Pediatric Nasogastric Feeding Tubes-Single ENFit® Port Instructions for Use

1. Description
These pediatric nasogastric feeding tubes are disposable, sterile medical devices to enable enteral hydration, feeding and/or administration of medications for pediatric patients.

2. Indication for Use:
The Pediatric Nasogastric Feeding Tubes - Single ENFit Port are intended for enteral feeding to deliver nutrition, fluids, and medications to the patient from an enteral feeding syringe or feeding set designed with ENFit connectors for enteral applications. This product is single use for no longer than 29 days.

3. Composition
Polyurethane (PU) tubes are transparent with a radiopaque edge, with numerical marking (5 to 50 or 75 cm), a closed distal tip, 2 lateral eyes (openings) and an ENFit male connector with screw cap and tether. The ENFit male connector is compatible with devices fitted with an ENFit female connector (compliant with ISO 80369-3).

4. Performance/Action Mechanism:
- Allows the administration of feeding or medicinal solutions directly into the digestive system.
- Can be connected to devices equipped with a standard ENFit connector.

5. Instructions for Use:
Procedures before insertion
Inserting a nasogastric tube is medically prescribed. Inserting the nasogastric tube is a medical procedure and it must be fitted by a nurse or doctor. Please refer to the recommendations and hygiene procedures in force in the facility for all insertion steps.

a. Route of insertion of the tube: The tube is inserted either orally or nasally, as medically prescribed. It is recommended to insert the tube through the nose, unless contraindicated. In infants who cannot breathe through the mouth, oral insertion is recommended.

b. Tube insertion: Refer to the institutional protocol. The information below is provided for information purposes only.
- Make sure the patient is comfortable.
- Measure the length of tube to be inserted then make a mark on the tube.
- Gently insert the tube up to the mark, without forcing it.
- Swallowing can make the insertion easier.
- Make sure the tube enters the esophagus and NOT the trachea.

c. Confirming the position of the tube:
X-ray is the recommended method of reference for confirming the correct placement of these radiopaque nasogastric tube. pH measurement can be another way to confirm the tube placement, refer to the hospital protocol to apply the method required. The location of the tube is verified at least once a day and systematically before each use. Regardless of the type of tube, its secure attachment must be verified periodically to prevent any secondary movement of the tube. If the patient is agitated, search for the causes likely to result in the removal of the tube and find a solution in conjunction with the physician.

d. Attaching the tube: Attach the tube with suitable adhesive tape immediately after insertion. The attachment is effective, comfortable, aesthetically pleasing and safe.
Make a mark on the tube and record it in the file as a positioning reference. Once the correct position has been confirmed, an indelible mark is made on the tube and the tube's external length is measured.

e. Use: For enteral administration of medications and when rinsing the tube, use a syringe with ENFit (female connector).

f. Rinsing: Rinse feeding tubes before and after each use (adapt the volume to the size of the patient).
The purpose of rinsing is to prevent the tube from clogging. It can also help unblock the tube. The most commonly used rinsing liquid is water, unless otherwise specified. In any event, it is preferable to obtain a prescription of the daily amount of liquid to be given, as well as the nature of the rinsing liquid, taking into account the volume of water required to administer the medications. It may be necessary to quantify these volumes according to the patient's clinical condition. To prevent the tubes from clogging, it seems appropriate to rinse the tube after each use, having checked its correct position.

g. Monitoring and care: Monitor the gastric residual volume using an enteral syringe. Change the pressure points of the tube once per day. Treat the nose at least once per day. Treat the mouth at least three times per day.

h.Tube removal: Refer to the institutional protocol. The information below is provided for information purposes only. Make sure the patient is comfortable. Rinse the tube with a volume of saline solution or warm water adjusted to the patient. Gently withdraw the tube. In the event of resistance, consult a doctor. Monitor the patient for 2 to 4 hours after the tube has been removed to ensure that there is no gastric distension, nausea or vomiting

6. Precautions for Use and Contraindications:

Precautions for Use:

