NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

MTG review decision document

Review of MTG37: Thopaz+ portable digital system for managing chest drains

This guidance was issued in March 2018.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However, the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Recommendation

Amend the guidance to reflect the new costs for Thopaz+.The factual changes proposed have no material effect on the recommendations.

Do not consult on the review proposal.

Please see Appendix 1 for a list of the options and their explanations for consideration.

The external assessment centre's (EAC) review of the clinical evidence and cost update can be found in the review report.

2. Original objective of guidance

To assess the case for adoption of Thopaz+ portable digital system for managing chest drains.

3. Current guidance

1.1 The case for adopting Thopaz+ for managing chest drains is supported by the evidence. Thopaz+ can reduce drainage time and length of stay in hospital, and improves safety for people with chest drains. Its use may also improve

clinical decision-making through continuous, objective monitoring of air leaks and fluid loss.

1.2 *Thopaz+ should be considered for people who need chest drainage after pulmonary resection or because of a pneumothorax. The system can increase patient mobility because it is portable. Staff find it more convenient and easier to use than conventional chest drains.*

1.3 *Cost modelling indicates that Thopaz+ is cost saving compared with conventional chest drains in people after pulmonary resection. The estimated saving is £111 per patient per hospital stay, with savings mainly achieved through reduced length of stay. The NICE resource impact assessment shows that, at a national level, adopting Thopaz+ is expected to save around £8.5 million per year in England.*

4. Rationale

The population covered in the scope was broad and included people requiring a chest drain, including for example those needing thoracic drainage from the pleural and mediastinal cavities for pneumothorax, post-operatively after cardiac or thoracic surgery, following thoracic injury, pleural effusion, pleural empyema or other related conditions. The evidence in the original assessment report included 13 studies, 11 studies in people undergoing pulmonary surgery and 2 studies in people with pneumothorax. There were no studies in the cardiac setting. The original guidance recommended the use of Thopaz+ for people who need chest drainage after pulmonary resection or because of a pneumothorax.

In total, there are 20 new publications, of which 2 reported results of the same study and were considered as 1 study in this review. Most studies were in the respiratory setting, including pulmonary resection for a range of indications (n=13), of which 2 were in paediatric populations, and pneumothorax (n=1). The new evidence in the respiratory setting broadly suggests that outcomes for patients are more favourable with digital drainage using Thopaz/Thopaz+ when compared with analogue drainage systems and are thus in line with the evidence presented in MTG37 for pulmonary resection and pneumothorax.

For the cost case, the original MTG37 model was updated using changes to the unit costs and the costs calculated for reinsertion of chest drains. The technology remains cost saving for pulmonary resection and pneumothorax.

There are 4 new publications in the cardiac setting and the population was predominantly patients undergoing cardiac surgery such as coronary artery bypass (2 RCTs and 2 comparative retrospective studies). No evidence for the use of Thopaz/Thopaz+ in a cardiac setting was available at the time of the original guidance and therefore no recommendation could be made for its use in this setting. The current evidence from 4 studies in the cardiac setting indicates that although the

duration of chest drainage in 3 studies was shorter with Thopaz than with analogue drainage (Tamura 2021, van Linden 2019, Barozzi 2020), there is uncertainty around the impact on duration of hospital stay with one comparative retrospective study reporting significantly shorter duration (Tamura 2021) and 2 studies (1 large RCT and 1 comparative retrospective) reporting that the duration of hospital stay was the same for both groups (van Linden 2019, Saha 2020). One clinical expert considered that 0.5-day reduction in drain removal or hospital length of stay would be clinically significant but noted that many factors can affect this. One expert said that following cardiac surgery in the UK, patients stay in the ICU for 1 to 2 days and on the ward for 6 to 8 days. They added that duration of chest drain is not the most important factor in determining length of stay but is one of the factors.

