

After removing the outerwrap, check for minute leaks by squeezing each of the solution bags firmly. If leaks are found, discard the solution because the sterility may be impaired. (A small amount of moisture may be present inside the outerwrap, which is normal condensation from the sterilization process).

Peritoneal dialysis should be done with great care, in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

Solutions containing lactate ion should be used with great care in patients with metabolic or respiratory alkalosis. Lactate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion and shock.

Excessive use of DELFLEX® peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

Serum calcium levels in patients using low calcium concentrations should be monitored and if found to be low, the peritoneal solution in use should be altered to one with a higher calcium concentration.

Precautions

General

Chronic patients that have been stabilized on peritoneal dialysis therapy should have routine evaluation of electrolyte blood chemistries and hematologic factors measured in order to determine the patient's ongoing condition.

DELFLEX® peritoneal dialysis solutions do not include potassium. Potassium chloride should only be added under the direction of a physician after careful evaluation of both serum and total body potassium.

Significant loss of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Information for Patients

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

The outerwrap should remain intact until time of use.

Administer only if the solution is clear, all seals are intact, and there is no evidence of leaking.

Do Not Heat In A Microwave Oven. Microwave ovens heat unevenly and can leave hot spots, which can burn the peritoneum.

It is important to mix the buffer (Mini-Bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, other prescribed medication(s) may be added prior to administration.

Care should be taken to ensure that there is not any leakage around the catheter, since if not controlled; the leakage can create edema from subcutaneous infiltration of the dialysis solution. This will also create an inaccurate fluid balance measurement. If any leakage is identified do not proceed with infusion and notify your physician.

Laboratory Tests

Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies with DELFLEX® peritoneal dialysis solutions have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy: Teratology Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with DELFLEX® peritoneal dialysis solutions. It is also not known whether DELFLEX® peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DELFLEX® peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Caution should be exercised when DELFLEX® peritoneal dialysis solutions are administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Adverse Reactions

Adverse reactions occurring with administration of peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions might include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome and muscle cramping.

If an adverse reaction does occur, institute appropriate therapeutic procedures according to the patient's needs and conditions, and save the remainder of the fluid in the bag for evaluation if deemed necessary.

Dosage and Administration

DELFLEX® peritoneal dialysis solutions are provided for intraperitoneal administration only. The mode of therapy, frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for the treatment of the individual patient.

To avoid the risk of severe dehydration or hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Additives may be incompatible. Do not store solutions containing additives.

For administration see Directions for Use section.

How Supplied

DELFLEX® peritoneal dialysis solutions are delivered in single-dose flexible bags. All DELFLEX® peritoneal dialysis solutions have overfills declared on the bag label. The flexible bags have the capacity for drainage in excess of their stated fill volume for ultrafiltration from the patient.

DELFLEX® Neutral pH peritoneal dialysis solutions are available in flexible bags as shown in Table 2 in the Description section.

Storage Conditions

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (between 59°F and 86°F). See USP Controlled Room Temperature. Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

Keep DELFLEX® and all medicines out of the reach of children.

Fresenius Medical Care

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Patent Pending

Revised
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Not for Intravenous Injection. Do not microwave.
Warm solution as directed by your health care provider.

<u>Directions for Use</u> (Aseptic technique is required)

Get Ready

1. Clean work surface.
2. Gather supplies:
   - DELFLEX® Neutral pH Peritoneal Dialysis bag.
   - Prescribed medication(s), if ordered by your healthcare provider.
   - Mask.
3. Put on mask. Wash your hands.
4. Tear the outerwrap from the slit edge down the length of the inner bags to open. Wipe away any moisture from the solution bags. Some opacity may be observed in the plastic of the bags 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 after removing outerwrap.

Inspect DELFLEX® Solution Bags:

5. Place the DELFLEX® solution set on the work surface. See **Figure A**.

Do Not Microwave

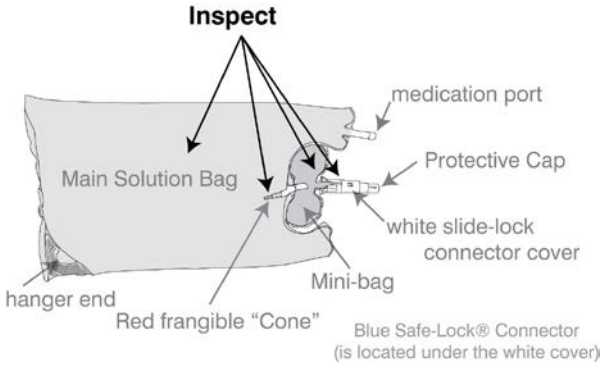

Figure A

- Firmly squeeze the Main Solution Bag and the Mini-Bag to check for leaks.
- When squeezing the Mini-Bag, the bag should remain firm and no solution should leak into the Main Solution Bag or from the Blue Safe-Lock® connector.

Do not use DELFLEX® Neutral pH solution if:

- leaks are found
- the solution bags are damaged
- solution is cloudy or discolored
- Red frangible "Cone" or Blue Safe-Lock® connector "Cone" broken

NOTE: Retain DELFLEX® Neutral pH peritoneal dialysis bag sample for manufacturer evaluation and notify your healthcare provider if any of the above defects are found.

Mix DELFLEX® Neutral pH Solution

Important: Mix the Mini-Bag and Main Bag solutions thoroughly. Use the solution within 24 hours after mixing.

1. With the Main Solution Bag laying on the work surface; break the Red frangible "Cone" by placing the thumb firmly on the Red frangible and pressing down upon it until the end of it breaks off. See **Figure B**.

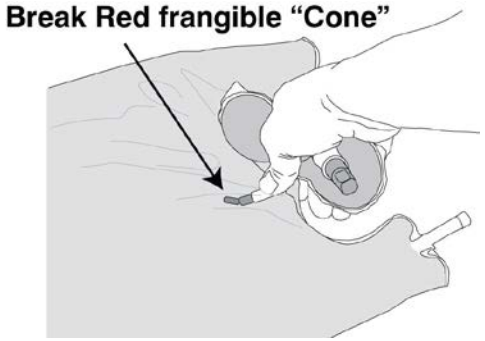

Figure B

2. Fold the Mini-Bag in half. Firmly squeeze the solution from the Mini-Bag into the Main Solution Bag by pressing the two halves together until the Mini-Bag is empty. See **Figure C**.

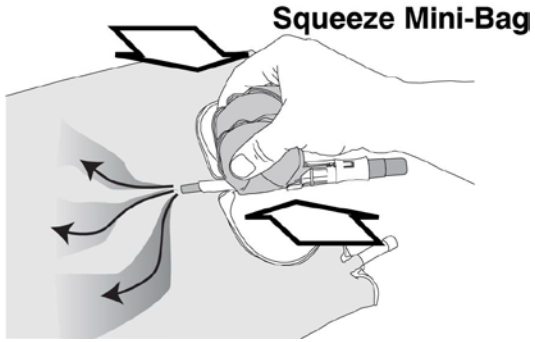

Figure C

3. Push down on the Main Solution Bag to flush solution back into the Mini-Bag. Completely refill the Mini-Bag with solution. See **Figure D**.

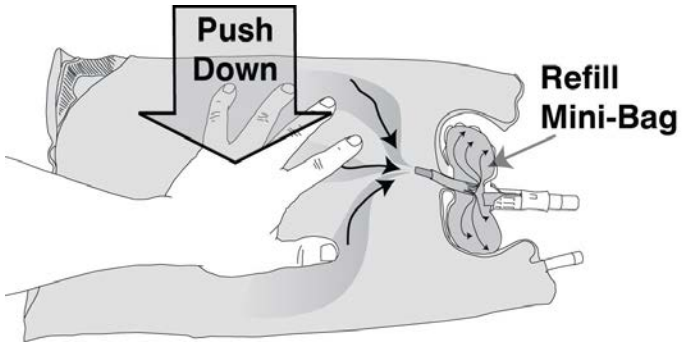

Figure D

4. Repeat **Step 2 (Figure C)** and **Step 3 (Figure D)** above, at least one time, to make sure that all of the contents of the Mini-Bag have been completely flushed into the Main Solution Bag.
5. Grasp the bottom end of the Main Solution Bag. While keeping the hanger end (top) portion of the bag on the table, flip the bag lengthwise using a back and forth motion to mix the solutions. See **Figure E**. Repeat this step to mix solution thoroughly.

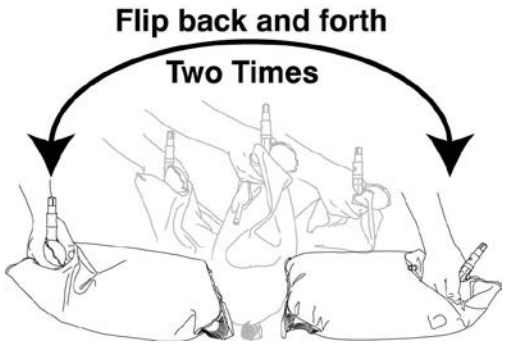

Figure E

6. With the Main Solution Bag still on the table, position it so that the "slit" in the white slide-lock connector cover is facing up.
7. Fold Mini-Bag in half and squeeze it empty of solution.
8. Slide the folded Mini-Bag into the "slit" of the white slide-lock connector cover. Ensure that the entire "grip" area of the Blue Safe-Lock® connector is exposed. If the square "grip" area is not exposed slide the slide-lock connector cover further onto the folded Mini-Bag to expose the "grip". See **Figures F and G.** Solution may flow back into the Mini-Bag slightly, this is normal.

NOTE: The protective cap should remain on the connector during this step to avoid touch contamination.

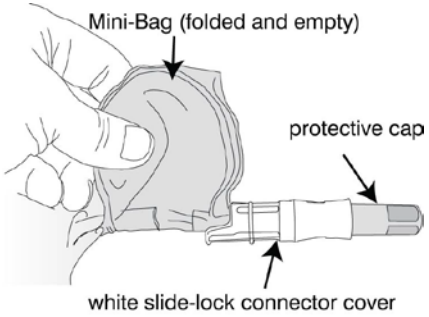

Figure F

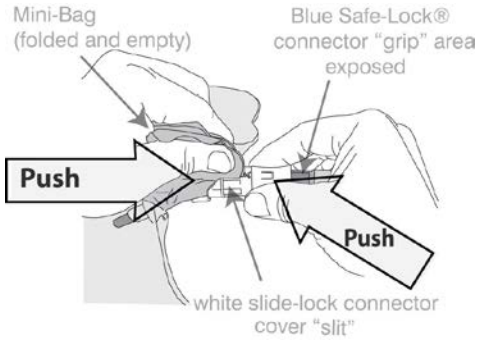

Figure G

The solution is now ready for use.

Administer DELFLEX® Neutral pH Peritoneal Dialysis Solution

1. If you will be adding medication(s):
   - Clean the medication port as instructed by your healthcare provider.
   - Add the medicine(s).

- Turn the bag upside down several times to mix the medicine(s).

2. Take off the protective cap from the Blue Safe-Lock® connector at the bottom of the Mini-Bag. Connect the Blue Safe-Lock® connector to the mating Safe-Lock® connector on the fluid delivery set connected to the PD cycler machine.
3. Remove your mask. Do not open the system during fluid exchange.
4. Break the Blue Safe-Lock® connector "Cone" by placing one hand on the Blue Safe-Lock® connector square "grip" area and placing the other hand on the white slide-lock connector cover and bending it to start solution flow. See **Figure H**.

NOTE: The white slide-lock connector cover may not allow you to see the entire lower portion (connector "Cone") of the Blue Safe-Lock® connector.

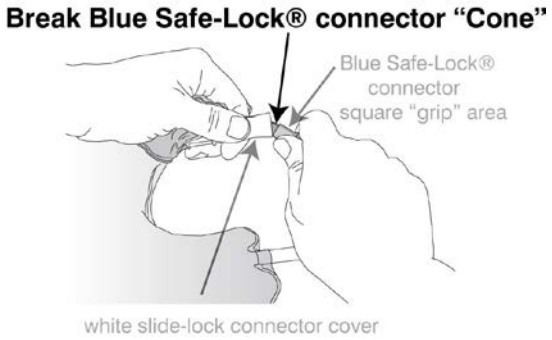

Figure H

5. Look at the drained fluid for cloudiness. Throw away the fluid and used set as instructed by your healthcare provider. **In case of cloudiness, save the fluid and the used set and immediately contact your healthcare provider.**

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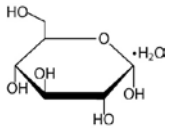
DELFLEX® Neutral pH
Peritoneal Dialysis Solutions
with Attached stay•safe® Exchange Set
For Intraperitoneal Administration Only

No Latex

Description

DELFLEX® Neutral pH, peritoneal dialysis solutions, (standard, low magnesium and low magnesium/low calcium) are sterile, non-pyrogenic formulations of dextrose and electrolytes in water for injection, USP, for use in peritoneal dialysis. These solutions do not contain antimicrobial agents or additional buffers. In comparison to conventional peritoneal dialysis solutions, DELFLEX® Neutral pH solutions are formulated to lower levels of glucose degradation products and provide a neutral pH of 7.0 ± 0.4, which is closer to the physiologic pH. The osmotic and buffer solutions are stored separately and mixed by the patient prior to use. The stay•safe® Exchange Set utilizes an easy to use dial designed to eliminate the use of clamps and to prevent touch contamination of internal connection components. Composition, calculated osmolarity, pH and ionic concentrations of the mixed solutions are shown in Table 2.

Dextrose USP is chemically designated D-glucose monohydrate ($C_6H_{12}O_6•H_2O$) a hexose sugar freely soluble in water. The structural formula is shown here.



Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2•2H_2O$) white fragments or granules freely soluble in water.

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$) colorless flakes or crystals very soluble in water.

Sodium lactate solution, USP, is chemically designated ($CH_3CH(OH)COONa$), a 60% aqueous solution miscible in water.

Sodium chloride, USP, is chemically designated (NaCl), a white, crystalline compound freely soluble in water.

Water for injection, USP, is chemically designated (H_2O).

Hydrochloric acid, and sodium hydroxide may be added for pH adjustment. pH is 7.0 ± 0.4.

