

Clinical guidelines for the
management of the open
abdomen with ABThera™
Open Abdomen Negative
Pressure Therapy System for
active abdominal therapy

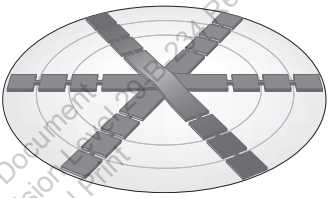
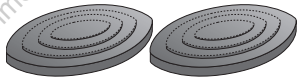
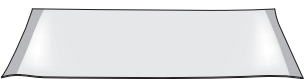
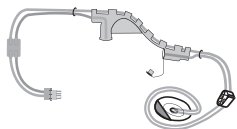



March 2010

ABTHERA™ OPEN ABDOMEN NEGATIVE PRESSURE THERAPY SYSTEM FOR ACTIVE ABDOMINAL THERAPY

INDICATIONS FOR USE

- The ABThera™ Open Abdomen Negative Pressure Therapy (NPT) System is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeated abdominal entries are necessary. The intended use of this system is for use in open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome.
- The ABThera™ NPT System is intended for use in the acute hospital setting: in trauma, general and plastic surgery wards. The abdominal dressing will most often be applied in the operating room.

	<p>The ABThera™ Open Abdomen Negative Pressure Therapy System* consists of the following components:</p>
Visceral Protective Layer (VPL)	
Perforated foam	
Drape	
Tubing set	
Negative pressure source	

*Check availability of ABThera™ Open Abdomen Negative Pressure Therapy System with your local KCI sales representative.

ABOUT THE GUIDELINES

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This booklet discusses the clinical value and use of the ABThera™ Open Abdomen Negative Pressure Therapy System for active abdominal therapy. In particular, it describes the practical application of the ABThera™ NPT System in the management of the open abdomen. The next generation ABThera™ NPT System builds on current expertise and clinical experience with the V.A.C.® Abdominal Dressing System and has been designed to simplify application and enhance removal of exudate.

Following a preliminary meeting in November 2007, an international consensus group convened in the Netherlands in January 2009 to develop the guideline content using group discussion. In addition, further input was received from specialists in the field unable to attend the consensus group meeting. The recommendations are based on current clinical evidence or, where this is not available, the majority consensus of the international group of experts (see below). The main outcomes from the 2009 meeting include the development of a new classification system, which can be used as a model of care for clinicians who are responsible for managing patients with an open abdomen; and the recognition that although different etiologies present separate challenges, the fundamental principles guiding the strategy for temporary abdominal closure remain similar for all patients. The new classification can be used by clinicians to clarify the position and application of the ABThera™ NPT System at predefined stages. As with any clinical guidance, each patient and circumstance is unique. Individual clinician discretion is advised.

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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 failure¹. ACS frequently requires operative decompression when elevated intra-abdominal pressure (IAP) is refractory to non-operative therapeutic interventions².

Adherence

The term is used to describe a deterioration in the open abdominal wall in which the intra-abdominal contents become adherent to the underside of the muscle or fascial edges. This process, unless interrupted, will compromise the surgeon's ability to achieve fascial closure.

Damage Control Surgery

This involves abbreviated resuscitative surgery and restoration of near normal physiology to control a life-threatening situation. In abdominal trauma it refers principally to the control of bleeding and in abdominal contamination to the control of the source of contamination/infection and peritoneal lavage^{3,4}. This staged approach using an initial abbreviated laparotomy requires temporary abdominal closure (TAC) and resuscitation in the ICU before subsequent definitive repair and 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 ≥ 12 mmHg¹.

Intra-Abdominal Pressure (IAP)

This refers to the pressure concealed within the abdominal cavity¹. 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 day⁵.

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. 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

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 IAP⁶.

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

- The septic contaminated abdomen that cannot be closed for infectious reasons (e.g. pancreatitis, necrotising fasciitis, peritonitis) and/or where re-explorations are necessary.
- 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 where the patient remains inadequately resuscitated and who needs a period of intensive care therapy prior to a definitive surgical procedure.
- The patient with primary or secondary ACS, who needs a life-saving decompressive laparotomy.

