



Composite Removable Sinus Stent

INSTRUCTIONS FOR USE

Rx Caution: Federal law restricts this device to sale by or on the order of a licensed physician

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Before using the device, please check local regulations. If any local legislation is violated, use cannot be authorized.

SYSTEM DESCRIPTION

The composite removable sinus stent provides sinus wall support following functional endoscopic sinus surgery. A delivery system is provided to insert the implant.

The system contains the following components:

STENT

The stent is balloon expandable and composed of an outer polyurethane and inner Nitinol alloy bodies. The stent is designed to accommodate the size and variability of the post-surgical ethmoid cavity anatomy. Once expanded the stent is designed to support the walls of ethmoid cavity, in order to maintain patency and prevent adhesions and middle turbinate lateralization into the septum. Stent can be removed within 4 weeks by cooling and self-crimping, see stent and stent on balloon in Figure 1.

DELIVERY SYSTEM

The delivery system (Figure 2) is designed to insert, position and deploy the stent, following functional endoscopic sinus surgery, guided by endoscopic direct vision. The delivery system consists of a water filled syringe connected to high compliance balloon via rigid shaft. The balloon is supplemented with color marker.



Figure 2: Stent on Delivery System



INTENDED USE

The Composite Removable Sinus Stent is intended for use in adult patients following sinus surgery, to provide steady support of nasal walls against swelling mucosa, stabilize middle turbinate and prevent obstruction by adhesions. The composite stent is intended to be left inside the ethmoid sinus cavity for up to 28 days. The stent can be removed at any time within 28 days after cooling and self-crimping.

CONTRAINDICATIONS

- Excessive polyps impairing visualization
- Known Nickel allergy
- Known Polyurethane induced dermatitis
- History of immune deficiency
- In rare instances, the physiochemical condition associated with sinus surgery, both with and without composite stent may present a risk of toxic shock syndrome (TSS).
- Avoid using the device adjacent to the skull base.

SAFETY

INSTRUCTIONS

Read and understand all instructions in this document before use. If you have any questions contact STS Medical Ltd.

GENERAL PRECAUTIONS AND WARNINGS

WARNING

Follow these safety guidelines to maintain a high level of patient and personnel safety.

- The device is provided sterile, in a single use package. The package should be examined for integrity before use. Do not use the device if its package seems damaged.
- The package should be stored in a cool, dry place and opened under sterile conditions only.
- The device should be used only by physicians who have been trained in its use.
- The patient should be advised by physician, to refrain from cold nasal washes / temperatures below 20°C for the time of implantation (refrain from cold nasal washes/ swimming/diving in cold water).
- The patient should be advised by physician, to refrain from practicing extreme sports or exercising in the cold environment (e.g. skiing, skating, snowboarding, ice climbing etc.) for the time of implantation.
- For single patient use only. Do not reuse, reprocess or re-sterilize. Re-use, re-processing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Do not use this device after the expiration date that appears on the packaging.
- The patient should be advised to consult with physician, in case of infection.
- Disposal of the device according to local regulations.
- Device should not come in contact with acetone / alcohol based solutions or ointments. These can damage the material if used over time.

SYMBOLS USED

The following symbols appear on the device packaging:

SYMBOL	DESCRIPTION
	Refer to instruction manual/booklet
	Single Patient Use / Do Not Reuse / Use only once
	Do not re-sterilize
	Expiration date
	CE Compliance Symbol
	Manufacturer
	Lot/Batch number
	Catalog number
	Do not use if package is opened or damaged
	Sterilized using EO
	Store between 10°C and 45°C

USE OF THE COMPOSITE REMOVABLE SINUS STENT

PREPARATIONS FOR USE

- As part of standard of care before functional endoscopic sinus surgery, perform a CT scan and verify the stent size is compatible with the nose size.
- Prepare warm saline wash to fill syringe in proximity to the surgical table.
- Remove the stent and delivery system from its protective package using sterile technique. Inspect for any obvious damage. Note: integrity of protective sheath, covered balloon and balloon shaft.

USE OF THE DEVICE

- Take the stent out from protective tube.
- Remove the stent protective sheath.
- Fill the BD Luer-Lok™ Disposable 3ml Syringe without Needle or similar, with ~ 2.5ml water / saline and attach the syringe to the balloon shaft.
- Upload stent on delivery catheter close to endoscopic marker facing towards catheter distal end.
- Fix stent on balloon catheter by inflation the balloon with about 0.5ml water / saline.
- Verify stent is secured on balloon catheter.
- Carefully advance the Delivery System into the sinus cavity using endoscopic visualization.
- Position the stent inside the ethmoid cavity.
- Inflate the balloon and expand the stent, by pressing the syringe plunger till the end.
- Keep balloon inflated for 10-20 seconds.
- Release plunger to deflate balloon then pull plunger to create vacuum and gently retrieve the Delivery System.
- Confirm final placement by endoscopic visualization.

