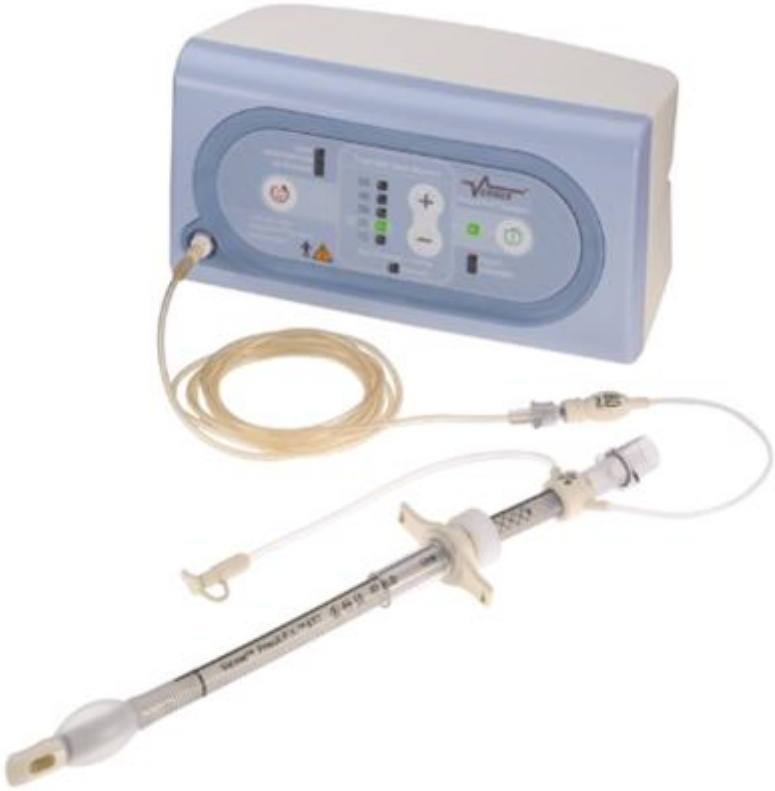
NHS Innovation Accelerator

Implementation Toolkit

PneuX Prevention System



UCLPartners Academic Health Science Partnership

The AHSN Network

NHS England

Introduction

NHS England's Innovation and Technology Tariff (ITT) went live on 1 April 2017. This new Tariff was introduced to incentivise the adoption and spread of transformational innovation in the NHS. The first two-year ITT runs from 2017 to 2019, with six themed product types identified as being suitable for at-scale introduction in the NHS and likely to result in great benefits for patients.

Four innovations on the NHS Innovation Accelerator (NIA) - an NHS England initiative supported by England's 15 Academic Health Science Networks (AHSNs) - meet the required theme specifications of the ITT.

These are: myCOPD, the Non-Injectable Arterial Connector (NIC), PneuX Prevention System, and Episcissors-60. Under the ITT, the first three innovations are funded under a zero cost model. Providers order the innovations directly from the supplier at no cost and NHS England reimburses the supplier directly. Episcissors-60 can be ordered via NHS Supply Chain, with providers reimbursed based on use.

In parallel, but separately from the ITT, NHS England is centrally funding the purchase of mobile ECG technology. A further NIA innovation, AliveCor's Kardia, meets the stringent specification of this technology, which will be available and managed via the AHSN Network.

The NIA has produced Implementation Toolkits for Episcissors-60, myCOPD, the Non-Injectable Arterial Connector (NIC), PneuX Prevention System, and AliveCor's Kardia. These toolkits detail how the innovations provide solutions to key challenges within our healthcare system; impact and outcomes, including cost savings, patient benefit and organisational advantage; an evidence summary and supporting testimonials; plus an overview of how to procure each innovation, including payment/price detail.

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Introducing the NHS Innovation Accelerator (NIA)

The NHS Innovation Accelerator (NIA) is an NHS England Initiative delivered in partnership with the Country's 15 Academic Health Science Networks (AHSNs), hosted by UCLPartners. It supports delivery of the *Five Year Forward View* by accelerating uptake of high impact innovations for patient, population and NHS staff benefit, and providing real time practical insights on spread to inform national strategy.

