

Insertion of the Blom Singer® Plug Insert

The plug insert is designed to prevent leakage through the voice prosthesis until such time that the voice prosthesis and TEP is evaluated by a clinician; it does not allow voicing.



RX
(USA)

Available since 1995

The plug insert is available in two sizes (16 Fr. and 20 Fr.) for use with the Blom-Singer Classic and Advantage Indwelling Voice Prostheses. Ensure that the size of the plug insert correctly matches the size of the voice prosthesis. Insert the plug insert only while using a close-up mirror and a bright light focused directly into the stoma. The indwelling accessory device should always be cleaned to prevent contaminants from entering into the tracheostoma, puncture, or esophagus. The user's hands should always be washed with soap and water prior to cleaning the plug insert.

INSERTION INSTRUCTIONS

1



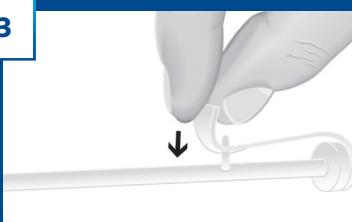
The plug insert consists of a plug tip (a) and neck strap with safety hole.

2



Place the tip of the inserter tool into the open end of the plug insert.

3



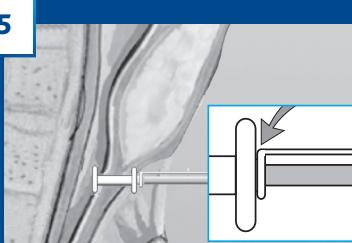
Attach the safety hole in the neck strap on the plug insert securely and completely down over the safety peg on the inserter tool. This should prevent inadvertent dislodgment of the plug insert off the inserter tool during insertion into the voice prosthesis.

4



Carefully and gently insert the plug insert until it is fully inserted and positioned flush with the voice prosthesis. Never force the plug insert into the voice prosthesis*.

5



After confirming that the plug insert is securely in place and fully inserted, the inserter tool should be carefully removed.

6



Hold the inserter tool and the neck strap together firmly in one hand. Carefully lift the neck strap off the safety peg on the inserter tool. Hold the neck strap against the neck while slowly and gently withdrawing the inserter tool with a twisting motion.**

7



Apply a strip of hypoallergenic medical adhesive tape over the neck strap to prevent strap movement.

*** CAUTION:** If the device does not insert easily on the first attempt, do not continue to try to insert it. Should you experience repeated difficulty in managing the plug insert, contact your physician/clinician as soon as possible.

******Caution should be exercised when removing the inserter tool to avoid accidental displacement of the plug insert or voice prosthesis which could result in aspiration (inhalation) of the device or voice prosthesis. Should aspiration occur, attempt to cough the device and/or voice prosthesis out of the windpipe. Seek medical attention **immediately** if unsuccessful.

CAUTION: Do not use plug insert with a 4 mm size voice prosthesis. The plug insert will not fully insert into a 4 mm size voice prosthesis due to the shorter length of the voice prosthesis shaft. This could result in pushing the voice prosthesis into the esophagus.

WARNING: Do not detach or in any way modify the neck strap on the plug insert. **The neck strap should not, under any circumstances, be cut or removed from the plug insert.** The neck strap is intended to help prevent accidental aspiration (inhalation) of the device should the device become dislodged. This device is designed for temporary use only (maximum of 30 days) and is not intended to replace the indwelling voice prosthesis.

INSTRUCTIONS FOR USE: <https://www.inhealth.com/vspfiles/pdf/IFU/R1/37582-01G.pdf>

Removal of the Blom Singer® Plug Insert

Removal of the plug insert should only be done while using a close-up mirror and a bright light focused directly into the stoma so that the open end of the prosthesis is clearly visible.

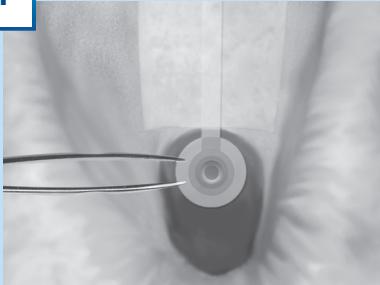


RX
ONLY
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REMOVAL INSTRUCTIONS

1



Stabilize the voice prosthesis by holding it carefully and firmly with tweezers to avoid displacement. Grasp the neck strap of the plug insert and gently pull it out from the voice prosthesis.

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