AbThera™
Open Abdomen Therapy

Clinical Guidelines

A reference source for the management of the open abdomen with 3M™ AbThera™ Open Abdomen Negative Pressure Therapy

Rx Only

This copy supercedes any previous revision. For revision level and contact information, refer to back cover of these guidelines.

These guidelines are not intended as a guarantee of results, outcome or performance of AbThera™ Open Abdomen Negative Pressure Therapy for active abdominal therapy. As with any application, please consult the patient's treating physician about individual conditions and treatment, and follow all applicable instructions for use and labeling for product use and operation.

For a medical emergency, contact your local emergency number. If you have any questions about operation or use, contact your local 3M representative. For further information, visit 3M.com/medical.

Caution: Federal (U.S.A.) law restricts these devices to sale/rental by or on the order of a physician.

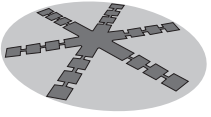
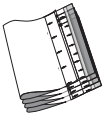
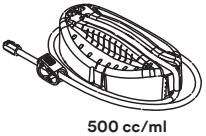
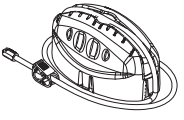
Rx Only

Contents

3M™ AbThera™ Open Abdomen Negative Pressure Therapy for Active Abdominal Therapy

Indications for Use

3M™ AbThera™ Open Abdomen Negative Pressure Therapy is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. The intended use of this therapy is for use in open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater. Please refer to **Appendix 1** for detailed Safety Information for AbThera Therapy.

3M™AbThera™ Open Abdomen Negative Pressure Therapy* consists of the following components:		
3M™ AbThera™ Fenestrated Visceral Protective Layer		
3M™ AbThera™ Perforated Foam and 3M™ AbThera™ Advance Perforated Foam	 **3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing**	 **3M™ AbThera™ Advance Open Abdomen Dressing**
3M™ V.A.C.® Drape		
3M™ SensaT.R.A.C.™ Pad		
3M™ V.A.C.® Canister	 **500 cc/ml**	 **1000 cc/ml**
3M™ V.A.C.® Ulta Therapy Unit		

*Check availability of AbThera Therapy with your local 3M sales representative.

About the Guidelines

This booklet discusses the clinical value and use of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy for active abdominal therapy. These guidelines are derived from current expertise and clinical experience with managing the open abdomen with negative pressure, and AbThera Therapy has been designed to simplify application and enhance removal of exudate.

In 2009, an international consensus group of 13 open abdomen management clinical experts convened in the Netherlands and developed the *AbThera Open Abdomen Negative Pressure Therapy Clinical Guidelines* to provide recommendations based on clinical evidence at that time as well as majority consensus when evidence was not available.

As of 2021, these clinical guidelines have been modified to include updated information and references in recognition of advancements on the treatment of abdominal compartment syndrome and the use of open abdomen techniques. These changes were made by a team of 3M Medical Directors.

Definitions

Abdominal Compartment Syndrome (ACS)

A sustained increase in the pressure (>20mmHg) within the abdominal compartment (bounded by the abdominal wall, pelvis, diaphragm and retroperitoneum), combined with new organ dysfunction and/or failure[1]. ACS frequently requires operative decompression when elevated intra-abdominal pressure (IAP) is refractory to non-operative therapeutic interventions[2].

Adherence

The term used to describe the process by which the intra-abdominal viscera becomes adherent to each other as well as to the underside of the anterolateral abdominal wall. This process, unless interrupted, will lead to a "frozen abdomen" and will compromise the surgeon's ability to enter the abdomen and/or achieve fascial closure due to the severity of adhesions.

Damage Control Surgery

The strategic use of an abbreviated laparotomy in critically ill patients, with the purpose of obtaining physiologic recovery before definitive surgery[3]. The index operation is aimed at controlling surgical bleeding, containing gastrointestinal spillage and applying a temporary abdominal closure.

Fixity

The term 'fixity' is used to describe a rigidity or a loss of compliance of the muscles or fascia of the abdominal wall. Fixity is often associated with a lateralization of the abdominal wall muscles, leading to a wide defect that is difficult to close.

Functional Abdominal Closure

A surgical procedure to close the open abdomen using mesh or other prosthetic materials when delayed primary fascial closure is not possible. The aim is to achieve a successful reconstruction with a fully functional abdominal wall.

Intra-Abdominal Hypertension (IAH)

A sustained or repeated pathologic elevation in abdominal pressure of IAP ≥12mmHg[1].

Intra-Abdominal Pressure (IAP)

This refers to the pressure concealed within the abdominal cavity[1]. IAP is most commonly measured indirectly via the bladder using the patient's indwelling urinary catheter. To observe a trend in elevation IAP should be measured several times a day[1].

Open Abdomen (OA)

A technique, also known as laparostomy, in which the fascia is left open intentionally to avoid elevation of IAP and where surgical re-exploration is desirable. Temporary Abdominal Closure (TAC) is achieved using a dressing or technology intended to protect the exposed viscera.