The model did not include the cardiac setting, but the EAC consider that the costs associated with use of Thopaz/Thopaz+ and analogue comparators are likely to be similar to those in the original cost model for respiratory settings. However, new evidence in the cardiac setting suggests uncertainty around the impact of Thopaz compared with conventional drainage on duration of hospital stay, with only 1 comparative retrospective study finding a significant difference. As the original cost saving was due to a reduced length of hospital stay, it is possible, based on the currently available evidence that Thopaz/Thopaz+ may not be cost saving in a cardiac setting.

The EAC suggested that the recommendation may need to be updated to include the evidence in the cardiac setting but is unsure if the cost case is supported.

5. New evidence

The search strategy from the original assessment report was re-run. References from June 2017 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The technology is still available to the NHS in the UK. No new models of the technology have been launched since the original guidance was published. However, it should be noted that there are currently 2 versions of the Thopaz device in use – Thopaz and Thopaz+. The difference between Thopaz and Thopaz+ is that Thopaz+ measures both air leak and fluid leak whereas Thopaz only measures air

leak. The consumables are the same for both devices. Since the original guidance, which included both devices, there has been a move towards the use of Thopaz+. The company indicated that only 14% are still using Thopaz and the reasons for not moving over to Thopaz+ are usually financial as many units rent the devices and there is a small increase in rental costs to make the change. The company is working with users to make the move to Thopaz+.

The CE mark and indication remain unchanged. There has been a slight increase in the price for the Thopaz+ pump itself.

5.2 Clinical practice

The NICE pathway is **trauma.** NICE's guideline on major trauma: assessment and initial management has not been updated since the publication of the Thopaz+ guidance (February 2016).

All three of the clinical experts contacted during the guidance review said that there have been no substantial changes to the clinical pathway since the publication of MTG37.

5.3 NICE facilitated research

None.

5.4 New studies

In total, 20 new publications were identified as potentially relevant (Aldaghlawi 2020, Alam 2020, Arai 2018, Barozzi 2020, de Waele 2017, Eriguchi 2021, Jacobsen 2019, Lee 2019, Lijkendijk 2019, Lijkendijk 2018, Mori 2017, Mitsui 2021, Perez-Egido 2018, Pompili 2016, Pfeuty 2020, Ruigrok 2021, Saha 2020, Takamochi 2018, Tamura 2021, van Linden 2019). It should be noted that Lijkendijk 2019 and Lijkendijk 2017 are separate publications reporting different outcomes from the same study and for the purposes of this review, are considered as one study.

Broadly the evidence falls into two settings, a respiratory setting and a cardiac setting. The respiratory setting was covered in the original guidance and recommendations were made in people undergoing pulmonary resection and people with pneumothorax. At the time of the original guidance, there was no evidence for the cardiac setting and therefore this was not covered. Most of the studies are in a respiratory setting (n=15). Most studies were in the respiratory setting, including pulmonary resection for a range of indications (n=14), of which 2 were in paediatric populations (Alam 2020, Perez-Egido 2018), and pneumothorax (n=1). There were fewer studies in a cardiac setting (n=4) and the population was predominantly patients undergoing cardiac surgery such as coronary artery bypass.

Systematic Reviews and Meta-Analyses

Five potentially relevant systematic reviews (Aldaghlawi 2020, Wang 2019, Zhou 2018, Deng 2017 and Gao 2017) were identified in the searches however all included digital drainage devices in addition to Thopaz. Therefore, they are not directly relevant to the scope. The most recent systematic review (Aldaghlawi 2020), summarised below, was used to check that all relevant studies were identified by the searches for the respiratory setting.

