Symbol	Explanation
LOT	Batch code
DK	Country and date of manufacture
REF	Catalogue number
	Consult instruction for use
UDI	Unique device identifier
	Tube length in centimetres
MD	Medical device
CE	CE marked in the EU under the Medical Device Regulation (2017/745)
NON STERILE	Non-sterile
	Store out of direct sunlight
	Keep Dry
	For single use only
LATEX	Latex free
PHT DEHP	phthalate free
	Do not use if package is damaged
STERILIZE	Do not resterilise
	Manufacturer

Instruction for use

Extension tube ENFit/Luer

For sizes: 27 cm.

1. PRODUCT NAME

Extension tube ENFit/Luer.

2. DEVICE DESCRIPTION

Silicon Extension tube with male ENFit connector to female Luer lock.

The tube is available in 27 cm lengths.

Item no.	Name
216027	Extension tube ENFit/Luer 27 cm.

3. INTENDED USE

The Extension tube ENFit/Luer connectors is intended to be used for manual delivery of Lecigon to PEG and PEG J tubes with Luer access by use of ENFit syringe.

4. INDICATIONS FOR USE AND CLINICAL BENEFIT

The Extension tube is a kink resistant tube and with wings on the connectors to ease assembly and disassembly. It can be connected to PEG and PEG J devices to be used for manual delivery of Lecigon to PEG and PEG J tubes by use of ENFit syringe. Shall not be left connected to the PEG and PEG J overnight or if the tubing needs to be cleaned for other reasons than flushing.

5. INTENDED USER

Medical personnel and/or appropriately trained individuals for home use.

6. CONTRAINDICATIONS

- The tube is not intended for parenteral use.

7. WARNINGS/ PRECAUTIONS

- The wings on the connectors are designed to enable ease of adding rotation force during connections. When attaching the connectors with wings, turn the connector until a clear increase in force is felt. Do not overtighten the connectors as this may led to failure in the connector parts.
- Stop the use of this past 7 days from its first use or 40 washes (whichever is sooner), as this may lead to leakage or infection after 7 days / or 40 washes period is expired.
- The Extension tube is intended for single use on a single patient only.
- Do not use if the packaging is open, ENFit/Luer connector is visibly blocked, or the tube is damaged.
- Discard after a maximum of 7 days/40 washes.
- Empty tube after use
- Should not be connected to pump or other active device of class IIa or higher
- The maximum pressure of the tube is 4 Bar. Shall not be left connected to the PEG and PEG J overnight.

8. DIRECTIONS OF USE

- Attached Male ENFit connector (clear connector) to the ENFit syringe with Lecigon. Do not overtighten.
- Prime/fill the tube with Lecigon fluid until it is 1 cm from the Female Luer connector.
- Attached the Female connector to the PEG/PEG J tube. Do not overtighten.
- Provide the Lecigon according to the prescribed dose.
- Disconnect the Extension tube and flush the tube with water.

9. CLEANING INSTRUCTIONS

- Empty the tube immediately after use.
- Place on clean fresh kitchen roll or paper towel to dry.
- Once dried, place in a dry airtight container away from sunlight
- Avoid touching the end of the ENFit/Luer connector.
- Inspect the tube ensuring that there are no residues in the tube and if the tube cannot be cleaned effectively or is damaged, discard it and use a new one.
- Clean the tube prior to disposal.

10. DISPOSAL

Dispose of tube as required by Hospital Protocols. If used in home, dispose in container for plastic or household

11. QUESTIONS

Please consult your health care provider whenever in doubt about the use or if there has been an adverse event, consult a health care professional immediately.

12. ADVERSE EVENTS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer: Innoventa Medica, Blokken 45, 3460 Birkeroed, Denmark, Email: info@innoventamedica.com, and the competent authority of the Member State in which the user and/or patient is established.