



# Practice Administrator's Handbook

## The Reltok Clear-Flo™ Nasal Airway

ALWAYS CLEAR, ALWAYS COMFORTABLE™

A Patented, FDA-cleared Airway Safety Device

- ✓ Better Patient Care
- ✓ Increases Revenue

*A New Standard of Care for All Nasal and Sinus Surgeries*

**RELTOK CLEAR-FLO™**  
NASAL AIRWAY SYSTEM

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# Introduction for Practice Administrators

## Happy Patients Help Drive Growth for the Practice

I was referred by my friend Chanel. She told me that I must see you for a consultation for my cosmetic and breathing surgery. She said you use an airway tube that made her surgery with you so much better than the first surgery she had with another doctor.

— Donna

Why not provide a better patient experience that will drive prospective patients to you? Your patients' friends and family members will contact you and not your competitors. When a practice becomes known in its community for being forward-thinking, patient focused and a leader in delivering excellent patient service, it has created its own brand: the best in town.

Today's patients—like all consumers—are kings. They have choices. They do their homework and research, particularly on the Internet. Why? First, they are afraid to make a mistake. Secondly, they see no reason to accept second-best. They're right.

## Believe It or Not...Nasal & Sinus Surgeries Get Bad Press

Every patient has "a story" of friends/relatives who report a miserable experience with nasal/sinus surgery. They may be happy with the result, but their impression is colored negatively by the post-op experience.

### 1. It's about the breathing—or lack of it

It's not the pain because there's not much and pain pills solve that problem. Whether the surgeon packs the nose or does not pack, no patient ever had a perfect nasal airway right after surgery. It's impossible.

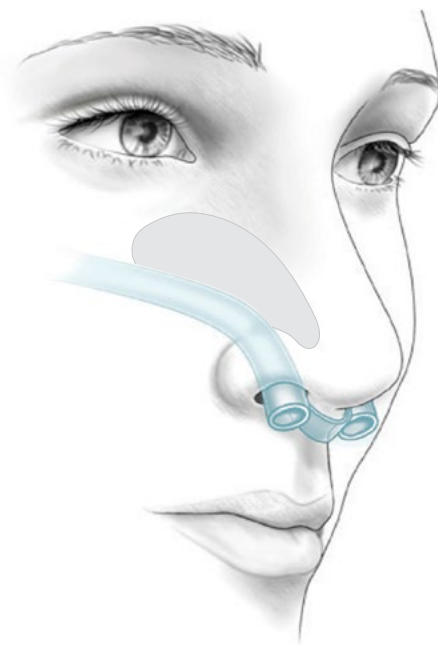
### 2. Patients may not voice unhappiness to the doctor or to the staff

They are grateful for other aspects of the care, but you can bet they don't have kind words for the post-op experience. For only one reason: they could not breathe through their nose. That limits referrals.

Skeptical? Pinch your nostrils shut for five minutes—by the clock. How was it? Now you know the patient experience without the Reltok Clear-Flo Nasal Airway.

The Reltok Clear-Flo Nasal Airway is a safe, practical and proven solution for providing a better experience for your patients.

Practices can spend thousands on marketing consultants, advertisements, publicists, hoping to fill their surgery schedule; however, these services cost big bucks and there's no guarantee for a bottom-line impact, right? Or, practices may buy some new, heavily-promoted, high-tech surgical machine. But there is a big capital cost that takes years to recoup, if ever. Or, it quickly becomes obsolete and you're stuck with a white elephant and an iron-clad lease. The Reltok Clear-Flo Nasal Airway can be leveraged as a free publicist and marketing tool via happy patients that costs nothing for the practice!



Reltok Clear-Flo Nasal Airway patient referrals cost nothing. And, even better, you don't front the cost of the Reltok Clear-Flo Nasal Airway. It is purchased by the surgery center or hospital and they bill insurance for reimbursement. Further, patients who are unhappy about not breathing perfectly after surgery usually require an extra office visit or two in those first several days. Visits that take staff and doctor time, often without additional compensation.

### Show How Good Your Practice Is!

Obamacare, or no Obamacare, today the patient-consumer is king. The doctor who is perceived as more caring and providing a better, safer, more comfortable experience will see their practice prosper. The practices which don't bother to concern themselves with patient satisfaction will indeed see hard times.

– Neil Baum, MD

Faculty, Tulane University & LSU Medical Schools

Author, Marketing Your Clinical Practice

## The Reltok Website

### A Powerful Marketing Tool for You

The Reltok Clear-Flo Nasal Airway has its own website. The contents have been deliberately developed to increase the quantity and quality of traffic to our website with organic search engine results. Patients who now START their doctor selection process on the Internet are being drawn to this site, which has a doctor referral section that geographically

lists surgeons who are active users of the airway. All the information including phone, e-mail, website and the name of the office "contact person" are listed. This is a free service we offer practices that use the Reltok Clear-Flo Nasal Airway, if they agree to opt in.

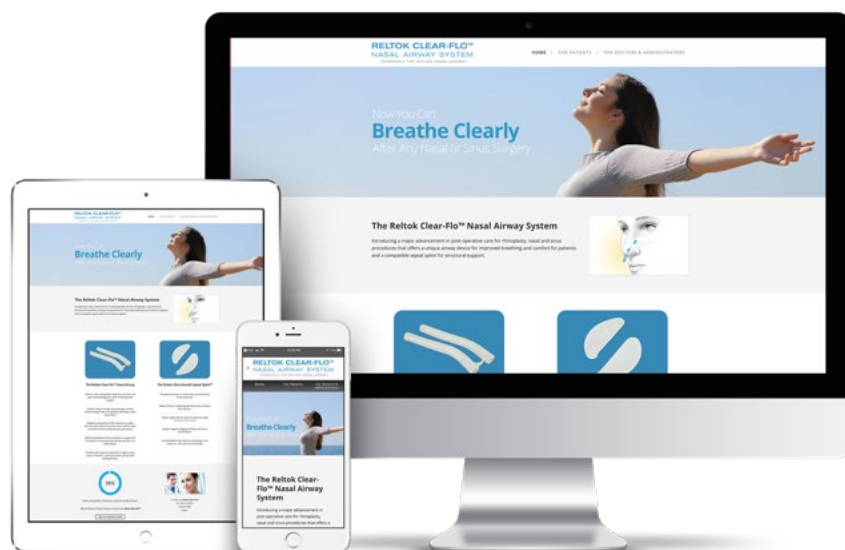
We believe our website is a great marketing tool for connecting your practice to prospective patients. With happier patients generating more referrals—plus additional, earned revenues, without capital investment—your practice can prosper.

