The product portfolio for post-operative wound drainage from pfm medical ag offers a variety of systems for drainage by high-vacuum for all clinical applications.

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## Foreword

## Drainage in breast surgery

Introduction and description of problem
Drainage systems (vacuum drainage)
Goals of using high vacuum wound drainage systems
General product description
Sequence of events in wound healing / Application of vacuum drainages
Drain placement in a wound
Advantages and disadvantages of high vacuum drainage


General principles of draining wound cavities in breast surgery
Placement drainage system
Case examples
Foreword

For over 200 years people have known how important it is to drain off body fluids. At first, metal tubes were used as drains, but only after the secretions had already occurred. Prophylactic wound drainage was first used by Heister in 1719. His technique made use of the principle of capillarity and is known today as a Penrose drain. In 1954, after centuries of improvement to the familiar drainage principle and experiments with negative pressure drains, Redon and colleagues succeeded in developing a high vacuum system for prophylactic drainage of wounds. This system enabled patients for the first time to be mobilised quickly. Redon drainage underwent many improvements during the rest of the past century, as did conventional gravity drainage. Low vacuum systems were also developed, making it possible to apply the principle in other fields as well. Today, development of clinical routine in wound drainage has reached a point where only detail improvements are possible. Further changes to the basic principle are unlikely.

Overview of the milestones in the history of drainage techniques

<table>
<thead>
<tr>
<th>Antiquity</th>
<th>Removal of pathological accumulation of secretion with metal tubes, and later with tubes made from stainless steel</th>
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</thead>
<tbody>
<tr>
<td>1719</td>
<td>Heister (GB)</td>
</tr>
<tr>
<td></td>
<td>First prophylactic wound drainage (Penrose drain)</td>
</tr>
<tr>
<td>1851</td>
<td>Chassaignac &amp; Potain (F)</td>
</tr>
<tr>
<td></td>
<td>First prophylactic wound drainage by suction</td>
</tr>
<tr>
<td>1898</td>
<td>Buelau (D)</td>
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<td>Siphon drainage in which suction is created with the aid of a waterjet pump</td>
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<td></td>
<td>A modified form of Buelau drainage is still in use today for thoracic drainage</td>
</tr>
<tr>
<td>1898</td>
<td>Heaton (USA)</td>
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<tr>
<td></td>
<td>Thoracic drainage with a suction pump driven by an electric motor</td>
</tr>
<tr>
<td>1949</td>
<td>Raffl (USA)</td>
</tr>
<tr>
<td></td>
<td>Motor-driven low vacuum wound drainage</td>
</tr>
<tr>
<td>1954</td>
<td>Redon, Jost, Troques (F)</td>
</tr>
<tr>
<td></td>
<td>Redon suction drainage (evacuated glass bottles with Redon suction drains)</td>
</tr>
<tr>
<td>1971</td>
<td>Introduction of pre-evacuated disposable plastic bottles</td>
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<tr>
<td></td>
<td>pfm medical GmbH founded by Jürgen Wolter</td>
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<tr>
<td>2000</td>
<td>Versatile application of drainage for many indications</td>
</tr>
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</table>
Drainage in breast surgery
Paepke S., Grosse Lackmann K., Ettl J., Paepke D., Kiechle M.

Introduction and description of problem

The formation of seromas is one of the most common complications following breast surgery. The sequence of events causing them is unclear. However it is possible to define subgroups of patients of whom a high percentage develop seromas leading to complications. Especially in these cases primary and secondary seroma formation can be reduced by using seroma-minimising techniques and instruments in the first place.

The basic principle in minimising the formation of seromas and haematomas is the diminution of wound cavities or so-called obliteration of dead space. This means actively adhere the areas mobilised, where extensive spaces are to be dissected, e.g. with active drainage creating negative pressure in the wound area. High vacuum drainage systems have this effect.

In the literature the incidence of seromas is reported as being between 15 and 81%. This makes seroma formation the most common complication of wounds.

A quality survey in the field of breast surgery performed in Bavaria, Germany, showed that, of 10,233 women undergoing breast surgeries in certified breast centres, 29.6% developed seromas. The different periods of time spent in hospital depend partly on complications such as bleeding/haematoma and seroma (see following table).