The concept of the open abdomen is not new, although historically it has been associated with significant morbidity and mortality. Over the past two decades, evolving physiological knowledge and intensive care practices, together with the advent of various TAC techniques, including KCI's open abdomen negative pressure therapy system, have resulted in many centers reporting significant improvements in patient outcomes⁷⁻⁹.

Trauma and sepsis

There is some confusion in the literature as to whether management should differ regarding the treatment of patients with trauma versus sepsis as the primary clinical cause of an open abdomen. However, regardless of etiology, the principles of management should be the same.

Differences in outcome may reflect the fact that trauma patients tend to be younger, are seen earlier and may recover more quickly from the inflammatory processes associated with the open abdomen. Source control and preservation of viable tissue in these patients is critical. In addition, patients with sepsis have an increased overall rate for small bowel fistula¹⁰.

1. THE OPEN ABDOMEN AS A TREATMENT OPTION

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 patients⁷. The ultimate goal is to achieve delayed primary fascial closure. On occasion, when the latter is not possible, functional abdominal closure using mesh or other prosthetic materials is reasonable and helps to minimize subsequent herniation.

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.

A consensus clinical pathway for managing the open abdomen over time using the ABThera™ Open Abdomen Negative Pressure Therapy System⁹ describes three treatment phases: acute (24 - 72 hours); intermediate (72 hours to 10 days) and late reconstructive (10 days to final closure).

In the early treatment phase, the initial task 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.

Once stabilized and in the ICU, the patient, depending on his/her underlying pathology, should undergo core re-warming, correction of coagulopathy, optimization of hemodynamics, ventilatory support and definitive investigation. Back in the operating theater, the dressing is removed and, if the criteria for closure can be met, the abdomen is closed.

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.

1. THE OPEN ABDOMEN AS A TREATMENT OPTION

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, 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; promote ambulation and early enteral feeding to permit early discharge from ICU.

2. TOTAL MANAGEMENT OF THE OPEN ABDOMEN

TEMPORARY ABDOMINAL CLOSURE

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 the ABThera™ Open Abdomen Negative Pressure Therapy System for active abdominal therapy, which have a number of advanced wound 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), the KCI system 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.

STRUCTURAL CLASSIFICATION OF THE OPEN ABDOMEN

The following classification scheme was developed during the consensus meetings on the management of the open abdomen using the V.A.C.® Abdominal Dressing System held in November 2007 and January 2009 and is based on previous work by Banwell and Téot¹⁵ and Swan and Banwell¹⁶. This new classification system uses grades to describe the natural history of clinical improvement or deterioration in patients with an open abdomen¹⁷.

Table 2.1: Classification of the open abdomen¹⁷

Grade		Description
1a	<p>Simple</p>	Clean open abdomen (OA) without adherence and/or fixity
1b		Contaminated OA without adherence and/or fixity
2a		Clean OA developing adherence and/or fixity
2b		Contaminated OA developing adherence and/or fixity
3		OA complicated by fistula formation
4	Complex	Frozen OA with adherent/fixed bowel, unable to close surgically, with or without fistula

2. TOTAL MANAGEMENT OF THE OPEN ABDOMEN

MANAGEMENT ACCORDING TO GRADES

The aim of treatment is to maintain the patient's open abdomen at the lowest and simplest grade (e.g. with a clean open abdomen without adhesences between the viscera and the abdominal wall, without lateralization of the fascia, contamination or fistula formation) and to prevent progression to a more complex grade. This goal is supported by the safe use of the KCI system for active abdominal therapy, together with adequate resources to ensure a successful outcome. Suboptimal treatment may cause adhesions to develop and/or the fascia to become fixed laterally.

Grade 1a: Clean open abdomen without adherence and/or fixity

This situation often occurs following a decompressive laparotomy for ACS, following a ruptured abdominal aortic aneurysm or following abdominal trauma not associated with visceral perforation. Provided the patient does not have other risk factors for poor outcome, the prognosis is good. The primary aim is to maintain the patient as a Grade 1a and to achieve delayed primary fascial closure with the support of a KCI system for active abdominal therapy (e.g. ABThera™ Open Abdomen Negative Pressure Therapy System).