Aldaghlawi 2020 The most recent systematic review (Aldaghlawi 2020) covered people after surgical resection or spontaneous pneumothorax and included a total of 23 studies of which 15 used the Thopaz/Thopaz+ device. Of these 15 included studies, 10 (Gilbert 2015, Jablonski 2014, Lijkendijk 2015, Marjanski 2013, Mier 2010, Miller 2016, Pompili 2011, Pompili 2014, Shoji 2016, and, Tunnicliffe & Draper 2014) were appraised as part of the original guidance; 4 were identified by the update searches (Arai 2017, De Waele 2017, Pompili 2016 and Takamochi 2018). One study was not accounted for. Chiappetta 2018 was not identified by the searches and the EAC cannot electronically access the full text to verify whether this study uses Thopaz/Thopaz+. Outcomes reported include mean chest tube duration and mean length of hospital stay for post-operative and secondary to spontaneous pneumothorax air leak. There is no meta-analysis included due to heterogeneity of the individual studies and therefore no results are discussed here.

Respiratory Setting

Randomised Trials

Alam 2020 is a randomised controlled trial based in India. The study randomised a total of 100 patients with empyema thoracis undergoing open decortications (50 to Thopaz and 50 to conventional chest drainage system). Patients of all ages were eligible for inclusion but most were children and young people; mean age in the standard care arm was 21.78±15.8 years (range 2 to 61 years) and was 19.87±14.6 (range 1.8 to 58) in the Thopaz group. Outcomes for the study included duration of air leak, duration of post-decortication chest tube placement, post-operative length of hospital stay, pre and post-operative lung function (FEV1, FVC) and post-operative complications. Results indicated FEV1 and FVC increased significantly in both groups post-operatively ($p<0.05$) compared with pre-operative measurements. Patients managed with Thopaz had a significantly shorter duration of air leak (5.34 days vs. 7.16 days; $p=0.001$), shorter duration of post-decortication chest tube placement (7.44 days vs. 10.44 days; $p=0.001$) and shorter length of hospital stay (10.16 vs. 14.76 days; $p=0.001$) compared with standard care. There was a statistically significant difference in post-operative complications between the two groups with fewer in the Thopaz group ($p<0.05$). No pneumothorax or subcutaneous emphysema was reported in the Thopaz group postoperatively compared with 6 each in the standard care arm.

De Waele 2017 is a randomised controlled trial based in Canada. The study randomised a total of 112 adult patients undergoing lung resection of primary or secondary lung malignancies (56 allocated to conventional analogue drainage and 56 randomised to digital drainage using Thopaz). Nine patients were excluded peri-operatively leaving a total of 103 patients in the final analysis (50 in the conventional analogue drainage arm and 53 in the digital arm). The primary outcome was total quantity of pleural drainage and secondary outcomes included chest tube duration, length of hospital stays, 90-day mortality and postoperative morbidity, rate of re-intervention, 30-day hospital readmission and pleural inflammatory markers. Results indicated no significant difference in mean volume of total pleural drainage between the groups (conventional analogue 944.0ml vs. Digital 1,001.4ml; p=0.467). Chest tube duration was shorter in the Thopaz arm but the difference was not statistically significant (2.3 versus 2.5 days; p=0.055). Incidence of prolonged post-operative air leak was significantly higher when using the conventional analogue system compared with Thopaz (p=0.025). No significant difference in length of hospital stay was observed between the groups (4.9 vs. 4.8 days, p=0.403). Analysis of pleural inflammatory mediators indicated elevated IL-8 (908.12 vs. 575.67pg/ml; p=0.009) and TNF-α (3.1 vs. 1.21 pg/ml, p=0.001) on the first day post-operatively with the use of conventional analogue drainage systems compared to Thopaz. On post-operative day 2 and 3 there was a significant increase in pleural fluid IL-8 concentration in the Thopaz group (790.20pg/mL) however while pleural IL-8 levels decreased in the analogue arm (to 588.58pg/mL) in the same time period (p=0.034).

The study also reported significant differences in outcomes when comparing open vs. video-assisted thoracoscopic surgery (VATS) procedures and lobar vs. sub-lobar procedures regardless of the drainage system used (details reported in Appendix C).

