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Clinical guidelines

Chest drainage with the Thopaz+ digital chest drainage system

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Medela Healthcare provides pioneering solutions for airway and surgical suction, vacuum-assisted delivery, fluid collection, chest drainage management and Negative Pressure Wound Therapy (NPWT).

Michael Larsson
Chairman of the Board, Medela AG

Editorial Review Board

Contents

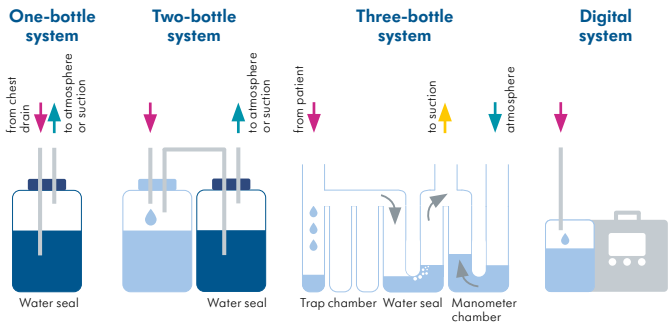
Context

The Thopaz+ system is designed to be used in conjunction with chest drains. This document will:

- Provide an overview of chest drainage after lung and heart surgery
- Describe the advantages and disadvantages of the different options currently available
- Describe the Thopaz+ digital chest drainage and monitoring system

Historical perspective

It has been understood for many years that chest drainage is often needed after certain thoracic surgical procedures. However, methods have remained stagnant for over 30 years, with only minor updates in technology. Water seals have been the most widely used way of managing chest drains. The simplest water-seal drains involve a one-bottle system (Figure 1).[1] The chest drain is connected to a tube that leads into a pre-filled (with sterile water) bottle. The bottle must be placed below the patient so it can function as a water seal to prevent air from returning into the patient. The **one-bottle system** allows small amounts of air to be drained from the pleural cavity, but is less appropriate for the management of fluid and may not be able to manage large air leaks. When fluid contents are drained from the patient, the fluid level rises in the one-bottle system. This requires an adjustment of the tube or more force is required to remove the air from the pleural cavity. Fluid drainage can be facilitated with the addition of a second bottle in the **two-bottle system**. This acts as a reservoir for collected fluid and reduces the production of foam.[1] The water-seal bottle prevents air from returning to the patient. As with the one-bottle system, a suction source can be added to the venting tube. **Three-bottle system:** When external wall suction is added to a system, a third bottle can be added to adjust the negative pressure (Figure 1). The distance the vent tube is placed below water is equal to the negative pressure generated. This means if the tube is placed below 3 cm of water, this can be interpreted as –3cmH_2O of negative pressure.



The traditional disposable systems available in some hospitals are based on the three-bottle system, combining them into one unit. However, these chest drainage systems have several disadvantages.[2] For instance, to determine a patient's healing status, users rely on a manual reading of drained fluid and a subjective bubbled reading in the water-seal chamber. The Quantification of bubbles can vary between between the staff who are assessing these and conventional water-seal drains can have poor inter-observer reliability.[3] They are not ideal for air leak monitoring over time as they only provide a snapshot view of the situation.[3] Water seals are also unreliable and can be lost if there is a leak in the system. Water-seal drains need to be placed below patient level and can be knocked over or disconnected, rendering them useless. There is no automatic means of alerting attending health-care professionals (HCPs) to blockages or other problems with water-seal drain systems. Identification of problems relies on carrying out regular visual inspections.

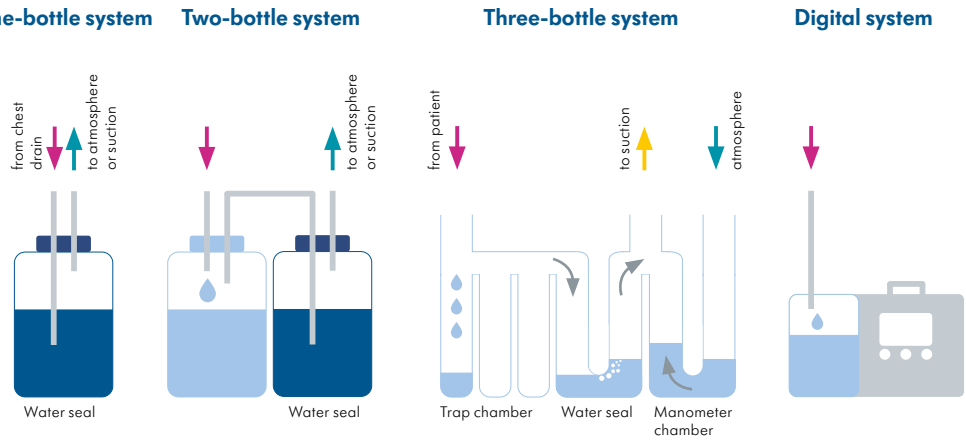
These systems are often reliant on wall suction. The setting on the wall suction regulator is not always what is applied to the patient. This can vary depending on several factors, including:

- The amount of fluid in the tube
- The elevation of the device relative to the patient
- Uncontrolled siphoning effects within the chest tube
- Sudden coughing
- Variable lung compliance, etc.

A column of fluid advancing downwards along the chest tube may transmit a sub-atmospheric pressure inside the chest, which corresponds to the distance reached by the fluid within the tube. If the fluid stops moving, it may actually increase resistance and, in turn, increase pleural pressure with risk of pneumothorax.

Any system using wall suction restricts patients' mobility. If patients disconnect the drains to mobilise themselves on the ward, there is a potential risk of infection, or clinical deterioration.[4]

The advent of modern digital drainage systems, which are able to detect air leaks and maintain preset intrathoracic pressure ("regulated pressure"),[5] have helped to address the above problems.



	One-bottle system	Two-bottle system	Three-bottle system	Digital system
Air-tight seal	✓	✓	✓	✓
Can drain air	✓	✓	✓	✓
Can be used with suction	✓	✓	✓	✓
One-way valve	✓	✓	✓	✓
Designed to manage fluid	x	✓	✓	✓
Provides regulated negative pressure when required	x	x	x	✓

Figure 1 – Comparison of traditional "water-seal drain" methods of chest drainage with digital methods.[1]

Clinical rationale behind chest drainage

Chest drains are commonly used to manage accumulations of air or fluid, including blood and pus. They can be inserted into the pleural space surrounding the lungs (Figure 2) or into the mediastinum surrounding the heart (Figure 3).

