

Technology Review

KCI an Acelity Company- Negative Pressure Wound Therapy (NPWT)

This technology review profiles the clinical features and functionality of the product(s) available in the United States for *Negative Pressure Wound Therapy (NPWT) devices*.

Device

NPWT uses a continuous or intermittent application that applies a subatmospheric pressure to the surface of many types of acute and/or chronic wounds ^[1]. The continual or intermittent pressure removes fluid, wound exudate, irrigation fluids, and infectious materials from the wound via a porous dressing that allows for an even distribution of pressure throughout the wound. NPWT can increase the number of wounds healed and reduce the time it takes to heal a wound in a number different types of wounds and settings, therefore NPWT may have cost saving benefits when compared to standard advanced wound care ^[2]. KCI an Acelity Company was the first commercially NPWT available and they offer many types of negative pressure wound therapy devices ranging from acute, extended and/or home care.

Product Summary

NPWT range in a variety of sizes of portable pumps that deliver continuous or intermittent levels of negative pressure. A tubing links the pump to a wound filler (gauze or foam dressing). The pump can be powered by AC power, rechargeable battery, or mechanical pump action. Various size canisters with charcoal filters, hydrophobic construction, and available gel packs are designed to be used with the units. Accessories are dressings, drapes, Y-connector, Sensa T.R.A.C. pad (tubing, clamp, and connector), tubing cap ^[3].

Key Points

- NPWT devices range in a variety of sizes. The key components are:
 - The Device
 - Canisters
 - Dressings
- NPWT has been applied to a wide range of clinical situations, including open abdomen or following surgical debridement of acute or chronic wounds²
- Available in portable and stationary
- Consider the advantages and disadvantages of NPWT
- Study outcomes show similar performance in devices and management of wounds
- The choice of devices is dependent on financial cost, availability, and personal choice⁸.

Technology Review

Comparison of KCI NPWT Devices (not an inclusive list) ^[4]

		KCI <u>V.A.C. Freedom</u> Acute care Extended care Home care	KCI <u>V.A.C. Ultra</u> Acute care Extended care	KCI <u>ActiV.A.C.</u> Acute care Extended care Home care	KCI <u>ABERTHA</u> Acute care (RETIRED 3.2020)	KCI <u>PREVENA</u> Home care	KCI <u>SNAP</u> Home care
		www. Woundsource.com					
Product Features	Accommodate large wounds	•	•	•	•		
	Accommodate small wounds	•	•	•			•
	Adjustable PSI	•	•	•	•		
	Antimicrobial interface available					•	
	Battery operated	•	•	•	•	•	
	Disposable					•	
	Foam interface	•	•	•	•	•	•
	Gauze interface	•		•			
	Instillation function		•				
	Intermittent-pressure setting	•	•	•			
	Irrigation function		•				
	Portable (< 1lb)	•		•		•	•
	Single use					•	•
	Touchscreen		•	•			
	Usable on closed wounds			•		•	
	Usable on open wounds		•	•			•
	Variable pressure setting		•	•	•		
	Educational Material Available	•	•	•	•	•	•
	Free Samples/Trials available		•		•	•	•
	Published Clinical Article Available	•	•	•	•	•	•

Note: This document is for informational purposes only and is not intended to replace individual clinical decision-making, which is the sole and independent responsibility of the practitioner. HealthTrust expressly disclaims any liability for treatment decisions. Please direct any questions or comments to clinical.research@healthtrustpg.com, or to your supplier representative. © 2020 HealthTrust. All Rights Reserved.