- Do not use a guidewire or stylet with pediatric enteral feeding tubes.
- Check the integrity of sterility protectors before use.
- If the tube is clogged, do not use a mandrel. Attempt to unblock the tube using warm water or change the tube. Large syringes must be used when undertaking unblocking operations. While various products can be used, none has demonstrated its superior performance.
- Make sure the tube is correctly positioned before initiating the hydration, administration of food or medications: The lack of movement of the tube can be verified by a visual inspection of the external marking of the tube and a chest X-ray.
- Using pliers to connect a tube to or disconnect it from its feeding tubing is prohibited; this may cause the ENFit tip to break and lead to tube replacement.
- Inserting the nasogastric tube is a procedure likely to result in complications in any patient, more specifically in those suffering from swallowing disorders and decreased alertness.
- Due to the potential risk of complication, the insertion of the nasogastric tube in children, infants and premature babies suffering from swallowing disorders or decreased alertness will be performed by a physician near a technical platform.
- The absence of a cough and lack of resistance during insertion do not mean that the nasogastric tube is correctly positioned.
- The best way to verify the initial location of the tube is via an X-ray. Epigastric auscultation after air has been injected into the nasogastric tube (risk of false positive) could only be considered if an X-ray is not an option.

Contraindications:

- Contraindications in the patient may present as: cranio-facial trauma, organic or functional impediment of the aerodigestive tract, alteration of the digestive tract, perforation of the digestive tract, mechanical occlusion of the digestive tract, impaired consciousness, or swallowing disorders.
- Inserting the nasogastric tube is a simple operation, likely to result in complications in any patient, more specifically in those suffering from swallowing disorders and decreased alertness.
- These tubes cannot be used for gastric aspiration.
- Do not administer medications containing glycerin (e.g., Acetem- or Myvacet-based products).

7. Warnings:

- Do not attempt transpyloric placement of this device.
-This device has the potential to misconnect with connectors of other healthcare applications.

8. Risks and Adverse Events:

-During placement: false passage, epistaxis, hemorrhaging of the digestive tract, regurgitation, vomiting, local irritation.
- After placement: displacement, pharyngeal pain, gastro-esophageal reflux, hemorrhaging of the digestive tract, respiratory tract infection, blockage of the tube, nasopharyngeal ulceration, necrosis of the nasal ala.
- In the event of a serious incident, the user must inform the manufacturer and the relevant heath authority in the jurisdiction or facility where the incident occurred.

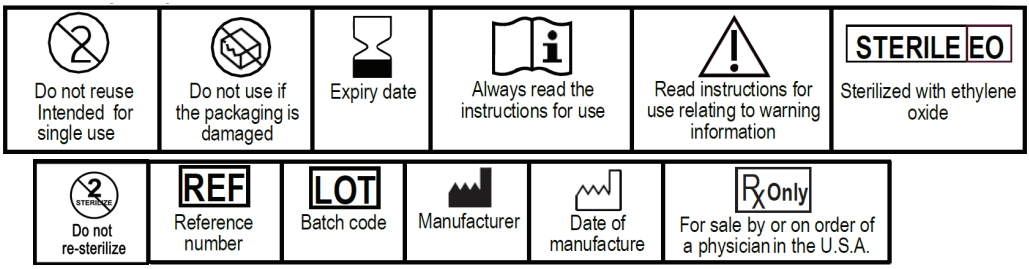
9. Storage/Handling/Disposal:

- Storage: The device must be stored in its original packaging, in a clean, dry area that is away from the light and at a temperature of between +5 and +40°C.
-Shelf life: The shelf-life is indicated on the primary packaging.
-Waste disposal: To dispose of this device, please refer to the regulation applicable to the disposal of hazardous waste, biological waste or infectious medical waste.

10. Single Use:

This product is not designed to be reprocessed, reused or resterilized. Reprocessing (e.g., cleaning or sterilization) may harm the device's structural integrity and risk the safety of the patient and/or user.

11. Glossary of Symbols:



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