A.N.D.Y.®•disc

The easy and safe double-bag system for CAPD

Fresenius Medical Care

Evolving towards the perfect product

Ensuring adequate patient care in an improved biocompatible manner is the principle that guides Fresenius Medical Care in the development of its products. We have applied this principle to the popular double-bag A.N.D.Y. PLUS® system, replacing the “clamp and snap” system with the new DISC and PIN technology. The result is A.N.D.Y.®•disc, which provides more safety and more ease of use both to the patient and to the physician.

Easier to use with the DISC and PIN technology.

The operation of the DISC’s internal valves simplifies handling during bag exchanges and significantly improves safety for all patients, including those with impaired sight or manual dexterity. The patient adjusts all the steps of the treatment by simply turning the DISC in a single direction. The clamps and internal guards are no longer necessary.

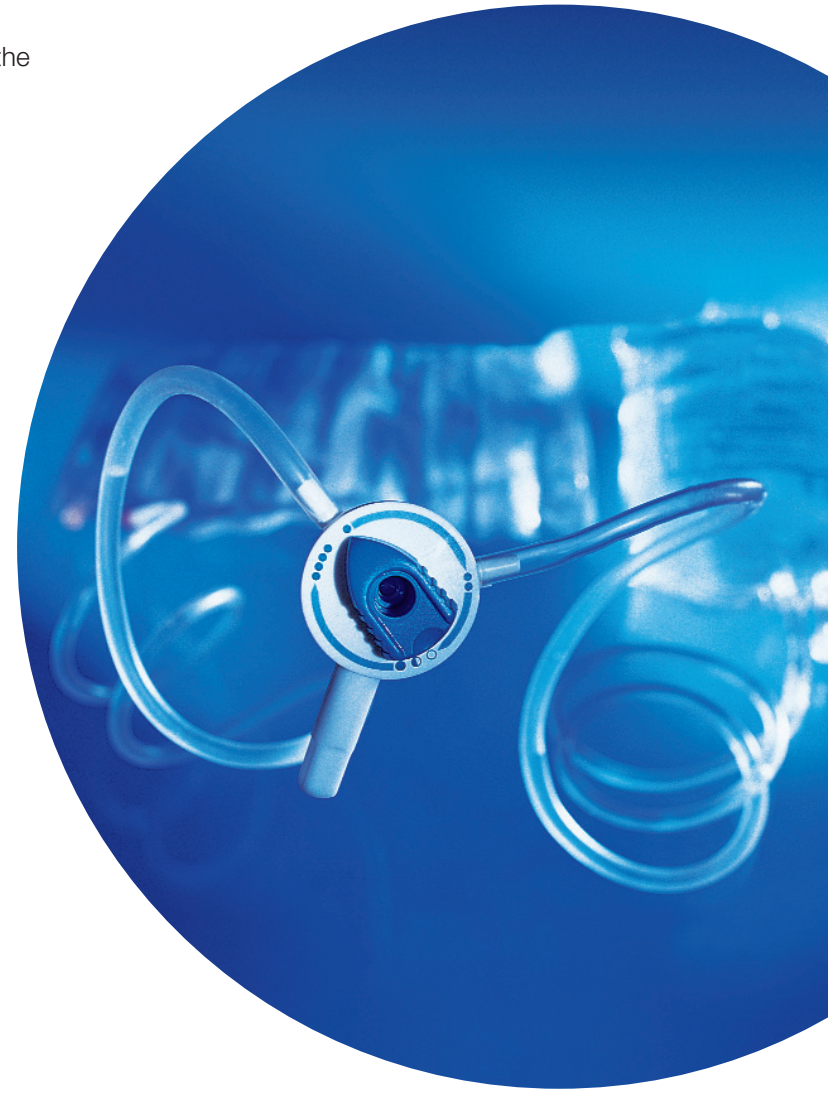
Errors such as clamping the wrong line or forgetting to flush are with this technique related to the past.

The automatic closure performed by the PIN technology, in addition to protecting against contamination, simplifies the bag exchange procedure for the patient.