Technology Review


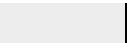
Comparison of KCI V.A.C and Smith & Nephew (S&N) RENASYS (not an inclusive list) ^[4]

		KCI <u>V.A.C.</u> <u>Ultra</u>	KCI <u>ActiV.A.C.</u>	S&N <u>RENASYS</u>
www.woundsource.com				
Product Features	Accommodate large wounds	•	•	•
	Accommodate small wounds	•	•	•
	Adjustable PSI	•	•	•
	Antimicrobial interface available			•
	Battery operated	•	•	•
	Disposable			
	Foam interface	•	•	•
	Gauze interface		•	•
	Instillation function	•		
	Intermittent-pressure setting	•	•	•
	Irrigation function	•		
	Portable (< 1lb)		•	
	Single use			
	Touchscreen	•	•	•
	Usable on closed wounds		•	•
	Usable on open wounds	•	•	•
	Variable pressure setting	•	•	•
	Educational Material Available	•	•	•
	Free Samples/Trials available	•		
	Published Clinical Article Available	•	•	

Comparison of KCI, Genadyne, and Smith & Nephew (S&N) single use devices ^[4]

		KCI <u>SNAP</u>	Genadyne <u>UNO</u>	S&N <u>PICO</u>
www.woundsource.com				
Product Features	Accommodate small wounds	•	•	•
	Battery operated		•	•
	Disposable			•
	Foam interface	•		
	Portable (< 1lb)	•	•	•
	Single use	•		•
	Usable on closed wounds			•
	Usable on open wounds	•		•
	Variable pressure setting		•	
	Educational Material Available	•		•
	Free Samples/Trials available	•		•

Note: This document is for informational purposes only and is not intended to replace individual clinical decision-making, which is the sole and independent responsibility of the practitioner. HealthTrust expressly disclaims any liability for treatment decisions. Please direct any questions or comments to clinical.research@healthtrustpg.com, or to your supplier representative. © 2020 HealthTrust. All Rights Reserved.

	Published Clinical Article Available	•		•
---	--------------------------------------	---	---	---

FDA Approval

The Ambuvac by Kinetics Concepts Inc., (KCI), a NPWT powered suction pump was first approved in 1997. The FDA defines negative pressure wound therapy (NPWT) is for wound management via application of continual or intermittent negative pressure to a wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. Indicated for the management of chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (diabetic or pressure), flaps and grafts ^[5].

Indications for Use

NPWT is intended to create an environment that promotes wound healing when healing by primary intention is not ideal. NPWT prepares the wound bed for closure, reduces edema, and promotes granulation tissue formation and perfusion. It removes exudate and infectious material in patients with chronic, acute, traumatic, sub-acute, dehisced wounds, partial-thickness burns, ulcer (diabetic, pressure, or venous insufficiency, flaps and grafts) ^[5].

NPTWT is often used in acute wounds when healing by advanced wound care is unlikely or not possible. The types of wound that benefit the most from NPWT are the following: ^[6]

- Surgical wounds, especially those which need to heal by secondary intention
- Open abdominal incisions
- Dehisced surgical wounds
- Burns
- Skin flaps and preparation for skin graft sites
- Traumatic wounds
- Chronic wounds, such as venous insufficiency ulcers, diabetic foot ulcers, and pressure ulcers
- Wounds at high risk for infection
- Wounds with copious drainage
- Meshed grafts, to either secure the graft in place or improve epithelialization
- Adjunct to skin graft/flap procedure

Treatment Goals ^[7]

The treatment goals for the NPWT application are the following:

- Provide a temporary wound cover
- Manage fluid and edema from the wound
- Accelerate patient mobility
- Improve pain
- Prevent wound progression
- Increase perfusion
- Stimulate granulation tissue formation
- Improve matrix material availability
- Reduce bacterial load
- Provide a moist environment that is preferable for wound healing

Note: This document is for informational purposes only and is not intended to replace individual clinical decision-making, which is the sole and independent responsibility of the practitioner. HealthTrust expressly disclaims any liability for treatment decisions. Please direct any questions or comments to clinical.research@healthtrustpg.com, or to your supplier representative. © 2020 HealthTrust. All Rights Reserved.

