Pensar Medical™ *Negative Pressure. Positive Results.*

Advanced sNPWT for Superior Wound Healing

Clinically Proven Negative Pressure Wound Therapy for Faster, More Effective Recovery

The MicroDoc® single-use NPWT system is engineered to deliver consistent, clinically validated outcomes, accelerating wound healing while minimizing infection risk for diverse wound types.

Pensar Medical™
Negative Pressure. Positive Results.

The MicroDoc® Difference

Advanced Wound Care with Multiple Pressure Settings and Discreet, Portable Therapy

The MicroDoc® sNPWT system combines the power of effective wound healing with cutting-edge AI software and an advanced dressing stack, ensuring optimal wound care tailored to each patient's needs. Designed to be quiet, discreet, and portable, the MicroDoc® allows patients to receive precise, automated wound therapy anywhere, without disrupting their daily lives, all while promoting faster recovery and reducing the risk of complications.

> **I love the MicroDoc. The portability and adjustability is outstanding.**
>
> I utilized it on a patient and they were able to travel to Mexico and it bridged their treatments."

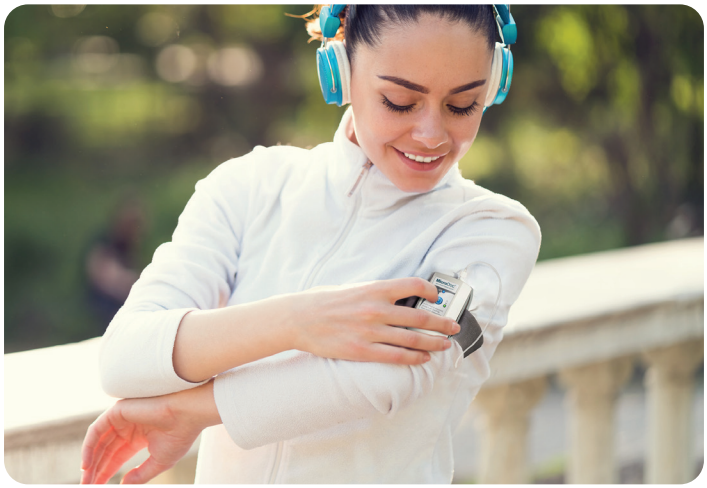
Benefits of the MicroDoc NPWT System

Multiple Pressure Settings

The MicroDoc's three pressure settings (-50, -80, -125mmHg) are designed to deliver negative pressures for effective healing for a range of wound types.

Effective Healing

MicroDoc enhances wound healing with adjustable pressures and advanced exudate management, promoting a moist environment ideal for treating a variety of wounds.



Cost Effective

The MicroDoc is on average 2.5x to 3x less expensive than similar sNPWT systems on the market.

Portable For Active Patients

Designed with mobile patients in mind, the MicroDoc is compact and lightweight, fitting easily on a belt, in a pocket, or under clothing.

Scientific & Clinical Peer-Reviewed Publications

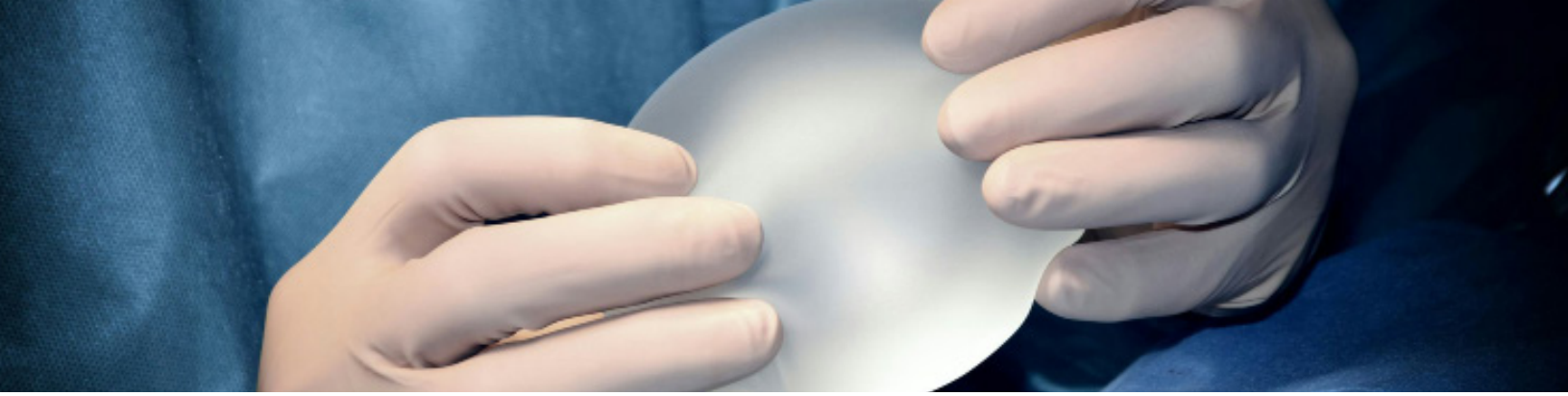
Improving patient outcomes is our driving force. We are continually focused on improving our approach, fueled by a passion for advancing the science of wound healing. Published papers continue to tell the stories of patient success using NPWT.

Costs of Surgical Site Infections

+ The total annual costs to the US Healthcare system for the 5 major infections were $9.8 billion (95% CI, $8.3-$11.5 billion), in 2012 dollars
+ Surgical site infections (SSI) contribute the most to overall costs (33.7% of the total) or roughly $3.3B annually in 2012 dollars
+ On an annual basis in the United States, there are approximately 160,000 instances of surgical site infections
+ Adjusted for inflation, surgical site infections now account for roughly $4.5B annually in the United States

> **“Since SSIs constitute the largest portion of HAI-related costs nationally, and since less progress has been made in preventing these infections than in other areas of care, research and quality improvement efforts are clearly needed in this area.”**

Zimlichman E, Henderson D, Tamir O, Franz C, Song P, Yamin CK, Keohane C, Denham CR, Bates DW. Health care-associated infections: a meta-analysis of costs and financial impact on the US health care system. JAMA Intern Med. 2013 Dec 9-23;173(22):2039-46. doi: 10.1001/jamainternmed.2013.9763. PMID: 23999949.



