# Compat® Soft

**COMPAT® SOFT 8 | 10 | 12 | 14FR 120CM**

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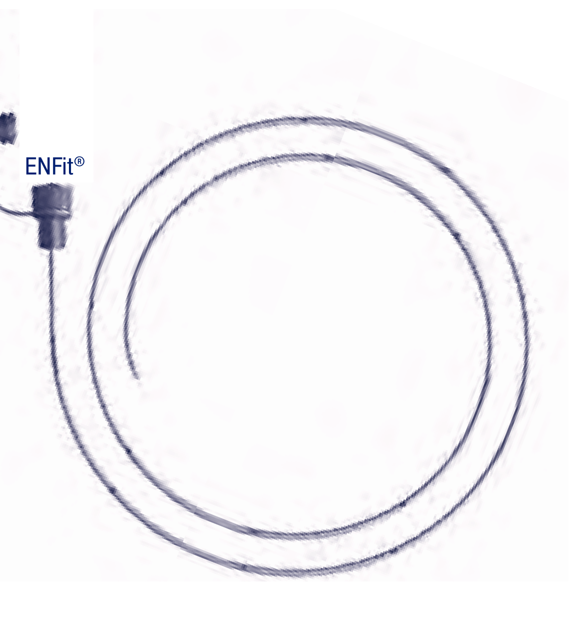


**COMPAT® SOFT 8 | 10 | 12 | 14FR 120CM S**

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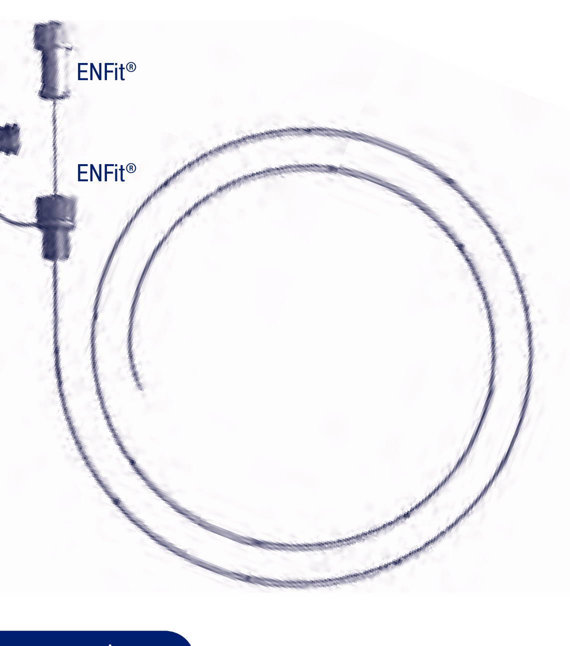