Exposure to temperatures above 25°C (77°F) during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. Since the flexible inner bag is compounded from a specific polyvinyl chloride, water may permeate from the inner bag into the outerwrap in quantities insufficient to affect the solution significantly. Solutions in contact with the plastic inner bag can cause certain chemical components of the bag to leach out in very small amounts; however, the safety of the plastic formulation is supported by biological tests for plastic containers.

Nominal glucose degradation product (GDP) levels (immediately following sterilization) in DELFLEX® Neutral pH solution and DELFLEX® solution are reported in Table 1. The clinical relevance of these differences in GDP levels in unknown.

Table 1. Glucose Degradation Product Levels*

Dextrose Concentration	DELFLEX® Neutral pH	DELFLEX®
1.5%	55	175
2.5%	70	255
4.25%	95	420

*This is the sum [µmol/L] of the various component GDPs including: formaldehyde, acetaldehyde, furaldehyde, glyoxal, methylglyoxal 5-hydroxymethylfurfural (5-HMF), and 3 deoxyglucosone (3DG).

Table 2. Composition, Calculated Osmolarity, pH, and Ionic Concentration

2.5 Liter DELFLEX® Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
Composition / 100ml	Main Bag Contents									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.53 g	2.55 g	4.34 g	1.53 g	2.55 g	4.34 g	1.53 g	2.55 g	4.34 g
	Sodium Chloride, USP (NaCl)	578 mg	578 mg	578 mg	549 mg	549 mg	549 mg	549 mg	549 mg	549 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	26.2 mg	26.2 mg	26.2 mg	26.2 mg	26.2 mg	26.2 mg	18.8 mg	18.8 mg	18.8 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.5 mg	15.5 mg	15.5 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg
	Mini-Bag Contents									
	Sodium Lactate, USP ($C_3H_5NaO_3$)	18.0 g	18.0 g	18.0 g	20.9 g	20.9 g	20.9 g	20.9 g	20.9 g	20.9 g
	Sodium Bicarbonate, USP ($NaHCO_3$)	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g
	Sodium Chloride, USP (NaCl)	567 mg	567 mg	567 mg	538 mg	538 mg	538 mg	538 mg	538 mg	538 mg
	Sodium Lactate, USP ($C_3H_5NaO_3$)	353 mg	353 mg	353 mg	409 mg	409 mg	409 mg	409 mg	409 mg	409 mg
	Sodium Bicarbonate, USP ($NaHCO_3$)	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
	Osmolarity (mOsmoL/L)(calc)	347	398	486	346	396	484	344	395	483
	pH 7.0 ± 0.4	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0
Ionic Concentration(mEq/L)	Main Bag Contents									
	Sodium	98.9	98.9	98.9	93.9	93.9	93.9	93.9	93.9	93.9
	Calcium	3.56	3.56	3.56	3.56	3.56	3.56	2.56	2.56	2.56
	Magnesium	1.52	1.52	1.52	0.51	0.51	0.51	0.51	0.51	0.51
	Chloride	104	104	104	98.0	98.0	98.0	97.0	97.0	97.0
	Mini-Bag Contents									
	Sodium	1785	1785	1785	2044	2044	2044	2044	2044	2044
	Lactate	1606	1606	1606	1865	1865	1865	1865	1865	1865
	Bicarbonate	179	179	179	179	179	179	179	179	179
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Sodium	132	132	132	132	132	132	132	132	132
	Calcium	3.50	3.50	3.50	3.50	3.50	3.50	2.50	2.50	2.50
	Magnesium	1.50	1.50	1.50	0.50	0.50	0.50	0.50	0.50	0.50
	Chloride	102	102	102	96.0	96.0	96.0	95.0	95.0	95.0
	Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5
	Bicarbonate	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50

Clinical Pharmacology

Peritoneal dialysis is the process of filtering excess water and toxins from the bloodstream through a semi-permeable membrane. This process does not cure the disease, but prevents progression of symptoms. Dialysis for chronic kidney failure is essential to maintain life, unless the patient receives a kidney transplant. A peritoneal dialysis procedure utilizes the peritoneum (lining of the abdomen) as the semi-permeable membrane. The procedure is conducted by instilling peritoneal dialysis solution through a catheter in the abdomen into the peritoneal cavity. Since the peritoneum is heavily supplied with blood vessels, the contact of the solution with the peritoneum causes excess water and toxins in the bloodstream to be drawn across the membrane into the solution. This osmosis and diffusion occurs between the plasma of the patient and the peritoneal dialysis solution. After a period of time called "dwell time," the solution is then drained from the patient.

This solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

Clinical studies have demonstrated that the use of low magnesium solutions resulted in significant increases in serum CO_2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications and Usage

DELFLEX® peritoneal dialysis solutions are indicated in the treatment of chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

Contraindications

None known.

Warnings

Not for Intravenous Injection.

Use Aseptic Technique.

It is important to mix the buffer (Mini-Bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, other prescribed medication(s) may be added prior to administration.

After removing the outerwrap, check for minute leaks by squeezing each of the solution bags firmly. If leaks are found, discard the solution because the sterility may be impaired. (A small amount of moisture may be present inside the outerwrap, which is normal condensation from the sterilization process).

Peritoneal dialysis should be done with great care, in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

Solutions containing lactate ion should be used with great care in patients with metabolic or respiratory alkalosis. Lactate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion and shock.

Excessive use of DELFLEX® peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

Serum calcium levels in patients using low calcium concentrations should be monitored and if found to be low, the peritoneal solution in use should be altered to one with a higher calcium concentration.

Precautions

General

Chronic patients that have been stabilized on peritoneal dialysis therapy should have routine evaluation of electrolyte blood chemistries and hematologic factors measured in order to determine the patient's ongoing condition.

DELFLEX® peritoneal dialysis solutions do not include potassium. Potassium chloride should only be added under the direction of a physician after careful evaluation of both serum and total body potassium.

Significant loss of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Information for Patients

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

The outerwrap should remain intact until time of use.

Administer only if the solution is clear, all seals are intact, and there is no evidence of leaking.

Do Not Heat In A Microwave Oven. Microwave ovens heat unevenly and can leave hot spots, which can burn the peritoneum.

It is important to mix the buffer (Mini-Bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, other prescribed medication(s) may be added prior to administration.

Disconnect from disc only when knob is in position 4 (••••) to ensure patient connector is sealed.

Care should be taken to ensure that there is not any leakage around the catheter, since if not controlled; the leakage can create edema from subcutaneous infiltration of the dialysis solution. This will also create an inaccurate fluid balance measurement. If any leakage is identified do not proceed with infusion and notify your physician.

Laboratory Tests

Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies with DELFLEX® peritoneal dialysis solutions have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy: Teratology Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with DELFLEX® peritoneal dialysis solutions. It is also not known whether DELFLEX® peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DELFLEX® peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Caution should be exercised when DELFLEX® peritoneal dialysis solutions are administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Adverse Reactions

Adverse reactions occurring with administration of peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions might include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome and muscle cramping.

If an adverse reaction does occur, institute appropriate therapeutic procedures according to the patient's needs and conditions, and save the remainder of the fluid in the bag for evaluation if deemed necessary.

Dosage and Administration

DELFLEX® peritoneal dialysis solutions are provided for intraperitoneal administration only. The mode of therapy, frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for the treatment of the individual patient.

To avoid the risk of severe dehydration or hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Additives may be incompatible. Do not store solutions containing additives.

For administration see Directions for Use section.

How Supplied

DELFLEX® peritoneal dialysis solutions are delivered in single-dose flexible bags. All DELFLEX® peritoneal dialysis solutions have overfills declared on the bag label. The flexible bags have the capacity for drainage in excess of their stated fill volume for ultrafiltration from the patient.

DELFLEX® Neutral pH peritoneal dialysis solutions with an attached stay•safe® Exchange Set is available in flexible bags as shown in Table 2 in the Description section.

Storage Conditions

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (between 59°F and 86°F). See USP Controlled Room Temperature. Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

Keep DELFLEX® and all medicines out of the reach of children.

Fresenius Medical Care

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Patent Pending

Revised
11/05/2012

Not for Intravenous Injection. Do not microwave.
Warm solution as directed by your health care provider.

Directions for Use (Aseptic technique is required)

Get Ready

1. Clean work surface.
2. Gather supplies:
   - Warmed DELFLEX® Neutral pH Peritoneal Dialysis bag with attached stay•safe® Exchange Set.
   - Povidone iodine prefilled stay•safe® Cap, a stand alone item provided separately.
   - stay•safe® Organizer, a stand alone item provided separately (Optional; FMCNA recommends its use).
   - Prescribed medication(s), if ordered by your healthcare provider.
   - Mask.
3. Put on mask. Wash your hands.
4. Ensure that the Extension Set coming from your catheter is clamped.
5. Tear the outerwrap from the slit edge down the length of the inner bags to open. Wipe away any moisture from the solution bags. Some opacity may be observed in the plastic of the bags 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 after removing outerwrap.

Inspect DELFLEX® Solution Bags:

6. Place the DELFLEX® solution set on the work surface. See **Figure A**.

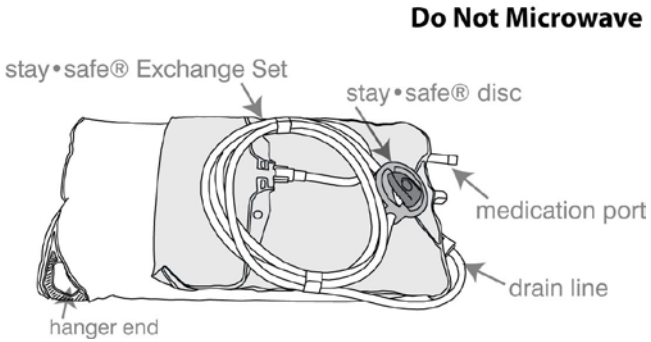


Figure A

- Position solution bags and drain bag as shown in **Figure B**.

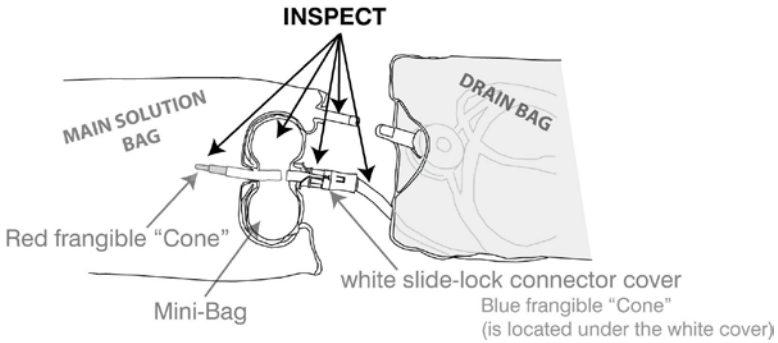


Figure B

- Firmly squeeze the Main Solution Bag and Mini-Bag to check for leaks.
- When squeezing the Mini-Bag, the bag should remain firm and no solution should leak into the Main Solution Bag or into the drain line.

Do not use DELFLEX® Neutral pH solution if:

- leaks are found
- the solution bags are damaged
- solution is cloudy or discolored
- Red or Blue frangible "Cone" is broken

NOTE: Retain DELFLEX® Neutral pH peritoneal dialysis bag sample for manufacturer evaluation and notify your healthcare provider if any of the above defects are found.

7. Turn the blue position indicator on the stay•safe® disc counter-clockwise until it fits into the cut-out portion of the colored plastic cover on the disc. Remove the colored plastic cover while the indicator is in this position (Position 1: •). Once the cover is removed, do not turn counter-clockwise. See **Figure C**. (This step is done in preparation to allow the effluent in your peritoneal cavity to drain later on in this procedure).

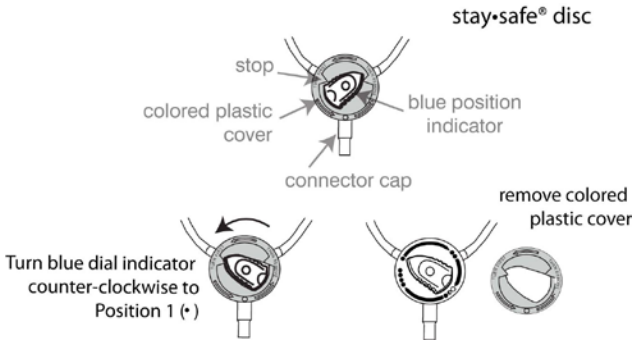


Figure C

<u>Mix DELFLEX® Neutral pH Solution</u>

Important: Mix the Mini-Bag and Main Bag solutions thoroughly. Use the solution within 24 hours after mixing.

1. With the Main Solution Bag laying on the work surface; break the Red frangible “Cone” by placing the thumb firmly on the Red frangible and pressing down upon it until the end of it breaks off. See **Figure D**.

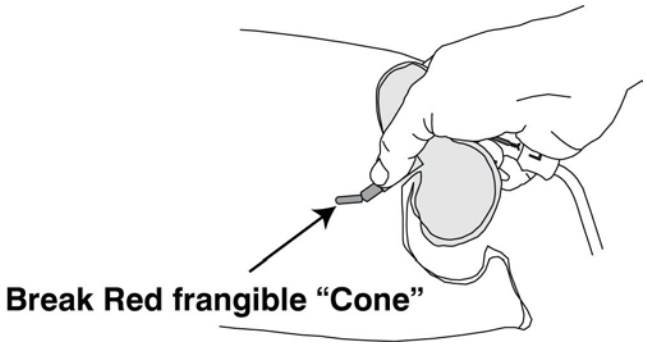


Figure D

2. Fold the Mini-Bag in half. Firmly squeeze the solution from the Mini-Bag into the Main Solution Bag by pressing the two halves together until the Mini-Bag is empty. See **Figure E**.