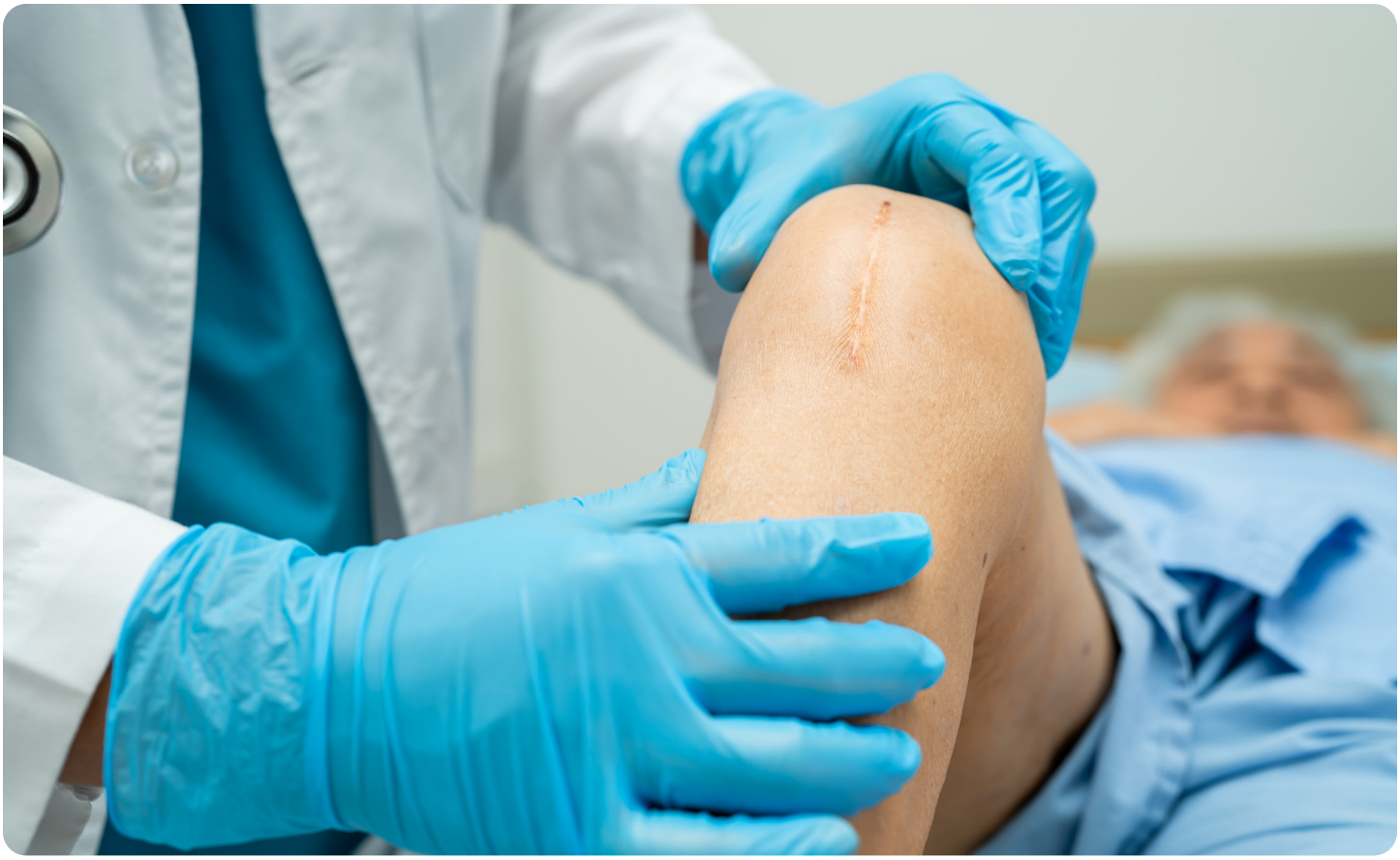
Plastic Surgery and Aesthetics

- Studies report that incision management with closed incision negative pressure therapy (ciNPT) may provide clinical benefits, including protecting surgical incisions, for postsurgical closed incisions (eg, orthopedic, sternotomy, and colorectal).
- This retrospective analysis compared postoperative outcomes in patients who received ciNPT versus standard of care (SOC) for incision management after breast reconstruction postmastectomy.
- Group using ciNPT saw a >53% reduction in rates of surgical site infections
- Overall complication rate was 8.5% (28/331) in ciNPT group compared with 15.9% (53/334) in SOC group (P = 0.0092).
- Compared with the SOC group, the ciNPT group had significantly lower
  - Infection rates [7/331 (2.1%) versus 15/334 (4.5%), respectively; P = 0.0225]
  - Dehiscence rates [8/331 (2.4%) versus 18/334 (5.4%), respectively; P = 0.0178]
  - Necrosis rates [17/331 (5.1%) versus 31/334 (9.3%), respectively; P = 0.0070]
- Seroma rates [6/331 (1.8%) versus 19/334 (5.7%), respectively; P = 0.0106]
- The ciNPT group required significantly fewer returns to operating room compared with the SOC group [8/331 (2.4%) versus 18/334 (5.4%), respectively; P = 0.0496]
- Patients who received ciNPT over closed incisions following postmastectomy breast reconstruction experienced a shorter time to drain removal and significantly lower rates of infection, dehiscence, necrosis, and seromas, compared with the SOC group.
- Time to complete drain removal per breast for ciNPT versus standard of care was 9.9 versus 13.1 days (P < 0.0001), respectively.
- More than 109,000 breast reconstructions were performed in the United States during 2016.
  - Although it is currently estimated that just less than 20% of U.S. women who require a mastectomy choose to undergo immediate reconstruction, this rate is also rising

Gabriel A, Sigalove S, Sigalove N, Storm-Dickerson T, Rice J, Maxwell P, Griffin L. The Impact of Closed Incision Negative Pressure Therapy on Postoperative Breast Reconstruction Outcomes. Plast Reconstr Surg Glob Open. 2018 Aug 7;6(8):e1880. doi: 10.1097/GOX.0000000000001880. PMID: 30324063; PMCID: PMC6181498.

Orthopedic Surgeries

+ Wound complications are reported in up to 10% hip and knee arthroplasties and there is a proven association between wound complications and deep prosthetic infections
+ A total of 220 patients undergoing elective primary total hip and knee arthroplasties were recruited into in a non-blinded RCT. For the final analysis there were 102 patients in the study group using incisional negative pressure wound therapy dressing ("iNPWTd") and 107 in the control group.
+ The use of iNPWTd decreased instances of post-operative surgical wound complications by >76% (8.4% control; 2.0% iNPWTd, p = 0.06)
+ Overall LOS reduction (0.9 days, 95% confidence interval (CI) -0.2 to 2.5) was not significant (p = 0.07) but there was a significant reduction in patients with extreme values of LOS in the iNPWTd group (Moses test, p = 0.003).
+ Peak post-surgical wound exudate was significantly reduced which may help to reduce wound edema and promoting healing.



Karlakki SL, Hamad AK, Whittall C, Graham NM, Banerjee RD, Kuiper JH. Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: A randomised controlled trial. Bone Joint Res. 2016 Aug;5(8):328-37. doi: 10.1302/2046-3758.58.BJR-2016-0022.R1. PMID: 27496913; PMCID: PMC5013893.

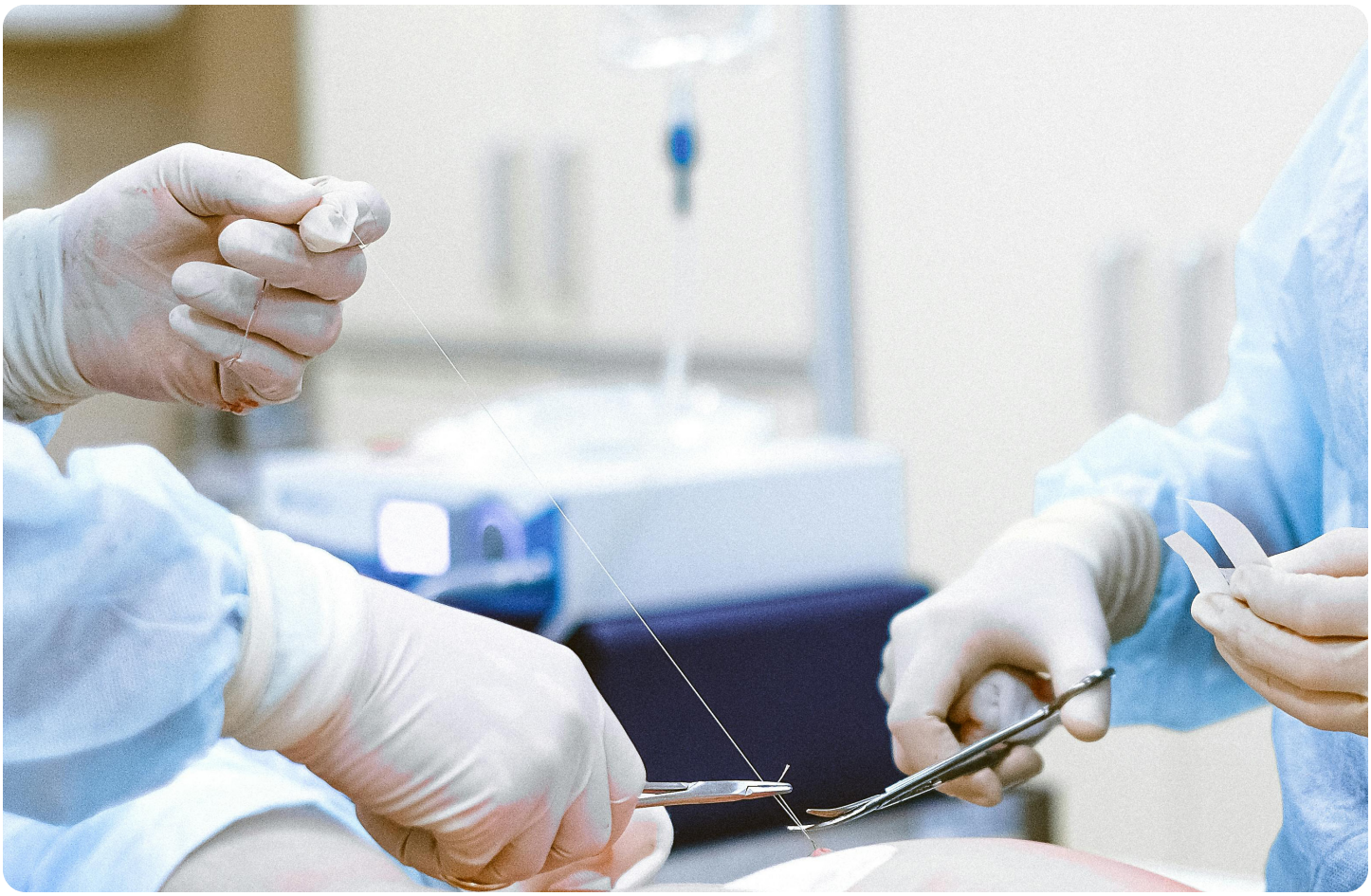
C-Sections

+ A group of 1,111 patients were treated with single-use negative pressure wound therapy (sNPWT) devices to support healing after a cesarean section (“c-section”) procedure
+ The results of the patients in this cohort were compared against published studies regarding surgical site infection rates across fourteen (14) NHS hospitals in England during 2009
    + Wloch C, Wilson J, Lamagni T, Harrington P, Charlett A, Sheridan E. Risk factors for surgical site infection following caesarean section in England: results from a multicentre cohort study. BJOG 2012;119:1324–1333.
+ Compared with prior research, the group with sNPWT devices had statistically significant decreases in rates of surgical site infections, with better than 60% reductions in SSIs for patients with BMI levels of 29.9 and lower
    + For BMI levels of 18.5-24.9 there was a 65.7% reduction in instances of surgical site infections (6.7% to 2.3%, P = 0.02)
    + For BMI levels of 25-29.9 there was a 63.5% reduction in rates of surgical site infections (9.6% to 3.5%, P = 0.002)
    + For BMI levels at or above 35 there was a 26.4% reduction in rates of surgical site infections (19.3% to 14.2%, P = 0.04)
    + For BMI levels of 30-34.9 there was a decrease in surgical site infections, but was not statistically significant (13.5% vs 8.9%; P = 0.12)
+ Additionally, for patients who had undergone a prior C-section, patients using sNPWT saw surgical site complications reduced by 39.8% (10.3% vs 6.2%, P = 0.006)

