



FLOCARE® BENCHMARK® PEG/J

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Production location: Nutricia Pharmaceutical Wuxi Co Ltd., P.R. China

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May 2026

FLOCARE[®] BENCHMARK[®] PEG/J

EN • INSTRUCTIONS FOR USE

BENCHMARK[®] PEG/J

DE • GEBRAUCHSANWEISUNG

BENCHMARK[®] PEG/J

NL • GEBRUIKSIJNSTRUCTIES

BENCHMARK[®] PEG/J

FR • MODE D'EMPLOI

BENCHMARK[®] PEG/J

ES • INSTRUCCIONES DE USO

SONDA BENCHMARK[®] DE GASTROEYUNOSTOMÍA ENDOSCÓPICA
PERCUÁTENA FLOCARE[®] (PEG/J)

IT • ISTRUZIONI PER L'USO

BENCHMARK[®] PEG/J

NO • BRUKSANVISNING

BENCHMARK[®] PEG/J

SV • BRUKSANVISNING

BENCHMARK[®] PEG/J

DA • BRUGSANVISNING

BENCHMARK[®] PEG/J

FI • KÄYTTÖOHJE

BENCHMARK[®] PEG/J

PL • INSTRUKCJA UŻYWANIA

BENCHMARK[®] PEG/J

TR • KULLANIM TALİMATLARI

BENCHMARK[®] PEG/J

EL • ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

BENCHMARK[®] PEG/J

CS • NÁVOD K POUŽITÍ

BENCHMARK[®] PEG/J

SK • NÁVOD NA POUŽITIE

BENCHMARK[®] PEG/J

HU • HASZNÁLATI UTASÍTÁS

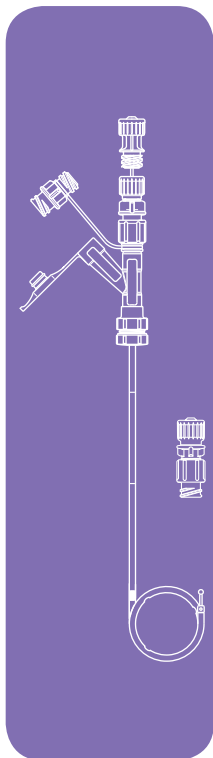
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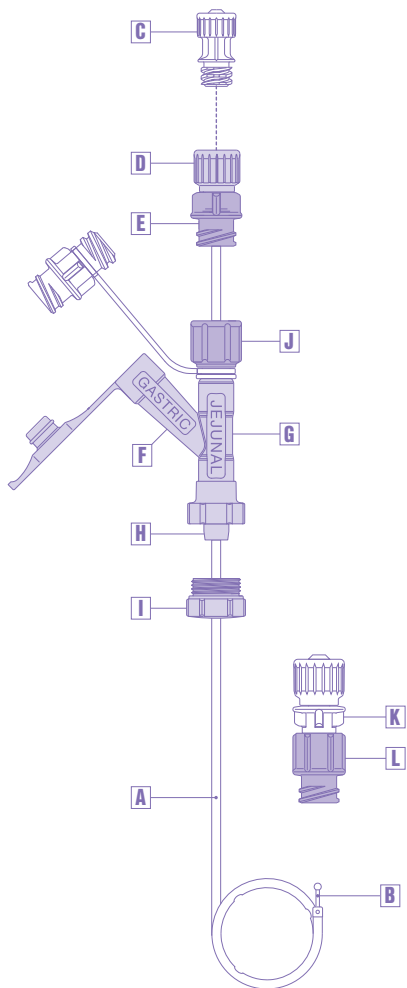
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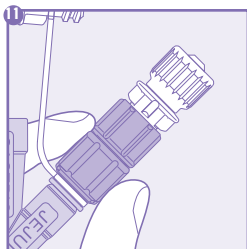
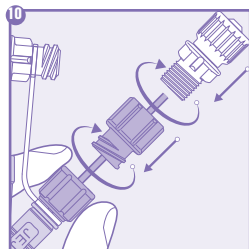
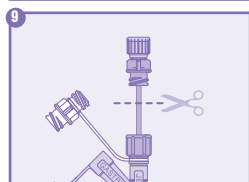
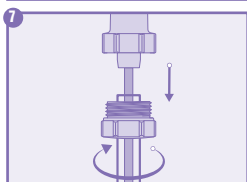
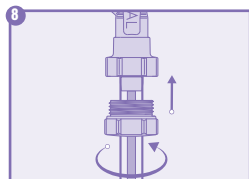
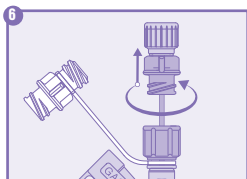
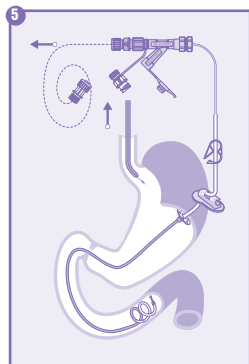
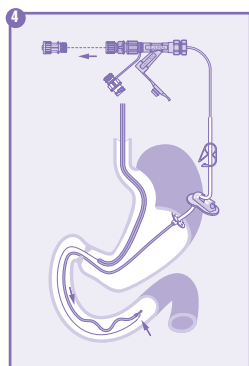
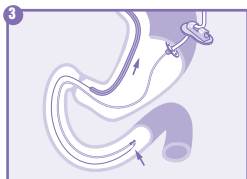
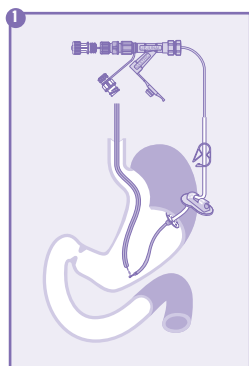
BENCHMARK[®] PEG/J