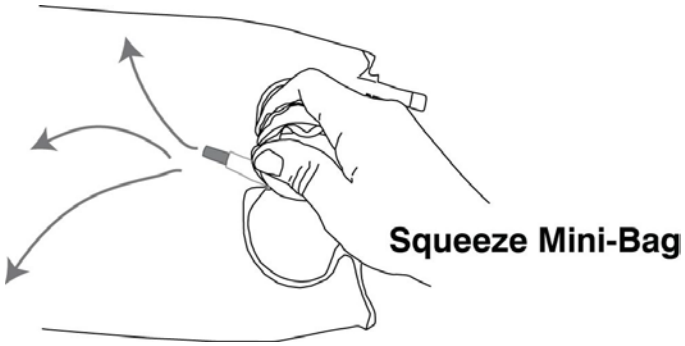


Figure E

3. Push down on Main Solution Bag to flush solution back into Mini-Bag. Completely refill the Mini-Bag with solution. See **Figure F**.

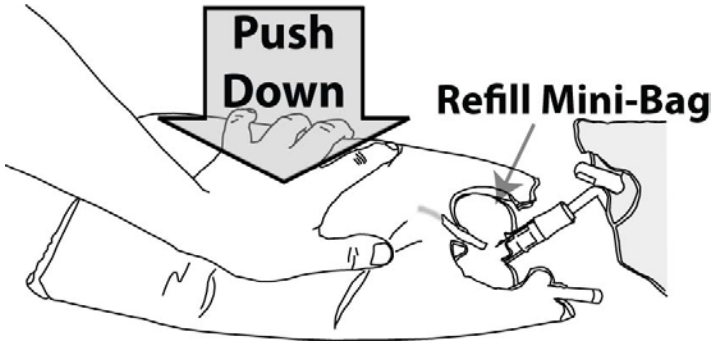


Figure F

4. Repeat **Step 2 (Figure E)** and **Step 3 (Figure F)** above, at least one time, to make sure that all of the contents of the Mini-Bag have been completely flushed into the Main Solution Bag.
5. Grasp the bottom end of the Main Solution Bag. While keeping the hanger end (top) portion of the bag on the table, flip the bag lengthwise using a back and forth motion to mix the solutions. See **Figure G**. Repeat this step to mix solution thoroughly.

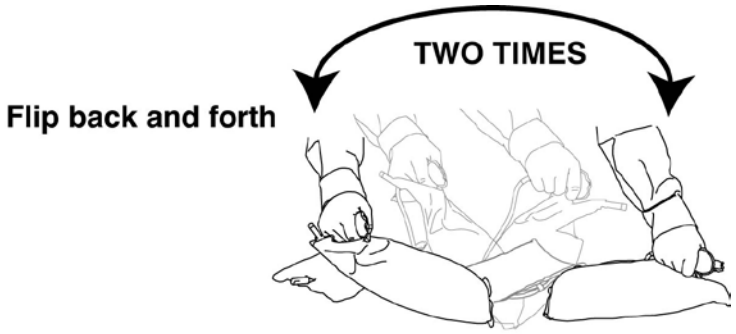


Figure G

6. With the Main Solution Bag still on the table, position it so that the “slit” in the white slide-lock connector cover is facing up.
7. Fold Mini-Bag in half and squeeze it empty of solution.
8. Slide the folded Mini-Bag into the “slit” of the white slide-lock connector cover. Ensure that the entire “grip” area of the Blue frangible is exposed. If the square “grip” area is not exposed slide the slide-lock connector cover further onto the folded Mini-Bag to expose the “grip”. See **Figure H.** Solution may flow back into the Mini-Bag slightly, this is normal.

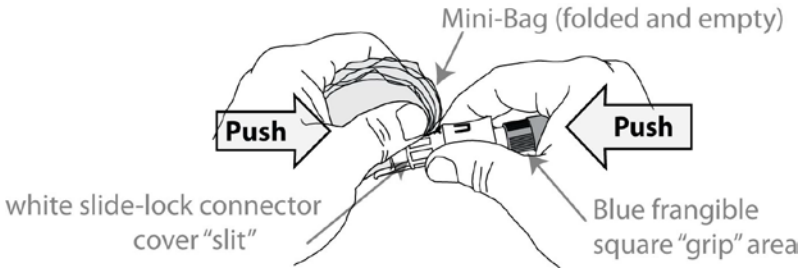


Figure H

The solution is now ready for use.

Administer DELFLEX® Neutral pH Peritoneal Dialysis Solution

1. If you will be adding medication(s):
   - Clean the medication port as instructed by your healthcare provider.
   - Add the medicine(s).
   - Turn the bag upside down several times to mix the medicine(s).
2. Hang the solution bag from the I.V. pole. Place the drain bag at floor level.

3. Break the Blue frangible "Cone" by placing one hand on the Blue frangible square "grip" area and placing the other hand on the white slide-lock connector cover and bending it. See **Figure I**. (If using the Organizer, place the stay•safe® disc in the Organizer as shown in **Figure J**).

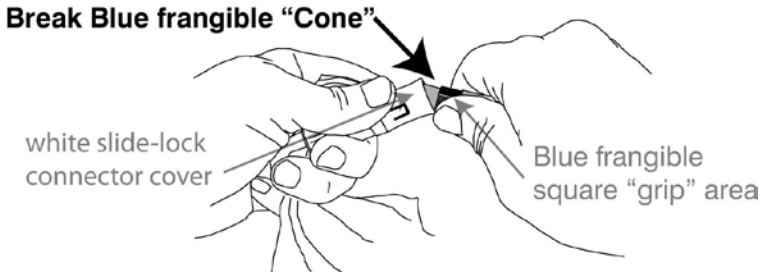


Figure I

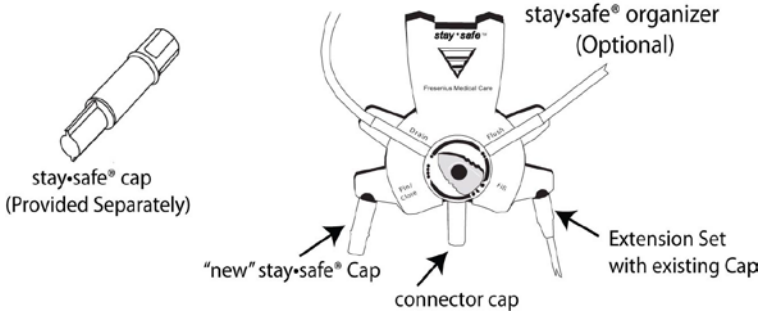


Figure J

4. Remove the new stay•safe® Cap from its package. (The new stay•safe® Cap is the stand alone item provided to the patient separately). **See Figure J**. (If using the Organizer place the new stay•safe® Cap in the left notch of the Organizer. Place the existing cap of the stay•safe® Extension Set, connected to the patient's catheter, in the other notch of the Organizer. See **Figure J**).
5. Aseptically remove the connector cap from the stay•safe® disc and throw the cap away. See **Figure J**. Remove the existing cap from the Extension Set connected to the patient's catheter by twisting the connection counter-clockwise. (If using the Organizer,

leave the capped end of the Extension Set in the Organizer and twist the Extension Set connector counter-clockwise to remove the set from its cap).

6. Aseptically connect the Extension Set to the connector on the stay•safe® disc. Twist clockwise to secure the connection.
7. Remove your mask. Do not open the system during exchange.
8. Open the Extension Set clamp to start drain.
9. When patient drain is complete, turn the stay•safe® disc position indicator to Position 2 (••). See **Figure K**. This will start flush from the solution bag to the drain bag.

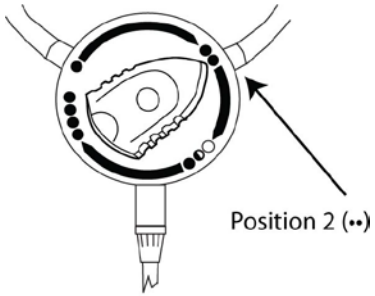


Figure K

10. After approximately 5 seconds turn the stay•safe® disc position indicator to Position 3 (•••). See **Figure L**. This will start the patient fill.

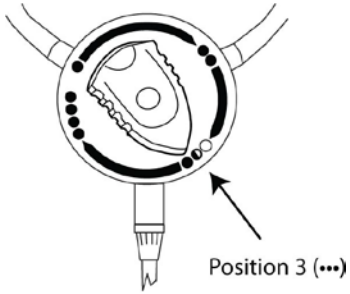


Figure L

11. When fill is complete, turn the stay•safe® disc position indicator to Position 4 (••••). See **Figure M**. This will insert the closure pin of the disc into the Extension Set connector and seal the system.

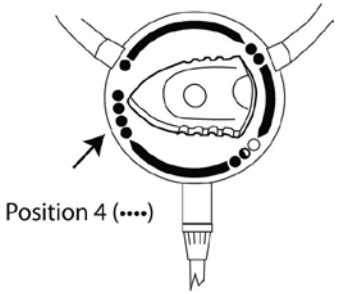


Figure M

12. Close the clamp on the Extension Set. Remove the white protective cover from the new stay•safe® Cap. Save for later use.
13. Remove the Extension Set from the stay•safe® disc and attach the new stay•safe® Cap. Twist clockwise to secure the connection.
14. Seal the disc by attaching the white protective cover from the new stay•safe® Cap to the disc connector. Twist clockwise to secure the connection and prevent leakage from the used system.

15. Look at the drained fluid for cloudiness. Measure the amount of fluid drained. Throw away the fluid and used set as instructed by your healthcare provider. **In case of cloudiness, save the fluid and the used set and immediately contact your healthcare provider.**

Figure 1: 6L Unit Labeling – 1.5% Dextrose Standard Mg/Standard Ca

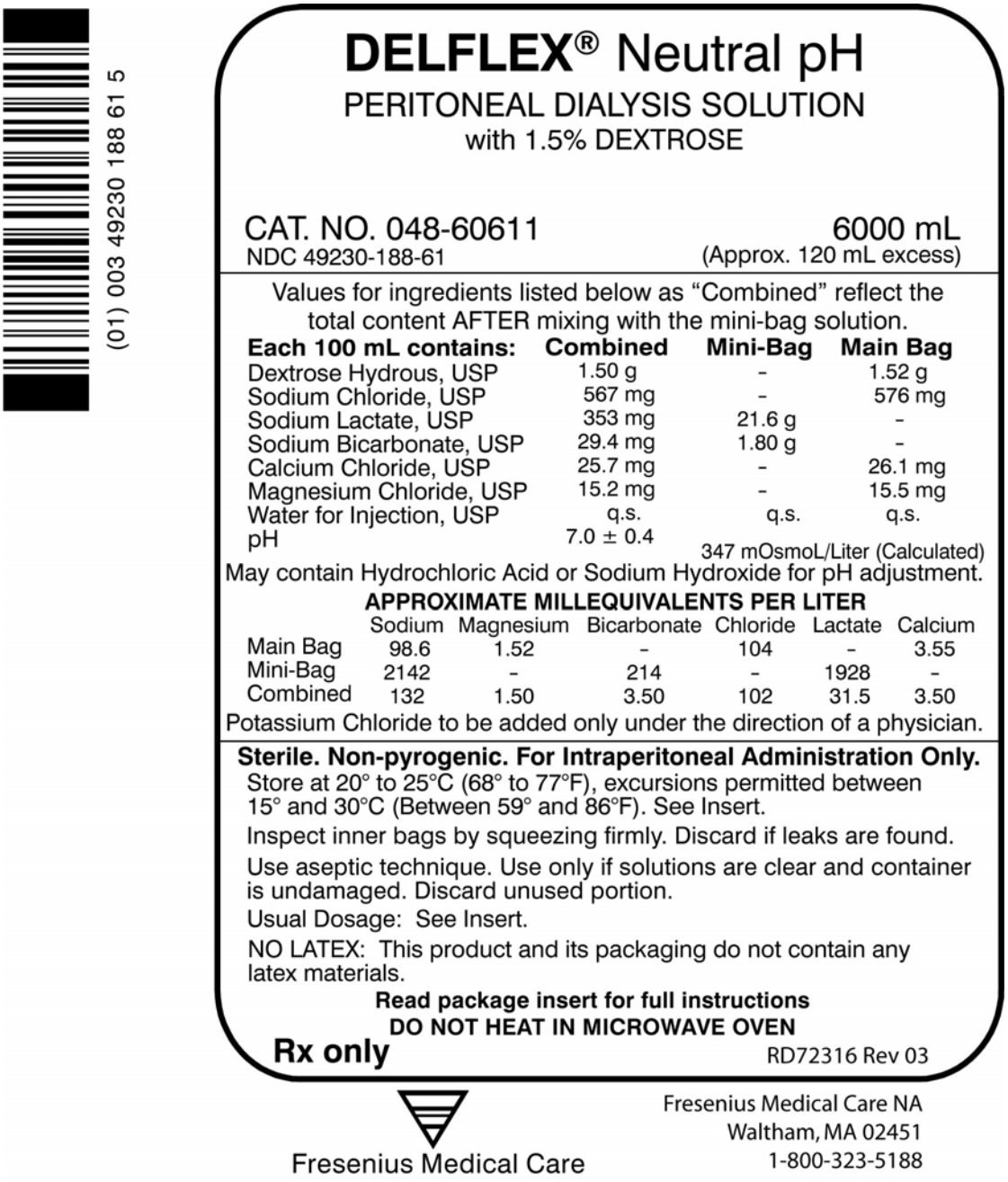


Figure 2: 6L Unit Labeling – 2.5 % Dextrose Standard Mg/ Standard Ca

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION
with 2.5% DEXTROSE

CAT. NO. 048-60612
NDC 49230-191-61

6000 mL
(Approx. 120 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-Bag	Main Bag
Dextrose Hydrous, USP	2.50 g	-	2.54 g
Sodium Chloride, USP	567 mg	-	576 mg
Sodium Lactate, USP	353 mg	21.6 g	-
Sodium Bicarbonate, USP	29.4 mg	1.80 g	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	15.2 mg	-	15.5 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

398 mOsmoL/Liter (Calculated)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	98.6	1.52	-	104	-	3.55
Mini-Bag	2142	-	214	-	1928	-
Combined	132	1.50	3.50	102	31.5	3.50

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (Between 59° and 86°F). See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions
DO NOT HEAT IN MICROWAVE OVEN

