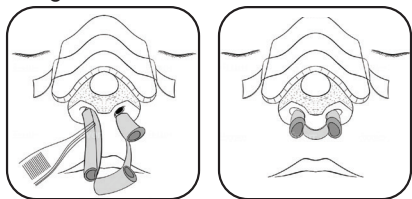
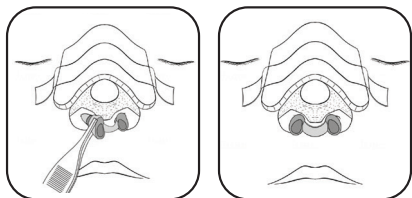


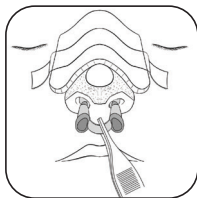
- Gently insert the left arm of the device in the right nostril.



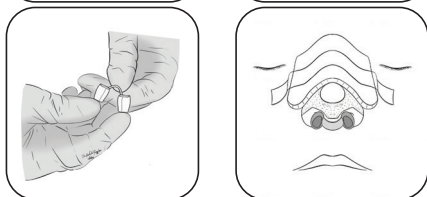
- Gently advance the left and right nostril dilator portions of the device into the nostrils.



- Physicians typically leave the device in the nasal cavity up to ten (10) days.
- To remove, grasp the portion connecting the right and left arms of the stent with forceps or fingers and gently withdraw.



- To convert Bstent into a Nostril Retainer after the initial recovery period, cleanse with warm water & soap to remove debris.
- Second, carefully remove both stent arms with a clean scissors or blade.
- Third, discard of both stent arms.
- The Nostril Dilator can be used as directed by physician, while following cleaning, storage and cumulative use instructions included herein.



BstentTM

NASAL STENT

INSTRUCTIONS FOR USE

REF 7001 & 7002

REF

Catalog Number

LOT

Lot Number

UDI

Unique Device Identifier

MD

Medical Device



Manufacturer



Consult Instructions for Use

R ONLY

Prescription Only



Caution



Use by date

STERILE (VH02)

Sterilized Vaporized Hydrogen Peroxide



No Resterilize



Single Use



Damaged Pack



Keep away from sunlight



Temperature Limit Symbol

R ONLY

Caution:

Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured for
 PS Devices, LLC
 29001 Cedar Rd. Suite 431
 Lyndhurst, OH 44124 USA
 P: 440-565-7112
 E: customerservice@bstentrhino.com

Intended Use

This device is intended for use postoperatively to provide septum support, prevent nostril collapse, and permit potential nasal breathing.

Device Description

Bstent™ combines the features and benefits of nostril retainers and septal stents into a single, dual purpose device, without the need for fixation. It is removable or modifiable with physician instruction. Bstent™ can be used in two configurations, as directed by a physician: 1) As a Conjoint Nasal Stent (as originally packaged); 2) As a Nostril Retainer, by removing both arms after the initial recovery period. Bstent™ is constructed from molded, medical grade liquid silicone rubber. The patient's cumulative nasal use period, in one or both configurations, should be less than thirty (30) days.



Indications for Use

Appropriate for use after Rhinoplasty, Turbinate reduction, Septoplasty, or Rhinoseptoplasty.



Contraindications

There are no known contraindications. Medical judgment is necessary when using this device in patients with severe head trauma and in patients whose facial anatomy may not readily accommodate the full splint length.

⚠ Warnings

-  Do not use if package is opened or damaged.
- Medical judgment is necessary when selecting appropriate size to use on the patient.
- Do not forcefully insert the device into the patient's nasal cavity or patient may experience discomfort.
- Do not modify the device other than as described in these Instructions for Use or malfunctions may occur resulting in increased possibility of adverse tissue complications.
- Medical judgment is necessary to determine when and how the stent should be removed from the patient's nasal cavity.
- Do not exceed 29 days of patient cumulative use.
-  This device is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse or resterilization may compromise the structural integrity of the device and / or create a risk of contamination of the device.

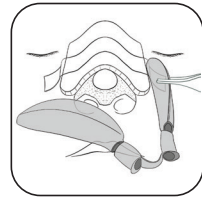
Storage

-  Keep in a cool, dry location away from light, heat and water.
-  Store in 10°–27°C (50°–81°F).
- If converted into a Nostril Retainer, store in a clean container

Instructions for Use

Each physician must exercise his or her own medical judgment in deciding which techniques and procedures are appropriate for using these devices. The following procedures are provided for general guidance to ensure this device functions as designed. Each physician must evaluate the appropriateness of the use of this device and the suggested direction for use based on his or her own medical training and experience and on the specific needs of the patient.

- If you plan to apply an external nose split, do so before inserting this device.
- If a portion of the tape is covering the nostril trim it first to expose the nostril.
- Suction the nasal cavity with soft suction.
- Lubricate the stent with antibiotic ointment of your choice.
- Make sure the narrower portion of the tube section is facing up to follow the contour of the nostrils.



- Beginning with the left nostril, gently advance the right arm of the stent posteriorly along the nasal floor until the entire arm is in the nose. Folded wings will open back into their original shapes inside the nose.

