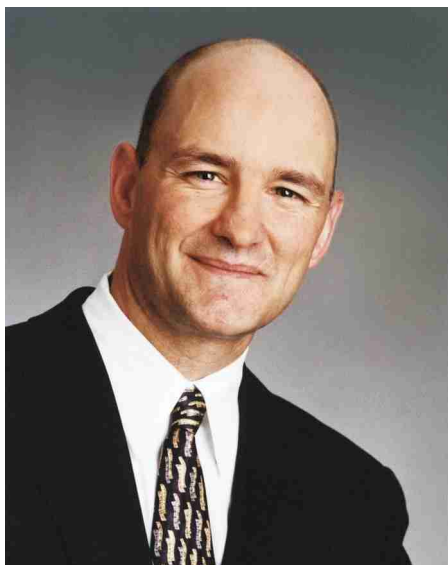


### Having completed Human Proof of Concept for their Tools and Procedures that Allow Tympanostomy Procedures (Ear Tube Surgery) to be Performed Outside the Operating Room, Preceptis Medical, Inc. is offering hope to Children with Eustachian Tube Dysfunction

#### Healthcare Medical Devices

**Preceptis Medical, Inc.**  
505 North Highway 169, Suite 560  
Plymouth, MN 55441  
763-568-7809  
[www.preceptismedical.com](http://www.preceptismedical.com)



**Steve Anderson**  
CEO

#### BIO:

Steve Anderson is the CEO of Preceptis Medical, Inc, a medical device ENT start-up developing tools and procedures, which allow pediatric tympanostomy surgery to be performed without the risk of general anesthesia or the costs associated with an OR. Prior to this position, he was the President of Acorn Cardiovascular, Inc., a medical device manufacturer developing life-sustaining therapies for the treatment of systolic heart

failure. Mr. Anderson has 30 years of experience in the medical device industry, starting with Medtronic and including senior management positions at St. Jude Medical, TÜV Product Service, St. Croix Medical, and Acorn Cardiovascular. His specific core competencies include development, regulatory, clinical, reimbursement, quality, and compliance.

Mr. Anderson has a BS in Materials Engineering and an MS in Biomedical Engineering from the University of Minnesota. He was an Adjunct Professor at the University of St. Thomas Graduate School, has served on multiple boards for medical device companies (both public and private), and has authored numerous publications on medical device regulation and reimbursement (both US and world-wide).

#### About Preceptis Medical, Inc.:

Preceptis Medical, Inc. is a medical device manufacturer developing tools and procedures to allow tympanostomy procedures (ear tube surgery) to be performed outside of the operating room, thereby eliminating the risk of general anesthesia and significantly reducing costs to the healthcare system. The Preceptis solution improves outcomes for all stakeholders, including patients, parents, providers, and payers. As such, Preceptis Medical is being viewed as an enabling technology for healthcare reform.

The company was incorporated in 2011, and is based in Plymouth, Minnesota.

#### Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine

**CEOCFO:** Mr. Anderson, what is the basic idea behind Preceptis Medical?

**Mr. Anderson:** Preceptis Medical is a startup device company. We are in the clinical stage, and we are developing tools which will allow tympanostomy procedures (in layman's terms that would be ear tube procedures) that are performed on children to be conducted out of the OR, without the risk of general anesthetic.

**CEOCFO:** About how many procedures are conducted? How common a problem is this?

**Mr. Anderson:** This is an interesting market in that it cannot be measured in common incidence and prevalence because of the fact that children with Eustachian tube dysfunction will generally outgrow it over time. We know from claims data that there are approximately 1.5 million ear tube procedures done annually in the United States.

**CEOCFO:** Is it becoming more common, less common? Is it the sort of standard of care, what are the alternatives and why are people still doing it?

**Mr. Anderson:** People are still doing ear tube procedures because they have not figured out a way to successfully treat Eustachian tube dysfunction. When we talk about ear infections, this typically means that the Eustachian tube in children is not draining normally. When it does not drain normally, you get an abscess in the middle ear. An irrigation tube is

essentially an alternative to the Eustachian tube blockage, allowing equalization of the pressure in the middle ear and, at the same time, allowing irrigation and drainage of the abscess.

**CEOCFO:** What have you figured out at Preceptis Medical that people have not known before to allow you to do the procedures outside of the ER?

**Mr. Anderson:** There are a number of reasons doing these in the OR is a bad thing. Number one, first and foremost, is the risk of general anesthesia for children. The risk from general anesthesia in children is actually greater than the risk of the tympanostomy surgery. That is an unacceptable benefit-risk analysis. Over the last few years, there has been a plethora of information, including publications by the FDA, by the Mayo Clinic, and a recent 10-year study that came out in September 2012, linking the use of general anesthesia in children to long-term neurocognitive deficit. We have a significant health, and we need to do everything we can to avoid using general anesthesia in children unless absolutely necessary. Second, because of the fact that they are doing tympanostomy procedures under general anesthesia, they are always doing them in an operating room. That is a major cost factor, which is incongruent with the changes needed today for healthcare reform and, specifically, the goals of Accountable Care Organizations. The beauty of the Preceptis approach is that all stakeholders benefit. Besides the cost reduction to the healthcare system, children have significant improvements in safety through the elimination of general anesthesia. You also significantly improve parent logistics because you do not have to do procedures in the OR. You can schedule these surgeries in procedure units and, eventually, in offices, which are much simpler and logistically easier. Kids can wear their own pajamas; mom and dad can be present holding their hand; and that makes things easier for both the parents and for the providers. Again, for your payers, you are reducing costs by not using an