ET • KASUTUSJUHEND

BENCHMARK[®] PEG/J







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PRODUCT DESCRIPTION

The Flo care® Benchmark® PEG/J is a jejunal feeding tube which should be used with a Flo care® PEG CH18, intended for patients requiring long term enteral tube nutrition.

CONTENTS

Tube material:	blue fully opaque polyurethane tubing (A)
External diameter:	CH 9
Length:	105cm
Tip:	antenna-tip with 2 lateral outlets (B).
Benchmark®-spiral (patented):	2,5 loops with a diameter of approx. 3 cm and a length of approx. 23 cm. These loops are straightened with a guide wire during insertion. After removal of the guide wire, the spiral allows optimal stable positioning in the small intestine. A black square shape marking printed on the tube about 25 cm from the tip indicates to which point the spiral will roll up when the guide wire is removed.
Guide wire:	a prelubricated metallic guide wire, partially inserted into the tube (C).
ENFit Connector:	consisting of lilac (D) and turquoise (E) parts, to enable connection of the jejunal tube with the Y-connector.
Y-Connector (red):	to allow simultaneous aspiration of gastric contents and feeding in the small intestine. The gastric leg (F) contains a funnel connector allowing connection of a step connector with a drainage bag. The jejunal leg (G) is pre-assembled on the jejunal tube. The Y-connector contains an inner ring (H) to attach the connector to the PEG, as well as a separate red ring (I) to fixate the connection. The turquoise ring (J) on top of the Y-connector enables connection with the jejunal tube.
Tuohy borst adapter:	adapter for connection after tube placement; consisting of white, transparent (K) and turquoise (L) components which can be disconnected separately.
Distance marks:	every 10 centimeters.

INTENDED USE

Flo care® Benchmark® PEG/J is intended for use in combination with a pre-placed Flo care® PEG CH18 to provide post-pyloric access to Jejunum for the delivery of enteral nutrition or liquids. The device enables jejunal feeding, with the possibility of concurrent gastric drainage via the PEG, in patients who are unable to meet their nutritional requirements through oral intake, but who have a functional intestinal tract. The device is intended for long term (>6 weeks) enteral tube feeding.

INDICATIONS

The Flocare® Benchmark® PEG/J, used in combination with Flocare® PEG CH18 is indicated for patients requiring post-pyloric enteral tube feeding, with or without simultaneous gastric drainage:

- Long-term post-pyloric tube feeding
- Gastric drainage/stomach decompression through the PEG

Indications for post pyloric tube feeding include, among others:

- Patients with increased risk of aspiration or reflux and vomiting
- Patients with limited gastric motility

It is recommended to administer post-pyloric tube feeding with an enteral feeding pump to control the flow rate.

INTENDED TARGET GROUPS/PATIENT POPULATION

The Flocare® Benchmark® PEG/J is intended for post-pyloric enteral tube feeding in adult patients. Use in selected paediatric patients may be considered based on the clinical judgement of qualified healthcare professionals, considering whether the patient's anatomy and body size are compatible with the use of a pre-placed PEG CH18.

INTENDED USERS AND QUALIFICATIONS

The set-up and placement of the Flocare® Benchmark® PEG/J in combination with the Flocare® PEG CH18 set must be performed by trained and qualified healthcare professionals.

Daily use, care and maintenance of the device may be carried out by a trained patient or caregiver under medical supervision.

