



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

AUG 31 2023

The Honorable Jack Reed
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Department's response to House Report 117-397, pages 196-197, accompanying H.R. 7900, the National Defense Authorization Act for Fiscal Year 2023, "Negative Pressure Wound Therapy Review," is enclosed.

The report provides an overview of negative pressure wound therapy (NPWT) use in the Department of Defense (DoD), the devices, and their utility. The report shows that upon review of DoD military medical treatment facilities and market research, the current supply of NPWT devices for use is considered adequate. Research and development of next generation devices is very robust, and DoD has a well-developed strategy for development of requirements and procurement management of next generation devices.

Thank you for your continued strong support for the health and well-being of our Service members. I am sending a similar letter to the Committee on the Armed Services of the House of Representatives.

Sincerely,

A large black rectangular redaction box covering the signature area.

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Roger F. Wicker
Ranking Member



UNDER SECRETARY OF DEFENSE

**4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000**

**PERSONNEL AND
READINESS**

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

AUG 31 2023

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Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

Report to the Committees on Armed Services of the Senate and the House of Representatives



Negative Pressure Wound Therapy

August 2023

The estimated cost of this report or study for the Department of Defense (DoD) is approximately \$20,000 in Fiscal Year 2023. This report includes \$900 in expenses and \$19,000 in DoD labor.

Generated on January 25, 2023
RefID: 3-A7322C9

EXECUTIVE SUMMARY

The management of combat-related injuries continues to evolve with advances in wound management and technologies. The combat-related injuries have unique characteristics such as, wound care complexity, environmental contamination, different echelons of medical care, and variation in medical evacuation procedures that pose challenges for wound management.

Negative pressure wound therapy (NPWT) devices, also known as vacuum-assisted closure (V.A.C.), have been an important adjunct to wound care used by the U.S. military for the last two decades as a treatment for wounds sustained in combat and other military operations in Afghanistan, Iraq, and other countries.¹

The Department of Defense (DoD) continuously assesses and updates the inventory of NPWT devices and has a strategy to define the requirements, key performance parameters, and specifications of the next-generation NPWT devices to meet operational needs and manage the wounds of warfighters. This strategy also includes research, development, and procurement of the next-generation NPWT devices.

BACKGROUND

This report is in response to House Report 117–397, pages 196-197, accompanying H.R. 7900, the National Defense Authorization Act for Fiscal Year 2023, which requests that the Secretary of Defense submit a report to the Committees on Armed Services of the Senate and House of Representatives providing:

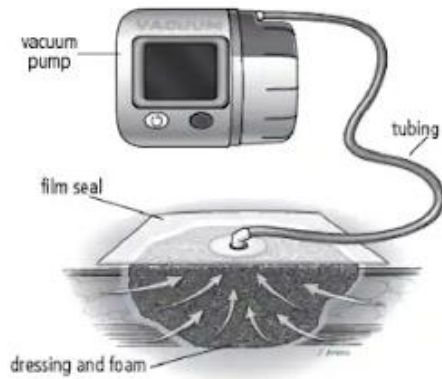
- (1) A review of negative pressure wound therapy devices currently in use across the Department, including an assessment of their utility in supporting wound treatment in future combat operations.
- (2) A comprehensive DoD strategy providing joint direction to the MHS outlining requirements, key performance parameters, and specifications for negative pressure wound therapy devices for use in future combat casualty care scenarios.
- (3) A strategy incorporating research, development, and procurement management of next-generation negative pressure wound therapy devices.

General Overview of Negative Pressure Wound Treatment

A NPWT device is used to manage open wounds by applying sub-atmospheric pressure to the wound surface. It provides enhanced wound healing by pulling wound edges together with evenly distributed negative pressure to promote tissue perfusion. NPWT devices also effectively remove wound fluids and infectious material to minimize risk for wound infection. The wound care system consists of an open-cell foam or gauze dressing, a semi-occlusive adhesive cover, a fluid collection system, and a suction pump. The NPWT device applies continuous or intermittent negative pressure, depending on the wound type and the clinical objectives, to the

wound with a sealed dressing, as shown in Figure 1. The constant mode of suction is most commonly used for surgical wounds.²

Figure 1. Negative Pressure Wound Treatment Device³



Adapted from Intermountain Healthcare

NPWT has been shown to be effective in treating various wounds, including surgical, traumatic, burns, and chronic wounds. Furthermore, the specific type of NPWT devices does not appear to impact the overall wound healing effects.

