

ABTHERA ADVANCE™

OPEN ABDOMEN DRESSING



An overview of temporary abdominal closure dressings and systems

Choosing the right open abdomen management solution

3M + **KCI**™

Temporary Abdominal Closure Overview

Temporary abdominal closure (TAC) methods allow for stabilization of the patient to better endure subsequent operations. The abdomen is left open at the time of operation to facilitate re-exploration after trauma, allowing the abdomen to be accessible for washouts, and to stabilize the patient for further surgery.¹

The method of a temporary abdominal closure may play an important role in positive clinical and economic outcomes.²



What the ideal TAC should be able to do³

- Limit mortality
- Support a high rate of closure
- Limit complications
- Limit dressing changes
- Protect the fascia and skin
- Minimize loss of domain prevent the development of ACS
- Limit contamination
- Be easily applied
- Prevent adhesions
- Allow room for abdominal contents to expand
- Decrease bowel edema
- Allow for evacuation of fluids

The importance of Primary Fascial Closure³

Patients in whom early definitive primary closure cannot be performed are more likely to experience:

- Sepsis
- Increased ICU and Hospital LOS
- Enteroatmospheric Fistulas
- Incisional Hernia

Patients with fascial closure within **4-7 days** are associated with:

↓ **lower mortality**

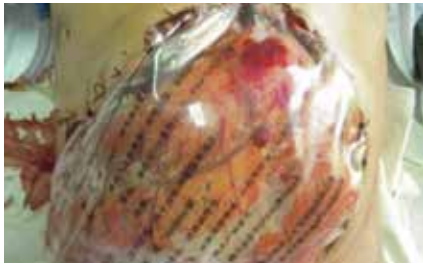
↓ **and fewer complications**

Methods of Temporary Abdominal Closure⁴



Skin-only Closure

A basic temporary abdominal closure method that involves using the skin to provide some abdominal wall stability. Up to 30 surgical clips (1cm apart from each skin edge) are utilized to perform a skin-only closure.



Bogota Bag

Technique involves cutting a previously sterilized IV bag into an open, oval shape and suturing it to the skin.

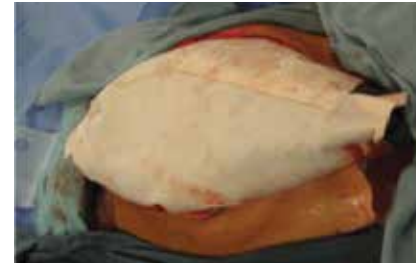


Barker's Vacuum Pack Technique

A technique that consists of multi-component layers from common materials available in most hospitals. It utilizes:

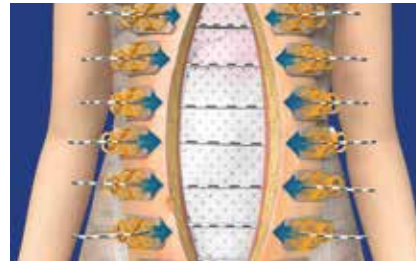
- A non-adherent polyethylene sheet (must be manually fenestrated)
- A moist surgical towel cover
- Two silicone drains over the towels
- An adhesive sheet.

Continuous wall suction is applied to remove fluid.



Wittmann Patch™

Consists of two detachable components: a loop sheet and a closure sheet sutured to the abdominal fascia. Closure is achieved by overlapping, and sequentially tightening the sheets.



ABRA® Abdominal⁵

A re-approximation anchor system intended to retract the abdominal wall defect by cyclic stretching of elastomer bands running across the wound opening.

Commercial NPWT Open Abdomen Dressing

All inclusive dressing kits specifically designed for use in the open abdomen like ABTHERA™ Therapy.



ABTHERA ADVANCE™ Dressing Components

ABTHERA™ Fenestrated Visceral Protective Layer

Provides separation between abdominal wall and viscera, protecting abdominal contents. It features 6 encapsulated foam arm extension that aid in fluid removal and negative distribution deep in the paracolic gutters.