Note: in case of wrong stent deployment / positioning flush stent with previously prepared saline which was pre-cooled in refrigerator for 24 hours and remove from ethmoid cavity using tweezers, grasper or other suitable medical instruments.

POST – OPERATIVE CARE

- Routine debridement may be performed as part of usual post-operative care.
- Warm saline wash (above 20°C) may be applied up to 3 times a day, at physician discretion.
- The implant may be removed at any time within 28 days, by cooling and self-crimping, and then pulled out using standard surgical instruments.

STENT RETRIEVAL

Use the BD Luer-Lok™ Disposable 20ml Syringe without Needle or any other medical instrument to flush the stent surface with 20ml saline which was pre-cooled in refrigerator for 24 hours.

MRI SAFETY INFORMATION



MR CONDITIONAL

Non-clinical testing demonstrated that the Composite Sinus Stent is MR Conditional. A patient with this implant can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the Composite Sinus Stent is lexpected to produce a maximum temperature rise of 2.0°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Composite Sinus Stent extends approximately 4-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

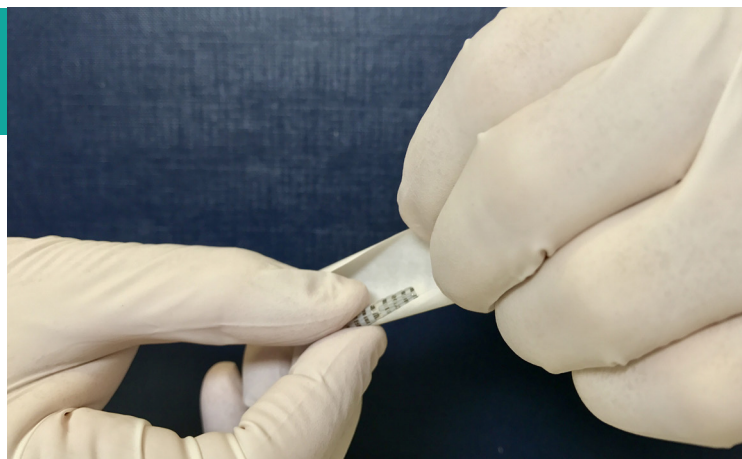
The lumen of this stent cannot be visualized on the T1-weighted, spin echo or gradient echo pulse sequences.

1



Remove constrictor.

2



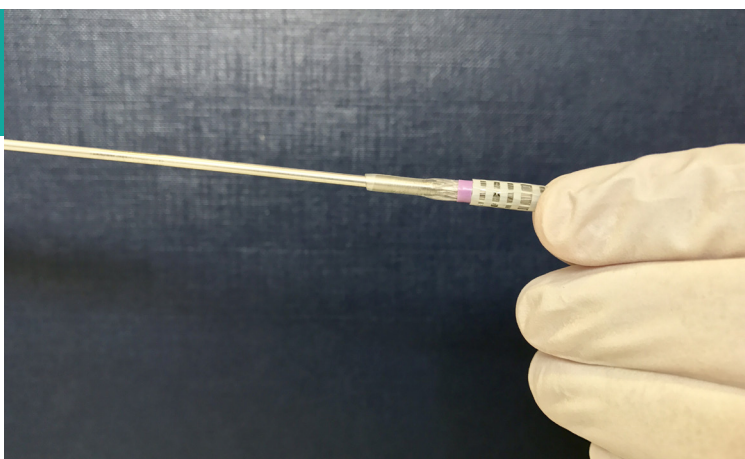
Remove the stent protective sheath.

3



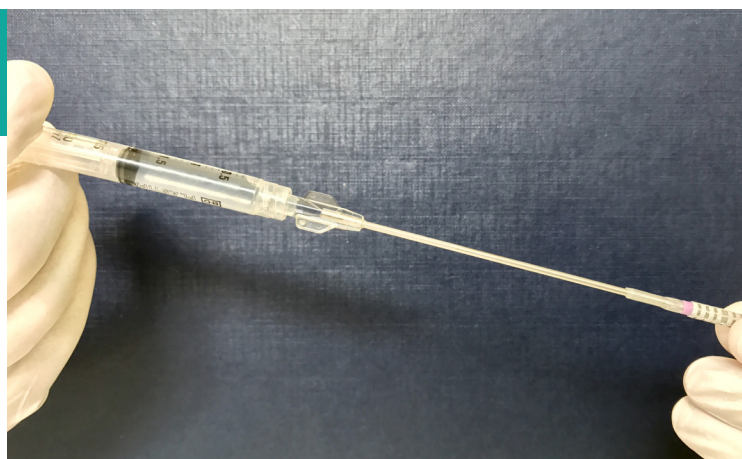
Fill syringe with 2.5ml saline and attach to balloon shaft.

