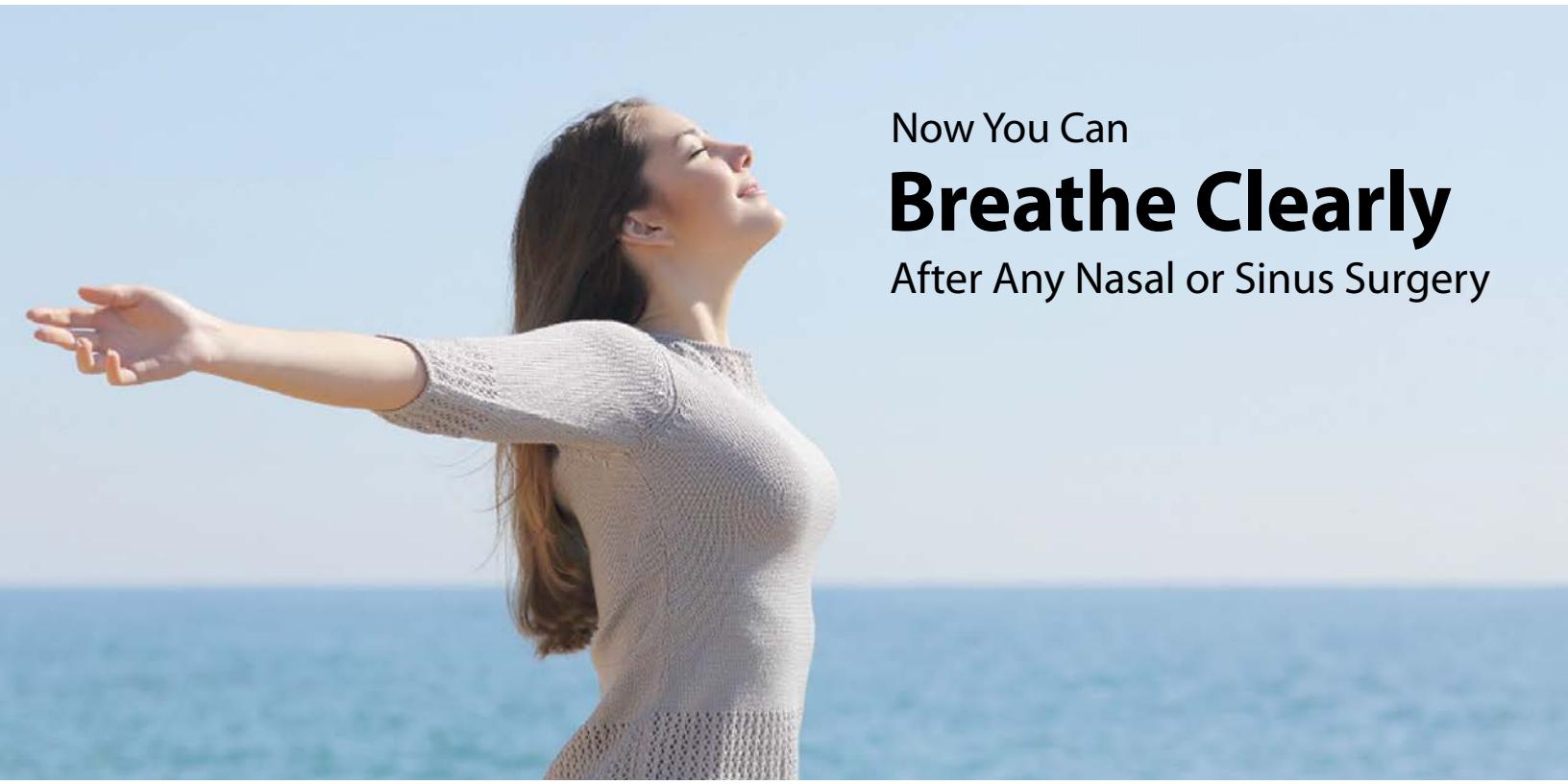
RELTOK CLEAR-FLO™
NASAL AIRWAY SYSTEM

INFORMATION GUIDE



THE NEW STANDARD IN POST-OP PATIENT COMFORT & SAFETY

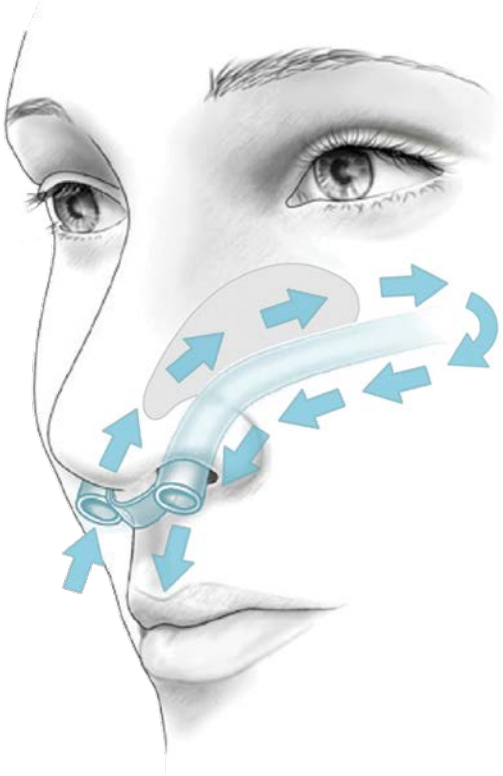
anthony products, inc.

A Patented, FDA-Cleared Airway Safety Device

A New Standard of Care for All Nasal and Sinus Surgeries

Better Patient Care

- Allows patients to breathe immediately through the nose
- Large-bore airways; delivers 12 times the air flow of other devices
- Aids in preventing blocked nasal passages, ear popping, claustrophobia, and anxiety during recovery
- Well-tolerated for up to 10 days
- Constructed from FDA-cleared Class VI medical grade silicone
- Non-stick, latex-free
- No suturing necessary; nests on nasal floor
- Easily inserted in 10 seconds or less
- Applicable for all nasal and sinus surgeries, "packing" or "no packing"
- Compatible with all nasal/sinus packing materials
- Can be used with all septal and intranasal splints
- Topical anesthetic administered into nose makes removal in office, simple, quick and painless
- 98% patient satisfaction rating



Increases Revenue

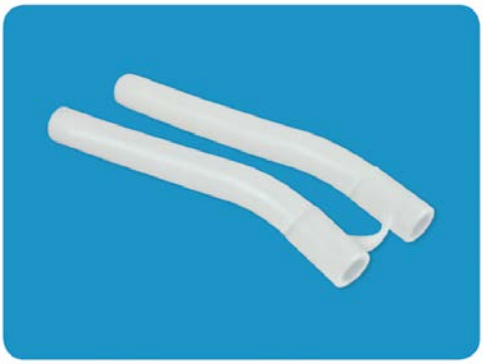
- Insurers pay surgeons for insertion and fixation
- Surgery center/hospital purchases device then bills insurer for reimbursement

The API Guarantee

1. Purchase one Reltok Clear-Flo™ Nasal Airway 5 Pack (Item No. RELTOK-CFNA-5).
2. Our Insurance Billing & Coding consultant will guide you through the reimbursement process for your first 3 cases. This is at **NO CHARGE**, courtesy of Anthony Products.
3. If your patients are not happy, and if you are not pleased – for any reason – return the unused kits and **receive a 100% refund for your purchase**.