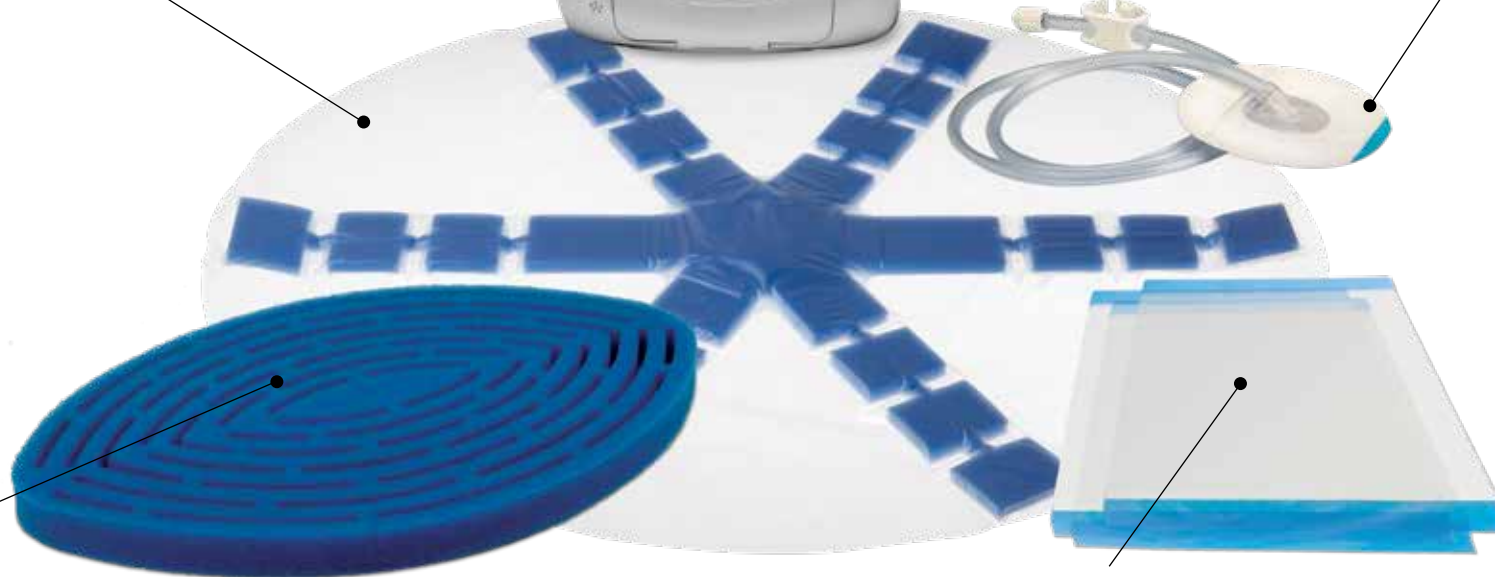
ABTHERA™ Therapy is the only TAC system in the US that features a visceral protective layer with encapsulated foam.



SENSAT.R.A.C.™ Pad and Technology

Our proprietary SENSAT.R.A.C.™ Technology provides a real-time pressure feedback system and adjusts and monitors pressure at the abdomen.

ABTHERA™ Therapy is the only open abdomen dressing designed to work with V.A.C.® Therapy and its patented SENSAT.R.A.C.™ Technology.



ABTHERA ADVANCE™ Perforated Foam

Under negative pressure, the unique configuration of the ABTHERA ADVANCE™ Perforated Foam is designed to collapse medially while maintaining its vertical rigidity.

ABTHERA ADVANCE™ Dressing is the only temporary abdominal closure dressing that features a foam with cutouts configured to draw the wound edges together.

V.A.C.® Drape

Provides a closed system to help isolate and protect abdominal contents from the external environment.