Removal of air, blood or other fluid from the pleural cavity

The visceral pleura covers the outside of the lungs and the parietal pleura adheres to the thoracic wall, the mediastinum and the diaphragm. The space between the lungs and thoracic wall, between these two pleura, is called the pleural space (Figure 2). The pressure inside this space is usually negative.

The pleural space is normally filled with between 2–4 ml of pleural fluid which lubricates the layers, allowing them to slide smoothly across each other during breathing. The pleural fluid also forms a seal that holds the outer surface of the lungs against the inner surface of the thoracic wall. This ensures that when the chest cavity expands with breathing, the lungs are kept in contact with the thoracic wall, allowing expansion of the lungs and therefore air can be drawn in. The negative pressure inside the pleural space also facilitates this close contact.

When the pleural cavity is contaminated with air, blood or too much fluid, patients have difficulty breathing (dyspnoea). Consequently, they may be unable to mobilise and find that they have to sit upright. Using their accessory muscles, breathing feels exhausting and requires more effort, which can lead to hyperventilation. Affected patients may require extra oxygen, and possible advanced ventilatory support.

Pneumothorax

A pneumothorax occurs in the event of an injury to the thoracic cavity or the lung that allows air to enter the pleural cavity. As this air cannot evacuate the chest, the lung collapses, creating a gap of air and separation of the pleural layers (Figure 2). This is informally known as a "collapsed lung". Removal of air from the pleural cavity is mediated via a drain inserted into the pleural space.

There are many causes of a pneumothorax including trauma (e.g. from a fracture penetrating the lung or a gunshot wound), post-surgical complication (e.g. after pulmonary resection), oesophageal perforation, respiratory failure or a bronchopleural fistula. Iatrogenic causes can include damage caused during central-line placement. A pneumothorax can also occur spontaneously.

A tension pneumothorax describes an accumulation of air in the pleural space under positive pressure. This compresses the lung and decreases venous return to the heart. The contents of the thorax are forced to the opposite side of the chest putting extra pressure on the heart and the uninvolved lung. This is an acute life-threatening emergency situation that requires immediate attention, such as needle decompression followed by the placement of a chest drain to remove the air from the pleural cavity.

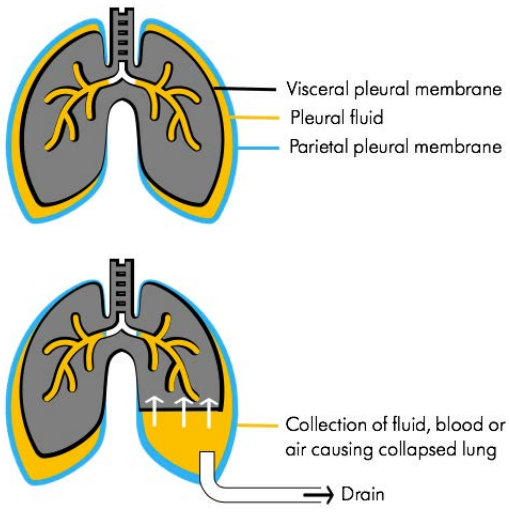


Figure 2 – Use of pleural drains to manage collections of air (pneumothorax), fluid (pleural effusion) including collections of serous fluid or blood (haemothorax) in the pleural cavity.

Pleural effusion

Pleural effusion is a generic term used to describe the build-up of fluid in the pleural cavity. This prevents the lung from expanding properly and can be caused by many different conditions including cancer, liver cirrhosis, and emphysema. Pleural effusion can be classified depending on the type of fluid involved as described in more detail below:

- Haemothorax
  Haemothrorax is defined as a collection of blood within the pleural cavity. By definition, a bloody pleural effusion contains a haematocrit value of at least 50% of the haematocrit of peripheral blood (Figure 2). Haemothorax may occur in the event of traumatic injury to the thoracic cavity, but can also arise as a result of post-surgical bleeding.
- Haemopneumothorax
  Haemopneumothorax refers to the collection of both blood and air in the pleural space.
- Empyema
  Empyema is defined as a collection of pus in a pre-existing cavity such as the pleural space. Empyema is caused by lung infection, most commonly pneumonia, but can also occur after injury or chest surgery.

These clinical indications typically require surgical intervention and commonly a chest drain would be used post-operatively to remove air, blood or fluid from the pleural space. The drainage tube is connected to a chest drainage device (Figure 2).

Removal of fluid from the pericardial space

The heart and the origins of the major arteries are enclosed in a double lining called the pericardium. This consists of an outer fibrous layer and an inner double layer of serous membrane. The fluid-filled pericardial cavity is between the two innermost serous membranes, the visceral pericardium and the parietal pericardium. The pericardial fluid serves to reduce friction between the pericardial membranes (Figure 3).

Cardiac tamponade

Cardiac tamponade occurs in the event of an injury to the heart or origins of the major vessels, most commonly following cardiac surgery. This leads to an accumulation of blood in the pericardial space, compression of the heart and reduced cardiac output. Patients may present with Beck's triad — distended veins in the neck caused by impaired diastolic filling, hypotension and muffled heard sounds.[6] This results in reduced ventricular filling and subsequent haemodynamic compromise. The build-up of fluid needs to be addressed via an emergency reintervention most often followed post-operatively by placement of a drain inserted into the pericardial space (Figure 3).

Post-operative atrial fibrillation (POAF)

Atrial fibrillation is an important complication that can arise through ineffective post-operative drainage.[7] POAF is one of the most common complications after heart surgery, occurring in 20% to 60% of patients,[8] and significantly increasing hospital costs and readmissions.[9] The reported incidence of atrial fibrillation following coronary artery bypass graft (CABG) is between 10% and 40%.[7]

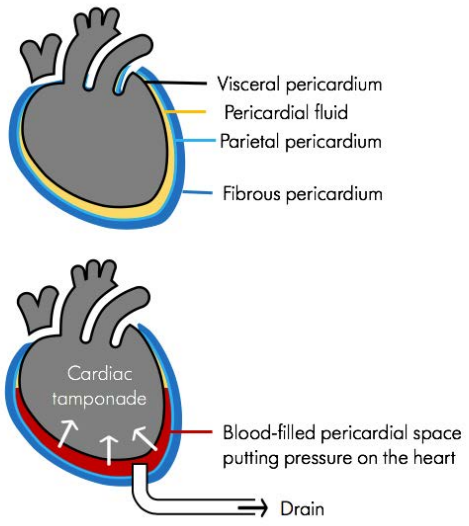


Figure 3 – Use of cardiac drains to manage collections of blood in the pericardial space to relieve cardiac tamponade.

