

IFU of Feeding Bag Set for Kangaroo 324 Feeding Pump

Intended use

Feeding bag for pump is used to transfer fluids with low viscosity, such as water, from an enteral reservoir to an enteral feeding catheter and the whole procedure is administered by feeding pump.

General description

The product consists of:

- 500 mL/1000 mL/1200 mL/ 1500mL bag with/without ice compartment for cooling the fluids.
- With closable filling port
- Can be connected to the enteral catheter which have male ENFit connector on it.
- With roller clamp.
- With ENFit Y-port.
- The whole bag set is Latex-free and DEHP free.

Contraindications for enteral feeding

Although the enteral route should always be the first option, there may be occasions when it is contraindicated. These include:

- 1) for the intravenous administration of infusion fluids.
- 2) if enteral feeding is contraindicated by medical prescription.
 - a) severe coagulopathies. It is recommended to check INR/PTT, Hemoglobin and platelets prior to procedure.
 - b) There is danger of perforation of the esophagus (recent esophageal repair, esophageal varices, esophageal strictures, gastric surgery, alkali ingestion).
 - c) recent gastric, duodenal, esophageal surgery
 - d) absence of intestinal function due to failure, severe inflammation or, in some instances, post-operative stasis.
 - e) complete intestinal obstruction.
 - f) inability to access the gut (i.e severe burns, multiple trauma).
 - g) high loss intestinal fistulae.
- 3) preterms (born < 37 weeks of pregnancy) and neonates (<1 month).
- 4) in Magnetic Resonance Imaging (MRI) environments.
- 5) in ambulances, helicopters, aircrafts and hyperbaric chambers.
- 6) ethical considerations (i.e terminal care)

Complications of enteral feeding

Potential complications which may arise during the enteral feeding procedure include:

- Nausea, Vomiting
- Large Gastric Residuals
- Diarrhea
- Constipation
- Peritonitis
- Dehydration
- Increased/Decreased Serum Electrolytes
- Leakage Around Tube
- Hypokalemia/Hypophosphatemia
- Hyperglycemia/Hypoglycemia
- Skin Excoriation
- Infection
- Granulation Tissue
- Pharyngeal or Oesophageal Pouch Perforation
- Precipitation of Variceal Bleeding

- a) stretched ostomy (i.e. feeding tube not secured to abdomen resulting in or excessive movement, site is always moist causing stoma to stretch and feeding tube is pulled too tightly causing the tract to stretch)
- b) abdominal distention (i.e. due to poor gastrointestinal motility, constipation)
- c) if balloon feeding device, may be deflated or tube or may have migrated further into stomach resulting in leakage around the internal securing device
- d) gastric outlet obstruction

Warning

1. Ensure this device is only connected to a male ENFit connector and not to an I.V. set.
2. Remove the device and discard per local hospital policy.
3. Contents are sterile in an unopened, undamaged package. Do not use this device if opened or damaged.
4. Avoid excessive heat. Protect from freezing.
5. Do not use for more than 24 hours.
6. Do not re-sterilize.
7. If it's the first time use this product, it's advisable to check the outlet volume with the setting volume.

Precaution

1. In order to protect users' health, please follow clean aseptic handling procedure for containers, sets or feeding tubes disposal.
2. Only Kangaroo 324 Feeding Pump can guarantee feeding reliability. Please refers to the compatible pump and compatible nutrition fluids.
 - Check the liquid container intended use regarding the feeding protocol, especially for patients requiring special

attention.

- Check the spike set and patient connection integrity before use.
- 3. The fluid in the giving set and the bag must be within normal temperature conditions: +10°/+40°C.
- 4. Set pump sound level to high before installation.
- 5. Do not put blended or pureed food or other liquids into the feeding bag.
- 6. Beware not to damage the portion of the tubing hanging between the feeding bag and the feeding tube.
- 7. See instructions for use of the pump before use the feeding bag.
- 8. This bag set can only connect with the ENFit connector which comply with EN ISO 80369-3.
- 9. Intended user:
 - a) Healthcare professionals who were trained in enteral feeding and management of the administration system.
 - b) Patients and cares (not professional) who were educated about and trained in the techniques of hand decontamination, enteral feeding and the management of the administration system before being discharged from hospital.

Direction for use

1. Read all warnings and precaution before using.
2. Make sure patient understand the procedure.
3. Pick out the bag and inspect it integrity for any cracks or breakage.
4. Liquid (e.g. water) should be at room temperature. Don't use refrigerated or hot liquid.
6. Check the expiry date of the liquid. Do not use expired liquid.
7. Close the roller clamp on the bag set.
9. Use one hand to hold the feeding bag filling port and the end of the catheter. Hold them in a vertical upright position so that the catheter makes a "U" shape.
10. Follow the tube feed schedule and pour the recommended amount of liquid into the feeding bag. Ensure the filling port is totally closed.
11. Keep the empty liquid container because you will use it later.
12. Keep the appropriate positions between patient, pump and feeding bag. Check the stability of the whole system. If the feeding bag is positioned lower than patient's head or 0.5 meter beneath the pump, this can lead to flow rate deviation.
13. Slowly open the roller clamp. The liquid should start to flow down the tube.
14. If the liquid is not flowing, try:
 - Squeezing the bag lightly.
 - Opening up the lid on the feeding container to allow some air in.
 - Squeezing the drip chamber.
15. Turn the drip chamber upside down. Let a little bit of the liquid fill the drip chamber (less than half full). Then turn the drip chamber upright again.
16. Remove the cap of the feeding container tubing. Place the end into the empty liquid container that you saved.
17. Close the roller clamp when the liquid gets to the end of the tubing.
18. Put the cap back on the end of the tubing.
19. Flush the feeding tube in patient's body with water once feeding bag is ready. Flushing feeding tube will make sure it is working well and is not blocked.
20. Fixed the pump set to the feeding pump according its instruction for use.
21. Open the roller clamp of feeding bag.
22. Start feeding procedure according to the feeding pump's instruction for use

Storage Conditions

- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet and fluorescent light.
- Store in manner preventing crushing.
- Stock rotation on first in first out basis.

Supplied

F01011	F01210	F01500	F70514	F71010	F71204	F71500	F50510	F51004	F51200
F01211	F01510	F00504	F71014	F71210	F71504	F50514	F51010	F51204	F51500
F01511	F00500	F01004	F71214	F71510	F70500	F51014	F51210	F51504	
F00510	F01000	F01204	F71514	F70504	F71000	F51214	F51510	F50500	
F01010	F01200	F01504	F70510	F71004	F71200	F51514	F50504	F51000	

More details and specifications please connect us.

Do not use if package is damaged	Consult instruction for use	Date of manufacture	Temperature limit	Not for use with I.V. connectors
Keep away from sunlight	Keep dry	Do not re-use	DEHP-free	Latex-free
Use-by date	Manufacturer	Authorised Representative in the European Community	Catalog number	Batch number
Medical Device	Sterilized using ethylene oxide	Ucomfor Scientific Co., Ltd. www.ucomfor.com LeKun Road, LeYu Town, 215621, Zhangjiagang City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA		Shanghai International Holding Corp. GmBH (Europe) Eiffenstr. 90, 20537 Hamburg GERMANY Made in China
				CE IFU-013 Rev-2100820