Rx only

RD72317 Rev 03

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Figure 3: 6L Unit Labeling - 4.25 % Dextrose Standard Mg/ Standard Ca

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION
with 4.25% DEXTROSE

CAT. NO. 048-60614
NDC 49230-194-61

6000 mL
(Approx. 120 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-Bag	Main Bag
Dextrose Hydrous, USP	4.25 g	-	4.32 g
Sodium Chloride, USP	567 mg	-	576 mg
Sodium Lactate, USP	353 mg	21.6 g	-
Sodium Bicarbonate, USP	29.4 mg	1.80 g	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	15.2 mg	-	15.5 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

486 mOsmoL/Liter (Calculated)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	98.6	1.52	-	104	-	3.55
Mini-Bag	2142	-	214	-	1928	-
Combined	132	1.50	3.50	102	31.5	3.50

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (Between 59° and 86°F). See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions
DO NOT HEAT IN MICROWAVE OVEN

Rx only

RD72318 Rev 03

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Figure 4: 6L Unit Labeling – 1.5 % Dextrose Low Mg/ Standard Ca

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION
with 1.5% DEXTROSE
LOW MAGNESIUM

CAT. NO. 048-60601
NDC 49230-197-61

6000 mL
(Approx. 120 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-Bag	Main Bag
Dextrose Hydrous, USP	1.50 g	–	1.52 g
Sodium Chloride, USP	538 mg	–	547 mg
Sodium Lactate, USP	409 mg	25.0 g	–
Sodium Bicarbonate, USP	29.4 mg	1.80 g	–
Calcium Chloride, USP	25.7 mg	–	26.1 mg
Magnesium Chloride, USP	5.08 mg	–	5.20 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

346 mOsmoL/Liter (Calculated)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.6	0.51	–	97.7	–	3.55
Mini-Bag	2445	–	214	–	2231	–
Combined	132	0.50	3.50	96.0	36.5	3.50

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (Between 59° and 86°F). See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found. Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions
DO NOT HEAT IN MICROWAVE OVEN

Rx only

RD72313 Rev 03

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Figure 5: 6L Unit Labeling – 2.5 % Dextrose Low Mg/ Standard Ca

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 2.5% DEXTROSE

LOW MAGNESIUM

CAT. NO. 048-60602 — 6000 mL

NDC 49230-200-61 — (Approx. 120 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-Bag	Main Bag
Dextrose Hydrous, USP	2.50 g	-	2.54 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate, USP	409 mg	25.0 g	-
Sodium Bicarbonate, USP	29.4 mg	1.80 g	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	5.08 mg	-	5.20 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

396 mOsmoL/Liter (Calculated)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.6	0.51	-	97.7	-	3.55
Mini-Bag	2445	-	214	-	2231	-
Combined	132	0.50	3.50	96.0	36.5	3.50

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (Between 59° and 86°F). See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

DO NOT HEAT IN MICROWAVE OVEN

Rx only

RD72314 Rev 03

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Figure 6: 6L Unit Labeling – 4.25 % Dextrose Low Mg/ Standard Ca

Figure 7: 2.5L Unit Labeling – 1.5% Dextrose Standard Mg/ Standard Ca

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION
with 1.5% DEXTROSE
and attached **stay•safe®** Exchange Set

CAT. NO. 059-25211 — 2500 mL
NDC 49230-188-97 — (Approx. 50 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-Bag	Main Bag
Dextrose Hydrous, USP	1.50 g	-	1.53 g
Sodium Chloride, USP	567 mg	-	578 mg
Sodium Lactate, USP	353 mg	18.0 g	-
Sodium Bicarbonate, USP	29.4 mg	1.50 g	-
Calcium Chloride, USP	25.7 mg	-	26.2 mg
Magnesium Chloride, USP	15.2 mg	-	15.5 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

347 mOsmoL/Liter (Calculated)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	98.9	1.52	-	104	-	3.56
Mini-Bag	1785	-	179	-	1606	-
Combined	132	1.50	3.50	102	31.5	3.50

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (Between 59° and 86°F). See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions
DO NOT HEAT IN MICROWAVE OVEN

Rx only RD72670 Rev 02

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Figure 8: 6L Carton Labeling – 1.5 % Dextrose Standard Mg/ Standard Ca

