**INFORMED CONSENT – FUNCTIONAL ENDOSCOPIC SINUS SURGERY**

**Instructions:** This is an informed consent document that has been prepared to help your surgeon inform you concerning functional endoscopic sinus surgery, its risks, and alternative treatment.It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your surgeon.

**Introduction:** Functional endoscopic sinus surgery is a surgical procedure to improve symptoms of inflammation, infection, and obstruction in the nose or sinuses. Sinus surgery is recommended only after it has been determined that medical management of your disease has been unsuccessful.

**Alternative Treatment:** Alternative forms of management consist of not treating the obstruction or treating it with medications.

**Risks of Functional Endoscopic Sinus Surgery:** Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with functional endoscopic sinus surgery. An individual’s choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following complications, you should discuss each of them with your surgeon to make sure you understand the risks, potential complications, and consequences of functional endoscopic sinus surgery.

**Specific Risks of Functional Endoscopic Sinus Surgery**

**Post-Operative Bleeding:** Mild to moderate bleeding is expected up to 48 hours after surgery. This is the most common complication. Avoiding blood thinning medications will help reduce the risk.

**Infection:** The most common reason patients undergo sinus surgery is usually related to infection. Therefore, the patient with sinusitis is at risk of developing certain other infections in this area (abscessed, meningitis, etc.) regardless of whether they manage the sinusitis with or without surgery.

**Smell:** The sense of smell usually improves, although it may occasionally worse, depending on the extent of infection, allergy, or polyps.

**Voice Changes:** One of the functions of the sinuses is to affect resonance, so vocal professionals should be aware of potential changes in their voice after sinus surgery.

**Nasal Obstruction:** Much of the nasal septum is made of cartilage, which has “memory” – the propensity to move back to its original position. Despite certain measures performed by the surgeon at the time of septopalsty this may still occur and require a secondary procedure. Small scar bands may also occur in the nose and require removal by the surgeon at postoperative visits. Consent for this surgery is also giving implicit consent to post operative debridement procedures that may be necessary in the office.

**Numbness:** A transient numbness of the front upper teeth, lip or nose may occur after balloon surgery but is usually self limiting.

**Intraorbital Complications:** Injury to tear duct or sac resulting in tearing of the eyes. This may require

further surgery. The orbit is situated next to the sinuses but is separated by a layer of bone. Visual loss and blindness have been reported but are extremely rare.

**Intracranial Complications:** Drainage of brain spinal fluid from the nose may occur, which may require further surgery. Further complications such as the infiltration of air into the cranium and possible permanent brain damage are possible although extremely unlikely.

**Anesthesia Complications:** Adverse reactions to local or general anesthesia may occur, including cardiac and pulmonary complications.

**Recurrence of Sinus Condition:** There is a possibility that the FESS will not meet my expectations in that surgery may not improve chronic sinus problems. Recurrence may result due to scarring or adhesions. Subsequent medical or surgical intervention may be required.

**General Risks of Surgery**

**Pain:** You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue.

**Allergic Reactions:** In rare cases, local allergies to tape, suture materials, glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during surgery and prescription medications. Allergic reactions may require additional treatment.

**Delayed Healing:** Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin loss and wound healing complications.**

**Sutures:** Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires removal.

**Shock:** In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

**Unsatisfactory Result:** Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of sinus surgery.

**ADDITIONAL ADVISORIES**

**Female Patient Information:** It is important to inform your surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

**Intimate Relations After Surgery:** Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

**Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):** Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication.

Please indicate your current status regarding these items below:

**☐ I am a non-smoker and do not use nicotine products. I understand the risk of second hand smoke exposure causing surgical complications.**

**☐ I am a smoker or use tobacco/nicotine products. I understand the risk of surgical complications due to smoking or use of tobacco/nicotine products.**

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

**Medications:** There are many adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications that you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

**ADDITIONAL SURGERY NECESSARY**

There are many variable conditions in addition to risk and potential surgical complications that may influence the long-term result of functional endoscopic sinus surgery. Secondary surgery may be necessary to obtain optimal results. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with functional endoscopic sinus surgery. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

**PATIENT COMPLIANCE**

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that

the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in

follow-up care, return for aftercare, and promote your recovery after surgery.

**FINANCIAL RESPONSIBILITIES**

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed.

Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. **In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

**DISCLAIMER**

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information that is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

**It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.**

**CONSENT FOR SURGERY / PROCEDURE or TREATMENT: PLEASE CHECK EACH BOX INDICATING YOU HAVE READ EACH LINE**

1. ☐ I hereby authorize Dr. Todd Miller and such assistants as may be selected to perform the following procedure or treatment: Septoplasty/Turbinate Reduction I have received the following information sheet.

**Informed Consent: Functional Endoscopic Sinus Surgery**

1. ☐ I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
2. ☐ I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
3. ☐ I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
4. ☐ I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes.
5. ☐ For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
6. ☐ I consent to the disposal of any tissue, medical devices or body parts which may be removed.
7. ☐ I understand that the surgeons’ fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
8. ☐ I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. ☐ I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical device registration, if applicable.
10. ☐ I realize that not having the surgery is an option.
11. ☐ The surgery has been explained to me in a way that I understand. I further understand that there may be alternative procedures or methods of treatment and that there are risks to the procedures or treatment proposed.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12). I AM SATISFIED WITH THE EXPLANATION.

**Patient or Person Authorized to Sign for Patient Date**

**Witness** **Date**