

# Instruction for Use

## Disposable Enteral Feeding Syringe

### Trade name

ENFit® Disposable Enteral Syringe

### Features

· ENFit Connector · Sterile & Pyrogen Free · DEHP Free · Latex Free

### Construction and Device Specifications:

- ENFit® Enteral Syringe includes a barrel, a plunger and a piston (granular type/ring type)
- Specifications:  
WE range: 1ml, 2.5ml, 5ml, 10ml, 20ml, 30ml, 60ml and 100ml  
WR range: 1ml, 2.5ml, 5ml, 10ml, 20ml, 60ml

### Intended Use:

- ENFit® Enteral Syringe is designed to connect with tubes to lead nutrition liquid or medicine into gastrointestinal tract.

### Instructions for Use:

- Peel open the package and take out the syringe.
- Draw nutrient solution or medicine into the syringe.
- Expel air bubbles. To expel air bubbles, hold syringe with tip pointing up. Tap side of syringe to allow bubbles to rise toward tip. Draw back slightly on plunger, then push plunger upwards to eject air into the barrel and tip. Repeat until all bubbles are eliminated.
- Connect to tubes to lead nutrition liquid or medicine into gastrointestinal tract.
- Use immediately or cap off and label the syringe until ready to use, but use within 24 hours.

### Contraindication:

- The syringe is not intended for parenteral use.

### Warnings and Precautions:

- The syringe is intended for use on a single patient only.
- Do not use if the package is opened or damaged, syringe tip is visibly blocked, or the syringe is damaged.
- Should fluid get into the tip of the syringe or the moat of the Low Dose syringes then it should be removed by tapping the syringe



### Harm of Reuse of the Product:

- Reuse of the disposable enteral feeding syringes may impact the sliding performance (force to operate the plunger). Reuse of the disposable enteral feeding syringes on different patients may cause cross infection among patients and lead to death. To avoid such risk, symbol of Single Use Only is shown on the labels.

### Directions:

- Always follow the protocol for using Enteral syringes as advised by the medical healthcare professional.
- Syringe must be connected to a male ENFit compatible connector during filling, delivery and any other plunger operation to reduce the risk of dosing volume inaccuracies. Wealy does not recommend the use of the "cupfill" technique for filling syringes.
- Draw liquid into syringe. For accurate measurement use the leading edge of the piston. Do not fill beyond the Maximum graduation.

### Disposal:

- Dispose of syringe as required by Hospital Protocols. If used in home, dispose in household rubbish, or contact the local state healthcare agency.

### Storage:

- To be protected from moisture and heat. Should be kept indoors, without corrosive gas, dry, well ventilated and clean.

### Symbols:

- Single use only.
- Sterilized using ethylene oxide.
- Do not use if packaging is damaged.



Expiry date 3 years



### Manufacturer

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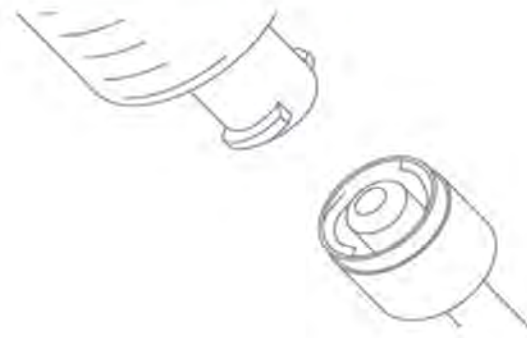
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ENFit® is a brand name of GEDSA.



