BARD* Button Replacement Gastrostomy Device

Dispositif de remplacement Button Bard*, pour gastrostomie
Button-Gastrostomie-Wechselsonde von Bard*
Strumento sostitutivo per gastrostomia Bard* Button
Dispositivo Button de sustitución para gastrostomía de Bard*
Bard* Button Vervangend Gastrostomiehulpmiddel
Dispositivo de Gastrostomia de Substituição Button Bard*
Συσκευή Γαστροστομίας Αντικατάστασης με κουμπί Bard* Button
Bard* Button erstatningsintrument til gastrotomi
Bard* Button Ersättningsinstrument vid gastrostomi
Bard* Button Korvaava gastrostomialaite
Bard* Button-utskifting Gastrostomienhet
Bard* Button Gasztrosztómiás Csereeszköz
Výměnné gastrostomické zařízení Bard* Button
Wymienny zestaw do gastrostomii Button Bard*
Bard* Button Değiştirme Gastrostomi Cihazı
Гастростомическое устройство производства компании **BARD***

Information for Use
Informations pour l'usage
Gebrauchsinformationen
Informazioni per l'uso
Información para su uso
Informatie voor gebruik
Informações de Utilização
Πληροφορίες Χρήσης
Brugsanvisning
Bruksanvisning
Käyttöohjeet
Informasjon om bruk
Felhasználási tájékoztató
Návod k použití
Informacje o stosowaniu
Kullanım Bilgileri
Информация об использовании

BARD

Manufacturer
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
1-800-545-0890 (USA)
801-522-5000
www.bardaccess.com

Technical or Clinical Support
1-866-893-2691 (USA)

medical.services@crbard.com

0732755 1205R

CE
0086

EC REP
Bard Limited
Forest House, Brighton Road
Crawley, West Sussex
RH11 9BP UK

BARD

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


Do not reuse

Do not resterilize


Attention, see instructions for use


Do not use if package is damaged

English

Device Description

The Bard* Button Replacement Gastrostomy Device is a low-profile gastrostomy device designed for percutaneous insertion through an established stoma tract. The Button device is packaged sterile in a kit which also includes a stoma measuring device, obturator, bolus and continuous feeding tubes, a decompression tube and a non-sterile 60 cc (mL) syringe.

REF	Button Device and Decompression Tube Size	Bolus Feeding Tube and Continuous Feeding Tube Size
000261	28F (9.3 mm) x 1.5 cm	28F (9.3 mm)
000262	28F (9.3 mm) x 2.7 cm	28F (9.3 mm)
000263	28F (9.3 mm) x 4.3 cm	28F (9.3 mm)
000282	18F (6.0 mm) x 1.7 cm	18F (6,0 mm)
000283	18F (6.0 mm) x 2.4 cm	18F (6.0 mm)
000284	18F (6.0 mm) x 3.4 cm	18F (6.0 mm)
000285	24F (8.0 mm) x 1.7 cm	24F (8.0 mm)
000286	24F (8.0 mm) x 2.4 cm	24F (8.0 mm)
000287	24F (8.0 mm) x 3.4 cm	24F (8.0 mm)
000292	18F (6.0 mm) x 1.2 cm	18F (6.0 mm)
000293	24F (8.0 mm) x 1.2 cm	24F (8.0 mm)
000296	24F (8.0 mm) x 4.4 cm	24F (8.0 mm)

Indications for Use

The Button replacement gastrostomy device is indicated for percutaneous placement of a low-profile, long-term gastrostomy feeding and decompression device through an established stoma. The stoma measuring device is used for measurement of a well-established gastrostomy stoma tract for selection of an appropriate length Button device.

Contraindications

- Placement of this device is contraindicated in individuals who do not have a well-established stoma tract or whose stomach has not been approximated to the stomach wall. In addition, any evidence of granulation tissue, infection or irritation should be addressed medically prior to insertion of this device.
- Placement of this device is also contraindicated in individuals with stoma tracts measured to be longer than 4.4 cm.