Imcha M, Liew NC, McNally A, Zibar D, O’Riordan M, Currie A, Styche T, Hughes J, Whittall C. Single-use negative pressure wound therapy to prevent surgical site complications in high-risk patients undergoing caesarean sections: a real-world study. Int J Qual Health Care. 2023 Oct 31;35(4):mzad089. doi: 10.1093/intqhc/mzad089. PMID: 37930777; PMCID: PMC10627297.

Multiple Surgery Sites

+ The overall weighted average rates of surgical-site infection in the closed incision negative-pressure therapy and control groups were 6.61% and 9.36%, respectively. This reflects a relative reduction in surgical site infection rate of 29.4%.
+ Across all studies, odds of surgical-site infections decreased 56.4% ($p < 0.00001$).
    + Abdomen (5 studies): 43.7% reduction in SSIs (P = 0.01)
    + Chest (3 studies): 63.3% reduction in SSIs (P = 0.002)
    + Groin (3 studies): 81.7% reduction in SSIs (P = 0.0001)
    + Lower Extremity (4 studies): 45.5% reduction in SSIs (P = 0.022)
    + All (15 studies): 56.4% reduction in SSIs (P = 0.00001)
    + All, Minus Groin: (12 studies): 49.6% reduction in SSIs (P = 0.00001)
+ In addition, overall rates of dehiscence in closed incision negative-pressure therapy and control groups were 5.32% and 10.68%, respectively, a >50% reduction



Semsarzadeh NN, Tadisina KK, Maddox J, Chopra K, Singh DP. Closed Incision Negative-Pressure Therapy Is Associated with Decreased Surgical-Site Infections: A Meta-Analysis. Plast Reconstr Surg. 2015 Sep;136(3):592-602. doi: 10.1097/PRS.0000000000001519. PMID: 26313829.

sNPWT for Closed Incisions

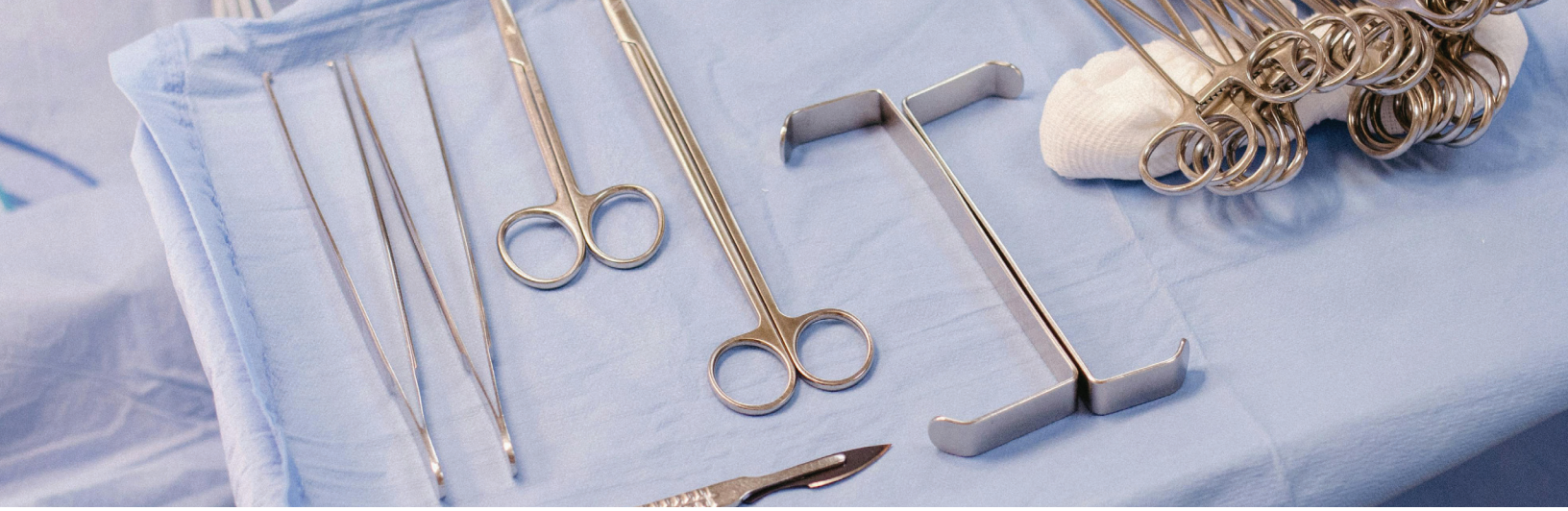
+ Approximately 0.5% - 3% of patients undergoing surgery will experience infection at or adjacent to the surgical incision site.
+ -80 mmHg sNPWT device reduces the incidence of composite, superficial, and deep SSIs when compared with standard care across a heterogenous at–risk surgical population containing a variety of surgical specialties.
+ Prophylactic negative pressure wound therapy (NPWT) has emerged as a successful intervention in patients at high risk for SSIs and other surgical site complications.

Kelly James, Amy Glasswell, Ben Costa, Single-use negative pressure wound therapy versus conventional dressings for the reduction of surgical site infections in closed surgical incisions: Systematic literature review and meta-analysis, The American Journal of Surgery. Volume 228,2024, Pages 70-77, ISSN 0002-9610, doi.org/10.1016/j.amjsurg.2023.10.031.

Hand Surgeries and Recovery

+ A significant proportion of hand injury cases are multiple faceted and heavily contaminated and involve composite soft tissue and bone injuries due to the complexity of the anatomy and function of the hand.
+ A total of 21 patients received conventional dressing using polyurethane foam and a short arm splint, and 30 patients received NPWT.
+ The time to cover over 90% of the range of motion (ROM) was reduced by nearly two weeks (33.3 days versus 46.9 days, P = 0.022)
    + A 90% recovery of ROM is almost full recovery of function, which enables daily activity, the end of rehabilitation, and the return to social life.
+ NPWT has been mostly used in patients undergoing hand surgery with soft tissue defects associated with trauma, burns, or infection.
+ The effective use of NPWT in preparing soft tissue defects before reconstruction has been well described, and favorable results have been achieved in patients with bone, tendon, or nerve exposure.
+ On the other hand, use of NPWT after reconstruction has only been reported in selective cases.
+ Most commonly, NPWT has been applied after skin grafting. NPWT stabilizes the graft and promotes adherence of the skin graft, which improves graft take.

Shim, H.S., Choi, J.S, & Kim, S.W. A role for postoperative negative pressure wound therapy in multi-tissue hand injuries. Biomed Res Int 2018, doi 10.1155/2028/3629643.



Cardiothoracic Surgery

+ Infection of leg wounds is a common complication following great saphenous vein harvesting (GSV) for coronary bypass grafting (CABG).
+ This study aimed to assess the efficacy of negative pressure wound therapy (NPWT) compared to conventional wound care in infected leg wounds following GSV harvesting for myocardial revascularization.
+ After applying the inclusion criteria of the study, we enrolled 127 cases of post-saphenous vein harvest patients
+ Overall complication rate fell from 90.0% in control group to 23.9% with NPWT ($P < 0.001$), a reduction of 73.4% in the rate
+ The NPWT group had a significantly lower rate of deep vein thrombosis ($p = 0.013$), osteomyelitis ($p < 0.001$), bed sores ($p < 0.001$), shorter duration of tissue edema ($p < 0.001$), and lesser discharge ($p < 0.001$)
    + Deep Vein Thrombosis rate decreased 76.4% ($P = 0.003$) with NPWT (from 25% in control to 5.9% in NPWT group)
    + Osteomyelitis rate decreased 91.7% with NPWT (from 53.3% in control to 4.4% in NPWT group)
    + Bed Sores rate decreased 83.9% with NPWT (from 36.7% in control to 5.6% in NPWT group)
    + Discharge reduced by 32.5% with NPWT (from 170.52 ml to 115.05 ml with NPWT)
+ Length of hospital stay was significantly shorter in the NPWT group ($p < 0.001$), with nearly a month difference, a reduction in 66.6%
+ Average stay of 14.9 days for the NPWT group versus 44.7 days for control

Shaalan, A.M., El Wakeel, E.E., Shaalan, K.M. et al. Surgical outcome after using negative pressure therapy in infected leg wounds in coronary bypass grafting surgery. Cardiothorac Surg 30, 30 (2022). https://doi.org/10.1186/s43057-022-00091-6

Healing In Your Pocket

The MicroDoc sNPWT System

Compact, portable, and designed for single use, the MicroDoc NPWT system efficiently delivers adjustable pressure settings (-50, -80, -125mmHg) with a simple button press. Engineered for a usage period of 7 days,* MicroDoc offers versatile therapy duration, accommodating both short-term and extended care needs across various care settings.