<table>
<thead>
<tr>
<th>Basic statistics</th>
<th>Hospital</th>
<th>Direct comparison (38 breast centres, German cancer association)</th>
<th>Total (165 hospitals/departments)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
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<td>Data sets</td>
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<tr>
<td>Patients</td>
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<tr>
<td>Unilateral treatment</td>
<td>425</td>
<td>100.0</td>
<td>408</td>
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<tr>
<td>Bilateral treatment</td>
<td>404</td>
<td>91.6</td>
<td>377</td>
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<tr>
<td>Operations</td>
<td></td>
<td></td>
<td>39</td>
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<tr>
<td>Operations per patient</td>
<td></td>
<td></td>
<td>504</td>
</tr>
<tr>
<td>Operations per breast</td>
<td></td>
<td></td>
<td>1.1</td>
</tr>
<tr>
<td>Operation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median duration of preoperative stay (days)</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
</tbody>
</table>
| Operation on day of admission | 149                     | 37.2                                                             | 69                                | 20.4                              | 2,262                              | 25.9                              | 2,189                              | 24.5                              | 23.2
| Operation on next day | 242                       | 60.4                                                             | 250                               | 73.0                              | 5,597                              | 64.1                              | 8,555                              | 65.6                              | 66.7
| Operation 2 – 4 days after admission | 6                      | 1.5                                                              | 15                                | 4.4                               | 298                                | 3.4                               | 536                                | 4.1                               | 4.2
| Operation 5 – 14 days after admission | 4                      | 1.0                                                              | 4                                 | 1.2                               | 292                                | 3.3                               | 451                                | 3.5                               | 3.9
| Operation over 2 weeks after admission | 0                      | 0.0                                                              | 1                                 | 0.3                               | 275                                | 3.2                               | 294                                | 2.3                               | 1.9
| Median duration of post-operative stay (days) | 4.0                     | 4.0                                                               | 4.0                               | 5.0                               | 4.0                                | 5.0                               | 4.0                                | 5.0                               |
| Outpatient surgery     | 0                         | 0.0                                                               | 1                                 | 0.3                               | 20                                 | 0.3                               | 49                                 | 0.4                               | 0.5
| Discharge on next day  | 7                         | 1.8                                                               | 5                                 | 1.8                               | 469                                | 5.4                               | 710                                | 5.5                               | 4.8
| Discharge after 2 days | 45                        | 11.2                                                              | 11                                | 12.1                              | 1,020                              | 11.7                              | 1,506                              | 12.2                              | 10.7
| Discharge after 3 – 7 days | 301                    | 75.1                                                             | 249                               | 73.2                              | 5,780                              | 56.3                              | 5,425                              | 64.6                              | 82.9
| Discharge after 8 – 14 days | 46                    | 11.5                                                             | 40                                | 11.8                              | 1,166                              | 13.4                              | 1,883                              | 14.5                              | 18.0
| Discharge after 15 days or more | 2                      | 0.5                                                               | 3                                 | 0.9                               | 209                                | 3.0                               | 378                                | 2.9                               | 3.1

Drainage in breast surgery

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Drainage in breast surgery

Seromas can have different causes. Most commonly they result from proinflammatory and inflammatory exudative processes in soft tissue. These are intensified by the release of lymph fluid occurring when lymph vessels are cut during breast surgery or when lymph nodes are removed in lymphadenectomies in breast surgery.

The lack of a clear definition of the term “seroma”, which reaches beyond the description of fluid accumulation in the wound cavity, is also a problem. The variation and lack of clarity in the definition make it difficult both to record the clinical situation and to make reliable scientific statements. The relevance of seroma formation varies considerably, especially as the degree of symptom development is not necessarily dependent on size, up to a clinically noticeable volume.

Any surgical procedure has a risk of leading to seroma formation, whether performed with a scalpel, by electrosurgery or using modern cutting techniques. Thermal and mechanical damages of tissue areas – adipose tissue, lymph vessels and muscle fascia in breast surgery – are established factors in this process.

