

# Napas Airway Management Device



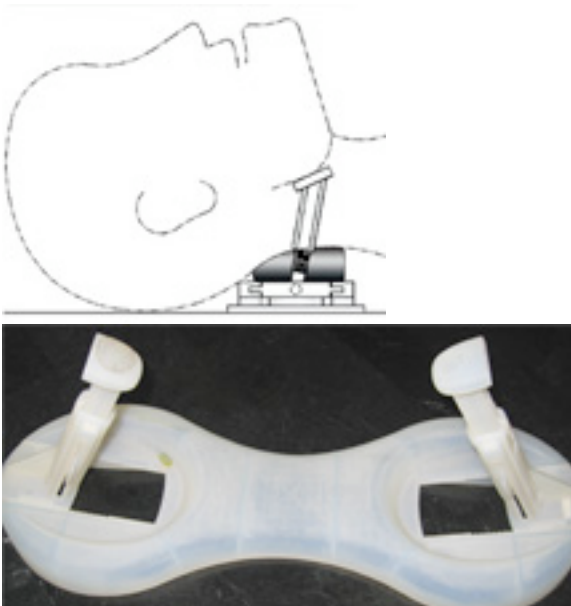
## I Product Opportunity Summary

This prospectus will introduce the Napas Airway Management Device, a newly patented technology available for licensing. This breakthrough airway management device keeps the airway open during short procedures or transportation, when the patient is anesthetized or otherwise unconscious. When using the Napas, the airways remain open simply by adjusting and holding the position of the patient's head and jaw with the device. This allows the anesthesiologist, EMT, or other caregiver to attend to other responsibilities while maintaining the patency of patients' airways

As shown above, essentially, the device is a molded plastic platform with a raised padded area (not shown) that is placed beneath the patient's head and neck. On each side of the neck pad, two adjustable posts can be raised and lowered, and then secured, to hold the jaw in the appropriate position when the patient's head/neck is lying against the pad. As shown, there is also a securing mechanism for side-to-side (possibly at a slight angle) movement of the posts. The platforms are padded for improved patient comfort. Once adjusted for the patient, this breakthrough results in a "jaw thrust" to keep the patient in the sniffing position and the airway open with little to no effort on the part of the caregiver.

In use, the Napas is placed beneath the patient's head/neck on an operating table or other flat surface. Each post can be adjusted horizontally, as well as vertically, so they are spaced apart the proper distance to accommodate the patient's head. The top of the posts

are then adjusted to contact the mandibular angle of the jaw. This maintains a jaw thrust that keeps the airways open. While the angle of the posts relative to the base will vary depending on the particular patient, the typical angle of the posts will be from about 70 to 75 degrees. The posts may be adjusted during the procedure to accommodate any movement of the jaw due to varying depths of anesthesia experienced by the patient. The device may be used for other patients by replacing the pad and padded heads with clean and/or new ones. The whole device can also be covered by plastic sheeting during use to eliminate the need of changing pads between patients. However, disposables padded covers would provide an increased revenue stream. The design can also feature a horizontally adjustable neck pad, however, this would add to the complexity of the mold, and subsequently the production cost



The target market for purchasing the Napas is comprised of hospitals, surgicenters, individual physicians and anesthesiologists, and emergency response organizations such as ambulance companies. There are 5,794 American Hospital Association registered hospitals in the U.S., according to the association. There are also 2,402 freestanding outpatient surgical and medical centers. According to the Bureau of Labor Statistics (BLS), there are 30,618 anesthesiologists in the U.S. According to the U.S. Census Bureau's latest statistics, there are 3,275 ambulance services. The BLS reports that emergency medical technicians (EMTs) and paramedics held about 179,000 jobs in 2002.

According to the American Society of Anesthesiology (ASA), 40 million anesthetics are administered each year in this country. In addition to operating room use, other potential application for the device include for patients in the recovery room after surgery, patients in MRI units, sleep research centers, or being transported in ambulances (used by EMTs). There is an estimated target market of 95,000 of these settings.

The primary distribution channels for the Napas are the 8,721 surgical, medical, and hospital supply wholesalers in the U.S. (Census Bureau) and direct distribution to group purchasing organizations. The Napas may also be distributed to end-users through catalogs, the Internet, and direct marketing, as well as through stores that sell equipment and supplies to fire, police, and EMS departments. A government contract for the military market may also be pursued.