Fellows supported by the NIA all share a set of values and passion for scaling evidence-based innovation to benefit a wider population, with a commitment to share their learnings. Some impressive results have been achieved by the NIA 25 Fellows in their first 20 months since July 2015, with 469 additional NHS commissioners and providers now using NIA innovations; £28.6m in external funds secured; 14 awards won; 51 jobs created; and ten innovations selling internationally. In addition, impact data is already available at adopter sites which demonstrates earlier intervention, reductions in complications and emergency admissions, alongside cost savings.

The NIA hosts 25 Fellows representing 26 innovations aimed at: activating people to self-manage; earlier intervention; long term conditions management and improving safety. The next NIA call, to be launched in June 2017, will select innovations that address the population challenges prioritised within the 44 Sustainability and Transformation Partnerships (STPs).

For more information about the NIA, email NIA@uclpartners.com

An overview of the Innovation and Technology Tariff (ITT)

The Innovation and Technology Tariff (ITT) has been introduced to incentivise the adoption and spread of transformational innovation in the NHS.

Introducing new innovative products to the NHS can often be hampered by the need for multiple local price negotiations. The ITT aims to remove this need, while guaranteeing that local NHS organisations will be reimbursed for the costs of purchasing an ITT-approved product type. At the same time, the ITT allows NHS England to optimise its purchasing power and negotiate national 'bulk buy' price discounts wherever possible on behalf of the whole NHS.

The first two-year ITT runs from 2017 to 2019. This first Tariff has been developed as a pathfinder, with six themed product types identified as being suitable for at-scale introduction in the NHS, and likely to result in great benefits for patients.

The ITT themes are:

- Guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury
- Arterial connecting systems to reduce bacterial contamination and the accidental administration of medication
- Pneumonia prevention systems which are designed to stop ventilator-associated pneumonia
- Web-based applications for the self-management of chronic obstructive pulmonary disease
- Frozen Faecal microbiota transplantation (FMT) for recurrent Clostridium difficile infection rates
- Management of Benign prostatic hyperplasia as a day case

The ITT operates under a zero cost model for four of the six themes, which allows providers to order ITT innovations without the need for multiple financial transactions. The zero cost model has been established to minimise the number of transactions and create a more efficient system to administer across the NHS. Both the 'guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury' and 'the Management of Benign prostatic hyperplasia as a day case' operate under separate arrangements.

Mobile ECG Technology

In parallel, but separately from the tariff, NHS England is centrally funding the purchase of mobile ECG technology to improve diagnosis of atrial fibrillation (AF). Taking repeat ECG recordings continuously over a 24-hour period or recording events over several days can increase the probability of detecting an arrhythmia, but needs small, portable ECG machines to be practical. The availability of this technology will be managed through the Academic Health Science Networks (AHSNs).

The NHS England Innovation and Technology Tariff 2017-2019 Technical Notes is available to download at: www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/

Introducing the PneuX Prevention System

Challenge/problem identified

Ventilator-associated pneumonia (VAP) is defined as pneumonia that occurs 48-72 hours following endotracheal intubation and mechanical ventilation and is seen in the Intensive Care Unit (ICU). VAP is the leading cause of infective hospital-acquired mortality, affecting up to 20,000 patients per year and causing almost a third of those affected to die. Each episode costs the NHS between £10,000 and £20,000.

VAP is caused by the use of standard leaky ventilation tubes, where bacteria contaminated secretions from the mouth and stomach leak into the patient's lungs, leading to the potentially fatal pneumonia often within 48 hours.

VAP increases the length of time a patient is mechanically ventilated and their length of stay in the ICU, by around 28%, significantly adding to treatment costs.[1] VAP increases antibiotic use, where one study highlighted that 50% of all antibiotics used in the ICU are to treat VAP. This can lead to multi-drug resistant bacteria.

Preventing VAP is highly beneficial for patients, reduces antibiotic pressure and resistance, and cost saving for the NHS.

Solution

The PneuX Pneumonia Prevention System was designed to stop VAP by preventing leakage of bacteria contaminated secretions from the mouth and stomach into the patient's lungs. Numerous laboratory and clinical studies have shown that the PneuX is the only cuffed ventilation tube of its kind to consistently eliminate this potentially fatal leakage.