The Reltok Clear-Flo™ Nasal Airway

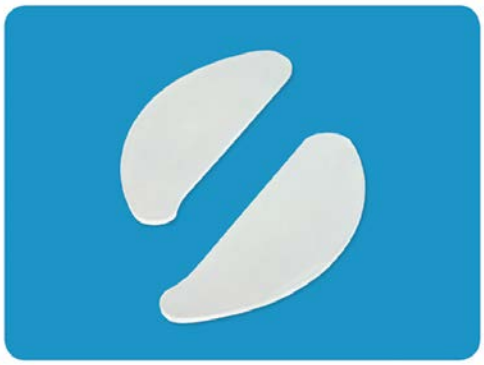
ALWAYS CLEAR, ALWAYS COMFORTABLE



- Designed, patented and FDA-cleared as a safety device, for rapid and direct access to pharynx post-operatively and endorsed by anesthesia specialists and recovery room RNs
- Post-operative airflow through nasal passages, packed or unpacked, delivers unmatched patient comfort and satisfaction
- Significant professional fee paid to surgeons for inserting airway because it is a safety device
- Illustrated "Instructions for Use" brochure with two-step insertion technique for surgeons, and patient "Home Care Instructions" for irrigating airway tubes during initial healing process, provided with each kit

The Reltok Ultra-Smooth Septal Splint™

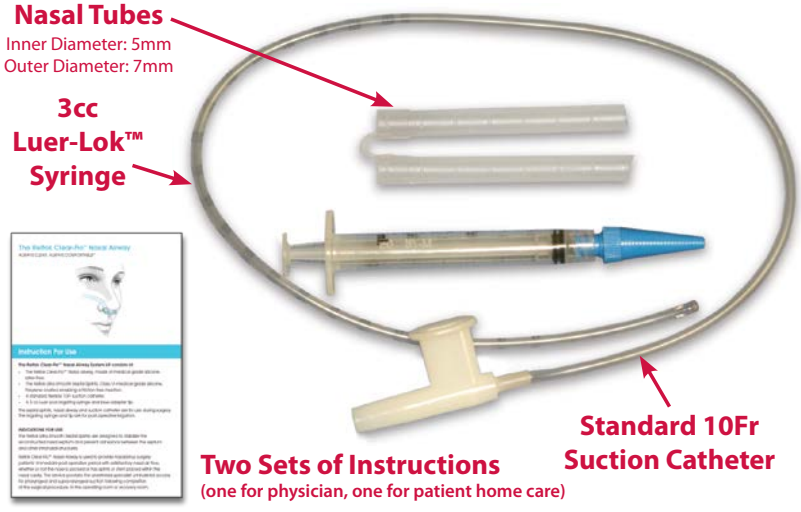
A SUPERIOR OPTION



- Occupies less space in nasal cavity which facilitates easier and more rapid insertion of stents and packing as compared to similar products
- Thin structure allows for alternative uses, e.g. vestibular or lateral wall stenting
- Made of Class VI medical grade silicone with excellent patient tolerance for ten days or more
- Ultra-smooth, low-friction Parylene coated surface allows stents, packing and the Reltok Clear-Flo™ Nasal Airway to glide smoothly and quickly into place and retards secretion adherence

Reltok Clear-Flo™ Nasal Airway Kit

(One Pack: Item No. RELTOK-CFNA-1 • Five Pack: Item No. RELTOK-CFNA-5)



Each kit Includes the following items:

- One-piece, Dual Tube Clear-Flo™ Nasal Airway
- 10Fr Suction Catheter
- One set of Ultra-Smooth Septal Splints™
- Illustrated Instructions *(for physician insertion)*
- A 3cc Luer-Lok™ syringe with adapter tip *(for post-operative home irrigation)*
- Illustrated instructions *(for patient home care)*

Airway and septal splints are packaged together in a sterile kit.

The Reltok Clear-Flo™ Nasal Airway was developed by Robert Kotler, MD, FACS, Clinical Instructor, Head and Neck Surgery, UCLA.

Proudly made in the USA.

Frequently Asked Questions

Q: Is The Reltok Clear-Flo™ Nasal Airway System a splint or a stent?

A: The Reltok system comes with both an intranasal airway and septal splints.

1. The Reltok Clear-Flo™ Nasal Airway is designed, patented and FDA-cleared as a safety device to serve OR and recovery room staff for rapid and direct access to the pharynx post-operatively. Its exclusive mission is to deliver an improved patient experience after nasal/sinus surgery via clear and open nasal passages for easier breathing.
2. The Reltok Ultra-Smooth Septal Splints provide structural support to the septal area after a septoplasty, but are designed to occupy less space within the nasal cavity as compared to similar products. The splints are made of Class VI medical grade silicone with a Parylene coating for a low-friction surface that allows stents, packing and the Reltok Clear-Flo™ Nasal Airway to glide smoothly.

Q: Any contraindications to using the airway?

A: No. The nasal airway is appropriate to use after rhinoplasty, septoplasty, turbinate and sinus surgeries. For open rhinoplasty cases, in deference to the external transcolumellar incision, the bridge connecting the two tubes can be divided and each tube secured by the suture technique of the surgeon's choice.

Q: How long can the airway stay in place?

A: The nasal airway tubes are able to stay in the patient for up to 7 days post-operatively without any adverse consequences.

Q: Can one use septal splints concomitantly with the nasal airway?

A: Yes. Every technique of intranasal splinting, stenting or packing is compatible with the indwelling nasal airway. It was designed that way. The key to internal harmony is that the device is designed so that it nests in the "surgically-quiet" always un-operated portion of the nasal fossa, the floor. The Reltok Clear-Flo™ Nasal Airway enables airflow through the nasal passages without compromising the function of the packing, splinting or other cavity fillers. The system comes with both an airway and septal splints because they are often used concomitantly.

Q: I don't routinely pack the nose, so why insert an airway?

