Series B Enteral Feeding Set Instructions for Use

1. Indications for Use/Intended use

[Indications for Use/Intended use]

The devices are used to deliver liquid nutrients (feeding solution) and/or water to patients via nasogastric, orogastric, nasojejunal, gastrostomy, and jejunostomy tubes. These enteral feeding sets are used with enteral feeding tubes and enteral feeding pumps.

[Indications]

Intended for any patients ages, including infant, child/adolescent and adult who are physically unable to eat and swallow or who are unable to get sufficient nutrition through eating and swallowing.

[Intended users]

1. Clinicians, nurses and dietitians with medical education.

2. Personnel who can read and understand the user manual.

3. Medical staff with knowledge of enteral feeding and management systems.

[Patient Population]

Adult and Pediatric (infant, child, and adolescent).

[Intended use environment]

Hospital and acute care settings, as well as long term and home care settings

[Clinical benefits]

The clinical benefit of Enteral Feeding Set is that it provide pipeline support for

nutrients delivered into human gastrointestinal tract by connecting feeding tube and feeding pump to forms a complete closed loop.

[Clinical performance]

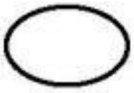
- ⩾80% of target energy infused by enteral feeding set
- Occlusion occurrence rate: ⩽23%

2. Warning instructions and precautions

The warning signs and graphic symbols in the manual are intended to enable you to use the product safely and correctly and to prevent harm to you and others. Warning marks and graphic symbols are described as follows:

Warning/precautions symbols	
 Warning	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 caution	Means a possibility of personal injury or property damage in case of improper use.
Notes	Indicates the need for attention, if not attention may lead to incorrect use of the product or property device damage.

3. Symbol description

	Batch code		Sterilization ethylene oxide
	Manufacturer		Date of manufacture
	Keep dry		Keep away from sunlight
	Use by date		Sterile
	Not made with DEHP		Single sterile barrier system

UDI	Unique device identifier	MD	Medical device
	Single use only	CE 2460	CE marking, Certificate issued by DNV (NB No.: 2460)
EC REP	Authorized representative in the European Community		Do not use if package is damaged
40℃ 5℃	Upper temperature limit (40℃) and lower limit (5 ℃) to which the medical device can be safely operated		Not For IV use
40°C 0°C	Upper temperature limit (40℃) and lower limit (0 ℃) to which the medical device can be safely stored and transported	STERILIZE	Do not resterilize
80% 0%	Humidity limitation	106kPa 70kPa	Atmospheric pressure limitation
	Consult instructions for use	LATEX	Not made with natural rubber latex

4. Safety information

Contraindications:

It is not recommended for infants under 3 months old and patients with uncontrolled shock, upper gastrointestinal bleeding, severe diarrhea or peritonitis, intestinal obstruction, severe trauma, intestinal fistula, severe coagulation disorder, bowel ischaemia/ileus.

Warning

1.This device is only used for enteral feeding. It is recommended to replace the

feeding set no more than every 24 hours.

2.The product is intended for single use only, open the package and use it directly. If the package is damaged, do not use it.

3.This product should be operated by professional medical personnel with relevant qualifications.

4.It needs to be monitored during use. If there is leakage or other unexpected situations, stop using it immediately.

5.Use of expired products is prohibited. Please destroy the product in time according to local and national regulations.

6.Because of its sterility, the products should be used immediately after unsealing. It should not be placed for a long time.

7.The product is sterilized with ethylene oxide and is sterile before the package is opened or damaged. Re-sterilization is prohibited. Re-sterilization will compromise the structural integrity of the device or biological infection.

8.If packaging is found to have been damaged, or intentionally opened before use, it is strictly prohibited to use it, and the unusable products will be destroyed to prevent misuse. Follow good clinical practice and all local and national regulations for transportation and disposal.

9.Do not reuse the product. It is intended for single use only. Re-use of this device may increase risk of leakage or biological infection.

10.The product may become a source of infection and have altered performance after use and in case of reuse. Do not re-use the product. After use, dispose of device per

hospital protocols and/or local or national regulations.

11.The maximum service pressure of the product shall not exceed 106 kPa.

12.Don’t use if the package is broken or there is a foreign matter.

13.This product is sterilized with ethylene oxide and is valid for 3 years from the date of sterilization.

14.Only for enteral infusion, and mustn't be used in intravenous infusion.

