INHEALTH™ TECHNOLOGIES

FREEMAN®
FRONTAL SINUS STENT

with Blom-Singer® Gel Cap Insertion System

MEDICAL PROFESSIONAL Instructions For Use
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**MEDICAL PROFESSIONAL Instructions For Use**
Precautions and symbol key

**STERILE**

CONTENTS STERILE unless seal is broken or package opened or damaged.

**Do not resterilize**

**This product is for single patient use only**

**Consult instructions for use**

**Read instructions prior to use**

**Caution: Federal law (USA) restricts this product to sale by or on the order of a physician.**

**Lot / Batch code**

**Date of manufacture**

**Expiration date**
FREEMAN™ FRONTAL SINUS STENT
with Blom-Singer® Gel Cap Insertion System

This Product Information Data Sheet is intended to provide instructions for use regarding the placement and removal of the InHealth Freeman Frontal Sinus Stent.

INDICATIONS
The Freeman Frontal Sinus Stent is intended to be placed at the time of surgery to provide postoperative drainage of the frontal sinus and to prevent blockage of the frontal sinus outflow tract following sinus surgery. The sinus stent is designed to be placed with the use of a gel cap and an insertion instrument under endoscopic or direct visualization. The sinus stent includes angled flanges to provide retention and is manufactured of silicone rubber. The sinus stent is intended to be removed within twenty-nine days postoperatively.

CONTRAINDICATIONS
The Freeman Frontal Sinus Stent is contraindicated in cases with difficult insertion that does not allow for direct or endoscopic visualization. The stent is contraindicated for patients with a known sensitivity or allergy to silicone rubber.

HOW SUPPLIED
The Freeman Frontal Sinus Stent is supplied sterile in a single-wrapped packaging system. It includes: Frontal Sinus Stent, Gel Caps, Gel Cap Loading Tool, and Insertion Instrument.

Contents are sterile only if package is not damaged or opened. Store in a cool and dry place.

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INSTRUCTIONS FOR USE
The Frontal sinus stent is designed to be loaded using a gel cap loading tool with a specially sized gel cap and then placed with the insertion instrument. The function of the gel cap is to:

Decrease the profile of the tip of the sinus stent by folding the sinus-end flange in a forward position inside the gel cap so that the sinus-end flange is fully encapsulated. This eliminates the presence of the sinus-end flange during insertion of the device.

Reduce the trauma and force that may be associated with sinus stent insertion by providing a smooth, rounded shape to the sinus-end flange, thus enabling easy entry into the sinus.

The gel cap will dissolve within 1-2 minutes after inserting the device. The sinus-end flange on the sinus stent which is of an appropriate length and which has been positioned correctly will unfold and the sinus stent will be in its proper position within the sinus. Please refer to Gel Cap Loading Instructions below.

Endoscopic Insertion
The Frontal sinus stent includes a sinus-end angled flange and a nasal-end angled flange. The nasal-end flange has a removal tab and a hole centered in a raised section on the flange.

Please refer to the diagrams located at the front of this data sheet.

The following procedure is provided by Stephen B. Freeman, F.A.C.S, of Head and Neck Surgery Associates, Indianapolis, Indiana.

1. Place a specially-sized gel cap on the sinus-end flange per Gel Cap Loading Instructions below.

Blom-Singer Gel Cap Loading Instructions:

a. Remove the sinus stent and gel cap loading tool from the tray. Hold the stent in one hand, (removal tab pointed down) and the gel cap loading tool in the other hand (diagram 1).

b. Place the shaft of the sinus stent in one side of the gel cap loading tool. Make sure the flanges exceed both ends of the
loading tool and the removal tab is pointed down. Close the gel cap loading tool capturing the shaft of the sinus stent (diagram 2).

c. Grasp the nasal-end flange between thumb and forefinger. While holding the gel cap loading tool closed, pull the sinus stent down until the sinus-end flange has folded within the cylinder of the loading tool (diagram 3).

d. Take the transparent, longer end of one gel cap and carefully place it over the top end of the gel cap loading tool (diagram 4). When properly placed, the gel cap will hold the tool in its closed position.

e. Remove the insertion instrument from tray and insert it into the open shaft of the sinus stent. Carefully push the insertion instrument into the sinus stent (nasal end). When the insertion instrument hits the inner lip of the sinus stent, it will start to push the sinus-end flange into the gel cap. This will free the sinus stent from the gel cap loading tool (diagram 5).

f. With the sinus stent on the insertion instrument, it is now ready to be inserted into the frontal sinus (diagram 6).