General principles for the management of chest drains

Pulmonary procedures

Air leaks

Air leaks are the most common complication after pulmonary resection.[1] They can be caused by a tear in the visceral pleura and peripheral lacerations of the lung.[10] While around 50 % of all patients experience some form of air leak,[11] in as many as 25 %, a prolonged air leak can occur.[12] This can be defined as an air leak that lasts more than 5 days.[1]

There has been much debate around definitions,[10] and little published information describing the correct timing for chest drain removal.[13] Ultimately, the responsibility for the decision is in the hands of the attending physician. Historically, the situation has been compounded by use of traditional chest drainage methods because these are unable to objectively measure air leaks. The use of digital systems that can quantify air leaks is the basis to develop standardised criteria to help decide when to remove chest drains.[14] Research has shown that data from digital systems have the potential to allow prediction of air-leak resolution, which may ultimately guide effective clinical decision-making.[12] The ability to predict fast-resolving air leaks may speed up chest drain removal and hospital discharge.[12] Indeed, consideration of early removal of chest drains in such patients has been a recent focus of interest among thoracic surgeons.[15]

Fluid drainage

The volume of fluid obtained from a chest drain is closely monitored. While, drainage needs to reduce before a chest drain can be removed, in practice, the cut-off point ranges from 250 ml/day to 450 ml/day, with little consensus.[1,3] Physiologically, daily pleural fluid filtration is estimated to be 350 ml, hence, many authors suggest removal when daily recorded drainage volume is less than 300 ml.[5] Guidelines for enhanced recovery after lung surgery, produced by the Enhanced Recovery After Surgery (ERAS®) Society and the European Society of Thoracic Surgeons (ESTS), and published in 2018,[16] recommend a relatively high pleural fluid output for chest drain removal (up to 450 ml/day).

A randomised controlled trial suggests the protein content of the drained fluid helps determine the timing of chest tube removal[15]. Accordingly their data suggests that a pleural fluid-to-blood protein ratio of less than 0.5 is a good indicator of safe chest drain removal.[15] Lymph fluid and blood need to be substantially absent from the fluid before the drain is removed (i.e. non-chylous, non-haematic).[5,16]

Use of this criterion may facilitate removal, reducing post-operative hospital stays (to the benefit of both patients and clinicians) while decreasing treatment costs for healthcare providers.[15]

Table 1 summarises key questions that may be used to determine whether a pleural chest drain is ready for removal.

Cardiac procedures

Multiple chest drains are often required following cardiac surgery. During surgery, lungs may have been deflated to enable the cardiac surgery to proceed and are reinflated towards the end of the procedure. Post-operatively, a chest drain may need to be inserted into the pleural cavity to keep the lungs reinflated. Patients undergoing coronary artery bypass grafting (CABG) may have the pleura opened and if both internal mammary arteries are used, there will be both left and right pleural drains. More commonly, the left internal mammary artery is used. Dissection of this may involve opening the left pleura, which will necessitate an appropriate drain.

Valve operations typically require a mediastinal and pericardial drain. The mediastinal drain lies in front of the heart whilst the pericardial drain is positioned under the diaphragmatic surface of the heart. Sometimes the mediastinal drain acts as a pleural drain as well; the side holes are in front of the heart whilst the tip of the tube lies high in the pleural space.

Recent ERAS® guidelines describing perioperative care in cardiac surgery state that while there are no standard criteria for the timing of mediastinal drain removal, evidence suggests that these can be safely removed as soon as the drainage becomes macroscopically serous.[18] Criteria for the removal of pericardial drains typically follow local practice, varying between countries and also on a hospital level. In some institutions, pericardial drains may be routinely removed at 6 a.m. when this is deemed appropriate, but in other instances, physicians may be guided by X-ray results.

Avoidance of complications is critical

Pain, drain blockage and accidental dislodgement are common complications of chest drains. More serious complications include organ injury, haemothorax, infections, and re-expansion pulmonary oedema. Protocols that reduce the duration of chest drain placement may reduce the risk of infection. Also, once chest drains are removed, associated pain recedes.

Should negative pressure be applied to chest drains? The debate

There has been conflicting evidence as to the value of negative pressure in chest drains. Suction promotes pleura-pleural apposition helping to seal air leaks and drain large air leaks. Lack of suction may compromise drainage of large air leaks and has been associated with an increased risk of other complications, such as pneumonia and arrhythmia.[16] However, in some circumstances, not applying suction may reduce the duration of air leaks,[19] presumably as a consequence of decreased air flow. In relation to this, suction can increase the flow through the chest drain proportional to the level of suction applied[20], and as previously mentioned, patient mobilisation is reduced if wall suction is used.

Given the contested benefits of applying wall suction to water-seal systems compared to a water seal alone, three meta-analyses have investigated a variety of outcomes in patients with these drains.[21–23] In all three meta-analyses, the incidence of post-operative pneumothorax was found to be significantly reduced following suction compared with water-seal alone.[21–23] However, in two of these analyses, no differences in length of hospital stay or the duration of the drains were observed with suction and no-suction water-seal protocols[21,22] while one study favoured the water seal alone.[23]

These underwhelming clinical outcomes, coupled with the fact that the patient is immobilised when external (unregulated) wall suction is used, have led recent guidelines produced by ERAS® and the European Society of Thoracic Surgeons to recommend that external wall suction is NOT used following lung surgery.[16]

It is important to recognise that digital chest drainage systems do not provide suction in the same way as wall suction. Their use is widely believed to provide benefits not provided by water-seal drains with or without suction.[16,24,25] The Thopaz+ digital chest drainage and monitoring system regulates pressure, providing suction only when necessary.

The evidence base describing the benefits of Thopaz+ is outlined on the following pages.

Table 1. Key questions to determine whether a chest drain is ready for removal. Local protocols may differ and should take precedence.

Is the drained fluid non-chylous?[16]
Does the drained fluid contain an acceptably low level of blood?
Has the air leak dropped to an acceptable level?
Do other factors support the decision to remove the chest drain? e.g. lung expansion on chest X-ray[17]

Benefits of Thopaz+

Thopaz+ is a digital chest drainage and monitoring system. At the end of a surgical procedure, if a decision is made to insert a chest drain, then a choice can be made regarding how to manage the chest drain according to the options shown in Figure 1. The choice of which negative pressure to apply to the chest drain should be made according to clinical judgement. The case for adopting Thopaz+ for managing chest drains is supported by the published clinical evidence.