Ruigrok 2021 is a randomised trial based in the Netherlands. The study randomised 102 adult patients with a primary spontaneous pneumothorax (PSP) to conventional analogue or digital drainage (Thopaz). Outcomes of the trial included length of hospital stay and recurrence of pneumothorax within 12 weeks. Cross-over to another drainage system was allowed and there were 4 crossovers from conventional analogue to digital and 1 cross-over from digital to conventional analogue during the study. Study results indicate no significant difference in duration of chest tube drainage (median 3 vs. 2 days; p=0.488) or hospital length of stay (median 3 vs. 2.5 days; p=0.640). In total, 19 patients underwent surgery due to prolonged air leak (6 in the conventional analogue group and 13 in the digital group (p=0.127)) and after excluding these patients, duration of chest tube drainage (median 1 vs. 3 days; p=0.024) and length of stay (median 1 vs. 3 days p=0.014) were significantly shorter in patients in the digital drainage arm compared with conventional analogue drainage. Three patients in each group had a clinically relevant pneumothorax within 1 week of discharge. Excluding patients with recurrence within one week, 7 patients in the conventional analogue group and 4

patients in the digital group had a recurrence (clinically relevant pneumothorax within 12 weeks).

Takamochi 2018 is a randomised trial based in Japan. The study randomised 320 patients undergoing anatomic lung resections to either digital chest drainage with Thopaz or conventional thoracic drainage. Outcomes for the study included duration of drain placement, duration of post-operative leak, frequency of post-operative leak, frequency of postoperative pleurodesis, days of hospitalization and postoperative adverse events. Results of the study reported no significant difference in duration of chest tube placement (median 2 days with Thopaz and 3 days with conventional analogue; p=0.149), length of hospital stay (6 days with Thopaz vs. 7 days with conventional analogue, p=0.548), incidence of post-operative air leaks (0.867) or frequency of post-operative adverse events (p=0.361) between the two groups. Frequency of chest tube clamping trial before removal was significantly lower with Thopaz (0.7% vs. 35.3%; p<0.001).

Non-Randomised Studies

Arai 2018 is a retrospective case-control study based in Japan. The study included a review of 540 lung surgeries performed in a single hospital between April 2014 and March 2015 (265 treated with a conventional 3 bottle drainage system and 275 treated with Thopaz). Outcomes included operative blood loss, operation time, duration of chest tube placement, chest tube reinsertions, clamping test and re-operation rates. Results indicated no significant difference between the groups for blood loss (Thopaz 34ml±96.5 vs. conventional 45.2mls±122.6; p=0.237), duration of chest tube placement (Thopaz 2.4days vs conventional 2.3 days; p=0.678), rate of chest tube reinsertion (8 reinsertions in Thopaz group reinsertions vs 6 in conventional group p=0.637), clamping test (9 in Thopaz group vs 15 in conventional group; p=0.178) or reoperation (4 reoperations in Thopaz group vs. 3 in conventional group; p=0.520). There were 5 incidences of minor complications in patients treated with the Thopaz system including increased air flow (n=1), marked subcutaneous emphysema (n=1), device malfunction (n=1) and canister displacement (n=2).

Perez-Egido 2018 is a prospective, observational study based in Spain. The study included 13 paediatric patients undergoing pulmonary resection and the Thopaz digital drainage was used. The group was compared with a historical cohort of patients in whom conventional drainage was used. Outcomes included duration of chest tube placement, number of postoperative radiographs, length of hospital stay and complications. The median number of days with the chest tube was 2 in the Thopaz group compared with 4 in the analogue group (p<0.05). Median number of postoperative radiographs was 3 in the Thopaz group vs. 4 in the analogue group (p<0.05). Median length of hospital stay in the Thopaz group was 4 days versus 7 days in the analogue group (p>0.05). No complications related to use of the Thopaz system were reported. It should be noted that the results section in the main text of the paper reports median values but the abstract reports mean values but it is not

clear why this is the case. The results reported in the abstract are included in the data tables in Appendix C for reference.