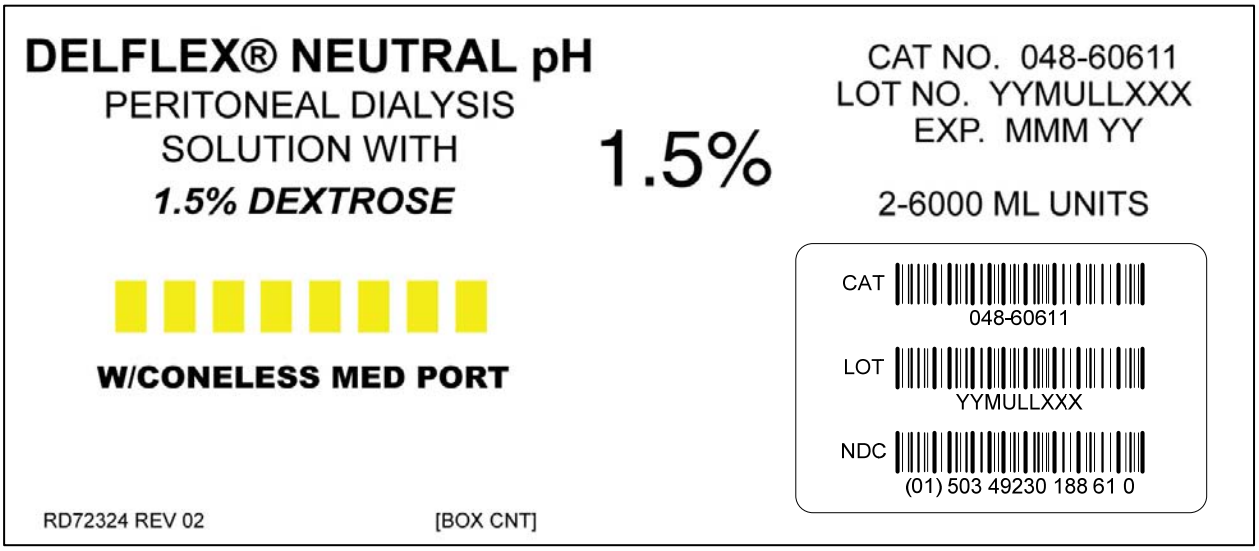


Figure 9: 6L Carton Labeling – 2.5 % Dextrose Standard Mg/ Standard Ca

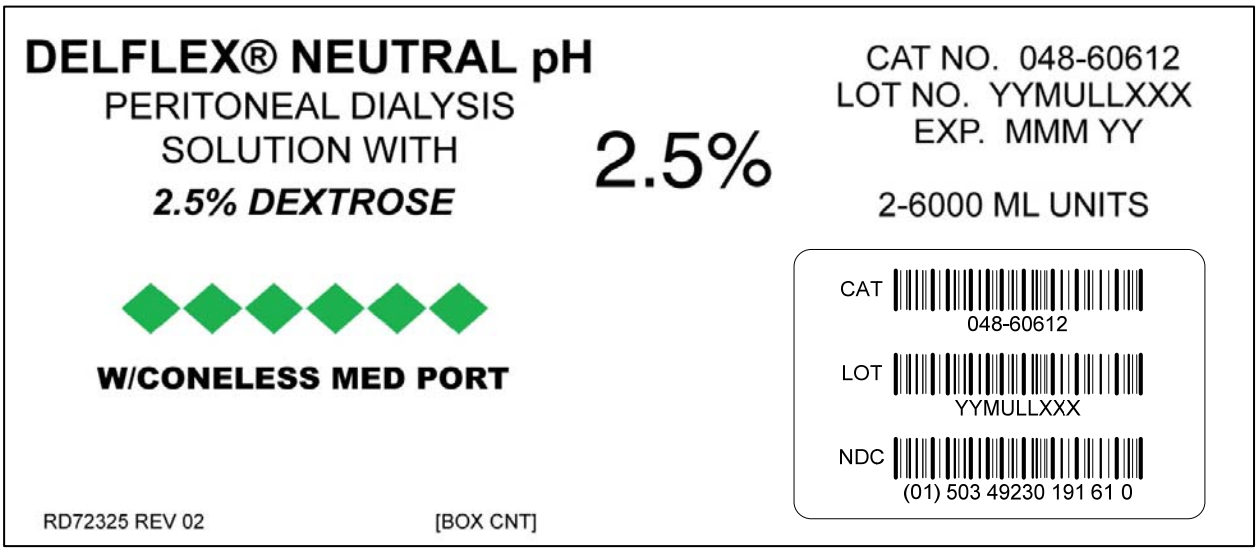


Figure 10: 6L Carton Labeling – 4.25 % Dextrose Standard Mg/ Standard Ca

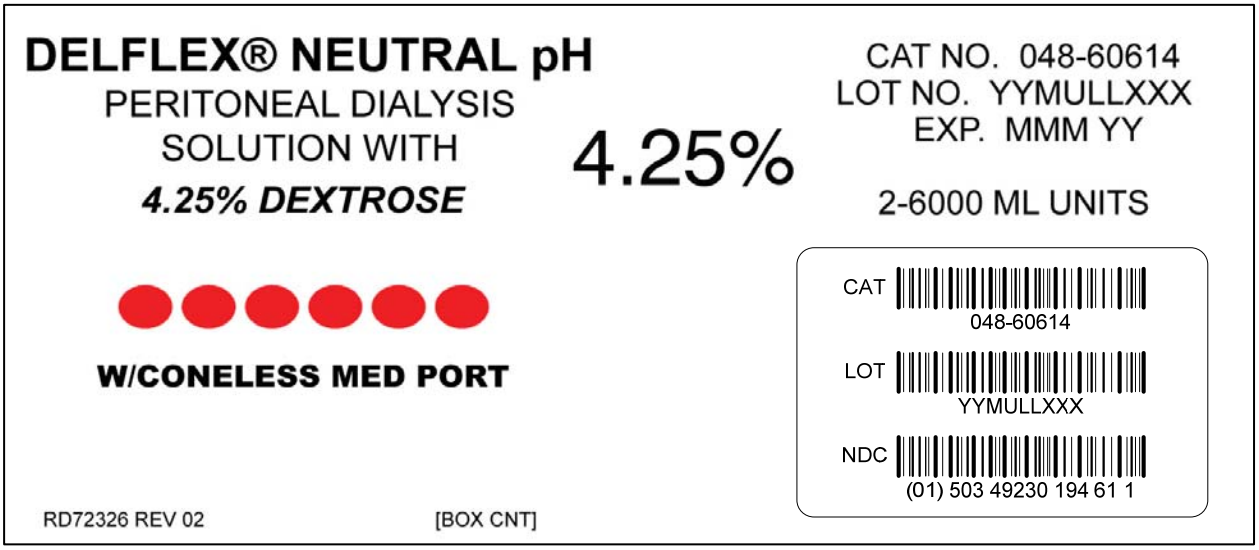


Figure 11: 6L Carton Labeling – 1.5 % Dextrose Low Mg/ Standard Ca

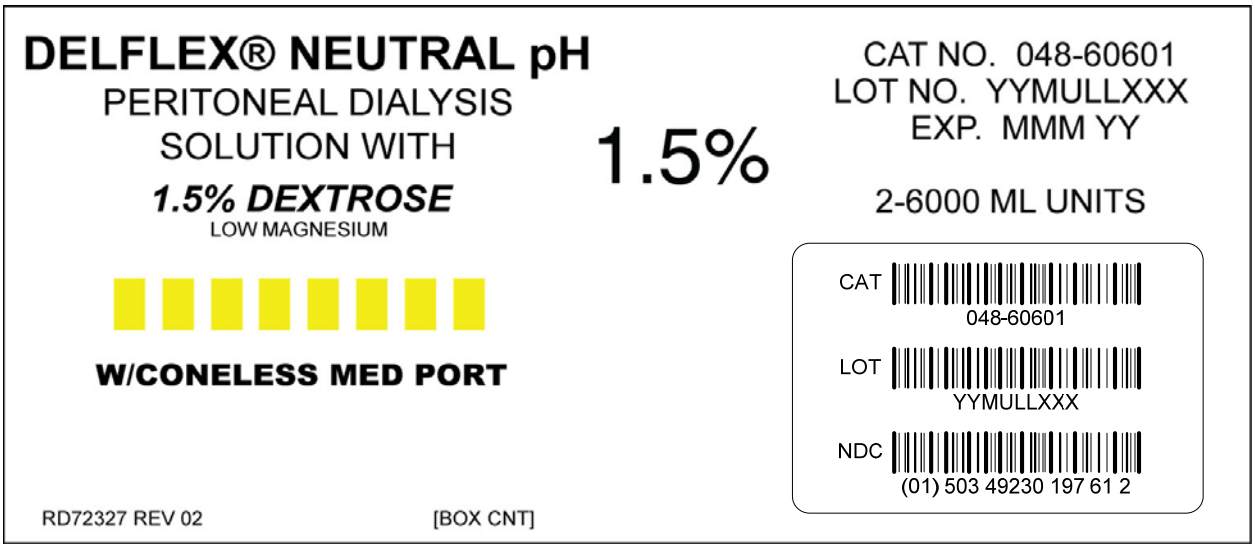


Figure 12: 6L Carton Labeling – 2.5 % Dextrose Low Mg/ Standard Ca

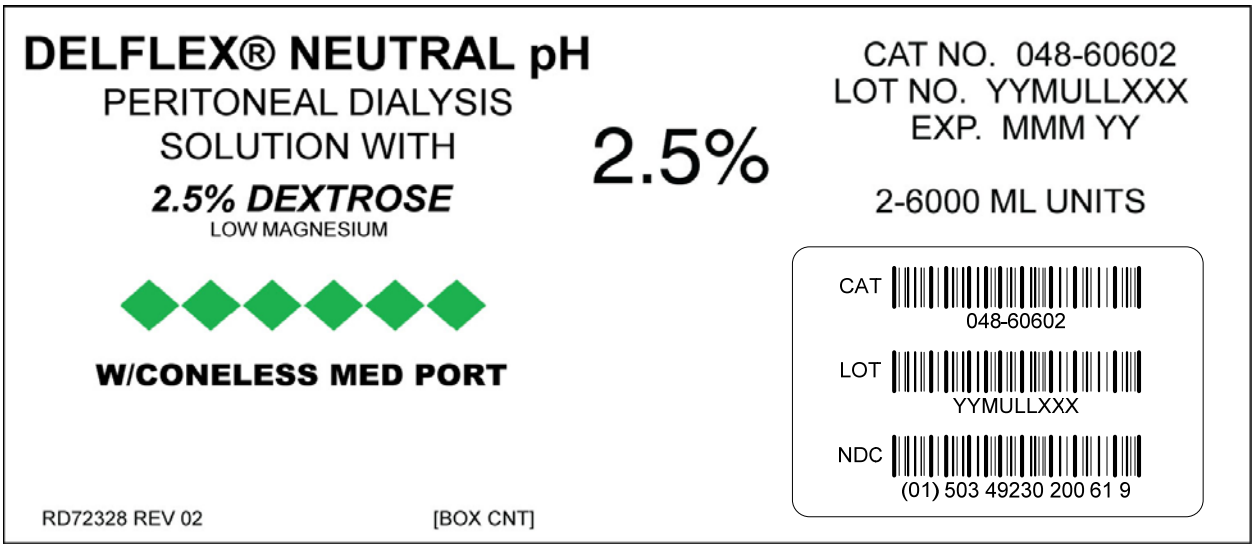


Figure 13: 6L Carton Labeling – 4.25 % Dextrose Low Mg/ Standard Ca

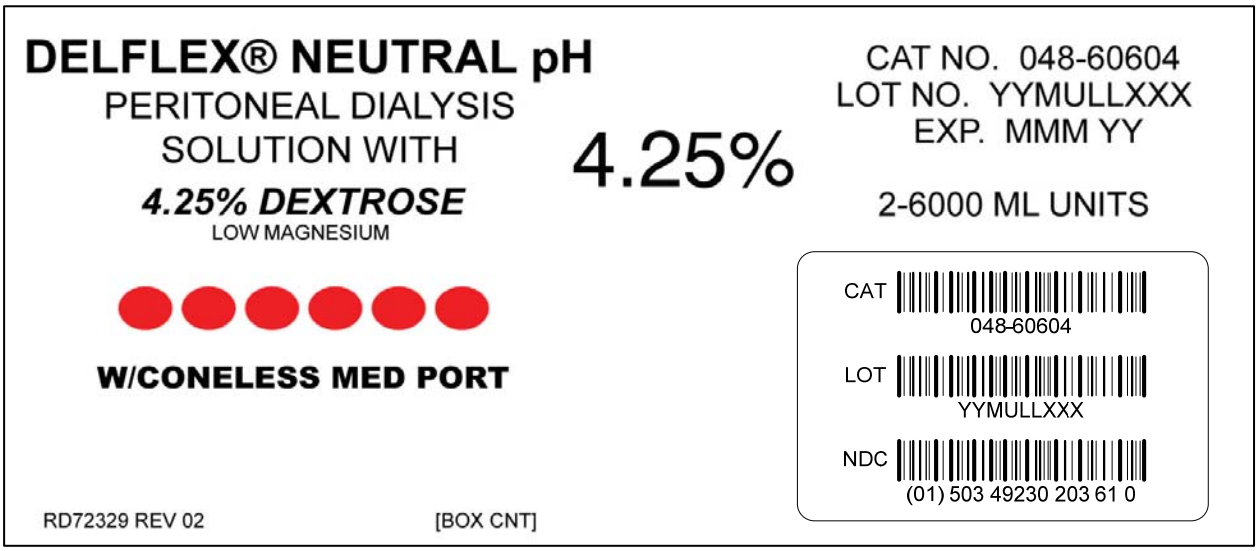


Figure 14: 2.5L Carton Labeling – 1.5 % Dextrose Standard Mg/ Standard Ca

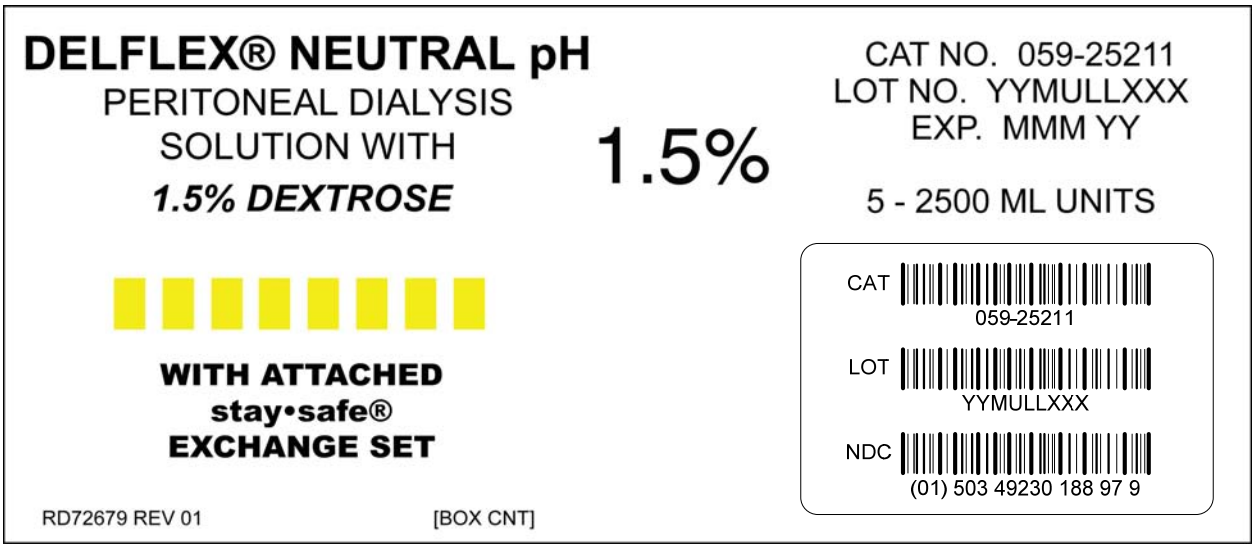
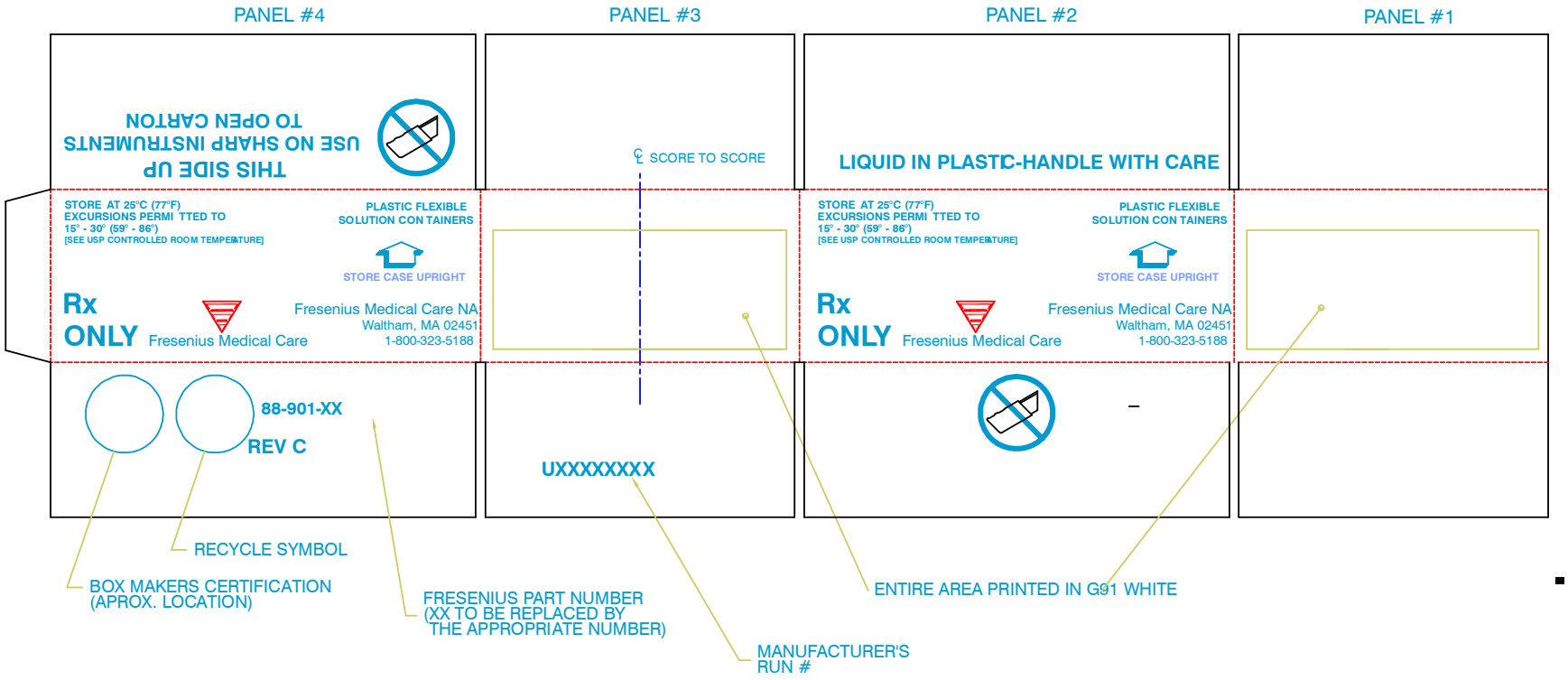


Figure 15: Outer Carton (Case) Labeling, Universal Artwork – Preprinted



[Bar Code]
[Document P/N and Revision]

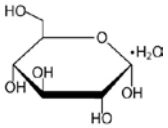
DELFLEX® Neutral pH
Peritoneal Dialysis Solutions
For Intraperitoneal Administration Only

No Latex

Description

DELFLEX® Neutral pH peritoneal dialysis solutions, (standard, low magnesium and low magnesium/low calcium) are sterile, non-pyrogenic formulations of dextrose and electrolytes in water for injection, USP, for use in peritoneal dialysis. These solutions do not contain antimicrobial agents or additional buffers. In comparison to conventional peritoneal dialysis solutions, DELFLEX® Neutral pH solutions are formulated to lower levels of glucose degradation products and provide a neutral pH of 7.0 ± 0.4, which is closer to physiologic pH. The osmotic and buffer solutions are stored separately and mixed by the patient prior to use. Composition, calculated osmolarity, pH and ionic concentrations of the mixed solutions are shown in Table 2.

Dextrose, USP, is chemically designated D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$) a hexose sugar freely soluble in water. The structural formula is shown here:



Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$) white fragments or granules freely soluble in water.

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$) colorless flakes or crystals very soluble in water.

Sodium lactate solution, USP, is chemically designated ($CH_3CH(OH)COONa$), a 60% aqueous solution miscible in water.

Sodium chloride, USP, is chemically designated (NaCl), a white, crystalline compound freely soluble in water.

Water for injection, USP, is chemically designated (H_2O).

Hydrochloric acid, and sodium hydroxide may be added for pH adjustment. pH is 7.0 ± 0.4.

Exposure to temperatures above 25°C (77°F) during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. Since the flexible inner bag is compounded from a specific polyvinyl chloride, water may permeate from the inner bag into the outerwrap in quantities insufficient to affect the solution significantly. Solutions in contact with the plastic inner bag can cause certain chemical components of the bag to leach out in very small amounts; however, the safety of the plastic formulation is supported by biological tests for plastic containers.

Nominal glucose degradation product (GDP) levels (immediately following sterilization) in DELFLEX® Neutral pH solution and DELFLEX® solution are reported in Table 1. The clinical relevance of these differences in GDP levels is unknown.

Table 1. Glucose Degradation Product Levels*

Dextrose Concentration	DELFLEX® Neutral pH	DELFLEX®
1.5%	55	175
2.5%	70	255
4.25%	95	420

*This is the sum [µmol/L] of the various component GDPs including: formaldehyde, acetaldehyde, furaldehyde, glyoxal, methylglyoxal 5-hydroxymethylfurfural (5-HMF), and 3 deoxyglucosone (3DG).