Seromas are also formed as a result of acute inflammatory exudates in reaction to surgical injury, e.g. with large wound areas and incompetent sealing after mastectomy, intensified by the removal of sufficient lymph vessels and lymph node tissue as inflammatory exudates without bacterial colonisation. Axillary dissection, resulting in bloating of the tissue with axillary lymph exudate, is also a cofactor. The self-maintaining process of exudate formation is also problematic because it causes the wound surfaces to move apart so that local tissue connecting factors cannot act. The result is dead space which favours increased seroma formation.

Seromas can cause various problems. The main complications are caused by infections and other disruptions of wound healing. Their effect on further stages of treatment is also different, e.g. after breast surgery. Seromas per se present problems when planning and carrying out radiotherapy but do not, themselves, present an obstacle to systemic therapy. The resulting complications alone can cause delays in further stages of treatment. Such complications follow seroma formation in about 15% of cases.

Seroma formation has been found to be increased by the use of heterologous materials in reconstructive breast surgery, e.g. implants, meshes and acellular dermal matrices. In these cases the duration of drainage is longer than average and an abrupt increase is seen in the occurrence of secondary seromas (seromas forming after drainage tubes have been removed). Highly specialised hospitals, where operations with these materials are performed, thus record a higher incidence of complications.

Active high vacuum suction is the key treatment approach for preventing the formation of clinically or radiologically significant seromas and their after-effects, whatever the potential cause may be.
Drainage in breast surgery

**Goals of using high vacuum wound drainage systems**

**Preventing accumulation of secretion, blood and lymphatic fluid**
Every operation involves some intra-operative bleeding. Similarly, post-operative bleeding are not always avoidable. This bleeding occurs in a closed wound space and leads to haematomas or seromas that are cut off from the blood circulation and hence from the body’s own defences. They create an ideal culture medium for microorganisms.

**Relief of surrounding tissue**
Intra- or post-operative haematomas or seromas compromise the adjacent tissue surrounding the wound space. This interferes with natural wound healing and, in a few cases, can lead to infections.

**Improving wound area contact**
Haematomas and/or seromas hinder contact between the affected wound areas. This may lead to a prolonged healing process.

**Faster patient mobilisation**
Faster wound healing leads to faster mobilisation of patients and thus to a shorter stay in hospital. This benefits the patient and also saves costs.

**Removal of abscesses (emergency indication)**
Should pus accumulate in newly created tissue cavities that are closed on all sides, it can be released by means of targeted drainage.

**Vacuum drainages** actively suck out wound secretions by exerting negative pressure. This means they are able to drain off cells and fluids out of the wound cavity more effectively than passive systems. The edges of the wound continue to be pulled towards each other and stabilised by the vacuum. The process is known as wound edge alignment.

Vacuum drainage systems can be divided into:

**High vacuum drainage**
These systems work with an average pressure difference of about 900 - 990 mbar.

**Low vacuum drainage**
These systems work with an average pressure difference of about 100 - 250 mbar.

Unlike low vacuum drainage systems, high vacuum drainage systems use pre-evacuated bottle systems with rigid walls. With exception of contraindications, such as the use in serous membranes, high vacuum drainage systems can be usefully applied almost universally. They are ideal for cleansing large wound areas because of their strong suction capability and the large capacity of the bottles.
General product description

① Drain connector
② Connection tube
③ Tube clamp
④ Bottle clamp
⑤ Tubing connector
⑥ Hanger / Vacuum-level indicator
⑦ Quick fastener
⑧ Vacuum indicator
⑨ Rough graduation
⑩ Fine graduation
⑪ Redon drain

Parts ①, ② and ③ are only included in the OR system packs.

Part ⑪ is only included in special packs (Redon sets) and is shown here for information purposes only.

Both the OR systems and ward systems are available with Luer Lock connectors on the connection tube ② and/or tubing connector ⑤.
Drainage in breast surgery

The wound has been closed with sutures. A fluid consisting of blood, cells and bits of tissue has accumulated in the wound cavity. The blood in the wound cavity starts to coagulate from the ground of the cavity upwards. A haematoma forms and stops the bleeding. The haematoma presses on the surrounding tissue making this process painful for the patient. Leucocytes enter the area through the tissue and surrounding vessels. Together with further substances reaching the area via blood vessels, these leucocytes act to dissolve the haematoma in the wound cavity. This process is associated with an increase in the acidity of the surrounding tissue, which swells as a result. At this stage the wound can easily burst open, letting in bacteria present on the skin. These are only facultatively pathogenic but can cause infection of the wound. After the blood clot has been dissolved, the actual healing process begins. The wound cavity needs to be bridged with new (scar) tissue.