2. Under endoscopic visualization, carefully advance the sinus stent into the frontal sinus ostium.

**Warning:** Avoid excessive force with the insertion instrument to avoid penetration into the orbit of the intracranial cavity. An open procedure under direct visualization is recommended for cases of difficult insertion.

3. After insertion, under direct or endoscopic visualization, use saline irrigation to clean the area and to dissolve any residual gel cap on the sinus-end flange.

4. After verification that the stent is properly placed, remove the insertion instrument from sinus stent.

**Direct Approach Insertion**

If the frontal sinus opening cannot be endoscopically visualized and cannulated, the direct (external) approach may be indicated.

1. A lynch incision is made and the frontal sinus is fenestrated with an osteotome or drill.
2. A 2-0 silk suture is passed through the hole provided on the nasal-end flange.

3. Curved antral suction is passed through the nose into the fenestration or retrograde from the fenestration into the nose.

4. The 2-0 silk is threaded through the antral suction to guide it into the fenestration or nose (retrograde technique).

5. The combination of gentle pulling of the suture and pushing of the sinus stent will guide the sinus stent into position. (A gel cap is not necessary.)

**Removal**

Under endoscopic visualization, use forceps to grasp the removal tab and gently withdraw the sinus stent.

**Warning:** Although silicone rubber is a durable material, care should be taken to avoid tearing the material with sharp instruments.

**WARNINGS AND PRECAUTIONS**

Avoid excessive force with the insertion instrument to avoid penetration into the orbit of the intracranial cavity. An external procedure under direct visualization is recommended for cases of difficult insertion.

**Caution:** If modification to the angle of the inserter shaft is desired by the user, care should be taken when modifying to avoid applying force to the inserter tip.

Although silicone rubber is a durable material, care should be taken to avoid tearing or nicking the material with sharp instruments.

Administration of antibiotics, either orally or topically, is recommended in case of purulent drainage.

An aqueous-based antibiotic/steroid cream may be used after stenting the frontal sinus.

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.
COMPLICATIONS
The following complications have been identified as possible occurrences with the Freeman Frontal Sinus Stent.
They include:

• accidental dislodgment and migration of the stent into the frontal sinus which will require removal by a physician
• accidental penetration into the orbit of the intracranial cavity during insertion and placement of the stent
• inflammatory reaction around the stent and the formulation of granulation tissue
• tearing or other damage to the stent from improper use of the insertion instrument; tearing or other damage to the stent from improper use of sharp instruments

SPECIAL ORDER PRODUCTS
If this instruction manual accompanies a Special Order Product, there may be differences in the physical characteristics between the product and the product descriptions described in this instruction manual. These differences will not affect the safety or desired beneficial effect of the special order product. Special Order products are nonreturnable.

ORDERING INFORMATION
USA
Blom-Singer products may be ordered directly from InHealth Technologies. TELEPHONE: Toll-Free (800)477-5969 or (805)684-9337, Monday — Friday, 9:30 am — 7:00 pm, Eastern Standard Time. FAX: Toll-Free (888)371-1530 or (805)684-8594. EMAIL: order@inhealth.com ORDER ON-LINE: www.inhealth.com POST: InHealth Technologies, 1110 Mark Avenue, Carpinteria, CA 93013-2918, USA, Attention: Customer Service.

Consumer Affairs
If you have any questions or dissatisfaction with a product please contact our customer service department via telephone, fax, post, or Email: productcomplaints@inhealth.com
BIBLIOGRAPHY

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