

MINI ONE® Balloon Button



Description

Sterile, single use, replacement gastrostomy tube for enteral administration.

Conformity

- Class IIb device
- MDSAP Certification
- ISO 13485:2016 Certification
- CE 0413 from the European Directive 93/42/EEC on medical devices

Utilization

The Mini ONE® button is designed for a well-established gastrostomy site. The Mini ONE® button has been designed to provide nutrition and medication directly into the stomach and allow for decompression of the stomach. Other applications are not advised

Characteristics

- French size (cm) 12, 14, 16, 18, 20, 24
- Length (cm) 0.8 – 6.5
- Adjustable fill volume
- Low profile external bolster
- Glow Green feed port and connector
- ENFit® compatible

Materials

- Medical-grade silicone
- Medical-grade silicone dispersion

Presentation

- Primary package: sealed tray



- Secondary package: box

Sterilization

- Ethylene Oxide (EtO)

Recommendations for Use

The Mini ONE® button is designed for placement in a well-established gastrostomy site with no evidence of infection, fistulous tracts, or separation of the gastric wall from the fistulous tract. A thorough understanding of the technical principles, clinical applications, and risks associated with gastrostomy tube replacement is necessary before using this product. Refer to the manufacturer's Directions for Use for nutrition administration, medication administration and gastric decompression.

Reuse Risks

- The device is provided STERILE for single use.

Verification of Connections

- This device has the potential to misconnect with small bore connectors of other healthcare applications.
- Only use this device to connect to compatible enteral devices.
- Do not use for non-enteral applications
- Ensure device is connected to an enteral port only and not to an IV set
- Only tighten by hand. Never use excessive force or a tool to tighten a rotating connector.

Duration of Use

Exact device longevity cannot be predicted. Device performance and functionality can degrade over time depending on usage and environmental conditions. Typical device longevity will vary for each patient depending on a number of factors, with typical device longevity ranging from 1-9 months. For optimal performance, it is recommended that Mini ONE® Balloon Button device be changed at least every 3 months or as often as indicated by your healthcare professional.

Manufacturer

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