PROTOCOL TITLE:

SinuSonic Study

The study will be conducted in compliance with the clinical study protocol, international good clinical practice principles (International Conference on Harmonization [ICH]-Good Clinical Practice [GCP]), and regulatory authority requirements.

PRINCIPAL INVESTIGATOR:

Dr. Zachary M. Soler, MD

1.0 Objectives / Specific Aims

- Primary: To determine the safety and efficacy of a single SinuSonic intervention.
- Seconday: Secondary objectives of this study is to determine:

  -the safety and efficacy of a twice daily SinuSonic intervention over 2 weeks.

  -the safety and efficacy of a twice daily SinuSonic intervention over 4 to 6 weeks.

2.0 Background

Chronic sinusitis/rhinosinusitis with or without nasal polyps is a multifactorial disease associated with asthma, cystic fibrosis, primary ciliary dyskinesia, acetylsalicylic acid intolerance, and possibly allergy. It is defined as an inflammation of 1 or more paranasal sinuses and is considered chronic when it lasts longer than 8 weeks (Slavin 2005). It is almost always accompanied by concurrent airway inflammation and in many cases is preceded by rhinitis symptoms.

Chronic sinusitis is one of the most commonly diagnosed diseases in the United States. It has been estimated to affect approximately 20 million Americans (Benson 1998) and up to an estimated 16% of the adult population annually in Europe (Huvenne 2009). There are currently no approved medications for treatment of chronic sinusitis. The cardinal clinical signs and symptoms of chronic sinusitis include nasal blockage/congestion, facial pain or pressure, mucosal erythema and thickening, purulent nasal secretions, headache, and a reduction in smell (Fokkens 2007). Chronic disease is distinguished in part by persistence of characteristic symptoms for ≥8 weeks (Slavin 2005).

Patients with nasal polyps tend to have a more pronounced nasal obstruction and loss of smell while those without nasal polyps tend to report headache and post-nasal drip more frequently. However, the pattern of symptoms mostly overlaps between patients with and without nasal polyps.

Current Treatment Options: There is clear need for a better medical therapy that reduces chronic sinusitis symptoms, thus improving morbidity and quality of life and decreasing the need for surgery. Currently, there are no approved medications for the treatment of chronic sinusitis. A

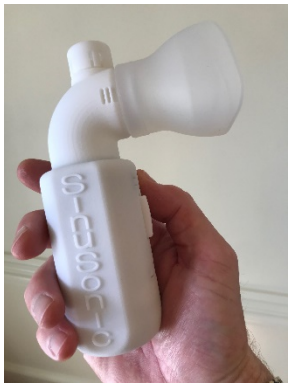
number of antibiotics have been approved for the treatment of acute sinusitis; however, there is no conclusive evidence that oral antibiotics, topical antibiotics, or topical antifungal agents are effective in the treatment of chronic sinusitis, and their use remains controversial, particularly due to concerns over emerging resistance (Ebbens 2006; Fokkens 2007; Videler 2008). As chronic sinusitis is characteristically an inflammatory disease, the anti-inflammatory effects of corticosteroids could be expected to be of benefit. There are no clinical studies published on the use of systemic corticosteroids for the treatment of chronic sinusitis without polyps, although there is evidence that systemic corticosteroids are effective at reducing the size of nasal polyps and improving rhinitis symptoms (Fokkens 2007; Van Zele 2010). Medical treatment with nasal corticosteroids (as currently available for treatment of rhinitis) is considered a first step in the treatment of chronic sinusitis; however, the data on sprays or drops does not suggest they are very effective.

Patients with chronic sinusitis currently have limited medical options for treatment and no medication is approved for the treatment of chronic sinusitis. Standard nasal spray pumps suffer from a number of drawbacks and they are considered suboptimal for reliable drug delivery to target sites beyond the nasal valve (Aggarwal 2004). Current congestion medications are not always fully effective. This study aims to test the safety and efficacy of the SinuSonic device on adults with moderate to severe nasal congestion. SinuSonic is a medical device that utilizes sound and pressure combined with normal breathing to relieve nasal congestion. The study will take place over the course of 4 to 6 weeks starting with a baseline assessment. This study will use patient responses to measure how effective SinuSonic devices are in treating adults with moderate to severe congestion in adults.