Total Management of the Open Abdomen

This refers to an integrated approach in patients who require an open abdomen and TAC that involves:

- managing the critically ill patient and preventing further decline and systemic complications
- managing the abdominal pathology and preparing the local defect to facilitate definitive closure (the aim of active abdominal therapy)
- applying definitive closure techniques that reduce the herniation rate

1 - The Open Abdomen as a Treatment Option

Indications for Open Abdomen Management

In the management of various surgical conditions including peritonitis, intra-abdominal trauma and mesenteric ischemia, early definitive closure of the abdominal wall (i.e., closure of the fascial layer and skin) may place the patient at risk of developing IAH and/or ACS. In these cases, patients are increasingly managed using a damage control approach with abbreviated operating times and a laparostomy to allow subsequent re-exploration or to prevent elevated IAP[4]. Furthermore, these patients are often in severe physiologic distress and are best resuscitated in a controlled ICU setting once bleeding and gastrointestinal spillage are controlled.

Clinical situations in which it is preferable or necessary to manage patients with an open abdomen include:

- Abdominal sepsis in patients with severe physiologic derangement, require a second-look laparotomy, or have a persistent source of peritonitis (lack of source control)
- The patient with a tense abdomen after massive resuscitation or a prolonged major surgical procedure, who is at risk of developing ACS
- A 'damage control' situation when the abdomen is left open strategically to allow adequate resuscitation prior to definitive procedure
- The patient with primary or secondary ACS, who needs a life-saving decompressive laparotomy

Historically, open abdomen management has been associated with a significant morbidity and mortality. However, over the past two decades evolving physiological knowledge and intensive care practices, together with the advent of various TAC techniques, including 3M™ AbThera™ Open Abdomen Negative Pressure Therapy, have resulted in many centers reporting significant improvements in patient outcomes[5-8].

Trauma and sepsis

Given the indication for open abdomen management, the treatment strategy may differ. Critically ill trauma patients receive "damage control resuscitation" with early blood product transfusion as well as temporizing hemostatic strategies to avoid massive crystalloid resuscitation which will aid in early primary fascial closure. Patients with abdominal sepsis are typically older, have additional medical co-morbidities and require massive crystalloid resuscitation. Several studies identified peritonitis as an independent predictor of failure of facial closure. In addition, patients with sepsis have an increased overall rate of small bowel fistula. However, regardless of etiology, the principles of management should be the same.

Principles for Managing the Open Abdomen

The principal goal is to manage the critically ill patient at risk of developing systemic complications by controlling both the abdominal contents and the opening that gives access to the abdominal cavity. The control of intra-abdominal fluid secretion and preservation of the fascia is a major challenge in the management of these patients[9]. The ultimate goal is to achieve primary fascial closure within 7 - 10 days to avoid serious complications that are associated with the open abdomen (e.g., frozen abdomen, enterocutaneous fistula and death).

Patients with an open abdomen represent a heterogeneous group and are infrequently seen by the majority of surgeons. Involvement of a surgeon with the relevant expertise is essential and prompt advice from a specialist center should be sought.

Initial management of a critically ill surgical patient is to resuscitate and stabilize the patient using damage control surgery involving an abbreviated laparotomy to control bleeding, IAH and contamination, followed by the application of a system to temporarily close the abdomen. This process helps to begin restoration of normal physiology and source control of infection/peritonitis.

The following criteria can be used by the surgeon at each dressing change when deciding whether to close the abdomen:

- IAP <15mmHg
- Fascia can be closed without excessive tension or increase in IAP
- Local infection is treated
- No further surgical interventions are planned

If the abdomen cannot be closed (e.g., due to intestinal edema and/or contamination), ongoing management aims to prevent clinical deterioration with loss of fascial mobility and domain.

Total Management of the Open Abdomen

The international consensus group agreed with the phrase 'total management of the open abdomen' to describe an integrated approach involving resuscitation, subsequent ICU management and definitive closure in patients who require an open abdomen and TAC. It involves regular evaluation and re-evaluation of the abdominal contents and the wound environment, paying particular attention to:

- preserving the fascia and skin
- minimizing the fascial defect (lateralization and fixity)
- preventing adhesion of the intestines to the bowel wall
- preventing associated complications, in particular fistula formation

During this process of optimizing the wound environment in preparation for definitive closure, the clinician also needs to concentrate on a number of important related factors, which can be categorized as follows:

- **Structural**
  - protect the exposed bowel loops
  - achieve source control (infection/hemorrhage)
  - prevent or minimize the risk of subsequent complications, such as hernia
  - minimize abdominal wall expansion (lateralization and fixity)
- **Physiological**
  - restore/maintain mesenteric circulation
  - control peritoneal fluid and third-space fluid loss
  - remove and quantify exudate
  - remove inflammatory mediators
  - minimize increase in IAP and risk of ACS
  - modify the immune response

Other practical goals include: facilitate nursing care (e.g., secure dressing, control of exudate, allow for prone ventilation); improve patient comfort and promote early enteral feeding to permit early discharge from ICU.

Warning: Risk of evisceration should be evaluated by the surgeon before ambulation is permitted.