A: Packing or no packing, the nasal cavities will fill with blood and mucus. Guaranteed. And there will always be some nasal mucosal edema. This will cause the non-packed patient to be dissatisfied. Since nose-blowing is unwise and generally forbidden in the immediate postoperative period, without a guaranteed airway, the patient will unhappily resort to mouth breathing. The Reltok Clear-Flo™ Nasal Airway is the patient's best friend after surgery because it provides clear nasal passages and mitigates their anxiety, claustrophobia, clogged ears and dry throat which detract from their satisfaction of a successful surgery. With the airway painlessly in place, the patient is content and appreciates the surgeon's efforts in providing an optimal post-operative experience.

Q: If the nose is packed tightly, can the airway device be compressed and rendered inoperative?

A: No. A specific durometer (measure of stiffness) silicone material was selected to rule out such a possibility. Never happened in the clinical study.

Q: Any packing material or technique of packing that is incompatible with the airway?

A: No. Absorbable and non-absorbable packing was used in every clinical study case. Packing is an independent issue.

Q: Is it possible for the airway tubes to become blocked by blood or mucus?

A: Yes. It is possible, but correctable. A home irrigation syringe and tip are included in the kit. Patients and caregivers, who assiduously follow the Instructions for Home Care card, will be able to prevent blockage. However, if home care is somehow inadequate, using a suction catheter at an office visit will solve the problem. Our experience was that fewer than 5% of patients required an office visit to clear the nasal airway device.

Q: Can the airway dislodge anteriorly? Posteriorly?

A: The "bridge" prevents any posterior migration. In our experience, no airway ever self-extruded, anteriorly for two reasons:

1. The airway is designed to fit snuggly onto the floor of the nose.
2. The act of swallowing tends to create a posteriorly-directed, negative intranasal pressure that mitigates against any anterior movement.

Q: Any worries about the tubes "sticking" to intranasal tissue and causing problems in removal?

A: Never a problem with removal because medical-grade silicone is the classic non-stick material. Artificial heart valves and joints are made of the same material. Even SuperGlue® will not stick to it.

Q: Is removal painful?

A: No. However, if you want to allay any patient anxiety, topically anesthetize the nose five minutes prior to removal. Here's what works for us: a 1:1 mixture of oxymetazoline 0.05 %, or phenylephrine 1%, with pontocaine 2%. This renders the nose anesthetic and shrinks the mucosa to help facilitate removal. Drip into nasal cavity and wait five minutes. Repeat if you like. Then remove the airway device and, as indicated, the packing. Another tip: For those patients raised on tales of the horrors of nasal pack removal, plan a pre-medication sedative routine. A dose of a tranquilizer and pain pill, of surgeon choice, taken one hour prior to pack removal and secretion suctioning will bring a less anxious patient to the office.

Q: Does the surgery center and/or hospital purchase the Reltok Clear-Flo™ Nasal Airway System?

A: Yes; analogous to supplying the anesthesiologist with endotracheal tubes. The facility is responsible for supplying the surgeon with all supplies, materials, and devices used in the OR. All consumables should be line-item billed by the facility to the insurer. Your medical biller or coder will know how to submit the charge.

Q: Will insurers compensate the surgeon for the additional service of inserting, positioning, and later removal of the airway?

A: Yes. Because the Reltok Clear-Flo™ Nasal Airway was designed, patented and FDA-cleared as a safety device to serve OR and recovery room staff for rapid and direct access to the pharynx post-operatively, nasal surgeons have the right to charge a fee—in addition to the surgical procedure fee—for the additional professional service of inserting and later removing it. This nasal 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. There is an established CPT billing code (30999-59 **by report**). Each surgeon will, of course, create a custom operative report for the surgical case. In any event, the above-mentioned procedure code should be accompanied by a descriptive title such as "insertion intranasal airway" or "prosthesis". Allowances and actual payments, of course, vary depending on policy benefits, deductibles, co-pays, etc. At the time of the printing of this brochure, allowances of up to $875 have been reported.

Q: Can these airway tubes be reused?

A: No. The Reltok Clear-Flo™ Nasal Airway and Ultra-Smooth Septal Splints are single use, sterile products. Federal law prohibits reusing these products.

"I don't pack..."

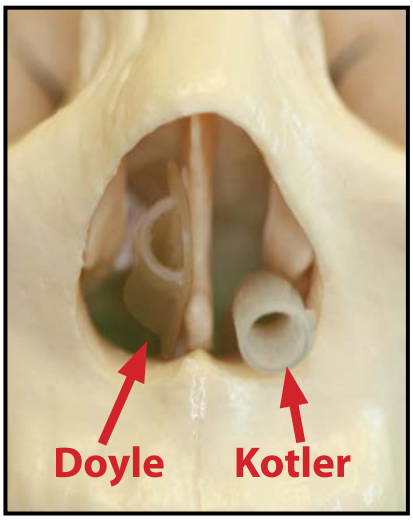
The Reltok Clear-Flo™ Nasal Airway was invented to provide a clear breathing channel with or without packing, stents or splints in place. "Not packing "may be what patients want to hear, because of the universal bad press about not breathing when the nose is packed. The Reltok Clear-Flo™ Nasal Airway has only one mission which is to provide patient comfort via satisfactory air passage through the nose. No other device can achieve what this airway can do for patients.

The reality is that "not packing" is not synonymous with clear breathing. There is mucus stagnation, some blood accumulation, edema and these cause blockages. Patients are advised not to blow their nose. And suggesting that they do home irrigations without medical supervision, adds some uncertainty. Another reality is that attempts with at home flushing to clear the crusty and thickened-secretions to re-establish satisfactory breathing is rarely successful.

Better to know there has been a deliberate pro-active maneuver, an airway placement, at the conclusion of the operation, to provide a device that works and eliminates the uncertainty and the risk of some interference with healing when self-irrigation is the only remedy prescribed. Surgeons that place the airway and pack are happy for another reason: the packing provides moisture retention and thus promotes more rapid healing. They report that when they remove the airway and pack at 4 to 7 days, the inside of the nose is moist, pristine and without crusts and free of unwanted contact between adjacent tissues, e.g. septum and turbinates.

"I use the Doyle splint..."

Fine. Are you using it as a septal splint? Or ostensibly as an airway, also? The septal splint or plate is good, however, the attached "airway" does not work. No secret there. The Reltok Clear-Flo™ Nasal Airway System offers the "best of both worlds" for you as the surgeon and your patients. An advanced septal splint design without the cumbersome and functionless ½ air tube attachment and a proven airway that works is what customers receive with the Reltok Clear-Flo™ Nasal Airway System. Plus, nasal surgeons have the right to charge a fee—in addition to the surgical procedure fee—for the additional professional service of inserting and later removing the nasal airway.