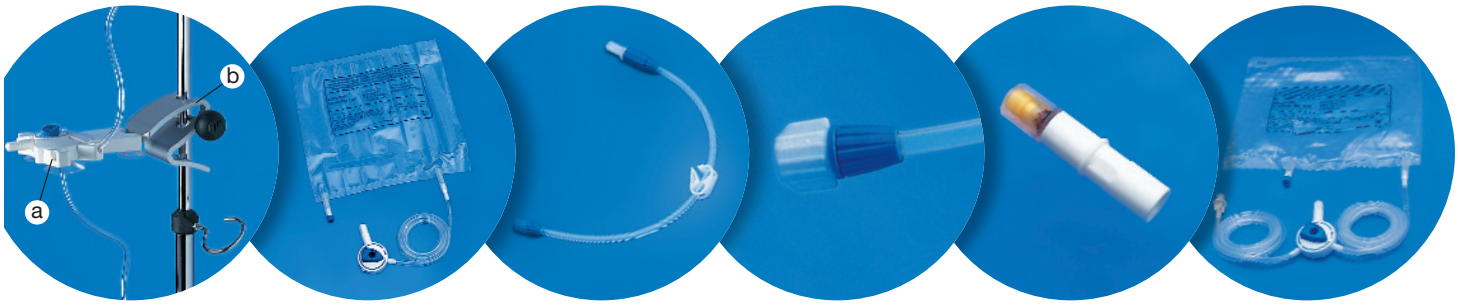
Improved safety in CAPD with A.N.D.Y.®•disc

Each part of the A.N.D.Y.®•disc has been designed considering the safety of the system as a whole. The introduction of the DISC reduces the number of potentially hazardous steps, thereby minimising the risk of contamination.

- With its ease of handling, patient training is quicker, safer and simpler.
- Reduced risk of contamination through minimum number of risk-steps.
- The core of the A.N.D.Y.®•disc is made using Polyolefine (Biofine®) material.



Accessories



a: stay•safe® Organizer
Art. No. 284 256 1

b: stay•safe® Holder
Art. No. 284 257 1

stay•safe® Drainage Set
Art. No. 209 990 1

stay•safe® Luer-Lock Catheter Extension
Art. No. 284 247 1 (25 cm)
284 248 1 (40 cm)

Luer-Lock Catheter Adapter
Art. No. 284 267 1

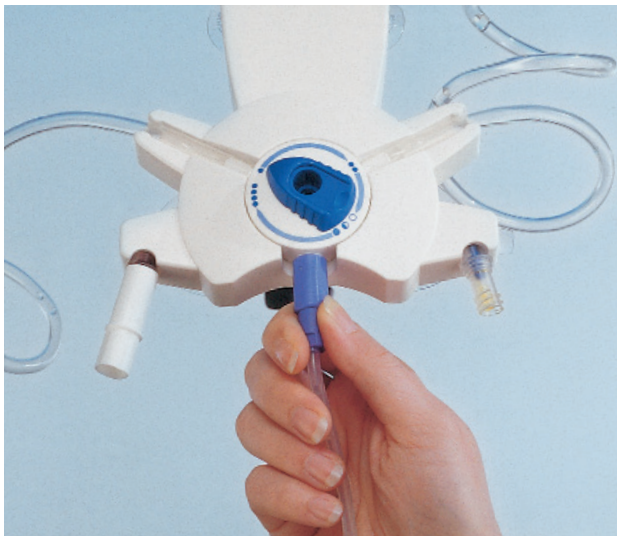
stay•safe® Disinfectant Cap
Art. No. 284 509 1

stay•safe® Luer-Lock S
Art. No. 209 991 1

Four Steps to Success

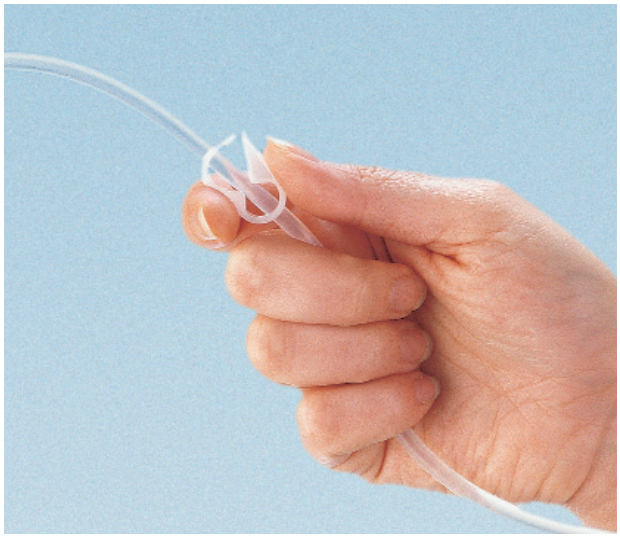
Easy handling with the DISC

The following description explains how the DISC is used.