2 - Total Management of the Open Abdomen

Temporary Abdominal Closure (TAC)

All patients with an open abdomen will require TAC to allow for a period of optimization prior to definitive closure. To achieve this balance of delayed primary fascial or functional abdominal closure as well as structural and physiological protection, the clinician needs to utilize a TAC technique that does more than simply contain the abdominal contents (viscera).

Techniques for TAC are varied and have evolved from basic methods, which can be used to simply contain the visceral contents, to more dynamic modern devices such as 3M™ AbThera™ Open Abdomen Negative Pressure Therapy for active abdominal therapy, which have a number of advanced open abdomen management functions. In addition to the obvious benefits (e.g., allowing rapid access for re-entry, placement without suturing, containing and protecting the viscera, and providing a barrier to external contaminants), AbThera Therapy is intended to provide active abdominal therapy by controlling the abdominal contents, removing exudate and infectious materials, helping to estimate third space fluid losses, reducing edema, and minimizing fascial retraction and loss of domain[8, 10-12].

Initial Application and Dressing Changes

Prior to application the surgeon or practitioner should check for necrosis, ischemia, contamination or infection and adhesions. In addition, the integrity of anastomoses should be protected and the IAP measured and recorded if appropriate.

The initial application of AbThera Therapy for active abdominal therapy and subsequent dressing changes should be performed under aseptic conditions in the operating theater or ICU, depending on the individual facilities.

The recommended interval between dressing changes is 24 - 72 hours. More frequent dressing changes may be indicated in the presence of infection or abdominal contamination. The actual timing of dressing changes may also vary depending on the patient's clinical status. Individual experience and patient needs will ultimately guide practice.

At each dressing change, the surgeon needs to re-evaluate whether the abdomen can be closed and, if not, whether treatment should be modified. At all times a strategy for discontinuing therapy or finally closing the abdomen should be considered.

Timing of Definitive Closure

The timing of closure will be determined by the surgeon's perception and clinical experience, together with various structural and physiological factors. In addition, a number of parameters including hypothermia, acidosis, coagulopathy and IAH may predict the development of ACS and contradict abdominal closure. However, these are usually of greater concern in the early treatment phase of the open abdomen and not at the time of late closure. Monitoring of these parameters and appropriate treatment strategies may lead to reduced mortality rates. For criteria of when to close the abdomen, see the **Principles for Managing the Open Abdomen** section.

It is important to have a clear strategy of therapy and to close the abdomen as early as possible to minimize the risk of complications.

Discontinuing 3M™ AbThera™ Open Abdomen Negative Pressure Therapy

Although most patients will benefit from abdominal closure, this is not the primary goal for a small percentage of patients for whom management of the open abdomen is an ongoing process. AbThera Therapy may be discontinued where it is felt that continuing to strive for delayed primary fascial closure is counterproductive (e.g., in the elderly individual with cardiopulmonary comorbidities who cannot tolerate repeated general anesthesia).

Conversely, it may be useful to continue with the dressings where this makes the patient more comfortable or easier to manage. For example, it may be possible for patients requiring prolonged treatment with an open abdomen to be nursed outside the ICU, allowing patients to ambulate and receive enteral feeding between dressing changes.

Warning: Risk of evisceration should be evaluated by the surgeon before ambulation is permitted.

3 - Application of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy for Active Abdominal Therapy

Prior to application please refer to the important safety information for the 3M™ AbThera™ Open Abdomen Negative Pressure Therapy located in Appendix 1.

Please refer to the Instructions For Use included with 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing, 3M™ AbThera™ Advance Open Abdomen Dressing as well as the 3M™ V.A.C.® Ulta Therapy Unit User Manual.

Using 3M™ AbThera™ Open Abdomen Negative Pressure Therapy for Active Abdominal Therapy

The decision to use AbThera Therapy should be made by the lead clinician. Patients should be assessed on an individual basis following a comprehensive examination in the operating theater. Consider applying AbThera SensaT.R.A.C. Dressing or AbThera Advance Dressing at the time of surgery or as early as possible.

Management of the open abdomen is complex. AbThera Therapy for active abdominal therapy should be used only by healthcare professionals who have received specific training and who will continue to gain expertise through regular clinical practice.

The first application of the AbThera Therapy for active abdominal therapy in the acute situation should take place in the operating theater under general anesthesia. Subsequent dressing changes usually take approximately 15 - 20 minutes when performed by an experienced surgeon or practitioner. Correct application is critical for optimal results. Specific indications, contraindications, warnings, precautions and safety information exists for the AbThera Therapy for active abdominal therapy. Read instructions for use accompanying the device prior to application. See **Appendix 1** for detailed safety information.

Wound Preparation

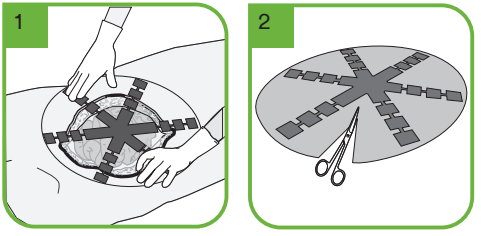
Warning: Review all 3M™ AbThera™ Open Abdomen Negative Pressure Therapy Safety Information before beginning wound preparation. Ensure adequate hemostasis has been achieved prior to dressing placement (refer to Bleeding section under Warnings in Appendix 1).