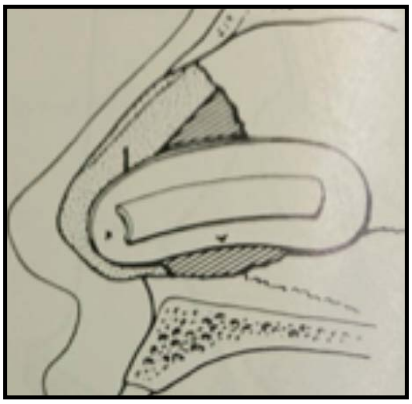


Side-by-side comparison

"I admit that the Doyle-type splint clogs, so won't the Clear-Flo™ Nasal Airway clog also?"

The Doyle splint clogs and itself contributes to obstruction within the even-unpacked nasal passages. Here is a comment from an experienced practitioner in New Jersey:

"I do embrace the concept of a patient airway during insertion of a packing or stenting device. My patients do complain of total nasal obstruction while the Doyles are in place..."



Standard Septal Splint with "airway"

"I don't believe insurance will pay me..."

The Reltok Clear-Flo™ Nasal Airway was designed, patented and cleared by the FDA's Division of Anesthesiology, as a safety device to serve OR and recovery room staff for rapid and direct access to the pharynx post-operatively. This " by-pass" is not a pack, nor a splint, nor a stent. It is not being used to influence the outcome of the surgery, as do splints and stents. Thus,not a component of the surgery per se. Only an independent breathing device. Hence, surgeons have the right to charge a fee—in addition to the surgical procedure fee—for the additional professional service of insertion and removal.

As usual, the surgeon will generate an operative report for the surgical procedures. To support the airway insertion charge, under **CPT code, 30999-59 by report**, a separate airway insertion report must be submitted. Downloadable, sample airway insertion reports are available in the MD/Administrator section at www.Reltok.com.

"My surgical facility is frugal and may not want to shell out the extra money..."

Yes, they have to watch the expenses as we all do. But, both the airway and the septal splint are consumable items that are billed, appropriately, just like the oral endotracheal tube or stitches or tips and hand pieces used during sinus surgery. That is a reasonable expense considering you get the airway, septal splints and accessory products like the suction catheter the anesthesiologist uses and the home care irrigation syringe and tip. The process of the surgical facility billing the insurance company and getting paid or reimbursed for their purchase of our devices should be easy. There must be a "HCPCS" code number to identify any and all surgical devices, supplies, materials for which the facility is entitled to be paid.

Some free-standing outpatient surgery centers, owned by using surgeons or not, are paid a flat or global fee by insurers. Contract modification where a new, patented FDA-cleared device is introduced, are easily done. As your reputation is enhanced in your community because your patients love that you use the nasal airway and they share their positive referrals with others, you will bring even more business which should make you and your surgery center happy.

"I like the idea of being paid for my time and skill to insert the airway, but my office billing department may rebel because it means 'more work."

It takes 60 seconds, max, to add the additional service charge to the billing form. Ask your distributor/sales rep about our templated process that includes how to properly complete the billing form and the words the surgeon plugs into their operative report to fulfill the "30999-59 report" code. Once you plug it into your billing program, you do not have to do it again.

But, it gets better. To get you off on the right foot and make sure that the initial billing fulfills all the requirements, your distributor is underwriting the cost of having a very experienced billing consultant work with you to ensure that your first three billings go smoothly.

Contact Information for Billing Consultant

Email: toddpetrucciani@anthonyproducts.com

or

Email: rkotler@robertkotlermd.com

Indications for Use

The Reltok Ultra-Smooth Septal Splints™ are designed to stabilize the reconstructed nasal septum and prevent adhesions between the septum and other intranasal structures.

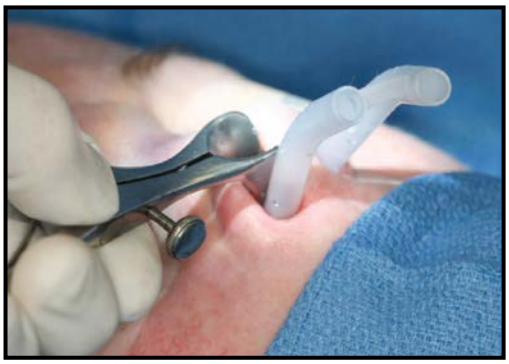
Reltok Clear-Flo™ Nasal Airway is used to provide nasal/sinus surgery patients' immediate post-operative period with satisfactory nasal air flow, whether or not the nose is packed or has splints or stent placed within the nasal cavity. The device provides the anesthesia specialist unhindered access for pharyngeal and supra-laryngeal suction following completion of the surgical procedure, in the operating room or recovery room.

WARNING: As with any surgical procedure, care should be exercised in the insertion and maintenance of these devices.

PRECAUTIONS: Inspect package before use. DO NOT USE if package has been opened or is damaged. The contents of this package are for single use only. DO NOT re-sterilize. DO NOT use after expiration date.

CAUTION: Federal law restricts this device for sale by, or on the order of, a license physician.

Surgeon Insertion Instructions

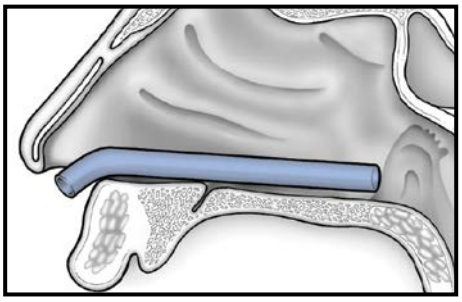


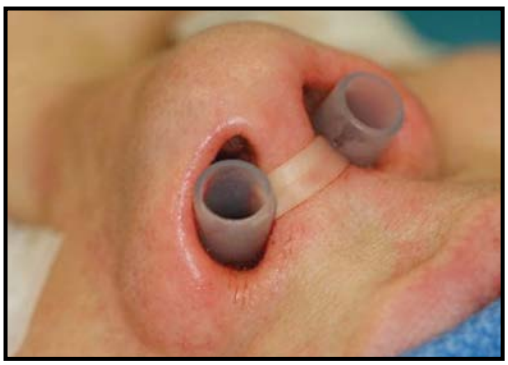
The Reltok Clear-Flo™ Nasal Airway is introduced at the conclusion of the operation before inserting any nasal packing or gels.

For ease of insertion, lubricate the airway tubes with saline, ointment, or lubricating jelly. After initially inserting the airway partly into the nasal cavity, use a standard, thin-tip nasal speculum to inspect the nasal cavity to ascertain the position of the tubes.

Using direct vision, advance the airway further into the nose. Next, use the inferior portion of the speculum blade or bayonet forceps to direct each airway tube downward onto the nasal floor.