Comparing TAC Techniques and Products⁴

ABTHERA ADVANCE™
OPEN ABDOMEN DRESSING



RENASYS[®] AB Suprasorb[®] CNP VivanoMed[®] Abdominal Kit Invia[®] Abdominal Dressing Kit Barker's Vacuum Pack Technique Wittmann Patch ABRA[®] Abdominal Bogota Bag

	ABTHERA ADVANCE™	RENASYS [®] AB	Suprasorb [®] CNP	VivanoMed [®] Abdominal Kit	Invia [®] Abdominal Dressing Kit	Barker's Vacuum Pack Technique	Wittmann Patch	ABRA [®] Abdominal	Bogota Bag
Provides medial tension	●	●	●	●	●	●			
Fluid removal	●	●	●	●	●	●			
Protects the skin and fascia	●	●	●	●	●	●			
No sutures or staples required	●	●	●	●	●	●			
Ability to monitor fluid output	●	●	●	●	●	●			
Visceral Protective Layer with encapsulated foam	●								
Perforated foam with cutouts designed to collapse medially	●								

Pre-Clinical Evidence

NO CORRELATION TO HUMAN USE

In a comparative study of 4 healthy pigs with an open abdominal wound that were treated with either ABTHERA™ SENSAT.R.A.C.™ OA Dressing or ABTHERA ADVANCE™ Dressing at -125mmHg for 5 minutes, results showed that the ABTHERA ADVANCE™ Dressing showed a difference in the following:

31%

increase in overall tissue movement⁶

(N=82, p<0.005)

39%

increase in skin movement⁶ (N=42, p<0.05)

20%

increase in fascia movement⁶ (N=40, p<0.05)

In this study, no change in intra-abdominal pressure was observed when negative pressure was applied.

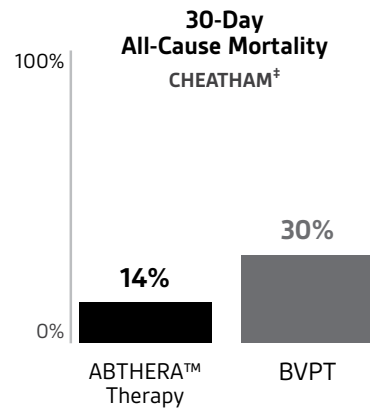
Wittmann Patch is a trademark of Starsurgical, Inc. ABRA Abdominal is a trademark of Dynamic Tissue Systems. Renasys AB is a trademark of Smith & Nephew, Inc. Invia® Abdominal Dressing Kit is a trademark of Medela AG. Suprasorb® CNP is a trademark of Lohmann & Rauscher GmbH & Co. KG. VivanoMed® Abdominal Kit is a trademark of PAUL HARTMANN AG.

ABTHERA™ Therapy Evidence



Decrease in all-cause mortality

In two separate studies, when compared to Barker's vacuum pack technique, ABTHERA™ Therapy demonstrated greater reduction in 30-day and 90-day all-cause mortality.^{2,7}

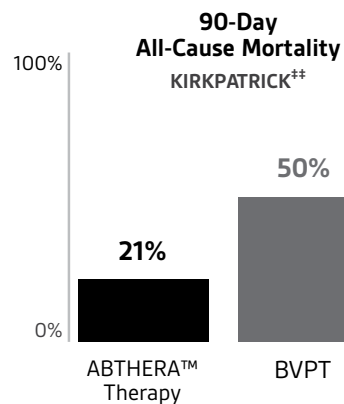


Prospective Study Examining Clinical Outcomes Associated with a Negative Pressure Wound Therapy System and Barker's Vacuum Packing Technique

Cheatham ML, Demetrios D, Fabian TC, Kaplan MJ, et al.

Of 280 patients enrolled from 20 study sites in the U.S., 168 patients received at least 48 hours of consistent Temporary Abdominal Closure (TAC) therapy (111 ABTHERA™ Therapy, 57 BVPT).

- **Thirty-day PFC rate:** 69% for ABTHERA™ Therapy and 51% for BVPT ($p = 0.03$)
- **Thirty-day all-cause mortality:** 14% for ABTHERA™ Therapy and 30% for BVPT ($p = 0.01$)
- **Median of days to PFC:** 9 days for ABTHERA™ Therapy vs 12 days for BVPT ($p = 0.12$)



Active Negative Pressure Peritoneal Therapy After Abbreviated Laparotomy: The Intraperitoneal Vacuum Randomized Controlled Trial

Kirkpatrick AW, Roberts DJ, Faris PD, et al.