In 2014, the original Thopaz digital chest drainage device was upgraded, resulting in the Thopaz+ device that is available today. Improved features include better handling and a graphic user interface, improved trouble-shooting support, improvements to the internal filters (making the device more hygienic), and new features to assess chest drainage management (measurement of fluid quantities and pleural pressure). The basic function of the Thopaz and Thopaz+ devices – to act as a digital chest drainage system – has not changed, and so their ability to improve clinical outcomes is considered to be equivalent.[24] Clinical evidence reported for the original Thopaz device therefore applies equally to the upgraded Thopaz+ device.[24]

The benefits of the Thopaz+ chest drainage system are shown in Figure 4.

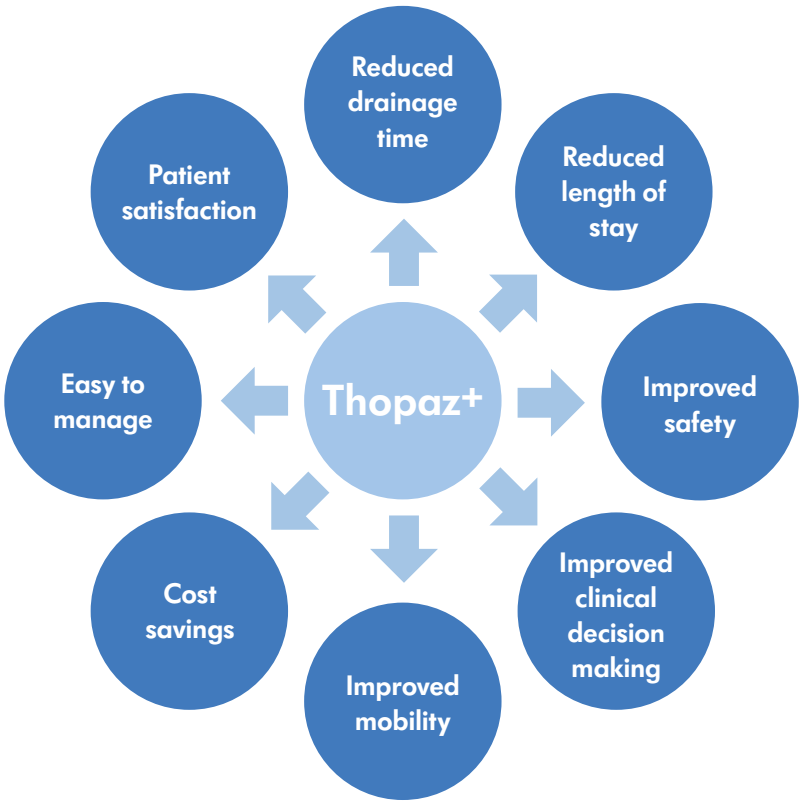


Figure 4 – Benefits of choosing Thopaz+ digital chest drainage system

Reduced drainage time

Patient outcomes may be improved by adopting less conservative management strategies for chest drains.[16] The longer a chest drain is in place, the higher the risk of complications such as infection, empyema, recurrence of pneumothorax and bleeding. In addition, patients find chest drains painful and respiratory function is inhibited. The recent guidelines describing thoracic surgery produced by ERAS® and the European Society of Thoracic Surgeons have highlighted the importance of early chest drain removal.[16]

Results from a number of studies showing statistically significant reductions in chest drain duration highlight the benefits available with the Thopaz+ system. Results from a multicentre, international, randomised controlled trial involving a total of 381 pulmonary resection procedures performed on 191 patients receiving digital drainage and 190 patients with traditional drains showed that those randomised to digital systems had a significantly shorter duration of chest drain placement (mean of 3.6 vs 4.7 days; p=0.0001).[26]

Several comparative studies have also shown statistically significant reductions in chest drain duration with the digital management system compared to traditional drains after pulmonary resection (Table 2). A recent study shows the significant reduction in chest tube duration after cardiac surgery (Table 3).

Based on the evidence available, guidelines produced by the UK National Institute for Health and Care Excellence (NICE) support the use of Thopaz+, stating "Thopaz+ can reduce drainage time."[25]

Table 2. Comparative studies showing reduced chest drain duration with digital management compared with traditional drains after pulmonary resection

	Chest drain duration, days (number of patients)		
Study	Traditional drain	Thopaz system	P value
Miller et al.[27]	5.3* (n=40)	3.7* (n=20)	0.01
Pompili et al.[26]	4.4 (n=51)	2.5 (n=51)	<0.0001
Shoji et al.[28]	3.7 (n=86)	2.7 (n=86)	0.031
Mier et al.[29]	4.5 (n=25)	2.4 (n=26)	0.00

*Median values; all other duration data show means.

Table 3. Comparative study showing reduced chest drain duration with digital management compared with traditional drains after cardiac surgery

	Chest drain duration, hours (number of patients)		
Study	Traditional drain	Thopaz system	P value
Van Linden et al.[38]	65* (n=188)	49* (n=152)	≤0.01

*Median values

Reduced length of stay in hospital

As well as enabling shorter chest drain times, three separate studies have shown that patients treated with Thopaz had shorter hospital stays than those receiving conventional/analogue drainage.[26,27,30] Results from the previously mentioned randomised controlled trial involving pulmonary resection procedures showed a mean length of stay of 4.6 (digital) and 5.6 (traditional) days respectively ($p<0.0001$).[26] The Benefits of digital drainage have also been quantified for patients experiencing a spontaneous pneumothorax with air leak: In a randomised controlled trial involving 60 affected individuals randomised to either a digital drainage device or traditional drainage, those receiving the digital device had a mean hospital stay length of 5.1 days, vs 7.0 days for those receiving traditional drainage. ($p<0.001$). The corresponding values for mean drainage duration were 48 and 85 hours respectively ($p<0.001$).[31] In addition, results from two of the comparative studies mentioned above also described reduced length of hospital stay with the digital drainage compared with conventional method, with medians of 4.1 and 5.6 days ($p=0.05$), respectively, in one,[27] and means of 4.5 and 6 days ($p<0.0003$), respectively, in the other.[26]

On the basis of available evidence, the NICE guidelines state that "Thopaz+ can reduce... length of stay in hospital."[25] These guidelines also recommend that "Thopaz+ should be considered for people who need chest drainage after pulmonary resection or because of a pneumothorax."[25]

Improved safety

Studies have documented fewer adverse events in patients treated with Thopaz compared with alternative ways of managing chest drains. In a randomised controlled trial involving a total of 64 patients who underwent pulmonary resection, Thopaz significantly reduced complication rates compared with traditional drainage (25% vs 50% [$p=0.039$]).[20] In addition, one of the comparative studies mentioned above also reported fewer overall complications with the digital system compared with conventional drainage: 22% vs 35% ($p=0.01$).[27,32]
The NICE guidelines state that "Thopaz+... improves safety for people with chest drains."[25] The system has built-in alarms.[25] Users can be warned of potential problems, such as patients losing large amounts of fluid, as well as system leakage, tube blockage, a full canister or a low battery.

