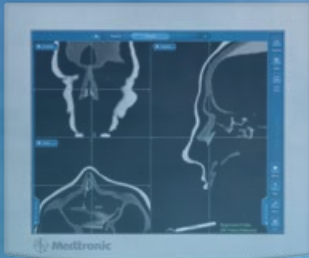




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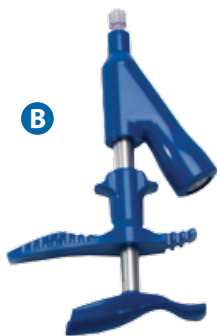
NuVent™

EM SINUS DILATION SYSTEM



Refer to product package insert for instructions, warnings, precautions, and complications.

Components

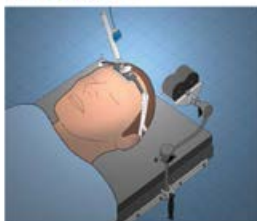


- A.** Balloons
- B.** Inflator
- C.** Extension Tube

Refer to product package insert for instructions, warnings, precautions, and complications.



Fusion® ENT Application Pocket Guide



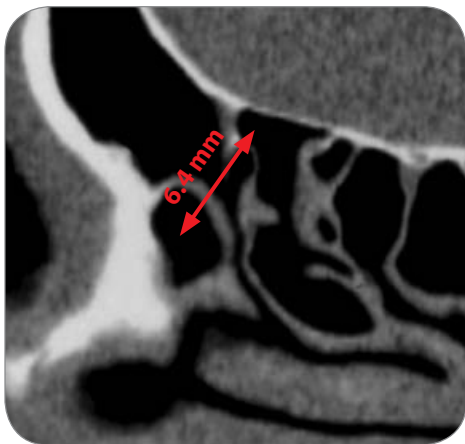
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9734349, Revision 4
09/2010

Refer to the Fusion® ENT Application Pocket Guide (Literature# 9734349) for instructions on how to set up Fusion Navigation System.

Refer to product package insert for instructions, warnings, precautions, and complications.

Choose Proper Balloon Size



1. Use measurement tool on patient CT scan on Fusion system. Determine correct balloon size based on the bony margins of the outflow tract.

Refer to product package insert for instructions, warnings, precautions, and complications.

Preparing the Inflator



- 1.** Connect the extension tube to the Luer fitting of the inflator.



- 2.** Fill a sterile container with saline solution. Place the extension tube in the container.

Refer to product package insert for instructions, warnings, precautions, and complications.

Prime the Inflator Barrel



- 1.** With the inflator barrel pointed up and the extension tube immersed in the saline solution, prime the inflator barrel by pulling and pushing on the inflator plunger, drawing saline solution into and out of the inflator. Prime the inflator barrel at least five times to remove all air bubbles from the extension tube and inflator barrel.
- 2.** Inspect the extension tube and inflator barrel for air bubbles. If air bubbles are still present, repeat step one until air bubbles are no longer present in the inflator barrel and extension tube.
- 3.** Remove the extension tube from the sterile saline solution and set the inflator aside while preparing the sinus seeker.

Refer to product package insert for instructions, warnings, precautions, and complications.

Connecting to EM Computer-Assisted Surgery System



- 1.** Place the tray on the sterile preparation surface with the connector and connecting wire on top. Without separating trays, remove the connector and connecting wire from the top tray.



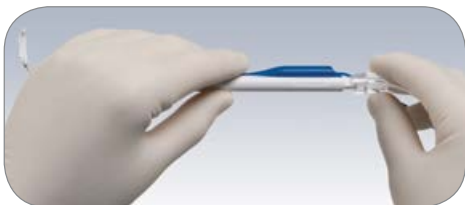
- 2.** Insert the connector to the EM Computer-Assisted Surgery System and unwrap wire.

Refer to product package insert for instructions, warnings, precautions, and complications.

Connecting Sinus Seeker to Inflator



- 1.** Grasp the sinus seeker handle in the recessed area indicated by the two arrows on the tray and remove sinus seeker from the bottom tray.



- 2.** Connect the extension tube to the luer fitting of the sinus seeker.

Refer to product package insert for instructions, warnings, precautions, and complications.

Dilating the Sinus Ostia



- 1.** Hold seeker at the distal end of the handle.
Do not use excessive force.

Refer to product package insert for instructions, warnings, precautions, and complications.