The airway tube will snap into place on the floor of the nose and maintain that position lateral to the pre-maxillary bone and medial to the inferior turbinate



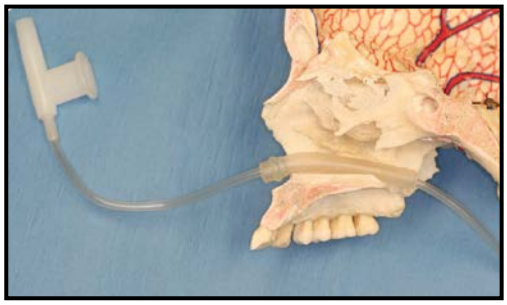


When both airway tubes are properly seated, the bridge connecting them will be flush against the columella.

NOTE: If an open rhinoplasty procedure has been performed, the surgeon may wish to divide the bridge and secure each airway tube separately, rather than have the bridge contact the transcolumellar incision.

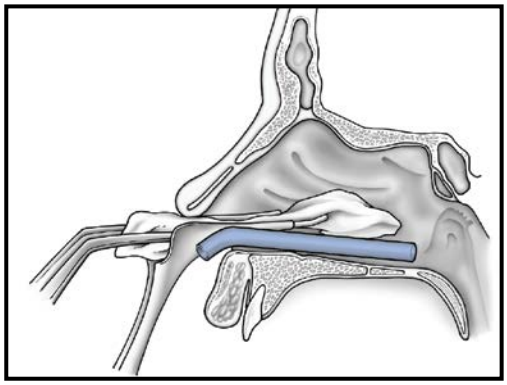
Surgeon Insertion Instructions (continued)

After inserting and seating the airway, pass the **10 Fr plastic suction catheter** through each tube and suction fluid from the pharynx.



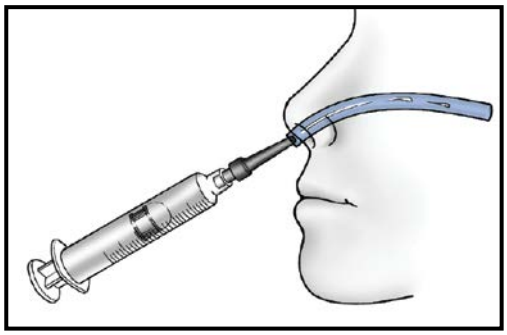
This maneuver also confirms that the back opening of the device is unobstructed. Later, the anesthesia specialist can use the same flexible suction catheter to remove blood and mucus from the throat.

While the packing of choice or gel is placed, the nasal speculum stabilizes the airway tube.



Post-Operative Care

The kit includes a separate envelope labeled **"NOT FOR USE IN O.R."** includes a standard 3cc Luer Lock irrigating syringe and adapter tip. During the post-op period, irrigating the airway tubes will relieve any clogging of mucus or blood. The enclosed **PATIENT HOME CARE INSTRUCTIONS** card should be reviewed by the recovery room nurse with the patient and caregiver of mucus or blood.



The enclosed P**ATIENT HOME CARE INSTRUCTIONS** card should be reviewed by the recovery room nurse with the patient and caregiver.

Office Removal Instructions

Prior to removing the airway, septal splints, and packing if present, instill a topical anesthetic/decongestant mixture into the nasal passages. Shrinking and anesthetizing the mucosa will facilitate a rapid, pain-free and removal and thus satisfactory patient experience. Using a hemostat clamp, grasp the wall of each tube and extract the device.

If the Reltok Ultra-Smooth Septal Splint™ has been employed, remove the airway first for easier access to the splint. Further topically anesthetize and decongest the septum prior to splint release and removal.

Before Surgery

Submit your Prior Authorization Request as usual. • DO NOT include airway insertion or its CPT code.

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!
- Insurers require only the lead diagnosis or diagnoses and identification of the anticipated main or primary surgical procedure.
- Insurers cannot dictate what procedure(s) your surgeon must perform.

Your distributor is underwriting the cost of having a very experienced billing consultant work with you to ensure that your first three billings go smoothly.

When your authorization is received, please contact Todd Petrucciani:

- **Email: todd@anthonyproducts.com**
- **Text: 317-697-3876**

Hours of operation: 8:00 am to 5:00 pm (EST)

We will provide the contact information for one of our independent billing consultants.

After Surgery

Airway Billing Guidance & Support

STEP 1: Complete Insurance Claim Form. Insert "30999-59 FDA- cleared safety device" where form asks for "Additional Claim Information" (i.e. CMS 1500 form Box 19).

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.

Ambulatory Surgery Centers & Hospitals: Bill for reimbursement using HCPCS Code and Revenue code 0379- Anesthesia Supplies

REMEMBER, refer to our Operative Report Instructions that provides appropriate details about the intranasal airway which must be included in the operative report per the CPT code 30999-59 by report requirements.

Payments to Surgeon for Insertion of Nasal Airway Device

Payments reflect variation in policies, including differential payments for contracting and non-contracting practices, deductibles, co-pays, etc. However, no carrier, which has honored the fee, has ever automatically reduced the charge that is in contrast to the surgical procedure(s). Most carriers are honoring this charge. If not, quickly appeal.

Operative Report Instructions for Billing Purposes

Step 1

Add the following information to your Operative Report for the intranasal airway:

Procedure: Insertion and Fixation intranasal airway prosthesis
CPT Code: 30999-59

Step 2

Insert the following information into your operative report to provide the appropriate details about the intranasal airway prosthesis:

Insertion and Fixation of Intranasal AIRWAY Prosthesis

Mission of the Inserted AIRWAY Prosthesis: The mission of said prosthetic device is to provide a secure, safe and practical post-operative AIRWAY to prevent asphyxiation in the operating room and recovery room and render a safer and satisfactory post-operative recovery for the nasal/sinus surgery patient.

This device holds two U.S. patents and is FDA-cleared to serve the anesthesiologist and recovery room staff. This AIRWAY device provides a rapid, safe and direct route to the pharynx—despite both nasal cavities being otherwise completely occluded—for aspiration of secretions as the operation is ending and the patient is emerging from the anesthetic. It allows the anesthesiologist and recovery nurse a route to clear the nasal airway, and thus prevent obstruction, cardiac and respiratory complications, including asphyxiation, without patient cooperation and mitigates their anxiety, claustrophobia, clogged ears and dry throat which detract from their satisfaction of a successful surgery. With the airway painlessly in place, the patient is content and appreciates the surgeon's efforts in providing an optimal post-operative experience.

