Operating Room Management Committee

New Product/Procedure Request

VENDOR TO COMPLETE SHADED SECTION ONLY

New Product Name: The Reltok Clear-Flo™ Nasal Airway	Manufacturer: Reltok Nasal Products, LLC 436 N Bedford Drive, Suite 201, Beverly Hills, CA 90210 Proudly made in the USA
Catalog #(s): _____ _____	Cost of Equipment: N/A Cost of Disposables: _____
Sales Rep: _____	Contact Information: Phone: _____ Email: _____

Is this product / equipment FDA approved for the application being requested? [X] YES [ ] NO

If yes, please provide a copy of the FDA Approval Letter.
Please list the approved FDA applications for this product / equipment: Nasopharyngeal Airway.

Is there an approved CSMC IRB Study related to this product / equipment? [ ] YES [X] NO

If yes, please provide IRB number.
The requesting MD must also provide us with a copy of the Patient Consent Form approved by the IRB Office.

If no, the requesting MD must provide a copy of the Patient Consent Form clearly indicating the risks associated with the off-label use. The following should also be attached:

1. Reltok Nasal Airway Research Paper, 2014
2. JAMA Facial Plastic Surgery Journal Article, September 6, 2018
3. Claim Appeal Letter

What training / certification do you recommend for use of this new product / equipment?
Not necessary. All nasal surgeons are familiar with insertion process.

Is it generally recommended that surgeons be proctored to use this product / equipment? [ ] YES [X] NO

Will you supply product / equipment at no charge for the purpose of evaluation? [X] YES [ ] NO

SURGEON / CN IV / AUTHORIZED HOSPITAL PERSONNEL TO COMPLETE SECTIONS 1 THROUGH 7

1. New product / equipment will be used for the following type(s) of procedures / applications:

a) Estimated # of procedures performed in a year: _____

b) Please provide a brief explanation of how this new product / equipment will add value:

c) Will the new product / equipment require additional equipment or supplies not currently available?
If yes, please identify.

Please note: You are required to submit peer-reviewed studies to support the efficacy of the new product / equipment.

2. Please explain the clinical advantage(s) of the new product / equipment over current method.

a) Will the new product / equipment improve patient outcome? If yes, please explain.

Nasal Airway is a safety device. Reduces possibility of airway obstruction and asphyxiation.
Endorsed by anesthesiologists. See attached Anesthesiologist Endorsement for Intranasal Airway.

b) Will the new product / equipment enable us to treat more or a different class of patients? If yes, please explain.

No. For all nasal and sinus surgery cases

c) Standard of Care. Please list leading edge hospitals that use the new product / equipment.

UCI Irvine; NYU Langione Medical Center; Ohio State University Health System;
Wilkes Regional Medical Center, North Carolina; Marion General Hospital, Indianapolis, IN

3. Please describe how you are currently performing this procedure. N/A

4. Please identify the product / equipment you are currently using. The airway is new and unique. See attached Nasal Airway U.S. Patent and Post-Op Nasal Airway System FDA Clearance Letter.

5. In your opinion, what would be a fair amount of time, or quantity of product, / equipment, in order for you to complete your evaluation? _____

6. Is vendor presence required in O.R.? ☐ YES ☒ NO For extended use? ☐ YES ☒ NO

7. Do you have financial interest or investment with this vendor or distributor? ☐ YES ☒ NO

EVALUATION REQUESTED BY:

Print Name _____ Signature _____ Date _____

Phone _____ Email _____

Service Line Director _____ Date _____

O.R. CNIV / CNIII _____ Date _____