Warnings

- Intended for Single Use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- **Proper location of the internal dome must be confirmed prior to initiating feeding. Placement or slippage of the device** into the peritoneal cavity will result in serious consequences including peritonitis, sepsis, and potentially death.
- **Improper placement or excessive traction on the external** portion of the device, whether intentional or unintentional,

could result in dislodgement or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

- **If device is not free-floating within the tract, do not attempt** to use traction as a method of removal as tract damage could occur.
- **After use, this product may be a potential biohazard.** Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Precautions

- **Excess tension should be avoided as it may result in selection of an improperly sized, i.e., too short, replacement** device and complications such as pressure necrosis.
- **If the stoma length falls between two markings, the one** which is external to the stoma tract should be selected.
- **Care should be taken to orient the device along the path of** the stoma during insertion.
- **Too much pressure may cause the entire Button device to be** pushed into the stomach.
- **Too much pressure may cause the entire Button device to be** prematurely pulled out of the stomach.

Adverse Reactions

May include: minor wound infection or pressure necrosis at stoma site; leakage of gastric contents; gastrocolic fistula; and gastric separation leading to peritonitis, sepsis and death. All of these potential complications increase in likelihood with improper placement. If the stoma measuring device is pulled too tightly against the stomach wall an improperly sized, i.e., too short, replacement device may be selected.

Instructions for Use

1. Inspect contents of kit for damage. If damaged, do not use.
2. The Button replacement gastrostomy device is designed for placement through a well-established stoma tract.
3. Measure stoma length to determine correct Button device sizing using either the existing gastrostomy tube or the stoma measuring device included in this kit.

   NOTE: Any evidence of infection, irritation or granulation tissue should be addressed medically prior to placement of this device.

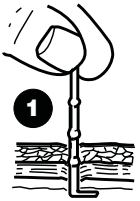
If the existing gastrostomy tube is used:

- Mark existing gastrostomy catheter with a marker at skin level.
- Remove gastrostomy tube per manufacturer's instructions.
- Measure catheter length from the top of the internal bolster to the skin-level on the tube.
- Cleanse gastrostomy site with soap and warm water or povidone-iodine.

If the enclosed stoma measuring device is used:

- Remove the existing gastrostomy tube per manufacturer's instructions. Any evidence of granulation tissue, infection or irritation should be addressed medically prior to measurement of the stoma tract.
- Cleanse gastrostomy site with soap and warm water or povidone-iodine.
- Five (for 18 French [6.0 mm] and 24 French [8.0 mm] Button devices) or three (for 28 French [9.3 mm] Button devices) raised bands on the stoma measuring device represent the exact length of Button devices available.

- Carefully insert the stoma measuring device into the stoma and advance into the stomach.
- Once in the stomach, gently pull up the device until slight resistance is met and the internal portion of the device rests against the gastric wall. ❶
- Count the number of raised bands exposed to determine the correct Button device size needed, as follows:



18 French (6.0 mm) / 24 French (8.0 mm) Button devices:

Exposed Bands	Recommended Device
1	REF 000296, 24F (8.0 mm) x 4.4 cm
2	REF 000284, 18F (6.0 mm) x 3.4 cm or REF 000287, 24F (8.0 mm) x 3.4 cm
3	REF 000283, 18F (6.0 mm) x 2.4 cm or REF 000286, 24F (8.0 mm) x 2.4 cm
4	REF 000282, 18F (6.0 mm) x 1.7 cm or REF 000285, 24F (8.0 mm) x 1.7 cm
5	REF 000292, 18F (6.0 mm) x 1.2 cm or REF 000293, 24F (8.0 mm) x 1.2 cm

28 French (9.3 mm) Button devices:

Exposed Bands	Recommended Device
1	REF 000263, 28F (9.3 mm) x 4.3 cm
2	REF 000262, 28F (9.3 mm) x 2.7 cm
3	REF 000261, 28F (9.3 mm) x 1.5 cm

- Discard the stoma measuring device after single use.