The duration of this phase depends on the size of the wound. With larger surgical wounds it can easily take 7 - 10 days. Renewed bleeding can occur if the wound is moved during this period. Healing time may additionally be extended by several days if the edges of the wound are also moved against each other. With repeated movement healing can even take weeks longer.

When using a vacuum drainage the process of wound healing is significantly reduced due to the following reasons:
• Blood, cells and tissue residues are sucked out of the wound cavity.
• The edges of the wound are drawn together and fixed by the negative pressure being exerted in the wound cavity. This means:
  • No haematoma is formed.
  • As there is no haematoma to be broken down, the wound does not swell.
  • The space that needs to be filled with new tissue has become considerably smaller. The wound cavity can be bridged with new tissue more quickly.
  • The edges of the wound can no longer shift against each other because they are fixed by the vacuum.

In large wound cavities or wounds with rigid boundaries (orthopaedics and trauma surgery) active drainage systems are the only logical choice as a drainage process would not start without suction from outside.

Cross-section of wound PRIOR application of vacuum

Cross-section of wound AFTER application of vacuum
Drainage in breast surgery

Drain placement in a wound

In most cases after surgery a trocar or a guide needle with a drain attached is passed out of the wound cavity through the skin. The exit point of this drain is below the actual wound so that the incision is not exposed to an increased risk of infection. This also prevents the wound from being reopened after it has been closed with sutures as a result of pulling on the drainage tube. In most cases the trocar leaves the body at a distance of about 5-10 cm from the wound. The distal end of the drain should be at the lowest point in the wound or as far away as possible from its exit point. This makes it impossible for blood to accumulate under the area to be drained. The drain perforations may not extend above the edges of the wound. The proximal end of the drain is, accordingly to kind and extent of the drainage, embedded in the bandage or connected to a container.

Figure 1:
Using a trocar to lead the drain out of the wound cavity. The distance from the wound in this case is about 5 cm.

Figure 2:
The Redon drain has three rings marking its distal end to prevent it from being pulled too far through.

Figure 3:
After the trocar has been separated from the drain with sterile scissors (not shown) the drain is fixed to the skin. This prevents it from being pulled out unintentionally.

Figure 4:
The distal end of the drain is now at the lowest point in the wound cavity. The drain is connected to the drainage tube of a Redon surgery system using a universal connector.
### Advantages and disadvantages of high vacuum drainage

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Due to the strong suction of these systems efficient cleansing of the wound area is effected. Serum, cells, germs, mediators and tissue remain efficiently from the wound area.</td>
<td>• Patients may be troubled by the relatively large, heavy collecting vessels for high vacuum drainage systems (usually Redon bottles).</td>
</tr>
<tr>
<td>• A closed system reduces the risk of infections. A system is 100% closed except at changes of collecting vessels. If the right bottle size is selected it may not be necessary to change bottles. It is not necessary to re-evacuate the collecting vessel. This also protects the surroundings against potentially pathogens.</td>
<td>• Although it is generally possible to examine the wound and test the fluid secreted, it is difficult to take samples hygienically from a Redon bottle. This is a result of the principle being applied. The Redon bottle is part of a closed wound drainage system and is not allowed to release any secreted fluid.</td>
</tr>
<tr>
<td>• Strong suction inhibits retrograde infection. If bottles are exchanged correctly a constant vacuum is maintained within the system (in the tube, drain and wound) which prevents germs from climbing back towards the wound.</td>
<td>• High vacuum systems should not be placed in contact with vasculature, nerves or organs that could be damaged by the vacuum system. Direct contact between the drain and the bowel should be avoided. High vacuum drainage systems are also contraindicated in serous membranes. Attention should also be given to any other contraindications that are known of within the individual departments.</td>
</tr>
<tr>
<td>• The systems offer easy handling. If more fluid is collected than was expected, vessels are changed very quickly. Re-evacuation is not necessary. This means the ward staff needs to spend less time and effort on it.</td>
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<tr>
<td>• The volume of the vessel is used effectively because of the high negative pressure. Viewed in physical terms, 100 per cent of the vessel would be used in the case of a 100 per cent vacuum (0 mbar). With a 90 per cent vacuum (100 mbar) still 90 per cent of the vessel volume would be used. With a 400 ml Redon bottle this is equivalent to 360 ml.</td>
<td></td>
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<tr>
<td>• As shown on page 8, the edges of the wound are pulled together and fixed by the high negative pressure. This results in a much shorter wound healing phase and therefore a shorter hospital stay for the patient.</td>
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</table>
Paepke S., Grosse Lackmann K., Ettl J., Paepke D., Kiechle M.