15.When a patient on EN requires medications, it is advisable to consult a pharmacist to determine whether a medication can be safely prepared and administered via the EN.

16. The enteral feeding sets are suitable for standard commercial enteral formulas that categorized IDDSI (the International Dysphagia Diet Standardization Initiative) levels ranging from 0 to 1.

 **Caution**

1. Check whether the package is sealed without damage.

2. In order to protect users’ health, please follow clean aseptic handling procedure for containers, sets or feeding tubes disposal.

3. Check the liquid container intended use regarding the feeding protocol, especially for patients requiring special attention.

4. The fluid in the feeding set and the bag must be within normal temperature conditions: 5~40℃.

5. Please refer to the instructions before use.

6. Select the product model and parameters that match the patient's treatment plan.

7. Check whether the joints ofthe product are firm and tight before use.

8. Do not put blended or pureed food or other liquids into the feeding bag.

9. Only use right compatible pump can guarantee feeding reliability. Please refers to the compatible pump and compatible nutrition fluids.

10.Make sure there is no air in the pipeline before using.

Notes:

Avoid direct sunlight to the device

Side effects:

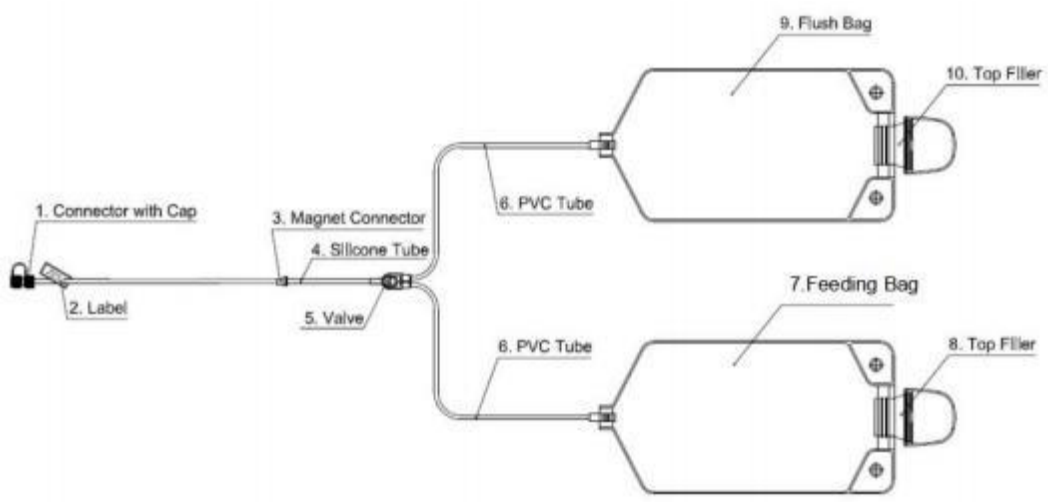
Gastrointestinal intolerance, such as nausea/vomiting, bloating, diarrhea, heartburn/reflux

5. Product description

Working principle

Enteral feeding set is connected to the nasogastric tube, gastric tube and other intestinal nutrition tubes, and the silicone tube is rotated and squeezed by the nutrition pump to deliver the feeding solution to the patient's intestines and stomach.

Diagram of Series B Enteral Feeding Set



1. Connector with cap, 2. Label, 3. Magnet connector, 4. Silicone tube, 5. Valve, 6. PVC tube, 7. Feeding bag, 8. Top Filler, 9. Flush Bag, 10. Top Filler.

Series B product specifications and configuration table		
Model	**Feeding Bag volume (mL)**	**Flush Bag volume (mL)**
B0505	500	500
B1005	1000	500
B1010	1000	1000
B1505	1500	500
B1510	1500	1000

6. Operating Instructions

1. Please check whether the product packaging is damaged before use. If it is damaged, do not use it.

2. Open the packaging and take out the enteral feeding set.

3. Fill the nutrition bag with the required volume of feeding solution from the top filler.

4. Close the top filler and hang up the nutrition bag.

5. Fill the flush bag with the required volume of water from the top filler.

6. Close the top filler and hang up the flush bag.

7. According to the instruction manual of the enteral nutrition pump, fix the valve into the holder of the pump, stretch the silicone tube around the runner of the pump, and then fix the magnet connector to the holder on the other side of the pump (make sure the feeding set is in place). According to the instruction manual of the enteral nutrition pump, confirm that the enteral feeding set has been installed properly and is ready to perform safely.