1. Sharp edges or bone fragments must be eliminated from wound area or covered.
2. Irrigate abdominal wound and cleanse periwound skin as indicated.
3. Clean and dry periwound tissue; consider use of a skin preparation product to protect periwound skin. Do not allow foam to overlap onto intact skin. Protect fragile/friable periwound skin with additional drape, hydrocolloid, or other transparent film.

3M™ AbThera™ Fenestrated Visceral Protective Layer Application

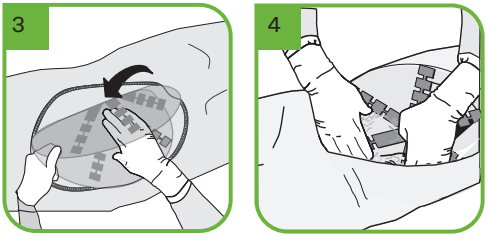
The 3M™ AbThera™ Fenestrated Visceral Protective Layer is fenestrated to allow for active fluid removal when negative pressure is applied and is designed to allow application of this layer directly over omentum or exposed internal organs.

Warning: The foam in the 3M™ AbThera™ Fenestrated Visceral Protective Layer is encapsulated for patient safety. Protect vital structures with the AbThera Fenestrated Visceral Protective Layer at all times during therapy. Never place exposed foam material directly in contact with exposed bowel, organs, blood vessels or nerves.



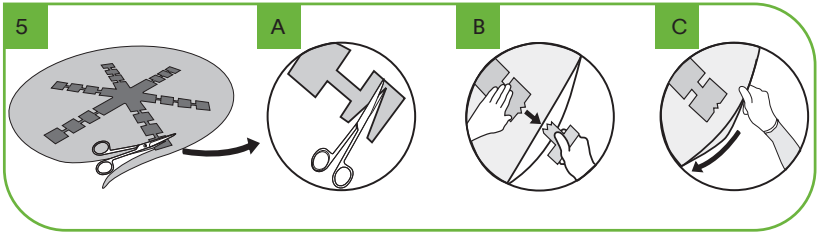
1. Remove contents from inner pouch and unfold the AbThera Fenestrated Visceral Protective Layer in a sterile field. Either side of the AbThera Fenestrated Visceral Protective Layer may be placed on the omentum or viscera.
2. Gently place the AbThera Fenestrated Visceral Protective Layer over the open abdominal cavity (Fig. 1).
3. Determine the orientation of the dressing for the specific application. If the AbThera Fenestrated Visceral Protective Layer will be placed around tubes, drains or the falciform ligament, cut only **between** the foam extensions (Fig. 2). (***Do not cut near or through foam extensions***). Orient the AbThera Fenestrated Visceral Protective Layer accordingly before cutting.
4. Size the AbThera Fenestrated Visceral Protective Layer by folding or cutting as described in the following sections.

Folding the 3M™ AbThera™ Fenestrated Visceral Protective Layer to Size



1. Hold dressing by the edge and slightly lift. Slowly lower dressing into the paracolic gutter, using the other hand to gently and evenly work the dressing down. (Fig. 3). Fold any excess AbThera Fenestrated Visceral Protective Layer up and over onto itself.
2. Continue placing the AbThera Fenestrated Visceral Protective Layer between abdominal wall and internal organs (Fig. 4) throughout the abdominal compartment. The goal is to ensure full coverage of all viscera.

Cutting the 3M™ AbThera™ Fenestrated Visceral Protective Layer to Size



1. Cut the AbThera Fenestrated Visceral Protective Layer away from wound, through center of large foam squares using sterile scissors (Fig. 5A). Do not cut through narrow connecting tabs between the large foam squares.
2. Pinch the remaining half of the foam square and its connecting tab and pull. The foam and tab will separate at the next square (Fig. 5B). This will ensure that edges of the AbThera Fenestrated Visceral Protective Layer cover exposed foam edge (Fig. 5C), and foam cannot contact organs (see **Warning** in previous section).
3. Document number of foam extensions removed and that each piece has been properly disposed of away from wound cavity.

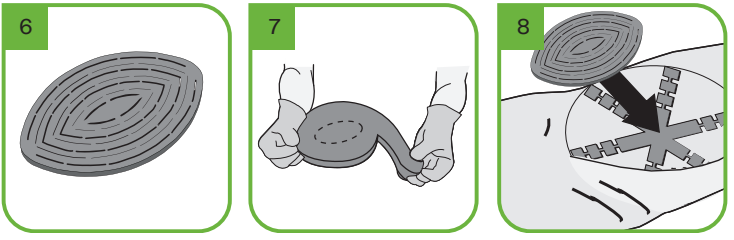
   Caution: Do not tear the foam over the wound, as fragments may fall into the wound. Rub or trim foam away from wound, removing any fragments to ensure loose particles will not fall into or be left in the wound upon dressing removal.

