Special Report for 30999-59 - by report Procedure

Insertion and Fixation of Intranasal Airway

Explanation of New, Patented, FDA-Cleared Anesthesia Safety Device

Mission of the inserted airway: The mission of said 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** by the **FDA Division of Anesthesiology**.

It is placed by the surgeon, uniquely skilled to perform such insertion without damaging the surgical reconstruction performed. It serves the anesthesiologist and recovery room staff. This 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

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 evacuated.