What's Included:

+ MicroDoc Unit
+ Two dressing changes
+ Velcro strap
+ Two skin prep pads

Compact Device, Mighty Features

Simple, One-Button Operation

+ Simple one-button operation simplifies startup and easy pressure-setting adjustments, reducing the technology learning curve for healthcare professionals.

Multiple Pressure Settings

+ The MicroDoc's three pressure settings (-50, -80, -125mmHg) are designed to deliver negative pressures for effective healing for a range of wound types.

Robust Battery Life

+ The single-use disposable MicroDoc provides ample power for 7 days* of wound therapy, reducing the need for frequent replacements.

AI-Powered Adaptive Technology

+ Our intelligent software enables the system to effectively manage small dressing leaks, ensuring that care is consistently delivered for the prescribed duration.

* The pump battery life can extend beyond 7 days under specific usage conditions.

MicroDoc's ComforTech™ "Peel 'n Stick" Wound Dressing

MicroDoc ComforTech Dressings enhance healing and comfort by efficiently managing exudates, reducing edema, and stimulating blood flow promoting granulation tissue formation. Our dressings are developed to promote faster healing and improved patient outcomes.

Enhanced Healing with Advanced Materials

+ The breathable film facilitates vapor transition, creating an optimal wound environment for faster recovery. Its flexible silicone adhesive contours effortlessly to the body, providing comfort and ensuring dressing stability with movement.

Innovative Fluid Handling for Better Wound Care

+ Our dressing features a super absorbent layer designed to pull in drainage and securely lock it within, preventing fluids from seeping back into the wound. This innovative system significantly lowers the risk of maceration and infection, ensuring consistent fluid removal for wounds with low levels of drainage.

Secure Exudate Management for Optimal Healing

+ The dome design of our dressing is strategically positioned higher than the wound to prevent blockages, ensuring uninterrupted fluid flow.

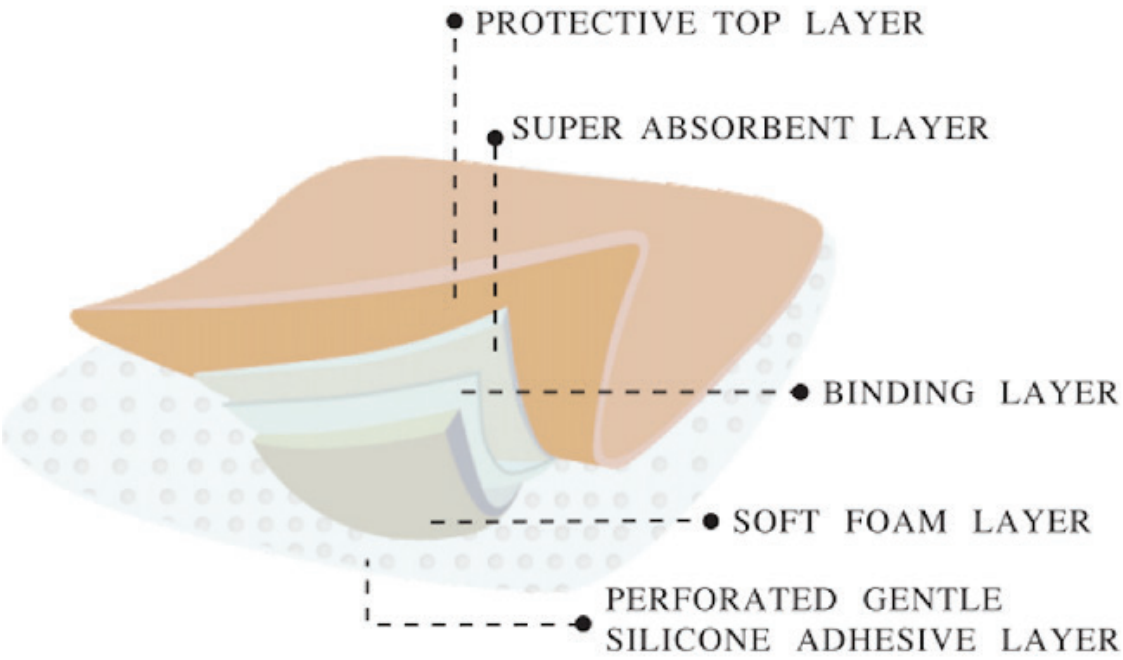
Protective Outer Layer for Added Safety

+ With a waterproof outer layer, our dressing offers an additional layer of protection against external contaminants.

Time-Efficient Application for Clinicians

+ Clinicians will find it easy and quick to apply, allowing for timely dressing changes and optimal wound care without sacrificing quality or protection.

Five Layer Healing System



Enhanced Features of MicroDoc's NPWT Dressing System

MicroDoc® ComforTech™ Silicel Hydrofiber Foam Dressing are equipped with powerful features for advanced wound care management, including high absorbency for a range of exudate volumes and multiple sizes for different wound types.

> **The MicroDoc is as easy as carrying a smartphone in your pocket and compatible with our modern, active lifestyles.**
>
> This tiny, portable high-tech unit is our missing link in transitioning patients who need negative pressure therapy but have wounds that are too small for large, bulky, noisy units."
>
> — *Plastic Surgeon*

Highly Absorbent

+ Features exceptional absorption capabilities for efficient exudate management, enhancing patient comfort.

Highly Breathable Film

+ Promotes an optimal healing environment by allowing vapor to escape, supporting faster recovery.

Easy Application

+ Comes as a convenient, single-piece dressing, with optional reinforcement strips for added security when needed.

Enhanced Comfort

+ The silicone adhesive is gentle on the skin, while the hydrofiber-foam layer absorbs fluids and provides cushioning for improved patient comfort.

No Canister Required

+ Eliminates the need for a bulky canister, enhancing patient mobility and encouraging greater compliance.

Fluid Management Prevents Pooling

+ Continuously draws fluids away from the wound, helping to maintain a dry environment and reduce the risk of infection or maceration.

Varied Sizes for Flexibility

+ Available in 10 cm x 20 cm, 10 cm x 30 cm, 15 cm x 20 cm, 20 cm x 25 cm, and breast dressings 20 cm x 25 cm. These sizes accommodate different wound dimensions.

Case Studies

The MicroDoc® sNPWT System in Practice

sNPWT in the Management of Abdominoplasty Dehiscence

Patient Profile

- 44-year-old female
- Comorbidity of obesity
- Engaged in tobacco use
- Patient presented with an abdominal wound dehiscence following an abdominoplasty procedure accompanied by ischemia and soft tissue necrosis (Fig. 1).

Fig. 1: Dehisced abdominal wound (Day 1)

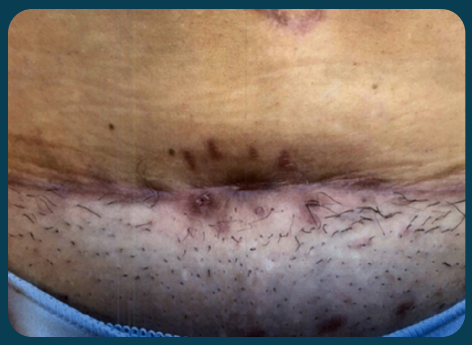


Fig. 2: Completion of Therapy (Day 86)

Treatment

- Wound was first treated with the traditional canister-based NPWT system (tNPWT), the WoundPro™ from Pensar Medical™ for a period of 9 days).
- After this initial course of tNPWT, the patient requested to transition to a more portable NPWT system, to facilitate their return to work as well as having a pump that was more convenient for in-home use.
- The sNPWT system, from Pensar Medical, was ordered at -125mm/Hg continuous therapy. A small foam dressing was placed in the wound bed to fill the depth and ensure contact with a self-adaptive dressing. Per standard application protocol, dressing change frequency was upon strike-through reaching dressing edges.

Outcomes

- After 10 days, significant healing progress was observed, with the discontinuation of the foam packing due to the wound bed filling with granulation tissue.
- Reduction in the wound size, facilitating primary wound closure and completion of therapy at day 86 (Fig. 2).
- Patient reported increased comfort, enhanced satisfaction, and ease of use with the sNPWT device.
- Patient was able to return to work sooner than anticipated as well as maintaining their lifestyle through the simplicity, size, and portability of the sNPWT system.