To access the "For Doctors & Administrators" section of our website, use the following username and password. This section offers information and resources regarding billing and reimbursement that is not available to the general public.

Website link: [www.reltok.com](http://www.reltok.com)

Username: reltok

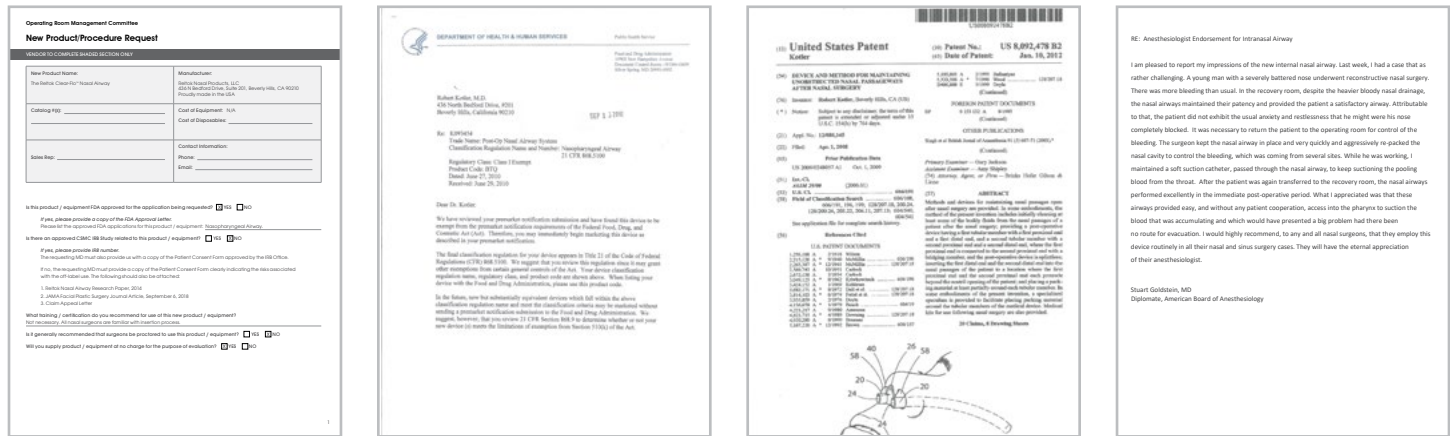
Password: Airway



# New Product/Procedure Request Form

If required, your distributor will complete this form for surgical facilities that want to use the airway. Also provided here are links to supporting documents such as our FDA Clearance Letter, US Patent document, and an Anesthesiologist Endorsement Letter.

Click on forms to view.



New Product/Procedure Request Form

Reltok Airway FDA Clearance Letter

Reltok Airway US Patent Information

Anesthesiologist Endorsement for Intranasal Airway

# Insurance Billing for Airway

## Billing Templates, Instructions & Supporting Documents

### Making Your Work Easier

Parallel to the technical development of the Reltok Clear-Flo Nasal Airway, we have developed [detailed content](#) to “copy and paste” into the surgeon-dictated op report by the transcription service. That portion of the op report supports the “30999-59 by report” procedure code. We paid attention to proper completion of the [HCFA-1500 billing form](#), particularly “**Line 19**”, which directs the claim processor to that airway verbiage within the op report and also notes that the device is “**FDA-cleared**”.

Next, we created a, photo-illustrated [Claim Appeal Letter](#) which includes every possible support documentation including the FDA clearance letter and the device’s patent identification. The appeals form became unassailable. We learned from a major insurer Medical Director (an MD) that **Medicare regulations REQUIRE payment for a safety device**. That explains why we have seen Medicare EOBs that document up to \$875+ in payment. This is huge because the insurers do look to Medicare for standards for claim processing.

Hard for “XYZ” insurer to deny payment when the most stringent payer of them all, Medicare, has honored 100% of reasonable charges.

Remember, you are not begging to be paid; you are ordering them to pay you because you have the force of the state regulations and particularly the Medicare precedent behind you. Employ a courteous but strong form letter.

Finally, in all fairness to insurers, not every delay or denial represents an exercise in cheating. Often, insurance company claim processors, inadequately trained in the processing of claims, particularly “30999-59, by report”, may just hit the “Deny” button because it is the quick and easy way out. Perhaps they don’t take the time to read the op report and collateral material because they are under pressure to process “X” number of claims per hour.

MDs are held to high standards. Why not insurers? Demand excellence and accuracy!

*Click to view document.*

- |   |   |
|---|---|
| 1. <a href="#">New Product/Procedure Request Form</a>                       | 7. <a href="#">Claim Appeal Letter</a>                                  |
| 2. <a href="#">Sample Billing Form</a>                                      | 8. <a href="#">Reltok Airway FDA Clearance Letter</a>                   |
| 3. <a href="#">Reltok Operative Report Instructions</a>                     | 9. <a href="#">Reltok Airway US Patent Document</a>                     |
| 4. <a href="#">Anthem - Example of Benefits</a>                             | 10. <a href="#">Anesthesiologist Endorsement for Intranasal Airway</a>  |
| 5. <a href="#">United Healthcare Explanation of Benefits (EOB), Example</a> | 11. <a href="#">JAMA Facial Plastic Surgery Article, September 2018</a> |
| 6. <a href="#">Cigna - Explanation of Benefits Examples</a>                 | 12. <a href="#">Original Research Paper, 2014</a>                       |



# FOR MEDICAL BILLING PROFESSIONALS

## Insurance Billing Overview

The nasal surgeon has the right to charge a fee—in addition to the surgical procedure fee—for the additional professional service of inserting and later removing the Reltok Clear-Flo Nasal Airway.