4. The obturator is designed to distend the Button device for insertion through the stoma. It should be slightly lubricated with a medical grade, water soluble lubricant. Prior to placement in the patient, insert the obturator through a side hole of the internal dome and into its dimple, then stretch to narrow the dome.
5. Lubricate the deformed dome of the Button device and stoma site. Carefully insert the tip of the device into the stoma and advance through into the stomach using slow, steady pressure.
6. Once the Button device's internal dome has been introduced into the stomach, carefully withdraw the obturator.
7. Confirm placement by rotating the device and verifying that there is no resistance encountered when the Button device stem is gently pushed into the stoma.

WARNING: Proper location of the internal dome must be confirmed prior to initiating feeding. Placement or slippage of the device into the peritoneal cavity will result in serious consequences including peritonitis, sepsis, and potentially death.

WARNING: Improper placement or excessive traction on the external portion of the device, whether intentional or unintentional, could result in dislodgement or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

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8. Cleanse the catheter and stoma site.
9. A bolus and continuous feeding tube have been included for administration of enteral feedings and medications and a decompression tube has been included for stomach decompression with the Button device kit.

Following are instructions for their use:

- Open safety cap of Button device.
- Select the desired tube and close its clamp.
- Attach the tube's adaptor to the Button device with a slight twisting action and slight pushing pressure. The adaptor should be completely inserted to assure a secure fit.
- The tube is now ready for use.
- Once feeding is complete, flush the Button device with the prescribed amount of warm water.
- Remove the feeding tube adaptor using a slight twisting action.
- Close the safety plug to keep the lumen clean, the profile cosmetically pleasing and to minimize reflux.
- Mechanically clean the feeding tube with soap and water and thoroughly rinse.

10. A decompression tube has been included for stomach decompression.

    Following are instructions for use:

    - Open the safety cap of the Button device.
    - Attach decompression tube adaptor to the Button device with a slight twisting action and slight pushing pressure. The adaptor should be completely inserted to ensure adequate decompression.

      If difficulties are encountered during decompression, it is important to take the following steps:

      - Back-flush the decompression tube with water.
      - Remove the tube and clean any food that has accumulated in the slot of the tube.
      - Reinsert tube.
      - Reposition the patient to improve decompression.
    - The device is now ready for use. Decompress for the amount of time prescribed by health care provider.
    - Once decompression is complete, remove decompression tube with a slight twisting action and slight pulling pressure.
    - Close the safety plug to keep the lumen clean, the profile cosmetically pleasing and to minimize reflux.
    - Mechanically clean the decompression tube with soap and warm water and thoroughly rinse.

Button Device Removal

I. Traction Method

- Grasp the flanges near the stoma site. Slowly rotate the Button device and gently push the tube into the stoma site if sufficient play is available, in order to disengage the tube from the fibrous tract.

WARNING: If device is not free-floating within the tract, do not attempt to use traction as a method of removal as tract damage could occur.

- While maintaining a firm grasp on the Button device flanges near the stoma site, place the fingers of the other hand around the base of the tube in order to apply counter pressure.
- Loosely cover the tract with either a towel or drape.
- Apply steady tension to the Button device until the internal bolster emerges through the abdominal wall.
- Traction removal may also be accomplished by placing an obturator through the feeding port down the center of the device to distend/ elongate the Button device's dome.
- If not replaced, the fibrous tract usually closes within 24 hours.

II. Endoscopic Method

- Introduce gastroscope, insufflate stomach and inspect stomach interior.
- Insert polypectomy snare and position under the internal bolster.
- Grasp the Button device flanges and slowly rotate the tube. Gently push device into stomach, and snare internal bolster.
- Cut the tube near the skin line and withdraw scope, snare and bolster.

III. Surgical Method

Surgically remove the internal bolster if unable to remove using either the traction or endoscopic method.

WARNING: After use, this product may be a potential **biohazard. Handle and dispose of in accordance with** accepted medical practice and applicable local, state and federal laws and regulations.

An issued or revision date and a revision number for these instructions are included for the user's information on the first page directly beneath the telephone number of Bard Access Systems. In the event that two years have elapsed between this date and product use, the user should contact Bard Access Systems to see if additional product information is available (Telephone Number: 1-800-545-0890 in the USA, or 801-522-5000).

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