



The PD Revolution Continues

**stay·safe**<sup>®</sup>  
Advancing PD Connectology  
Fresenius Medical Care



## Another revolutionary innovation from Fresenius Medical Care

Fresenius Medical Care is the world's largest, integrated provider of products and services for people affected by chronic kidney failure. As the worldwide leader, we are committed to raising the standards of peritoneal dialysis by continuing to develop innovative dialysis products. We understand all the components of home therapy and are dedicated to improving the quality and convenience of this therapy.

By consolidating our resources and unifying our worldwide network, we are able to offer you and your patients an unprecedented resource for home therapy.

With a history of superior quality outcomes and state-of-the-art technological achievement, we lead the field in developing programs and therapies that instill renal patients with confidence. We are continually exploring new technologies in our quest to provide superior products and services to optimize patient handling and safety.

Fresenius Medical Care now offers stay•safe. This new generation of PD connectology offers even easier handling and is designed to reduce risk associated with touch contamination secondary to fewer connections.

## Connectology Simplified



The heart of the stay•safe CAPD system is the disc, which is a central control dial that walks the patient through the treatment steps – Drain, Flush, Fill, & Close. The patient simply turns the dial to advance from one step to the next... no more need for clamps!

## CAPD

**Drain**  
To begin the CAPD exchange, simply connect to the stay•safe CAPD system and turn the stay•safe dial to Position 1, Drain. Draining will begin immediately upon the release of the catheter extension set clamp. The drain should take about 20-30 minutes.

**Flush**  
When Drain is complete, turn the dial to Position 2 to flush. Flushing will begin immediately.

**Fill**  
Following the Flush procedure, turn the dial to Position 3 to begin the Fill step. The Fill normally takes 10 to 15 minutes.

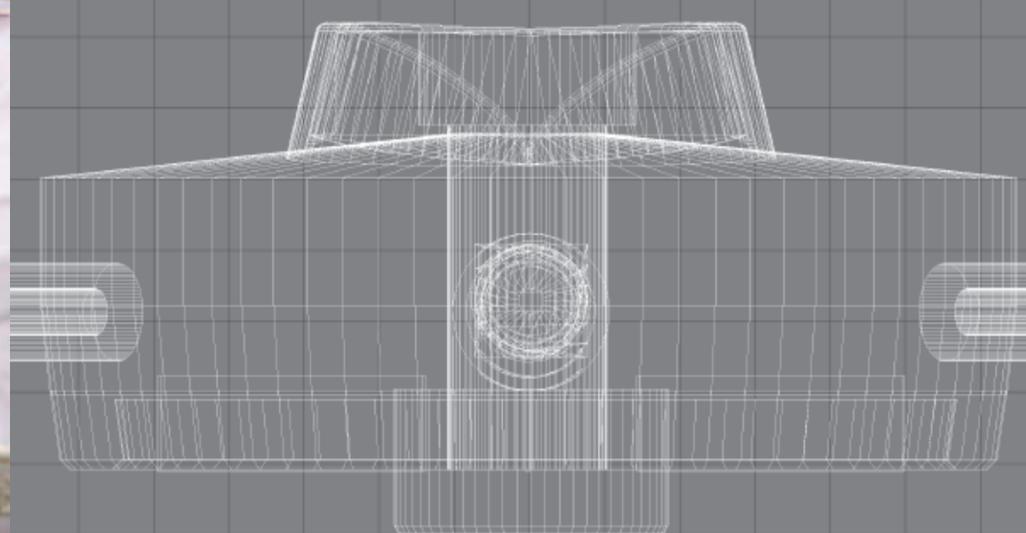
**Close**  
When fill is complete, turn the dial to Position 4 to Close. This step automatically inserts a pin into the patient's extension set, which may help to minimize the risk of touch contamination while disconnecting.

The stay•safe disc is now disconnected from the extension set. A protective cap is then placed over the PIN to secure it in place to further protect the connection from touch contamination via a povidone iodine bath.

## APD

At the end of the prescribed treatment, the disconnect procedure is as simple as the push of a button. Simply turn the PIN trigger clockwise until it stops. Press the trigger button to release the PIN into the catheter extension set. Connect the stay•safe protective cap to the catheter extension set for further protection from touch contamination.