Surgeon insertion of the Reltok Clear-Flo Nasal Airway is a separate professional service. It is not integral to the surgical procedure. The airway is not a pack; it is not a splint; it is not a stent. The airway is not being used to influence the outcome of the surgery, as the splints and stents are used. The airway nests distant to the surgically-operated arena.

## No need to pre-authorize the Reltok Clear-Flo Nasal Airway

Asking permission of the insurer to pay for new and relatively unknown surgical service, before surgery, is not productive. Their default answer will be “NO”. Nonetheless, when you bill properly, the claim will be honored.

Based on a review of six plus years of experience of how payers handle claims, which includes a separate charge for the airway, our advice is: DON'T ASK FOR PRE-AUTHORIZATION OR PERMISSION FROM THE PAYER. JUST DO THE BILLING AFTER SURGERY. [All template samples and forms are available for download on our website.](#)

If pre-auth is needed for the septoplasty or whatever, OK, but you are not obligated to specify, pre-operatively, all the procedures you may do at surgery. That is determined at the time of surgery. After surgery, just bill the case's surgical procedure(s) and also fill in another line with the charge for the airway. Be sure to include proper text (we provide a template of such) in the [op report](#) to support the charge. Then, closely examine the EOB when the payment is made. You learn by studying “what happened” at the insurance processing office. That's how we learned.

## Payers will not automatically cut your fee for the airway

Insurers never “cut” or reduce the charge, as contrasted with the second or third surgical procedure done at the same session.

Dollar payment to the surgeon is determined by the specifics of the insured's policy. Maybe the policy pays only 50% to a non-contracting MD, or there is a big co-pay that is eaten up by this surgery, or likewise, a high deductible. We have no control over policy specifics. The “allowable” dollar amount for “Insertion and fixation..., CPT 30999-59”, is not automatically discounted as is the case for the actual surgical procedure.



# FOR MEDICAL BILLING PROFESSIONALS

## Short Course in Billing for Airway

### Pre-Authorization of the Airway is Not Required

- If the insurer requires “pre-authorization” for the surgical procedure, do not specifically request permission to use the Reltok Clear-Flo Nasal Airway! Since the service carries a 30999-59, by report, code, such a request will only slow and complicate the pre-authorization process.
- Insurers require only the lead diagnosis or diagnoses and identification of the anticipated main or primary surgical procedure. There is no requirement to pre-authorize any secondary, tertiary, etc., procedure that is planned or contemplated. In over 200 insurance cases, no carrier ever failed to honor the charge because of a lack of pre-authorization specifically for the Reltok Clear-Flo Nasal Airway.
- Insurers cannot dictate what procedure(s) your surgeon must perform. What the surgeon chooses to do at the time of surgery is solely within his/her discretion. As long as an **anticipated main or primary procedure**, e.g. CPT 30520, nasal septoplasty, has been “approved”, additional or ancillary procedures cannot be rejected by the carrier. Even if the “findings at surgery” mandated a different (but related) procedure, e.g., open reduction nasal septal fracture with septal reconstruction, CPT 21335, the claim should not be disqualified. The key, as usual, is op report documentation, the findings at surgery, the “what was done and why it was done”.

### Sample Billing Form

- Be sure to list “Insertion and Fixation of Intranasal Airway Prosthesis” as another line item charge for professional services.
- Box 19—any additional comments (limited to 49 characters) insert the following:  
“CPT30999-59 FDA Cleared Safety Device”.
- [Click here](#) to view a sample form. Note the completed Box 19. Note the line item billing for the airway below the primary and secondary surgical procedures. This is the independent professional fee for the surgeon’s additional time and skill to insert and remove the airway. Fees within the range of up to \$875 have been honored.

### Applicable CPT Code for Airway

- Applicable CPT code “**30999-59, by report**” for the surgeon’s professional service. CPT code, **30999-59, “unlisted procedure on nose”**, requires documentation/written explanation for, and description of, the airway insertion. Either in the op report or as a separate report. Failure to include such may be a cause for no payment.





# FOR MEDICAL BILLING PROFESSIONALS

## Airway Billing Directions & Support

**Step 1:** Complete Insurance Claim Form (see sample form). Insert "CPT 30999-59 FDA- cleared safety device" where form asks for "Additional Claim Information"

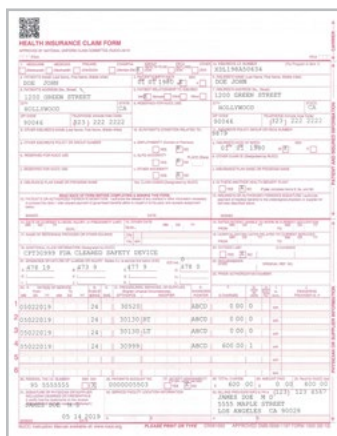
**Step 2:** Review our Operative Report Instructions and complete your Operative Report accordingly.

**Step 3:** Have billing consultant review your completed insurance claim form and Operative Report before submitting them to the insurance company.

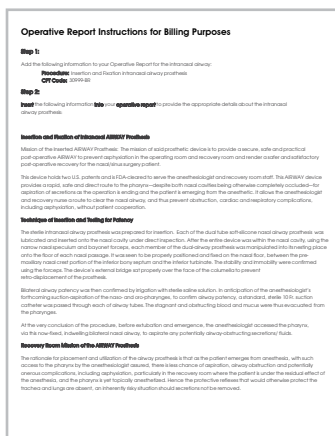
**Step 4:** Mail or email completed Insurance Claim Form and Operative Report to insurance company for processing and payment.

**Step 5:** After claim submission, copy billing consultant on all communication with insurance company regarding this claim.

*Click on forms to view.*

A sample of a medical insurance claim form, specifically a CMS-1500 form, which is used for billing services. It contains various fields for patient information, provider information, and service details.