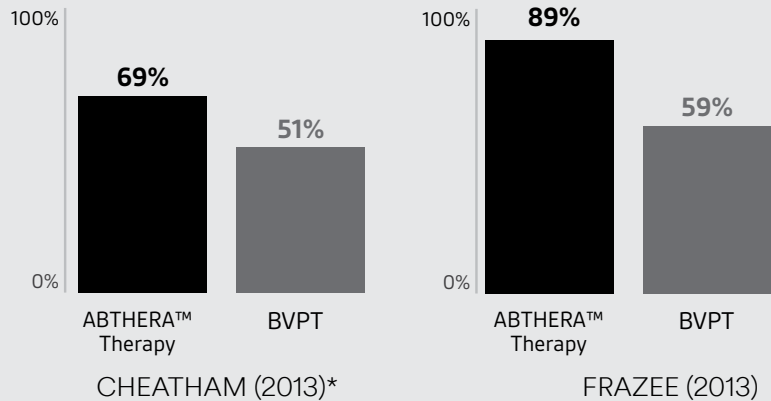
A total of 45 adults with abdominal injuries (46.7%) or intra-abdominal sepsis (52.3%) were randomly allocated to ABTHERA™ Therapy ($n = 23$) or Barker's vacuum pack ($n = 22$). Primary endpoint to identify the difference in plasma concentration of interleukin-6 at 24- and 48-hours after application were not met.

- **90-day mortality:** 50% for Barker's vacuum pack and 21.7% for ABTHERA™ Therapy ($p = 0.04$)



Increase in primary fascial closure

In two separate studies, when compared to Barker's vacuum pack technique, ABTHERA™ Therapy demonstrated an increase in primary fascial closure.^{2,8}



Are commercial negative pressure systems worth the cost in open abdomen management?

Frazer RC, Abernathy SW, Jupiter DC, et al.

Thirty-seven open abdomen patients who had temporary abdominal closure with the ABTHERA™ Therapy device were compared with 37 open abdomen patients managed with the Barker's technique.

Ultimate midline fascial closure:

89% (33/37) for ABTHERA™ Therapy and 59% (22/37) Barker's Vacuum Packing Technique (BVPT) ($p < 0.05$)

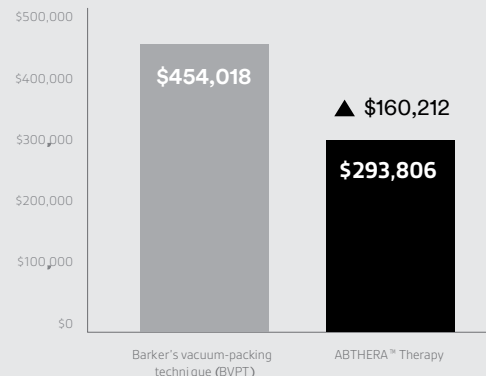
*Of 280 patients enrolled from 20 study sites in the U.S., 168 patients received at least 48 hours of consistent Temporary Abdominal Closure (TAC) therapy (111 ABTHERA™ Therapy, 57 BVPT). Median of days to PFC were 9 days for ABTHERA™ Therapy vs 12 days for BVPT ($p = 0.12$). Thirty-day PFC rate was 69% for ABTHERA™ Therapy and 51% for BVPT ($p = 0.03$). Thirty-day all-cause mortality was 14% for ABTHERA™ Therapy and 30% for BVPT ($p = 0.01$).



Decrease in resource utilization⁹

In a 42-patient study, hospital charges were lower in the patient population who received ABTHERA™ Therapy when compared to Barkers vacuum packing technique

	ABTHERA™ Therapy	BVPT
Hospital Days ($p=0.1$)	20	31
ICU Days ($p=0.17$)	11	17
Ventilator Days ($p=0.19$)	9	13
# of Dressing Changes ($p=0.047$)	2	3



ABTHERA™ Therapy demonstrated a decrease in:

- ICU days
- Ventilator days
- Hospital days
- Days to abdominal closure
- Hospital charges.