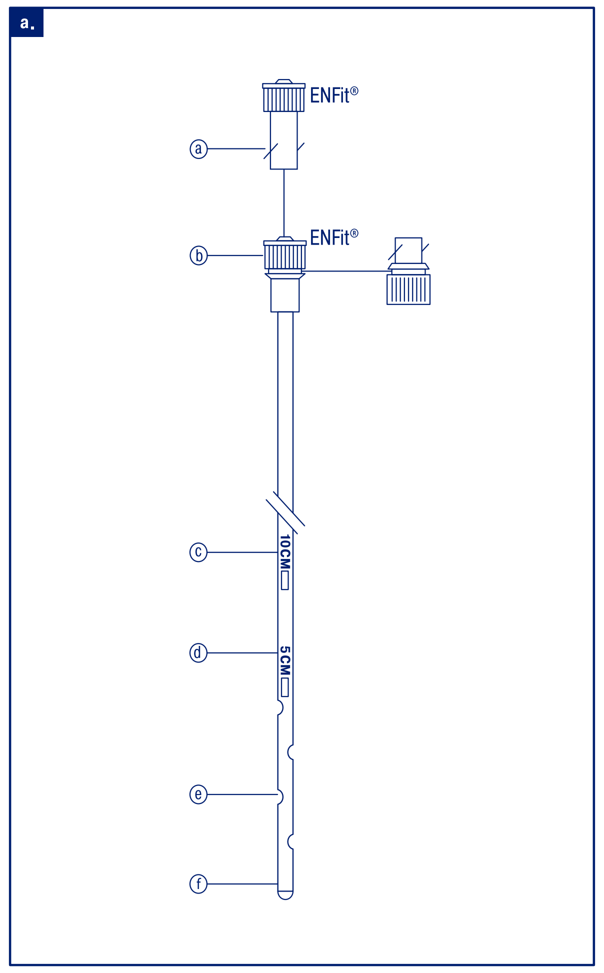


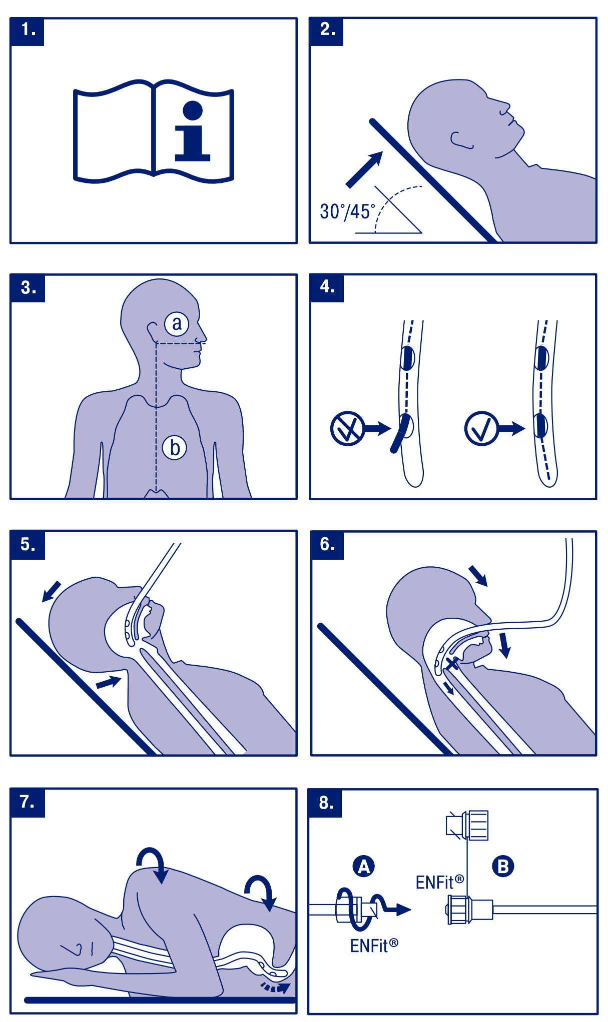


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**AR** تعليمات الاستخدام. اقرأ التعليمات بعناية قبل الاستخدام !

**CS** **Návod kpoužití.** Před použitím si pozorně pročtěte pokyny.

**DA** **Brugsanvisning.** Læs brugsanvisningen omhyggeligt før brug!

**DE** **Gebrauchsanweisung.** Vor der Verwendung aufmerksam lesen!

**EL** **Οδηγίες χρήσης.** Διαβάστε προσεκτικά τις οδηγίες πριν από τη χρήση!

**EN** **Instructions For Use.** Read instructions carefully prior to use!

**ES** **Instrucciones de uso.** Lea atentamente las instrucciones antes de usar el dispositivo.

**FI** **Käyttöohjeet.** Lue ohjeet huolellisesti ennen käyttöä!

**FR** **Mode d'emploi.** Lire attentivement les instructions avant utilisation.

**HR** **Upute za uporabu.** Pažljivo pročitajte prije uporabe!

**HU** **Használati utasítás.** Használat előtt figyelmesen olvassa el a használati utasítást!

**IT** **Istruzioni per l'uso.** Leggere attentamente le istruzioni prima dell'uso.

**NL** **Gebruiksaanwijzing.** Lees de instructies zorgvuldig voorafgaand aan het gebruik!

**NO** **Bruksanvisning.** Les instruksjonene nøye før bruk!

**PL** **Instrukcja użycia.** Przed użyciem przeczytaj dokładnie instrukcję!

**PT** **Instruções de uso.** Leia atentamente as instruções antes de utilizar o dispositivo.

**SK** **Návod na použitie.** Pred použitím si dôkladne prečítajte pokyny!

**SL** **Navodila za uporabo.** Pred uporabo natančno preberite navodila za uporabo!

**SV** **Bruksanvisning.** Läs anvisningarna noggrant innan du använder produkten!

**TR** **Kullanım Talimatları.** Kullanımdan önce talimatları dikkatli bir şekilde okuyun!

**ZH** **使用说明：** 使用前请仔细阅读说明！

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**EL Μέρη (Εικ. a):**
a) Προσυναρμολογημένο οδηγό σύρμα
b) Μονή θύρα ENFit®
c) Ένδειξη μήκους
d) Κορμός σωλήνα
e) Πλευρικές οπές
f) Στρογγυλεμένη απόληξη