Sample Billing Form

A document titled "Operative Report Instructions for Billing Purposes" providing detailed guidance on how to write an operative report for billing. It includes sections for "Step 1: Add the following information to your Operative Report for the Intersol airway prosthesis," "Step 2: Add the following information to your Operative Report," and "Recovery from Intubation of the Intersol Airway Prosthesis." It also includes a section for "Recovery from Intubation of the Intersol Airway Prosthesis" and a section for "Recovery from Intubation of the Intersol Airway Prosthesis." The document is dated 05-14-2019.

Operative Report Instructions

For billing questions, please email Reltok Nasal Products for access to an independent reimbursement specialist that will assist customers with their first 3 airway billings at no charge.

**Reltok Nasal Products**

Email: [info@reltok.com](mailto:info@reltok.com)





## List of Payers Allowing Benefit of Surgeon Insertion Reltok Clear-Flo™ Nasal Airway

Aetna	Guardian	National Association of Letter Carriers Health Benefit Plan
Anthem Blue Cross	Golden Rule	Preferred One Administrative Services
Blue Cross	Harvard Pilgrim HealthCare	Screen Actors Guild- Health Plan
Blue Shield	HealthNet	Tricare
Cigna	HealthPartners	United Healthcare
Directors Guild of America - Producers Health Plan	International Longshoremans Union-PMA Welfare Plan Benefits	
E.B.A. & M. Corporation Self Pay	Medicare	



# Claims Appeal Module

## Challenging Insurers' Claim Denial for the nasal airway

### Why Give Up YOUR Hard-earned Money?

... It seems that most insurers deny first and ask questions later...gambling that doctors won't have the patience or persistence to run a bureaucratic obstacle course.

It's a game for them. They know that if their denials and demands for more information take up a lot of staff time, most healthcare providers will give up nor not make the effort.

– Los Angeles Times; April 17, 2014

### Why Let Your Practice Be Cheated?

The *L.A. Times* had the right diagnosis. Why be cheated without a fight? Better to slip on the boxing gloves and just say "We did the work, now pay up". Multiply the lost revenue by the number of cases in which there is a denial, even if for just several hundred dollars, and you'll realize there is big money to be mined. YOUR money.

### Automate Your Appeals

- The key is having template forms with prepared documentation to support the appeal or demand for payment. After all, insurers are the masters of non-specific forms and templates. They insert the policy specifics, punch a key and out goes their letter. You know, "Dear Provider". Do the same.
- Your template says: "Dear Insurer". The only portions of the **Claim Appeal Letter** that needs "filling in" are: Insurance company name, from information, patient claim number, patient name, date of service. If other identification seems necessary, plug that in also.
- Should take less than 60 seconds and you have your Claim Appeal out the door.
- Make sure it is directed to a "Claims Supervisor" in the appeal office. There is usually a distinct mailing address for appeals as opposed to primary claims.



# Claims Appeal Module (continued)

## Infer Negative Consequences if Claim Not Paid

The detailed and illustrated **Claim Appeal Letter**, is very appropriate and effective when the claim has been denied due to the insurer's misunderstanding of the nature and mission of the device.

Often, claims are rejected because of lack of sophistication on the part of the claims examiners. Therefore, it is our duty to educate claims processors and supervisors at insurance companies.

Once a given carrier honors the claim, a precedent is established that cannot be erased.

All major Payers, including Medicare, Aetna, Cigna, Blue Cross, Blue Shield, Guardian and Tricare honor the fee—without halving or quartering it.

The message that has properly resonated with the insurers is: "Any advance in surgical care and anesthesia that creates a safer experience for the patient cannot be disregarded and charges for such must be honored". You are welcome to use those very words.

The sample document can be reproduced, excerpted, customized, modified at your discretion and submitted in support the claim for surgeon payment.

As a Claims Appeal document, it has been uniformly successful in reversing payer denials.

- Make the insurer aware that persistent malperformance, intentional or not, will be brought to the attention of the state regulatory agency; the state's Insurance Commissioner or it's Department of Managed Care.
- Insurers do not like regulators opening "new files". Insurers are obliged to respond to every complaint filed with the regulatory agency. The regulatory agencies are required to keep count of the number of complaints. Just like the airlines which are required to keep "on-time departure and arrival" rosters. Such performance records are always fodder for the media, so insurance companies are sensitive about seeing themselves at the top of the complaint list. Also, creates more work for them so that would not be popular.
- To give your form letter some further heft, just "cc" the appropriate regulatory agency's name and you have now placed a perceived thorn into their side. Whether you actually complain to the agency or not is your decision, but that "cc" suggests an unwanted hassle for the insurer.
- Your practice attorney should be listed in the "cc" grouping. Why not? Shows you mean business.
- In life, generally, tenacity and persistence is rewarded. Per the *L.A. Times*, insurers assume MDs don't fight back. Prove them wrong! They're holding your money hostage, right?

Claim Appeal Letter

*Click on form to view.*



## Physician Testimonials

“I have used the Reltok Clear-Flo Nasal Airway and found it very easy to insert, comfortable for the patient, effective and easy to remove.

– Joe Parell, MD  
Diplomate, American Board of Otolaryngology  
Head and Neck Surgery  
Clinical Assistant Professor  
University of Florida Medical School  
Panama City, FL

“The Reltok Clear-Flo Nasal Airway is one of those nifty, intuitive devices that I am surprised no one has come up with before.

– Jennifer Derebery, MD, FACS  
Clinical Professor, Otolaryngology, USC  
Past President, American Academy of Otolaryngology  
Head and Neck Surgery  
Los Angeles, CA

“The Reltok Clear-Flo Nasal Airway makes sense and it works. Since my patients like it, I like it. Highly recommended.