Clinical Assessment of sNPWT in the Management of a Non-Healing Venous Leg Ulcer

Patient Profile

- 62-year-old male
- Multiple comorbidities
- Engaged in daily tobacco use.
- Diagnosed with Peripheral Arterial Disease (PAD), Type 1 Diabetes (using an insulin pump) and Hepatic Cirrhosis.
- Non-healing venous leg ulcer with exposed bone.
- Had a stent placement following vascular intervention and was five months post-op.

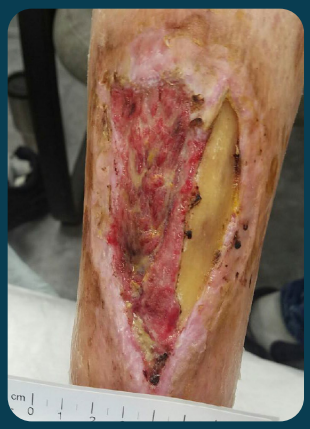


Fig. 1: Non-healing venous leg ulcer (Day 1)

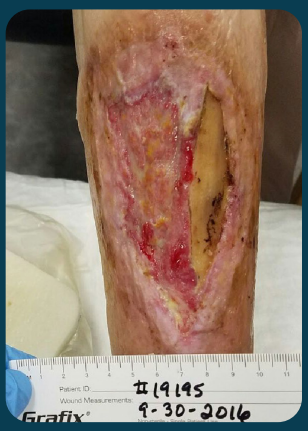


Fig. 2: Improved wound healing (Day 7)

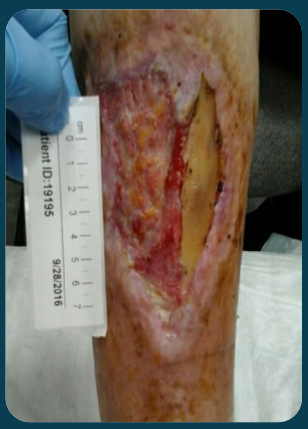


Fig. 3: Healthy granulating tissue (Day 9)

Treatment

- MicroDoc sNPWT therapy was ordered with an integrated adaptive dressing. The Initial order was for a period of 7 days with a pressure setting of -50 mmHg.
- Initial dressing change frequency was upon strikethrough reaching the dressing edges, and then changed to weekly as drainage decreased.
- The aim was to visibly improve wound healing by identifying epithelization and reducing hypergranulation with further prevention of infection and skin breakdown through the use of sNPWT system. An additional aim was to ensure patient experience and comfort was optimized during the continuum of care.

Outcomes

- On Day 7 dressing change (Fig. 3), the clinician assessed a reduction in wound depth leading to a more uniform appearance. She noted epithelialization starting to occur and migrate at the wound edges, and that the wound bed was becoming flatter aligning with the edges, indicating ongoing healing processes.
- The hypergranulated tissue also showed improvement and was resolving (Fig. 3).
- No wound odor was detected during dressing change.
- Patient stated a notable decrease in discomfort with the lower pressure setting of -50 mmHg4 as noted with the patient rating a 1 on a pain scale of (1-10).

ISO 13485 Certification

We are thrilled to share that Pensar Medical has been awarded ISO 13485 certification, an international standard for quality and excellence in the medical device industry.

This certification reinforces our commitment to quality in our products and services and signifies our dedication to delivering the highest-caliber medical devices.

Our clients can further trust that Pensar's products are designed, manufactured, and distributed under the strictest quality standards, ensuring safety and effectiveness.

Enhancing Customer Confidence in the US and Beyond

Enhancing Customer Confidence in the US and Beyond By reaching this important milestone, Pensar hopes to strengthen trust with our current customers and position ourselves for broader global outreach, opening doors to new markets and opportunities.

With ISO 13485 in hand, Pensar Medical is now actively engaging in the global arena and seeking partnerships with international distributors. We are on the lookout for like-minded partners who share our vision of bringing top-quality medical devices to a worldwide audience.

We invite you to reach out with any inquiries about our products or the ISO 13485 standard.

Customer Service

Orders through PensarMedical.com

Please contact us for regular order placement, consignment order placement & billing, inventory availability inquiries, shipment confirmation, service fee & invoicing inquiries.

Monday – Friday: 9 AM – 5 PM CST

Email: hello@pensarmedical.com

Phone: +1 (800) 669-4757

Reimbursement Support

Our goal is to make wound care a seamless process for everyone. Providing reimbursement information is one more way we are respecting our mission to honor our donors and make healing possible for those who need it.

Pensar Medical is committed to working with health care providers to make our products available to their patients.

If you have any additional questions regarding coding, coverage and payment; or require assistance with pre-certification, prior-authorization, or coverage appeals for a particular patient, please contact the Pensar Medical support team

Our most recent reimbursement coding guides can be provided upon request.

Ready to Elevate Your Healthcare Solutions with Pensar Medical?

Pensar Medical™ *Negative Pressure. Positive Results.*

Reorder Number	Product Description
4001	MicroDoc Complete System - Qty 1, with 15cm x 20cm (10cm x 15cm) Dressings
4002	MicroDoc Complete System - Qty 1, with 10cm x 20cm (5cm x 15cm) Dressings
4003	MicroDoc Complete System - Qty 1, with 10cm x 30cm (5cm x 25cm) Dressings
4004	MicroDoc Complete System - Qty 1, with 20cm x 25cm (15cm x 20cm) Dressings
4005	MicroDoc Complete System - Qty 1, with 20cm x 25cm (15cm x 20cm) Breast Dressings
4021	MicroDoc ComforTech Dressings, 15cm x 20cm (10cm x 15cm), Case of 10
4022	MicroDoc ComforTech Dressings, 10cm x 20cm (5cm x 15cm), Case of 10
4023	MicroDoc ComforTech Dressings, 10cm x 30cm (5cm x 25cm), Case of 10
4024	MicroDoc ComforTech Dressings, 20cm x 25cm (15cm x 20cm), Case of 10
4025	MicroDoc ComforTech Breast Dressings, 20cm x 25cm (15cm x 20cm), Case of 10
4031	MicroDoc Complete System - Qty 3, with 15cm x 20cm (10cm x 15cm) Dressings
4032	MicroDoc Complete System - Qty 3, with 10cm x 20cm (5cm x 15cm) Dressings
4033	MicroDoc Complete System - Qty 3, with 10cm x 30cm (5cm x 25cm) Dressings
4034	MicroDoc Complete System - Qty 3, with 20cm x 25cm (15cm x 20cm) Dressings
4035	MicroDoc Complete System - Qty 3, with 20cm x 25cm (15cm x 20cm) Breast Dressings

Contact Us

www.pensarmedical.com
hello@pensarmedical.com

Pensar Medical™

October 23, 2020

Pensar Medical, LLC
% Pierre Bounaud
Senior Regulatory specialist
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K200223
Trade/Device Name: PocketDoc™ Micro Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 24, 2020
Received: January 29, 2020

Dear Pierre Bounaud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -S

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
DHT4B: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200223

Device Name
PocketDoc™ Micro Wound Therapy System

Indications for Use *(Describe)*
PocketDoc Micro Wound Therapy System is indicated for patients who may benefit from a suction device as it may promote wound healing through the removal of low to moderate levels of exudate and infectious material.

Appropriate wound types include:
• Chronic
• Acute
• Traumatic
• Subacute and dehisced wounds
• Partial-thickness burns
• Ulcers (such as diabetic or pressure)
• Flaps and grafts
• Closed surgical incisions

PocketDoc Micro Wound Therapy System is suitable for use in both a healthcare and homecare setting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Pensar Medical™
Negative Pressure. Positive Results.

510(k) Summary
K200223

DATE PREPARED
October 23, 2020

MANUFACTURER AND 510(k) OWNER
Pensar Medical, LLC
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DEVICE INFORMATION

Proprietary Name/Trade Name:	PocketDoc™ Micro Wound Therapy System
Common Name:	Negative Pressure Wound Therapy Powered Suction Pump
Regulation Number:	21 CFR 878.4780
Class:	II
Product Code:	OMP
Premarket Review:	General & Plastic Surgery
Review Panel:	OPEQ/OHT4/Infection Control and Plastic Surgery Devices (DHT4B)

PREDICATE DEVICE IDENTIFICATION
The PocketDoc is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K151436	PICO Single Use Negative Pressure Wound Therapy System / Smith & Nephew Medical Inc.	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The PocketDoc™ Micro Wound Therapy System (PocketDoc) is a negative pressure wound therapy (NPWT) system that is specifically designed for shallow wounds with low to moderate amounts of exudate (~10 ml/day) that no longer or never required a collection canister. The system consists of a disposable, small, lightweight, battery operated, portable suction device (pump control unit) containing an electric motor driven vacuum pump, Enluxtra Humifiber Wound Dressings made of a hydrophilic gelling fiber (K122297), adhesive polyurethane drapes and StingRay TPE flanges with PVC tubing to connect the dressing/drape to the suction device.