Grade 1b: Contaminated open abdomen without adherence and/or fixity

Typical scenarios include patients with local or generalized perforation due to infection such as diverticulitis, or perforation due to ischemia, anastomotic breakdown after colorectal surgery, or trauma affecting the gastrointestinal tract. The aim is to convert the open abdomen to a clean situation and to prevent fixity or lateralization. In addition, in patients with a Grade 1b open abdomen that is unlikely to close rapidly, mesh, elastic loops or other adjuncts may be considered to help prevent retraction of the fascia and to avoid progression to a Grade 2 open abdomen.

Grade 2a: Clean open abdomen developing adherence and/or fixity

Where adhesions have developed between the intestines and the abdominal wall and/or the fascia has retracted laterally, delayed primary fascial closure becomes difficult to achieve. Treatment should aim to minimize the retraction of the fascial edges and prevent further deterioration, with the goal of converting the patient to a Grade 1a open abdomen.

After addressing any complications or fixity, the ABThera™ Open Abdomen Negative Pressure Therapy System for active abdominal therapy may be applied. Insertion of the visceral protective layer deep into the paracolic gutters is essential to completely separate the viscera from contact with the abdominal wall and to ensure drainage of exudate. Formation of adhesions of the viscera to the abdominal wall may reduce the likelihood of fascial reapproximation and increase the risk of fistula development, common complications in patients with exposed viscera. When adhesions are dense and difficult to divide, caution and good clinical judgement are vital to avoid damage to the bowel and an increased risk of fistula formation.

2. TOTAL MANAGEMENT OF THE OPEN ABDOMEN

Grade 2b: Contaminated open abdomen developing adherence and/or fixity

In patients where source control has not yet been achieved and where adhesions and/or fixity may preclude subsequent fascial closure, the primary aim is to control the contamination and to convert the patient to a Grade 2a with no further deterioration. A KCI system for active abdominal therapy can be applied as above (see Grade 2a).

Grade 3: Open abdomen complicated by fistula formation

The development of an enteroatmospheric/enterocutaneous fistula represents a major deterioration that significantly impacts on management. The bowel is not always fixed in this situation and some patients may be converted to a Grade 1a if managed early and correctly. This requires attention to sepsis, anatomy, nutrition and the timing of surgery. The primary aim is to control the fistula and prevent loss of abdominal domain, lateralization of the fascia or damage to the skin. If the fistula can be controlled, the patient may be successfully moved into a Grade 1 or 2, with subsequent delayed fascial closure. However, in practice, conversion from a Grade 3 to a Grade 1 is difficult and is not achieved in many individuals. Prevention of adhesions and/or fixity is of great importance to avoid progression to a fixed and frozen abdomen (Grade 4).

There are limited reports on the use of standard V.A.C.[®] Therapy in these patients, but it is not recommended as a first-line treatment for fistula and should be used only by healthcare professionals with appropriate training and expertise. The aim is to manage and isolate the fistula effluent to prevent continual contamination of the abdomen.

Grade 4: Frozen open abdomen with adherent/fixed bowel, unable to close surgically, with or without fistula

Patients with a frozen abdomen, with or without fistula, need a very different management approach compared to other grades and will require referral to a specialist center. In patients with a Grade 4 open abdomen with a fistula the primary aim is to control the fistula and optimize the patient's physiology, protecting the skin and fascia and preventing sepsis.

Simple closure of the skin over the granulated wound bed/viscera or planned ventral hernia may be possible. These strategies allow for early patient discharge, but are associated with subsequent herniation and requirement for further reconstructive surgery.

In specialist centers, definitive reconstruction for Grade 4 often entails staged closure to manage the fistulating bowel and to achieve temporary fascial closure using an absorbable mesh. The risk of hernia is high and therefore the need for subsequent surgical procedures is common.

2. TOTAL MANAGEMENT OF THE OPEN ABDOMEN

It has been reported that techniques such as component separation¹⁸ or other progressive fascial closure methods may help surgeons achieve fascial or functional abdominal closure. Biologic materials such as Alloderm® Regenerative Tissue Matrix or Strattice™ Reconstructive Tissue Matrix may be considered to support fascial closure by reinforcing the primary midline repair. This allows for a single stage repair without the need for a planned repair procedure 6 - 18 months later. Alternatively, tissue matrix may be considered as a bridge to abdominal closure if delayed primary fascial closure is not possible. However, it is important to continue to follow the same philosophy with the goal of re-approximating the midline and taking measures to minimize the fascial defect as much as possible prior to definitive closure¹⁹.