– William Binder, MD, FACS  
Associate Professor, Head and Neck Surgery, UCLA  
Diplomate, American Board of Otolaryngology Head and Neck Surgery  
Beverly Hills, CA

“I was a bit skeptical at first that something as simple in design and concept as the Reltok Clear-Flo Nasal Airway could be as effective as claimed. After having used the airway on a dozen patients, I can attest to the tremendously positive impact it has on the post-operative experience for patients undergoing septorhinoplasty. Placing them is straightforward, and instead of mouth-breathing for a week, patients have been pleasantly surprised to be able to breathe through their nose immediately. Exceeding a patient's expectations is my goal, and the airway now plays a role in achieving that aim.

– Don Yoo, MD  
Fellow, Facial Plastic & Reconstructive Surgery  
USC Division of Head and Neck Surgery  
Los Angeles, CA

“It is with great enthusiasm that I recommend the Reltok Clear-Flo Nasal Airway to anyone doing nasal, septal or turbinate procedures. The airway together with the clearing and suctioning apparatus included in the packaging have truly made the nasal surgery recovery period much more comfortable, effective and easier.

– Michael D. Storch, MD, FACS  
Diplomate, American Board of Plastic Surgery  
Aventura, FL

“Love the Reltok Clear-Flo Nasal Airway!!

– W. Matthew White, MD  
Facial Plastic and Reconstructive Surgery  
Assistant Professor in Otolaryngology  
NYU Langone Medical Center  
New York City, NY

“I have witnessed the operative insertion of the Reltok Clear-Flo Nasal Airway and observed patients in the recovery room at our surgery center. I liked what I saw. Delivering a better patient experience should be the stock and trade of every MD. Towards that end, the Reltok Clear-Flo Nasal Airway is doing a good job.

– Gary Alter, MD  
Assistant Clinical Professor of Plastic Surgery  
UCLA Diplomate, American Board of Plastic Surgery  
Beverly Hills, CA



## Physician Testimonials Cont.

“I think the Reltok Clear-Flo Nasal Airway is a great product. I used the one you sent me for a case of surgical treatment of traumatic (animal bite to face) vestibular stenosis. It helped maintain light pressure on my composite and full thickness grafts as well as giving the patient an excellent airway so she got a good nights' sleep the first day of her recovery.

– Ronald W. Strahan, MD  
Los Angeles, CA

“Anesthesiologists are often confronted with difficult challenges to support and maintain the airway passages in post nasal surgery patients. The new and innovative approach with the Reltok Clear-Flo Nasal Airway allows patients to have a clear and open passage to breath after surgery. As an anesthesiologist I can rest easier because I can suction directly through the nasal airway and clear any blood and blood clots from the patient's airway. Equally important, I am able to maintain a patent airway and provide supplemental oxygen, especially at the end of the nasal operation and emergence from anesthesia. Simply, patient comfort and acceptance, is enough reason for surgeons to start using the Reltok Clear-Flo Nasal Airway on every nasal operation.

– Kevin Tehrani, MD  
Diplomate, American Board of Anesthesiology  
Anesthesiologist, Summit Surgery Center  
Beverly Hills, CA

“I really like it...nice and soft without being too compressible. I like that it comes with an instruction sheet for patients and the irrigation syringe.

– Paige Powers, MD  
Diplomate, American Board of Otolaryngology  
Head and Neck Surgery  
Charlottesville, VA

“Love it!

– Walter Dishell, MD  
Diplomate, American Board of Otolaryngology  
Head and Neck Surgery  
Encino, CA

“I have delivered anesthesia for cases in which the Reltok Clear-Flo Nasal Airway was used. I found the product to be very clever, and indeed valuable for me, as an anesthesiologist. During emergence from anesthesia, having a guaranteed airway is a safety plus. Without a reliable airway, patients are apt to struggle and be combative while emerging from the anesthetic. In addition, having a clear and direct route to the pharynx for suctioning allows an anesthesiologist to have fewer grey hairs.

– Shawn Taheri, MD  
Diplomate, American Board of Anesthesiology  
Medical Director, Summit Surgery Center  
Beverly Hills, CA

“I am pleased to report my impressions of the Reltok Clear-Flo Nasal Airway. Last week, I had a case that was rather challenging. A young man with a severely battered nose underwent reconstructive nasal surgery. There was more bleeding than usual. In the recovery room, despite the heavier bloody nasal drainage, the nasal airway maintained its patency and provided the patient a satisfactory airway. Attributable to that, the patient did not exhibit the usual anxiety and restlessness that he might were his nose completely blocked.

It was necessary to return the patient to the operating room for control of the bleeding. The nose was very aggressively packed to control the bleeding, which was coming from several sites. Once again, the nasal airway performed excellently in the immediate post-operative period.

What I appreciated was that the airway provided easy, and without any patient cooperation, access into the pharynx to suction the blood that had accumulated at the end of the procedure.

I would highly recommend, to any and all nasal surgeons, that they employ this device routinely in all their nasal and sinus surgery cases. They will have the eternal appreciation of their anesthesiologist.

– Stuart Goldstein, MD  
Diplomate, American Board of Anesthesiology  
Orange, CA



## Patient Testimonials

“For me, the absolute worst thing about nasal surgery is the post-op packing. During the recovery from my first three surgeries elsewhere, I took pain killers back to back until the packing was out. The Reltok Clear-Flo Nasal Airway used on me made all the difference. What the tubes did was essential - they took out the torture feeling element and made those first five days tolerable and even comfortable at times.

– Laurie Wilson

“I put off having nasal revision surgery for seven years because the nasal packing from my first surgery was such a bad experience. Dr. Kotler showed me the alternative of using the Reltok Clear-Flo Nasal Airway. My mother was amazed to see me being mentally comfortable and looking relaxed compared to my first experience of wanting the packing taken out every minute. The airway is the only way to go!

– TLR

“I wanted to comment on the unbelievable results the Reltok Clear-Flo Nasal Airway provided. I had nasal surgery without the use of the airway and the improvement in my comfort and ability to breathe during my recovery was dramatic. I would highly recommend that anyone considering any type of surgery could benefit from the use of the Reltok Clear-Flo Nasal Airway. PLEASE USE THEM.

