



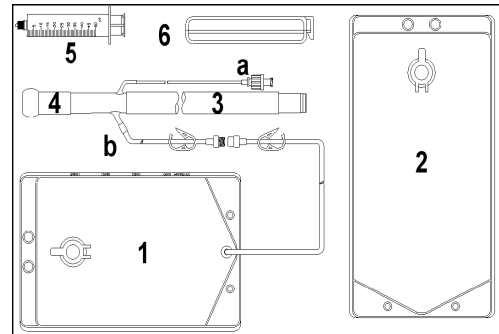
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## Coloclean® Instructions for Use

### Contents

- 1 2 litre irrigation bag with luer lock connector and clip (1)
- 1 3 litre discharge bag with plug connector and sealable valve (2)
- 1 silicone collection tube (1.5 m) with adaptor for the collection bag (3)
- 1 cuffed rectal tube (4) with silicone balloon and connectors for:
  - balloon filling lumen with cuff (a)
  - irrigation lumen with screw connector and clip (b)
- 1 Syringe with luer lock connection to block balloon in correct position (5)
- 1 clip for silicone discharge tube (6)
- 1 bag stand for each pack containing 10 units

**Materials** PVC, Silicone, ABS



### Precautions

-The system must not be re-assembled for re-use because doing so will cause changes to the equipment which will render it impossible to ensure safe use of the system. No procedures for re-assembling the system have been tested or approved. If the system is re-assembled and re-used this will constitute an infringement of the instructions for proper use and will lead to an increased risk in the malfunctioning of the product

-This product contains DEHP.

-This product must be used only by staff who understand the risks involved in inserting intestinal tubes via the rectum and who have been properly trained to carry out this procedure.

- Do not use the irrigation bag support stand to lift the discharge bag once this is full. This support will not bear the weight of the full discharge bag and this may cause the bag to become disconnected from the system.

### Uses

The **Coloclean®** bowel management system is used for bowel irrigation and artificial evacuation of the rectum in adults under medical supervision. This procedure should not last for more than one hour. Bowel irrigation may be used as a preparatory measure for:

- Diagnostic procedures, such as
  - Clinical investigations like rectoscopy, sigmoidoscopy
  - Colonoscopy
  - For introducing radiology contrast media into the bowel
- Therapeutic measures:
  - Ante-natal procedures
  - In paralytic ileus
  - To promote colonic peristalsis
  - In obstipation (constipation) and solid stools
  - In pre-surgical preparations for visceral surgical interventions
  - To promote defaecation as part of a fasting program
  - To reduce fever
  - In cirrhosis of the liver (Lactulose enemas)
  - In hyperkalemia (resonium enemas)

### Contraindications

The **Coloclean®** bowel management system should not be used in:

- Perforated bowels
- In acute
  - Mechanical ileus (intestinal obstruction)
  - Following post-surgical abdomino-surgical interventions
- Abdominal symptoms of unknown cause (abdominal pain, vomiting)
- Cases where there is bleeding in the
- Stenoses and strictures in the rectal area
- Tumours and other pre-cancerous growths
- Where it is possible that a woman may become pregnant; use with care if woman is already pregnant
- Where there is a prolapse in the anal and/or rectal region
- Cases of congenital deformity (e.g. megacolon)
- Cases of haemorrhoids
- Where there are intestinal fistulas
- Irritable bowel syndrome.

- Diverticulitis or diverticulosis
- Inflammatory bowel conditions (e.g. Crohn's disease, ulcerative colitis)
- Bowel invagination
- Coproliths

### Risks

Improper use of this equipment may result in perforations to, bleeding in and other serious injuries to the bowel.

### Use

When using this equipment for anatomical reasons the patient should be lying on their left side in a comfortable position with the knees slightly bent. Smear the tip of the irrigation tube with lubricating gel before insertion in order that the insertion is made as smoothly as possible. Insert the tube into the rectum whilst twisting it with a slight circular motion. Once the irrigation tube is correctly positioned it can be "blocked" into position using air from the syringe supplied and attached to the luer lock connector. This will prevent the accidental slipping out of position of the rectal tube. The rectal tube is correctly positioned if it is blocked into position directly behind the sphincter muscle.

**Caution:** When using air from the syringe to block the rectal tube into position care must be taken not to inject more than 60 ml of air via the connector of the balloon fill lumen. This quantity of air must never be exceeded or this could lead to compression of the bowel tissue which in turn can result in ischaemia (and reduced blood circulation) which can lead to necrosis or to the bursting of the balloon in the bowel.

Following insufflation, disconnect the syringe from the air supply tube. Use the plug connector on the silicon tube to connect it firmly to the discharge bag. Close the clip on the tube on the irrigation bag and fill the irrigation bag with approximately 2 litres of water warmed to body temperature.

### Caution:

The temperature of the liquid to be inserted into the rectum will influence the simulating action on the bowel. Generally the fluid to be inserted into the rectum should be at body temperature. Fluids inserted at colder temperatures (24-35°C) will result in increased stimulation of the bowel but will be experienced by the patient as being uncomfortable and may lead to the development of severe pains or cramps. Liquids inserted at higher temperatures will lead to a greatly increased danger of unconsciousness, especially in patients with unstable circulation.

Connect the irrigation tube with the connector of the adaptor for the irrigation fluid supply. Now lift the irrigation fluid sac above the level of the patient's bowel, open the clip on the irrigation tube of the irrigation bag and allow the fluid to run into the bowel. To control the quantity of fluid discharged in accordance with the age and the physical condition of the patient, the clip on the tube may be opened and closed to suit the patient's individual needs. The connection to the fluid supply should be closed before it runs out. Once the irrigation of the bowel has been continued for an appropriate length of time the discharge bag should be suspended below the level of the patient's bowel in order to ensure that fluid and excrement can run off unhindered. This procedure may be repeated as required. Once the discharge bag is full to capacity, use the clip to close the silicone tube so that the discharge bag may be changed without difficulty. Dispose of the full bag in the container for the disposal of faecal matter supplied. Once the colonic irrigation is complete the irrigation tube must be unblocked by inserting the syringe with the plunger pushed into the body of the syringe into the air supply tube. The plunger can then be withdrawn to suck the air out of the rectal tube.

### Caution:

If the patient complains of pain or if there is any resistance in the bowel during the insertion of the tube the procedure should be discontinued.

### Disposal

After the bowel management system has been used it is contaminated and liable to cause infection. It should therefore be disposed of in an appropriate waste container.



For single use only



Always follow the usage instructions



Lot number



Date of manufacture



Use by



Certification in accordance with RL 93/42