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The dressing is applied over the wound and the drape is applied over the dressing to hold it in place. The flange on top of the drape is connected to the pump control unit via the tubing. The dressings, drapes, flanges and tubing are supplied sterile and are for single use. The pump control unit is for single patient use and is provided nonsterile. The PocketDoc™ Micro Wound Therapy System is suitable for use in both a healthcare and homecare setting. The portable suction device can be placed in a pocket, a carrier or attached to the body with an arm/leg Velcro strap which is provided.

INDICATIONS FOR USE
PocketDoc Micro Wound Therapy System is indicated for patients who may benefit from a suction device as it may promote wound healing through the removal of low to moderate levels of exudate and infectious material.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PocketDoc Micro Wound Therapy System is suitable for use in both a healthcare and homecare setting.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
Pensar Medical believes that the PocketDoc™ Micro Wound Therapy System (PocketDoc) is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions and uses similar materials (plastic body, thermoplastic flange, PVC tubing, highly adsorbent dressing) as the device cleared in K151436. The subject device has the same intended use and similar technological characteristics (powered suction pump for negative pressure wound therapy) to the device cleared in K151436.

The technological differences of the PocketDoc™ Micro Wound Therapy System, when compared to the predicate device cleared in K151436, are that the subject device includes two additional set pressures (-50 and -125 mmHg), uses non-replaceable AAA alkaline batteries instead of replaceable AA lithium batteries, includes a smaller dressing size (4”x4” instead of 4”x8”), incorporates a different wound kit fixation method (film drape instead of fixation strips), and involves a different sterilization method (gamma radiation instead of ethylene oxide).

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The PocketDoc has undergone testing to ensure the differences in technological characteristics do not raise different questions of safety and effectiveness compared to the predicate device.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the PocketDoc™ Micro Wound Therapy System (PocketDoc). The following tests were performed to demonstrate safety based on current industry standards:

- Sterilization validation per ISO 11137-1, ISO 11137-2, and AAMI TIR33
- Packaging and shelf life validations
- Biocompatibility per ISO 10993-1 (for a device having prolonged contact duration with breached or compromised skin)
- Software validation per IEC 62304
- Electrical safety per ANSI/AAMI ES60601-1
- Electromagnetic compatibility per IEC 60601-1-2
- Performance bench testing
    - Pressure accuracy test: Evaluate the ability of the device to administer accurate pressure in side-by-side testing with the predicate.
    - Low pressure indicator test: Evaluate the ability of the device to detect a low pressure condition in the system and engage a low pressure indicator in side-by-side testing with the predicate.
    - 96-hour exudate test: Demonstrate the ability of the device to collect exudate in the dressing during a worst-case simulated clinical scenario in side-by-side testing with the predicate.
    - Effect of PocketDoc on Enluxtra Humifiber Wound Dressing fluid management performance: Evaluate the effect of the device on the dressing fluid management performance, specifically, fluid capacity under a simulated worst-case clinical scenario.
    - Battery test: Evaluate the ability of the device to function for at least 168 hours and to engage the low battery indicators.
    - Negative pressure safety limit test: Evaluate the ability of the device to not go above the upper boundary pressure values in the event of a failure of the device in side-by-side testing with the predicate.
- Human factor studies with two groups (healthcare professionals, lay users)

The results of these tests indicate that the PocketDoc™ Micro Wound Therapy System is substantially equivalent to the predicate device.

CONCLUSION

Based on the testing performed, including sterilization validation, packaging validation, shelf life validation, biocompatibility, software validation, electrical safety, electromagnetic compatibility, performance bench testing, and human factor studies, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed PocketDoc™ Micro Wound Therapy System are assessed to be substantially equivalent to the predicate device.

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See *Specific Instructions* on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

Lion Street Medical, LLC

2 Business name/disregarded entity name, if different from above.

Pensar Medical

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☑ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☐ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) . . . .

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions . . . . . ☐

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

5 Address (number, street, and apt. or suite no.). See instructions.

109 N Post Oak Lane Suite 525

6 City, state, and ZIP code

Houston, TX 77024

Requester's name and address (optional)

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–			–				

or

Employer identification number

9	3	–	1	9	0	3	2	1	0

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** Jason A. Bandy | **Date 1/1/24**

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

must obtain your correct taxpayer identification number (TIN), which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid).
- Form 1099-DIV (dividends, including those from stocks or mutual funds).
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds).
- Form 1099-NEC (nonemployee compensation).
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers).
- Form 1099-S (proceeds from real estate transactions).
- Form 1099-K (merchant card and third-party network transactions).
- Form 1098 (home mortgage interest), 1098-E (student loan interest), and 1098-T (tuition).
- Form 1099-C (canceled debt).
- Form 1099-A (acquisition or abandonment of secured property).

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

Caution: If you don't return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See *What is backup withholding*, later.

By signing the filled-out form, you:

1. Certify that the TIN you are giving is correct (or you are waiting for a number to be issued);
2. Certify that you are not subject to backup withholding; or
3. Claim exemption from backup withholding if you are a U.S. exempt payee; and
4. Certify to your non-foreign status for purposes of withholding under chapter 3 or 4 of the Code (if applicable); and
5. Certify that FATCA code(s) entered on this form (if any) indicating that you are exempt from the FATCA reporting is correct. See *What Is FATCA Reporting*, later, for further information.

Note: If you are a U.S. person and a requester gives you a form other than Form W-9 to request your TIN, you must use the requester's form if it is substantially similar to this Form W-9.

Definition of a U.S. person. For federal tax purposes, you are considered a U.S. person if you are:

- An individual who is a U.S. citizen or U.S. resident alien;
- A partnership, corporation, company, or association created or organized in the United States or under the laws of the United States;
- An estate (other than a foreign estate); or
- A domestic trust (as defined in Regulations section 301.7701-7).

Establishing U.S. status for purposes of chapter 3 and chapter 4 withholding. Payments made to foreign persons, including certain distributions, allocations of income, or transfers of sales proceeds, may be subject to withholding under chapter 3 or chapter 4 of the Code (sections 1441–1474). Under those rules, if a Form W-9 or other certification of non-foreign status has not been received, a withholding agent, transferee, or partnership (payor) generally applies presumption rules that may require the payor to withhold applicable tax from the recipient, owner, transferor, or partner (payee). See Pub. 515, Withholding of Tax on Nonresident Aliens and Foreign Entities.

The following persons must provide Form W-9 to the payor for purposes of establishing its non-foreign status.

- In the case of a disregarded entity with a U.S. owner, the U.S. owner of the disregarded entity and not the disregarded entity.
- In the case of a grantor trust with a U.S. grantor or other U.S. owner, generally, the U.S. grantor or other U.S. owner of the grantor trust and not the grantor trust.
- In the case of a U.S. trust (other than a grantor trust), the U.S. trust and not the beneficiaries of the trust.

See Pub. 515 for more information on providing a Form W-9 or a certification of non-foreign status to avoid withholding.

Foreign person. If you are a foreign person or the U.S. branch of a foreign bank that has elected to be treated as a U.S. person (under Regulations section 1.1441-1(b)(2)(iv) or other applicable section for chapter 3 or 4 purposes), do not use Form W-9. Instead, use the appropriate Form W-8 or Form 8233 (see Pub. 515). If you are a qualified foreign pension fund under Regulations section 1.897(l)-1(d), or a partnership that is wholly owned by qualified foreign pension funds, that is treated as a non-foreign person for purposes of section 1445 withholding, do not use Form W-9. Instead, use Form W-8EXP (or other certification of non-foreign status).

Nonresident alien who becomes a resident alien. Generally, only a nonresident alien individual may use the terms of a tax treaty to reduce or eliminate U.S. tax on certain types of income. However, most tax treaties contain a provision known as a saving clause. Exceptions specified in the saving clause may permit an exemption from tax to continue for certain types of income even after the payee has otherwise become a U.S. resident alien for tax purposes.

If you are a U.S. resident alien who is relying on an exception contained in the saving clause of a tax treaty to claim an exemption from U.S. tax on certain types of income, you must attach a statement to Form W-9 that specifies the following five items.

1. The treaty country. Generally, this must be the same treaty under which you claimed exemption from tax as a nonresident alien.
2. The treaty article addressing the income.
3. The article number (or location) in the tax treaty that contains the saving clause and its exceptions.
4. The type and amount of income that qualifies for the exemption from tax.
5. Sufficient facts to justify the exemption from tax under the terms of the treaty article.