Technique of Insertion and Testing for Patency

The sterile intranasal airway prosthesis was prepared for insertion. Each of the dual tube soft-silicone nasal airway prosthesis was lubricated and inserted onto the nasal cavity under direct inspection. After the entire device was within the nasal cavity, using the narrow nasal speculum and bayonet forceps, each member of the dual-airway prosthesis was manipulated into its nesting place onto the floor of each nasal passage. It was seen to be properly positioned and fixed on the nasal floor, between the premaxillary nasal crest portion of the inferior bony septum and the inferior turbinate. The stability and immobility were confirmed using the forceps. The device's external bridge sat properly over the face of the columella to prevent retro-displacement of the prosthesis.

Bilateral airway patency was then confirmed by irrigation with sterile saline solution. In anticipation of the anesthesiologist's forthcoming suction-aspiration of the naso- and oro-pharynges, to confirm airway patency, a standard, sterile 10 Fr. suction catheter was passed through each of airway tubes. The stagnant and obstructing blood and mucus were thus evacuated from the pharynges.

At the very conclusion of the procedure, before extubation and emergence, the anesthesiologist accessed the pharynx, via this now-fixed, indwelling bilateral nasal airway, to aspirate any potentially airway-obstructing secretions/fluids.

Recovery Room Mission of the AIRWAY Prosthesis

The rationale for placement and utilization of the airway prosthesis is that as the patient emerges from anesthesia, with such access to the pharynx by the anesthesiologist assured, there is less chance of aspiration, airway obstruction and potentially onerous complications, including asphyxiation, particularly in the recovery room where the patient is under the residual effect of the anesthesia, and the pharynx is yet topically anesthetized. Hence the protective reflexes that would otherwise protect the trachea and lungs are absent, an inherently risky situation should secretions not be removed.

Research

JAMA Facial Plastic Surgery | Original Investigation

Evaluation of Safety and Efficacy for an Intranasal Airway Device in Nasal Surgery

Prem B. Tripathi, MD, MPH; Pejman Majd, BS; Tuan Ngo, BS; Jefferey T. Gu, BS; Giriraj K. Sharma, MD; Christopher Badger, BS; Naveen D. Bhandarkar, MD; Brian J. F. Wong, MD, PhD

IMPORTANCE Postoperative packing in nasal surgery often results in nasal obstruction and discomfort. Commercially available silicone intranasal airways (IAs) serve as dual-nasal airway tubes aimed at alleviating this process, but the safety and efficacy of these devices are unknown.

OBJECTIVE To evaluate the safety and efficacy of an intraoperatively placed IA device in rhinoplasty and nasal surgery.

DESIGN, SETTING, AND PARTICIPANTS In this retrospective record review, the medical records of patients undergoing nasal surgery with insertion of the IA at a single institution from 2012 to 2017 were reviewed. After review of over 200 patients, a questionnaire was developed to assess device efficacy.

EXPOSURES Use of the IA device. The IA is 12 cm long, anchored across the columella, extends distally along the nasal floor, and has a proximal external portion used for cleaning and maintaining patency. Placed intraoperatively, the device aims to support air flow postoperatively in the face of edema, hemorrhage, and packing.

RESULTS A total of 302 operations in 300 patients were analyzed, including primary and revision septorhinoplasty. A total of 24 (7.9%) patients self-removed or inadvertently dislodged the IA. Minor acute postoperative complications not unique to airway insertion included cellulitis in 4 (1.3%) participants and epistaxis in 6 (2%). Postoperatively, 1 (0.3%) patient developed dehiscence along transcolumellar incisions. A total of 59 patients (100% compliance) completed the efficacy questionnaire. The mean breathing score was between good and average (2.9 of 5), comfort scores between comfortable and average (2.9 of 5), and mean ease of irrigation score was between very easy and easy (1.96 of 5). The device was irrigated on average 3.57 times per day. A total of 43 (76%) particpiants had full patency or only partial obstruction, compared with 13 (24%) patients with total obstruction. In all patients, with or without obstruction, the effect lasted an average of 4 days.

CONCLUSIONS AND RELEVANCE The device is safe and well-tolerated for maintaining patency of the nasal airway in patients undergoing rhinoplasty and nasal reconstruction without increased risk of incisional dehiscence.

LEVEL OF EVIDENCE 4.

Supplemental content

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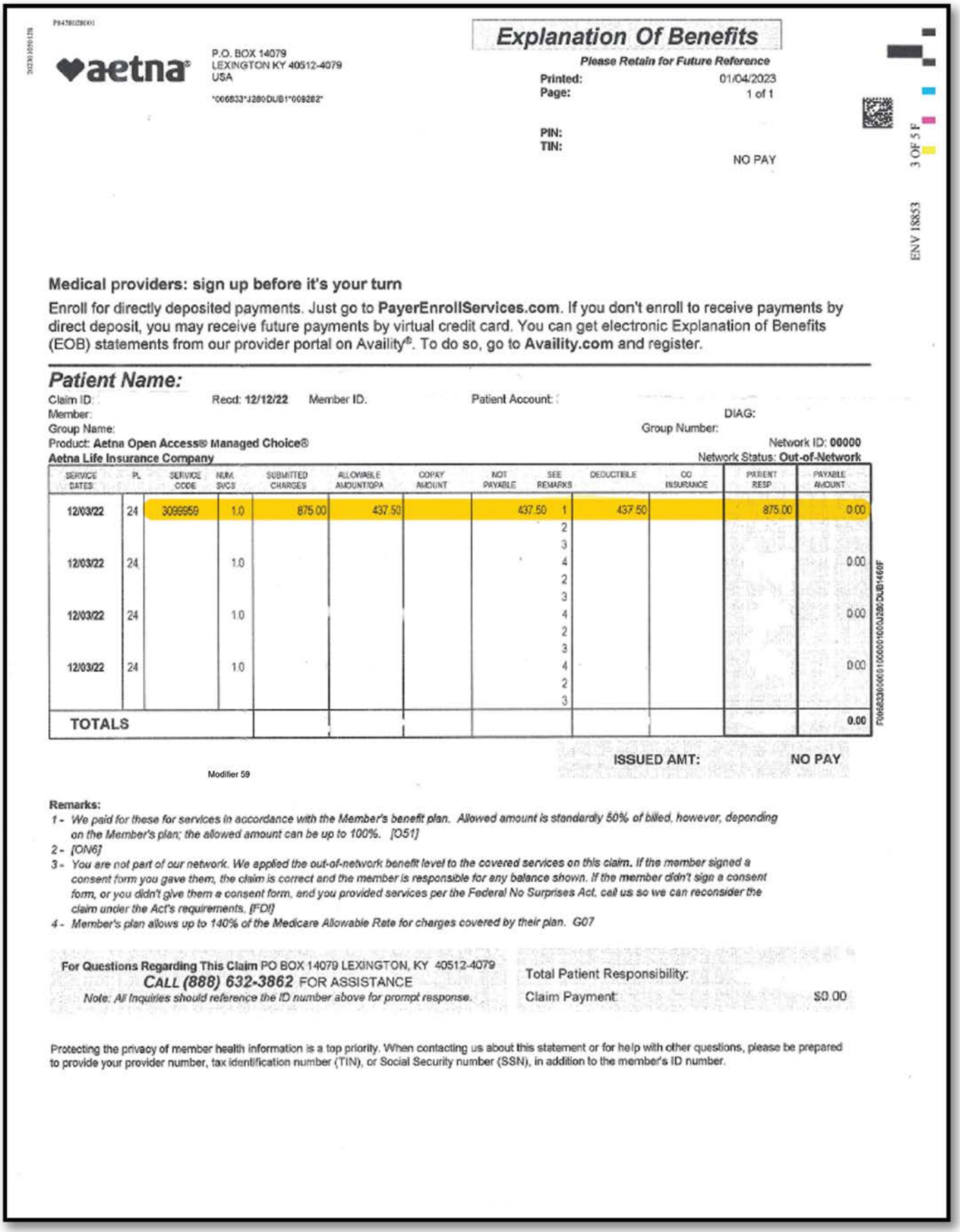