Improved clinical decision making

When using traditional systems, it can be a subjective decision to understand when an air leak has resolved. The decision to remove the drain may therefore be delayed, in turn delaying hospital discharge in many cases. The recent series of guidelines for thoracic surgery produced by the ERAS® and the European Society of Thoracic Surgeons stated that "Digital drainage systems reduce variability in decision-making and should be used."[16]

The Thopaz+ system may improve clinical decision making through continuous, objective monitoring of air leaks and fluid loss.[25] The ability to store information and display trends in air leaks over time allows more informed decision-making about chest drain removal.[16] Inter-observer and clinical practice variability is reduced.[3,16,33] Scientific monitoring of patient progress provides a more scientific rationale for drain management and removal.[2] An article describing a single-centre randomised controlled trial involving Thopaz+ concluded that "the technology holds promise for leading to a deeper understanding of pleural space mechanics after pulmonary resection, and to refinement of evidence-based practice in chest drain management."[34] Furthermore, in patients with spontaneous pneumothorax, digital air leak measurements early in the treatment course have the potential to predict future treatment failure.[35]

Improved mobility

In the multicentre, randomised controlled study mentioned above, patients perceived an improved ability to get out of bed following surgery when using Thopaz compared with traditional chest drainage ($p=0.008$).[26] The light weight of the Thopaz+ system and its ability to offer portable suction provide benefits in this regard.[2] Indeed in another study, evaluation of patient and staff feedback following the use of Thopaz in 120 surgical cases found that "patients appreciated that it was portable and light which meant they could mobilise on suction, giving them more independence."[4] This study also reported that, as patients could be mobilised earlier, nursing and physiotherapy were easier.[4]

On the basis of available evidence, the NICE guidelines state that Thopaz+ allows "increased mobility which aids recovery…." [25] Use of Thopaz has been reported as part of a regimen employing early mobilisation in an attempt to improve outcomes after lung cancer surgery. [36] However, Thopaz+ is also relevant for patients needing chest drainage after cardiac surgery and trauma, as well as after pulmonary resection. [25]

Cost savings

Thopaz+ is more cost-effective than traditional chest drainage. [24,25] Studies have shown that using the Thopaz+ system saves up to £550 per patient treated for pneumothorax, and £111 per patient per hospital stay after pulmonary resection. [24,25]

Cost savings are driven mainly by reduced length of stay. [24] However, NICE modelling confirming the cost savings included a range of parameters to reflect both evidence and practice: [25]

- A hospital stay of 5.4 days for Thopaz+ and 5.8 days for conventional chest drainage
- A drainage time of 3.5 days for Thopaz+
- Costs for consumables and training associated with standard drainage
- Cost of chest drain reinsertion and complications
- Consumer and training costs for Thopaz+

Easy to manage

Digital drainage systems may improve and unify hospital practice. [5] Their simplicity enables relatively easy introduction into hospital wards and theatres. [2] Thopaz+ has a user-friendly set up, and nurses report being pleased that with such technology, which contains sealed, dry-unit canisters, there is no need for priming and the risk of spillage/infection is reduced. [4] On-screen displays and alarms increase the safety of patient management and facilitate accurate assessment of air leaks. [4] Greater consensus with regard to the severity of air leaks may translate into increased cooperation among multidisciplinary care teams. The importance of such cooperation, and communication to execute patient care algorithms for air-leak management, cannot be overemphasised. [33]
As a consequence of this objective evaluation and clear definition of algorithms, chest drain removal may be delegated to staff nurses. [37] Furthermore, use of digital chest drainage technology may help to streamline communication and agreement in the clinical research setting, allowing air leaks to be objectively assessed following procedural interventions. [33]

Higher rates of patient satisfaction

Increased patient satisfaction is apparent with Thopaz+. [25] In the multicentre, randomised controlled study mentioned above, patients treated with Thopaz reported that the system was more convenient than conventional technology. [26] Fewer patients felt they would want to change the system compared with those treated with a traditional drainage device. [26]

In another study, where patients appreciated the portability and light weight of the system enabling them greater mobility as described above,[4] patients had more independence. They preferred the lack of bubbling noise and the compactness over conventional drains and suction. This feedback was particularly prominent in individuals with pneumothoraces who had previously experienced standard water-seal bottles on continuous wall suction. [4] Greater mobility may reduce complications associated with decreased mobility, as well as benefitting patients' privacy and dignity. [2]

Thopaz+ system

Product details

Thopaz+ is a high-quality digital chest drainage and monitoring system. The compact system provides regulated negative pressure close to the patient's chest. It monitors the air leak and the and the collection of fluid. Thopaz+ only applies the vacuum required to maintain the negative pressure prescribed and set by the managing physician. As this is a dry system, no fluids are necessary for operation.

Thopaz+ has an electronic measuring and monitoring system with optical and acoustic status indications. A digital colour display provides objective data in real time as well as in historical graphs, which allows easy tracking of the progress of therapy. When therapy is complete, the data can be transferred to a computer.

Thopaz+ operates quietly and has a light sensor to regulate screen brightness, enabling adjustment to the surrounding light conditions and avoiding night-time disturbance.

The main elements of Thopaz+ are shown in Figure 5.

