

PleuraFlow Active Clearance Technology for maintaining chest tube patency

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is PleuraFlow Active Clearance Technology (ACT). It is a chest drain that incorporates a tube clearance system.
- The **innovative aspects** are that it is designed to prevent the formation of blood clots within chest tubes and, if they do occur, to actively remove them.
- The intended **place in therapy** would be to replace standard chest drains in people who need them, such as those who have had cardiothoracic surgery or surgery after trauma.
- The **main points from the evidence** summarised in this briefing are from 4 studies involving a total of 827 adults. They suggest that PleuraFlow ACT may be more effective than conventional chest tubes for reducing complications in people having cardiac surgery.

- **Key uncertainties** around the evidence base, which is still developing, are the variety of outcome measures used and the lack of randomised studies to compare PleuraFlow ACT with standard chest drains. There are also no published reports from the UK, so it is unclear if the results are generalisable to the NHS.
- The **cost** of PleuraFlow ACT is £295 per unit (exclusive of VAT). The **resource impact** is likely to be greater than standard chest drains, which cost around £6, because PleuraFlow ACT costs more. These costs may be offset if using PleuraFlow ACT reduces complications and subsequent NHS resource use.

The technology

PleuraFlow Active Clearance Technology (ACT; ClearFlow) is a chest drain that incorporates a tube clearance system.

It comprises a silicone chest tube and the PleuraFlow clearance apparatus. The PleuraFlow clearance apparatus is a PVC guide tube that is used to channel drained blood, fluid and air to the drainage catheter. Inside the guide tube is the clearance guidewire and loop, which moves back and forth inside the chest tube, driven by 2 sets of magnets housed in a shuttle on the outside of the tube. When the shuttle is released and slid along the tube (actuated), the magnets move the guidewire and loop. This pulls blood, clots and any debris toward the drainage canister, which helps to prevent and break up blockages.

The device's instructions for use specify that the PleuraFlow clearance apparatus should be actuated manually inside the chest tube every 15 minutes during the first 8 hours after surgery (when bleeding is more common), then every 30 minutes for the next 16 hours and every hour thereafter. Each actuation takes approximately 10 seconds. The PleuraFlow clearance apparatus should be removed within 5 days (or once bleeding and clotting has stopped, whichever is sooner). The chest tube can then remain in place for up to 2 weeks after being inserted.

The PleuraFlow chest tube is inserted through the chest wall into the pleural or mediastinal space according to local protocols. It is recommended that at least 1 PleuraFlow system is used in the anterior mediastinum, where postoperative bleeding is most common.

PleuraFlow ACT is available in 4 different chest tube sizes: 20, 24, 28 and 32 French. It cannot be used in people who are intolerant to implantable silicone materials.

Innovations

PleuraFlow ACT differs from standard chest drains in that it incorporates an active tube clearance system. The clearance mechanism is contained within the tube but actuated externally, so the tube remains sterile.

Current care pathway

Chest drains are used after all types of cardiothoracic surgery to re-inflate the lung and to assist with draining air and fluid from the pleural cavity. The NICE guideline on [major trauma](#) recommends using chest drains when managing chest trauma in pre-hospital and hospital settings, but there is no NICE guidance on managing chest drains specifically.

The British Thoracic Society guidelines on [pleural disease](#) include recommendations for inserting and maintaining chest drains. The guidelines state that chest drains should be connected to a drainage system that contains a valve mechanism to prevent fluid or air from entering the pleural cavity.

PleuraFlow ACT would be used instead of standard chest drains currently used in the NHS. Most NHS trusts have varied local guidelines and protocols for chest drain management, but general principles include regular monitoring of the drain and noting changes that may indicate that the chest tube is kinked or blocked. Stripping and milking of the tubing using roller clamps to remove blockages is no longer recommended.

Population, setting and intended user

PleuraFlow ACT is intended for use in adults and children aged over 6 months who need a chest drain after cardiothoracic surgery or trauma. It would be used by healthcare professionals working in secondary or tertiary care who are trained in cardiothoracic surgery. A cardiothoracic surgeon would insert the chest tube in an operating theatre, where it would be connected to the clearance apparatus and a standard drainage system. The patient would then be transferred to an intensive care unit or recovery ward, where nurses would use PleuraFlow ACT to maintain patency of the chest tube until it is removed.

Competency training and education is included in the device cost and provided by the company.

Costs

Technology costs

PleuraFlow ACT costs £295 per device (excluding VAT), which includes 1 chest tube and 1 PleuraFlow clearance system.