**EN Components (Fig. a):**
a) Pre-assembled stylet
b) Single ENFit® port
c) Marking
d) Shaft
e) Side holes
f) Distal/Round tip

**ES Componentes (Fig. a):**
a) Fiador preensamblado
b) Entrada única ENFit®
c) Marca
d) Cuerpo de la sonda
e) Orificios laterales
f) Extremo distal redondeado

## EN

### 1. Description

Compat® Soft enteral feeding tubes are comprised of flexible polyurethane tubing, are radio-opaque and have a single ENFit® enteral specific connection/access port. They are available in 8, 10, 12, 14 FR sizes and are 120 cm long, which is printed on the tube shaft as well as on the pouch label. They include a pre-assembled metal stylet (optional), which is used to assist in tube placement. (Fig. a). Markings on the tube every 5 cm are used for measuring the tube length inserted into the alimentary tract. Tubes are sterilized using ethylene oxide.

### 2. Intended use

Compat® Soft tubes are intended for enteral administration of nutrients, fluids and/or medications into the alimentary tract via the natural nasoenteric route.

### 3. Indication for use

Compat® Soft tubes are for the administration of enteral tube feeding, fluids and/or medications by the natural nasoenteric route for patients who are physically unable to ingest enough nutrients through normal mastication and swallowing.

### 4. Contraindications

Compat® Soft tubes are contraindicated for patients who have anatomic abnormalities or diseases of the nose, throat, or esophagus or with known sensitivities or allergies to its components. Not to be used with patients below 5 kg.

### 5. ⚠ Cautions

- Contents are sterile unless package is damaged or opened.
- To ensure proper device function, do not nick, cut, tear, puncture, or otherwise damage the device.

### 6. ⚠ Warnings

- Single use. Only to be used once, in one patient.
- Not made with natural rubber latex.
- For enteral use only.
- Not for intravenous use.
- Do not use if package is damaged.
- **Do not reuse.** Reuse creates a potential risk of patient or user infection through device contamination. Any reprocessing (especially sterilization) may compromise the structural integrity of the device.
- The device is not intended for use over 42 days.
- Use only enteral administration sets with ENFit® connectors. The feeding sets with different system connections, e.g. ENLock or Luer Lock, are not compatible with the Compat® Soft tubes.
- When using feeding sets with the ENFit® connection system, screw the feeding set Ⓐ clockwise into ENFit® feeding port Ⓑ firmly by hand (Fig. 8).
- To prevent patient injury, never insert or retract the stylet during intubation. Never insert a stylet into an indwelling tube.
- Always ensure appropriate, timely and regular patient monitoring.
- For products with a stylet: before insertion make sure that the stylet's tip is not exiting the tube through one of its distal holes (Fig. 4).