Table 2. Composition, Calculated Osmolarity, pH, and Ionic Concentration

5 Liter DELFLEX® Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
Composition / 100ml	Main Bag Contents									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.53 g	2.55 g	4.34 g	1.53 g	2.55 g	4.34 g	1.53 g	2.55 g	4.34 g
	Sodium Chloride, USP (NaCl)	578 mg	578 mg	578 mg	549 mg	549 mg	549 mg	549 mg	549 mg	549 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	26.2 mg	26.2 mg	26.2 mg	26.2 mg	26.2 mg	26.2 mg	18.8 mg	18.8 mg	18.8 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.5 mg	15.5 mg	15.5 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg
	Mini-Bag Contents									
	Sodium Lactate, USP ($C_3H_5NaO_3$)	18.0 g	18.0 g	18.0 g	20.9 g	20.9 g	20.9 g	20.9 g	20.9 g	20.9 g
	Sodium Bicarbonate, USP ($NaHCO_3$)	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g
	Sodium Chloride, USP (NaCl)	567 mg	567 mg	567 mg	538 mg	538 mg	538 mg	538 mg	538 mg	538 mg
	Sodium Lactate, USP ($C_3H_5NaO_3$)	353 mg	353 mg	353 mg	409 mg	409 mg	409 mg	409 mg	409 mg	409 mg
	Sodium Bicarbonate, USP ($NaHCO_3$)	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
	Osmolarity (mOsmoL/L)(calc)	347	398	486	346	396	484	344	395	483
	pH 7.0 ± 0.4	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0
Ionic Concentration(mEq/L)	Main Bag Contents									
	Sodium	98.9	98.9	98.9	93.9	93.9	93.9	93.9	93.9	93.9
	Calcium	3.56	3.56	3.56	3.56	3.56	3.56	2.56	2.56	2.56
	Magnesium	1.52	1.52	1.52	0.51	0.51	0.51	0.51	0.51	0.51
	Chloride	104	104	104	98.0	98.0	98.0	97.0	97.0	97.0
	Mini-Bag Contents									
	Sodium	1785	1785	1785	2044	2044	2044	2044	2044	2044
	Lactate	1606	1606	1606	1865	1865	1865	1865	1865	1865
	Bicarbonate	179	179	179	179	179	179	179	179	179
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Sodium	132	132	132	132	132	132	132	132	132
	Calcium	3.50	3.50	3.50	3.50	3.50	3.50	2.50	2.50	2.50
	Magnesium	1.50	1.50	1.50	0.50	0.50	0.50	0.50	0.50	0.50
	Chloride	102	102	102	96.0	96.0	96.0	95.0	95.0	95.0
	Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5
	Bicarbonate	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50

6 Liter DELFLEX® Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
Composition / 100ml	Main Bag Contents									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.52 g	2.54 g	4.32 g	1.52 g	2.54 g	4.32 g	1.52 g	2.54 g	4.32 g
	Sodium Chloride, USP (NaCl)	576 mg	576 mg	576 mg	547 mg	547 mg	547 mg	547 mg	547 mg	547 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	26.1 mg	26.1 mg	26.1 mg	26.1 mg	26.1 mg	26.1 mg	18.7 mg	18.7 mg	18.7 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.5 mg	15.5 mg	15.5 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg
	Mini-Bag Contents									
	Sodium Lactate, USP ($C_3H_5NaO_3$)	21.6 g	21.6 g	21.6 g	25.0 g	25.0 g	25.0 g	25.0 g	25.0 g	25.0 g
	Sodium Bicarbonate, USP ($NaHCO_3$)	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g	1.80 g
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g
	Sodium Chloride, USP (NaCl)	567 mg	567 mg	567 mg	538 mg	538 mg	538 mg	538 mg	538 mg	538 mg
	Sodium Lactate, USP ($C_3H_5NaO_3$)	353 mg	353 mg	353 mg	409 mg	409 mg	409 mg	409 mg	409 mg	409 mg
	Sodium Bicarbonate, USP ($NaHCO_3$)	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
	Osmolarity (mOsmoL/L)(calc)	347	398	486	346	396	484	344	395	483
	pH 7.0 ± 0.4	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0
Ionic Concentration(mEq/L)	Main Bag Contents									
	Sodium	98.6	98.6	98.6	93.6	93.6	93.6	93.6	93.6	93.6
	Calcium	3.55	3.55	3.55	3.55	3.55	3.55	2.54	2.54	2.54
	Magnesium	1.52	1.52	1.52	0.51	0.51	0.51	0.51	0.51	0.51
	Chloride	104	104	104	97.7	97.7	97.7	96.7	96.7	96.7
	Mini-Bag Contents									
	Sodium	2142	2142	2142	2445	2445	2445	2445	2445	2445
	Lactate	1928	1928	1928	2231	2231	2231	2231	2231	2231
	Bicarbonate	214	214	214	214	214	214	214	214	214
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Sodium	132	132	132	132	132	132	132	132	132
	Calcium	3.50	3.50	3.50	3.50	3.50	3.50	2.50	2.50	2.50
	Magnesium	1.50	1.50	1.50	0.50	0.50	0.50	0.50	0.50	0.50
	Chloride	102	102	102	96.0	96.0	96.0	95.0	95.0	95.0
	Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5
	Bicarbonate	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50

Clinical Pharmacology

Peritoneal dialysis is the process of filtering excess water and toxins from the bloodstream through a semi-permeable membrane. This process does not cure the disease, but prevents progression of symptoms. Dialysis for chronic kidney failure is essential to maintain life, unless the patient receives a kidney transplant. A peritoneal dialysis procedure utilizes the peritoneum (lining of the abdomen) as the semi-permeable membrane. The procedure is conducted by instilling peritoneal dialysis solution through a catheter in the abdomen into the peritoneal cavity. Since the peritoneum is heavily supplied with blood vessels, the contact of the solution with the peritoneum causes excess water and toxins in the bloodstream to be drawn across the membrane into the solution. This osmosis and diffusion occurs between the plasma of the patient and the peritoneal dialysis solution. After a period of time called "dwell time," the solution is then drained from the patient.

This solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

Clinical studies have demonstrated that the use of low magnesium solutions resulted in significant increases in serum CO_2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications and Usage

DELFLEX® peritoneal dialysis solutions are indicated in the treatment of chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

Contraindications

None known.

Warnings

Not for Intravenous Injection.

Use Aseptic Technique.

It is important to mix the buffer (Mini-Bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, other prescribed medication(s) may be added prior to administration.

After removing the outerwrap, check for minute leaks by squeezing each of the solution bags firmly. If leaks are found, discard the solution because the sterility may be impaired. (A small amount of moisture may be present inside the outerwrap, which is normal condensation from the sterilization process).

Peritoneal dialysis should be done with great care, in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

Solutions containing lactate ion should be used with great care in patients with metabolic or respiratory alkalosis. Lactate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion and shock.

Excessive use of DELFLEX® peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

Serum calcium levels in patients using low calcium concentrations should be monitored and if found to be low, the peritoneal solution in use should be altered to one with a higher calcium concentration.

Precautions

General

Chronic patients that have been stabilized on peritoneal dialysis therapy should have routine evaluation of electrolyte blood chemistries and hematologic factors measured in order to determine the patient's ongoing condition.

DELFLEX® peritoneal dialysis solutions do not include potassium. Potassium chloride should only be added under the direction of a physician after careful evaluation of both serum and total body potassium.

Significant loss of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Information for Patients

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

The outerwrap should remain intact until time of use.

Administer only if the solution is clear, all seals are intact, and there is no evidence of leaking.

Do Not Heat In A Microwave Oven. Microwave ovens heat unevenly and can leave hot spots, which can burn the peritoneum.

It is important to mix the buffer (Mini-Bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, other prescribed medication(s) may be added prior to administration.

Care should be taken to ensure that there is not any leakage around the catheter, since if not controlled; the leakage can create edema from subcutaneous infiltration of the dialysis solution. This will also create an inaccurate fluid balance measurement. If any leakage is identified do not proceed with infusion and notify your physician.

Laboratory Tests

Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies with DELFLEX® peritoneal dialysis solutions have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy: Teratology Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with DELFLEX® peritoneal dialysis solutions. It is also not known whether DELFLEX® peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DELFLEX® peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Caution should be exercised when DELFLEX® peritoneal dialysis solutions are administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Adverse Reactions

Adverse reactions occurring with administration of peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions might include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome and muscle cramping.

If an adverse reaction does occur, institute appropriate therapeutic procedures according to the patient's needs and conditions, and save the remainder of the fluid in the bag for evaluation if deemed necessary.

Dosage and Administration

DELFLEX® peritoneal dialysis solutions are provided for intraperitoneal administration only. The mode of therapy, frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for the treatment of the individual patient.

To avoid the risk of severe dehydration or hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Additives may be incompatible. Do not store solutions containing additives.

For administration see Directions for Use section.

How Supplied

DELFLEX® peritoneal dialysis solutions are delivered in single-dose flexible bags. All DELFLEX® peritoneal dialysis solutions have overfills declared on the bag label. The flexible bags have the capacity for drainage in excess of their stated fill volume for ultrafiltration from the patient.

DELFLEX® Neutral pH peritoneal dialysis solutions are available in flexible bags as shown in Table 2 in the Description section.

Storage Conditions

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (between 59°F and 86°F). See USP Controlled Room Temperature. Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

Keep DELFLEX® and all medicines out of the reach of children.

Fresenius Medical Care

Fresenius Medical Care
North America
920 Winter Street
Waltham, MA 02451
1-800-323-5188

Patent Pending

Revised
11/01/2012

Not for Intravenous Injection. Do not microwave.
Warm solution as directed by your health care provider.

<u>Directions for Use</u> (Aseptic technique is required)

Get Ready

1. Clean work surface.
2. Gather supplies:
   - DELFLEX® Neutral pH Peritoneal Dialysis bag.
   - Prescribed medication(s), if ordered by your healthcare provider.
   - Mask.
3. Put on mask. Wash your hands.
4. Tear the outerwrap from the slit edge down the length of the inner bags to open. Wipe away any moisture from the solution bags. Some opacity may be observed in the plastic of the bags 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 after removing outerwrap.

Inspect DELFLEX® Solution Bags:

5. Place the DELFLEX® solution set on the work surface. See **Figure A**.

Do Not Microwave

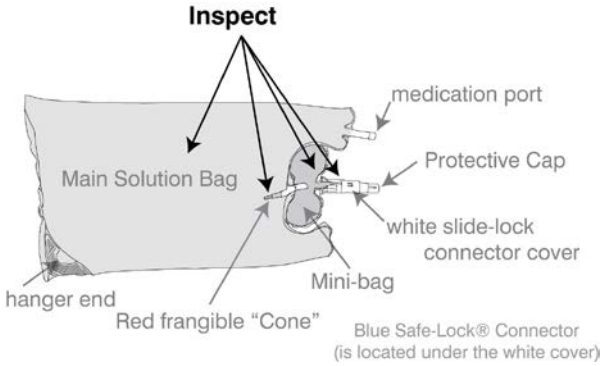


Figure A

- Firmly squeeze the Main Solution Bag and the Mini-Bag to check for leaks.
- When squeezing the Mini-Bag, the bag should remain firm and no solution should leak into the Main Solution Bag or from the Blue Safe-Lock® connector.

Do not use DELFLEX® Neutral pH solution if:

- leaks are found
- the solution bags are damaged
- solution is cloudy or discolored
- Red frangible "Cone" or Blue Safe-Lock® connector "Cone" broken

NOTE: Retain DELFLEX® Neutral pH peritoneal dialysis bag sample for manufacturer evaluation and notify your healthcare provider if any of the above defects are found.

Mix DELFLEX® Neutral pH Solution

Important: Mix the Mini-Bag and Main Bag solutions thoroughly. Use the solution within 24 hours after mixing.

1. With the Main Solution Bag laying on the work surface; break the Red frangible "Cone" by placing the thumb firmly on the Red frangible and pressing down upon it until the end of it breaks off. See **Figure B**.

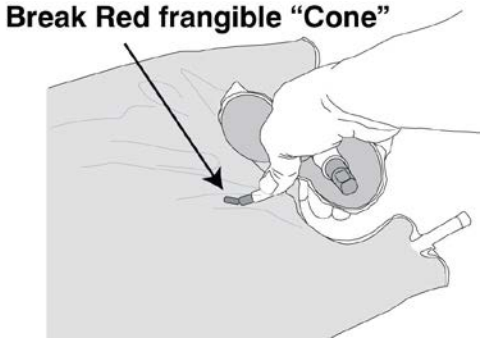


Figure B

2. Fold the Mini-Bag in half. Firmly squeeze the solution from the Mini-Bag into the Main Solution Bag by pressing the two halves together until the Mini-Bag is empty. See **Figure C**.

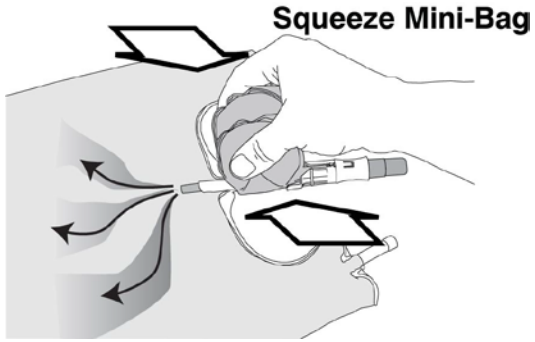


Figure C

3. Push down on the Main Solution Bag to flush solution back into the Mini-Bag. Completely refill the Mini-Bag with solution. See **Figure D**.

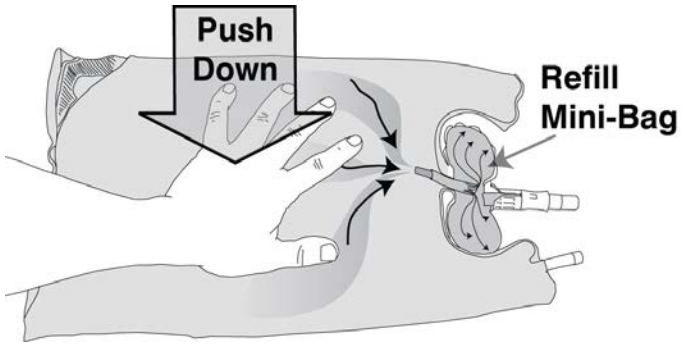


Figure D

4. Repeat **Step 2 (Figure C)** and **Step 3 (Figure D)** above, at least one time, to make sure that all of the contents of the Mini-Bag have been completely flushed into the Main Solution Bag.
5. Grasp the bottom end of the Main Solution Bag. While keeping the hanger end (top) portion of the bag on the table, flip the bag lengthwise using a back and forth motion to mix the solutions. See **Figure E**. Repeat this step to mix solution thoroughly.

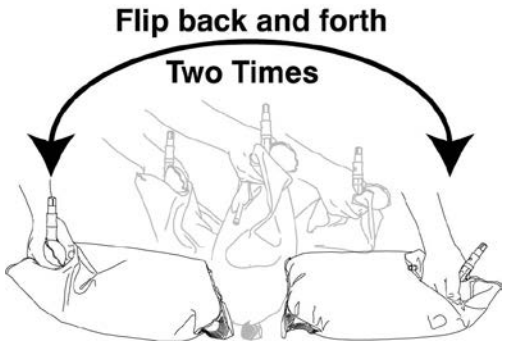


Figure E

6. With the Main Solution Bag still on the table, position it so that the "slit" in the white slide-lock connector cover is facing up.
7. Fold Mini-Bag in half and squeeze it empty of solution.
8. Slide the folded Mini-Bag into the "slit" of the white slide-lock connector cover. Ensure that the entire "grip" area of the Blue Safe-Lock® connector is exposed. If the square "grip" area is not exposed slide the slide-lock connector cover further onto the folded Mini-Bag to expose the "grip". See **Figures F and G.** Solution may flow back into the Mini-Bag slightly, this is normal.