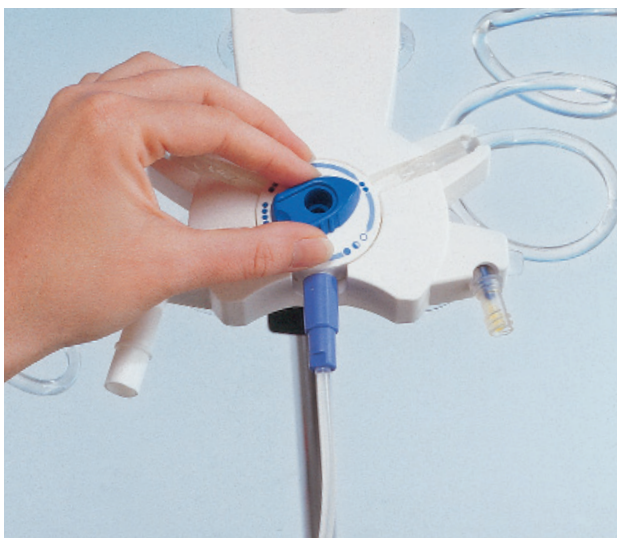
Connecting the new system

Unscrew the catheter adapter from the disinfection cap and connect it to the DISC. (Unscrew the protection cap of the DISC and discard it). The used disinfection cap (with the PIN) remains in the organizer.



1. Drainage or emptying

Open the clamp on the catheter extension. The DISC's control wheel is already in the "Drainage" position "●". The emptying process starts.



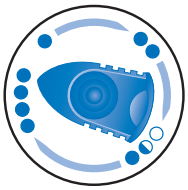
2. System flush

Turn the control switch of the DISC clockwise to the position "●●". The flush starts by making a connection between the solution and the drainage bag. (Count to 5).

3. Inflow

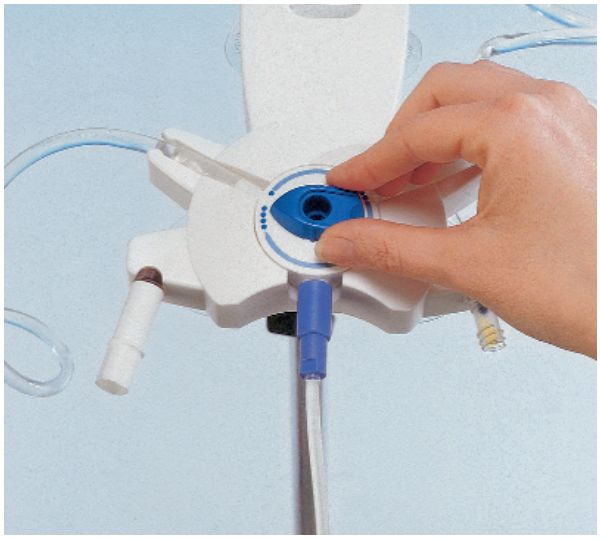
Turn the control switch of the DISC clockwise until you reach the position "○◐●" when the connection between the bag and the catheter is made. Turning the control switch of the DISC between the three dots "○◐●" makes it possible to control the flow rate.

"○" no inflow
"◐" half inflow rate
"●" full inflow rate



4. Automatic closing with the PIN (security step "●●●●")

After the inflow procedure has been completed, turn the control wheel to the very end position which is "●●●●". The closure of the catheter adaptor is done automatically by introducing the PIN.



Note: if you wish to stop the procedure during any step of the exchange, please turn the control switch to the position "●●●●" (Security Closure with the PIN).

