

PATIENT CONSENT FORM
Aerin® Procedure with RhinAer® Stylus

SAMPLE PATIENT CONSENT FORM

The following is an example of a patient consent form for treatment with the RhinAer® Stylus and is provided for informational purposes only. Aerin Medical Inc. is not making specific recommendations for treatment with the RhinAer Stylus or any other procedure. It is always the provider's responsibility to determine the medical necessity and appropriateness of a course of treatment, and ensure that a patient receives information regarding the risks and costs associated with any procedure or treatment plan. Aerin Medical cannot and does not recommend standard operating procedures related to patient consents or the practice of medicine in general.

PATIENT CONSENT FORM
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[INSERT PRACTICE / PHYSICIAN NAME AND CONTACT INFORMATION]

Patient Name

Date of Birth

Do not sign this form without reading and understanding its contents.
Treatment with the RhinAer® Stylus for Chronic Rhinitis has been explained to me.
I understand the benefits and potential risks associated.

Indications for Use

The RhinAer® Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in patients with chronic rhinitis and/or nasal airway obstruction

Contraindications

- Patients who have had nasal surgery within the last 3 months.
- Patients with extreme nasal pathology or a history of extreme nasal injuries.
- Patients with medical conditions that may impair normal healing processes or be exacerbated by the stress of surgery.

Expectations

Before treatment with the RhinAer® Stylus, anesthetic may be applied to the treatment area. During treatment, you may experience mild discomfort, but treatment should not be painful. After the treatment:

- Avoid blowing your nose for the 1st week following your procedure.
- We may recommend keeping the inside of your nose moist using a nasal saline spray.
- You may experience temporary increased congestion, increased sensitivity, and/or pain during the healing process.
- You may have some mild bloody discharge for the first 3-5 days following the procedure, especially after a nasal rinse. Call us immediately if you have any bright red bleeding or the bleeding is heavy.
- Most patients can return to normal activities the same day.

Efficacy

Most patients will see improvements to their chronic rhinitis symptoms between 2 and 6 weeks following the treatment, while some patients may not experience improvement or the level of improvement they desired. You may require additional treatments.

Complications

Potential adverse effects related to the use of radiofrequency energy on tissue in the nasal airway include infection, bleeding, mucosal necrosis, scar formation with increased obstruction, external deformity, sensory changes at treatment site, inflammation/generalized redness, temporary swelling/edema, blanching (generalized whiteness), temporary numbness/tingling, bruising including around the orbital area (black eyes), temporary soreness/pain, and disruption of mucosal flow/crusting.

I am aware that other unexpected risks or complications may occur and that no guarantees or promises have been made to me concerning the results of the treatment. My questions regarding this treatment, its alternatives, its complications and risks have been answered by my doctor and/or his or her staff.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT AND BELIEVE THAT YOU UNDERSTAND IT. ASK ANY

PATIENT CONSENT FORM

Aerin[®] Procedure with RhinAer[®] Stylus

QUESTIONS YOU MIGHT HAVE BEFORE SIGNING THIS FORM. DO NOT SIGN THIS FORM IF YOU HAVE TAKEN MEDICATIONS WHICH MAY IMPAIR YOUR MENTAL ABILITIES OR IF YOU FEEL RUSHED OR UNDER PRESSURE.

I have read this form and understand it, and I request the performance of the treatment.

_____ Date _____
Patient Signature

I have informed the patient of the available alternatives to treatment and of the potential risks and complications that may occur as a result of this treatment.

_____ Date _____
Physician Signature

_____ Date _____
Nurse or Medical Assistant