operating for a non-sterile surgical procedure. The savings to the payers by eventually moving these procedures to the office will be greater than 60%. Because of the trauma involved with a tympanostomy in children, the medical community has been using general anesthesia and operating rooms. Preceptis has developed tools that significantly decrease the time and the trauma involved in the surgery. Instead of a standard surgical tray that could require 4-6 passes into the ear canal, and take 1-3 minutes/ear for an experienced ENT surgeon or 5-15 minutes/ear for an ENT surgical resident, the Preceptis tool enables ENT surgeons to do these procedures in one pass in less than 10 seconds/ear. Because of the fact that we are significantly reducing trauma, we can also significantly reduce the anesthetic regimen, and,

**"We have developed a surgical instrument that allows the surgeon to do the incision into the eardrum and deploy the irrigation tube in less than 2 seconds. We are reducing the multiple passes into the ear canal and the ear tube manipulation that are done by a standard surgical tray and methodology. The result is significant reduction in trauma for the patient and an increase in efficiency for the ENT surgeon." - Steve Anderson**

because you are reducing the anesthetic regimen, you can get these procedures out of the OR.

**CEOCFO:** How do your tools allow for one pass instead of several?

**Mr. Anderson:** We have developed a surgical instrument that allows the surgeon to do the incision into the eardrum and deploy the irrigation tube in less than 2 seconds. We are reducing the multiple passes into the ear canal and the ear tube manipulation that are done by a standard surgical tray and methodology. The result is significant reduction in trauma for the patient and an increase in efficiency for the ENT surgeon.

**CEOCFO:** Has the portion of the medical community that should be paying attention, doing so?

**Mr. Anderson:** The ENT community is recognizing the changes that are

required to patient care. With the increase in pressure on cost from payers and Accountable Care Organizations, ENT's are already starting to make procedural changes to reduce costs. Secondly, parents of young children are increasingly knowledgeable in the risk of general anesthesia. It is interesting that the parents of children who are having ear tube procedures are typically below thirty years of age. These parents have a remarkable ability to gather information. It is really a characteristic of the younger generation, and they have figured out that they want to avoid general anesthesia and the OR whenever possible. This message is being clearly conveyed to the ENTs. Further, Preceptis and the ENT community are analyzing options for replacing general anesthesia. We believe that there is great potential for the use

of nitrous oxide. Nitrous oxide has been used very, very safely for decades by the dental sector and oral surgeons, and there has also been significant uptake in its attention from the medical community in the last couple of years because of a significant study done by Dr. Judith Zier at Children's Hospital of Minnesota. The study was published in December 2011,

and described a very successful experience of eight thousand cases with pediatric non-sterile surgical procedures in which they used nitrous. When you put all of these factors together, there is innate pressure, and a message that is being heard by the ENT community. Another key impetus for change is the proliferation of Pediatric Procedure Units. There are now over three hundred procedure units in the United States, and they are designed for pediatric, non-sterile surgical procedures. The idea is that these procedures can be performed safely and with less cost than putting the children through an OR procedure. This is win-win for everybody. Preceptis is one of the few projects today in which all of the stakeholders are benefitting significantly.

**CEOCFO:** Where are you in the commercialization process?

**Mr. Anderson:** We broke escrow with our company in December 2011, and in about ten and a half months, and with less than a million dollars in seed capital, we have completed human proof of concept. We are doing an A round in the first quarter of 2013 in which we will gather additional clinical data affirming the benefit and the safety of our device. Upon completion, we will freeze our design in anticipation of a commercial release.

**CEOCFO:** You have been in the industry for a considerable amount of time; what are the lessons you have learned in previous ventures that are most helpful at Preceptis Medical?

**Mr. Anderson:** Over the last decade, I have been increasingly concerned about the venture capital model for medical devices. With increasing FDA time frames, the amount of money that it takes to get a product onto the market, and then the amount of money it takes to become cash-flow positive, the capital required has become unattainable for companies and many

venture capitalists. There is just too much risk, and we have seen that the venture community is becoming increasingly reticent with the medical device sector. We wanted to do something that would provide significant cost savings and benefit for the healthcare community, while at the same time providing improved outcomes for the patients. We describe ourselves as a 'small ball model', with less capital required and less financial risk for all parties. We recognized Preceptis as an opportunity where we could put those principles into play.

**CEOCFO:** What are the next steps? What can we expect in six months or a year?

**Mr. Anderson:** The next step is to close our A round, continue to gather data, get that data into publication, and then we would expect to see a commercial release shortly thereafter.

**CEOCFO:** Why should investors and people in the business community

pick Preceptis Medical out of the crowd to pay attention to today?

**Mr. Anderson:** From an investment standpoint, here is what Preceptis offers:

For funds fund below a hundred million dollars, we have a unique situation in that we have already completed proof of concept in the seed round. At the completion of the A round, with minimal capital needed, we are going to have a commercially available device. The path from an FDA clearance standpoint is extremely simple. Reimbursement coverage, codes and payment are already in place. You have an annual available U.S. market of about \$750 million -- worldwide it is greater than \$1 billion. This is the most common pediatric surgery done in the United States, outside of circumcision. You put all of those things together, and Preceptis is a really unusual and attractive investment opportunity.



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