Costs of standard care

Standard chest drains without active clearance mechanisms cost approximately £6 each ([NHS Supply Chain](#)).

Resource consequences

PleuraFlow ACT costs much more than standard chest drains, but this could be offset if its use reduced complications caused by chest tube blockages.

PleuraFlow ACT may also need more staff time than standard chest drains: the recommended actuation schedule equates to 11 minutes of using the device in the first 24 hours after surgery. However, staff time could be reduced if tubes do not need to be manually unblocked or changed.

No changes in facilities and infrastructure would be needed to adopt PleuraFlow ACT, because it can attach to any standard drainage canister.

According to the company, 3 NHS centres are currently using PleuraFlow ACT.

Regulatory information

PleuraFlow Active Clearance Technology (ACT) was CE marked as a class IIa device in July 2010.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

People needing a chest drain may have a chronic condition, which may mean they are disabled if this has a significant and long-term effect on their ability to carry out daily activities. Many people eligible for PleuraFlow Active Clearance Technology (ACT) are likely to be older. Age and disability are protected characteristics under the Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 4 published studies on PleuraFlow Active Clearance Technology (ACT): 3 retrospective cohort studies ([St-Onge et al. 2017](#), [Maltais et al. 2016](#), [Sirch et al. 2016](#)) and 1 user experience study ([Perrault et al. 2012](#)), including a total of 827 adults having cardiac surgery in the US, Canada and Germany.

All 3 retrospective cohort studies showed a reduction in the rates of a composite outcome, 'retained blood syndrome', with patients having PleuraFlow ACT compared with standard chest drains. Two studies also showed a reduction in the rates of postoperative atrial fibrillation. Table 1 summarises the included studies as well as their individual strengths and limitations.

Overall assessment of the evidence

The evidence base on PleuraFlow ACT is still developing and currently limited in both quantity and quality. Most of the studies were non-randomised retrospective analyses of cohort studies, which compared the outcomes of different patient groups during consecutive time periods. Although the patients in these studies were not randomised, propensity match scoring or logistic regression was used to attempt to match individuals in the intervention and control group, control for confounding and mimic randomisation. Changes in chest tube management protocols and other variables were not controlled for. Moreover, none of the studies was done in the UK, which may limit their generalisability to the NHS.

Multicentre, randomised controlled trials and evidence from a UK setting comparing PleuraFlow ACT with standard chest drains would be useful. These should include relevant technical and clinical outcomes such as incidence of tube occlusion, postoperative atrial fibrillation and reintervention rates.

Table 1 Published evidence on PleuraFlow ACT

<u>St-Onge et al. (2017)</u>	
Study size, design and location	Non-randomised retrospective cohort study of 300 patients having cardiac surgery in 2 separate time periods. Used propensity match scoring between groups. Primary end point: POAF Single centre in Canada.
Intervention and comparator(s)	People with PleuraFlow ACT (n=142). People with standard chest drains (n=158). Using a 1:1 propensity score match, 214 patients were included in paired analysis (107 in each group).

Key outcomes	<p>Unmatched patients having PleuraFlow ACT had a 34% reduction in POAF rate compared with those having standard chest drains (23% vs 35%, $p=0.01$).</p> <p>In the matched cohort, PleuraFlow ACT was associated with a 31% reduction in POAF rate (24% vs 35%, $p=0.09$) and a trend toward shorter postoperative length of stay (5.0 [4.0; 7.0] vs 6.0 [5.0; 8.0], $p=0.08$).</p> <p>In multivariate analysis, chest drainage with PleuraFlow ACT showed a protective effect on POAF with odds ratio of 0.5 (95% CI 0.1 to 0.9; $p=0.02$).</p>
Strengths and limitations	<p>This was a non-randomised, single-centre study with interventions used at different time points. One of the authors has served on a company scientific advisory board and 2 others have received honorarium for scientific presentations.</p>
<p><u>Maltais et al. (2016)</u></p>	
Study size, design and location	<p>Non-randomised, retrospective cohort analysis of prospectively collected data from 252 patients having cardiac surgery.</p> <p>Primary end point: composite end point of additional interventions for RBS defined as: any re-exploration for bleeding, delayed sternal closure, pericardial interventions for drainage (pericardial window or pericardiocentesis), and pleural interventions for drainage for haemothorax or bloody effusions.</p> <p>Single centre in the US.</p>
Intervention and comparator(s)	<p>Patients were divided into 2 groups for analysis:</p> <p>Group 1 was patients having standard chest drains ($n=77$, April 2009 to May 2013). Group 2 was patients having PleuraFlow ACT according to a defined ICU use protocol ($n=175$, June 2013 to July 2015).</p>