Now patients can easily transition from CAPD to APD.



stay•safe, the newest generation of PD connectology offers easy handling with the benefit of one system opening per exchange. The heart of the stay•safe system is the disc, which is a central control dial that walks the CAPD patient through each treatment step – Drain, Flush, Fill, & Close. The innovative PIN for both CAPD and APD is designed to seal the fluid pathway prior to disconnect minimizing the potential for touch contamination.

With stay•safe, there's no need to memorize a confusing sequence of clamping and unclamping steps. By eliminating confusion, the potential risk associated with accidental touch contamination of the system may be reduced.

## Easy to learn, and easy to use.

Issad et al., evaluated the relationship between enhanced patient product handling and satisfaction with the reduction of handling errors and infection risk potential. In a 116 patient, 29 center study, patients were asked to evaluate the handling of the stay•safe system. Patients were asked to evaluate overall satisfaction with the stay•safe system three times during a 12-month period. Results were very favorable, with high overall satisfaction. These patients were found to maintain these high satisfaction levels over long-term use. Peritonitis incidence was noted at 1 episode every 38 patient months (30 episodes).<sup>1</sup>



**Reduced connections.**  
**Reduced risk potential.**

## Advancing PD Connectology

The heart of the stay•safe system lies in its PIN technology. The uniquely designed PIN is automatically inserted into the lumen of the patient's catheter which closes and is designed to seal the system prior to disconnect, which may minimize the risk of touch contamination secondary to fewer connections.

### Improved Ease of Handling

With only one system opening required per treatment and the elimination of cumbersome clamping and unclamping procedure, the stay•safe system has simplified the exchange procedure even further.

## Reduced contamination potential

Peritonitis is the most frequent, serious complication of continuous ambulatory peritoneal dialysis. Recognizing the need to reduce the potential for infections caused by touch contamination, major focus has been placed on CQI programs, Patient Education initiatives as well as PD system enhancements.

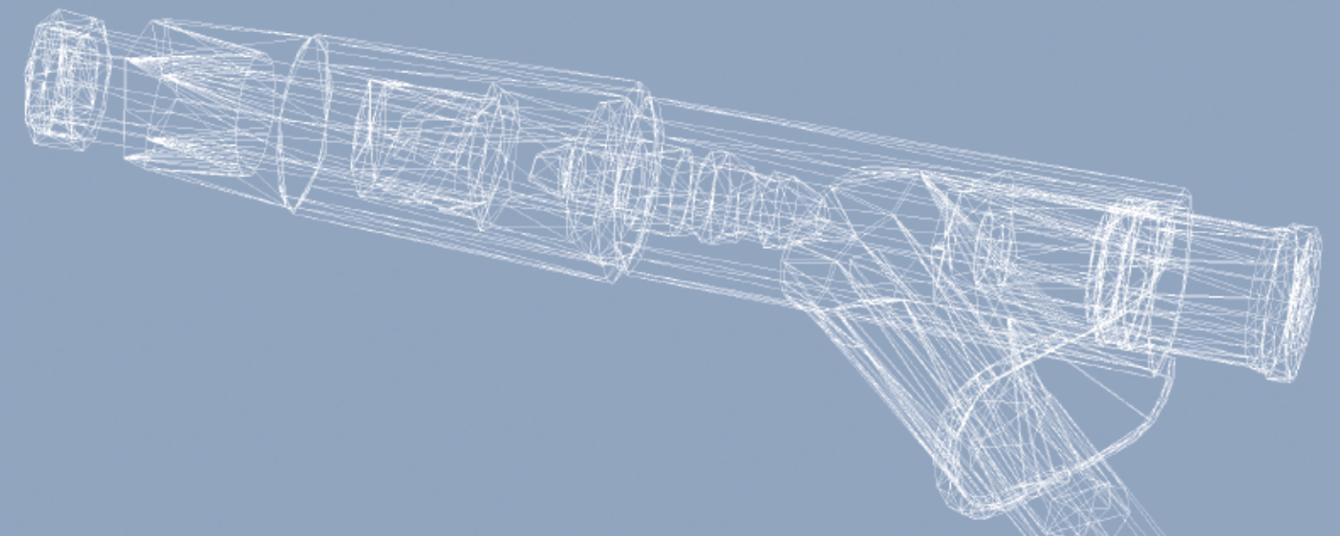
Sources cite lower rates of infection directly corresponding to the reduction in the number of connections and disconnections associated with PD systems.