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 the ABThera™ System 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, lactemia, coagulopathies 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 Principles for Managing the Open Abdomen, page 4.

2. TOTAL MANAGEMENT OF THE OPEN ABDOMEN

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 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. Abdominal 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.

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3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

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

Also, for detailed instructions for use, please refer to the ABThera™ Open Abdomen Negative Pressure Therapy System instructions for use included with each ABThera™ dressing and therapy unit.

USING THE ABTHERA™ OPEN ABDOMEN NEGATIVE PRESSURE THERAPY SYSTEM FOR ACTIVE ABDOMINAL THERAPY

The decision to use the ABThera™ Open Abdomen Negative Pressure Therapy System for active abdominal 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 dressing at the time of surgery or as early as possible. Complications such as adhesions and fistula development are common in patients with exposed viscera.

Management of the open abdomen is complex. The ABThera™ NPT System 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™ Open Abdomen Negative Pressure System for active abdominal therapy in the acute situation should take place in the operating room 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™ Open Abdomen Negative Pressure Therapy System for active abdominal therapy. Read instructions for use accompanying the device prior to application.

WOUND PREPARATION

WARNING: Review all ABThera™ Negative Pressure Therapy System Safety Information before beginning wound preparation. Ensure adequate hemostasis has been achieved prior to dressing placement (refer to "Bleeding" section under **WARNINGS**).

1. Sharp edges or bone fragments must be eliminated from wound area or covered (refer to "Bleeding" section under **WARNINGS**).
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.

3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

ABTHERA™ VISCERAL PROTECTIVE LAYER (VPL) APPLICATION

Sizing the Visceral Protective Layer can be achieved by folding or cutting.

WARNING: The foam in the visceral protective layer is encapsulated for patient safety. Protect vital structures with Open Abdomen visceral protective layer at all times during therapy. **Never** place exposed foam material directly in contact with exposed bowel, organs, blood vessels or nerves.

NOTE: The 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.

1. Remove contents from inner pouch and unfold the visceral protective layer in a sterile field. Either side of the visceral protective layer may be placed on the omentum or viscera.
2. Gently place visceral protective layer over the open abdominal cavity (Fig. 2).
3. Determine the orientation of the dressing for the specific application. If visceral protective layer will be placed around tubes, drains or the falciform ligament, cut only **between** the foam extensions (Fig. 1). (**Do not cut near or through foam extensions**). Orient the visceral protective layer accordingly before cutting.

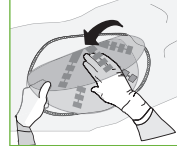
Fig. 1



Fig. 2



Fig. 3



FOLDING VISCERAL PROTECTIVE LAYER TO SIZE

1. Hold dressing by the edge and slightly lift. Then slowly lower dressing into the paracolic gutter, while using the other hand to gently and evenly work the dressing down. (Fig. 3). Fold any excess visceral protective layer up and over onto itself.
2. Continue placing 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.

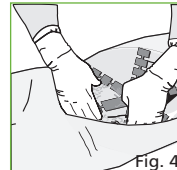
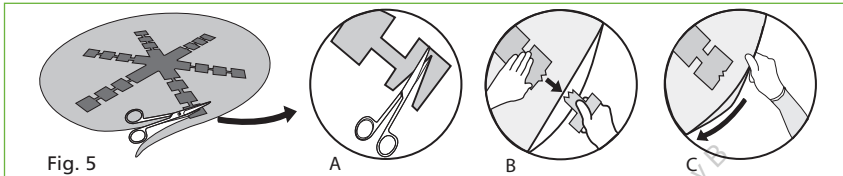


Fig. 4

3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

CUTTING VISCERAL PROTECTIVE LAYER TO SIZE



1. Cut 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 visceral protective layer cover exposed foam edge (Fig. 5C), and foam cannot contact organs (see **WARNING** in previous section).

NOTE: 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

1. Tear the perforated foam to the needed size along perforations. The foam should fit directly over the visceral protective layer while still being in contact with all 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 visceral protective layer (Fig. 6). Ensure that perforated foam does not go below the level of the abdominal incision or wound. Do not force foam into any area of the wound.

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.