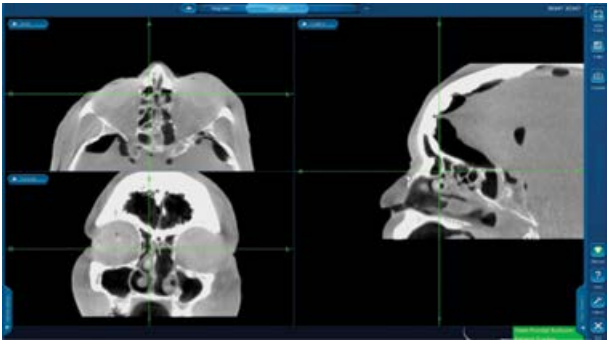
Checking EM Accuracy



- 1.** Confirm that the Fusion software displays the correct sinus seeker.
- 2.** Prior to use, confirm accuracy of the sinus seeker by touching the tip of the sinus seeker to several bony anatomical landmarks and observing the cross-hair centers on the monitor.
- 3.** If accuracy is not acceptable, visually inspect the seeker. If the seeker is bent or damaged, replace the sinus seeker and contact Medtronic Technical Services. If accuracy is still not acceptable with a new seeker, re-register the patient.

Refer to product package insert for instructions, warnings, precautions, and complications.

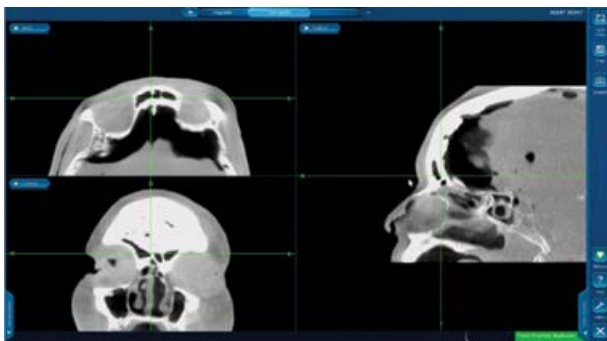
Locating the Sinus Ostia



- 1.** Insert the prepared sinus seeker into the desired anatomical location using an endoscope and EM navigation. The probe description and balloon diameter will be displayed on the Fusion software.

Refer to product package insert for instructions, warnings, precautions, and complications.

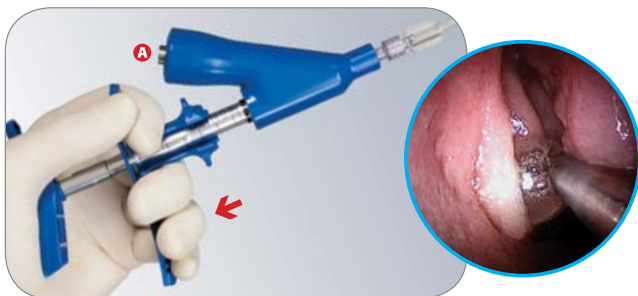
Confirming Balloon Placement



1. Confirm the proper positioning of the tip of the sinus seeker using EM navigation. The cross hairs on the screen indicate the center of the sinus seeker's tip.

Refer to product package insert for instructions, warnings, precautions, and complications.

Dilating the Sinus Ostia



1. Squeeze the inflator plunger into the inflator over the course of at least two seconds until the inflator indicator protrudes (A). Hold inflation for up to five seconds. This action inflates the balloon in the selected ostium to approximately 10 atm.

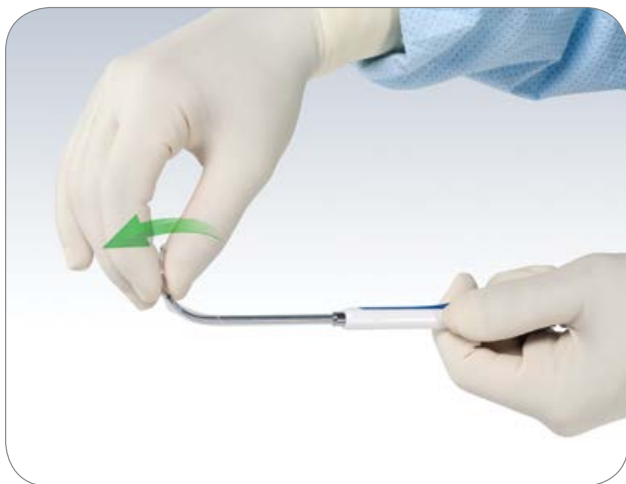


2. Upon completion of up to two dilations per sinus ostium, deflate the balloon before removing the sinus seeker from patient's anatomy by pulling back on the inflator handle until it stops.

Note: Only remove the sinus seeker when the balloon is completely deflated.

Refer to product package insert for instructions, warnings, precautions, and complications.

Preparing the Balloon for the Other Sinus



- 1.** Balloon may be wrapped with a gentle twisting motion to reduce its profile before reinsertion.

Refer to product package insert for instructions, warnings, precautions, and complications.

For questions call Customer Service at 1-800-874-5797 or 904-296-9600.
For general information, you may also visit our website at www.MedtronicENT.com.

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