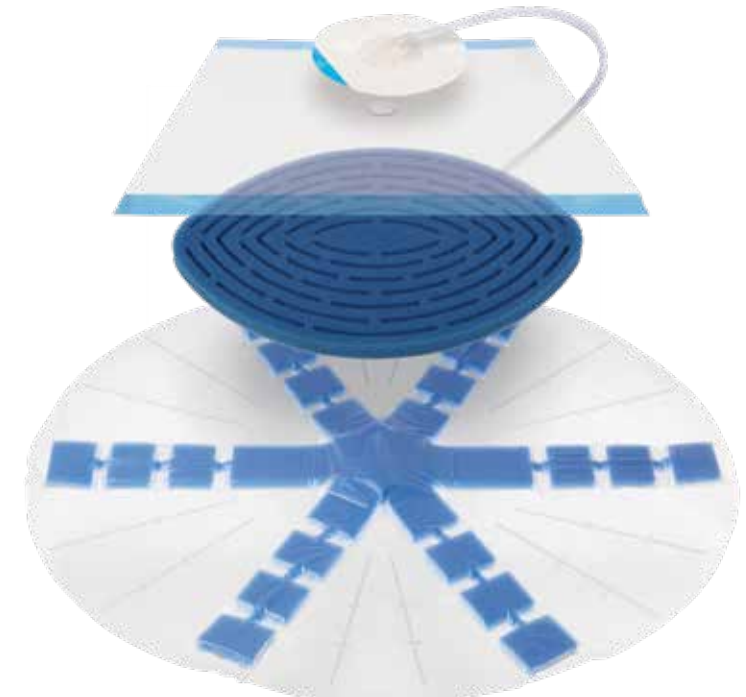
Patients who received ABTHERA™ Therapy reduced hospital charges per patient by \$160,212.

Graphs adapted from data in Safcsak K, et al. American Surgeon, 2011.

Ordering Information

Item Number	Qty.
ABT1055 (Includes ABTHERA™ Fenestrated Visceral Protective Layer, (2) ABTHERA ADVANCE™ Perforated Foam, (4) V.A.C.® Drapes, and SENSAT.R.A.C.™ Pad and Tubing)	5 per case

For use with negative pressure therapy provided by the V.A.C.ULTA™ Therapy Unit or INFOV.A.C.™ Therapy Unit.



References

1. Franklin ME, Alvarez A, Russek K. Negative Pressure Therapy: A Viable Option for General Surgical Management of the Open Abdomen. *Surgical Infections* 2012 December 1;19(4):353-63.
2. Cheatham ML, et al. Prospective Study Examining Clinical Outcomes Associated with a Negative Pressure Wound Therapy System and Barker's Vacuum Packing Technique. *World Journal of Surgery*. 2013 Sep;37(9):2018-30.
3. Fitzpatrick ER. Open abdomen in trauma and critical care. *Critical care nurse*. 2017 Oct 1;37(5):22-45.
4. Huang Q, Li J, Lau WY. Techniques for Abdominal Wall Closure after Damage Control Laparotomy: From Temporary Abdominal Closure to Early/Delayed Fascial Closure-A Review. *Gastroenterol Res Pract*. 2016;2016:2073260. doi:10.1155/2016/2073260
5. Dynamic Tissue Systems. ABRA® Abdominal. *Instructions for Use*. Accessed June 2019.
6. Schmidt M, Hall C, Mercer D, Kieswetter K. Novel Foam Design Actively Draws Wound Edges Together Under Negative Pressure: Benchtop and Pre-clinical Assessment. *Presented at: Society of Advanced Wound Care / Wound Healing Society*; November 3, 2018; Las Vegas, Nevada.
7. Kirkpatrick AW, Roberts DJ, Faris PD et al. Active Negative Pressure Peritoneal Therapy After Abbreviated Laparotomy: The Intraperitoneal Vacuum Randomized Controlled Trial. *Ann Surg* 2015;262:38-46.
8. Frazee RC, Abernathy SW, Jupiter DC, et al. Are commercial negative pressure systems worth the cost in open abdomen management? *J Am Coll Surg* 2013;216:730-735.
9. Safcsak K, Cheatham ML. ABTHERA™ Open Abdomen Negative Pressure System versus Barker's Vacuum Pack Technique: analysis of resource utilization. *Poster presented at the Fifth World Congress on the Abdominal Compartment*, Orlando, FL. August 10-13, 2011.

NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application.

© 2020 3M. All rights reserved. 3M and the other marks shown are marks and/or registered marks. Unauthorized use prohibited.
PRA-PM-EU-00388 (10/20)