# ENFit® Reusable Enteral Syringe

## Instruction for Use



### DEVICE DESCRIPTION

ENFit® Reusable Enteral Syringe

### FEACTURES

- ENFit Connector
- Not made with natural rubber latex
- Not made with DEHP

### CONSTRUCTION AND DEVICE SPECIFICATIONS:

- ENFit® Enteral Reusable Syringe includes a barrel, a plunger and a piston (ring type).
- Specifications:
  - WR01LD (1ml Low Dose Tip), WR025LD (2.5ml Low Dose Tip), WR05 (5ml), WR10 (10ml), WR20 (20ml), WR60 (60ml)

### INTENDED USE:

The ENFit® Reusable Enteral Syringe is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body orally or enterally. It is intended to be used multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

### INTENDED USER GROUPS AND ENVIRONMENT:

Wealy ENFit® Reusable Enteral Syringe is intended to be used multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

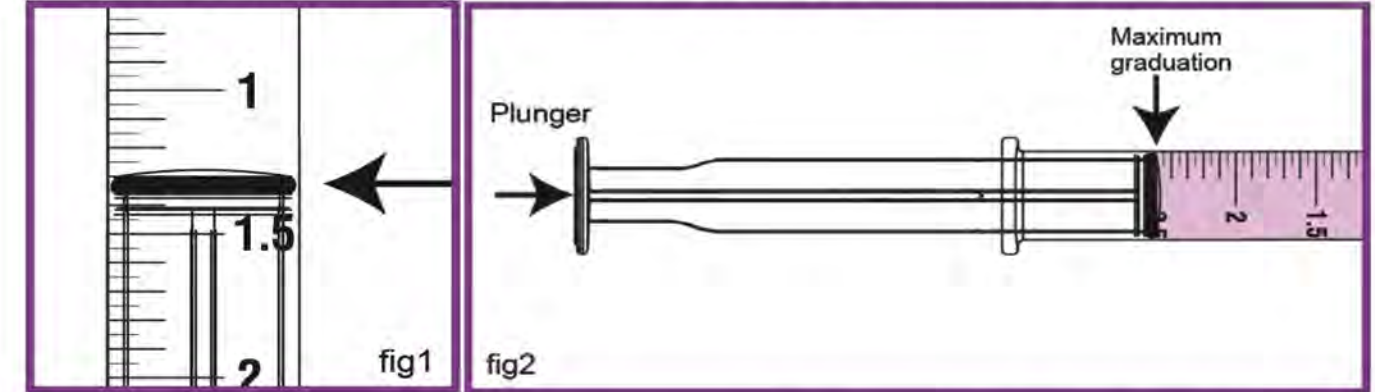
Age groups are as below:

- Neonates/Newborns (birth to 28 days)
- Infants (29 days to less than 2 years old)
- Children (2 years old to less than 12 years old)
- Adolescents (12 years old to less than 18 years old)
- Transitional Adolescents A (18 years old to less than 22 years old)
- Transitional Adolescents B (18 years old to less than 22 years old but treated like adult)
- Adults only (at least 22 years old)

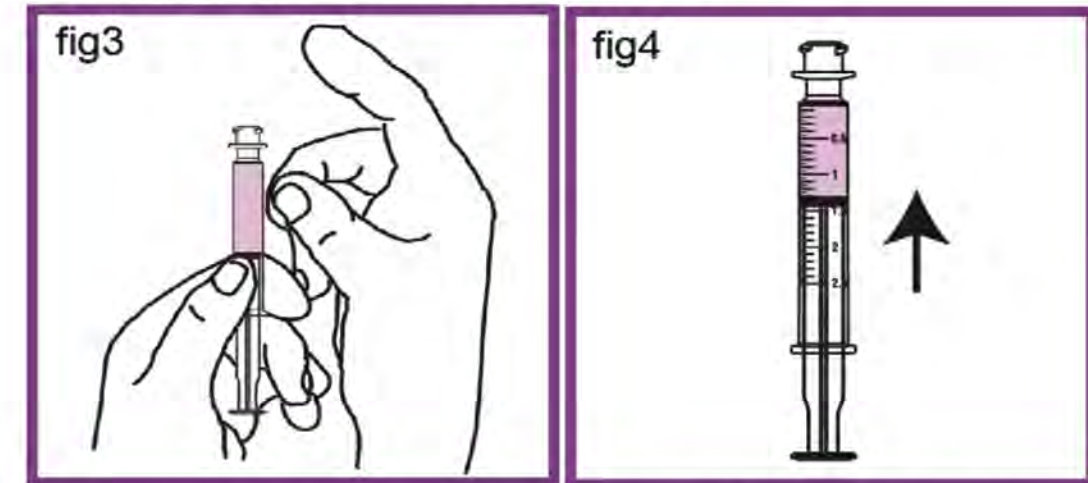
### INSTRUCTIONS FOR USE:

Always follow the protocol for using Enteral syringes as advised by the medical healthcare professional.