General principles of draining wound cavities in breast surgery

Choice of drainage system
The choice of drainage system with regard to tube diameter depends on the expected average volume of fluid. Additionally, it depends on whether the choice of drainage system also depends on whether both haematomas and seromas need to be drained, in which case drainage systems with a larger lumen are preferable. If blood is likely to be released, clotting processes can lead to coating of the inner walls of the drainage tube and can even partially block the lumen by producing smaller or longer blood clots.

The choice of size of the drainage system also depends on the expected duration of draining.
It has occasionally been postulated that drainage systems per se increase the risk of wound infection. This is not confirmed, either in our experience or by data in the literature.

Placing drainage tubes in the wound area
The aim in positioning the drainage tubes is to achieve the greatest possible contact area in relation to the wound area. The open lumen of the drainage tube should lie in the region where seroma formation is expected to be greatest.
Managing drainage systems in breast surgery

Placement drainage system

Trocar pushing through

Disinfection outer wound surface

Suture: Fixation to the skin

Suture: Bridge formation for better tube mobility

Example of complications:
Seroma after removal of drainage tube

Example of complications:
Subcutaneous haematoma with insufficient drainage
Case examples

Case description 1
High vacuum system for drainage of large wound areas with an expected seroma fluid quantity of >50 ml/day in large-scale breast surgery

Case:
Secondary wound healing problems after radical mastectomy and axillary lymph node dissection
78-year-old patient
First operation 24 days earlier, secondary wound healing problems with wound dehiscence and granulation starting to occur from the wound bed. Microbiological smears: bacteria-free.

Problems:
As well as the clearly visible wound dehiscence, the large wound cavity also presents a problem. A seroma, which formed primarily after surgery, prevented the wound surfaces from healing onto the thoracic wall. A large dead space was created in the whole ablation area as a result.

Strategy:
Excision of wound edges along the full length of the scar and freshening up to vital tissue in the skin and on the thoracic wall. Absolutely thorough disinfection and draining.

Expected drainage volume > 75 ml for the first few days with consecutive reduction as healing proceeds.

Note:
All stages are to be carried out by trained medical staff applying surgical standards (hygiene etc.).

Situation at start:
Sterilisation, draping in operating room.

Choice of drain:
pfm medical high vacuum Redon drainage system, diameter 18 Fr; bottle volume 600 ml, high vacuum 980 mbar; luer lock connector for bottle changes that will be necessary later.
Surgical situation after excision of wound edges and surgical freshening of all wound edges. The length of the wound is 14.5 cm.

Parallel to thorough disinfection of the wound cavity the theatre nurse prepares the drainage system. The non-sterile nurse opens the outer packaging of the drainage system and passes on the inner sterile package.

The sterile theatre nurse takes the sterile package from the drainage set.

The sterile theatre nurse places the drainage system components separately on the instrument table. These components are a Redon tube system with connected trocar and a high vacuum bottle system with tube connector.
The site of the skin puncture made with the trocar, to which the Redon drain is connected, is chosen under consideration of the following points:

- distant from the wound (about 5 cm);
- at the lowest anatomical point to make use of the force of gravity as well as the high vacuum of the system;
- following the functional aspect, so that the lateral placing of the drainage tube limits the patient’s mobility as little as possible.
- the puncture area is disinfected again both inside and out.