3.0 Intervention to be studied

- Initial intervention: Subjects will use the SinuSonic device for 3 minutes in the clinic setting.
- Secondary intervention: Subjects will use SinuSonic device twice daily for 3 minutes in the home setting for 14 days.
- Tertiary intervention: Subjects will continue to use the SinuSonic device twice daily for 3 minutes in the home setting for 2-4 weeks.

3.1 Device Instructions



Instructions for use:

1. Hold the SinuSonic device at a 45-degree angle
2. Deep breathe
3. Hold the SinuSonic to your mouth and blow out into the mask of the SinuSonic. The goal here is to hear the "target flutter" sound that is desired during treatment with the SinuSonic
4. Put the device over the nose using the nasal mask
5. Breathe in and out thru the nose if possible. If nasal breathing is not possible it is ok to open mouth to breathe in and try and hear the "target flutter" sound when you breathe out
6. You will feel a little resistance to breathe out and a vibration sensation from a speaker in the device
7. Remove the device to "blow the nose" if nasal drainage occurs
8. Return the device to the nose then breathe in and out thru the nose to try and hear the "target flutter" sound
9. Time of use is 2-5 minutes of nasal breathing with the device - as tolerated

3.2 Device Usage and Safety

The SinuSonic consists of a fully-disposable medical grade silicone nosepiece mounted to a resin body. The device is equipped with a flutter valve located at the top of the device which creates gentle, self-guided oscillating expiratory resistance.

4.0 Inclusion and Exclusion Criteria/ Study Population

The study population will consist of individuals present for care at the Otolaryngology clinics at the Medical University of South Carolina with nasal congestion, friends/family members of patients presenting for care at MUSC's Otolaryngology clinics.

Inclusion Criteria

- Adults ≥18 years of age
- Complaints of nasal congestion present for 2 weeks or more and a qualifying nasal congestion score of >5 (10 point VAS scale).

Exclusion Criteria

- Fixed structural cause of nasal congestion (moderate or severe septal deviation, moderate or severe nasal valve collapse, Grade 3-4 polyp)
- Inability to read and understand English
- Allergic sensitivity to silicone or any other component of device
- History of severe nose bleeding within last 3 months
- Anticoagulation (Aspirin ok)
- Known pregnancy
- Current nasal crusting or ulceration revealed on rhinoscopy
- Inability to perform treatment due to underlying medical condition

- Topical decongestant use in last week

5.0 Number of Subjects

This is a pilot study. The anticipated study population is 40 subjects.

6.0 Setting

Research will be conducted at the Medical University of South Carolina. Potential participants screening as well as the 2-week post treatment assessment will take place in the outpatient sinus clinics. The 4-6 week assessment will be done via emailing of surveys.

7.0 Recruitment Methods

MUSC Otolaryngologists will notify the study coordinator (SC) of potential participants through the Sinus Clinic. If the patient is interested, the SC will approach them and explain the study in further detail and begin the informed consent process.

8.0 Consent Process

Patients who are deemed eligible for this study will be approached by the Principal Investigator or Co-Investigator in the Sinus Clinic at the Medical University of South Carolina about the study. A member of the study team will describe in full detail the study and the informed consent form to the potential subject. The prospective participant will be given adequate time to review the informed consent form and ask any questions that they have before the consent is obtained. Participants will be given a signed copy of the ICF.

8.1 Withdrawal

At any point during the study, a subject may withdraw from the study.

9.0 Study Design / Methods

This study is designed as a pilot study.

Data will be collected by the ENT fellows as well as the subjects themselves throughout the entirety of the study. The data will consist of answers from subjects for questionnaires asked by the clinicians as well as self-reported answers from the subjects.

Safety will be monitored throughout the study based on monitoring of adverse events, performing nasal, measuring vital signs (i.e. blood pressure, pulse) and weight, and through collection of concomitant medication information.

The period of observation for collection of non-serious adverse events extends from the time the subject gives informed consent until completion of the End-of-study visit or Early Termination Visit. Serious adverse events (SAE) will be reported from the time of informed consent through 30 days after the last use of the SinuSonic. Adverse event data listings will be reviewed by SinuSonic at regular intervals throughout the study. In addition, SinuSonic will be alerted of Adverse Events of interest via automated emails programmed in the EDC system.