Information

CAPD/DPCA 2, 3, 4 A.N.D.Y.®•disc

Composition:

1 litre of the ready-to-use solution contains:			
Active substances (g/l)	**CAPD/ DPCA 2**	**CAPD/ DPCA 3**	**CAPD/ DPCA 4**
Sodium chloride	5.786	5.786	5.786
Sodium lactate (as sodium lactate solution)	3.925	3.925	3.925
Calcium chloride $2H_2O$	0.2573	0.2573	0.2573
Magnesium chloride $6H_2O$	0.1017	0.1017	0.1017
Anhydrous glucose (as glucose-monohydrate)	15	42.5	22.73

1 litre of the ready-to-use solution contains:			
Active substances (mmol/l)	**CAPD/ DPCA 2**	**CAPD/ DPCA 3**	**CAPD/ DPCA 4**
Na^+	134	134	134
Ca^{2+}	1.75	1.75	1.75
Mg^{2+}	0.5	0.5	0.5
Cl^-	103.5	103.5	103.5
Lactate	35	35	35
Theoretical osmolarity (mosm/l)	358	511	401

Excipients: Water for injections, hydrochloric acid, sodium hydroxide.

Indications: End-stage chronic renal failure of any origin treated with peritoneal dialysis.

Contraindications: Hypokalaemia, hypercalcaemia. Solutions containing 2.3% or 4.25% glucose additionally: reduced body fluids (hypovolaemia) and low blood pressure.

Treatment related: Recent abdominal surgery or injury; severe abdominal burns; extensive inflammation of the abdominal skin (dermatitis) in the region of the catheter; peritonitis; abdominal perforation; a history of multiple operations with adhesions or fibrous adhesions; inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis), intra-abdominal tumours; ileus; umbilical, inguinal or other abdominal hernia; internal or external abdominal fistula; pulmonary disease, esp. pneumonia; sepsis; hyperlactataemia; extreme malnutrition (cachexia) and weight loss, particularly in cases in which an adequate protein supplement is not guaranteed; in rare cases of ureaemia, which cannot be managed by PD, extreme hyperlipidaemia; in patients who are physically or mentally incapable of performing peritoneal dialysis as instructed by the doctor. Please note that premature discontinuation of peritoneal dialysis therapy may have life-threatening consequences, if no other renal replacement therapy is carried out. Pregnancy and breast-feading: only after evaluation of benefit versus risk for mother/child by the treating doctor. Children: the dialysate volume should be reduced in accordance with age, size and body weight. Elderly patients: the increased incidence of hernia should be taken into account.

Side effects: Possible treatment related side effects: peritonitis; infections of the catheter exit site and tunnel, sepsis. Peritoneal loss of proteins (5–15 g/day), amino acids (1.2–3.4 g/day) and water-soluble vitamins, hypoproteinaemia; Transport characteristics of the peritoneal membrane may change during longterm peritoneal dialysis primarily indicated by a loss of ultrafiltration. Abdominal distension; in- and outflow disturbances of the dialysis solution; hernia; shoulder pain; breathing difficulties caused by elevation of the diaphragm, diarrhoea and constipation.

Possible solution related side effects: disturbances of electrolyte balance such as hypercalcaemia, hypokalaemia. Low blood pressure and hypovolaemia (solutions containing 2.3% or 4.25% glucose); hyperhydration and dehydration; hyperglycaemia; dyslipoproteinaemia; increase in body weight.

Drug interactions: The use of these peritoneal dialysis solutions can lead to a loss of efficacy of other medicinal products if these are dialysable through the peritoneal membrane. A distinct reduction of serum-potassium-level can increase the frequency of digitalis-associated adverse reactions. The concomitant administration of calcium-containing medicinal products or vitamin D may cause hypercalcaemia. The use of diuretic agents may result in water and electrolyte imbalances. In diabetic patients the daily dose of blood sugar reducing medication must be adjusted to the increased glucose load.

Warnings and precautions: Do not use unless solution is clear and container undamaged. Any unused portion of the solution is to be discarded. Do not store above 25°C. Do not refrigerate or freeze. Keep out of the reach of children. Addition of medication to the dialysis solution is only to be undertaken on the instructions of a doctor. Aseptic conditions must be maintained during exchange of the dialysate bag. Levels of serum electrolytes, blood sugar, serum protein, parathyroid hormone and concentrations of creatinine and urea as well as acid-base balance and fluid balance should regularly be monitored.

Date: May 2004,
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