Military Specific Use of NPWT Devices

During the wars in Iraq and Afghanistan, surgeons commonly used NPWT devices on traumatic wounds of U.S. military casualties after surgical debridement and before evacuation from combat-theater hospitals. Almost all U.S. military casualties with extremity wounds arrived in the United States with NPWT devices in place. NPWT simplifies wound care by decreasing the number of dressing changes, keeps the debrided wound area clean and separate from contaminated wounds, lengthens the interval between trips to the operating room, reducing recovery time for patients, and can cover complex wounds that are difficult to access or care for by regular nursing care.¹

Some NPWT devices allow the delivery of fluids, such as saline or antibiotics, to irrigate the wound; intermittent removal of used fluid supports the cleaning and drainage of the wound bed. A NPWT device can be left in place for 24 to 72 hours, making the NPWT dressings less labor-intensive. Application of a NPWT device is the preferred method of wound care for aeromedical evacuations.²

NPWT treatment is cost-effective despite the high cost associated with the device and associated supplies than conventional therapy. Specifically, this is because it allows fewer trips to the operating room and fewer dressing changes by medical staff. The device can achieve improved healing in a shorter period of time, thereby increasing the time between surgeries and often reducing the number of surgeries required as compared to standard dressings without negative pressure.¹

The demands of future combat operations may require more advanced or specialized medical technologies. There is concern that the injury patterns and medical and logistical burdens anticipated in future combat operations may pose a challenge to the use of NPWT. For example, NPWT devices may be difficult to maintain and repair in austere or resource-limited settings. All these factors and others are considered in determining the procurement of next-generation NPWT devices.

NEGATIVE PRESSURE WOUND THERAPY DEVICES IN DOD INVENTORY

A review of existing NPWT devices currently used across the Department shows 231 NPWT devices in the military medical treatment facilities (MTFs) and an estimated 2000 NPWT devices in deployment assemblages. The number of NPWT devices currently meets the demand of MTFs and operational units.

The majority of devices in the MTFs and deployed inventory are from the manufacturer Kinetic Concepts, Inc. (KCI/3M) under the V.A.C. branding. KCI had the first NPWT device cleared by the Food and Drug Administration (FDA) in 1995, and it is also widely used in civilian hospitals.

Additional, NPWT models used in MTFs are: V.A.C. Ultra – 128 devices, V.A.C. Freedom – 48 devices, INFO V.A.C. – 16 devices, ACTI V.A.C. – 15 devices, V.A.C. VERAFLOR – 14 devices, V.A.C. RX4 – 6 devices, and V.A.C. Simplicity 4 devices. The life expectancy for a NPWT device is 8 years. The median life remaining for the Defense Health Agency's (DHA) NPWT devices in the inventory is 3 years.

The V.A.C. Freedom and the V.A.C. RX4 models are the only NPWT devices listed on the Military Services' Safe to Fly list. Seventeen percent (17 percent) of the devices are the V.A.C. Freedom model, one of two flights certified NPWT devices. This device will reach an end of service life (EOSL) and will no longer be available for purchase effective September 30, 2023, with retirement on September 30, 2024.⁴ The EOSL means that the equipment manufacturer will no longer provide parts and service to that device. However, the devices may be fully functional, and parts and accessories may be available through third-party vendors for an extended period beyond the EOSL. KCI will continue to support the other NPWT models which have not reached EOSL.

Table 1. NPWT devices in DoD Inventory for MTFs

Kinetic Concepts/3M	V.A.C. Ultra	128	
Kinetic Concepts/3M	V.A.C. Freedom*	48	
Kinetic Concepts/3M	INFO V.A.C	16	
Kinetic Concepts/3M	ACTI V.A.C.	15	
Kinetic Concepts/3M	V.A.C. VERAFL0	14	
Kinetic Concepts/3M	V.A.C. RX4*	6	
Kinetic Concepts/3M	V.A.C. Simplicity		
Total		231	

**Safe to Fly List*

DOD STRATEGY ON WOUND TREATMENT AND COMBAT CASUALTY CARE

The Military Health System strategy on defining the requirements, key performance parameters, and specifications for medical devices is to meet the operational needs in future combat casualty care scenarios. This strategy is aligned with the National Defense Strategy.

The future threat environment does not guarantee that the U.S. military will have advantages over its competitors in weapons, technologies, air, land, and sea superiority as in past conflicts due to peer-to-peer or near-peer competition. The future operational environment will be characterized by dispersed operations, austere environments, contested communications, emerging weapons that can cause high volumes of casualties and new injury patterns, and delayed casualty movement due to the denial of access.⁵ A large number of casualties will stress the deployed MTFs, medical personnel, supplies, and medical evacuation networks.⁶