9.1 Schedule of Events

Phase	Screening	Treatment		
Week	0	0	2	4-6
Visit	1	2	3	4
Informed Consent	x			
Inclusion/Exclusion Criteria	x			
Medical History	x			
Height	x			
Rhinoscopy	x		x	
Vital Signs	x			
Pregnancy Test	x			
Distribution of SinuSonic	x			
NOSE Questionnaire	x		x	x
SNOT-22	x		x	x
TNSS Questionnaire	x		x	x
Global Assessment of Nasal/Sinus Problems	x	x	x	x
PNIF	x	x	x	

10.0 Data Management

All analyses and graphs will be performed with SPSS 24.0, Sample Power 3.0, and Sigma Plot 10.0 (SPSS, Chicago, IL.). Disease information and demographic variables, such as age, gender, race, quality of life (QOL) scores, and VAS scores will be summarized using frequencies, means, and standard deviation as appropriate. Outcome metrics will be compared between baseline and 5 minutes (AIM 1), baseline and 2 weeks (AIM 2), and baseline and 4-6 weeks (AIM 3). Categorical variables will be compared using Chi Square or McNemar's test. Continuous variables will be compared using One-Way ANOVA with repeated measures follow by post-hoc analysis. Data regarding safety and patient satisfaction will be summarized for each time point. A p-value ≤ 0.05 will be considered statistically significant. Due to the exploratory nature of this study, no p-value correction (ie Bonferroni) will be applied. If appropriate, subgroup analysis can be performed based on underlying disease classification (allergic rhinitis, nonallergic rhinitis, CRSsNP, CRSwNP).

11.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Safety will be monitored throughout the study based on the monitoring of adverse events, performing nasal exams, measuring vital signs (i.e. blood pressure, pulse) and weight, and through the collection of concomitant medication information.

The period of observation for collection of non-serious adverse events extends from the time the subject gives informed consent until the completion of the End-of-Study visit or Early Termination Visit. Serious adverse events (SAE) will be reported to the MUSC IRB and to the sponsor from the time of informed consent through 30 days after the last use of the SinuSonic. Adverse event data listings will be reviewed by Principal Investigator and the research team at regular intervals throughout the study.

12.0 Risks to Subjects

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

There are risks to subjects using the SinuSonic device. Subjects may experience a degree of pain due to use of the device. This degree of pain is unknown. There may also be risk of nose bleeds or crusting around the nasal cavity.

The Rhinoscopy may activate the gag reflex. Additionally, nasal discomfort, nose bleeds, spasms, and coughing may also occur.

13.0 Potential Benefits to Subjects or Others

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

14.0 Sharing of Results with Subjects

Information about the subjects (including your identifiable private information) may have all of their identifiers removed and used for future research studies.

Records of the subjects' participation in this study will be held confidential except as disclosure is required by law or as described in the ICF.

15.0 Payment

For participating in this study, participants will be compensated $50 per visit for a maximum of $150. This payment will be mailed to each participant within four weeks after completion of each visit.

18.0 Devices

Dispensing and storage of SinuSonic devices will be done by the study team. All SinuSonic devices will be stored on the 11th floor of Rutledge Tower in Room 1126 and locked in a cabinet for ambient storage. The device will be dispensed in the Outpatient Sinus Clinic. Only study participants will receive the SinuSonic for use.

19.0 DATA SAFETY MONITORING AND REPORTING

Safety data listings will be reviewed by Principal Investigator, Co-Investigators, and the research team at regular intervals throughout the study.

Safety will be monitored throughout the study based on monitoring of adverse events, performing nasal exams, measuring vital signs (ie blood pressure, pulse) and weight, and through collection of concomitant medication information.

The period of observation for collection of non-serious adverse events extends from the time the subject gives informed consent until completion of the End-of-study visit or Early Termination Visit. Serious adverse events (SAE) will be reported to the MUSC IRB and to the sponsor from the time of informed consent through 30 days after the last use of the SinuSonic. Adverse event data listings will be reviewed by the principal investigator, co-investigators, and the research team at regular intervals throughout the study.

All AEs, regardless of seriousness or relationship to SinuSonic use, spanning from the signature of the informed consent form until the end of the study as defined by the protocol for that patient, are to be reported to the Healthy Humming, LLC. All AEs which follow the MUSC IRB qualifications will also be reported to the MUSC IRB within 24 hours of site knowledge of the event.

The Investigator will take appropriate measures to follow all AEs until clinical recovery is complete and laboratory results have returned to normal, or until progression has been stabilized, or until death, in order to ensure the safety of the patients. This may imply that observations will continue beyond the last planned visit per protocol, and that additional investigations may be requested by the monitoring team up to as noticed by Healthy Humming, LLC.