The hand on the inside marks the point of the inner drainage puncture and lifts the wound surface to see whether there are blood vessels in the skin so that they are not injured. The hand guiding the trocar places the trocar parallel to the thoracic wall to minimise the risk of injury.

The trocar is inserted while lifting a wide area of the wound surface to ensure visibility.

It is pushed slowly but forcefully through the skin.
After the whole trocar has been pushed through, the non-perforated part of the Redon drain is pulled out about 10 cm.

The Redon is cut diagonally just above the connection between the Redon drain and the trocar.

The perforated section of the Redon drain is placed in the caudal and medial part of the large wound. This ensures that the lowest anatomical point of the wound area is maximally drained.

Attachment of the Redon drain by suture so that the knot encloses the drain softly but fixes it firmly. This secures the Redon drain in position and prevents constriction of the diameter.
Managing drainage systems in breast surgery

Joining the distal end of the Redon drain to the high vacuum bottle (luer lock connection).

The multi-level connector is cut off at the proximal end of the connecting tube system to join the Redon drain to the high vacuum bottle (at 18 Fr as appropriate for the diameter chosen for the whole system).

Final picture of the surgical site after layered wound closure with sterile self-adhesive strips along and across the wound to release tension at the wound edges. The drainage system is fixed with the distal end of the Redon drain still open.

A plug-in connection joins the distal end of the Redon drain to the proximal end of the connection tube to the high vacuum bottle.
After an overall closed, completely sterile system has been created the high vacuum is activated by manual opening of the sealing system at the proximal end of the high vacuum suction bottle.

The Redon system is disinfected again and a split dressing is applied to the skin to keep the area sterile.

Final state of high vacuum drainage system site: dressed wound, dressed site at which drainage tube leaves the body, totally closed system with active high vacuum.
**Case description 2**  
High-vacuum drainage system for small wound cavities in small breast operations

**Case presentation:**
56-year-old female patient with Paget’s disease of the nipple and direct retroareolar DCIS, confirmed by histological examination (surrounding area of 5 x 9 mm suspected of containing microcalcifications).
Indications to remove the nipple and a retroareolar segment of tissue with the aim of rebuilding the nipple from the remaining areolar skin using the skate flap technique.
Expected drainage volume < 15 ml/day for 2 days.

**Note:**
All stages are to be carried out by trained medical staff applying surgical standards (hygiene etc.).

Postmenopausal female patient with histologically confirmed left central DCIS associated with microcalcifications. It is planned to mark the extent of microcalcification mammographically with a wire and then to remove the segment via a periareolar incision.

It is estimated that the quantity of fluid to be drained as a result of the volume deficit caused by segment removal will be about 35 - 50 ml per day for 1 - 2 days. It has been decided to use a high vacuum suction drainage system (980 mbar) and a trocar with a sharp tip, 12 Fr (4 mm) drainage system, total drainage volume 200 ml.

The non-sterile theatre nurse opens the non-sterile covering and passes the sterile inner bag with the drainage and trocar system to the sterile theatre nurse.
The sterile theatre nurse takes the drainage and trocar system out of the sterile inner bag.

The sterile theatre nurse takes out the sterile inner bag containing the drainage bottle.

The sterile theatre nurse takes the drainage bottle out of the sterile inner bag.

The sterile theatre nurse shortens the plug-in system of the drainage tube to fit the plug-in system of the drainage bottle to be connected.
View into the segmentectomy cavity which is held open with 4 Roux retractors and free of blood. The drainage system can now be positioned.

The Redon drain is placed in the segmentectomy cavity. The trocar is inserted through the skin at the lowest point in the segmentectomy cavity.

The trocar leaves the body at the lowest point in the segmentectomy cavity in the area of the submammary fold.

The Redon drain is cut off just above the trocar needle. The cut is diagonal to give a better connection.
The Redon drain is fixed with a slowly absorbable suture. The proximal end of the drain is placed in the segmentectomy cavity so that the openings in the Redon drain the wound as effectively as possible. Care must be taken to ensure that all the drainage openings remain in the wound area (see marking on Redon drain).

The end of the Redon drain, which is cut diagonally, is connected to the corresponding end of the vacuum bottle (push-fit connection). This creates a closed system.

Drainage can now be activated.