– Colleen Kamens

“My experience with the Reltok Clear-Flo Nasal Airway was great. It was very easy to breathe. I would recommend it to a friend/family member.

– Orly Kashri

“The tubes made it a lot easier to breathe from my nose and it helped me sleep better being able to breathe. It was a new and positive experience.

– Peter Chairez

“I am writing to you to let you know how much I appreciated the post-op breathing tube that was inserted for me after my nasal surgery with last week. For me, the absolute worst thing about nasal surgery is the post-op packing. The breathing tubes made all the difference. What the tubes did do was essential - Great invention!

– Lauriann Wright

“While everything was in, I found it very helpful to be able to breathe out of one nostril versus not being able to breathe at all out of the other. If given the choice, I would opt for the Reltok Clear-Flo Nasal Airway.

– Don Zirlin

“Having the nasal tube in my right nostril only, I could definitely appreciate the ability to be able to breathe. I would definitely recommend the Reltok Clear-Flo Nasal Airway to anyone undergoing nasal surgery.

– Laura Meiojas

“The most amazing thing was that I could breathe after surgery!!! I had never experienced this with my other surgeries nor had I ever heard of it. The fact that I could breathe out of my nose because of these tiny tubes made recovery so much more comfortable and easy. All I can say is “WOW!”

– Georgia Mayfield

“The first time I had surgery, the packing caused the most discomfort during the recovery process. The Reltok Clear-Flo Nasal Airway was really easy to take care of and whenever I felt it getting clogged, I could flush it out and feel better. I couldn't feel the airway in my nose and it wasn't uncomfortable. I also felt it was easier to keep clean.

– Michelle Ocampo





## Resource Documents

Operating From Management Committee	
<b>New Product/Procedure Request</b>	
VISITOR TO COMPANY BOARD MEMBER ONLY	
<b>New Product Name:</b> The Delta Group's "Next" Activity	<b>Manufacturer:</b> Delta Wood Products, LLC 100 Westwood Drive, Suite 200 Beverly Hills, CA 90210
<b>Greeting FOP:</b> _____	<b>Call or Appointment:</b> Yes _____ Call or Disposition: _____
<b>Sales Rep:</b> _____	<b>Contact Information:</b> <b>Name:</b> _____ <b>Email:</b> _____

If the product / equipment IS approved for the application being requested? ☐ YES ☒ NO

If, please attach a copy of the RMA Approval Letter.  
Please see the approved CDR Application for the proposed equipment: [https://openroad.com](#).

If we are approved CDR, has Study reviewed this product? ☐ YES ☒ NO

If, please attach M&E notes.

We are requiring M&E note, provide us with a copy of the Robert Center form approved by the CDC Office.

If so, the resulting M&E note would be a copy of the Robert Center Form clearly indicating the risks associated with the introduction. The industry approval can be obtained.

- 1. Delta Health Agency Research Project, 2014
- 2. Delta Health Agency Research Project, September 2016
- 3. Clean Appraisal Project

**What finding / callouts do you recommend for our office new product / equipment?**  
None. All research completed was timely and without new products.

It is generally recommended that equipment be procured to use the product / equipment? ☐ YES ☒ NO

Will you consider product / equipment if no change to the process is required? ☐ YES ☒ NO

[illegible]

## Operative Report Instructions for Billing Purposes

**Step 1**

Add the following information to your Operative Report for the intended device:

- Device name
- Device code
- Device ID
- Device SN

**Step 2**

Use the following information to **add** **operating room** to provide the appropriate details about the intended device/procedure.

**Instructions on how to add Additional AED/Defibrillator Procedures**

Make sure of the intended AED/Defibrillator. The reason of adding procedure details is to provide necessary and appropriate information to the hospital and insurance company. The reason of adding procedure details is to provide necessary and appropriate information to the hospital and insurance company.

The device has been used in the operating room. The reason of adding procedure details is to provide necessary and appropriate information to the hospital and insurance company.

**Instructions on how to add Defibrillator/Resuscitator**

The device has been used in the operating room. The reason of adding procedure details is to provide necessary and appropriate information to the hospital and insurance company.

[illegible]

## New Product/Procedure Request Form

## Sample Billing Form

## Operative Report Instructions

## AETNA Explanation of Benefits (EOB), Examples

[illegible]

bluebird of california

November 19, 2019

Robert Kotler, MD  
426 E. Bedford Dr.  
Suite 201  
Beverly Hills, CA 90210-4312

Dear Robert Kotler, MD:


We are responding to your letter addressed to Tania B., Executive Injury Coordinator. Thank you for taking the time on October 19, 2019 to express your concern with claims processing.

You have requested the review and further reimbursement of CPT code 20999-BA on claim number xxxxxx. We are pleased to advise your request has been approved.

Upon further review of the claim above, it was determined that the claim processed incorrectly. Procedure 20999 should have allowed per Table 1.1 Standard Fee Schedule at 40% of other charges which would have been \$270. The claim has been retrospectively corrected, and once finalized you will receive an explanation of benefits (EOB).

If you have general questions about the member's plan benefits, please contact Provider Customer Service at (800) 341-6462. If you have specific questions about this process, please contact me directly at the number below:

Sincerely,

  
Amanda V. Insalaco, Injury Coordinator  
Glennco Department  
(916) 300-6223

Blue Bird of California  
Company Incorporated 401, Box 00077, Pittsburg, CA 95660  
10/20/2019 10:00 AM

##000219 \_\_\_\_\_

MC NAME \_\_\_\_\_

NAME OF PRACTICE \_\_\_\_\_

Street Address \_\_\_\_\_

City / State / Zip \_\_\_\_\_

INSURANCE COMPANY NAME \_\_\_\_\_

Street Address OR POSTAL BOX NUMBER \_\_\_\_\_

City / State / Zip \_\_\_\_\_

Recheck: Claim submitted to carrier/Carrier at attention of Attorney/Under-Write, COT 10055-00

Robert D. Clemen number \_\_\_\_\_ Referral name \_\_\_\_\_ Date of service \_\_\_\_\_

**Be Charge submitted for Invention and Election of Inherited Airway Prosthesis, COT 10010-00**

This portion of the claim was inappropriately denied. Let me say for your understanding of the nature and reason of the safety device involved, transport below will clarify.