Perforated Foam Application

(Illustrations in the steps in this section show the 3M™ AbThera™ Advance Open Abdomen Dressing)

The perforated foam provided with the 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing and AbThera Advance Dressing is intended to:

- Transfer negative pressure from the 3M™ V.A.C.® Ulta Therapy Unit to the AbThera Fenestrated Visceral Protective Layer to promote active fluid removal.
- Provide medial tension upon foam collapse to help maintain fascial domain.



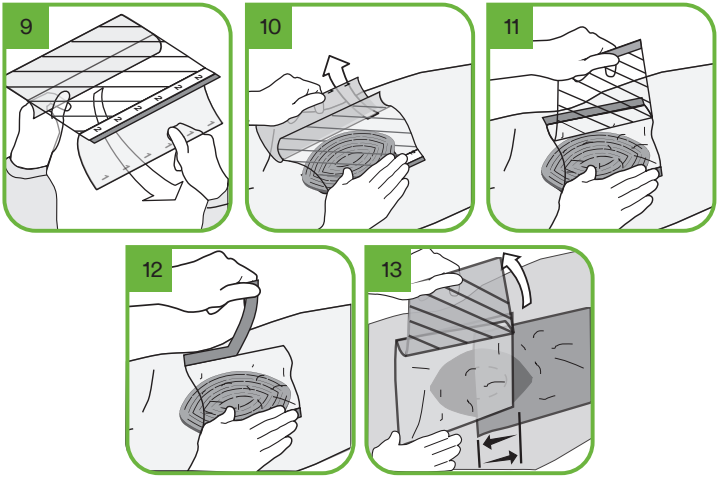
1. Tear or cut perforated foam to needed size as shown (**Fig. 7**). The foam should fit directly over the AbThera Fenestrated Visceral Protective Layer and be in contact with wound edges. Do not allow foam to contact intact skin. One or both pieces of the provided perforated foam can be used, depending on the wound profile.
2. Gently place perforated foam into wound cavity over the AbThera Fenestrated Visceral Protective Layer (**Fig. 8**).

Note: Ensure foam-to-foam contact for even distribution of negative pressure.

Note: Always note the total number of pieces of foam used and document on the drape and in the patient's chart.

3M™ V.A.C.® Drape Application

(Illustrations in the steps in this section show the 3M™ AbThera™ Advance Open Abdomen Dressing)



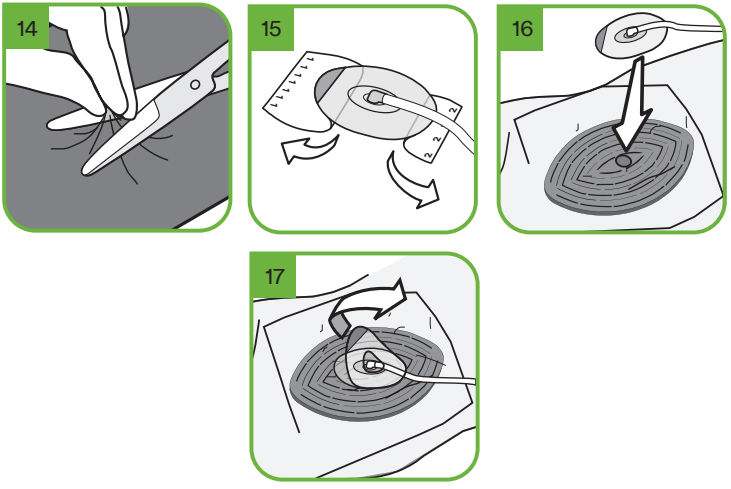
1. Holding the drape, partially pull back one side of layer 1 to expose adhesive (**Fig. 9**). Be sure to hold layer 1 flap back, to prevent re-adherence to drape.
2. Place the drape adhesive-side down to cover foam and intact skin, ensuring drape covers at least an 8 - 10 cm border of intact periwound tissue (**Fig. 10**). Use any excess drape to seal difficult areas, if needed.

   Note: To avoid trauma to the periwound skin, do not pull or stretch the drape over the foam dressing. Minimize wrinkles, as they may be a source of negative pressure leaks (refer to **Precautions, Protect Periwound Skin** section in **Appendix 1**).
3. Remove remaining tab 1 backing material and pat around drape to ensure an occlusive seal.
4. Remove green-striped stabilization layer 2 (**Fig. 11**).
5. Remove perforated blue handling tabs from drape (**Fig. 12**).

   Note: When using multiple pieces of drape, ensure that the edges of the drape overlap in order to achieve a seal (Fig. 13).

3M™ SensaT.R.A.C.™ Pad Application

(Illustrations in the steps in this section show the 3M™ AbThera™ Advance Open Abdomen Dressing)

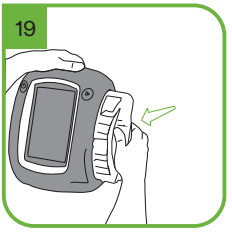


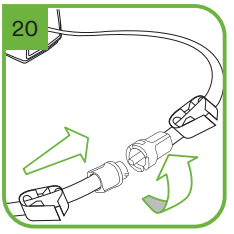
Note: Do not cut off the pad or insert the tubing into the foam dressing. This may occlude the tubing and cause the negative pressure therapy unit to alarm and could injure underlying viscera.