Key outcomes	<p>Univariate and multivariate analyses were done, adjusting for the use of conventional sternotomy and minimally invasive left thoracotomy.</p> <p>Univariate analysis showed a 65% reduction in re-exploration ($p<0.001$) and an 82% reduction in delayed sternal closure ($p<0.001$). In a subanalysis of conventional sternotomy only, there continued to be a significant 53% reduction in re-exploration (45% vs 21%, $p=0.0011$) and a 77% reduction in delayed sternal closure (35% vs 8%, $p<0.001$) in group 2.</p> <p>Using a logistic regression model adjusting for conventional sternotomy versus minimally invasive left thoracotomy, there was a significant reduction in re-exploration (OR=0.44, 95% CI 0.23 to 0.85; $p=0.014$) and delayed sternal closure (OR=0.20, 95% CI 0.08 to 0.46; $p<0.001$) in group 2.</p> <p>Other postoperative outcomes, such as POAF, length of stay, time in ICU and mortality were similar between groups.</p>
Strengths and limitations	<p>This was a non-randomised study with interventions used at different time points. Changes in ICU protocols over time and other variables were not controlled for. Patients were grouped according to their treatment and no other matching was done, but differences between groups were controlled for in analyses.</p> <p>The study was partly funded by the company. One of the authors was a consultant and equity holder in the company and another has received a grant from the company.</p>
<u>Sirch et al. (2016)</u>	
Study size, design and location	<p>Non-randomised retrospective cohort analysis of prospectively collected data of 2,327 patients having cardiac surgery in 3 separate periods, using propensity match scoring between groups.</p> <p>Primary end point: RBS composite outcome consisting of any of the following: take back for re-exploration for haemorrhage; pericardial interventions; and pleural interventions for haemothorax, pneumothorax and effusions.</p> <p>Single centre in Germany.</p>

Intervention and comparator(s)	<p>3 phases, data were collected during consecutive time periods:</p> <ul style="list-style-type: none"> • patients having cardiac surgery with conventional chest tubes (n=1,849) • using PleuraFlow ACT in all patients, after a period of training (n=256) • return to use of conventional tubes (n=222).
Key outcomes	<p>51 of 256 matched patients (19.9%) had at least 1 intervention for RBS in phase 1, compared with 29 (11.3%) in phase 2 (a 43% reduction; $p=0.0087$). This was mainly because of a reduction in interventions to treat pleural effusions. There were non-significant reductions in re-explorations for bleeding, interventions for pericardial effusions, and interventions for pneumothorax.</p> <p>There was a significant reduction in POAF in phase 2 compared with phase 1 ($p=0.013$), but not in hospital mortality, cardiac arrest or permanent stroke. There was a significant reduction in median chest drainage ($p=0.0024$) and ventilation hours ($p=0.0047$), but not in overall length of stay ($p=0.24$).</p> <p>In phase 3, there was an increase in the outcomes from phase 2 and the differences with phase 1 were not statistically significant. POAF was the only outcome that neared statistical significance (phase 1 31.5% v 23.9% phase 3, $p=0.079$).</p>
Strengths and limitations	<p>This was a non-randomised study with interventions used at different time points. Changes in ICU protocols over time and other variables were not controlled for.</p> <p>Treatment and control groups were propensity matched to limit differences in patient characteristics between groups. RBS was a composite outcome which did not specifically measure retained mediastinal blood. The study did not have an end point to directly image retained blood and quantify the reduction with imaging.</p> <p>Phase 2 and 3 could not be compared because of small sample sizes. The study was also part funded by the company, and 1 of the authors is a founding shareholder and board member of the company.</p>
Perrault et al. (2012)	