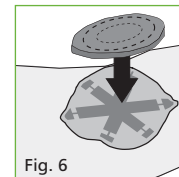
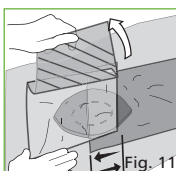
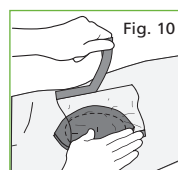
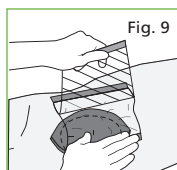
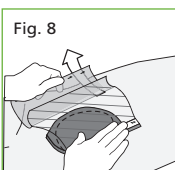
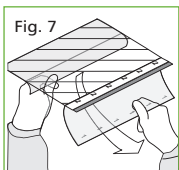


Fig. 6

3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

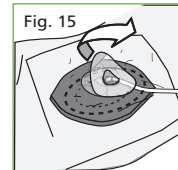
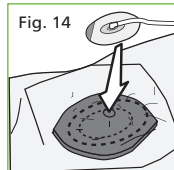
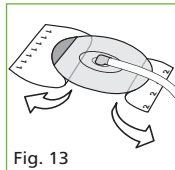
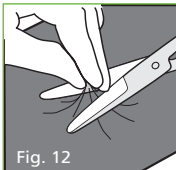
DRAPE APPLICATION



1. Holding the open abdomen drape, partially pull back one side of layer 1 to expose adhesive (Fig. 7). 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 a 8 - 10cm border of intact periwound tissue (Fig. 8). 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).
3. Remove remaining tab 1 backing material and pat around drape to ensure an occlusive seal.
4. Remove green-striped stabilization layer 2 (Fig. 9).
5. Remove perforated blue handling tabs from drape (Fig. 10).
NOTE: When using multiple pieces of drape, ensure that the edges of the drape overlap in order to achieve a seal (Fig. 11).

3. APPLICATION OF THE ABThera™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

TUBING SET/INTERFACE PAD APPLICATION



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

1. Choose interface pad application site. Give particular consideration to fluid flow and tubing position to allow for optimal flow and avoiding placement over bony protuberances or within creases in the tissue.
2. Pinch drape and cut a 2.5cm hole (not a slit) through the drape (Fig. 12). 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 interface pad, which has a central disc and a surrounding outer adhesive skirt.
 - Gently remove both backing layers 1 and 2 to expose adhesive (Fig. 13).
 - Place interface pad opening in central disc directly over hole in drape (Fig. 14).
 - Apply gentle pressure on the central disc and outer skirt to ensure complete adhesion of the interface pad.
4. Pull back on blue tab to remove pad stabilization layer (Fig. 15). ABThera™ Dressing application is complete. See the **PREPARATION FOR USE** section.

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, packing 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**.

DRESSING CHANGES

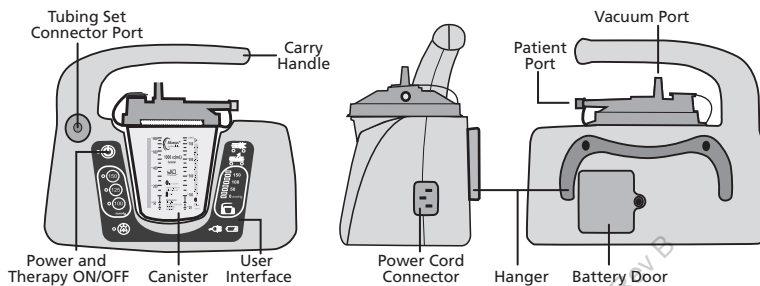
Dressing changes should occur every 24 - 72 hours, or more frequently based upon a continuing evaluation of wound condition and patient presentation. Consider more frequent dressing changes in the presence of infection or abdominal contamination.

WARNING: Refer to "Application Setting" section under **WARNINGS**.

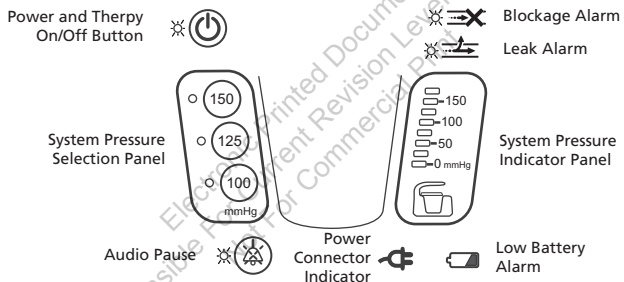
Whenever the open abdomen dressing is changed, always replace all ABThera™ Dressing components with components from an unopened sterile package.