Technology Review

- Influence expression of genes involved in the wound-healing process

Advantages of NPWT ^[1,2,6,7]

- NPWT may be a cost-effective intervention when compared to advanced wound care.
 - The number of wounds healed can increase and the time to heal the wounds may be decreased³.
- Single studies comparing NPWT to standard advanced wound care (moist wound-healing principles) stated that NPWT can lead to accelerated wound healing and closure, such as a diabetic foot ulcer⁷.
- Traditional therapy consists of moist saline dressings changed three times/day.
- NPWT dressings are changed every 2 to 3 days, easier to tailor and maintain in position.
- Reduced the time of wound closure in diabetic patients.
- Reduced complexity of subsequent reconstructive procedures.
- Improved healing of transplanted skin and decreased length of stay for patients receiving split thickness skin grafts.
- Decreased wound infections in patients following orthopedic trauma and open fractures.
- Improved wound healing, shorter length of stay, lower hospital mortality in patients with mediastinitis and unsuccessful wound healing following sternotomy.
- Improved wound healing in patients with diabetes mellitus and gangrene that might require amputation.

Disadvantages of NPWT ^[1]

- Carry a portable pump
- Can be more expensive than traditional advanced wound care

Contraindications ^[3,6,7]

The contraindications for NPWT application are the following:

- Exposed vital structures (organs, blood vessels, or vascular grafts) which increases the risk for tissue erosion and can lead to complications such as abnormal connection in the intestines or bleeding
- Intestinal fistulas
- Invasive soft tissue infection or ongoing infection
- Wound necrosis or ischemic wounds
- Active bleeding
- Weakened tissue
- Malignant tissue
- Fragile skin caused from chronic steroid use or collagen vascular disorder
- Adhesive allergy

If NPWT is not properly monitored or improperly applied, it can cause the following:

- Pain
- Necrosis around the wound edges
- Bleeding
- Infection

Note: This document is for informational purposes only and is not intended to replace individual clinical decision-making, which is the sole and independent responsibility of the practitioner. HealthTrust expressly disclaims any liability for treatment decisions. Please direct any questions or comments to clinical.research@healthtrustpg.com, or to your supplier representative. © 2020 HealthTrust. All Rights Reserved.

Technology Review

- Retention of foreign bodies from the dressing
- Possible death

Placement ^[7]

When applying NPWT to a wound, a porous dressing is applied for even distribution of pressure throughout the wound. The dressing is placed directly on the wound with a drain attached to a vacuum device along with a polyurethane covering. The polyurethane covering must extend approximately 2 cm beyond the wound edges to create an airtight seal.

Refer to physician order and the manufacturer's instructions before application.



Photo 1: Example of clear occlusive dressing cut to size. Photo courtesy of David Schnur.



Photo 2: Example of hole cut into clear dressing prior to attaching vacuum tubing pad. Photo courtesy of David Schnur.



Photo 3: Pad and vacuum tubing placed over the hole on clear dressing. Photo courtesy of David Schnur.



Photo 4: Example of dressing and foam fully collapsed when vacuum is turned on. Photo courtesy of David Schnur.

Clinical Data

A Cochrane systematic review from March 2019 judged the evidence to be of low certainty for all surgical site infection outcomes. The evidence had high risk of bias. Uncertainty remains whether NPWT compared to standard of care dressings reduced or increased surgical outcomes or if it increased cost. Larger, well-designed trials are needed ^[2].

A retrospective comparison performance study by Hurd et al. (2017) ^[8], compared the performance of the two most widely used NPWT systems, the KCI V.A.C. therapy system and the Smith & Nephew RENASYS NPWT systems.

Both devices consist of a portable pump that is capable of delivering adjustable levels of negative pressure. The pump is linked by a tube to a wound filler. The most common applied wound filler applied was substantially equivalent to black polyurethane foam. For the wounds that were high risk for infection, nanocrystalline silver was used. The use of the nanocrystalline silver was determined by the study.

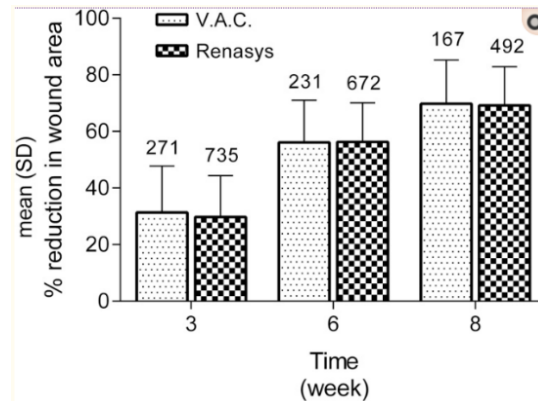
The difference between the two devices was the tubing that connected to the wound filler and pump. The V.A.C. system used traditional tubing. The RENASYS included a soft compressible Softport device, designed for comfort.

