Figure 2: Stent on Delivery System

The delivery system (Figure 2) is designed to insert, position and deploy the stent, following functional 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.

STENT 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 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 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 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 endoscopic sinus surgery, guided by endoscopic direct vision.

USE OF THE COMPOSITE REMOVABLE SINUS STENT

PREPARATIONS FOR USE

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

USE OF THE DEVICE

1. Take the stent out from protective tube.
2. Warm the syringe and syringe plunger using warm water.
3. 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.
4. Position the stent inside the ethmoid cavity.
5. Inflate the balloon and expand the stent, by pressing the syringe plunger till the end.
7. Remove the stent from balloon catheter.
8. Carefully advance the Delivery System into the sinus cavity using endoscopic visualization.
9. Position the stent inside the ethmoid cavity.
10. Confirm final placement by endoscopic visualization.

SAFETY

GENERAL PRECAUTIONS AND WARNINGS

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

1. Before using the device, please check local regulations. If any local legislation is violated, use cannot be authorized.
2. The device should be used only by physicians who have been trained in its use.
3. Do not use re-use, re-processing or re-sterilization. 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.
4. Do not use the device after the expiration date that appears on the packaging.
5. 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.
6. Do not use the device if its package seems damaged.
7. Remove the stent from protective sheaths, covered balloon and balloon shaft.
8. Before using the device, please check local regulations. If any local legislation is violated, use cannot be authorized.
9. Do not warm the syringe and syringe plunger using warm water.
10. 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.
11. Position the stent inside the ethmoid cavity.
12. Inflate the balloon and expand the stent, by pressing the syringe plunger till the end.
14. Remove the stent from balloon catheter.
15. Carefully advance the Delivery System into the sinus cavity using endoscopic visualization.
16. Position the stent inside the ethmoid cavity.
17. Confirm final placement by endoscopic visualization.

POST - OPERATIVE CARE

1. Routine debridement may be performed as part of usual post-operative care.
2. Warm saline wash (above 20°C) may be applied up to 3 times a day, at physician discretion.
3. 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 and remove from ethmoid cavity using tweezers, grasper or other suitable medical instruments.

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 4000-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 expected 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 imaging 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 k-space of this stent cannot be visualized on the T1-weighted, spin echo or gradient echo pulse sequences.
**INSTRUCTIONS FOR USE**

1. Remove constrainer.
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.
8. Deflate balloon catheter.
9. Remove the delivery system.