CLINICAL BENEFITS

The Flocare® Benchmark® PEG/J provides post-pyloric access for enteral nutrition in patients for whom gastric feeding is not appropriate or not tolerated. Its use allows delivery of enteral nutrition beyond the stomach and supports ongoing nutritional management, including the option for simultaneous gastric drainage when clinically indicated.

CONTRAINDICATIONS

- Intestinal absorption failure
- Paralytic ileus
- Acute abdomen

More detailed information can be found in the Instructions For Use for the Flocare® PEG.

Notice: any serious incident that has occurred in relation to this device is to be reported to Nutricia and the local competent authority.

PLACEMENT INSTRUCTIONS

PEG and PEG/J placement is only to be executed by trained and qualified healthcare professionals.

Preparation of the Flocare® PEG CH 18.

After initial placement of the Flocare® PEG CH 18, with the endoscope still in stomach:

- Cut-off PEG tube at 35-cm marking.
- Pull external retention disc over the tube, but do not fix the tube in the disc yet.
- Place quick release clamp on the tube.
- Lubricate the inner-lumen of the PEG tube with approx. 10 ml water, using a syringe.

A. Endoscopic placement:

1. Insert the guide wire completely into the jejunal tube. Withdraw the guide wire about 10-20 cm, and then push the guide wire until it reaches the end of the tube. Attach the handle of the guide wire (C) firmly to the ENFit Connector (D).
2. Lubricate the stretched jejunal tube with water to facilitate intubation.
3. Push the antenna tip (B) of the jejunal tube through the PEG CH 18 until the tip is visible in the stomach. If necessary add some extra water through the PEG CH 18 tube.
4. Grasp the antenna-tip with the endoscope forceps (fig.1) and with help of the endoscope guide the tube through the pylorus. The tube tip should be positioned as far down the small intestine as possible, preferably beyond the Treitz ligament (fig. 2).
5. Keep the tube tip in place with the forceps, whilst withdrawing the endoscope (withdrawal of the endoscope approximately 30 cm is possible) (fig. 3).
6. Whilst the tube is still held by the forceps, withdraw the guide wire about 25 cm from the tube. Now the spiral will begin to form. With the forceps still in place, move the blue jejunal tube forward further into the small intestine (fig. 4).
7. Finally remove the endoscope, the forceps and the guide wire cautiously (fig. 5) being careful not to move the tube backwards at the same time.
8. Detach the ENFit connector from the Y-connector by unscrewing the turquoise ring (J) on top of the Y-connector (fig. 6).
9. Unscrew the separate red ring (I) from the Y-connector and move it over the PEG CH18 (fig. 7).
10. Connect the Y-connector to the PEG CH18 by fitting the red inner shaft (H) tightly into the PEG tube. Screw the separate red ring (I) into the Y-connector to fixate the Y-connector on the PEG tube (fig. 8).
11. Cut the ENFit connector from the jejunal tube (5 cm above the Y-connector) (fig. 9). If necessary, check the position of the tip of the tube endoscopically, to rule out any dislocation at this time.
12. Unscrew the turquoise ring (L) of the Tuohy borst adapter from the transparent part (K). Slide the turquoise ring over the blue jejunal tube. Fix the jejunal tube over the metallic pin inside the transparent part of the Tuohy borst adapter. Make sure the tube is completely moved over the metallic pin. Connect the turquoise and transparent parts of the Tuohy borst adapter by screwing in the turquoise part. Afterwards, connect the complete assembled connector to the Y-connector, by rotating the turquoise ring of the Y-connector (J). (fig. 10 and fig. 11).
13. Fix the PEG CH 18 tubing in the external retention disc. Ensure the correct positioning of the external retention disc is maintained by placing the blue safety clamp immediately behind the disc (if present).
14. Check that the jejunal tube works by flushing with approx. 20 ml water.
15. Check if the jejunal tube is in the correct position with an X-ray. Note the length of the remaining part of the intestinal tube.

B. Fluoroscopic placement:

Follow point 1-3 of the instructions mentioned under A.

4. Check that the tube tip is in the stomach with fluoroscopy and direct the tip towards the pylorus. Withdraw the guide wire approximately 2-3 cm which will cause the tube to bend. This can facilitate finding the pylorus and help inserting the tube-tip through it. The safety tip design of the Bengmark® PEG/J tube enables manipulation with the guide wire in situ without the risk of lateral guide wire penetration, which could cause tissue damage. After pylorus penetration the guide wire should be brought back in the original position.
5. Insert the Bengmark® PEG/J tube with the guide wire as far as possible in the small intestine, preferably beyond the Treitz ligament.
6. Once the tube is in place, withdraw the guide wire.
7. Follow point 8-15 of the instructions mentioned under A.