3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

ABTHERA™ OPEN ABDOMEN NEGATIVE PRESSURE THERAPY UNIT



USER INTERFACE



1000 (CC/ML) CANISTER



Canister used with the ABThera™ Open Abdomen Negative Pressure Therapy Unit is a single-use, latex free, non-sterile, 1000 (cc/mL) clear container with graduated markings at 100 (cc/mL) increments up to 800 (cc/mL).

NOTE: Never reuse a canister.

3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

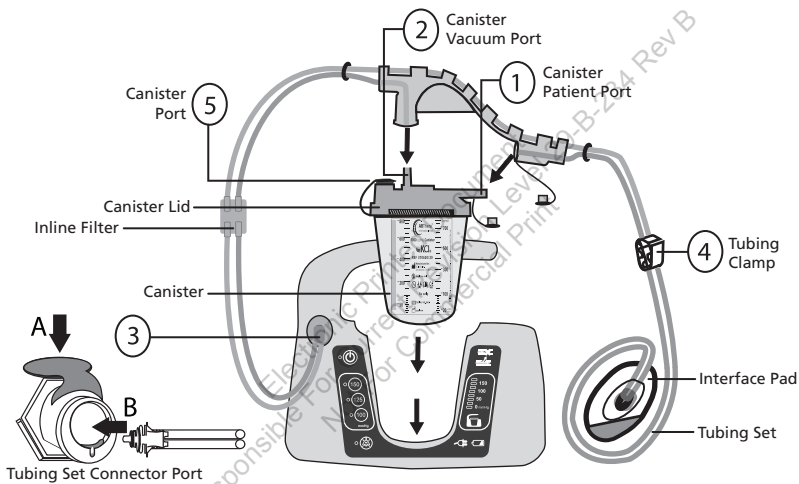
17

PREPARATION FOR USE

CONNECT TUBING SET/INTERFACE PAD TO CANISTER

NOTE: Tubing Set is not compatible with hospital vacuum sources.

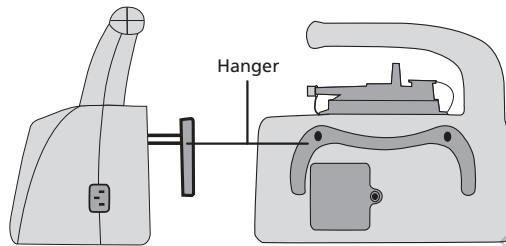
1. Place canister lid onto canister.
2. Place canister into therapy unit ensuring graduated markings on the canister can be viewed.
3. Attach tubing set to canister lid; see picture and steps 1-5 below.



1. Slide tubing set onto canister patient port - **1**.
2. Push tubing set down onto the canister vacuum port - **2**.
3. Plug tubing set into connector port; the release latch on the connector port must be in the down position "A" before tubing is plugged in - **3 A & B**. A click will indicate proper connection. Push release latch down to unplug tubing set.
4. Ensure tubing clamp is open - **4**.
5. Ensure canister access port cap is securely in place - **5**. Canister's access port is for adding a gel to solidify contents (not provided by KCI).

3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

ABTHERA™ OPEN ABDOMEN NEGATIVE PRESSURE THERAPY UNIT PLACEMENT



The therapy unit is equipped with a hanger for footboard placement.

1. To place therapy unit on a footboard, pull out spring-loaded hanger on back of unit.
2. Place therapy unit over footboard and gently allow the hanger to retract. If desired, therapy unit may be placed on a solid, level surface near the same level as the patient's abdomen.

BEGINNING THERAPY

WARNING: Monitor Fluid Output: The ABThera™ Open Abdomen Dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with the ABThera™ NPT System, the volume of exudate in the canister and tubing should be frequently examined.