Cardiac Setting

Randomised Trials

Van Linden 2019 is a randomised controlled trial based in Germany. The study randomised 354 adult patients (340 included in analysis) undergoing cardiac surgery. There were 16 cross-overs giving 152 patients in the Thopaz+ arm and 188 in the analogue arm. Outcomes included number of drains, amount of evacuated fluid, chest tube duration, length of ICU stay and length of hospital stay. The mean number of drains per patients was 2±0.8 and the median amount of fluid evacuates was 705ml with analogue drain and 686ml with Thopaz+ ($p=0.83$). Total chest tube duration was significantly shorter with Thopaz+ compared with analogue drainage (median 49 hours vs. 65 hours; $p\leq0.01$) but the length of ICU stay (median 1 day for both arms, $p=0.57$) and length of hospital stay (median 9 days for both arms, $p=0.65$) were not significantly different between the arms. Incidence of chest x-rays with clamped drains to detect air leaks was significantly lower with Thopaz+ compared with analogue drainage (8.6% vs 20.2%; $p<0.01$).

Barozzi 2020 is a randomised trial conducted in Italy and Switzerland. The study randomised 120 adult cardiac patients undergoing elective coronary artery bypass graft and/or valve surgery. There were 7 cross-overs from Thopaz+ to conventional analogue drainage, 2 for massive air leak due to incorrectly connected reservoir, 2 after reoperation for bleeding and 3 for surgeon preference. There was no significant difference in size and number of tubes between the two groups. There was significantly higher drainage in the Thopaz+ group at the end of operation before transport and on arrival in ICU ($p<0.01$), after which no difference in drainage was reported between the groups. Mean duration of chest drainage was not significantly different with 29.8 hours with Thopaz+ and 38.4 hours with analogue drains ($p=0.19$).

Halfway through the study, a web-based Satisfaction Assessment Questionnaire was completed by 52 healthcare professionals (12 ICU nurses, 10 operating room nurses, 16 ward nurses, 8 surgeons and 6 cardiac anaesthetists). Satisfaction with Thopaz+ was overall reported as “high” although nurses reported slightly lower satisfaction for ease of use and use for data collection. All staff scored Thopaz+ highly for noise reduction and for mobility.

Non-randomised studies

Tamura 2021 is a retrospective study based in Japan which included 80 consecutive adult patients (n=42 analogue drainage and n=38 digital drainage with Thopaz) who underwent cardiac surgery (excluding coronary artery bypass grafting only, with or

only aortic surgery, emergency operation, and patients with haemolysis). Outcomes included duration of chest drainage, rate of drainage related complications and length of hospital stay. The study reported a significantly shorter duration of drainage in the Thopaz group (Analogue: 94.8± 31.5 vs. Digital: 81.1 ± 20.6 h, p = 0.036) and the length of hospitalisation was significantly shorter in the Thopaz group compared with analogue drainage (Analogue: 22.7 ± 7.9 vs. Digital: 19.5 ± 7.2 days, p = 0.041, although it should be noted that elsewhere in the paper length of hospitalisation is reported to be Analogue: 21.9±5.3 vs. Digital: 18.8±7.2 days, p = 0.031). No significant difference in duration of ICU stay was reported between both groups (p = 0.134).

Saha 2020 is a retrospective study based in Germany which included 265 consecutive adult patients who underwent cardiac surgery. There were 65 patients with analogue conventional drainage systems and 200 patients with digital systems (Thopaz+) and the majority of patients had undergone coronary artery bypass grafting (72.5%). The amount of fluid collected during the first 6 hours post-operatively was significantly higher with Thopaz+ (250ml vs. 200ml with analogue systems; p=0.043) but the total amount of fluid collected did not differ between the groups (p=0.741). Length of stay on ICU (median 2 days for both Thopaz+ and analogue drainage; p=0.107) and total hospital stay (median 14 days for both groups; p=0.714) were similar in both groups. Clotting of connectors in the tubing system was observed in 13 patients with a digital drainage system (p=0.042) which were managed by a change of tubing system without any further negative implications for the patients. The authors noted that as analogue display units do not provide any alarms, there may have been undetected clotting events in the analogue group.