MAINTENANCE AND AFTER CARE

- Check the position of the PEG tube by checking the .cm markings. Perform this check each time the feed container is changed.
- The Flocare® Bengmark® PEG/ J is used solely in combination with the Flocare® PEG CH 18, which in turn implies similar maintenance practices. Ensure you follow the maintenance instructions for the PEG carefully, also when used in combination with the Bengmark® PEG/ J. Be aware that maintenance with the PEG/J - PEG combination differs in one area (see below).

Within the PEG instructions for use the following is mentioned:

- Release the tube out of the external retention disc, rotate the tube daily by 180° on its axis, and move weekly the tube up and down in the fully healed stoma (min 20 mm). When the PEG is combined with a Bengmark® PEG/J, the tube should NOT be rotated on its axis, but only weekly moved up and down in the fully healed stoma (min 20 mm).
- Turning the tube is NOT carried out so as to avoid twisting of the Bengmark® PEG/J tube, leading to possible dislocation of the PEG/J Bengmark® coil. Always return the tube to its original position with the PEG's blue safety clamp behind the external retention disk (if present). (see figure 12). The cm markings may also be used.
- Appropriate ancillaries, including enteral extension sets, giving sets and syringes, should be used using ENFit (enteral) connectors of a recognized standard (ISO80369-3) in order to avoid misconnection errors.
- Start feeding gradually and monitor the patient.

WARNINGS

Disinfectants such as Povidone - Iodine (PVP - 1; e.g.: Iso - Batadine®, Braunol®) and Octenidindihydrochlorid -Phenoxvethanol (e.g.: Octenisept®) should not be used because repeated exposure to this disinfectant might negatively affect the physical/mechanical properties of the tube. It is recommended to use disinfectants based on Polyhexanid (e.g. Prontosan®)

- The Flocare® PEG/J Tuohy borst adaptor has a metal connection pin for fixation in the tube - do not expose the PEG/J to areas of strong magnetic fields, e.g. MRI equipment.
- There are no incompatibilities known in the choice of substances or (enteral) medicinal products administered via the PEG/J. Precaution is to be in place in delivering any kind of (enteral) medication via the PEG/J, as unknown effects - for other substances or higher concentrations - can occur. After any medication delivery, the PEG/J is to be flushed with water.
- Material defects and tube occlusion can be largely ruled out if the Flocare® PEG/J is adequately flushed before and after every administration of nutrition and/or medication.
- Avoid using acidic substances such as cranberry juice and cola beverages to flush feeding tubes as the acidic quality when combined with formula proteins may actually contribute to tube clogging.

GENERAL FLUSHING AND SYRINGE USE POLICY

- Routinely flush the tube with water before and after the administration of feed or medication and at least every 8 hours to prevent blockage of the tube.
- As practicable, use an enteral syringe (minimum size of 20mL) for flushing the tube and always flush in a controlled manner.
- For medication administration directly into the tube, always administer using an appropriate size enteral syringe for the volume of medication but ensure delivery is in a controlled manner. In case more than one medication is administered at one time; make sure the tube is flushed thoroughly between types.
- Never use excessive force. If there is any resistance, stop the procedure and consult your clinician.

DURATION OF USE

The PEG/J is intended to provide for long-term (>6 weeks) access for jejunal tube feeding. The life span of the device may vary depending on several factors, including use of medication use, gastric pH, patient motility and tube care.

The Tuohy borst adapter (K+L) is available as a spare part and may be used to replace a worn out or leaking connector within the normal foreseeable use period of use, helping to maintain the functionality of the Flocare® PEG/J system.

POTENTIAL COMPLICATIONS LINKED TO THE JEJUNAL EXTENSION

- Retrograde migration of the jejunal extension of the tube into the stomach
- Tube malfunction due to kinking and/or obstruction
- Pyloric ulcer

(see the “potential complications” paragraph of the Flocare® PEG set IFU for further information).

REMOVAL OR REPLACEMENT

It is recommended to place a new Flocare® Bengmark® jejunal tube at 6 week- intervals. The need for removal or replacement may differ from this recommendation, based on clinical assessment, the condition of the device, and patient-specific factors. It must be determined by a qualified healthcare professional. Removal of the jejunal extension must be performed under the instruction or supervision of a qualified healthcare professional. Stop enteral feeding. Loosen the Tuohy-borst adapter. Gently withdraw the jejunal extension through the PEG. After removal, secure the PEG and check the stoma site according to standard care procedures.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local policy.

SINGLE PATIENT USE

Do not reuse this product - Do not reuse, reprocess or re-sterilize this device. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.