Please note that Medicare and all major insurers and independent plans have the charge for the important physician safety service in the patient.

Kindly issue supplemental payment immediately.

Sincerely,

MC NAME \_\_\_\_\_

Your Job Title \_\_\_\_\_


	DEPARTMENT OF HEALTH & HUMAN SERVICES	Public Health Service
		Food and Drug Administration Division of Regulatory Operations Consumer Product Division    200-855-1200
N		
Robert Kotler, M.D. C/O Nurel Medical, Inc. #051 Beverly Hills, California 90211		
		SEP 3 1970
Re: K20904		
Trade Name Pre-Paid Urinary System		
Classification Regulate Name and Number: Unapparelled Airway		
Regulatory Class Class I Emper		21 CFR 84.1000
Product Code 8723		
Dated June 27, 1970		
Rescinded: June 28, 1970		
Dear Dr. Kotler:		
<p>We have received your premarket notification submission and have found this device to be acceptable under the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act ("Act"). Therefore, you may immediately begin marketing this device as described in our premarket notification.</p> <p>The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 84.1000. This regulation states that your device is classified as a first class other classification from certain general controls of the Act. Your device classification regulation name, regulatory class, and product code are given above. When taking your device with the Food and Drug Administration, please use this product code.</p> <p>In the future, we will substantially upgrade devices which will utilize the above classification regulations and move them from their classification criteria so we instead will allow through a premarket notification submission to the Food and Drug Administration. We encourage you to submit such information to us by September 1st of next year or new design or modify the limitations of instruction from Section 713(a) of the Act.</p>		

## Anthem Explanation of Benefits (EOB), Example

## Blue Shield of CA \_ Claims Appeal Approval Letter, Example

## Claim Appeal Letter

## Reltok Airway FDA Clearance Letter

		UNITED STATES PATENT AND TRADEMARK OFFICE	
United States Patent Office		(21) Patent No. <b>US 8,092,472 B2</b> (22) Filed <b>Jun. 10, 2013</b>	
(54) DEVICE AND METHOD FOR MANIPULATING MULTIPLE SURFACES AFTER TISSUE REMOVAL		(51) Int. Cl. A61B 1/00 (2006.01) A61B 1/24 (2006.01) A61B 1/26 (2006.01)	
(73) Inventor <b>Robert Kiefer, Jr.</b> , (US) CA, 92373		(72) Inventor <b>Robert Kiefer, Jr.</b> , (US) CA, 92373	
(74) Attorney Sullivan & Worcester, LLP 10000 Wilshire Blvd., Suite 2000 Los Angeles, CA 90024-3208 Tel. 310.277.1000 Fax 310.277.1001 E-mail: <a href="mailto:Robert.Kiefer@sw-law.com">Robert.Kiefer@sw-law.com</a>		(56) Reference FOREIGN PATENT DOCUMENTS JP 2005-018191 A (2005) JP 2005-018192 A (2005) JP 2005-018193 A (2005) JP 2005-018194 A (2005) JP 2005-018195 A (2005) JP 2005-018196 A (2005) JP 2005-018197 A (2005) JP 2005-018198 A (2005) JP 2005-018199 A (2005) JP 2005-018200 A (2005) JP 2005-018201 A (2005) JP 2005-018202 A (2005) JP 2005-018203 A (2005) JP 2005-018204 A (2005) JP 2005-018205 A (2005) JP 2005-018206 A (2005) JP 2005-018207 A (2005) JP 2005-018208 A (2005) JP 2005-018209 A (2005) JP 2005-018210 A (2005) JP 2005-018211 A (2005) JP 2005-018212 A (2005) JP 2005-018213 A (2005) JP 2005-018214 A (2005) JP 2005-018215 A (2005) JP 2005-018216 A (2005) JP 2005-018217 A (2005) JP 2005-018218 A (2005) JP 2005-018219 A (2005) JP 2005-018220 A (2005) JP 2005-018221 A (2005) JP 2005-018222 A (2005) JP 2005-018223 A (2005) JP 2005-018224 A (2005) JP 2005-018225 A (2005) JP 2005-018226 A (2005) JP 2005-018227 A (2005) JP 2005-018228 A (2005) JP 2005-018229 A (2005) JP 2005-018230 A (2005) JP 2005-018231 A (2005) JP 2005-018232 A (2005) JP 2005-018233 A (2005) JP 2005-018234 A (2005) JP 2005-018235 A (2005) JP 2005-018236 A (2005) JP 2005-018237 A (2005) JP 2005-018238 A (2005) JP 2005-018239 A (2005) JP 2005-018240 A (2005) JP 2005-018241 A (2005) JP 2005-018242 A (2005) JP 2005-018243 A (2005) JP 2005-018244 A (2005) JP 2005-018245 A (2005) JP 2005-018246 A (2005) JP 2005-018247 A (2005) JP 2005-018248 A (2005) JP 2005-018249 A (2005) JP 2005-018250 A (2005) JP 2005-018251 A (2005) JP 2005-018252 A (2005) JP 2005-018253 A (2005) JP 2005-018254 A (2005) JP 2005-018255 A (2005) JP 2005-018256 A (2005) JP 2005-018257 A (2005) JP 2005-018258 A (2005) JP 2005-018259 A (2005) JP 2005-018260 A (2005) JP 2005-018261 A (2005) JP 2005-018262 A (2005) JP 2005-018263 A (2005) JP 2005-018264 A (2005) JP 2005-018265 A (2005) JP 2005-018266 A (2005) JP 2005-018267 A (2005) JP 2005-018268 A (2005) JP 2005-018269 A (2005) JP 2005-018270 A (2005) JP 2005-018271 A (2005) JP 2005-018272 A (2005) JP 2005-018273 A (2005) JP 2005-018274 A (2005) JP 2005-018275 A (2005) JP 2005-018276 A (2005) JP 2005-018277 A (2005) JP 2005-018278 A (2005) JP 2005-018279 A (2005) JP 2005-018280 A (2005) JP 2005-018281 A (2005) JP 2005-018282 A (2005) JP 2005-018283 A (2005) JP 2005-018284 A (2005) JP 2005-018285 A (2005) JP 2005-018286 A (2005) JP 2005-018287 A (2005) JP 2005-018288 A (2005) JP 2005-018289 A (2005) JP 2005-018290 A (2005) JP 2005-018291 A (2005) JP 2005-018292 A (2005) JP 2005-018293 A (2005) JP 2005-018294 A (2005) JP 2005-018295 A (2005) JP 2005-018296 A (2005) JP 2005-018297 A (2005) JP 2005-018298 A (2005) JP 2005-018299 A (2005) JP 2005-018300 A (2005) JP 2005-018301 A (2005) JP 2005-018302 A (2005) JP 2005-018303 A (2005) JP 2005-018304 A (2005) JP 2005-018305 A (2005) JP 2005-018306 A (2005) JP 2005-018307 A (2005) JP 2005-018308 A (2005) JP 2005-018309 A (2005) JP 2005-018310 A (2005) JP 2005-018311 A (2005) JP 2005-018312 A (2005) JP 2005-018313 A (2005) JP 2005-018314 A (2005) JP 2005-018315 A (2005) JP 2005-018316 A (2005) JP 2005-018317 A (2005) JP 2005-018318 A (2005) JP 2005-018319 A (2005) JP 2005-018320 A (2005) JP 2005-018321 A (2005) JP 2005-018322 A (2005) JP 2005-018323 A (2005) JP 2005-018324 A (2005) JP 2005-018325 A (2005) JP 2005-018326 A (2005) JP 2005-018327 A (2005) JP 2005-018328 A (2005) JP 2005-018329 A (2005) JP 2005-018330 A (2005) JP 2005-018331 A (2005) JP 2005-018332 A (2005) JP 2005-018333 A (2005) JP 2005-018334 A (2005) JP 2005-018335 A (2005) JP 2005-018336 A (2005) JP 2005-018	