A questionnaire about user experience was completed by 11 doctors and 59 nurses. ICU staff did not report any difference in ease of set-up, connection of tubes, ease of obtaining probes, positioning of CDUs or reading of displays/scales however on the regular wards, the Thopaz+ system was significantly more favoured (p<0.001).

5.5 Cost update

Updating the original MTG37 model using changes to the unit costs and the calculated cost for reinsertion of chest drains indicated that Thopaz+ remains cost saving compared to standard care. The estimated saving per patient arising from Thopaz+ (£107.99) is attenuated by a very small amount compared to that of NICE MTG37 (£111.34) (NICE, 2018). The full costing report can be found.

6. Summary of new information and implications for review

The new evidence for the respiratory setting is unlikely to have a material effect on the recommendations in the published guidance. The EAC concluded that the key evidence consisting of 4 randomised controlled trials broadly suggests that outcomes

for patients are more favourable with digital drainage using Thopaz/Thopaz+ when compared with analogue drainage systems. However, the differences were only significant in 1 study.

The EAC updated the cost model using changes to the unit costs and the calculated cost for reinsertion of chest drains. It showed that Thopaz+ is still cost saving. The EAC considered that as all the new randomised trials continue to show a reduced length of hospital stay with Thopaz/Thopaz+ and as the economic model is most sensitive to changes in length of hospital stay, Thopaz/Thopaz+ is likely to remain cost saving.

The new evidence for the cardiac setting is unlikely to have a material effect on the recommendations in the published guidance. No evidence for the use of Thopaz/Thopaz+ in a cardiac setting was available at the time of the original guidance and therefore no recommendation could be made for its use in this setting. The EAC consider that the costs associated with use of Thopaz/Thopaz+ and analogue comparators are likely to be similar to those in the original cost model for respiratory settings. The current evidence from 4 studies (2 RCTs and 2 retrospective studies) in the cardiac setting indicates that although the duration of chest drainage in 3 studies was shorter with Thopaz than with analogue drainage (Tamura 2021, van Linden 2019, Barozzi 2020), there is uncertainty around the impact on duration of hospital stay with one retrospective study reporting significantly shorter duration (Tamura 2021) and 2 studies (1 RCT and 1 retrospective study) reporting that the duration of hospital stay was the same for both groups (van Linden 2019, Saha 2020). One clinical expert considered that 0.5-day reduction in drain removal or hospital length of stay would be clinically significant but noted that many factors can affect this. One expert said that following cardiac surgery in the UK, patients stay in the ICU for 1 to 2 days and on the ward for 6 to 8 days. Duration of chest drain is not the most important factor in determining length of stay but is one of the factors. Other factors include patient co-morbidities, renal function, pulmonary rehabilitation, and cognitive function. Early removal of chest drains allows the patient to improve mobility and thus can lead to better post-operatively recovery and shorter hospital stay. Compared with standard care Thopaz can improve recovery. However, one expert highlighted that completed randomised controlled trials in the setting are small and it can be difficult to appropriately power them. As the original cost saving was due to a reduced length of hospital stay, it is possible, based on the currently available evidence that Thopaz/Thopaz+ may not be cost saving in a cardiac setting. This however cannot be stated with certainty without a full review of the economic model cost and resource inputs to ensure that they are appropriate to the cardiac setting, as well as discussion around the most appropriate choice of hospital stay data.

There were no reports on the MHRA website for Thopaz+. However, 1 additional adverse event, reporting injury due to an undetected gas leak, was reported on FDA

Maude in 2021. This is a single device failure and not indicative of a widespread recall or design problem.