The PneuX is a cuffed ventilation tube and an electronic cuff monitoring and inflating device (the tracheal seal monitor), that prevents leakage of bacteria contaminated secretions to the lung. The PneuX, unlike standard ventilation tubes, has a cuff which achieves an effective seal inside the patient's trachea, which prevents leakage or aspiration of bacteria-contaminated secretions into the lungs. It also has multiple drainage ports, to remove the secretions which sit above the cuff by suctioning these out through the subglottic ports, and is the only ventilation tube which allows irrigation and wash out of the airway above the cuff, to keep the oropharynx as clean as possible. The cuff pressure monitor continuously measures pressure and ensures the seal remains effective at all times, even when the patient coughs or moves.

PneuX can be used in any patient requiring mechanical ventilation in the ICU, emergency department or for patients undergoing major surgery in operating theatres.

Impact and outcomes

Key statistics

- Out of the 100,000 patients that are admitted for ventilation in the UK each year, 10-20% will develop VAP
- Between 3,000 and 6,000 people die each year from this type of pneumonia and prevention could save many lives
- Treating VAP costs the NHS between £10,000-£20,000 per patient
- A highly conservative saving estimate to the NHS from prevention of VAP is over £100 million per year.
- An independent health economic evaluation by the University of Birmingham and the Royal College of Surgeons, based on an NHS England funded patient study at New Cross Hospital, showed that using the PneuX has a cost saving to the NHS of £718 for every patient, when introduce into the ICU.[4]
- PneuX shows zero leakage of bacteria, compared with other cuffs on the market, each of which show a degree of leakage (FIGURE I.)

Impact Modelling Tool

The NIA has developed an Impact Modelling Tool to provide an indication of the savings that could be achieved through implementation of PneuX.

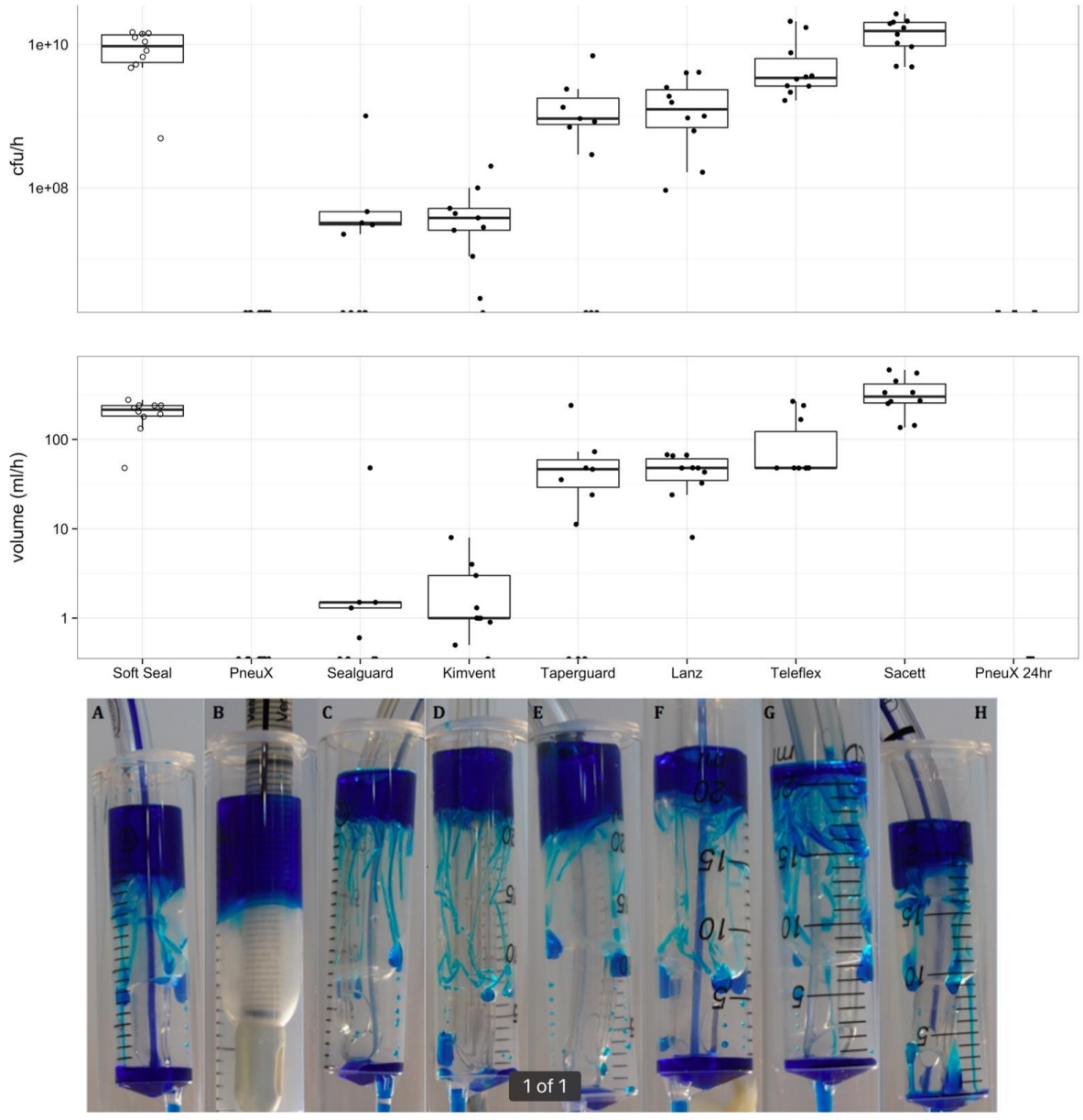
PneuX_economicmodellingspreadsheet.

