



Balloon Stoma Measuring Device



Description

Sterile, single use, balloon stoma measuring device

Conformity

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

Utilization

The AMT Balloon Stoma Measuring Devices are to be used by medical professionals and home health givers in association with replacement gastrostomy feeding devices. The purpose of the AMT Balloon Stoma Measuring Devices is to aid in determining the depth (length) of an established stoma tract in order to assist in determining the proper length replacement gastrostomy feeding device to be used. Minimum French Size is 10FR.

Characteristics

- Minimum French Size 10FR
- Not made with latex
- Not made with DEHP

Materials

- Medical-grade thermoplastic
- Medical-grade silicone
- Stainless steel spring
- Medical-grade silicone pad print ink

Presentation

- Primary package: sealed pouch
- Secondary package: box



Sterilization

- Ethylene Oxide (EtO)

Recommendations for Use

The AMT Balloon Stoma Measuring Device is to be used by medical professionals and home health givers in association with replacement gastrostomy feeding devices. Refer to the manufacturer's Directions For Use for the selection of the replacement feeding tube and instructions for placement.

Reuse Risks

- The device is provided STERILE for single use.

Verification of Connections

Not applicable.

Duration of Use

The device is for single use only.

Manufacturer

Name of Manufacturer: Applied Medical Technology, Inc.

Address: 8006 Katherine Blvd.

City/State/Zip: Brecksville, Ohio 44141

Country: USA

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