Based on these future scenarios, the DoD determines the acquisition of systems based on a set of requirements for new or enhanced capabilities. The Joint Staff uses the Joint Capabilities Integration and Development System or JCIDS process to manage the review and approval of capability requirements documents. In 2021, the DoD's Joint Capabilities Board approved the Doctrine, Organization, Training, materiel, Leadership and Education, Personnel, Facilities and Policy (DOTmLPF-P) Change Recommendation (DCR) on combat casualty care for future operations. It tasked the Office of the Secretary of Defense, the Military Departments, the Combatant Commands, the Joint Staff, and the Defense Agencies to implement the actions outlined in the DCR. The DCR identified several shortfalls, including short-term and long-term consequences of wound and polytrauma patterns caused by emerging weapon systems. To address these shortfalls, the DCR recommended a series of actions, including reviewing and revising the equipment sets for combat casualty care, damage control, and wound management requirements in future operating environments.⁵

As medical devices reach the end of their serviceable life, DHA will submit new equipment requests, for those devices in use at the MTF, that initiate replacement of the devices that meet the activity's requirements. The Military Services also did their own capability gap assessment and are pursuing a procurement to address the EOSL gap for the deployed inventory. DHA will define the requirements for the NPWT devices in use at the MTF level. In the future, partnerships between DHA and the Military Services may also be built to ensure joint operability between the MTF and the deployed inventory.

Next-generation NPWT devices that are on the market and available for purchase by the DoD will be evaluated and purchased during the procurement process based on their specifications. The devices are identified and evaluated to meet specified requirements, key performance parameters, and specifications for NPWT devices for use in future combat, such as clearance by the FDA, cost, weight, portability, pressure applications, battery charge times, and length of usage, and air worthiness or safe to fly. Other Military Services can adopt the products selected by one Military Service. If there are no available commercial off-the-shelf (COTS) devices, the Department will research and develop the prototypes for production.

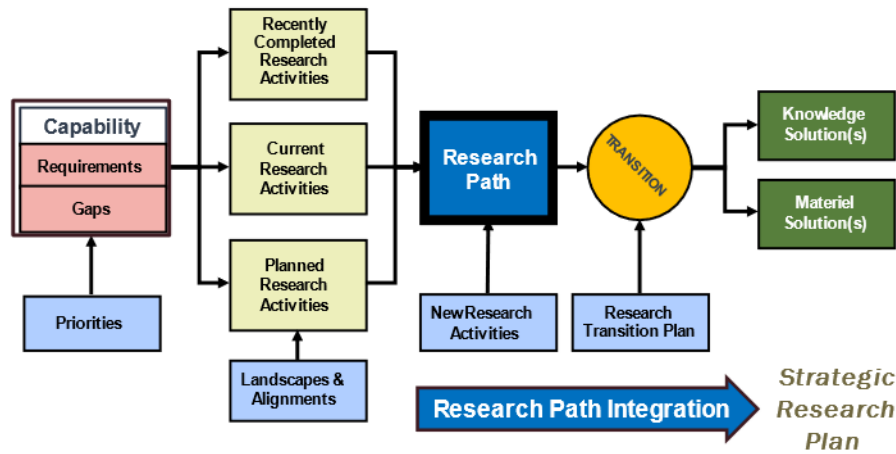
The Military Services and DHA have begun their modernization projects for the NPWT devices by reviewing the requirements with subject matter experts and doing market research on the next-generation NPWT devices. They completed comprehensive research using FDA premarket notification database, open-source market information, device literature review, and vendor or supplier responses to email inquiries.⁷ The research for a replacement option for alternative, commercially available, and portable NPWT devices concluded with the availability of multiple COTS options.

DOD STRATEGY FOR RESEARCH, DEVELOPMENT, AND PROCUREMENT MANAGEMENT OF THE NEXT-GENERATION NPWT DEVICES

Research

The DHA research strategic plan is based on the Department's priorities. The capability gap is determined based on Military Health System requirements and capabilities. The capability gap will drive a review of past and current research activities and a plan for future research activities to deliver knowledge and material solutions for the capability gap. The research strategy is described in Figure 2.⁸

Figure 2. Research Strategic Plan



The DoD continues to leverage the extensive research efforts addressing the effectiveness of NPWT being conducted within academia and industry. A recently published analysis of NPWT studies identified 62 randomized controlled trials and six economic studies that evaluated NPWT across a wide range of surgeries, and a search of PubMed database conducted in October 2022 identified over 350 studies of NPWT since December 2021.⁹ In September 2022, the Congressionally Directed Medical Research Program initiated a \$2.2 million clinical study comparing antibiotic cement bead pouch versus negative-pressure wound therapy for managing severe open tibia fracture wounds under the Peer Reviewed Orthopaedic Research Program. This effort will add to the growing body of research comparing the effectiveness of NPWT with other treatment methods.

Development

With the existing COTS NPWT devices meeting the Military Services’ needs, there is no capability gap identified to drive additional investments in research and development for new solutions.