NOTE: The protective cap should remain on the connector during this step to avoid touch contamination.

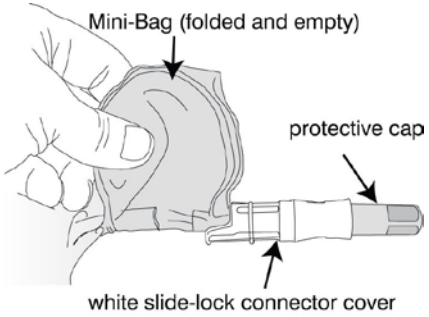


Figure F

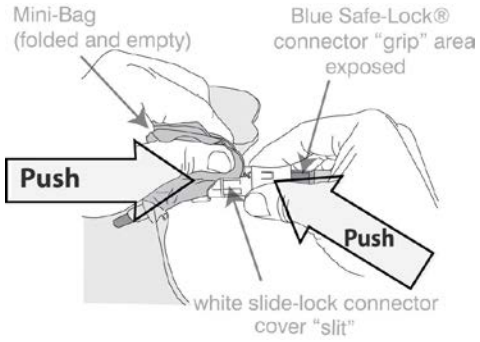


Figure G

The solution is now ready for use.

Administer DELFLEX® Neutral pH Peritoneal Dialysis Solution

1. If you will be adding medication(s):
   - Clean the medication port as instructed by your healthcare provider.
   - Add the medicine(s).

- Turn the bag upside down several times to mix the medicine(s).

2. Take off the protective cap from the Blue Safe-Lock® connector at the bottom of the Mini-Bag. Connect the Blue Safe-Lock® connector to the mating Safe-Lock® connector on the fluid delivery set connected to the PD cycler machine.
3. Remove your mask. Do not open the system during fluid exchange.
4. Break the Blue Safe-Lock® connector "Cone" by placing one hand on the Blue Safe-Lock® connector square "grip" area and placing the other hand on the white slide-lock connector cover and bending it to start solution flow. See **Figure H**.

NOTE: The white slide-lock connector cover may not allow you to see the entire lower portion (connector "Cone") of the Blue Safe-Lock® connector.

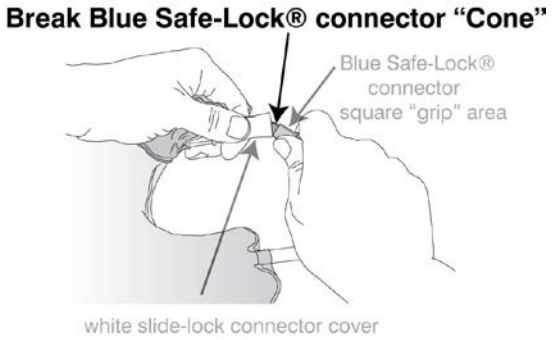


Figure H

5. Look at the drained fluid for cloudiness. Throw away the fluid and used set as instructed by your healthcare provider. **In case of cloudiness, save the fluid and the used set and immediately contact your healthcare provider.**

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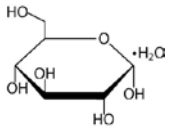
DELFLEX® Neutral pH
Peritoneal Dialysis Solutions
with Attached stay•safe® Exchange Set
For Intraperitoneal Administration Only

No Latex

Description

DELFLEX® Neutral pH, peritoneal dialysis solutions, (standard, low magnesium and low magnesium/low calcium) are sterile, non-pyrogenic formulations of dextrose and electrolytes in water for injection, USP, for use in peritoneal dialysis. These solutions do not contain antimicrobial agents or additional buffers. In comparison to conventional peritoneal dialysis solutions, DELFLEX® Neutral pH solutions are formulated to lower levels of glucose degradation products and provide a neutral pH of 7.0 ± 0.4, which is closer to the physiologic pH. The osmotic and buffer solutions are stored separately and mixed by the patient prior to use. The stay•safe® Exchange Set utilizes an easy to use dial designed to eliminate the use of clamps and to prevent touch contamination of internal connection components. Composition, calculated osmolarity, pH and ionic concentrations of the mixed solutions are shown in Table 2.

Dextrose USP is chemically designated D-glucose monohydrate ($C_6H_{12}O_6•H_2O$) a hexose sugar freely soluble in water. The structural formula is shown here.



Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2•2H_2O$) white fragments or granules freely soluble in water.

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$) colorless flakes or crystals very soluble in water.

Sodium lactate solution, USP, is chemically designated ($CH_3CH(OH)COONa$), a 60% aqueous solution miscible in water.

Sodium chloride, USP, is chemically designated (NaCl), a white, crystalline compound freely soluble in water.

Water for injection, USP, is chemically designated (H_2O).

Hydrochloric acid, and sodium hydroxide may be added for pH adjustment. pH is 7.0 ± 0.4.

Exposure to temperatures above 25°C (77°F) during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. Since the flexible inner bag is compounded from a specific polyvinyl chloride, water may permeate from the inner bag into the outerwrap in quantities insufficient to affect the solution significantly. Solutions in contact with the plastic inner bag can cause certain chemical components of the bag to leach out in very small amounts; however, the safety of the plastic formulation is supported by biological tests for plastic containers.

Nominal glucose degradation product (GDP) levels (immediately following sterilization) in DELFLEX® Neutral pH solution and DELFLEX® solution are reported in Table 1. The clinical relevance of these differences in GDP levels in unknown.

Table 1. Glucose Degradation Product Levels*

Dextrose Concentration	DELFLEX® Neutral pH	DELFLEX®
1.5%	55	175
2.5%	70	255
4.25%	95	420

*This is the sum [µmol/L] of the various component GDPs including: formaldehyde, acetaldehyde, furaldehyde, glyoxal, methylglyoxal 5-hydroxymethylfurfural (5-HMF), and 3 deoxyglucosone (3DG).

Table 2. Composition, Calculated Osmolarity, pH, and Ionic Concentration

2.5 Liter DELFLEX® Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
Composition / 100ml	Main Bag Contents									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.53 g	2.55 g	4.34 g	1.53 g	2.55 g	4.34 g	1.53 g	2.55 g	4.34 g
	Sodium Chloride, USP (NaCl)	578 mg	578 mg	578 mg	549 mg	549 mg	549 mg	549 mg	549 mg	549 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	26.2 mg	26.2 mg	26.2 mg	26.2 mg	26.2 mg	26.2 mg	18.8 mg	18.8 mg	18.8 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.5 mg	15.5 mg	15.5 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg	5.20 mg
	Mini-Bag Contents									
	Sodium Lactate, USP ($C_3H_5NaO_3$)	18.0 g	18.0 g	18.0 g	20.9 g	20.9 g	20.9 g	20.9 g	20.9 g	20.9 g
	Sodium Bicarbonate, USP ($NaHCO_3$)	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g	1.50 g
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g	1.50 g	2.50 g	4.25 g
	Sodium Chloride, USP (NaCl)	567 mg	567 mg	567 mg	538 mg	538 mg	538 mg	538 mg	538 mg	538 mg
	Sodium Lactate, USP ($C_3H_5NaO_3$)	353 mg	353 mg	353 mg	409 mg	409 mg	409 mg	409 mg	409 mg	409 mg
	Sodium Bicarbonate, USP ($NaHCO_3$)	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg	29.4 mg
	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
	Osmolarity (mOsmoL/L)(calc)	347	398	486	346	396	484	344	395	483
	pH 7.0 ± 0.4	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0
Ionic Concentration(mEq/L)	Main Bag Contents									
	Sodium	98.9	98.9	98.9	93.9	93.9	93.9	93.9	93.9	93.9
	Calcium	3.56	3.56	3.56	3.56	3.56	3.56	2.56	2.56	2.56
	Magnesium	1.52	1.52	1.52	0.51	0.51	0.51	0.51	0.51	0.51
	Chloride	104	104	104	98.0	98.0	98.0	97.0	97.0	97.0
	Mini-Bag Contents									
	Sodium	1785	1785	1785	2044	2044	2044	2044	2044	2044
	Lactate	1606	1606	1606	1865	1865	1865	1865	1865	1865
	Bicarbonate	179	179	179	179	179	179	179	179	179
	Total ingredient content AFTER mixing Main Bag and Mini-Bag solutions									
	Sodium	132	132	132	132	132	132	132	132	132
	Calcium	3.50	3.50	3.50	3.50	3.50	3.50	2.50	2.50	2.50
	Magnesium	1.50	1.50	1.50	0.50	0.50	0.50	0.50	0.50	0.50
	Chloride	102	102	102	96.0	96.0	96.0	95.0	95.0	95.0
	Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5
	Bicarbonate	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50	3.50

Clinical Pharmacology

Peritoneal dialysis is the process of filtering excess water and toxins from the bloodstream through a semi-permeable membrane. This process does not cure the disease, but prevents progression of symptoms. Dialysis for chronic kidney failure is essential to maintain life, unless the patient receives a kidney transplant. A peritoneal dialysis procedure utilizes the peritoneum (lining of the abdomen) as the semi-permeable membrane. The procedure is conducted by instilling peritoneal dialysis solution through a catheter in the abdomen into the peritoneal cavity. Since the peritoneum is heavily supplied with blood vessels, the contact of the solution with the peritoneum causes excess water and toxins in the bloodstream to be drawn across the membrane into the solution. This osmosis and diffusion occurs between the plasma of the patient and the peritoneal dialysis solution. After a period of time called "dwell time," the solution is then drained from the patient.

This solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

Clinical studies have demonstrated that the use of low magnesium solutions resulted in significant increases in serum CO_2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications and Usage

DELFLEX® peritoneal dialysis solutions are indicated in the treatment of chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

Contraindications

None known.

Warnings

Not for Intravenous Injection.

Use Aseptic Technique.

It is important to mix the buffer (Mini-Bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, other prescribed medication(s) may be added prior to administration.

After removing the outerwrap, check for minute leaks by squeezing each of the solution bags firmly. If leaks are found, discard the solution because the sterility may be impaired. (A small amount of moisture may be present inside the outerwrap, which is normal condensation from the sterilization process).

Peritoneal dialysis should be done with great care, in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

Solutions containing lactate ion should be used with great care in patients with metabolic or respiratory alkalosis. Lactate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion and shock.

Excessive use of DELFLEX® peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

Serum calcium levels in patients using low calcium concentrations should be monitored and if found to be low, the peritoneal solution in use should be altered to one with a higher calcium concentration.

Precautions

General

Chronic patients that have been stabilized on peritoneal dialysis therapy should have routine evaluation of electrolyte blood chemistries and hematologic factors measured in order to determine the patient's ongoing condition.

DELFLEX® peritoneal dialysis solutions do not include potassium. Potassium chloride should only be added under the direction of a physician after careful evaluation of both serum and total body potassium.

Significant loss of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Information for Patients

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

The outerwrap should remain intact until time of use.

Administer only if the solution is clear, all seals are intact, and there is no evidence of leaking.

Do Not Heat In A Microwave Oven. Microwave ovens heat unevenly and can leave hot spots, which can burn the peritoneum.

It is important to mix the buffer (Mini-Bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once solutions are mixed, other prescribed medication(s) may be added prior to administration.

Disconnect from disc only when knob is in position 4 (••••) to ensure patient connector is sealed.

Care should be taken to ensure that there is not any leakage around the catheter, since if not controlled; the leakage can create edema from subcutaneous infiltration of the dialysis solution. This will also create an inaccurate fluid balance measurement. If any leakage is identified do not proceed with infusion and notify your physician.

Laboratory Tests

Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies with DELFLEX® peritoneal dialysis solutions have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy: Teratology Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with DELFLEX® peritoneal dialysis solutions. It is also not known whether DELFLEX® peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DELFLEX® peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Caution should be exercised when DELFLEX® peritoneal dialysis solutions are administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Adverse Reactions

Adverse reactions occurring with administration of peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions might include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome and muscle cramping.

If an adverse reaction does occur, institute appropriate therapeutic procedures according to the patient's needs and conditions, and save the remainder of the fluid in the bag for evaluation if deemed necessary.

Dosage and Administration

DELFLEX® peritoneal dialysis solutions are provided for intraperitoneal administration only. The mode of therapy, frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for the treatment of the individual patient.

To avoid the risk of severe dehydration or hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Additives may be incompatible. Do not store solutions containing additives.

For administration see Directions for Use section.

How Supplied

DELFLEX® peritoneal dialysis solutions are delivered in single-dose flexible bags. All DELFLEX® peritoneal dialysis solutions have overfills declared on the bag label. The flexible bags have the capacity for drainage in excess of their stated fill volume for ultrafiltration from the patient.

DELFLEX® Neutral pH peritoneal dialysis solutions with an attached stay•safe® Exchange Set is available in flexible bags as shown in Table 2 in the Description section.

Storage Conditions

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (between 59°F and 86°F). See USP Controlled Room Temperature. Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

Keep DELFLEX® and all medicines out of the reach of children.

Fresenius Medical Care

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Patent Pending

Revised
11/05/2012

Not for Intravenous Injection. Do not microwave.
Warm solution as directed by your health care provider.

Directions for Use (Aseptic technique is required)

Get Ready

1. Clean work surface.
2. Gather supplies:
   - Warmed DELFLEX® Neutral pH Peritoneal Dialysis bag with attached stay•safe® Exchange Set.
   - Povidone iodine prefilled stay•safe® Cap, a stand alone item provided separately.
   - stay•safe® Organizer, a stand alone item provided separately (Optional; FMCNA recommends its use).
   - Prescribed medication(s), if ordered by your healthcare provider.
   - Mask.
3. Put on mask. Wash your hands.
4. Ensure that the Extension Set coming from your catheter is clamped.
5. Tear the outerwrap from the slit edge down the length of the inner bags to open. Wipe away any moisture from the solution bags. Some opacity may be observed in the plastic of the bags 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 after removing outerwrap.