In the case of occurrence of an SAE, the Investigator will immediately (within 24 hours) report the event to Healthy Humming, LLC and to the MUSC IRB, as applicable.

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Appendix

Attachment 1: Patient Medical History

SinuSonic Study

PI: Zachary M. Soler, MD

Subject ID#: _____ Subjects Initials: _____

OVER THE LAST 2 WEEKS, HOW TROUBLESOME HAS THE FOLLOWING SYMPTOM BEEN? PLEASE PLACE A MARK ON THE LINE.	
	Not troublesome **Worst thinkable/troublesome**
Nasal blockage/obstruction/congestion	◆——————————————————◆

DEMOGRAPHIC AND CLINICAL VARIABLES (If not previously collected):

Age at enrollment (years): | | |

Gender: Male Female

What is/was your profession (current/retired)?_____

LANGUAGE, ETHNICITY, RACE, MARITAL STATUS

Please mark one of the following categories which describes your native language:

- ☐ American English
- ☐ Other: please specify _____

Please mark one of the following categories which describes your ethnicity:

- ☐ Not Hispanic or Latino
- ☐ Hispanic or Latino

Please mark one or more of the following categories which describes your race:

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Other

SMOKING HISTORY

1. Do you **currently** smoke tobacco products? **Yes** **No** **(If No please go to question 2)**

How many tobacco products do you use in a day? _____ Singles Packs

2. Are you **currently** exposed to secondhand smoke? **Yes** **No** **(If No please skip ahead)**

How many years have you been exposed to secondhand smoke?_____

How many hours a day are you exposed to secondhand smoke?_____

CURRENT MEDICATION USAGE

- ☐ Nasal steroid sprays (Flonase, Nasonex, etc) ☐Yes ☐No
- ☐ Nasal antihistamine spray (Astelin, etc) ☐Yes ☐No
- ☐ Oral antihistamines (Allegra, Claritin, Benedryl, etc) ☐Yes ☐No
- ☐ Oral decongestant (Sudafed, etc) ☐Yes ☐No
- ☐ Mucolytic (Mucinex, etc) ☐Yes ☐No
- ☐ Luekotriene (Singulair, etc) ☐Yes ☐No

COMORBID MEDICAL CONDITIONS: Check box and provide details if present

- ☐ Depression history: ☐Resolved/past diagnosis ☐Present/medicated ☐Present/not medicated
- ☐ Anxiety history: ☐Resolved/past diagnosis ☐Present/medicated ☐Present/not medicated
- ☐ Obstructive Sleep Apnea: ☐Currently being treated ☐History / No current treatment
- ☐ Allergic rhinitis:_____
- ☐ Previous allergy testing (blood test or skin prick): ☐Yes ☐No
- ☐ Immunotherapy shots for allergies: ☐Yes ☐No ☐Currently
- ☐ Asthma ☐Yes ☐No

_____

- ☐ Height (ft/in):_____
- ☐ Weight (lbs):_____

Attachment 2: Baseline Questionnaires

BASELINE QUESTIONNAIRES

PATIENT QUESTIONS					
How long have you had nasal problems?	<3 months	3-6 months	6-12 months	1-3 years	>3 years

OVER THE LAST WEEK, HOW TROUBLESOME HAVE THE FOLLOWING SYMPTOMS BEEN? PLEASE PLACE A MARK ON THE LINE.		
	Not troublesome	**Worst thinkable/troublesome**
Nasal blockage/obstruction/congestion	◆———	———◆
Nasal discharge/drainage out of the front or back of nose	◆———	———◆
Pain/pressure in nose or sinuses	◆———	———◆
Sense of smell	◆———	———◆
OVERALL ASSESSMENT OF NASAL AND SINUS PROBLEMS	◆———	———◆

BASELINE Total Nasal Symptom Score

Please answer all questions to the best of your ability. This information will assist us in understanding and treating symptoms. Please rate how your symptoms have been over the **past week.**

Symptom	**None**	**Mild: Symptom clearly present but easily tolerated**	**Moderate: Symptom bothersome but tolerable**	**Severe: Symptom difficult to tolerate – interferes with activities**
Nasal congestion/obstruction	0	1	2	3
Runny nose/secretions	0	1	2	3
Nasal itching	0	1	2	3
Sneezing	0	1	2	3
Sleep difficulty with nasal symptoms	0	1	2	3

BASELINE NOSE scale

Please help us to better understand the impact of nasal obstruction on your quality of life by completing the following survey. Thank you!