4



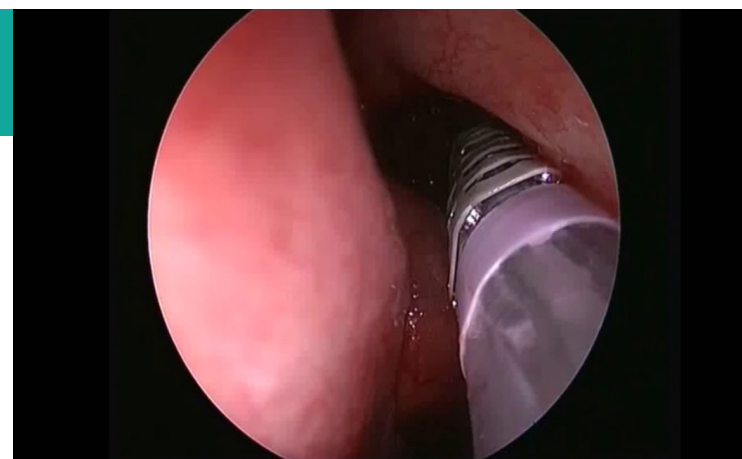
Upload stent on delivery catheter close to endoscopic marker.

5



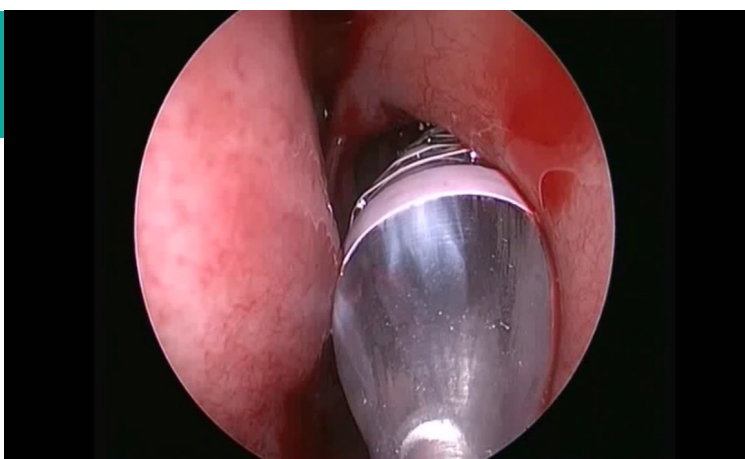
Fix stent on balloon catheter by inflation the balloon with 0.5ml saline. Verify stent securement.

6



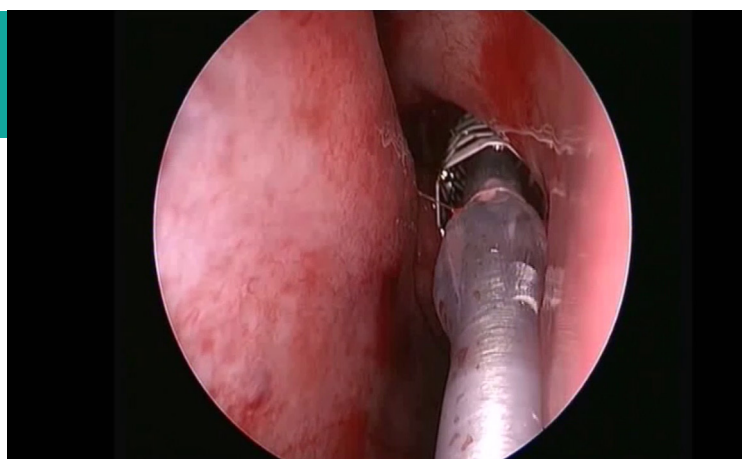
Insert and position the stent.

7



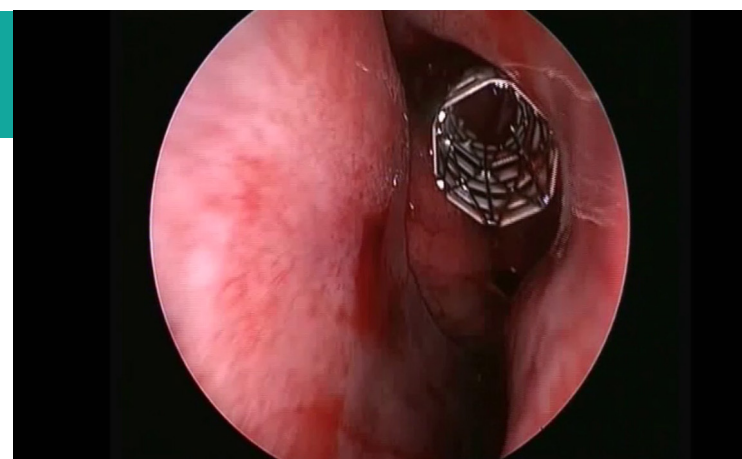
Inflate balloon catheter.
Keep balloon inflated for 10-20 seconds.

8



Deflate balloon catheter.

9



Retrieve the delivery system.