It is believed that the potential for touch contamination may be reduced with the improved ease of handling associated with a double-bag system. For example, Daly et al performed a systematic review of randomized or quasi-randomized controlled trials comparing double-bag and Y-set CAPD exchange PD systems in patients treated with CAPD. Twelve trials with a total of 991 randomized patients were included. Fewer patients experienced peritonitis among those patients using double-bag systems and Y-sets as compared with standard systems. Furthermore, fewer patients experienced peritonitis (OR 0.44, 95% CI 0.27-0.71) and the number of patient-months on CAPD per episode of peritonitis was also greater when double bag systems were compared to Y-sets.<sup>2</sup>

In a retrospective analysis of a 29-month experience with 33 CAPD patients utilizing the stay•safe system, Basile, et al., reviewed the peritonitis (P) occurrence against the previous 60-month experience with 35 CAPD patients on conventional systems (Bieffe, Sifra). The same standard surgical, medical or training procedures were applied to both groups. The data show a reduction of CAPD-related P: 1 peritonitis episode in 51.1 patient months for stay•safe versus 1 in 19.4 patient months for these conventional systems.<sup>3</sup>



Number of Connections Based on 4 Exchanges Per Day						
	Catheter Connections		Bag Connections		Total Connections	
	per day	per year	per day	per year	per day	per year
stay•safe®	4	1460	0	0	4	1460
Conventional System	8	2920	0	0	8	2920



# Our Program and Patient Support Services

## Clinical Consulting Services

Partnering with your PD Clinic staff, we offer product inservices, transition support, and assist in the development of strategies for program growth and improved outcomes.



## Professional Support PD Resource Center

Staffed by experienced, certified nephrology nurses, our PDServe Professional Resource Center offers direct consultation for nephrologists and nurses. 1-888-557-3737. PDServeNA@fmc-na.com



## Web Site

Our Web Site, [www.advancedrenaeducation.com](http://www.advancedrenaeducation.com) offers the dialysis professional access to comprehensive on-line educational materials and resources.

## Professional Workshops

Providing educational offerings for both nephrologists and nurses, workshops include on-line and instructor-led novice and advanced curricula.



## Technical Support

Trained professionals offer APD technical support 24/7. 1-800-227-2572

## Customer Service

Our New Patient Team offers your new patients the extra support they need. A dedicated Customer Service Team is assigned to work with the dialysis clinic staff and patients to manage product supplies. The latest communication technology and our comprehensive staff training allow us to service your patients quickly and efficiently.



## TruBlu Logistics Outstanding Delivery Services

Our delivery specialists deliver products directly to your patient's home, placing supplies conveniently and rotating supplies. They evaluate the home environment and provide feedback to your team. We strive for very high service levels, with approximately 99% of home patient orders filled accurately. We have a special name for our delivery services. It's called TruBlu Logistics. The truck delivering your supplies will have TruBlu on the side and drivers will wear uniforms with this logo. The trucks and drivers are of course Fresenius Medical Care, North America but we've changed the name to protect your privacy.

## Hospital Support

We offer assistance in educating hospital staff on peritoneal dialysis patient care. In addition, we offer ongoing on-line education programs specifically designed for the hospital RN unfamiliar with PD or the Fresenius Medical Care product portfolio.

## Transition Support Teams

A specialized multidisciplinary team works with the Clinic staff to develop a product transition plan. Through our vast experience, we have developed simple tools and systems to assist you and your patients every step of the way.

## Kidney Options® Program

Kidney Options® is a comprehensive Pre-ESRD education program, designed to educate pre-dialysis patients on their treatment options. Program offerings include staff training, marketing, and patient education resources, including [www.kidneyoptions.com](http://www.kidneyoptions.com) our hallmark web site.

## Patient Education Materials

Through our success@home program, a variety of patient education materials are available for use in educating patients on PD therapy. Over 30 tools are available, including flip charts, training manuals, brochures, procedure cards, and videos.