Testimonial

"We are hugely impressed with the direct benefits to patient safety, through [preventing] avoidable harm and improving outcomes. We urge healthcare providers… to ensure the system is adopted. From a patient's perspective, this is an opportunity that cannot be ignored."

Trevor Fernandes, co-chair, East of England Citizen's Senate

FIGURE I.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How to procure the PneuX Prevention System

The below is detailed within The NHS England Innovation and Technology Tariff 2017-2019 Technical Notes, available to download at:

www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/

Payment/price detail

The ITT agreed price for this innovation is £150.00, based on the purchase price of the tubing. From 1 April, the PneuX device can be ordered direct from the manufacturer under the zero cost model.

Refer to pages 17-18 of the ITT Technical Notes for reporting instructions.

Availability

Qualitech Healthcare is currently the only supplier identified by NHS England as able to provide this innovation in accordance with the specification detailed in the ITT Technical Notes. The ITT for this theme covers the cost of the tracheal tubes valued at £150 per unit. Qualitech will provide the PneuX tracheal seal monitor (TSM) required to use the PneuX tubing system on a loan basis to hospitals. Trusts requiring the monitor will be provided with one on a loan basis from Qualitech when a minimum order of 24 tubes is placed by the Trust.

Contact Qualitech directly for more information: www.qualitechhealthcare.co.uk/home.html

NHS England is working to include this product on the NHS Supply Chain by the end of summer 2017.

Evidence summary

PneuX™ prevents leakage of subglottic secretions past the endotracheal tube cuff

- Standard endotracheal tubes have cuffs which develop folds when inflated inside the trachea. Studies have shown bacteria from the mouth and gastric secretions from the stomach leak past the folds in these cuffs[2, 15-16] and it is the aspiration of these secretions which cause VAP.[2-3]
- The cuff of the PneuX™ endotracheal and tracheostomy tubes are made of silicone and does not develop folds when inflated inside the trachea, thus preventing VAP. This has been shown in several clinical and laboratory studies.
- The tracheal seal monitor, automatically senses the size of the patient's trachea and inflates the cuff to the correct size to prevent tracheal ischaemia (this can occur with other cuffs if they are over-inflated or if a correctly inflated cuff moves to a smaller diameter portion of the trachea).