With a low manufacturing cost, the margins are good for both the manufacturer and retailer. The manufacturer of this product could easily attain gross margin earnings of 86 percent or more. Financial projections are contained in Section V. The Napas is expected to wholesale for \$122.50.

Millennium Marketing Group, Ltd. has been retained by the patent owner to secure a licensing or sales agreement in order to bring the unique features, quality, effectiveness, and value of this technology to the marketplace. The first firm to bring this exciting design to the market will capitalize with a favorable return on investment and enjoy the commercial benefits well into the future. Currently, we are seeking a partner that can fully and profitably exploit this rare and lucrative licensing opportunity.

## II Competitive Landscape

### Competitive Advantages / Breakthrough Opportunity

During surgery, keeping the respiratory passageway open so patients breathe well is critical. This is especially important in procedures where anesthesia is used as anesthesia causes the muscles to relax, which, in most cases, causes airway obstruction. When patients are deeply sedated, their tongues become relaxed and fall back, obstructing the airway. If this is the case, anesthesiologists and other care givers respond with a jaw thrust. With a jaw thrust, the lower jaw is manually lifted so the tongue is off the airway. The patient is then put into the "sniffing position," which extends the neck. However, the patient's head must be held in this position throughout the procedure. Thus, the anesthesiologist or other staff will be unable to perform other tasks that may be needed during the procedure. Further, during long operations, the anesthesiologist may become fatigued from having to hold the patient's head in a particular position for an extended period of time. Although endotracheal tubes usually overcome this problem because they keep the tongue from blocking the airway, endotracheal tubes can cause irritation of the throat and/or vocal cords that may lead to additional problems. However, the tubes are not typically used in shorter procedures. For procedures that last an hour or less, an oral or nasal airway is often used, but these devices are not without complications.

Oral airway devices can cause dental damage or, in rare instances, long lasting tongue numbness. Even with these devices, sometimes there is airway obstruction. Nasal airway devices may cause a nosebleed, could break off cartilage that itself could obstruct the airway, and can lead to a sensation of a stuffy nose that lasts for several days.

The inexpensive and easy to use Napas (which means "air" in Persian) provides an adjustable device that ensures that the patient's airways remain open during surgical

procedures. The design includes dual padded posts can be properly positioned aligned with the patient's jaw to open and maintain patency of the airway. The easily adjusted nature of the Napas is key as a patient will often experience varying depths of anesthesia, more jaw thrust will be required as the patient goes into deeper depths of anesthesia.

#### Product Features and Benefits

- Noninvasive - externally applied
- Reusable
- Ensures that a person's airway remains open during anesthesia or unconsciousness
- Properly contact the patient's jaw
- May be adjusted to compensate for different depths of anesthesia
- Fully adjustable design to allow it to be used with all patients
- Will not cause tongue numbness or dental damage
- Reusable – no need for sterilization
- Allows the anesthesiologist to attend to other responsibilities
- Improved patient outcomes

#### Comparable Established Products

Research indicates that the Napas will be the jaw thrust device for use in airway management available on the market. Unlike oropharyngeal airways, the Napas is noninvasive, reusable, and, unlike this type of device, will not cause tongue numbness or dental damage. Further, in contrast to nasopharyngeal airways, the Napas will not cause nosebleeds, nasal stuffiness, or infection. Also, unlike LMAs, the Napas is noninvasive, requires no resterilization, and is a lot less expensive.

#### Referenced Patented Products

The United States Patent and Trademark Office referenced the following patents when issuing the patent for the NAPAS:

- U.S. Patent No. 4,220,147, issued to Allen, III, September 1980
- U.S. Patent No. 4,266,759, issued to Liebman, May 1981
- U.S. Patent No. 4,565,408, issued to Palley, January 1986
- U.S. Patent No. 4,643,174, issued to Horiuchi, February 1987
- U.S. Patent No. 5,297,540, issued to Kaiser et al., March 1994
- U.S. Patent No. 5,487,395, issued to Strowe, January 1996
- U.S. Patent No. 5,682,632, issued to Cotroneo, November 1997
- U.S. Patent No. 6,000,401, issued to Herrick, December 1999
- U.S. Patent No. 6,171,314, issued to Rotramel, January 2001
- U.S. Patent No. 6,899,690, issued to Saunders et al., May 2005

None of the above referenced patented products offer all the features and benefits of the Napas.