1. Ensure the open abdomen dressing has been applied as described in the Open Abdomen Dressing Application instructions in this guide.
2. Plug ABThera™ power cord into therapy unit.
3. Plug ABThera™ power cord into AC wall outlet. Power connected indicator on the user interface will illuminate with a blue backlight.
4. Press and hold the Therapy ON/OFF button for two seconds to turn therapy unit on and start therapy. The green light next to the Therapy ON/OFF button will illuminate.

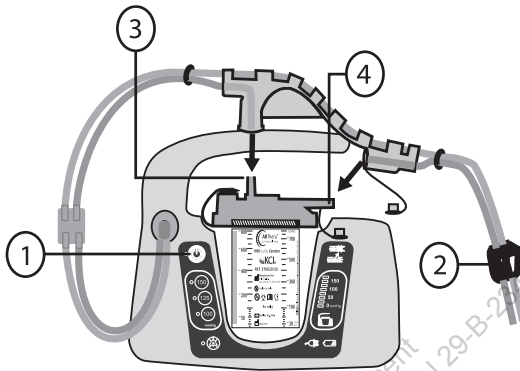
NOTE: The system will automatically default to 125mmHg.

NOTE: The pump will begin running, then slow down as it nears the selected pressure. When selected pressure is reached, pump will stop running and only come on to maintain pressure.

5. Push the desired pressure on the system pressure selection panel; a green light next to the selection will illuminate.
6. With therapy on, assess dressing to ensure integrity of seal.
 - Dressing should have a slightly wrinkled appearance when therapy is active.
 - There should be no hissing sounds.
 - If there is any evidence of an air leak around dressing or tubing connectors, refer to ABThera™ Instructions for Use.

3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

STOPPING THERAPY/CHANGING THE CANISTER



CAUTION: Follow Standard Precautions as the system may contain body fluids.

1. Press and hold the Therapy ON/OFF button for approximately three seconds to power off therapy unit - **1**.
2. Squeeze tubing clamp several clicks to close - **2**.
3. Lift up tubing set from canister's vacuum port - **3**.
4. Pull tubing set away from canister's patient port - **4** and cap tubing set using tethered cap.
5. Ensure caps on canister's lid are secured before removing canister. Canister vacuum port does not have a cap; canister filter prevents fluid from exiting.
6. Lift canister straight up and out of therapy unit.
7. To continue therapy, insert new canister. **Never reuse a canister.**
8. Connect tubing set to canister, restart therapy (see Preparation for Use section).

NOTE: Tubing set is included with dressing kit and replaced at time of dressing change.

NOTE: The system will automatically default to 125mmHg.

9. Dispose of the canister according to local hospital or facility protocols.

An additional supply of dressings and canisters may be ordered by calling your local KCI representative or 1-800-275-4524.

3. APPLICATION OF THE ABTHERA™ SYSTEM FOR ACTIVE ABDOMINAL THERAPY

CARE AND CLEANING

If the product becomes soiled while in use, disinfectants containing quaternary ammonium compounds or other similar disinfectant products may be used to clean the ABThera™ Therapy Unit. All visible organic material should be cleaned from the device prior to disinfection. Use personal protective equipment (PPE) and hand hygiene protocols in accordance with local protocols for cleaning and disinfection.

CAUTION: Avoid spilling fluid on any part of the therapy unit. Fluids remaining on electronic controls can cause corrosion which can cause the electronic controls to fail. Component failure may cause the therapy unit to operate erratically, possibly causing a potential hazard to patient or care providers. Refer to qualified service personnel.

TIPS FOR APPLYING THE ABTHERA™ SYSTEM 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 typical pressure settings for KCI systems for active abdominal therapy in the open abdomen is a continuous pressure of 125mmHg. For further information, please refer to the current version of the V.A.C.® *Therapy Clinical Guidelines. Recommendations for Clinicians.*

For more detailed safety information for the ABThera™ Open Abdomen Negative Pressure Therapy System, please refer to Appendix 1.

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APPENDIX 1

ABTHERA™ OPEN ABDOMEN NEGATIVE PRESSURE THERAPY SYSTEM SAFETY INFORMATION

Disposable components of the ABThera™ Open Abdomen Negative Pressure Therapy (NPT) System, including the foam dressing, tubing and drape are packaged sterile and are latex-free. ABThera™ NPT System canisters are supplied non-sterile and are latex-free. All disposable components of the ABThera™ NPT System are for single use only. To help ensure safe and effective use, the ABThera™ Open Abdomen Dressing is to be used only with the ABThera™ Unit.