1. Choose pad application site. Give particular consideration to fluid flow and tubing position to allow for optimal flow and avoid placement over bony protuberances or within creases in the tissue.
2. Pinch drape and cut a 2.5 cm hole (not a slit) through the drape (**Fig. 14**). It is not necessary to cut into the foam.

   Note: Cut a hole rather than a slit, as a slit may self-seal during therapy.
3. Apply pad, which has a central disc and a surrounding outer adhesive skirt.
   - Gently remove both backing layers 1 and 2 to expose adhesive (**Fig. 15**).
   - Place pad opening in central disc directly over hole in drape (**Fig. 16**).
   - Apply gentle pressure on the central disc and outer skirt to ensure complete adhesion of the pad.
4. Pull back on blue tab to remove pad stabilization layer (**Fig. 17**). Dressing application is complete.

3M™ V.A.C.® Ulta Therapy Unit Application





Note: Only for use with Negative Pressure Therapy provided by 3M™ V.A.C.® Ulta Therapy Units. Refer to the therapy unit user manual for complete instructions for use.

Note: 3M™ SensaT.R.A.C.™ Pad tubing is not compatible with hospital vacuum systems.

Warning: Review all Negative Pressure Therapy Safety Information before initiating therapy.

1. Remove canister from packaging.
2. Slide the canister into the side of the V.A.C.® Ulta Therapy Unit (**Fig. 18**).
3. Push the canister (500 cc/ml shown) firmly into place on the V.A.C.® Ulta Therapy Unit (**Fig. 19**). An audible click indicates the canister is fully seated. Ensure the canister is installed directly onto the therapy unit. Do not twist or turn the canister as it is being installed.

   Note: Abdominal wounds often have copious drainage. Consider using the 1000 cc/ml canister. Ensure an adequate supply of canisters is readily available.

   Caution: Consider the size and the weight of the patient, patient condition, wound type, monitoring capability and care setting when using the 1000 cc/ml canister.

   Note: If the canister is not fully engaged, the therapy unit will alarm.
4. Connect SensaT.R.A.C. Pad tubing to canister tubing by pushing the connectors together (**Fig. 20**) Ensure clamp on each tube is open. Position clamps away from patient.
5. Turn on power to the therapy unit and select 125 mmHg, continuous mode therapy setting for efficient fluid removal rates. Negative pressure therapy settings below 125 mmHg are not recommended.

   Caution: Do not use intermittent therapy/Dynamic Pressure Control™ Therapy with the 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing or 3M™ AbThera™ Advance Open Abdomen Dressing.

6. Initiate therapy. Assess dressing to ensure integrity of seal. The dressing should collapse and have a wrinkled appearance. There should be no hissing sounds. If there is any evidence of nonintegrity, check drape and 3M™ SensaT.R.A.C.™ Pad seals, tubing connections, and canister insertion, and ensure clamps are open. Secure excess tubing to prevent inadvertent tension on tubing, which may disrupt the seal.

   Monitor Fluid Output - The dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with the 3M™ V.A.C.® Ulta Therapy Unit, the volume of exudate in the canister and tubing should be frequently examined.

   Bleeding: Patients with abdominal wounds must be closely monitored for bleeding as these wounds may contain hidden blood vessels which may not be readily apparent. If sudden or increased bleeding is observed in the dressing, tubing or canister, immediately discontinue Negative Pressure Therapy, take appropriate measures to stop bleeding, and contact the physician. Negative Pressure Therapy is not designed to prevent, minimize or stop bleeding. (Refer to Warnings, Bleeding section in Appendix 1).

Dressing Changes

Dressing changes should occur every 24 to 72 hours, or more frequently based upon a continuing evaluation of wound condition and patient presentation. Consider more frequent dressing changes in the presence of infection or abdominal contamination.

Refer to **Application Setting** section under **Warnings** in **Appendix 1**.

Whenever the dressing is changed, always replace all dressing components with components from an unopened sterile package.

Dressing Removal

Remove and discard previous dressing per institution protocol. Completely inspect wound, including paracolic gutters, to ensure all pieces of dressing components have been removed. If intra-abdominal packing material is present, this material may be drier than anticipated. Evaluate packing material prior to removal and rehydrate if necessary to prevent adherence or damage to adjacent structures.

Warning: Refer to Dressing Removal section under Warnings in Appendix 1.

Tips for Applying 3M™ AbThera™ Open Abdomen Negative Pressure Therapy

Tips for applying AbThera Therapy for active abdominal therapy include:

- Adequately prepare the skin.
- Ensure the drape is gently applied over the foam to create a seal without causing the dressing to be too tight.
- Remove skin wrinkles before fixing the dressing.
- Turn on the therapy unit and check that the foam collapses, the target negative pressure is achieved and there are no visible signs of leakage.
- Check the fluid in the canister for blood or feces.

Pressure Settings

The recommended pressure settings for AbThera Therapy for active abdominal therapy in the open abdomen is a continuous negative pressure of 125mmHg. For further information, please refer to the current version of the *V.A.C.® Therapy Clinical Guidelines*.

For more detailed safety information for AbThera Therapy, please refer to Appendix 1.