1. Peel off the package and take out the syringe.
2. Draw nutrient solution or medicine into the syringe. Before drawing liquid such as nutrient solution or medicine liquid into the syringe, push the plunger to the end of the syringe. For accurate measurement use the leading edge of the piston (fig 1). Do not fill beyond the maximum graduation (fig 2).



3. Expel air bubbles. To expel air bubbles, hold syringe with tip pointing up. Tap side of syringe to allow bubbles to rise toward tip (fig 3). Draw back slightly on plunger, then push plunger upwards to eject air into the barrel and tip (fig 4). Repeat until all bubbles are eliminated.



4. ENFit syringe connect to gastrointestinal delivery system such as gastric or nasogastric devices to deliver nutritional formulations or medicine to patients physically unable to eat or swallow for various physiological conditions.
5. Use immediately or cap off and label the syringe until ready to use.

### CONTRAINDICATION:

The syringe is not intended for parenteral use.

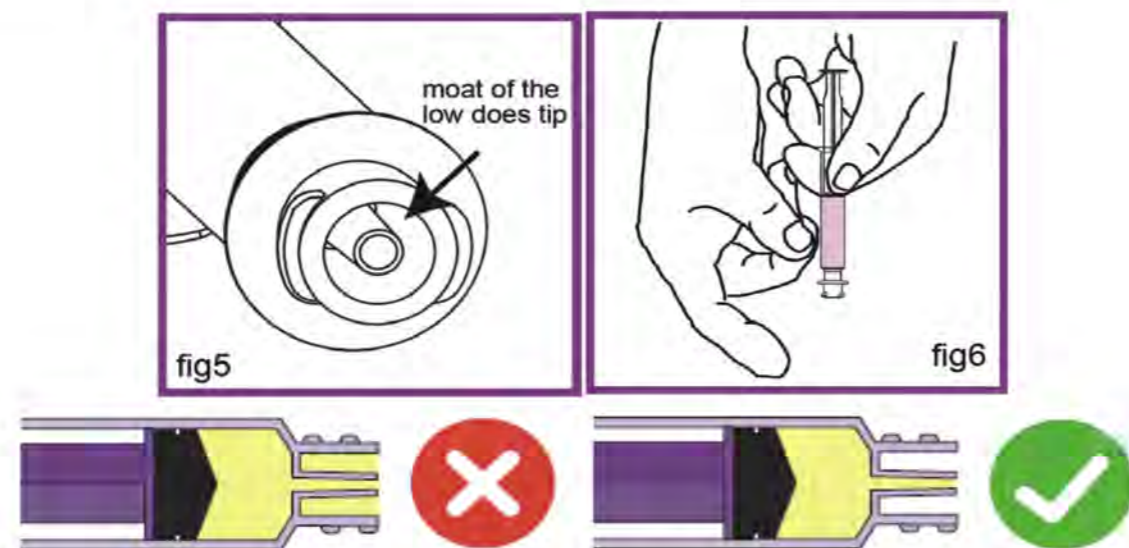
### WARNINGS AND PRECATIONS:

- The syringes should be thoroughly cleaned after use. Dry it ready for the next use.
- Stop the use of this reusable syringe past 7 days from its first use or 20 washes (whichever is sooner).
- The syringe is intended for reuse on a single patient only.
- Do not use if the syringe tip is visibly blocked, or the syringe is damaged.