7. Implementation

According to the company Thopaz+ has been used in about 50 hospitals England. In 22 of those trusts, the technology was used for more than 1 department (i.e., thoracic, respiratory, trauma, ICU, upper GI and cardiac). There are 33 hospitals using it in thoracic departments (including a small number of private hospitals) and 20 using it in respiratory departments. Additionally, 3 hospitals are using it in cardiac departments.

8. Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were raised in the original guidance. No new equality issues were identified during guidance review.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

Published

PleuraFlow Active Clearance Technology for maintaining chest tube patency (2017) NICE medtech innovation briefing 125

Insertion of pleuro–amniotic shunt for fetal pleural effusion (2006) NICE interventional procedures guidance 190

In progress

None found.

Registered and unpublished trials

Trial name and registration number	Details
Ideal regulated pressure level on the digital thoracic drainage system for earlier resolution for postoperative air leak after pulmonary resection: A prospective multicentre randomized trial Trial: JPRN-jRCT1032180388	Intervention & comparator: thoracic drainage is performed after pulmonary resection under the setting of pleural pressure at -8cmH2O or -15cmH2O on the Thopaz or the Thopaz+ Status: recruiting Target sample size: 206 Estimated primary completion date: Not stated Location: Japan Respiratory setting
Prospective Randomized Trial of the Effectiveness of Managing Postoperative Air Leak between Electronic Versus Traditional Chest Drainage System in Pulmonary Resection Trial JPRN-UMIN000016715	Status: Recruitment complete: follow up complete Primary comparator: conventional chest drainage system Target sample size: 300 Estimated primary completion date: Not stated Location: Japan Respiratory setting

Trial name and registration number	Details
A Randomized, one-center, Phase 2 Study to Compare the efficacy of the treatment of patients with spontaneous pneumothorax (SP) with air leak (AL) using digital versus traditional suction drainage systems. Trial ACTRN12613000931774	Status: Recruitment complete Primary comparator: conventional suction drainage systems. Target sample size: 60 Estimated primary completion date: Not stated Location: Poland Respiratory setting
Manual Aspiration Versus Digital drainage system in spontaneous primary pneumothorax: open blinded two parallel group randomised controlled trial Trial ISRCTN46137912	Status: Recruitment completed Primary comparator: traditional analogue drainage Target sample size: 104 Estimated primary completion date: Not stated Location: Spain Respiratory setting
Comparison of Two Different Pleural Drainage Systems Trial NCT03021369	Study design: randomised controlled trial Status: Recruitment completed Primary comparator: pleural drainage with analogue Actual enrolment: 374 Completion date: March 2018 Location: Germany Cardiac setting
A Randomized Comparison of Active Suction vs. Passive Chest Tube Drainage and Regulated and Unregulated Pleural Pressure After Anatomic Lung Resection Trial NCT02282462	Status: recruitment completed Primary comparator: analogue system Atrium OCEAN Estimated enrolment: 600 Completion date: December 2017 Location: US The company confirmed that this study is not continuing.