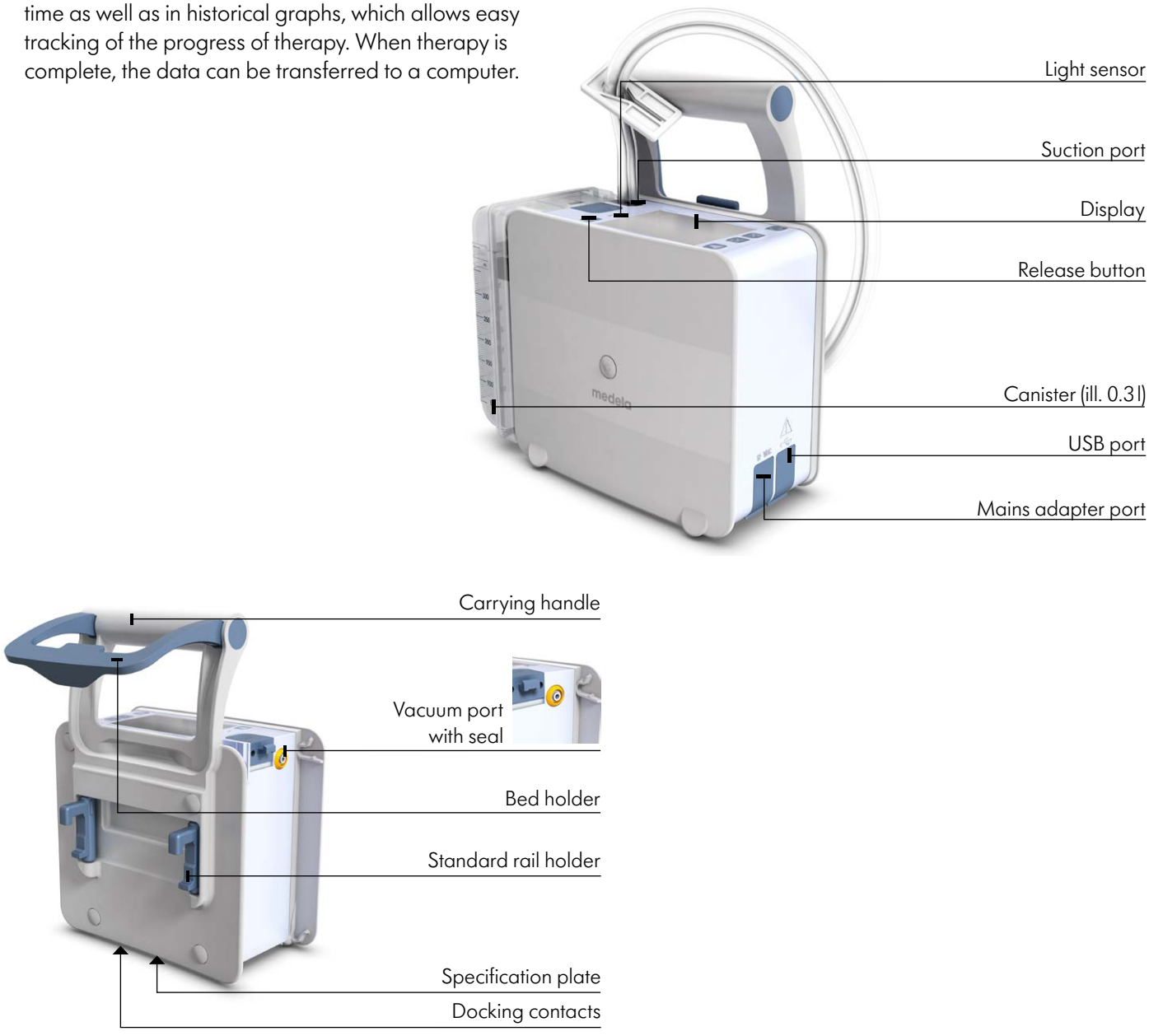


Figure 5 – Main elements of Thopaz+

Indications

Thopaz+ is used for chest drainage in the pleural and mediastinum. It can be used after:

- Pneumothorax
- Cardiac or thoracic surgery
- Thorax injury
- Pleural effusion
- Pleural empyema
- Or other related conditions

Thopaz+ is indicated for all situations where chest drains are applied.

Thopaz+ is intended to be used for aspiration and removal of surgical fluids, tissues, gases, bodily fluids or infectious materials and for use on patients in appropriate care settings.

Contraindications

There are no known contraindications.

Application

Please refer to the product Instructions for Use to obtain detailed guidance on the application of Thopaz+. Additional safety information is provided in the Quick Reference Guide at the end of this booklet.

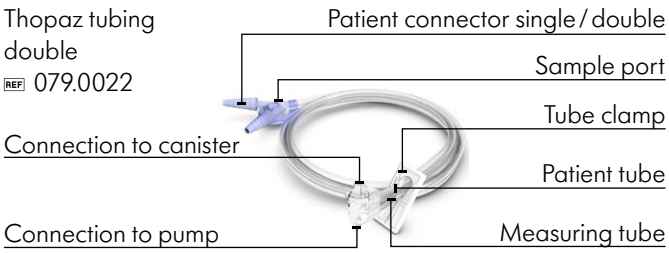
IMPORTANT: Please review all the available safety information before using Thopaz+.

Step 1. Check before use

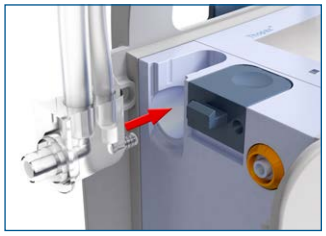
Check the Thopaz+ system for damage and to ensure proper functioning. The seal should be correctly placed in the vacuum port. The battery should be charged in case the system will be operated in the battery mode.
All accessories should be checked (and replaced if necessary) and the connectors must be firmly attached.

Step 2. Select and connect the Thopaz tubing

Patient tubing is available with normal, small and large single or double patient connectors. It is recommended to use the biggest possible connector size compatible with the catheter.



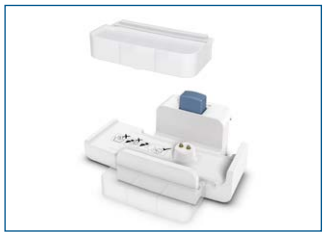
Open the external packaging containing the tubing, keeping the patient connector in the internal bag for hygiene reasons. Insert the smaller of the two connectors (the connection to the pump) horizontally in the direction of the arrow.



Step 3. Snap in the canister

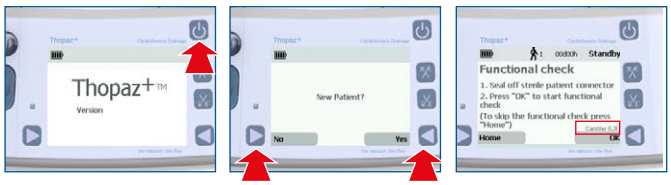
Unpack the canister. Position the openings at the top and attach the bottom part of the canister to Thopaz+.
Push the canister into the unit until a "click" is heard.

Canisters are available in three sizes: 0.3l, 0.8l and 2l. Each of these is available with or without solidifier (which aids disposal, see below). If a 2l canister is used, the adapter to the optional docking station must be attached.



