

Silicone Stoma Button



Product Information and Instructions for Use



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SYMBOLS										
REF	Catalogue Number	**	Manufactured By	NON STERILE	Non-Sterile					
LOT	Lot Number	EC REP	Authorised Representative in the European Community		Instructions For Use					
	Use by date (YYYY-MM)	(39)	Do Not Use if Packaging is Open or Damaged	Батрх	Latex Free					
类	Keep away from Sunlight	*	Keep Dry	РНТ	Phthalate Free					

ENGLISH - INSTRUCTIONS FOR USE

Intended Use:

Medasil Silicone Stoma Buttons are intended to be used for temporary non-surgical maintenance of tracheostomas in the adult patient population. Each device is intended to be used up to 29 days. The device is supplied non-sterile, for single patient use.

Device Description:

Stoma Buttons are a self-retaining device, moulded from silicone elastomer which is biocompatible, and latex and phthalate free . They are soft and durable, with all edges radiused and the outer surface entirely smooth, to enhance patient comfort and tolerance. Stoma Buttons are discrete, passive, friction-fit devices that do not require an external tie or strap, and only the narrow outer flange is visible when the device is in situ. The device contains Barium Sulphate (BaSO4) which may aid visibility under X-ray. Available in three sizes.

Indications for Use:

Indications include, but are not limited to:

- For maintaining patency of the tracheostoma following laryngectomy.
- For patients who need to continuously keep their tracheostoma open (long-term tracheal access) and who no longer require a tracheostomy tube or no longer reliant on positive ventilation or the mechanical support afforded by a fulllength-tube.
- For patients who may require repeated tracheostomies, such as those who have myasthenia gravis, spinal cord injuries or sleep apnoea.
- For patients undergoing rehabilitation while working towards de-cannulation, or in patients for whom a future surgery is planned.

Contraindications:

Include, but are not limited to:

- Patients with a blockage in the larynx.
- Patients who have infected or damaged tracheostoma tissue.
- Patients with granuloma tissue in the tracheostoma.
- Patients who require a tracheostomy tube rather than a Stoma Button.
- Patients who are under any form of mechanical ventilation.
- Patients with bleeding disorders or patients on anticoagulants should not use
 Stoma Buttons if it causes bleeding that re-occurs.
- Should not be used if the patient has a known allergic reaction towards silicone.

Possible Adverse Effects:

Include, but are not limited to:

- Foreign body aspiration which could potentially cause infection to the chest.
- Stoma irritation and bleeding.
- Clogging of the Stoma Button if strong viscid secretions are produced. If it is not
 possible to clear the button, it may require removal and replacement.
- Granulomatous reactions of the stoma, requiring removal of the Stoma Button.
- Procedures involving Stoma Button contact with the Central Nervous System or Central Circulatory System.

If such events occur, medical attention should be sought.

Warnings and Precautions:

Prior to use, the HCP should consider the following:

- Carefully choose the size of the Stoma Button to ensure it meets the requirements of each specific clinical condition, while minimising adverse effects.
- Ensure that the patient is fully trained in the use of the device and has demonstrated the ability to understand and consistently follow the Instructions for Use.
- The Stoma Button must not be pushed too far into the tracheostoma or inserted with sharp objects as it may dislodge into the airway which may obstruct breathing. The use of excessive force during insertion may also cause bleeding.
- The Stoma Button should never be cleaned while inside the tracheostoma, as this could cause tissue damage and irritation. It could also dislodge the device.

- Only a clean and intact Stoma Button should be used. Any dirty or damaged device can cause tissue damage, aspiration of small parts or formation of granulation tissue.
- Due to the radio-dense structure of the mediastinum, aspiration of a stoma button may not present itself upon initial X-Ray assessment. In the event or suspicion of accidental aspiration a CT scan may need to be performed as a secondary assessment measure if the foreign body is not initially detected.
- Must not be used if the patient has known allergic reaction towards silicone.
- Must not be used beyond expiry date on the label.
- Must not be used if the packaging is compromised.
- Must be stored in the original unopened packaging.
- Must be stored away from moisture and direct sunlight.
- Are single patient use devices.

Cleaning instructions:

Any material worn against the skin should be cleaned on a regular basis using conventional personal hygiene methods, and always determined in consultation with the HCP. Medasil recommends the following cleaning regime:

- 1- Gather all the items you will need:
 - Clean container
 - Personal hygiene soap (fragrance-free, dermatologically and hypoallergenic tested)
 - Gauze swabs / soft brush
- 2- Using the soap, clean your operating surface.
- 3- Wash your hands with soap and water. Rinse and dry with a clean towel.
- 4- Add a solution of 1 part of soap to 10 parts of water at room temperature into the clean container.
- 5- Place the Stoma Button into the container, ensuring the device is fully submerged with the solution for 10 minutes.
- Gently wash the Stoma Button using gauze swabs. Use a soft brush if needed, to remove any secretions or crusts. Make sure the outer and inner surfaces are washed with special consideration to all edges by making physical contact with all surfaces using a backwards/forwards/twisting motion.
- 7- Thoroughly rinse the device with running water.
- 3- Allow the device to dry by placing it on the clean operating surface
- 9- Before re-insertion, inspect the device to make sure the surface is clean. Check for signs of visible damage and deterioration (cuts, tear, abrasion etc.). If damaged, do not re-use and replace with a new device.
- 10- After insertion, check the device fits well, does not feel lose and is well retained. If not, remove and seek advice from HCP.

Number of reuses

The device is recommended to be cleaned in a daily basis, once or twice a day up to a limit of four times a day for a maximum of 29 days.

Directions for insertion:

- 1. Before insertion:
 - The HCP prescribing the use of the device will assist in selecting an appropriately sized device.
 - Optimum sizing is based on the individual's tracheostoma diameter, it may be necessary to test various sizes for an adequate and comfortable fit.
 - Ensure hands are clean and dry before handling the Stoma Button visually inspect the device before each use for any signs of contaminants or damage, if present replace the device with a new one.
 - Device must be cleaned and dried before use following the recommended cleaning instructions.
 - If possible, the HCP should demonstrate the technique for insertion on an anatomical model

2. For self-insertion:

- Use a mirror with sufficient lighting to illuminate the tracheostoma.
- Follow the instructions for insertion recommended by the HCP
- Check the fit by slightly tugging the button, it should be a snug fit with very minimal movement.

Directions for removal:

Follow instructions for removal given by the HCP.

Sterility

Supplied non-sterile. It is not intended to be sterilised before use.

Single Patient Use:

The device may be used multiple times on the same patient only.

Disposal of Devices:

Devices **must** be disposed of in accordance with local and national regulations.

Table 1. Product REF Specifications

REF	Old REF	Neck OD Diameter	Outer Flange Diameter	Length
130-1010-1710	139C	10 mm	21.75 mm	24 mm
130-1010-1712	139D	12 mm	21.75 mm	24 mm
130-1010-1714	139E	14 mm	21.75 mm	24 mm

^{*}Box code for 10 packed devices