Appendix 3 – changes to original guidance

Section of MTG	Original MTG	Proposed amendment
Page 4, 1.3	Cost modelling indicates that Thopaz+ is cost saving compared with conventional chest drains in people after pulmonary resection. The estimated saving is £111 per patient per hospital stay, with savings mainly achieved through reduced length of stay. The NICE resource impact assessment shows that, at a national level, adopting Thopaz+ is expected to save around £8.5 million per year in England.	Cost modelling indicates that Thopaz+ is cost saving compared with conventional chest drains in people after pulmonary resection. The estimated saving is £108 per patient per hospital stay, with savings mainly achieved through reduced length of stay [2022]. The NICE resource impact assessment shows that, at a national level, adopting Thopaz+ is expected to save around £8.5 million per year in England.
Page 5, 2.2	The rental cost of each Thopaz+ unit, as stated in the company's submission, is £115 per month. It can also be purchased for £3,400.	The rental cost of each Thopaz+ unit, as stated in the company's submission, is £115 per month. It can also be purchased for £3,570 [2022].
Page 9, 3.10	The company's base case resulted in a cost saving per patient of £35.56 for Thopaz+ compared with conventional chest drainage over the length of hospital stay. After the EAC's changes, this cost saving increased to £111.33 per patient.	The company's base case resulted in a cost saving per patient of £35.56 for Thopaz+ compared with conventional chest drainage over the length of hospital stay. After the EAC's changes, this cost saving increased to £107.99 per patient [2022].
Page 11, 4.8	The committee noted that the estimated cost savings with Thopaz+ of £111.33 per patient in people after pulmonary resection was largely attributable to a reduced length in hospital of up to 1.5 days (average 0.4 days) per patient compared with conventional chest drainage. The committee considered the implications of this reduced length of stay and whether it was realisable in practice. The clinical experts explained that the continuous, objective monitoring possible with Thopaz+ helps reliable decisionmaking and encourages earlier chest drain removal and discharge. The committee noted that Thopaz+	The committee noted that the estimated cost savings with Thopaz+ of £107.99 per patient in people after pulmonary resection was largely attributable to a reduced length in hospital of up to 1.5 days (average 0.4 days) per patient compared with conventional chest drainage [2022]. The committee considered the implications of this reduced length of stay and whether it was realisable in practice. The clinical experts explained that the continuous, objective monitoring possible with Thopaz+ helps reliable decision making and encourages earlier chest drain removal and discharge. The committee noted that Thopaz+

	remained cost saving even with a difference in length of stay of only 0.071 days.	remained cost saving even with a difference in length of stay of only 0.071 days.
Page 12, 4.10	The committee considered the different options through which Thopaz+ is available (that is, purchase or rental). It noted that the EAC scenario analysis based on a £3,400 purchase price resulted in increased savings of £124.76 per patient. However, including the purchase of 5-year warranties reduced the cost savings by £1.90 per patient. The company stated that leasing arrangements are available and that volume purchasing discounts are available; for example, buying over 20 devices would reduce the individual purchase price to £2,700.	The committee considered the different options through which Thopaz+ is available (that is, purchase or rental). It noted that the EAC scenario analysis based on a £3,570 purchase price resulted in increased savings of £120.74 per patient. However, including the purchase of 5-year warranties reduced the cost savings by £1.96 per patient [2022]. The company stated that leasing arrangements are available and that volume purchasing discounts are available; for example, buying over 25 devices would reduce the individual purchase price to £3,000 [2022].
Page 12, 4.12	The committee concluded that cost savings are also likely in people with pneumothorax. It noted that the EAC's scenario analysis, which produced a cost saving of £550.90 per patient, was based on a single comparative study. This reported a larger difference in length of hospital stay between Thopaz+ and conventional chest drain use in people with pneumothorax compared with people after pulmonary resection (1.9 days compared with 0.4 days). The clinical experts clarified that shorter drainage times and lengths of stay were plausible in this patient group. The committee concluded that Thopaz+ is likely to be cost saving in people with pneumothorax, but that the evidence is more uncertain than in people after pulmonary resection.	The committee concluded that cost savings are also likely in people with pneumothorax. It noted that the EAC's scenario analysis, which produced a cost saving of £653.82 per patient, was based on a single comparative study [2022]. This reported a larger difference in length of hospital stay between Thopaz+ and conventional chest drain use in people with pneumothorax compared with people after pulmonary resection (1.9 days compared with 0.4 days). The clinical experts clarified that shorter drainage times and lengths of stay were plausible in this patient group. The committee concluded that Thopaz+ is likely to be cost saving in people with pneumothorax, but that the evidence is more uncertain than in people after pulmonary resection.
Page 12, 4.14		For the guidance review, the external assessment centre revised the model to reflect 2021 costs (original guidance values given in brackets). The main

		parameter changes were the cost of Thopaz+ £3,570 (£3,400). Further parameter changes were associated with staff costs, bed days, complications. Further details of the 2021 revised model are in the revised model summary [2022].

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