## DELFLX® Peritoneal Dialysis Solution with Attached stay•safe® Exchange Set Peritoneal Dialysis Solution with Dextrose

Fill Volume	Bag Size	Dextrose %	Low Ca <sup>+</sup> , Low Mg	Std Ca <sup>+</sup> , Low Mg
1500	2000	1.5%	054-15221	054-15201
		2.5%	054-15222	054-15202
		4.25%	054-15224	054-15204
2000	2000	1.5%	054-20221	054-20201
		2.5%	054-20222	054-20202
		4.25%	054-20224	054-20204
2500	3000	1.5%	054-25321	054-25301
		2.5%	054-25322	054-25302
		4.25%	054-25324	054-25304
3000	3000	1.5%	054-30321	054-30301
		2.5%	054-30322	054-30302
		4.25%	054-30324	054-30304

### Extension Sets

050-95014 6" stay•safe extension set with Safe-Lock  
050-95001 12" stay•safe extension set with Safe-Lock  
050-95002 18" stay•safe extension set with Safe-Lock

050-95013 6" stay•safe extension set with Luer-Lock  
050-95004 12" stay•safe extension set with Luer-Lock  
050-95005 18" stay•safe extension set with Luer-Lock

### Cycler Sets

050-87208 Newton IQ cycler set with 2 stay•safe PIN technology connectors  
050-87211 Newton IQ cycler set with 1 stay•safe PIN technology connector  
050-87212 Liberty cycler set with 2 stay•safe PIN technology connectors  
050-87215 Liberty cycler set with 1 stay•safe PIN technology connector  
050-87216 Liberty integrated cycler set with 1 stay•safe PIN technology connector

### Adapters:

050-95003 stay•safe Luer-Lock Adapter  
050-95006 stay•safe Safe-Lock Adapter

### Organizers

030-10807 stay•safe organizer  
030-10808 stay•safe organizer holder  
030-10809 stay•safe organizer APD adapter (clip)

### Miscellaneous

050-95012 stay•safe caps  
030-10810 stay•safe Handi-Tool  
050-50758 stay•safe Multiple Tubing Set (MTS)  
026-20030 stay•safe Drain set

## DELFLEX®

### Dextrose Peritoneal Dialysis Solutions With Attached stay•safe® Exchange Set

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<sub>2</sub> 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 continuous ambulatory peritoneal dialysis, when nondialytic medical therapy is judged to be inadequate.

#### CONTRAINDICATIONS

None Known.

#### WARNINGS

NOT FOR INTRAVENOUS INJECTION.

#### USE ASEPTIC TECHNIQUE.

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, which carries 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 electrolyte blood chemistries and hematologic factors, as well as other indicators that determine the patient's ongoing status.

#### PRECAUTIONS

##### GENERAL:

Do not administer unless the solution is clear, all seals are intact and there is no evidence of leaking. Care should be taken to see that the catheter is inserted completely, since leakage around the catheter, if not controlled, can create edema from subcutaneous infiltration of the dialysis solution. This will also create an inaccurate fluid balance measurement.

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.

The overwrap must be removed immediately before use and is provided with a "Tear Open" feature to make removal easy. See instructions in Exchange Procedure section. Disconnect from disk only when knob is in position 4 (●●●●).

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

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

#### 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 reproductive 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 to 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 may 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.

**REFERENCES:** <sup>1</sup>Issad, B. et al, stay•safe®; New PVC free system for CAPD: Results of a French multicentre survey\* <sup>2</sup>Daly C, Campbell M, MacLeod A, Cody J, Vale L, Grant A, Donaldson C, Wallace S, Lawrence P, Khan I, "Do the Y-set and double-bag systems reduce the incidence of CAPD peritonitis?" Nephrol Dial Transplant (2001) 16: 341-347. <sup>3</sup>Basile C, DePadova F, Giordano R, Montanaro A, De Malo P, Di Marco L, Ligorio VA, Semeraro A, "The Incidence of Peritonitis (P) Declines after Implementation of the Stay-Safe-System (SSS)." Blood Purif 2001; 19:73-106.\*

\*abstracts reflect the individual authors' opinions and experience only. Infection rates are impacted by multiple factors – FMCNA does not make any claims related to infections.



Fresenius Medical Care

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P/N 100371-01 Rev 02 09/2009