Clinical studies

- Several published clinical studies have shown the benefits of using the PneuX system. [16-23]
- One independent study funded by NHS England assessed the PneuX™ against standard endotracheal tubes in high risk patients undergoing cardiac surgery. Even during short intubation times, the incidence of pneumonia was significantly lower with the PneuX™ than with standard endotracheal tubes ($P = 0.03$).[7]
- Another study assessed the bacterial colonisation rates of endotracheal tubes, comparing the PneuX™ to standard endotracheal tubes. Endotracheal tubes were in situ for 48 hours. After extubation, endotracheal tubes were sent for bacterial analysis, and results showed lower incidence of bacterial colonisation of the PneuX™ endotracheal tubes compared with the standard endotracheal
- One study examined the use of the PneuX™ in critically ill patients that were ventilated for more than seven days. They used the CPIS score (a standardised and validated VAP scoring system which reflects lung injury due to infection and chemical damage) to assess VAP rates, comparing the PneuX™ to standard endotracheal tubes. The CPIS score was significantly lower with the PneuX™ endotracheal tubes compared with standard endotracheal tubes ($P < 0.05$).[9]
- This clinical study assessed the PneuX™ in clinical practice, where patients were both initially intubated with the PneuX™ or underwent an elective tube exchange from a standard tube to a PneuX™ tube. They found that that there were no episodes of VAP whilst the PneuX™ was in situ. Importantly during the 14-month study period no antibiotics were needed to treat VAP or lracheal/lung colonization. Tube exchange was found to be safe and straightforward to perform in this study.[10]

Laboratory studies

- A study conducted at Massachusetts General Hospital, USA, compared the performance of the PneuX ™ system to four standard endotracheal tubes. This study found that PneuX™ was the only endotracheal tube to prevent leakage of fluid past the cuff in all trials, and was superior to all other endotracheal tubes tested ($P < 0.01$).[11]
- Another study performed at the University Hospital of Wales, looked at the performance of subglottic secretion drainage endotracheal tubes in preventing leakage of bacteria past the

cuff. The Pneux™ prevented leakage of bacteria past the cuff and was superior in performance to all other 7 tested endotracheal tubes ($P < 0.001$). Four of the best performing endotracheal tubes were also tested in model tracheas of varying sizes and the PneuX™ was found to prevent leakage of fluid in every trachea size.[12]

- This study compared the PneuX™ against standard endotracheal tubes in preventing leaking of fluid past the cuff in mechanical and cadaveric models. They found that the PneuX prevented leakage past cuff in all experiments, including tracheal suction and tube movement.[13]

Cost of VAP

- A health economic analysis assessed the cost effectiveness interventions used to preventing ventilator associated pneumonia in the ICU. They stated that the cost of a single episode of VAP in the ICU is around $40,000 in the US and around £10,000 in Europe, and this is the equivalent of a further 10 days of ventilation in the ICU. Their calculations state that, if an ICU has a VAP rate of 10%, that ICU can spend £500 on any intervention that prevents VAP by only 50%, and still be cost saving for the NHS.[14]
- This study conducted by the compared the cost effectiveness of converting to the PneuX™ endotracheal tube from standard endotracheal tube. Their study results were independently analysed by statisticians at the Royal College of Surgeons and health economists the University of Birmingham, who found the using the PneuX™ endotracheal tube saved their hospital >£700 per patient. They found that using the PneuX™ reduced VAP by 50%, however in order for it to be cost neutral it only had to reduce VAP rates by 8%.[4]