- If the syringe is used with a pump system, follow instructions provided with the pump system. Improper selection of syringe profile in a pump menu may lead to inaccurate delivery to the patient.
- Do not connect the device with the following equipment:  
Intravascular devices; hypodermic applications; breathing systems and driving gas devices; urethral/urinary devices; limb cuff inflation devices; and neuraxial devices.
- Do not use soapy water that contains ester, strong acid or strong alkali to clean the syringe as this will impact the life of the syringe.
- This device is intended for enteral applications only. Do not use this device with small bore connectors from other healthcare applications as it has the potential risk of misconnection.

#### For the 1ml and 2.5ml ENFit Low Dose Tip Syringes:

- Pay attention to avoid medication in the moat area at the top of the low dose tip syringe. (fig 5) Tap the end of the syringe on a paper towel or end of the cup to dispel the extra fluid (fig 6) if there is additional medication filling the moat when filling the ENfit low dose tip syringe. For thicker fluids, use a sterile cloth to gently wipe the outside and around the tip of the syringe to remove extra fluid.
- The accuracy of graduations of low dose tip syringes is  $\pm 4\%$  of expelled volume.



- Ensure the syringe is free of air bubbles and the moat of the syringe is free from fluids by tapping or flicking the tip of the syringe before administering the medication.
- Use a filling adapter, such as an ENFit compatible cap or medication straw, to prevent fluid and medications from entering the moat area of the syringe tip.
- Be aware that using a medicine cup to fill may cause fluid or medications to enter the moat of the syringe and lead to possible overdose.
- Use a new syringe to flush the medication or fluid after administering any medication to prevent overdose due to the dead space (the remaining fluid in the tip of the syringe after administration) in the syringe.

#### DIRECTIONS:

- Always follow the protocol for using Enteral syringes as advised by the medical healthcare professional.
- Syringe must be connected to a male ENFit compatible connector during filling, delivery and any other

plunger operation to reduce the risk of dosing volume inaccuracies. When use the syringe with transitional connectors but fail to draw liquid, users should check if the connector is misconnected to the IV set. The connector must be connected with the enteral port, otherwise, the syringe will be unavailable to draw liquid or be used. Wealy does not recommend the use of the “cupfill” technique for filling syringes.

#### CLEANING INSTRUCTIONS:

- Clean the syringe immediately after use.
- Pull the plunger to the end of the barrel and gently manipulate the plunger from side to side while pulling gently-the plunger will come out of the barrel. Rinse the barrel and the plunger in cold tap water.
- Place on a dry container or clean fresh kitchen roll or paper towel to dry.

To reassemble for the next use:

- Inspect the barrel and plunger ensuring that there are no traces of feed or medicines.
- Check that the inside of the barrel is free from scratches or abrasions and the surface of the piston is not damaged or distorted
- The piston must lie flat and secure in the groove on the plunger.
- Gently manipulate the plunger back into the barrel and push the plunger until the piston covers the zero line of the graduation printed on the barrel.
- Sock the syringe in normal dishwashing liquid (40~50°C) for 10 min.
- Flush the syringe with cold tap water to flush the residue of dishwashing liquid. According to Point 2 to 4 mentioned in INSTRUCTION FOR USE, use the syringe for a maximum of 7 days or 20 washes before it is discarded and a fresh one used.
- The cleaning must be completed. To inspect the device for visible soil following cleaning and to repeat the steps should any be detected.
- If the syringe cannot be cleaned effectively or is damaged, discard it and use a fresh one.
- The cleaning and rinse water can drain away as normal. There is no need for any special precautions.
- Do not attempt to use the syringe if the markings are unclear or the syringe is stiff or difficult to operate.

#### DISPOSAL:

Dispose of syringe as required by Hospital Protocols. If used in home, dispose in household rubbish, or contact the local state healthcare agency.

#### STORAGE:

To be protected from moisture and heat. Should be kept indoors, without corrosive gas, dry, well ventilated and clean.

 **EXPIRY DATE** 3 YEARS

 **MANUFACTURER**

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ENFit® is a brand name of GEDSA

Ver: ENFITWRIFU001 Effective date: 2021.11.12

 **0197**

 **EU REPRESENTATIVE**

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Ver: ENFITWRIFU001 Effective date: 2021.11.12