Care and Cleaning

Cleaning and disinfection of the therapy unit includes wipe down of all hard surface components. Follow institutional procedures used for cleaning and disinfection of other hard surface durable electronic medical equipment. The therapy unit must be cleaned and disinfected:

- If it becomes soiled during patient use
- At least weekly

Caution: Ensure that the therapy unit is powered off and disconnected from AC power when using cleaning fluids of any nature.

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Appendix 1 - 3M™ AbThera™ Open Abdomen Negative Pressure Therapy Safety Information

Disposable components of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy, including the foam dressing, tubing and drape are packaged sterile and are latex-free. 3M™ V.A.C.® Canisters are supplied non-sterile and are latex-free. All disposable components of AbThera Therapy are for single use only. To help ensure safe and effective use, the 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing and 3M™ AbThera™ Advance Open Abdomen Dressing are to be used only with the 3M™ V.A.C.® Ulta Therapy Unit.

Sterile/aseptic technique is recommended when applying AbThera Therapy to an open abdominal wound.

Important: As with any prescription medical device, failure to consult a physician and carefully read and follow all therapy unit and dressing instructions and safety information prior to each use may lead to improper product performance and the potential for serious or fatal injury. Do not adjust therapy unit settings or perform therapy application without directions from/or supervision by the clinical caregiver.

Indications for Use

AbThera Open Abdomen Negative Pressure Therapy is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. The intended use of this therapy is for use in open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater.

Contraindications

- Never place exposed foam material directly in contact with exposed bowel, organs, blood vessels or nerves. Protect vital structures with the 3M™ AbThera™ Fenestrated Visceral Protective Layer **at all times** during therapy.
- Patients with open abdominal wounds containing non-enteric unexplored fistulas should not be treated with AbThera SensaT.R.A.C. Dressing and AbThera Advance Dressing.

Management of the open abdomen has been documented in case reports and consensus panel literature. Please refer to the **References** section of this document.

Warnings

Not for use with Instillation Therapy: Although it is accepted medical practice to flush a contaminated open abdominal cavity with saline or other medical solutions, the 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing and 3M™ AbThera™ Advance Open Abdomen Dressing were not designed for this purpose, and 3M has no studies to support its safe and effective use with instillation therapy. Potential risks of instillation into the open abdomen include:

- Instillation of fluid in the abdomen without sufficient fluid recovery may lead to abdominal compartment syndrome.
- Instillation of fluids in the abdomen that are untested for safety and efficacy with this application could lead to severe hollow viscus and solid organ damage.
- Instillation of unwarmed fluid in large quantities may lead to hypothermia.

Only Use the 3M™ SensaT.R.A.C.™ Pad: Substitution with any other tubing, alteration of the SensaT.R.A.C. Pad or breach of the prescribed SensaT.R.A.C. Pad application for the purpose of instilling fluids into the open abdomen is not recommended under any circumstance. This may lead to loss of therapy efficacy or harm to the patient.

Bleeding: Patients with abdominal wounds must be closely monitored for bleeding as these wounds may contain hidden blood vessels which may not be readily apparent. If sudden or increased bleeding is observed in the dressing, tubing or canister, immediately discontinue Negative Pressure Therapy, take appropriate measures to stop bleeding, and contact the physician. Negative Pressure Therapy is not designed to prevent, minimize or stop bleeding.

Hemostasis must be achieved prior to dressing placement.

The following conditions may increase the risk of potentially fatal bleeding.

- suturing and/or anastomosis
- trauma
- radiation
- inadequate wound hemostasis
- non-sutured hemostatic agents (for example bone wax, absorbable gelatin sponge, or spray wound sealant) applied in the abdomen may, if disrupted, increase the risk of bleeding. Protect against dislodging such agents.
- infection in the abdominal wound may weaken visceral organs and associated vasculature, which may increase susceptibility to bleeding.
- use of anticoagulants or platelet aggregation inhibitors
- bone fragments or sharp edges could puncture vessels or abdominal organs. Beware of possible shifting in the relative position of tissues, vessels or organs within the abdominal wound that might increase the possibility of contact with sharp edges.

Intra-abdominal Pressure Monitoring: Laparotomy with the placement of any temporary abdominal closure does not eliminate the possibility of elevation in intra-abdominal pressure (IAP). When using Negative Pressure Therapy, IAP monitoring (for clinical or diagnostic signs and symptoms of elevated IAP) should continue as indicated by patient condition and in accordance with institutional clinical practice or guidelines. If intra-abdominal hypertension (IAH) or abdominal compartment syndrome (ACS) is observed or suspected, note intra-abdominal pressures and turn off power to the Negative Pressure Therapy Unit, discontinuing negative pressure. After full expansion of the perforated foam, obtain a new intra-abdominal pressure measurement. If IAH/ACS persists without negative pressure, discontinue the use of Negative Pressure Therapy and address the underlying condition as medically indicated.

Use of the 3M™ AbThera™ Fenestrated Visceral Protective Layer: When using Negative Pressure Therapy, ensure that the AbThera Fenestrated Visceral Protective Layer completely covers all exposed viscera and completely separates the viscera from contact with the abdominal wall. Place the AbThera Fenestrated Visceral Protective Layer over the omentum or exposed internal organs, and carefully tuck it between the abdominal wall and internal organs, making sure the AbThera Fenestrated Visceral Protective Layer completely separates the abdominal wall from the internal organs.