### III Industry & Market Analysis

#### Industry Size and Trends

According to market research firm Medtech Insight, "In the U.S. more than \$1.3 billion was spent on ventilators, oxygen therapy systems, and airway management accessories in 2004. Growing at a healthy compound annual rate of 6.3 percent, sales of these products are expected to reach more than \$1.9 billion by the year 2010" (October 2005).

Overall, Frost & Sullivan reports, revenues in the U.S. anesthesia and respiratory device market totaled \$427.9 million in 2004 and are expected to reach \$630.8 million in 2011 (Frost & Sullivan press release September 2005). Frost & Sullivan industry manager Amit Bohora says, "The increasing competition and growing price sensitivity is compelling manufacturers to turn to innovation as means to maintain brand loyalty." Frost & Sullivan sees "a steady increase in the elderly patient population and the trend toward more outpatient surgeries is raising the demand for various anesthesia and respiratory products. The surge in emergency medical services and freestanding surgery centers is also expected to prop up market growth" ("U.S. Anesthesia and Respiratory Products Markets," January 2003).

#### Target Market Analysis

The target market for the Napas is comprised of hospitals, surgicenters, individual physicians and anesthesiologists, and emergency response organizations such as ambulance companies. There are 5,794 American Hospital Association registered hospitals in the U.S., according to the association. There are also 2,402 freestanding outpatient surgical and medical centers. According to the Bureau of Labor Statistics, there are 30,618 anesthesiologists in the U.S. According to the American Society of Anesthesiology, an estimated 40 million anesthetics are administered each year in this country.

According to the U.S. Census Bureau's latest statistics, there are 3,275 ambulance services and 210 air ambulance services. The U.S. Department of Labor's Bureau of Labor Statistics (BLS) reports that emergency medical technicians (EMTs) and paramedics held about 179,000 jobs in 2002. About four out of 10 worked as employees of private ambulance services. Three out of 10 worked in local government for fire departments, public ambulance services and EMS. Another two out of 10 were found in hospitals, working full time within the medical facility or responding to calls in ambulances or helicopters to transport critically ill or injured patients.

Research from a variety of sources indicate that there are approximately 35,000 to 45,000 operating rooms (ORs), excluding the roughly 5,000 ORs in outpatient surgical centers in the U.S. The average number of operating rooms per hospital is six, according to a recent Gallup survey. There are approximately 40,000 ambulances currently operating in the United States and about 10,000 magnetic resonance imaging scanners.

#### Distribution Channels

The Napas will primarily be distributed to institutional markets via the 8,721 surgical, medical, and hospital supply wholesalers in the U.S. (Census Bureau) and direct distribution to group purchasing organizations.

#### IV Product Analysis

##### Product Specifications

The Napas has a base with a padded headrest and a pair of spaced apart, padded posts that can be adjusted vertically, horizontally, and angularly, and secured in position. The components may be made from just about any material, but a primarily plastic molded product is preferred. Other materials include pad and cloth-like materials for areas of the headrest and post tops to provide comfortable contact points against the jaw and head/neck of the patient. These pads can be disposable or reusable. As mentioned previously, the device, including the pads, can be covered in a plastic sheeting or fabric that is replaced for each patient.

The Napas base is sized to be comfortably placed underneath the patient's neck and head. The base may be of any of a variety of shapes and sizes. A pad is placed on top of the horizontal bar to provide a comfortable, safe surface for the head to rest on. The cloth covered pad is attached to the bar with a strip of hook and loop type fasteners to allow for the pad to be replaced for subsequent procedures. So that they properly and effectively contact the jaw, the posts are attached to the base or horizontal bar so that the posts are slightly angled.

##### Estimated Manufacturing Cost

Using estimated material cost for the foregoing items and a small burden charge, the estimated manufacturing cost would approximate \$17.50 per unit.

##### Expected Pricing

Assuming a 7.0 markup from manufacturing cost, which is estimated at \$17.50 per unit and is detailed in the previous section, the projected wholesale price would be \$122.50 to \$150.00.

##### Patent Value Enhancement

A working prototype of the Napas is available to demonstrate the design and functionality of the product. Dr. Taimoorazy has used the device "for nearly a year on patients in deep sedation for surgeries that last less than an hour and for claustrophobic patients who need to be sedated before going in MRI machines. Of 60 patients at BroMenn Regional Medical Center and at The UroHealth Institute, both in Normal, the only side effect was in one patient who had some mild transient jaw discomfort afterward (Pantagraph, November 1, 2006).