References

1. Ventilator Associated Pneumonia - an overview. BJMP 2009; 2: 16-19.
2. Ventilator associated pneumonia: evolving definitions and preventive strategies. Respir Care. 2013; 58:990-1007. http://rc.rcjournal.com/content/58/6/990.short
3. New Endotracheal Tubes Designed to Prevent Ventilator-Associated Pneumonia: Do They Make a Difference? Respir Care. 2010;55:1046-1055. http://rc.rcjournal.com/content/55/8/1046.short
4. VAP cost effectiveness study. Presented at the 29th European Association for Cardio-Thoracic Surgery. 2015, Amsterdam.
5. Ventilator-associated pneumonia. Am J Respir Crit Care Med. 2002;165:867-903. http://www.atsjournals.org/doi/pdf/10.1164/ajrccm.165.7.2105078
6. Tracheobronchial aspiration of gastric contents in critically ill tube-fed patients: Frequency, outcomes, and risk factors. Crit Care Med. 2006;34:1007-1015. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2396145/
7. Significant reduction in ventilator-associated pneumonia with the Venner-PneuX System in high-risk patients undergoing cardiac surgery: the Low Ventilator-Associated-Pneumonia study. Eur J Cardiothorac Surg. 2015;47(3): e92-6 https://academic.oup.com/ejcts/article/47/3/e92/524144/Significant-reduction-in-ventilator-associated
8. Incidence of endotracheal tube colonization with the use of PneuX endotracheal tubes in patients following cardiac surgery. J Hosp Infect. 2016;S0195-6701(16):30394-2. http://www.journalofhospitalinfection.com/article/S0195-6701(16)30394-2/pdf
9. PneuX P.Y.TM System. Clinical application and the reduction of Clinical Pulmonary Infection Scores (CPIS) in long-term ventilated intensive care patients. 2011; 48(1):43-47 http://link.springer.com/article/10.1007/s00390-010-0211-4

10. The incidence of ventilator-associated pneumonia using the PneuX System with or without elective endotracheal tube exchange: A pilot study. BMC Research Notes 2011;4:92 http://www.biomedcentral.com/1756-0500/4/92
11. Performance of the PneuX System: A Bench Study Comparison With 4 Other Endotracheal Tube Cuffs. Respir Care. 2016; 62(1) (epub). http://rc.rcjournal.com/content/early/2016/11/22/respcare.04996
12. An in vitro microbiological study comparing eight endotracheal tubes and their ability to prevent microaspiration. BMC Anaesthesiology 2017 (in press). https://pdfs.semanticscholar.org/ba90/a5a2d91aea42ad2422f69e24af2b0c6de741.pdf
13. Evaluation of a new design of tracheal tube cuff to prevent leakage of fluid to the lungs. British Journal of Anaesthesia 1998;80(6):796-799 http://bja.oxfordjournals.org/content/80/6/796
14. Number needed to treat and cost-effectiveness in the prevention of Ventilator Associated Pneumonia. Critical Care. 2012; 16(3):430 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3580630/
15. Cost effectiveness in the prevention of VAP. Journal of the Intensive Care Society 2014:15:265–66 http://journals.sagepub.com/doi/pdf/10.1177/175114371401500322
16. A low-volume, low-pressure tracheal tube cuff reduces pulmonary aspiration. Critical Care Medicine 2006;34(3):632-9 http://journals.lww.com/ccmjournal/Abstract/2006/03000/A_low_volume,_low_pressure_tracheal_tube_cuff.8.aspx
17. The LoTrach system: its role in the prevention of ventilator-associated pneumonia. Nursing In Critical Care 2008;13(5):260-8 http://onlinelibrary.wiley.com/wol1/doi/10.1111/j.1478-5153.2008.00286.x/abstract
18. The LoTrach™: A Tracheal Tube for Critical Care. Journal of the Intensive Care Society 2007;8(1):72-75 http://journals.sagepub.com/doi/abs/10.1177/175114370700800128
19. Prevention of tracheal aspiration using the pressure-limited tracheal tube cuff. Anaesthesia 1999;54(6): 559-563 http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2044.1999.00850.x/full
20. The prevention of pulmonary aspiration with control of tracheal wall pressure using a silicone cuff. Anaesthesia and Intensive Care 2000; 28(6):660-5 http://www.aaic.net.au/document/?D=2000086
21. Improving the shape and compliance characteristics of a high volume low pressure cuff improves tracheal seal. British Journal of Anaesthesia 1999;83(6):887-889 http://bja.oxfordjournals.org/content/83/6/887.short
22. Inflation of a pressure-limited cuff inside a model trachea. Med Eng Phys. 2003;25(6):465-73 http://www.medengphys.com/article/S1350-4533(02)00252-7/abstract
23. The pressure exerted on the tracheal wall by two endotracheal tube cuffs: A prospective observational bench-top, clinical and radiological study. BMC Anaesthesiology 2010;10:21 http://bmcanesthesiol.biomedcentral.com/articles/10.1186/1471-2253-10-21

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