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3 OF 5 F

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Recd: **12/12/22** Member ID.

Patient Account:

DIAG:
Group Number:
Network ID: **00000**
Network Status: **Out-of-Network**

SERVICE DATES	PL	SERVICE CODE	NUM. SVCS	SUBMITTED CHARGES	ALLOWABLE AMOUNT/OPA	COPAY AMOUNT	NOT PAYABLE	SEE REMARKS	DEDUCTIBLE	CO INSURANCE	PATIENT RESP	PAYABLE AMOUNT
12/03/22	24	3099959	1.0	875.00	437.50		437.50	1	437.50		875.00	0.00
								2				
								3				
12/03/22	24		1.0					4				0.00
								2				
								3				
12/03/22	24		1.0					4				0.00
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12/03/22	24		1.0					4				0.00
								2				
								3				
TOTALS												**0.00**

P006833600001000001600J280DUB1460F

Modifier 59

ISSUED AMT: **NO PAY**

Remarks:

1 - *We paid for these for services in accordance with the Member's benefit plan. Allowed amount is standardly 50% of billed, however, depending on the Member's plan; the allowed amount can be up to 100%. [O51]*
2 - *[ON6]*
3 - *You are not part of our network. We applied the out-of-network benefit level to the covered services on this claim. If the member signed a consent form you gave them, the claim is correct and the member is responsible for any balance shown. If the member didn't sign a consent form, or you didn't give them a consent form, and you provided services per the Federal No Surprises Act, call us so we can reconsider the claim under the Act's requirements. [FD!]*
4 - *Member's plan allows up to 140% of the Medicare Allowable Rate for charges covered by their plan. G07*

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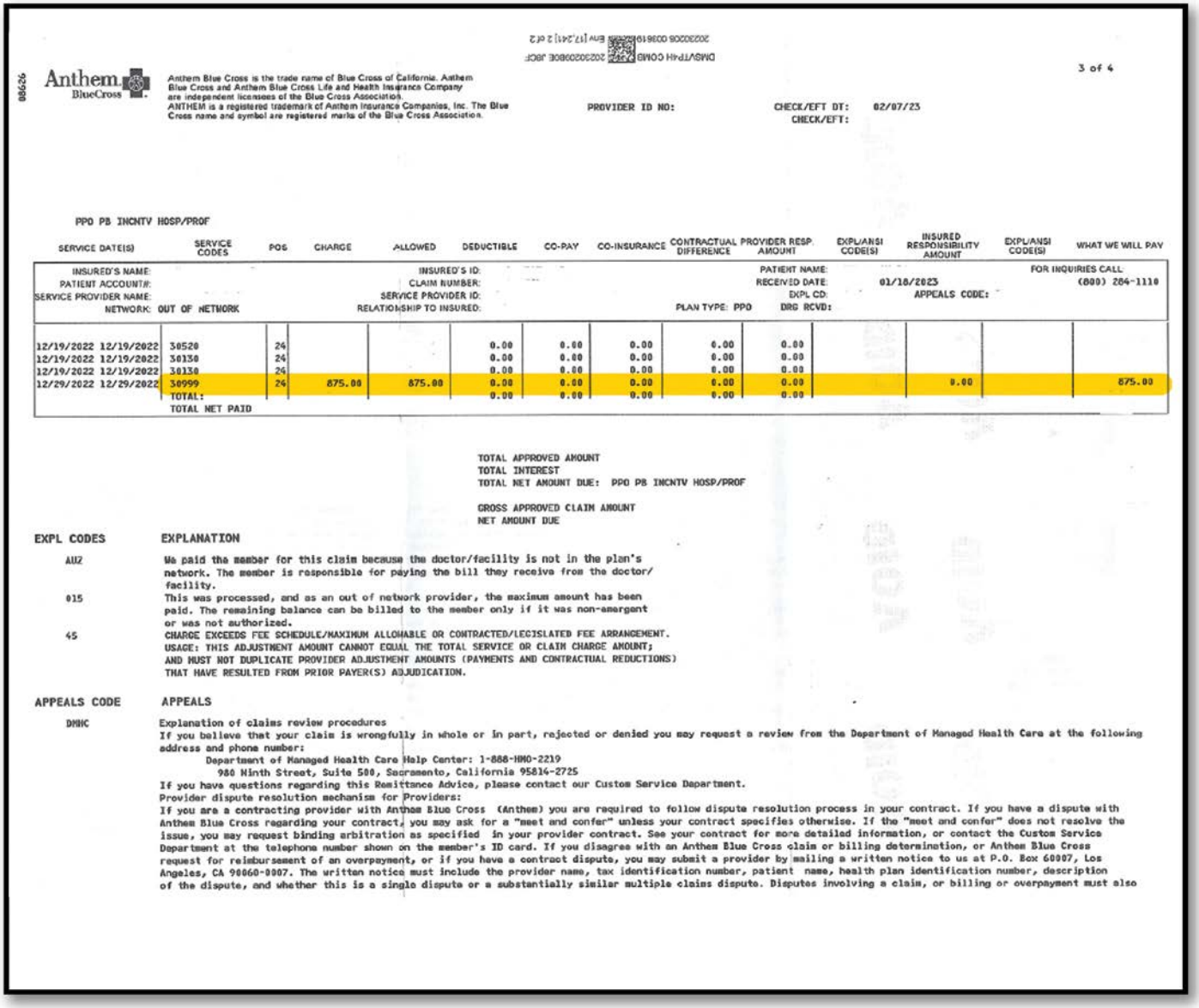
Note: All inquiries should reference the ID number above for prompt response.

