



BK - 2085





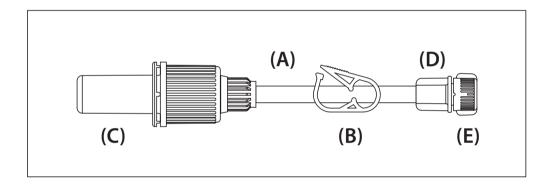






Indications for Use: The U Deliver Bolink™ ENFit® Enteral Feeding Sets are intended for over-the-counter use to deliver liquid nutritional formulas or water to a patient's enteral access device (feeding tube).

Device Description: The Bolink[™] small cap gravity feeding set consists of tubing (A) with a clamp (B), a small cap with cross spike (C), an ENFit® connector (D) for connecting to feeding tubes and a protective cap (E).



The Bolink™ small cap gravity feeding set is intended to connect compatible commercially available collapsible food containers with 8mm diameter connectors to feeding tubes with ENFit® proximal connectors. Not made with natural rubber latex. Not formulated with DEHP or BPA.

Warnings:

- For enteral feeding only.
- This device incorporates an ENFit® Connector and a Cross Spike which are designed to reduce the likelihood of tubing misconnections; however, the potential to misconnect this device with connectors of other healthcare applications still exists.
- Small parts are a potential choking hazard if this device is not used as intended. Use under adult supervision.

Precautions:

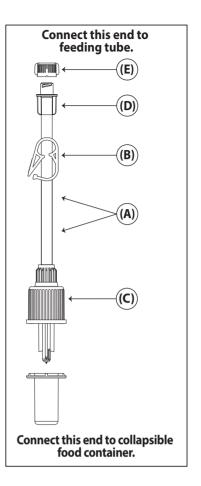
- This device should be discarded after 24 hours and replaced with a new device.
- For single patient use only.
- Dispose with household waste. Do not recycle.

Instructions for Use:

- **1.** Confirm feeding tube position and flush following manufacturer's instructions.
- 2. Close clamp (B) on Bolink™ Tubing (A).
- **3.** Remove cap on food pouch, attach screw cap **(C)** to food pouch and confirm cap is secured tightly.
- **4.** Open clamp **(B)** and squeeze food pouch to fill Bolink[™] tubing **(A)**.
- **5.** When tubing is filled, close clamp **(B)**.

WARNING: Before connecting to a feeding tube, confirm that the Bolink[™] tubing is being connected to a feeding tube only. DO NOT connect to non-feeding tube. This includes confirming that any transitional connector with a Christmas tree tip is connected to a feeding tube and not IV tubing.

- **6.** Remove protective cover **(E)**, use ENFit® connector to attach Bolink™ tubing to feeding tube. If the feeding tube has a funnel connector instead of an ENFit® connector use a transition connector with Christmas tree tip.
- **7.** Open clamp **(B)** and squeeze container with steady, consistent pressure to deliver nutrition.
- **8.** When finished, close clamp **(B)**, disconnect Bolink[™] tubing **(A)** from feeding tube and food pouch.
- **9.** Flush Bolink[™] tubing **(A)** with tap water by holding under a faucet and letting water flow through the tubing until the water runs clear.
- **10.** Flush feeding tube following manufacturer's directions.



Symbol Glossary:

C-1-1		11 I J	
Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified. Ref. 5.1.6 in ISO 15223-1:2016	REF	Use-by date Indicate the date after which the medical device is not to be used. Ref. 5.1.4 in ISO 15223-1:2016	\sum
Non sterile.	^	Consult instructions for use	}
Indicates a medical device that has not been subjected to a sterilization process. Ref. 5.2.7 in ISO 15223-1:2016	NON STERILE	Indicates the need for the user to consult the instruction for use. Ref. 5.4.3 in ISO 15223-1:2016	i
Keep Dry.	4.614	Do not use if package is damaged	
Indicates a medical device that needs to be protected from moisture. Ref. 5.3.4 in ISO 15223-1:2016		Indicates a medical device that should not be used if the package has been damaged or opened. Ref. 5.2.8 in ISO 15223-1:2016	
Do not reuse	0	Manufacturer	
Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. Ref. 5.4.2 in ISO 15223-1:2016	\otimes	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. Ref. 5.1.1 in ISO 15223-1:2016	
Batch code			
Indicates the manufacturer's batch code so that the batch or lot can be identified. Ref. 5.1.5 in ISO 15223-1:2016	LOT		

Note: Symbols are contained in ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

For more information on Bolink™ tubing and U Deliver Medical products, visit www.UDeliverMedical.com.



U Deliver Medical, LLC. 7900 Excelsior Blvd, Suite 108 Hopkins, MN 55343 Made in Italy