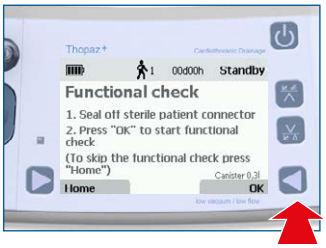
Step 4. Switch on Thopaz+

It is important that Thopaz+ is switched on before connecting the system to the patient. When Thopaz+ is switched on, a self-test will start, after which an acoustic signal (beep) will be heard. After this, confirm whether a new patient will be connected, so that Thopaz+ can issue a new patient number if necessary. The patient number enables patient-specific recording of data. Next, check that the size of the canister attached is correctly displayed on the screen; if not, dispose of the canister.



Step 5. Perform a functional check

Seal the connector of the patient tubing with a thumb through the packaging and ensuring the tubing is not kinked. Press "OK" on Thopaz+. If the test is passed, Thopaz+ will be on Standby and ready for use with the factory settings.



Connect the Thopaz+ system to the patient catheter (drain) according to hospital guidelines. To start the therapy, press "On".

Place the tubing with the sample port facing towards the patient.

If the Thopaz+ system fails the functional check, it will be necessary to rectify any leaks.

Step 6. Check progress of therapy

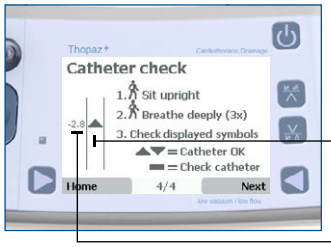
The main display of the Thopaz+ system displays the current size of the air leak and the total amount of fluid collected.

An additional fluid management parameter can be set to zero at any given time, by pressing the button indicated below for more than 3 seconds. A timer then indicates when the parameter was set to zero and the volume of drained fluid in that time period. To reset the timer and fluid volume, press the same button again for more than 3 seconds. The total amount of fluid drained is not influenced by this.

Step 7. Catheter check

The catheter check works only with a patient drain (catheter) in the interpleural space and is only active if the air leak is 0 ml/min. Access the air leak history first, then scroll to page 4/4 by pressing "Next".

When accessing the catheter check, follow the on-screen instructions. A pressure difference of a minimum of 3 cmH_2O between inspiration [▲] and expiration [▼] is displayed at an air leak of 0 ml/min. This pressure difference is an indication for the respiration cycle of the patient and confirms that the patient catheter (drain) is not clogged.



▲ ▼ Patient catheter (drain) open

▬ Patient catheter (drain) clogged?

This number shows the maximum and minimum pressure measured for each breathing cycle. This pressure is indicated by the set pressure unit.

Step 8. After therapy

To switch Thopaz+ off, clamp the patient tubing with the tube clamp, then clamp the patient catheter (drain). Press "Standby" for longer than 3 seconds to switch off the pressure. Press [⏻] to switch off Thopaz+.

Remove and seal the canister with the canister seal. Dispose of the canister and patient tubing in accordance with internal hospital guidelines. Clean Thopaz+ according to the general cleaning guidelines.

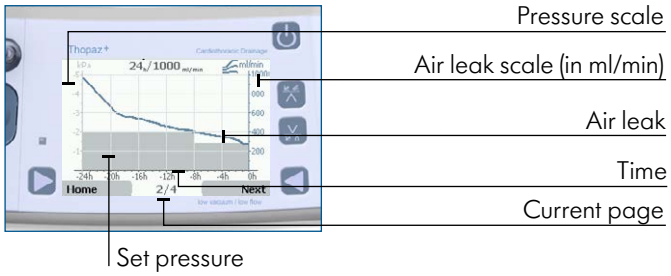
Step 9. Transferring data to a PC (optional)

Connect Thopaz+ to a PC via a USB cable. Data can then be transferred using the ThopEasy+ software provided on the Thopaz+ CD provided with the system.

Data collection

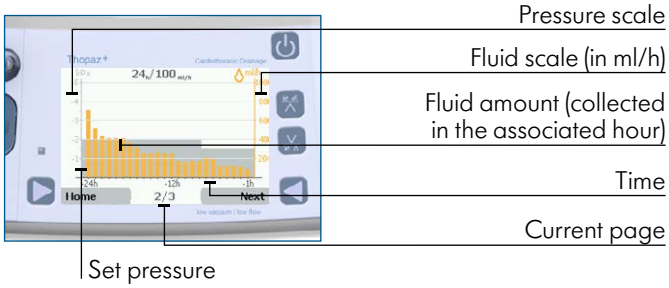
In addition to the current size of the air leak and the total amount of collected fluid collected during therapy, Thopaz+ provides graphs of the air leak and fluid history.

Three different air leak history graphs can be accessed via a button on the main display: 72 h/Autoscale, 24 h/1000 ml/min, 24 h/100 ml/min, plus the catheter check. The air leak autoscale history graph adjusts the air leak scale to the largest measured air leak from the last 72 h to 1000/2000/3000/4000/5000 ml/min.



To scroll through the graphs press "Next". To return to the main display, press "Home".

Three different fluid history graphs can be accessed via a button on the main display: 72 h/Autoscale, 24 h/100 ml and 6 h/Autoscale. The fluid autoscale history graph shows the total amount of fluid collected over the last 72 h.



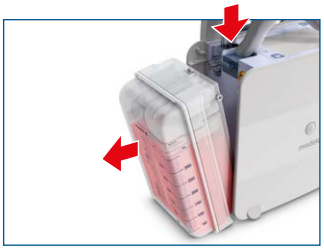
To scroll through the graphs press "Next". To return to the main display, press "Home".

During treatment with Thopaz+

Canister replacement

Canisters should be replaced based on a visual check or the appearance of relevant instructions on the Thopaz+ display (a warning signal). Canister changes should be recorded for safety reasons.

To change a canister, clamp the patient tubing with the tube clamp. Switch Thopaz+ to Standby by pressing "Standby" for longer than 3 seconds. Press the release button to release the used canister and then remove the canister.



Unpack a new sterile canister and then attach this to Thopaz+ as previously described, ensuring the canister size matches that detected. Press "On". When the pressure has built up, unclamp the patient tubing and check that the air leak value appears to be accurate.

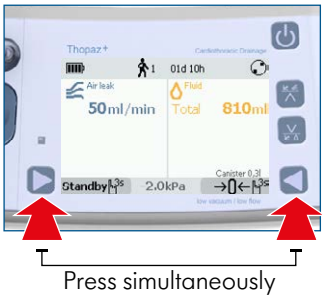
Canister disposal

Used canisters should be sealed with the canister seal and disposed of according to internal hospital guidelines.