Example. Article 20 of the U.S.-China income tax treaty allows an exemption from tax for scholarship income received by a Chinese student temporarily present in the United States. Under U.S. law, this student will become a resident alien for tax purposes if their stay in the United States exceeds 5 calendar years. However, paragraph 2 of the first Protocol to the U.S.-China treaty (dated April 30, 1984) allows the provisions of Article 20 to continue to apply even after the Chinese student becomes a resident alien of the United States. A Chinese student who qualifies for this exception (under paragraph 2 of the first Protocol) and is relying on this exception to claim an exemption from tax on their scholarship or fellowship income would attach to Form W-9 a statement that includes the information described above to support that exemption.

If you are a nonresident alien or a foreign entity, give the requester the appropriate completed Form W-8 or Form 8233.

Backup Withholding

What is backup withholding? Persons making certain payments to you must under certain conditions withhold and pay to the IRS 24% of such payments. This is called "backup withholding." Payments that may be subject to backup withholding include, but are not limited to, interest, tax-exempt interest, dividends, broker and barter exchange transactions, rents, royalties, nonemployee pay, payments made in settlement of payment card and third-party network transactions, and certain payments from fishing boat operators. Real estate transactions are not subject to backup withholding.

You will not be subject to backup withholding on payments you receive if you give the requester your correct TIN, make the proper certifications, and report all your taxable interest and dividends on your tax return.

Payments you receive will be subject to backup withholding if:

1. You do not furnish your TIN to the requester;
2. You do not certify your TIN when required (see the instructions for Part II for details);
3. The IRS tells the requester that you furnished an incorrect TIN;
4. The IRS tells you that you are subject to backup withholding because you did not report all your interest and dividends on your tax return (for reportable interest and dividends only); or
5. You do not certify to the requester that you are not subject to backup withholding, as described in item 4 under "*By signing the filled-out form*" above (for reportable interest and dividend accounts opened after 1983 only).

Certain payees and payments are exempt from backup withholding. See *Exempt payee code*, later, and the separate Instructions for the Requester of Form W-9 for more information.

See also *Establishing U.S. status for purposes of chapter 3 and chapter 4 withholding*, earlier.

What Is FATCA Reporting?

The Foreign Account Tax Compliance Act (FATCA) requires a participating foreign financial institution to report all U.S. account holders that are specified U.S. persons. Certain payees are exempt from FATCA reporting. See *Exemption from FATCA reporting code*, later, and the Instructions for the Requester of Form W-9 for more information.

Updating Your Information

You must provide updated information to any person to whom you claimed to be an exempt payee if you are no longer an exempt payee and anticipate receiving reportable payments in the future from this person. For example, you may need to provide updated information if you are a C corporation that elects to be an S corporation, or if you are no longer tax exempt. In addition, you must furnish a new Form W-9 if the name or TIN changes for the account, for example, if the grantor of a grantor trust dies.

Penalties

Failure to furnish TIN. If you fail to furnish your correct TIN to a requester, you are subject to a penalty of $50 for each such failure unless your failure is due to reasonable cause and not to willful neglect.

Civil penalty for false information with respect to withholding. If you make a false statement with no reasonable basis that results in no backup withholding, you are subject to a $500 penalty.

Criminal penalty for falsifying information. Willfully falsifying certifications or affirmations may subject you to criminal penalties including fines and/or imprisonment.

Misuse of TINs. If the requester discloses or uses TINs in violation of federal law, the requester may be subject to civil and criminal penalties.

Specific Instructions

Line 1

You must enter one of the following on this line; **do not** leave this line blank. The name should match the name on your tax return.

If this Form W-9 is for a joint account (other than an account maintained by a foreign financial institution (FFI)), list first, and then circle, the name of the person or entity whose number you entered in Part I of Form W-9. If you are providing Form W-9 to an FFI to document a joint account, each holder of the account that is a U.S. person must provide a Form W-9.

• **Individual.** Generally, enter the name shown on your tax return. If you have changed your last name without informing the Social Security Administration (SSA) of the name change, enter your first name, the last name as shown on your social security card, and your new last name.

Note for ITIN applicant: Enter your individual name as it was entered on your Form W-7 application, line 1a. This should also be the same as the name you entered on the Form 1040 you filed with your application.

• **Sole proprietor.** Enter your individual name as shown on your Form 1040 on line 1. Enter your business, trade, or "doing business as" (DBA) name on line 2.

• **Partnership, C corporation, S corporation, or LLC, other than a disregarded entity.** Enter the entity's name as shown on the entity's tax return on line 1 and any business, trade, or DBA name on line 2.

• **Other entities.** Enter your name as shown on required U.S. federal tax documents on line 1. This name should match the name shown on the charter or other legal document creating the entity. Enter any business, trade, or DBA name on line 2.

• **Disregarded entity.** In general, a business entity that has a single owner, including an LLC, and is not a corporation, is disregarded as an entity separate from its owner (a disregarded entity). See Regulations section 301.7701-2(c)(2). A disregarded entity should check the appropriate box for the tax classification of its owner. Enter the owner's name on line 1. The name of the owner entered on line 1 should never be a disregarded entity. The name on line 1 should be the name shown on the income tax return on which the income should be reported. For example, if a foreign LLC that is treated as a disregarded entity for U.S. federal tax purposes has a single owner that is a U.S. person, the U.S. owner's name is required to be provided on line 1. If the direct owner of the entity is also a disregarded entity, enter the first owner that is not disregarded for federal tax purposes. Enter the disregarded entity's name on line 2. If the owner of the disregarded entity is a foreign person, the owner must complete an appropriate Form W-8 instead of a Form W-9. This is the case even if the foreign person has a U.S. TIN.

Line 2

If you have a business name, trade name, DBA name, or disregarded entity name, enter it on line 2.

Line 3a

Check the appropriate box on line 3a for the U.S. federal tax classification of the person whose name is entered on line 1. Check only one box on line 3a.

IF the entity/individual on line 1 is a(n) . . .	THEN check the box for . . .
• Corporation	Corporation.
• Individual or • Sole proprietorship	Individual/sole proprietor.
• LLC classified as a partnership for U.S. federal tax purposes or • LLC that has filed Form 8832 or 2553 electing to be taxed as a corporation	Limited liability company and enter the appropriate tax classification: P = Partnership, C = C corporation, or S = S corporation.
• Partnership	Partnership.
• Trust/estate	Trust/estate.

Line 3b

Check this box if you are a partnership (including an LLC classified as a partnership for U.S. federal tax purposes), trust, or estate that has any foreign partners, owners, or beneficiaries, and you are providing this form to a partnership, trust, or estate, in which you have an ownership interest. You must check the box on line 3b if you receive a Form W-8 (or documentary evidence) from any partner, owner, or beneficiary establishing foreign status or if you receive a Form W-9 from any partner, owner, or beneficiary that has checked the box on line 3b.

Note: A partnership that provides a Form W-9 and checks box 3b may be required to complete Schedules K-2 and K-3 (Form 1065). For more information, see the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

If you are required to complete line 3b but fail to do so, you may not receive the information necessary to file a correct information return with the IRS or furnish a correct payee statement to your partners or beneficiaries. See, for example, sections 6698, 6722, and 6724 for penalties that may apply.

Line 4 Exemptions

If you are exempt from backup withholding and/or FATCA reporting, enter in the appropriate space on line 4 any code(s) that may apply to you.

Exempt payee code.

• Generally, individuals (including sole proprietors) are not exempt from backup withholding.

• Except as provided below, corporations are exempt from backup withholding for certain payments, including interest and dividends.

• Corporations are not exempt from backup withholding for payments made in settlement of payment card or third-party network transactions.

• Corporations are not exempt from backup withholding with respect to attorneys' fees or gross proceeds paid to attorneys, and corporations that provide medical or health care services are not exempt with respect to payments reportable on Form 1099-MISC.

The following codes identify payees that are exempt from backup withholding. Enter the appropriate code in the space on line 4.

1—An organization exempt from tax under section 501(a), any IRA, or a custodial account under section 403(b)(7) if the account satisfies the requirements of section 401(f)(2).

2—The United States or any of its agencies or instrumentalities.

3—A state, the District of Columbia, a U.S. commonwealth or territory, or any of their political subdivisions or instrumentalities.

4—A foreign government or any of its political subdivisions, agencies, or instrumentalities.

5—A corporation.

6—A dealer in securities or commodities required to register in the United States, the District of Columbia, or a U.S. commonwealth or territory.

7—A futures commission merchant registered with the Commodity Futures Trading Commission.

8—A real estate investment trust.

9—An entity registered at all times during the tax year under the Investment Company Act of 1940.

10—A common trust fund operated by a bank under section 584(a).

11—A financial institution as defined under section 581.

12—A middleman known in the investment community as a nominee or custodian.

13—A trust exempt from tax under section 664 or described in section 4947.

The following chart shows types of payments that may be exempt from backup withholding. The chart applies to the exempt payees listed above, 1 through 13.