Sterile/aseptic technique is recommended when applying the ABThera™ NPT System 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

- The ABThera™ NPT System 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 system is for use in open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome.
- The ABThera™ System is intended for use in the acute hospital setting: in trauma, general and plastic surgery wards. The abdominal dressing will most often be applied in the operating room.

CONTRAINDICATIONS

- Patients with open abdominal wounds containing non-enteric unexplored fistula should not be treated with the ABThera™ NPT System.
- Protect vital structures with ABThera™ Visceral Protective Layer **at all times** during therapy. Never place exposed foam material directly in contact with exposed bowel, organs, blood vessels or nerves.

Management of the open abdomen has been documented in case reports and consensus panel literature. Please refer to the Reference section at the end of the dressing application instructions.

APPENDIX 1. ABThera™ OPEN ABDOMEN NEGATIVE PRESSURE THERAPY SYSTEM SAFETY INFORMATION

WARNINGS

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 turn off the ABThera™ NPT System, take appropriate measures to stop bleeding, and contact the physician. The ABThera™ NPT System 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 anastomoses
- 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.

Use of Visceral Protective Layer: When using the Open Abdomen Negative Pressure System, ensure that the Open Abdomen Visceral Protective Layer completely covers all exposed viscera and completely separates the viscera from contact with the abdominal wall. Place the visceral protective layer over the omentum or exposed internal organs, and carefully tuck it between the abdominal wall and internal organs, making sure the 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 are common complications 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 dressing application instructions for details regarding dressing change frequency (see pages 11 - 14).

Dressing placement: Always use an ABThera™ 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 ABThera™ Dressing components are not bioabsorbable. Always remove all dressing components from the abdomen at every dressing change.

APPENDIX 1. ABThera™ OPEN ABDOMEN NEGATIVE PRESSURE THERAPY SYSTEM SAFETY INFORMATION

Keep negative pressure on: Never leave the ABThera™ Dressing in place without active negative pressure for more than 2 hours. If negative pressure is off for more than 2 hours, change the dressing as shown in these Clinical Guidelines. Either apply a new ABThera™ 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 ABThera™ Drape has an acrylic adhesive coating, which may present a risk of an 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 ABThera™ 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.

Magnetic Resonance Imaging (MRI) – Therapy Unit: The ABThera™ NPT Unit is **MR Unsafe**. Do not take the device into the MR environment.

Magnetic Resonance Imaging (MRI) – Open Abdomen Dressing: The ABThera™ Dressing can remain on the patient with minimal risk in an MR environment, assuming that use of the ABThera™ NPT System is not interrupted for more than 2 hours; please refer to **Keep negative pressure on**.

Hyperbaric Oxygen Therapy (HBO): Do not take the ABThera™ NPT Unit into a hyperbaric oxygen chamber. The ABThera™ NPT Unit is not designed for this environment, and **should be considered a fire hazard**. After disconnecting the ABThera™ Unit, either (i) replace the ABThera™ Dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the unclamped end of the ABThera™ Dressing tubing with moist cotton gauze. For HBO therapy, the tubing must not be clamped. Never leave an ABThera™ Dressing in place without active negative pressure for more than 2 hours; please refer to the **Keep Negative Pressure ON** section.

Application setting: ABThera™ Dressing applications and changes should be performed under strict sterile conditions in the surgical suite. If a dressing change is performed outside the surgical suite, it must be performed in an environment equipped to address the onset of critical complications (refer to **WARNINGS** section), 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 the ABThera™ NPT System, packing material may be drier than anticipated. Evaluate packing material prior to removal and rehydrate if necessary to prevent adherence or damage to adjacent structures.

APPENDIX 1. ABThera™ OPEN ABDOMEN NEGATIVE PRESSURE THERAPY SYSTEM SAFETY INFORMATION

Monitor fluid output: The ABThera™ Open Abdomen Dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with the ABThera™ NPT System, 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 the ABThera™ NPT System. 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 25mL from dressing 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 ABThera™ NPT System must not be placed in proximity to the vagus nerve.

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

Protect periwound skin: Consider the 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 tubing assembly 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 ABThera™ NPT System, please contact your local KCI Clinical Representative.

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