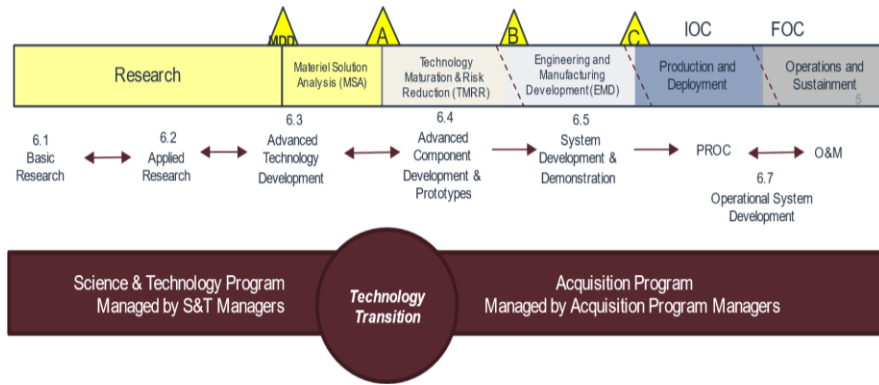
Procurement

It is important to note that the acquisition of medical equipment and supplies, including NPWT devices, is subject to strict regulations and oversight to ensure the safety and effectiveness of the products being used. Additionally, the DoD may have additional requirements or guidelines in place for the procurement of medical equipment and supplies to ensure that they meet the needs of military personnel and are of high quality.

To acquire NPWT equipment and supplies for use in the DoD, the responsible medical unit or facility would typically follow the procurement processes and guidelines established by the DoD. This may include identifying the specific NPWT products and quantities needed, obtaining quotes from vendors, and submitting a request for purchase through the appropriate channels. In some cases, the DoD may have contracts with specific vendors for the procurement of NPWT supplies and equipment.

The pathway to alignment of science, technology, and acquisition programs is outlined in Figure 3.⁸

Figure 3. Alignment of Science, Technology, and Acquisition Programs



CONCLUSION

NPWT has been used for several decades in the DoD and has proven to be an effective treatment adjunct to traditional wound management for many types of wounds. It is very likely that NPWT devices will continue to be used in future combat operations. New technologies will likely be developed to complement or enhance the use of NPWT rather than replacing it entirely.

DoD will continue to maintain an adequate inventory of NPWT devices for use both in MTFs and in military operations. DoD strategy will set requirements, key performance parameters, and specifications for the next generation NPWT devices along with the research, development, and procurement of the next-generation NPWT devices.

NOTES

1. Rex E. Atwood, M.J. Bradley, and E.A. Elster. “Use of negative pressure wound therapy on conflict-related wounds.” *The Lancet. Global health* 8(3) (March 2020): e319–e320. [https://doi.org/10.1016/S2214-109X\(20\)30041-3](https://doi.org/10.1016/S2214-109X(20)30041-3)
2. Richard J. Strilka, Brian J Gavitt, Melissa Proctor, et al. “Negative Pressure Wound Therapy During Critical Care Air Transport Clinical Practice Guideline (CPG).” *Joint Trauma System* (February 11, 2020). https://jts.amedd.army.mil/assets/docs/cpgs/Negative_Pressure_Wound_Therapy_CCAT_11_Feb_2020_ID49.pdf
3. Intermountain Healthcare. n.d. “Negative Pressure Wound Therapy.” Accessed January 9, 2023. <https://intermountainhealthcare.org/services/wound-care/wound-care/treatments/negative-pressure-wound-therapy/>
4. Medical Solutions Division Memo. “End of Sustainable Life Cycle for the V.A.C. FREEDOM Single-Channel Negative Pressure Wound Therapy (NPWT) System.” *3M Health Care*, October 8, 2020.
5. Office of the Assistant Secretary of Defense for Health Affairs. Joint DOTmLPPF-P Change Recommendation (DCR) for Combat Casualty Care (C3) Support for Future Operations. Rauch, Terry. Washington, D.C.: Office of the Assistant Secretary of Defense for Health Affairs: 2021, https://jts.health.mil/assets/docs/policies/C3_210901_Support_for_Future_Operations_DCR_with_JROCM.pdf (accessed December 27, 2022)
6. “National Defense Strategy,” Department of Defense, accessed November 29, 2022, <https://www.defense.gov/National-Defense-Strategy/>
7. Operation Healthcare Technology Management/Clinical Engineering, Engineering, Test, and Sustainment Services, Air Force Medical Readiness Agency. “Negative Pressure Wound Therapy Market Research Report.” 2020.
8. “DHA Research, Development & Acquisition University Roadshow.” Defense Health Agency Research and Engineering, December 2022.
9. Norman, Gill, En Lin Goh, et al. (2020). “Negative Pressure Wound Therapy for Surgical Wounds Healing by Primary Closure.” *The Cochrane ProDatabase Syst Rev.*(2020). CD009261. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7192856/>