

Instructions For Use

Please read these instructions before use. If in doubt please consult your professional healthcare advisor.

INTENDED USE

ISOSAF[™] ENFit[®] Syringe is intended for delivery of liquid medications and formula enteral feeds, aspiration and flushing. The ISOSAF[™] ENFit[®] Syringe is intended to be connected to ISO 80369-3 ENFit[®] compatible devices. The ISO 80369-3 ENFit[®] connector is used to reduce the misconnection of other connection systems to ENFit[®] compliant devices.

INDICATIONS FOR USE

The ISOSAF[™] ENFit[®] Syringe / Low Dose Tip ENFit[®] is single use syringe indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids or nutritional formula into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

INTENDED USER

ISOSAF[™] - Single Use ENFit[®] Syringe is intended to be used in a clinical or home care setting by users ranging from laypersons (under the supervision of a clinician) to clinicians. The device is intended for single use only and to be disposed of immediately after use as per hospital protocols. For home use, the device should be disposed in the household rubbish/trash.

CONTRAINDICATIONS

The device is not intended for parenteral and neuraxial use.

WARNINGS & PRECAUTIONS

The syringes may misconnect to connectors of other healthcare applications.

The syringes are intended to connect to enteral feeding devices only.

Do not use if packaging is damaged.

Do not use if there are no dose marking on the syringe.

Do not re-use or reprocess the device as this may lead to leakage or infection.

Do not use if the tip is visibly blocked or the device is damaged.

STORAGE CONDITIONS

Keep dry and away from direct sunlight.

DISPOSAL

Dispose of the device as per hospital protocol. If used at home, dispose of in household rubbish/trash.

SYRINGE TIP VARIANTS

Concentric

The standard ENFit[®] connection



Low Dose

Low dose syringes have a male design feature within the ENFit[®] Female connector to reduce the volume in the space.



Eccentric

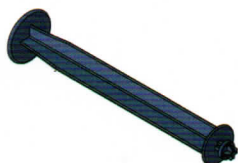
Eccentric syringes avoid the delivery of lipid bolus, which may separate from the formulation over the delivered time period.



DEVICE COMPONENTS



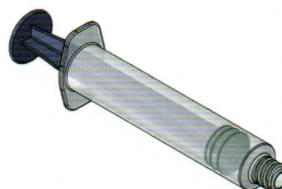
1 x Gasket



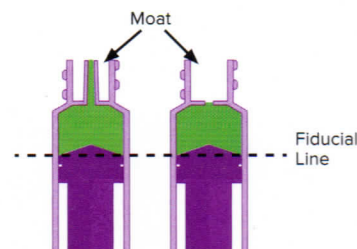
1 x Plunger Rod



1 x Barrel



Assembled Syringe



HOW TO USE

When using enteral syringes always be sure to follow the hospital protocol

- Verify that the feeding tube or access device/extension set is compatible with ISO 80369-3 ENFit[®] syringe to reduce the risk of misconnections.
- If a transitional connectors are used on this device, the user must check that the transitional connector is for enteral use only and it should not connect to any Parenteral devices i.e Intravenous ports.
- Aseptic technique shall be used. Fully depress the plunger before filling the syringe with enteral feed/medication. Fill the syringe up to the volume required.
- For accurate measurement, the fiducial line of the plunger must be in line with the required graduation mark.
- The accuracy of the low dose tip graduation is $\pm 4\%$ of the expelled volume.
- After filling, ensure the syringe moat is free of excess enteral feed/medication and there is no air bubble in the syringe. If there is excess enteral feed/medication or air bubble, Remove this by flicking the side of the syringe.
- The Fig 1. highlights how the ENFit[®] syringe moat should look once filled.
- The Fig 2. highlights how the Low Dose Syringe moat should look once filled.
- Attach the ISO 80369-3 ENFit[®] compliant syringe into the compatible medication port or feeding tube port. Once this is secure, gently push the syringe plunger to transfer the medication/feed into the enteral access site.
- After completely expelling the medication from the syringe, detach the syringe and dispose immediately as per hospital protocols.
- A syringe cap may be used with this device for advance preparation and secure storage and transport of medication/fluids or nutritional formula.
- Attach an ISO 80369-3 ENFit[®] compliant syringe with flush solution to the patient tube or extension set and administer the flush. Detach the syringe and dispose as per hospital protocol.

Fig.1 ENFit Syringe Moat

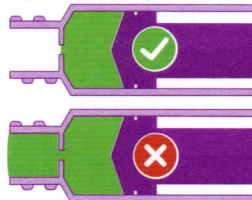
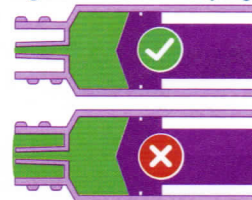


Fig.2 Low Dose ENFit Syringe Moat



The syringe should be filled using a bottle adaptor or a straw to keep the syringe tip (moat) clear of fluid. You must check the moat is clear of any excess fluid before administration.

AVAILABLE PRODUCTS

Product Code Product Description

ELDISO-PFC-1	ISOSAF Low Dose Enteral Syringe with Push Fit Cap, Single Use 1ml
ELDISO-PFC-3	ISOSAF Low Dose Enteral Syringe with Push Fit Cap, Single Use 3ml
ELDISO-PFC-6	ISOSAF Low Dose Enteral Syringe with Push Fit Cap, Single Use 6ml
EISO-PFC-12	ISOSAF Enteral Syringe with Push Fit Cap, Single Use 12ml
EISO-PFC-20	ISOSAF Enteral Syringe with Push Fit Cap, Single Use 20ml
EISO-PFC-35	ISOSAF Enteral Syringe with Push Fit Cap, Single Use 35ml
EISO-PFC-60	ISOSAF Enteral Syringe with Push Fit Cap, Single Use 60ml
SELDISO-PFC-1	ISOSAF Low Dose O-Ring Gasket Enteral Syringe with Push Fit Cap, Single Use 1ml
SELDISO-PFC-3	ISOSAF Low Dose O-Ring Gasket Enteral Syringe with Push Fit Cap, Single Use 3ml
SELDISO-PFC-6	ISOSAF Low Dose O-Ring Gasket Enteral Syringe with Push Fit Cap, Single Use 6ml
SEISO-PFC-12	ISOSAF O-Ring Gasket Enteral Syringe with Push Fit Cap, Single Use 12ml
SEISO-PFC-20	ISOSAF O-Ring Gasket Enteral Syringe with Push Fit Cap, Single Use 20ml
SEISO-PFC-35	ISOSAF O-Ring Gasket Enteral Syringe with Push Fit Cap, Single Use 35ml
SEISO-PFC-60	ISOSAF O-Ring Gasket Enteral Syringe with Push Fit Cap, Single Use 60ml
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SELDISO-6	ISOSAF Low Dose O-Ring Gasket Enteral Syringe, Single Use 6ml
SEISO-12	ISOSAF O-Ring Gasket Enteral Syringe, Single Use 12ml
SEISO-20	ISOSAF O-Ring Gasket Enteral Syringe, Single Use 20ml
SEISO-35	ISOSAF O-Ring Gasket Enteral Syringe, Single Use 35ml
SEISO-60	ISOSAF O-Ring Gasket Enteral Syringe, Single Use 60ml



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Cautions: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Symbol glossary available at www.gbukenteral.com

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