Study size, design and location	Survey responses from 7 surgeons and 42 intensive care nurses caring for 19 adults having cardiac surgery using PleuraFlow ACT at a centre in Canada.
Intervention and comparator(s)	PleuraFlow ACT and standard chest tubes.
Key outcomes	<p>41 (98%) of nurses considered the system was easy to use and all that it was easy to understand.</p> <p>35% of nurses reported that they had to strip or milk conventional chest tubes when clotting formed.</p> <p>77% of nurses considered the device more efficient than stripping, milking or tapping the chest tube to keep it open, and 86% that it was more effective than these methods.</p> <p>ICU specialists inspected tubes on removal: standard chest tubes were visually noted to be obstructed 33% (5/15) of the time, correlating with observed respiratory variation. Some non-obstructive clot on the guidewire was noted in the PleuraFlow ACT chest tubes in only 13% (2/15).</p> <p>Respiratory variation was intact in all the PleuraFlow ACT systems, suggesting that the tubes were open and functional.</p> <p>All the PleuraFlow chest tubes were found to be functional on removal.</p>
Strengths and limitations	This was a single-centre study with small patient numbers. One of the co-authors is the inventor of PleuraFlow ACT.
Abbreviations: ACT, active clearance technology; CI, confidence interval; ICU, intensive care unit; OR, odds ratio; POAF, postoperative atrial fibrillation; RBS, retained blood syndrome.	

Recent and ongoing studies

- [Active clearance technology \(ACT\) II German multicenter trial](#). ClinicalTrials.gov: NCT02479737. Status: recruiting. Indication: heart surgery. Devices: PleuraFlow ACT.
- [The effect of chest tubes using active clearance technology on the incidence of postoperative atrial fibrillation \(ACT-POAF\)](#). ClinicalTrials.gov: NCT02808897. Status: recruiting. Indication: heart surgery. Devices: PleuraFlow ACT.

- [Active clearance technology \(ACT\) registry](#). ClinicalTrials.gov: NCT02682849. Status: recruiting. Indication: heart surgery. Devices: PleuraFlow ACT.

Specialist commentator comments

Comments on this technology were invited from specialist commentators working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Nine responses from specialist commentators were received. One specialist commentator had used this technology before, and 1 had heard of it.

Level of innovation

Three specialist commentators considered PleuraFlow Active Clearance Technology (ACT) to be a minor variation on existing technologies, 3 considered it to be a significant modification with potential for different outcomes, and 3 that it was thoroughly novel. One described it as both a minor and significant variation, because any promise needed to be proven in a large trial and any evidence is currently anecdotal. Another considered it to be only somewhat innovative because there are other technologies that provide a similar function.

Potential patient impact

The safe evacuation of blood clots, avoiding cardiac tamponade and decreased risk of tube occlusion and subsequent complications were identified as possible benefits for patients, as well as the opportunity to use a smaller and more comfortable tube. Specialist commentator opinion was mixed on the frequency and seriousness of the complications that the technology sought to avoid and how many patients would benefit.

Potential system impact

Two commentators considered that the technology would improve patient safety. Three noted that if it did reduce the incidence of complications including retained blood, this could reduce hospital stays. Two commentators felt that the device might lead to fewer reoperations for bleeding, and another noted that it could reduce the need for tube

reinsertions and allow faster effusion draining. All but 1 of the commentators felt that training would be needed to use the device; 1 noted that it was easy to establish and use.

Although most of the commentators considered that PleuraFlow ACT would increase costs, particularly in the short term, 2 felt it had the potential to reduce costs through reducing complications, or if it were used instead of non-portable suction devices. One commentator felt that it would need to be used on a large a number of patients to generate any savings.

General comments

Four of the specialist commentators felt that the evidence was limited and that more evidence, particularly randomised controlled trials, would be needed to confirm the technology's promise.

One commentator said that it could be used for people at high risk of bleeding, but that using PleuraFlow ACT would not lessen the actual rate of bleeding.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr Fabrizio de Rita, consultant in congenital cardiothoracic surgery. No relevant conflicts of interest.
- Mrs Claire Horsfield, quality improvement lead nurse. No relevant conflicts of interest.
- Professor Daniel Keenan, consultant cardiothoracic surgeon. No relevant conflicts of interest.
- Prof Mahmoud Loubani, consultant cardiothoracic surgeon. No relevant conflicts of interest.
- Mr Edward K McLaughlin, consultant cardiothoracic surgeon, Society for Cardiothoracic Surgery in Great Britain and Ireland. Mr McLaughlin has carried out fee-paid educational activities for Ethicon Biosurgery, a Johnson & Johnson company.
- Mr Richard Page, consultant in cardiothoracic surgery. No relevant conflicts of interest.

- Mr Kostas Papagiannopoulos, senior consultant cardiothoracic surgeon. No relevant conflicts of interest.
- Mrs Catherine Plowright, consultant nurse. No relevant conflicts of interest.
- Mr Steven Woolley, consultant cardiothoracic surgeon. No relevant conflicts of interest.

Development of this briefing

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