Over the past **ONE month**, how much of a problem were the following conditions for you?

	Not a problem	**Very mild problem**	**Moderate problem**	**Fairly bad problem**	**Severe problem**
Nasal congestion or stuffiness	0	1	2	3	4
Nasal blockage or obstruction	0	1	2	3	4
Trouble breathing through my nose	0	1	2	3	4
Trouble sleeping	0	1	2	3	4
Unable to get enough air through my nose during exercise or exertion	0	1	2	3	4

Attachment 3: Baseline SNOT-22

BASELINE SNOT22

1. Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is **over the last 2 weeks** by circling the number that corresponds with how you feel using this scale: →	No problem	Very mild problem	Mild or slight problem	Moderate Problem	Severe Problem	Problem as bad as it can be
1. Need to blow nose	**0**	**1**	**2**	**3**	**4**	**5**
2. Sneezing	**0**	**1**	**2**	**3**	**4**	**5**
3. Runny nose	**0**	**1**	**2**	**3**	**4**	**5**
4. Cough	**0**	**1**	**2**	**3**	**4**	**5**
5. Post-nasal discharge	**0**	**1**	**2**	**3**	**4**	**5**
6. Thick nasal discharge	**0**	**1**	**2**	**3**	**4**	**5**
7. Ear fullness	**0**	**1**	**2**	**3**	**4**	**5**
8. Dizziness	**0**	**1**	**2**	**3**	**4**	**5**
9. Ear pain	**0**	**1**	**2**	**3**	**4**	**5**
10. Facial pain/pressure	**0**	**1**	**2**	**3**	**4**	**5**
11. Difficulty falling asleep	**0**	**1**	**2**	**3**	**4**	**5**
12. Wake up at night	**0**	**1**	**2**	**3**	**4**	**5**
13. Lack of a good night's sleep	**0**	**1**	**2**	**3**	**4**	**5**
14. Wake up tired	**0**	**1**	**2**	**3**	**4**	**5**
15. Fatigue	**0**	**1**	**2**	**3**	**4**	**5**
16. Reduced productivity	**0**	**1**	**2**	**3**	**4**	**5**
17. Reduced concentration	**0**	**1**	**2**	**3**	**4**	**5**
18. Frustrated/restless/irritable	**0**	**1**	**2**	**3**	**4**	**5**
19. Sad	**0**	**1**	**2**	**3**	**4**	**5**

20. Embarrassed	**0**	**1**	**2**	**3**	**4**	**5**
21. Loss of smell or taste	**0**	**1**	**2**	**3**	**4**	**5**
22. Nasal obstruction	**0**	**1**	**2**	**3**	**4**	**5**

Attachment 4: Follow Up Questionnaire

FOLLOW UP 5 MINUTES

AFTER USING SINUSONIC, HOW TROUBLESOME ARE THE FOLLOWING SYMPTOMS? PLEASE PLACE A MARK ON THE LINE.		
	Not troublesome	**Worst thinkable/troublesome**
Nasal blockage/obstruction/congestion	◆———	———◆
Nasal discharge/drainage out of the front or back of nose	◆———	———◆
Pain/pressure in nose or sinuses	◆———	———◆
Sense of smell	◆———	———◆
OVERALL ASSESSMENT OF NASAL AND SINUS PROBLEMS	◆———	———◆

Change in nasal symptoms and use of device

Please rate changes in your nasal symptoms and use of device.

Symptom	**None**	**Mild**	**Moderate**	**High**
Improvement in nasal obstruction/stuffiness	0	1	2	3
Improvement in nasal drainage/discharge	0	1	2	3
Improvement in nasal or sinus pressure	0	1	2	3
Improvement in ability to smell	0	1	2	3
Pain with use of device	None	Mild	Moderate	Severe
Comfort and ease of use	Poor	Low	Moderate	High
Bleeding:	Yes	No		

Attachment 5: 2-Week Follow Up

FOLLOW UP 2 WEEKS
PHYSICIAN ASSESSMENT

OVER THE LAST WEEK, HOW TROUBLESOME HAVE THE FOLLOWING SYMPTOMS BEEN? PLEASE PLACE A MARK ON THE LINE.	
	Not troublesome — **Worst thinkable/troublesome**
Nasal blockage/obstruction/congestion	
Nasal discharge/drainage out of the front or back of nose	
Pain/pressure in nose or sinuses	
Sense of smell	
OVERALL ASSESSMENT OF NASAL AND SINUS PROBLEMS	

Change in nasal symptoms and use of device

Please rate changes in your nasal symptoms and use of device.