The study outcomes showed similar performance of both devices in challenging wounds. In the management of acute and chronic wounds prior to skin grafting, there was no difference in healing rates, time on therapy, or complications between the two devices. The choice of which system to use is no longer dependent on clinical efficacy or the size of the body of evidence. The choice is more dependent on financial cost, availability, and personal choice.

Note: This document is for informational purposes only and is not intended to replace individual clinical decision-making, which is the sole and independent responsibility of the practitioner. HealthTrust expressly disclaims any liability for treatment decisions. Please direct any questions or comments to clinical.research@healthtrustpg.com, or to your supplier representative. © 2020 HealthTrust. All Rights Reserved.

Technology Review

Comparison with Market Leaders KCI V.A.C and Smith & Nephew Renasys^[8]



Median reduction in wound area at weeks 3, 6, and 8 in chronic surgical wounds treated with V.A.C. or RENASYS. Mean \pm SD and *N* number at each time point shown. No significant differences between NPWT devices were seen at any time point ($p=0.1364$, $p=0.8524$, and $p=0.6360$ at 3, 6, and 8 weeks, respectively)⁸.

The Key Clinical Outcomes^[8]

	V.A.C. N= 299	V.A.C. and Silver N= 88	RENASYS N= 808	RENASYS and Silver N= 291
% of patients meeting their treatment goal	90%	92%	93.6%	94.8%
Median time in days to achieve treatment goal (range)	8 (1-20)		8 (1-35)	
Mean % reduction in area throughout therapy	64.2	68.2	65.3	63.9
Median % reduction in wound area per week	9.7	9.4	9.4	9.5

Note: This document is for informational purposes only and is not intended to replace individual clinical decision-making, which is the sole and independent responsibility of the practitioner. HealthTrust expressly disclaims any liability for treatment decisions. Please direct any questions or comments to clinical.research@healthtrustpg.com, or to your supplier representative. © 2020 HealthTrust. All Rights Reserved.

Technology Review

References

1. Gestring, MD, M. (2019, April 10). Negative Pressure Wound Therapy (R. Berman, MD, A. Cochran, MD, & K. Collins, MD, Eds.). Retrieved from <https://www.uptodate.com/home>
2. Webster, J., Liu, Z., Norman, G., Dumville, J. C., Chiverton, L., Scuffham, P., . . . Chaboyer, W. P. (2019). Negative pressure wound therapy for surgical wounds healing by primary closure [Abstract]. *Cochrane Database of Systematic Reviews*. doi:10.1002/14651858.cd009261.pub4
3. Acelity. Retrieved from <https://mykci.com>
4. The World's Definitive Source for Wound Care & Product Information. (1970, January 01). Retrieved July 17, 2019, from <https://www.woundsource.com/>
5. U.S. Food & Drug Administration. FDA. Retrieved from <https://www.fda.gov/>
6. Bonsall, MSN, RN, CRNP, L. (2016, April 16). The Essentials of Negative Pressure Wound Therapy (NPWT): Part 1 and 2. Retrieved from <https://www.nursingcenter.com/>
7. Kirwan, H., & Pignataro, R. (2016). The Skin and Wound Healing. In *Pathology and Interventions in Musculoskeletal Rehabilitation* (2nd ed.). <https://www.sciencedirect.com/topics/medicine-and-dentistry/negative-pressure-wound-therapy>
8. Hurd, T., Rossington, A., Trueman, P., & Smith, J. (2017). A Retrospective Comparison of the Performance of Two Negative Pressure Wound Therapy Systems in the Management of Wounds of Mixed Etiology. *Advances in Wound Care*, 6(1), 33-37. doi:10.1089/wound.2015.067

Initial or Update	Date	Completed by Whom	Changes Made
Update	June 2020	DD	Updated logo
Update	June 2020	DD	Reformattd
Initial	January 2020	DD	Created