For used canisters with solidifier and "press & shake™" technology, check the canister is sealed. Then press the middle of the solidifier chamber to open and shake (to activate the solidification process) before disposal.

Changing pressure during operation

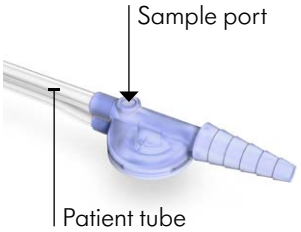
The negative pressure may only be changed by a physician or under medical direction. Press [▶] and [◀] simultaneously, then change the pressure by pressing [▲] or [▼] and confirm with "OK" [◀].



Physiological pressure can be activated for patients who are to be treated by gravity drainage (equivalent to a water seal). To do this, press "Physio" [▶] and confirm with "OK" [◀]. This mode corresponds to a pressure of -0.8 kPa/-6 mmHg/-8 cmH_2O/-8 mbar.

Taking a drainage sample

To take a drainage sample, ensure that the patient tube contains fluid, then clamp the catheter (drain). Switch Thopaz+ to Standby by pressing "Standby" for longer than 3 seconds. Disinfect the sample port (using hospital approved wipes) and remove air from the patient tubing with a syringe (17 G [1.4 mm] or thinner). Repeat the process until fluid has gathered at the sample port and a sample can be taken. Switch Thopaz+ on by pressing "On". To ensure Thopaz+ can reduce the pressure, it is essential to wait 30 seconds before unclamping the patient catheter (drain).



Quick reference guide

Intended use/indications

Thopaz+ is intended to be used on patients in appropriate care settings for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. It is indicated for all situations where chest drains are applied, particularly for thoracic drainage in the pleural and mediastinum in situations such as:

- Pneumothorax
- Cardiac or thoracic surgery
- Thorax injury
- Pleural effusion
- Pleural empyema
- Or other related conditions

Thopaz+ should only be operated by properly instructed users who should have adequate visual faculty and must not be hearing impaired or deaf. Physicians should evaluate the appropriateness of the treatment based on their knowledge and experience, complying with proper surgical procedures and techniques.

Contraindications

There are no known contraindications. However, Thopaz+ should only be used on patients exhibiting conditions as described above. The use of Thopaz+ for any other indication than intended is neither desired nor authorised. The Thopaz+ system is not designed for retransfusion.

Instructions

Thopaz+ should only be used by medically trained and qualified persons who have been adequately trained to use the device. The Instructions for Use are a general guide for the product, and medical matters must be addressed by a physician.

⚠ Warnings

Before operating Thopaz+ please read and observe the warning and safety points in the Instructions for Use. Key points are given below:

- Safe functioning of the system can only be guaranteed when Thopaz+ is used in combination with the original Thopaz+ accessories (canisters, tubing etc)
- Gloves should be worn for all operations
  - Do not touch the patient and the docking contacts simultaneously
- Do not use Thopaz+ in MRT (magnetic resonance tomography)
- The pressure range to be set must be determined by a physician in accordance with the age and weight of the patient
  - For paediatric patients adapt pressure settings according to hospital guidelines
- Patients should be regularly monitored according to internal hospital guidelines
- Do not use Thopaz+ if the drainage therapy indicates:
  - A pressure greater than the maximum pressure range of -10 kPa
  - A flow rate greater than the maximum flow capacity of 5 l/min
  - No pressure should be applied to a patient
- Do not connect bilateral thoracic drains to one Thopaz+ unit. In such cases, the use of two Thopaz+ units is recommended
- The catheter/connector interface is a location where clotting may occur. Regular monitoring of this interface is recommended and an appropriate removal procedure should be in place in case this occurs
- Thopaz+ is not suitable for use while bathing, showering or in a hazardous explosive environment
- Wireless communications equipment can affect Thopaz+ and should be kept at least 30 cm away
- If an internal fault occurs (e.g. broken cable, defective battery), Thopaz+ turns off and an acoustic warning is sounded for at least 3 minutes (powered by a backup battery)
  - Under these conditions Thopaz+ functions as a one-way valve. Replace Thopaz+ immediately
- A replacement must always be available for patients for whom the breakdown of Thopaz+ may lead to a critical situation

Other points relating to use

As with the warnings above, full details are available in the Instructions for Use. Key points are given below:

- Single use, sterile products are not intended to be reprocessed
  - Reprocessing could cause loss of mechanical, chemical and/or biological characteristics
  - Reuse could cause cross-contamination
- If a persistent air leak is indicated, check the system is assembled correctly before taking further corrective action. Ensure the system is airtight by clamping the catheter and observing the air leak decrease to zero
- Thopaz+ 2 l canisters are not for portable use (either by hand or using the carrying strap)

- All canisters should be replaced on the basis of a visual check or in line with the relevant instructions on the Thopaz+ display (a warning signal)
- When attaching a new canister, verify that the canister size displayed on the screen is the same size as the canister attached
- When taking a drainage sample, to ensure Thopaz+ can reduce the pressure, it is essential to wait 30 seconds between taking the sample collection and unclamping the patient catheter (drain)
- Data transfer via USB is not permitted during therapy
- After each use of Thopaz+, the parts that have been in contact with aspirated secretions must be cleaned and disinfected or disposed of
- Before cleaning Thopaz+, disconnect the plug from the mains socket

Abbreviations/Definitions

CABG
Coronary artery bypass graft

Cardiac tamponade
Compression of the heart resulting from an accumulation of fluid, pus, blood or gas in the sac in which the heart is enclosed.

Chest drain/chest tube
A flexible tube inserted through the chest wall and into the pleural space or mediastinum. Note that for the purposes of this article, the term chest drain has been used throughout.

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HCPs
Healthcare professionals

MRT
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NICE
National Institute for Health and Care Excellence

Pleural effusion
Abnormal accumulation of fluid in the pleural space.

Pleural empyema
One kind of pleural effusion, with an accumulation of pus caused by microorganisms, often occurring in the context of pneumonia, injury or chest surgery.

Post-operative atrial fibrillation (POAF)
An irregular heartbeat caused by uncoordinated contraction of the top two chambers of the heart, and occurring in patients after surgery.

Pulmonary resection
A surgical procedure to remove part, or all, of the lung, performed on patients with lungs that are diseased or damaged. These resections can be categorised as anatomical (also known as typical) resections (e.g. segmentectomy, lobectomy, pneumonectomy) and extra-anatomical (or atypical) resections such as wedge resections.

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CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

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