Symptom	None	Mild	Moderate	High
Improvement in nasal obstruction/stuffiness	0	1	2	3
Improvement in nasal drainage/discharge	0	1	2	3
Improvement in nasal or sinus pressure	0	1	2	3
Improvement in ability to smell	0	1	2	3
Use of the Device				
Pain with use of device	None	Mild	Moderate	Severe
Comfort and ease of use	Poor	Low	Moderate	High
Bleeding:	Yes	No		
Willingness to use again	Yes	No		
Willingness to recommend to friend/family	Yes	No		

Total Nasal Symptom Score

Please answer all questions to the best of your ability. This information will assist us in understanding and treating symptoms. Please rate how your symptoms have been over the **past week.**

Symptom	**None**	**Mild: Symptom clearly present but easily tolerated**	**Moderate: Symptom bothersome but tolerable**	**Severe: Symptom difficult to tolerate – interferes with activities**
Nasal congestion/obstruction	0	1	2	3
Runny nose/secretions	0	1	2	3
Nasal itching	0	1	2	3
Sneezing	0	1	2	3
Sleep difficulty with nasal symptoms	0	1	2	3

NOSE Scale

Please help us to better understand the impact of nasal obstruction on your quality of life by completing the following survey. Thank you!

Over the past **ONE month**, how much of a problem were the following conditions for you?

	Not a problem	**Very mild problem**	**Moderate problem**	**Fairly bad problem**	**Severe problem**
Nasal congestion or stuffiness	0	1	2	3	4
Nasal blockage or obstruction	0	1	2	3	4
Trouble breathing through my nose	0	1	2	3	4
Trouble sleeping	0	1	2	3	4
Unable to get enough air through my nose during exercise or exertion	0	1	2	3	4

Attachment 6: SNOT-22 Survey

SNOT22 Survey

2. Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale: →	No problem	Very mild problem	Mild or slight problem	Moderate Problem	Severe Problem	Problem as bad as it can be
1. Need to blow nose	**0**	**1**	**2**	**3**	**4**	**5**
2. Sneezing	**0**	**1**	**2**	**3**	**4**	**5**
3. Runny nose	**0**	**1**	**2**	**3**	**4**	**5**
4. Cough	**0**	**1**	**2**	**3**	**4**	**5**
5. Post-nasal discharge	**0**	**1**	**2**	**3**	**4**	**5**
6. Thick nasal discharge	**0**	**1**	**2**	**3**	**4**	**5**
7. Ear fullness	**0**	**1**	**2**	**3**	**4**	**5**
8. Dizziness	**0**	**1**	**2**	**3**	**4**	**5**
9. Ear pain	**0**	**1**	**2**	**3**	**4**	**5**
10. Facial pain/pressure	**0**	**1**	**2**	**3**	**4**	**5**
11. Difficulty falling asleep	**0**	**1**	**2**	**3**	**4**	**5**
12. Wake up at night	**0**	**1**	**2**	**3**	**4**	**5**
13. Lack of a good night's sleep	**0**	**1**	**2**	**3**	**4**	**5**
14. Wake up tired	**0**	**1**	**2**	**3**	**4**	**5**
15. Fatigue	**0**	**1**	**2**	**3**	**4**	**5**
16. Reduced productivity	**0**	**1**	**2**	**3**	**4**	**5**
17. Reduced concentration	**0**	**1**	**2**	**3**	**4**	**5**
18. Frustrated/restless/irritable	**0**	**1**	**2**	**3**	**4**	**5**
19. Sad	**0**	**1**	**2**	**3**	**4**	**5**

20. Embarrassed	**0**	**1**	**2**	**3**	**4**	**5**
21. Loss of smell or taste	**0**	**1**	**2**	**3**	**4**	**5**
22. Nasal obstruction	**0**	**1**	**2**	**3**	**4**	**5**

Attachment 7: 5-Week Follow Up

FOLLOW UP 5 WEEKS

OVER THE LAST WEEK, HOW TROUBLESOME HAVE THE FOLLOWING SYMPTOMS BEEN? PLEASE PLACE A MARK ON THE LINE.	
	Not troublesome — **Worst thinkable/troublesome**
Nasal blockage/obstruction/congestion	
Nasal discharge/drainage out of the front or back of nose	
Pain/pressure in nose or sinuses	
Sense of smell	
OVERALL ASSESSMENT OF NASAL AND SINUS PROBLEMS	

Change in nasal symptoms and use of device

Please rate changes in your nasal symptoms and use of device.

