AventaMed device for tympanostomy tube placement

TECHNOLOGY

The AventaMed device has been developed by AventaMed Ltd to perform tympanostomy tube surgery in children and adults with otitis media with effusion, Eustachian tube dysfunction and barotrauma.

A tympanostomy tube (also known as a grommet or myringotomy tube) is a small drainage tube inserted into a small incision in the ear drum to relieve pressure, retain aeration and prevent the accumulation of fluid in the middle ear by allowing it to drain.

The AventaMed device is a single use, disposable surgical device that combines the surgical instruments and tympanostomy tube into one, hand-held instrument. The device (pictured above) comes in two parts: (i) a hand piece (with blue activation button) and (ii) a cartridge (grey), which includes a myringotomy knife and a pre-loaded tympanostomy tube at the tip. Each hand piece and cartridge is sterile packaged and the handpiece can be used with two cartridges, for a bilateral procedure.

To carry out the procedure, the device is placed into the patient's ear and the ear drum is pierced using the myringotomy knife. The blue activation button is then pressed to deploy the preloaded tympanostomy tube into the incision. The company claim this takes less than one second with the AventaMed device. The company state the AventaMed device has been designed to allow fast, safe and convenient placement of a tympanostomy tube either in the operating theatre or an outpatient setting, with local (LA) or topical anaesthesia.

The company anticipate a CE mark and UK NHS launch of the AventaMed device (formerly known as the V-tube device) in 2016.
The TULA system by Acclarent Inc. is another tympanostomy tube delivery system that is currently in development for the placement of tympanostomy tubes in children with otitis media. The system is used to make an incision in the tympanic membrane and insert a pre-loaded tympanostomy tube, in a single automated motion, under LA in an outpatient setting. The TULA system is FDA approved.

**POTENTIAL FOR IMPACT**

Currently, tympanostomy tube placement surgery is usually carried out in a surgical theatre under general anaesthesia (GA). This involves making an incision in the tympanic membrane to insert a tympanostomy tube, which can approximate to a 30 minute procedure per patient.

According to the company, the AventaMed device allows for safer, simpler and faster tympanostomy tube placement surgery. Deployment of the pre-loaded tympanostomy tube takes less than one second and eliminates the need for multiple surgical instruments, thereby reducing the total procedure time. The speed of insertion and the devices safety features makes it possible to treat patients without GA in an outpatient setting. The company claim, the simplicity and speed of tympanostomy tube deployment are key innovative features of the AventaMed device, along with its use outside of the operating theatre.

According to the company, benefits for patients of the AventaMed device include improved safety through the use of LA as opposed to GA. Patients may also experience less pain due to the small incision made by the device and a quicker recovery time when employed with LA. The reduced total procedure time and its application in an outpatient setting may also allow patients to be treated earlier, potentially reducing waiting times.

The company state that usability testing by ENT surgeons in the UK showed the AventaMed device to be intuitive to use and easy to assemble, requiring little training (up to five minutes). The company claim that application of the procedure in an outpatient setting may contribute towards health care resource savings, reduced costs for healthcare providers and more convenience for patients. The AventaMed device may also reduce hospital length of stay and complication rates associated with the use of GA. If clinical and cost effectiveness can be demonstrated, the AventaMed device may offer an additional therapeutic option for patients requiring tympanostomy tube placement.

This technology is predicted to have an impact on the following domains of the NHS Outcomes Framework:

- **Domain 2** Enhancing quality of life for people with long-term conditions
- **Domain 4** Ensuring that people have a positive experience of care

For more information on the NHS Outcomes Framework, please go to [www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk](http://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk)

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**

O'Driscoll O, Vaughan J, Narula A *et al.* An all-in-one tympanostomy tube and insertion device; results of usability testing. 12th International Congress of the European Society of Paediatric Otorhinolaryngology (ESPO) 2014.
ONGOING STUDIES

The company report further clinical trials of the AventaMed device are ongoing.

INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.