8. Remove the protective cap on the connector at the end of the set.

9. According to the instruction manual of the enteral nutrition pump, pre-fill the feeding set so that the tube lumen is filled with feeding solution and empty the air in the tube lumen.

10. Connect the feeding set to the feeding tube and start feeding.

7. Storage conditions

1. This product should be stored in a room with a relative humidity not exceeding 80%, non-toxic, non-corrosive gases and well-ventilated, with adequate protection for the feeding set.

2. This product should be protected from heavy pressure, direct sunlight, rain and snow during transportation.

3. Storage temperature: 0 ~ 40 ℃

4. Atmospheric pressure: 70kPa~106kPa

8. Specification

Technical Item	**Parameter**				
Product Name	Enteral feeding set				
Model No.	B0505	B1005	B1010	B1505	B1510
Feeding Bag volume (mL)	500	1000	1000	1500	1500
Flush Bag volume (mL)	500	500	1000	500	1000
Compatible pump	KangarooIII ePump Enteral Feeding Pump	KangarooIII Joey Enteral Feeding Pump	KangarooIII Joey Enteral Feeding Pump	KangarooIII ePump Enteral Feeding Pump	KangarooIII ePump Enteral Feeding Pump
Length of tube (mm)	1000~2600mm				
Tube inner diameter (mm)	2.0~5.5 mm				
Tube out	3.0~6.5 mm				

diameter (mm)	
Mechanism of Action	Feeding pump use (peristaltic feeding pumps periodically squeeze the enteral feeding set by rotating the rollers, creating a peristaltic wave that pushes the nutrient solution forward in the tubing.)
ENFit connector	Conform with ISO 80369-3
Tensile strength	Withstand a tensile force of 15N before breaking, becoming detached, or cracking
Leakage	Distal to the driving mechanism of the pump: enteral feeding set shall not show signs of leakage sufficient to form a falling drop of water while being subjected to a internally applied pressure greater than 103kPa over a hold period of 120s to 130s; Proximal to the driving mechanism of the pump: enteral feeding set shall not show signs of leakage sufficient to form a falling drop of water while being subjected to a internally applied pressure between 20kPa and 22kPa over a hold period of 30s to 35s
Shelf Life	3 years
Sterility	Yes
Ethylene oxide residue	less than 10 μg/g
Main materials	PVC, Silicone, ABS
DEHP free	No DEHP
Whether for single use	For single use
Operating environment	Temperature: 5℃~40℃ Humidity ： 0~80%RH Atmospheric pressure：70kPa~106kPa
Storage and transportation conditions	Temperature: 0℃~40℃ Humidity ： 0~80%RH Atmospheric pressure：70kPa~106kPa

9. Maintenance and Replacement Parts

The device contains no user serviceable parts inside. Modification of any kind is prohibited.

10. Declaration of conformity:

Medika Medical Technology (Zhejiang) Co., Ltd. declares that the device conforms

to the following standards (EU) 2017/745, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-7, EN ISO 10993-10, EN ISO 10993-23, EN ISO 14971, EN 62366-1, EN ISO 15223-1, EN ISO 20695, EN ISO 11135, EN ISO 11138-2, EN ISO 11607-1 and EN ISO 11607-2.

11. Trouble shooting

Consult the medical device company or retailer for the problems in the use of the product.

12. Disposal

All waste from the device must be disposed of using methods appropriate to the civil authority of the location where disposed.

13. Packing List

General, the package include the below contents:

No.	Name	Model	Quantity
1	Enteral Feeding Set	B0505, B1005, B1010, B1505, B1510	A packaging box can hold 30 PC set.
2	Instruction manual		1 PC

The enteral feeding sets are used with enteral feeding pumps.

Note: Compatible Feeding Pump (not include in this Enteral Feeding Set)

Manufacturer: Cardinal Health 200, LLC

Address: 3651 Birchwood Drive Waukegan, IL 60085 USA

Recommended model of enteral feeding pumps: Kangaroo™ ePump Enteral Feeding Pump or Kangaroo™ Joey Enteral Feeding Pump.

14. WARRANTY

Consult the medical device company or retailer for the problems in the use of the

product.

15. Reporting adverse events

If users/patients/customer think that they or someone in their family has experienced a serious incident that has occurred in relation to the device, users/patients/customer are encouraged to report the incident to the manufacturer and the competent authority of the Member State in which the users/patients/customer is established.

16. Other information

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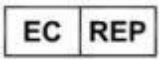

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