AventaMed Ltd.  
Office-based, one-shot tympanostomy tube placement

It may seem surprising that one of the most commonly occurring and costly childhood illnesses in the US involves the ear. More than 2.2 million cases of otitis media with effusion (OME) – the inflammation and collection of fluid in the middle ear with hearing loss but without signs or symptoms of ear infection – are diagnosed each year worldwide, with as many as 90% of children having at least one episode by age 10. The procedure leads to an estimated annual health care cost of more than $5 billion, according to the US Department of Health and Human Services’ Agency for Healthcare Research and Quality (AHRQ). The standard of care for this condition – the most common ambulatory surgery performed on children in the US, according to recent studies – is placement of tiny tympanostomy tubes (about the size of a half of a grain of rice) to ventilate the middle ear space. However, tube placement is a complex procedure, involving general anesthesia and costly operating room time. Ireland-based start-up AventaMed Ltd., winner of the 2014 MedTech Innovator competition at Informa’s April IN3 Medical Device 360° Dublin conference, is working to dramatically reduce costs in treating otitis media and to improve the patient experience with a novel device for tympanostomy tube placement that takes less than one second in an office setting.

AventaMed’s technology was developed by its two medical device bioengineer founders, Olive O’Driscoll and John Vaughan, at the Medical Engineering Design and Innovation Centre (MEDIC) within the Cork Institute of Technology. The company was founded last August, and is now in the process of being the first medical device entity to be spun out from the institute. Olive O’Driscoll, the company’s president and CEO, has 14 years of commercial, clinical, R&D, and regulatory experience in the device industry, as well as having served in the academic arena at University College London, working on a radiotherapy device for breast cancer, and as a clinical scientist with the United Kingdom’s National Health Service. She has held key management positions for various multinational and venture capital-backed start-up medical technology company, Crescent Diagnostics Ltd., and has led, designed, and managed international clinical trials involving more than 15,000 patients in 200 countries, including for CryoCath Technologies Inc. (now Medtronic CryoCath LP, part of Medtronic Inc.). She also worked as a field-based research engineer and was a member of a large sales force in the European Union responsible for launching cardiovascular medical devices. O’Driscoll, along with Vaughan, has invented a number of medical devices over nearly four years at the MEDIC center, from concept to commercialization. The two developed the concept for AventaMed’s tympanostomy tube placement device as they were working on another ear, nose, and throat product, and gaining insight into the clinical treatment of ENT conditions by attending tympanostomy surgeries. They noticed that tube placement procedures were very complex and time-consuming, with multiple surgical instruments used and a high learning curve for surgeons, and they decided to develop a simpler, faster solution.

Working with a number of ENT surgeons around the world, and after a number of iterations, O’Driscoll and Vaughan developed a novel, single-use, low-risk ENT device, the V-Tube, which allows specifically designed, small plastic tubes to be placed in a child’s ear safely and quickly in an office setting. The V-Tube is an “all-in-one” disposable device that inserts a pre-loaded tube into the eardrum with a click of a button, in under one second. The V-Tube procedure can be performed by a single ENT surgeon using local anesthetic on the eardrum, without the need for an anesthetist or other surgical staff. The tubes stay in place in the patient’s ear(s) for six to nine months, and then through the growth of the tympanic membrane, the tube is ejected naturally. In a typical hospital-based procedure, surgeons use a series of instruments to make a tiny incision in the tympanic membrane, place a tympanostomy tube in the eardrum, and then push it into place, with the procedure usually performed on both ears, under general anesthesia.

The company has performed cadaver testing on its product with excellent feedback from the surgeons involved regarding
the ergonomics of the handpiece, visibility into the key delivery area of the eardrum, and tube delivery. A lot of IP is built into the cartridge end of the device, which houses a cutting instrument, tube, tube delivery, and retraction mechanism.

The V-Tube, which has been developed and will be manufactured in Ireland, has the potential to save hospitals more than $2,000 per procedure, increasing hospital margins and freeing up valuable OR time for more profitable surgeries, says O’Driscoll. The easy-to-use device is packaged in two sterile containers, which the physician assembles prior to the procedure. According to the company, its technology can save $700,000 per hospital per year, equivalent to $1.5 billion in annual health care savings in the US alone. AventaMed filed its initial patents in 2012, and now has several patents filed to protect its intellectual property, both in the US and internationally.

AventaMed sets its product apart from the competition, which includes ENT companies such as Acclarent Inc./Johnson & Johnson and Preceptis Medical Inc., among others, with its differentiated tube material and unique rapid deployment device. With standard surgery, complications from tube placement can include penetration into the middle ear space during surgery, along with postsurgical infection. AventaMed’s applicator incorporates a backstop element at the tip, so that the device can’t be pushed too far into the ear.

Being chosen by the IN3 Medical Device 360° Dublin conference audience as the winner of the annual MedTech Innovator competition (produced by RCT Ventures), out of more than 30 start-up device presenters, has been a very positive experience for AventaMed, in terms of exposure to potential investors and strategic partners. “We didn’t realize how beneficial it was going to be,” says O’Driscoll. The response from families with children who have had tubes placed or need to have the procedure done has been overwhelmingly positive, as well, she says.

The co-founders have brought in approximately €600,000 (approximately $815,000) in government funding to date, and it has just started a €3 million (approximately $3.5 million) seed funding round. It is in discussions with venture capitalists, seed funders, and potential strategic partners, and expects to close its round later this year. It is keeping all of its options on the table at the moment with regard to investors and partnerships. It also has ideas for other ENT products, but is first focused on bringing its V-Tube to market.

AventaMed’s immediate priorities – and challenges – include proceeding efficiently through clinical trials, fundraising, and finalizing its regulatory plans with European notified bodies and the FDA. The sooner it can get its low-cost, office-based product onto the market and treat as many young patients with otitis media the better, says O’Driscoll.

- Tracy Neilssen

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