Total Patient Responsibility:
Claim Payment: $0.00

Protecting the privacy of member health information is a top priority. When contacting us about this statement or for help with other questions, please be prepared to provide your provider number, tax identification number (TIN), or Social Security number (SSN), in addition to the member's ID number.



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PPO PB INCNTV HOSP/PROF

SERVICE DATE(S)	SERVICE CODES	POS	CHARGE	ALLOWED	DEDUCTIBLE	CO-PAY	CO-INSURANCE	CONTRACTUAL DIFFERENCE	PROVIDER RESP. AMOUNT	EXPL/ANSI CODE(S)	INSURED RESPONSIBILITY AMOUNT	EXPL/ANSI CODE(S)	WHAT WE WILL PAY
INSURED'S NAME:				INSURED'S ID:					PATIENT NAME:				FOR INQUIRIES CALL
PATIENT ACCOUNT#:				CLAIM NUMBER:					RECEIVED DATE:		01/18/2023		(800) 284-1110
SERVICE PROVIDER NAME:				SERVICE PROVIDER ID:					EXPL CD:		APPEALS CODE:		
NETWORK: OUT OF NETWORK				RELATIONSHIP TO INSURED:				PLAN TYPE: PPO	DRG RCVD:				
12/19/2022 12/19/2022	36520	24			0.00	0.00	0.00	0.00	0.00				
12/19/2022 12/19/2022	36130	24			0.00	0.00	0.00	0.00	0.00				
12/19/2022 12/19/2022	36130	24			0.00	0.00	0.00	0.00	0.00				
12/29/2022 12/29/2022	36999	24	875.00	875.00	0.00	0.00	0.00	0.00	0.00		0.00		875.00
	TOTAL:				0.00	0.00	0.00	0.00	0.00				
	TOTAL NET PAID												

TOTAL APPROVED AMOUNT
TOTAL INTEREST
TOTAL NET AMOUNT DUE: PPO PB INCNTV HOSP/PROF

GROSS APPROVED CLAIM AMOUNT
NET AMOUNT DUE

EXPL CODES	EXPLANATION
AU2	We paid the member for this claim because the doctor/facility is not in the plan's network. The member is responsible for paying the bill they receive from the doctor/facility.
015	This was processed, and as an out of network provider, the maximum amount has been paid. The remaining balance can be billed to the member only if it was non-emergent or was not authorized.
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APPEALS CODE	APPEALS
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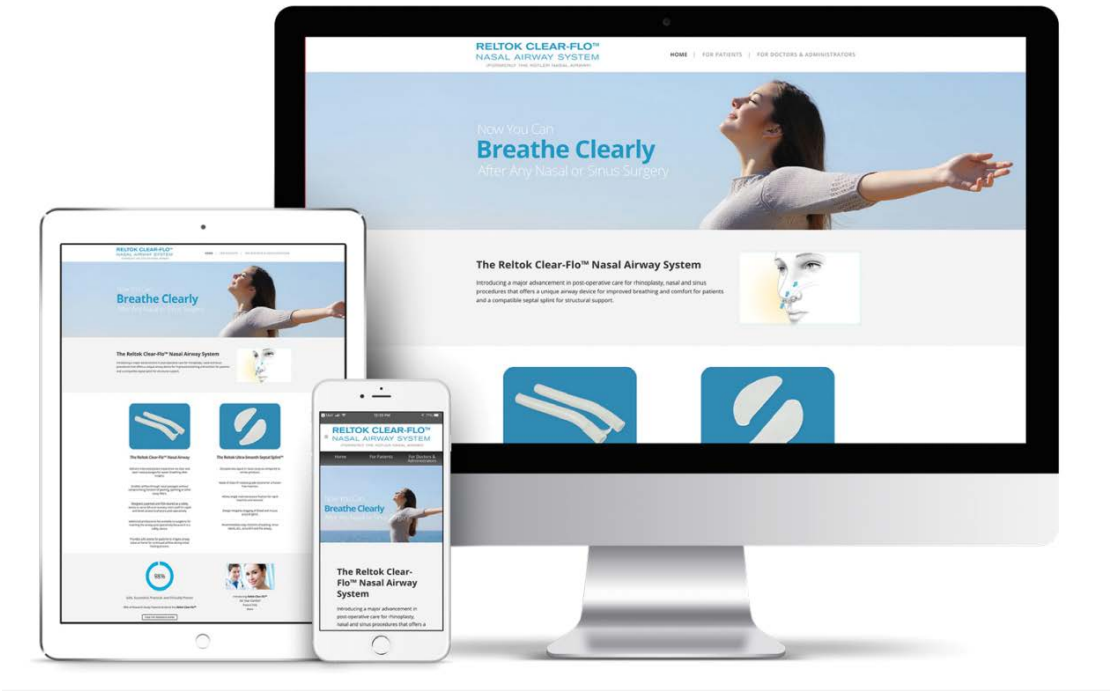

www.Reltok.com

Starting with the Home Page, you can view the contents of the site appropriate for patients.

To enter and view the passcode-controlled MD/Administrator section for first time use the following login:

Username: reltok
Password: Airway

Feel free to create your log-in as instructed.

A 3:56 minute video covers everything.

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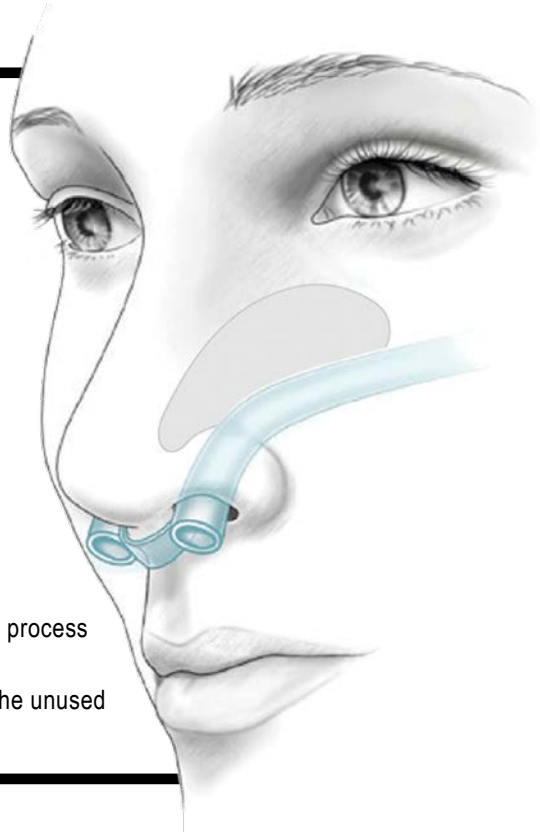
INFORMATION GUIDE



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