Adhesions and fistula development: Formation of adhesions of the viscera to the abdominal wall may reduce the likelihood of fascial reapproximation and increase the risk of fistula development which is a common complication in patients with exposed viscera.

Infection: Infected abdominal wounds should be monitored closely and may require more frequent dressing changes than non-infected wounds, dependent upon factors such as patient condition, wound condition and treatment goals. Refer to the **Initial Application and Dressing Changes** found in **Section 2** of these guidelines for details regarding dressing change frequency.

Dressing placement: Always use a dressing from a sterile package that has not been opened or damaged. Do not force any dressing component into the wound, as this may damage underlying tissue.

Dressing removal: The dressing components are not bioabsorbable. Always remove all dressing components from the abdomen at every dressing change.

Keep Negative Pressure On: Never leave the dressing in place without active negative pressure for more than two hours. If negative pressure is off for more than two hours, change dressing as shown in **Section 3 - Application of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy for Active Abdominal Therapy**. Either apply a new dressing from an unopened sterile package and restart negative pressure, or apply an alternative dressing.

Defibrillation: Remove adhesive drape from area of defibrillation to prevent inhibition of electrical energy transmission.

Acrylic Adhesive: The 3M™ V.A.C.® Drape has an acrylic adhesive coating, which may present a risk of adverse reaction in patients who are allergic or hypersensitive to acrylic adhesives. If a patient has a known allergy or hypersensitivity to such adhesives, do not use the dressing. If any signs of allergic reaction or hypersensitivity develop, such as redness, swelling, rash, urticaria or significant pruritus, discontinue use and ensure appropriate emergency medical treatment. If bronchospasm or more serious signs of allergic reaction appear, remove dressing and ensure appropriate emergency medical intervention as indicated.

Magnetic Resonance Imaging (MRI) – Therapy Unit: The 3M™ V.A.C.® Ulta Therapy Unit is MR unsafe. Do not take the device into the MR environment.

Magnetic Resonance Imaging (MRI) – Open Abdomen Dressing: The dressing can remain on the patient with minimal risk in an MR environment, assuming that use of Negative Pressure Therapy is not interrupted for more than two hours; please refer to **Keep Negative Pressure On** section in **Appendix 1**.

Hyperbaric Oxygen Therapy (HBO): Do not take the V.A.C.® Ulta Therapy Unit into a hyperbaric oxygen chamber. The therapy unit is not designed for this environment, and **should be considered a fire hazard**. After disconnecting the therapy unit, either (i) replace the dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the unclamped end of the SensaT.R.A.C. Pad Tubing with dry gauze. For HBO therapy, the tubing must not be clamped. Never leave a dressing in place without active negative pressure for more than two hours (refer to **Keep Negative Pressure On** section in **Appendix 1**).

Application Setting: Dressing applications and changes should be performed under strict sterile conditions in the operating theater. If dressing change is performed outside the operating theater, it must be performed in an environment equipped to address the onset of critical complications and where strict aseptic technique can be utilized.

Precautions

Standard precautions: To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluids is likely.

Intra-abdominal Packing: When using intra-abdominal packing with Negative Pressure Therapy, packing material may be drier than anticipated. Evaluate this material prior to removal and rehydrate if necessary to prevent adherence or damage to adjacent structures.

Monitor fluid output: The dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with Negative Pressure Therapy, the volume of exudate in the canister and tubing should be frequently examined.

Patient size and weight: The size and weight of the patient should be considered when prescribing Negative Pressure Therapy. Initial lower negative pressure should be considered for certain small or elderly patients who are at risk of fluid depletion or dehydration. Monitor fluid output including the volume of exudate in both the tubing and canister. This therapy has the potential to remove and collect large volumes of fluid. Tubing volume is approximately 25 ml from 3M™ SensaT.R.A.C. Pad to canister.

Spinal cord injury: In the event a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue Negative Pressure Therapy to help minimize sensory stimulation.

Bradycardia: To minimize the risk of bradycardia, the dressing must not be placed in proximity to the vagus nerve.

Enteric fistula or leak: When treating an open abdomen where enteric fistulas are present, clinicians should consider the potential for abdominal contamination if effluent is not appropriately isolated or managed.

Protect periwound skin: Consider use of a skin preparation product to protect periwound skin. Do not allow foam to overlap onto intact skin. Protect fragile/friable periwound skin with additional drape, hydrocolloid or other transparent film.

- Multiple layers of the drape may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the drape, foam or SensaT.R.A.C. Pad tubing appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the drape over the foam dressing during drape application.

If there are any questions regarding the proper placement or usage of the 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing and 3M™ AbThera™ Advance Open Abdomen Dressing, please contact your local 3M clinical representative.

Note: Specific indications, contraindications, warnings, precautions and safety information exist for 3M products and therapies. Please consult a physician and product instructions for use prior to application. Rx only.

29-B-234 Rev C 7/2021