Inspect DELFLEX® Solution Bags:

6. Place the DELFLEX® solution set on the work surface. See **Figure A**.

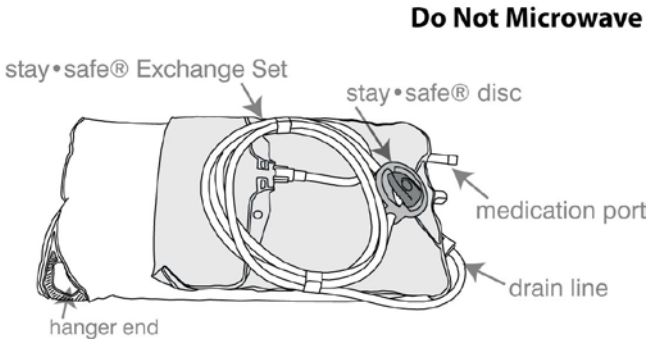

Figure A

- Position solution bags and drain bag as shown in **Figure B**.

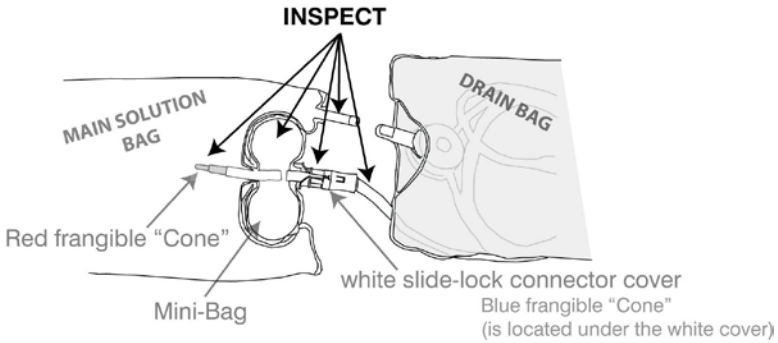

Figure B

- Firmly squeeze the Main Solution Bag and Mini-Bag to check for leaks.
- When squeezing the Mini-Bag, the bag should remain firm and no solution should leak into the Main Solution Bag or into the drain line.

Do not use DELFLEX® Neutral pH solution if:

- leaks are found
- the solution bags are damaged
- solution is cloudy or discolored
- Red or Blue frangible "Cone" is broken

NOTE: Retain DELFLEX® Neutral pH peritoneal dialysis bag sample for manufacturer evaluation and notify your healthcare provider if any of the above defects are found.

7. Turn the blue position indicator on the stay•safe® disc counter-clockwise until it fits into the cut-out portion of the colored plastic cover on the disc. Remove the colored plastic cover while the indicator is in this position (Position 1: •). Once the cover is removed, do not turn counter-clockwise. See **Figure C**. (This step is done in preparation to allow the effluent in your peritoneal cavity to drain later on in this procedure).

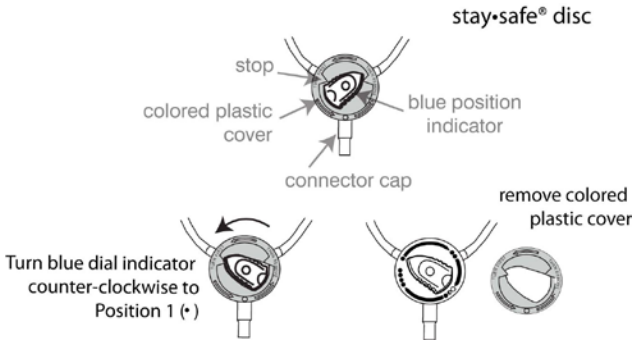

Figure C

<u>Mix DELFLEX® Neutral pH Solution</u>

Important: Mix the Mini-Bag and Main Bag solutions thoroughly. Use the solution within 24 hours after mixing.

1. With the Main Solution Bag laying on the work surface; break the Red frangible “Cone” by placing the thumb firmly on the Red frangible and pressing down upon it until the end of it breaks off. See **Figure D**.

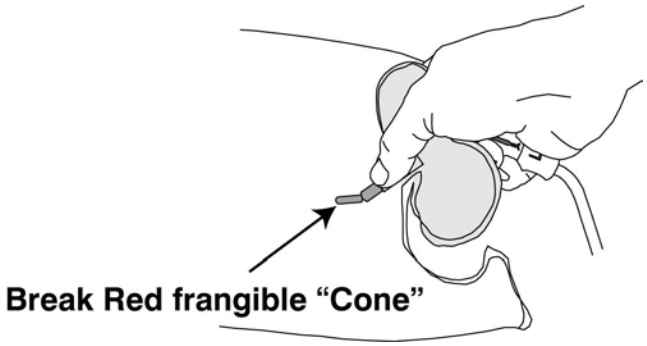

Figure D

2. Fold the Mini-Bag in half. Firmly squeeze the solution from the Mini-Bag into the Main Solution Bag by pressing the two halves together until the Mini-Bag is empty. See **Figure E**.

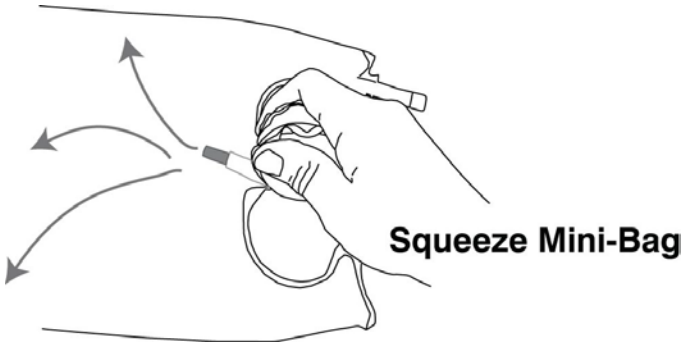

Figure E

3. Push down on Main Solution Bag to flush solution back into Mini-Bag. Completely refill the Mini-Bag with solution. See **Figure F**.

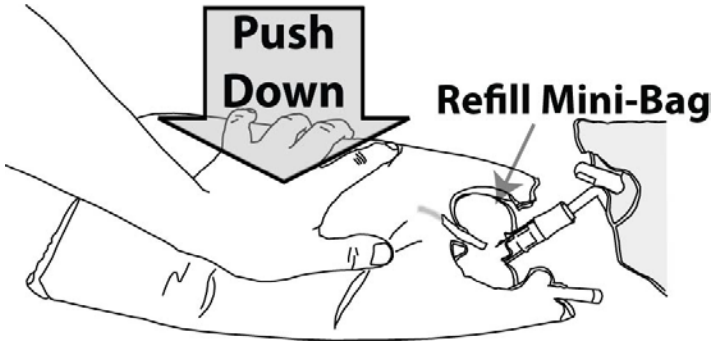

Figure F

4. Repeat **Step 2 (Figure E)** and **Step 3 (Figure F)** above, at least one time, to make sure that all of the contents of the Mini-Bag have been completely flushed into the Main Solution Bag.
5. Grasp the bottom end of the Main Solution Bag. While keeping the hanger end (top) portion of the bag on the table, flip the bag lengthwise using a back and forth motion to mix the solutions. See **Figure G**. Repeat this step to mix solution thoroughly.

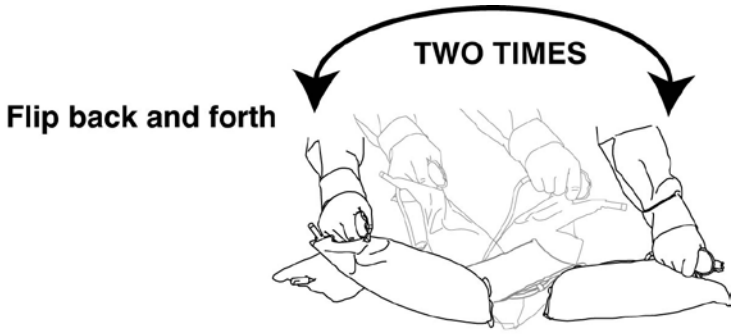

Figure G

6. With the Main Solution Bag still on the table, position it so that the “slit” in the white slide-lock connector cover is facing up.
7. Fold Mini-Bag in half and squeeze it empty of solution.
8. Slide the folded Mini-Bag into the “slit” of the white slide-lock connector cover. Ensure that the entire “grip” area of the Blue frangible is exposed. If the square “grip” area is not exposed slide the slide-lock connector cover further onto the folded Mini-Bag to expose the “grip”. See **Figure H.** Solution may flow back into the Mini-Bag slightly, this is normal.

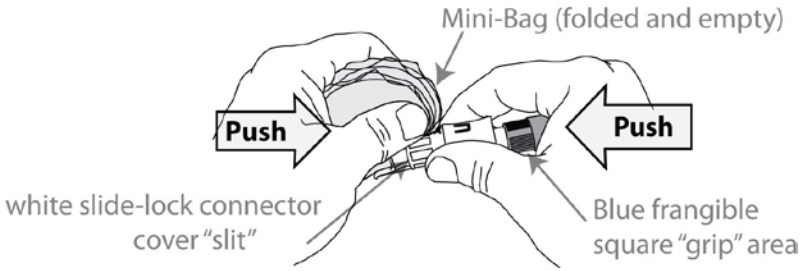

Figure H

The solution is now ready for use.

Administer DELFLEX® Neutral pH Peritoneal Dialysis Solution

1. If you will be adding medication(s):
   - Clean the medication port as instructed by your healthcare provider.
   - Add the medicine(s).
   - Turn the bag upside down several times to mix the medicine(s).
2. Hang the solution bag from the I.V. pole. Place the drain bag at floor level.

3. Break the Blue frangible "Cone" by placing one hand on the Blue frangible square "grip" area and placing the other hand on the white slide-lock connector cover and bending it. See **Figure I**. (If using the Organizer, place the stay•safe® disc in the Organizer as shown in **Figure J**).

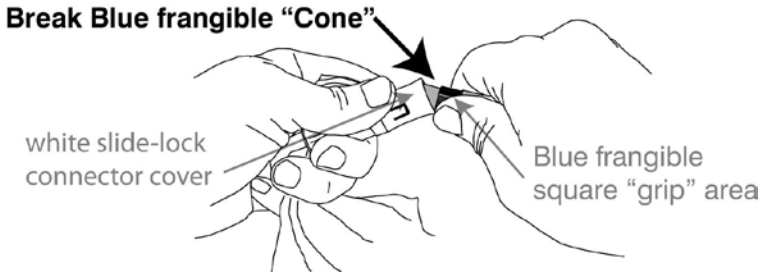

Figure I

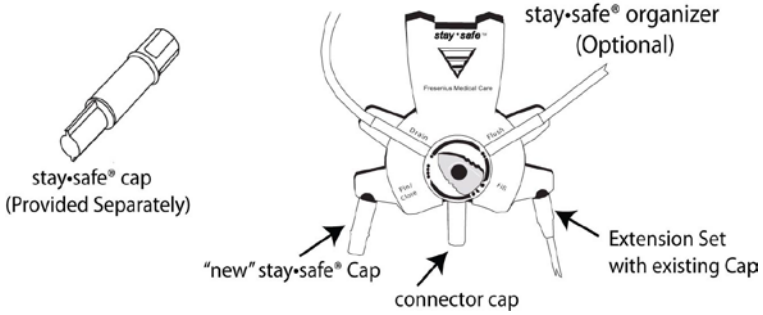

Figure J

4. Remove the new stay•safe® Cap from its package. (The new stay•safe® Cap is the stand alone item provided to the patient separately). **See Figure J**. (If using the Organizer place the new stay•safe® Cap in the left notch of the Organizer. Place the existing cap of the stay•safe® Extension Set, connected to the patient's catheter, in the other notch of the Organizer. See **Figure J**).
5. Aseptically remove the connector cap from the stay•safe® disc and throw the cap away. See **Figure J**. Remove the existing cap from the Extension Set connected to the patient's catheter by twisting the connection counter-clockwise. (If using the Organizer,

leave the capped end of the Extension Set in the Organizer and twist the Extension Set connector counter-clockwise to remove the set from its cap).

6. Aseptically connect the Extension Set to the connector on the stay•safe® disc. Twist clockwise to secure the connection.
7. Remove your mask. Do not open the system during exchange.
8. Open the Extension Set clamp to start drain.
9. When patient drain is complete, turn the stay•safe® disc position indicator to Position 2 (••). See **Figure K**. This will start flush from the solution bag to the drain bag.

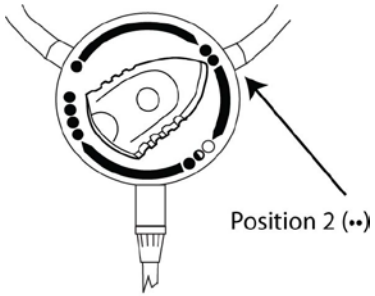

Figure K

10. After approximately 5 seconds turn the stay•safe® disc position indicator to Position 3 (•••). See **Figure L**. This will start the patient fill.

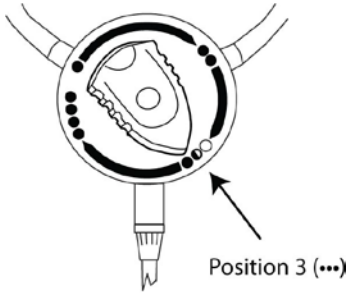

Figure L

11. When fill is complete, turn the stay•safe® disc position indicator to Position 4 (••••). See **Figure M**. This will insert the closure pin of the disc into the Extension Set connector and seal the system.

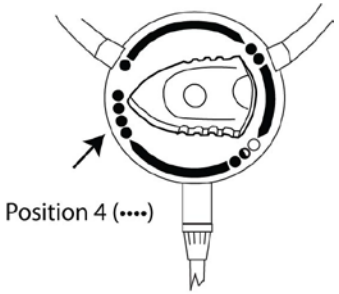

Figure M

12. Close the clamp on the Extension Set. Remove the white protective cover from the new stay•safe® Cap. Save for later use.
13. Remove the Extension Set from the stay•safe® disc and attach the new stay•safe® Cap. Twist clockwise to secure the connection.
14. Seal the disc by attaching the white protective cover from the new stay•safe® Cap to the disc connector. Twist clockwise to secure the connection and prevent leakage from the used system.

15. Look at the drained fluid for cloudiness. Measure the amount of fluid drained. Throw away the fluid and used set as instructed by your healthcare provider. **In case of cloudiness, save the fluid and the used set and immediately contact your healthcare provider.**