Symptom	**None**	**Mild**	**Moderate**	**High**
Improvement in nasal obstruction/stuffiness	0	1	2	3
Improvement in nasal drainage/discharge	0	1	2	3
Improvement in nasal or sinus pressure	0	1	2	3
Improvement in ability to smell	0	1	2	3
Use of the Device				
Pain with use of device	None	Mild	Moderate	Severe
Comfort and ease of use	Poor	Low	Moderate	High
Bleeding:	Yes	No		
Willingness to use again	Yes	No		
Willingness to recommend to friend/family	Yes	No		

Total Nasal Symptom Score

Please answer all questions to the best of your ability. This information will assist us in understanding and treating symptoms. Please rate how your symptoms have been over the **past week.**

Symptom	**None**	**Mild: Symptom clearly present but easily tolerated**	**Moderate: Symptom bothersome but tolerable**	**Severe: Symptom difficult to tolerate – interferes with activities**
Nasal congestion/obstruction	0	1	2	3
Runny nose/secretions	0	1	2	3
Nasal itching	0	1	2	3
Sneezing	0	1	2	3
Sleep difficulty with nasal symptoms	0	1	2	3

NOSE Scale

Please help us to better understand the impact of nasal obstruction on your quality of life by completing the following survey. Thank you!

Over the past **ONE month**, how much of a problem were the following conditions for you?

	Not a problem	**Very mild problem**		**Moderate problem**	**Fairly bad problem**	**Severe problem**
Nasal congestion or stuffiness	0	1		2	3	4
Nasal blockage or obstruction	0	1		2	3	4
Trouble breathing through my nose	0	1		2	3	4
Trouble sleeping	0	1		2	3	4
Unable to get enough air through my nose during exercise or exertion	0	1		2	3	4

Attachment 8: SNOT-22 Survey

SNOT22 Survey

3. Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale: →	No problem	Very mild problem	Mild or slight problem	Moderate Problem	Severe Problem	Problem as bad as it can be
1. Need to blow nose	**0**	**1**	**2**	**3**	**4**	**5**
2. Sneezing	**0**	**1**	**2**	**3**	**4**	**5**
3. Runny nose	**0**	**1**	**2**	**3**	**4**	**5**
4. Cough	**0**	**1**	**2**	**3**	**4**	**5**
5. Post-nasal discharge	**0**	**1**	**2**	**3**	**4**	**5**
6. Thick nasal discharge	**0**	**1**	**2**	**3**	**4**	**5**
7. Ear fullness	**0**	**1**	**2**	**3**	**4**	**5**
8. Dizziness	**0**	**1**	**2**	**3**	**4**	**5**
9. Ear pain	**0**	**1**	**2**	**3**	**4**	**5**
10. Facial pain/pressure	**0**	**1**	**2**	**3**	**4**	**5**
11. Difficulty falling asleep	**0**	**1**	**2**	**3**	**4**	**5**
12. Wake up at night	**0**	**1**	**2**	**3**	**4**	**5**
13. Lack of a good night's sleep	**0**	**1**	**2**	**3**	**4**	**5**
14. Wake up tired	**0**	**1**	**2**	**3**	**4**	**5**
15. Fatigue	**0**	**1**	**2**	**3**	**4**	**5**
16. Reduced productivity	**0**	**1**	**2**	**3**	**4**	**5**
17. Reduced concentration	**0**	**1**	**2**	**3**	**4**	**5**
18. Frustrated/restless/irritable	**0**	**1**	**2**	**3**	**4**	**5**
19. Sad	**0**	**1**	**2**	**3**	**4**	**5**

20. Embarrassed	**0**	**1**	**2**	**3**	**4**	**5**
21. Loss of smell or taste	**0**	**1**	**2**	**3**	**4**	**5**
22. Nasal obstruction	**0**	**1**	**2**	**3**	**4**	**5**