NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

The Thopaz+ portable digital system for the management of chest drains

1 Technology

1.1 Description of the technology

Thopaz+ (Medela UK) is a portable digital chest drain system that provides regulated negative pressure close to the patient's chest and continuously monitor the air leak. Thopaz+ maintains negative pressure at a level prescribed and set by the managing physician. The digital display provides objective air leak data in real time as well as in historical graphs, which allows tracking of the therapy progress. Thopaz+ also monitors fluid drainage and therefore measures fluid loss as well.

Thopaz+ consists of an in-built, regulated suction pump with digital display, rechargeable battery, tubing to connect to any standard chest drain catheter and a Thopaz+ disposable fluid collection canister. Thopaz+ is compact and lightweight (223 x 255 x 95 mm and 1 kg) and has an early warning alarm to alert users if safety issues arise, such as a full canister, blocked tubing or a low battery.

Thopaz+ is intended to be used by suitably trained healthcare professionals in hospital operating theatres, intensive care and high dependency units as well as recovery wards.

1.2 Regulatory status

The Thopaz system first received a CE mark in 2008 (Thopaz) and 2014 (Thopaz+) as a class IIb medical device (classification from IIa to IIb due to Indication Extension, addition of mediastinal indication, in November 2012). Thopaz+, the upgraded device with both digital fluid and air leak management was launched in to the UK in 2014[1].

[1] From 2017 only the Thopaz+ system will be available to new users, although the manufacturer will continue to support both systems.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- Reduced chest tube duration
- Reduced length of hospital stay
- Reduced rates of patient complications
- Higher patient satisfaction

The benefits to the healthcare system claimed by the sponsor are:

- Reduced hospital costs
- Increased convenience for doctors and nursing staff
- Improved chest drain management
- Better prediction of patient outcomes

1.4 Relevant diseases and conditions

In England in 2014-15, there were 31,710 episodes of insertions of tube drains into the pleural cavity, 10,853 drainages of the pleural cavity and 6,633 episodes requiring attention to tube drains into the pleural cavity[1].

Thopaz+ is indicated for all people who receive a chest drain, such as those requiring thoracic drainage from the pleural and mediastinal cavities in circumstances such as pneumothorax, recovery after cardiac or thoracic surgery (post-operative), thorax injury, pleural effusion, pleural empyema or other related conditions.

1.5 Current management

Chest drains are used after all types of thoracic surgery to assist with drainage of air and fluid from the pleural cavity and encourage the re-inflation of the lung. Chest drains are kept in place after surgery until the lung(s) has re-inflated, fluid drainage has reduced and air drainage stopped (NHS Scotland – patient information).

Insertion of chest drains is recommended in the NICE guideline for major trauma in the management of chest trauma in pre-hospital and hospital settings, but chest drain management is not covered by NICE guidance.

The British Thoracic Society (BTS) guidelines on pleural disease include recommendations for chest drain insertion. The guidelines state that chest drains should be connected to a drainage system that contains a valve

[1] Hospital Episode Statistics

mechanism to prevent fluid or air entering the pleural cavity. This may be an underwater seal, flutter valve or other recognised mechanism. Underwater seal chest drains appear to be the standard of care in the NHS and consist of a water seal, suction control and drainage collection bottle. These drains collect fluid and prevent backflow into the pleural cavity while at the same time allowing a subjective assessment of air leaks and fluid loss. The drainage bottle must be placed below chest level and kept upright. Suction may or may not be needed depending on the patient's condition, but can be provided with underwater seal drains usually using a wall suction unit.

After a chest drain is inserted (by a surgeon or physician, it is attached to the Thopaz+ drainage system, usually by a nurse. Air leak and fluid drainage is monitored using a readout on the digital display.

2 Reasons for developing guidance on Thopaz systems for the portable digital management of chest drains

The committee concluded that Thopaz+ has the potential to offer significant patient and healthcare system benefits, compared with standard care for patients who require a chest drain for pleural conditions or following thoracic surgery. The evidence suggests that Thopaz+ may reduce the duration of chest tube requirement and hospital length of stay, improve patient safety and aid clinicians in decision-making about the timing of chest drain removal.

The committee considered that there is uncertainty around clinical outcomes for patients managed with Thopaz+ in the community, but considered that exploring this further would be an important element to the evaluation.

3 Statement of the decision problem

	Scope issued by NICE
Population	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.
Intervention	Thopaz+
Comparator(s)	• Underwater seal chest drains • Chest drains using a flutter valve or any other recognised valve mechanism
Outcomes	The outcome measures to consider include: • duration of chest tube placement • incidence of drain re-insertion

	• fluid loss measurement • length of hospital stay • rates of complications and device-related adverse events • staff time • patient satisfaction (including measures of patient discomfort)	
Cost analysis	The intervention and comparators for the cost analysis are described above. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters.	
Subgroups to be considered	Use in children. Specific indications: • pneumothorax (differentiating spontaneous and other air leaks) • post-operative use after cardiac or thoracic surgery • patients with pleural disease • thoracic trauma or injury	
Special considerations, including those related to equality	No equality issues were identified. People undergoing thoracic surgery as a result of a long-term condition may be classed as disabled under the Equality Act 2010.	
Special considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

- Major trauma: assessment and initial management. NICE clinical guideline NG39 (February 2016) Available from https://www.nice.org.uk/guidance/ng39

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association for Perioperative Practice (formerly National Association of Theatre Nurses)
- Association of Operating Department Practitioners
- Association of Paediatric Emergency Medicine
- Association of Surgeons of Great Britain and Ireland
- Association of Upper GI Surgeons
- British Association of Critical Care Nurses
- British Cardiovascular Intervention Society
- British Cardiovascular Society
- British Thoracic Society
- Faculty of Intensive Care Medicine
- Intensive Care Society
- National Association of Theatre Nurses
- Primary Care Respiratory Society
- Royal College of Emergency Medicine
- Royal College of Nurses
- Royal College of Physicians
- Royal College of Surgeons
- Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS)

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association for Perioperative Practice (formerly National Association of Theatre Nurses)
- Association of Operating Department Practitioners
- Association of Paediatric Emergency Medicine
- Association of Surgeons of Great Britain and Ireland
- Association of Upper GI Surgeons
- British Association of Critical Care Nurses
- British Cardiovascular Intervention Society
- British Cardiovascular Society
- British Thoracic Society
- Faculty of Intensive Care Medicine
- Intensive Care Society
- National Association of Theatre Nurses
- Primary Care Respiratory Society
- Royal College of Emergency Medicine
- Royal College of Nurses
- Royal College of Physicians
- Royal College of Surgeons
- Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS)

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- British Heart Foundation
- British Lung Foundation
- British Red Cross

- Cardiovascular Care Partnership (UK)
- Critical Care Patient Liaison Committee (CritPaL)
- Cystic Fibrosis Trust
- ICD Patient and Family Heart Support Group
- June Hancock Mesothelioma Research Fund
- Pulmonary Fibrosis Trust
- Pumping Marvellous Foundation
- Roy Castle Lung Cancer Foundation
- Royal College of Surgeons of England
- Trauma Care
- UK Health Forum (formerly National Heart Forum)
- UK Lung Cancer Coalition (UKLCC)
- Wound Care Alliance UK