**RE: Anesthesiologist Endorsement for Intranasal Airway**

I am pleased to report my impression of the new internal nasal airway, last week, I had a case that is rather challenging. A young man with a severely battered nose underwent reconstructive nasal surgery. There was more bleeding than usual. In the recovery room, despite the heavier bloody nasal drainage, the nasal airways maintained their patency and provided the patient a satisfactory airway. Attributable to that, the patient did not exhibit the usual anxiety and restlessness that he might have when his nose completely blocked. It was necessary to return the patient to the operating room to correct the bleeding. The surgeon took the nasal airway in place and very quickly and aggressively re-packed the nasal cavity to control the bleeding, which was coming from several sites. While he was working, I maintained a soft suction catheter, passed through the airway, to keep suctioning the pooling blood from the throat. After the patient was again transferred to the recovery room, the nasal airways performed excellently in the immediate post-operative period. What I appreciated was that these airways provided ease, and without any patient cooperation, access into the pharynx to suction the blood that was accumulating and which would have presented a big problem had there been no route for evacuation. I would highly recommend to any and all nasal surgeons, that they employ this device routinely in any of their nasal and sinus surgery cases. They will save the eternal agony of their anesthesiology.

Stuart Goldstein, MD  
Diplomate, American Board of Anesthesiology

[illegible]

# Solving the Problem of Post-operative Airway Obstruction in Nasal/Sinus Surgery

## A Strategy and New Device to Ensure Patient Safety, Comfort, and Satisfaction

Robert K. Lippert, MD, FACS<sup>\*\*\*</sup>  
 Joseph W. Smith, MD, FACS<sup>\*\*\*</sup>  
 La Jolla, CA  
 La Jolla, CA

Sinus surgery, septoplasty, with or without turbinate reduction and rhinoplasty are among the most common surgical procedures performed by our specialty. In 2004, 600,000 sinus procedures were performed in the United States.<sup>1</sup> Approximately 100,000 rhinoplasties were done per year.<sup>2</sup> Unintended and ancillary procedures accounted for an additional 49,000 procedures.

**Packing or No Packing, the Post-operative Period is Not Popular with Patients**

Some surgeons choose not to place any packing. However, patients still complain of impaired breathing due to edematous tissues and blood mucus accumulation. Nasal and sinus irrigation may feature some support, "packing," placed or injected into the nasal fissure, at the conclusion of the operation. It is a tedious, limited, and uncomfortable procedure. Patients are required to come packing 80-100% of the time, and the surgical procedure is packing for 3 to 3 days post-operatively.<sup>3</sup>

The common indications for packing are as follows:

- Stabilize maxillofacial/mandibular/maxillofacial/reconstructed elements in the proper and anatomically correct positions
- Prevent tissue/flap formation
- Reduce the chance of bleeding and prevent hematoma formation
- Act as a substitute for medications (e.g., antibiotics and steroids)
- Act as a control for postoperative discomforts to be inflicted after surgery (e.g., nasal decongestant drops to reduce bleeding and/or relieve congestion)

<sup>\*\*\*</sup> Clinical Instructor, Department of Surgery, Division of Head and Neck Surgery, David Geffen School of Medicine at UCLA, Los Angeles, CA. Corresponding author, [robert@lipper.com](mailto:robert@lipper.com)

<sup>\*\*\*</sup> Clinical Assistant Professor, Department, USC School of Medicine, Division of Otolaryngology, Department of Surgery, Los Angeles, CA.

<sup>\*\*\*</sup> Clinical Assistant Professor, Department of Surgery, Division of Head and Neck Surgery, David Geffen School of Medicine at UCLA, Los Angeles, CA.

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Reltok Airway US Patent  
Document

### Anesthesiologist Endorsement for Intranasal Airway

JAMA Facial Plastic Surgery  
Article, September 2018

Original Research Paper,  
2014