### 7. Placement instructions

- Placement must only be performed by trained professionals (e.g. physicians, nurses) according to your institution's policy.
- Carefully wash your hands according to your institution's policy.
- Read all WARNINGS and CAUTIONS prior to tube insertion (Fig. 1).
- Consult your institution's policy and procedure manual for a detailed description of the enteral intubation process.
- Position the patient in a sitting or Fowler's (30-45°) position as tolerated. The patient should not lean forward, nor should the head and neck be extended (Fig. 2).
- Determine the nostril to be used.
- Measure the length of tube to be inserted in order to reach either the stomach or the small intestine (Fig. 3). The insertion distance depends on the patient. One method is determined by measuring the distance from the tip of the nose to the earlobe (a) and from the earlobe to the Xyphoid process (b) for gastric placement or adding an appropriate length for intestinal placement.
- Assessing the required tube length to be inserted is essential because occlusion may result from an excess of tubing.
- An insertion distance marker should be written on the tube prior to insertion.
- For the products with a stylet: firmly by hand, screw the stylet handle clockwise into the ENFit® feeding port to connect the pre-assembled stylet to the ENFit® feeding port of the Nasoenteric tube. Verify that the stylet's connector stays firmly seated in the ENFit® feeding port and that the stylet's tip is not exiting the tube through one of its distal holes. If necessary, reposition the stylet correctly before inserting the tube in the patient (Fig. 4).
- Gently insert the tube into the chosen nostril, parallel to the nasal septum and superior to the surface of the hard palate (Fig. 5).
- Tilting the patient's head forwards should ensure easier tube migration to the nasopharynx (Fig. 6).
- Conscious/Co-operative patients: When the tube reaches the nasopharynx, instruct the patient to lower the head slightly and to begin swallowing.
- The patient should sip water through a straw to facilitate tube insertion down through the esophagus into the stomach.
- For unconscious/un-responsive patients: extreme care should be taken when the tube reaches the nasopharynx. Check to ensure the tube passes into the esophagus and NOT into the trachea.

> ⚠ **Warning:** If the patient coughs or any resistance is felt, this may be a sign of passage of the tube into the trachea. If this is the case, remove the tube and place it again. If necessary, notify a physician.

- Continue tube insertion until you reach the insertion distance marker.
- Post-pyloric placement: If the tube is to be passed through the pylorus, placing the patient in the Fowler's position with rotation to the right side may facilitate post-pyloric placement of the tube (Fig. 7). Spontaneous transpyloric passage of the feeding tube tip usually occurs within 24 to 48 hours.

### 8. Placement confirmation

- Prior to the feeding tube use, confirm tube placement according to the hospital or institution's preferred procedures and authorization.
- Post-pyloric placement should be confirmed by X-ray.
- Confirmation of tube position can be done with or without the stylet in place (some products do not have stylets). If a stylet is present, gently remove the stylet before first feeding tube use. Verify the feeding tube stays in place.
- After correct placement is confirmed, confirm the tube function by flushing the tube with 10mL of warm water.
- Secure the tube with adhesive dressing.
- Record the insertion depth using the centimeter graduations on the tube.

### 9. Removal and disposal

- Tube removal must only be performed by trained professionals (e.g. physicians, nurses) according to your institution's policy.
- Assist the patient to a Fowler's position with rotation to the right side.
- Flush the tube with approx. 10-20mL of normal saline solution or lukewarm water, using a 20mL or larger syringe.
- Carefully remove the tube. If any resistance is felt, consult with a physician.
- Dispose of the feeding tube according to local hospital or national policy.
- Monitor patient for 2 to 4 hours after tube removal for gastric distention, nausea, or vomiting.
- Follow Good Clinical Practices as well as all local and national regulations for transportation and disposal.

### 10. Additional Information

Check daily for tube migration. If tube migration is suspected, assess tube placement with appropriate placement confirmation techniques and as per hospital or institution's preferred procedures. Flush regularly with approx. 10-20mL warm water, using a 20mL or larger syringe, before and after each feeding or administration of medication or every 4-8 hours if feeding is continuous. Occasionally reposition the tube to change the location that the tube touches the nostril. Always verify that the medication delivered by feeding tube is suitable for enteral administration.

### 11. Storage

The Compat® Soft tubes should be stored in the original packaging at room temperature, and in dry environment. Avoid direct sunlight and heat radiation.

## ES

### 1. Descripción

Las sondas nasoentéricas Compat® Soft son sondas de nutrición enteral flexibles y con conectores enterales específicos ENFit®. El cuerpo de la sonda está fabricado con poliuretano radioopaco. Las sondas de nutrición incluyen un conector ENFit® de entrada única y un fiador metálico premontado (opcional) que puede ayudar a su inserción y a mantenerla en su lugar (Fig. a). [...]

- Para la referencia con fiador: enroscar manualmente y con firmeza en el sentido de las agujas del reloj el fiador a la entrada ENFit® de la sonda. Verificar que el fiador permanezca firmemente conectado a la entrada de alimentación ENFit® y que el extremo del fiador no sobresalga de la sonda a través de uno de sus orificios del extremo distal. Si fuese necesario, reposicionar el fiador correctamente antes de insertar la sonda en el paciente (Fig. 4).

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