IF the payment is for . . .	THEN the payment is exempt for . . .
• Interest and dividend payments	All exempt payees except for 7.
• Broker transactions	Exempt payees 1 through 4 and 6 through 11 and all C corporations. S corporations must not enter an exempt payee code because they are exempt only for sales of noncovered securities acquired prior to 2012.
• Barter exchange transactions and patronage dividends	Exempt payees 1 through 4.
• Payments over $600 required to be reported and direct sales over $5,000[1]	Generally, exempt payees 1 through 5.[2]
• Payments made in settlement of payment card or third-party network transactions	Exempt payees 1 through 4.

[1] See Form 1099-MISC, Miscellaneous Information, and its instructions.

[2] However, the following payments made to a corporation and reportable on Form 1099-MISC are not exempt from backup withholding: medical and health care payments, attorneys' fees, gross proceeds paid to an attorney reportable under section 6045(f), and payments for services paid by a federal executive agency.

Exemption from FATCA reporting code. The following codes identify payees that are exempt from reporting under FATCA. These codes apply to persons submitting this form for accounts maintained outside of the United States by certain foreign financial institutions. Therefore, if you are only submitting this form for an account you hold in the United States, you may leave this field blank. Consult with the person requesting this form if you are uncertain if the financial institution is subject to these requirements. A requester may indicate that a code is not required by providing you with a Form W-9 with "Not Applicable" (or any similar indication) entered on the line for a FATCA exemption code.

A—An organization exempt from tax under section 501(a) or any individual retirement plan as defined in section 7701(a)(37).

B—The United States or any of its agencies or instrumentalities.

C—A state, the District of Columbia, a U.S. commonwealth or territory, or any of their political subdivisions or instrumentalities.

D—A corporation the stock of which is regularly traded on one or more established securities markets, as described in Regulations section 1.1472-1(c)(1)(i).

E—A corporation that is a member of the same expanded affiliated group as a corporation described in Regulations section 1.1472-1(c)(1)(i).

F—A dealer in securities, commodities, or derivative financial instruments (including notional principal contracts, futures, forwards, and options) that is registered as such under the laws of the United States or any state.

G—A real estate investment trust.

H—A regulated investment company as defined in section 851 or an entity registered at all times during the tax year under the Investment Company Act of 1940.

I—A common trust fund as defined in section 584(a).

J—A bank as defined in section 581.

K—A broker.

L—A trust exempt from tax under section 664 or described in section 4947(a)(1).

M—A tax-exempt trust under a section 403(b) plan or section 457(g) plan.

Note: You may wish to consult with the financial institution requesting this form to determine whether the FATCA code and/or exempt payee code should be completed.

Line 5

Enter your address (number, street, and apartment or suite number). This is where the requester of this Form W-9 will mail your information returns. If this address differs from the one the requester already has on file, enter "NEW" at the top. If a new address is provided, there is still a chance the old address will be used until the payor changes your address in their records.

Line 6

Enter your city, state, and ZIP code.

Part I. Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. If you are a resident alien and you do not have, and are not eligible to get, an SSN, your TIN is your IRS ITIN. Enter it in the entry space for the Social security number. If you do not have an ITIN, see *How to get a TIN* below.

If you are a sole proprietor and you have an EIN, you may enter either your SSN or EIN.

If you are a single-member LLC that is disregarded as an entity separate from its owner, enter the owner's SSN (or EIN, if the owner has one). If the LLC is classified as a corporation or partnership, enter the entity's EIN.

Note: See *What Name and Number To Give the Requester*, later, for further clarification of name and TIN combinations.

How to get a TIN. If you do not have a TIN, apply for one immediately. To apply for an SSN, get Form SS-5, Application for a Social Security Card, from your local SSA office or get this form online at *www.SSA.gov*. You may also get this form by calling 800-772-1213. Use Form W-7, Application for IRS Individual Taxpayer Identification Number, to apply for an ITIN, or Form SS-4, Application for Employer Identification Number, to apply for an EIN. You can apply for an EIN online by accessing the IRS website at *www.irs.gov/EIN*. Go to *www.irs.gov/Forms* to view, download, or print Form W-7 and/or Form SS-4. Or, you can go to *www.irs.gov/OrderForms* to place an order and have Form W-7 and/or Form SS-4 mailed to you within 15 business days.

If you are asked to complete Form W-9 but do not have a TIN, apply for a TIN and enter "Applied For" in the space for the TIN, sign and date the form, and give it to the requester. For interest and dividend payments, and certain payments made with respect to readily tradable instruments, you will generally have 60 days to get a TIN and give it to the requester before you are subject to backup withholding on payments. The 60-day rule does not apply to other types of payments. You will be subject to backup withholding on all such payments until you provide your TIN to the requester.

Note: Entering "Applied For" means that you have already applied for a TIN or that you intend to apply for one soon. See also *Establishing U.S. status for purposes of chapter 3 and chapter 4 withholding*, earlier, for when you may instead be subject to withholding under chapter 3 or 4 of the Code.

Caution: A disregarded U.S. entity that has a foreign owner must use the appropriate Form W-8.

Part II. Certification

To establish to the withholding agent that you are a U.S. person, or resident alien, sign Form W-9. You may be requested to sign by the withholding agent even if item 1, 4, or 5 below indicates otherwise.

For a joint account, only the person whose TIN is shown in Part I should sign (when required). In the case of a disregarded entity, the person identified on line 1 must sign. Exempt payees, see *Exempt payee code*, earlier.

Signature requirements. Complete the certification as indicated in items 1 through 5 below.

1. Interest, dividend, and barter exchange accounts opened before 1984 and broker accounts considered active during 1983. You must give your correct TIN, but you do not have to sign the certification.

2. Interest, dividend, broker, and barter exchange accounts opened after 1983 and broker accounts considered inactive during 1983. You must sign the certification or backup withholding will apply. If you are subject to backup withholding and you are merely providing your correct TIN to the requester, you must cross out item 2 in the certification before signing the form.

3. Real estate transactions. You must sign the certification. You may cross out item 2 of the certification.

4. Other payments. You must give your correct TIN, but you do not have to sign the certification unless you have been notified that you have previously given an incorrect TIN. "Other payments" include payments made in the course of the requester's trade or business for rents, royalties, goods (other than bills for merchandise), medical and health care services (including payments to corporations), payments to a nonemployee for services, payments made in settlement of payment card and third-party network transactions, payments to certain fishing boat crew members and fishermen, and gross proceeds paid to attorneys (including payments to corporations).

5. Mortgage interest paid by you, acquisition or abandonment of secured property, cancellation of debt, qualified tuition program payments (under section 529), ABLE accounts (under section 529A), IRA, Coverdell ESA, Archer MSA or HSA contributions or distributions, and pension distributions. You must give your correct TIN, but you do not have to sign the certification.

What Name and Number To Give the Requester

For this type of account:	Give name and SSN of:
1. Individual	The individual
2. Two or more individuals (joint account) other than an account maintained by an FFI	The actual owner of the account or, if combined funds, the first individual on the account[1]
3. Two or more U.S. persons (joint account maintained by an FFI)	Each holder of the account
4. Custodial account of a minor (Uniform Gift to Minors Act)	The minor[2]
5. a. The usual revocable savings trust (grantor is also trustee)	The grantor-trustee[1]
b. So-called trust account that is not a legal or valid trust under state law	The actual owner[1]
6. Sole proprietorship or disregarded entity owned by an individual	The owner[3]
7. Grantor trust filing under Optional Filing Method 1 (see Regulations section 1.671-4(b)(2)(i)(A))**	The grantor*
8. Disregarded entity not owned by an individual	The owner
9. A valid trust, estate, or pension trust	Legal entity[4]
10. Corporation or LLC electing corporate status on Form 8832 or Form 2553	The corporation
11. Association, club, religious, charitable, educational, or other tax-exempt organization	The organization
12. Partnership or multi-member LLC	The partnership
13. A broker or registered nominee	The broker or nominee
14. Account with the Department of Agriculture in the name of a public entity (such as a state or local government, school district, or prison) that receives agricultural program payments	The public entity
15. Grantor trust filing Form 1041 or under the Optional Filing Method 2, requiring Form 1099 (see Regulations section 1.671-4(b)(2)(i)(B))**	The trust

[1] List first and circle the name of the person whose number you furnish. If only one person on a joint account has an SSN, that person's number must be furnished.

[2] Circle the minor's name and furnish the minor's SSN.

[3] You must show your individual name on line 1, and enter your business or DBA name, if any, on line 2. You may use either your SSN or EIN (if you have one), but the IRS encourages you to use your SSN.

[4] List first and circle the name of the trust, estate, or pension trust. (Do not furnish the TIN of the personal representative or trustee unless the legal entity itself is not designated in the account title.)

* **Note:** The grantor must also provide a Form W-9 to the trustee of the trust.

** For more information on optional filing methods for grantor trusts, see the Instructions for Form 1041.

Note: If no name is circled when more than one name is listed, the number will be considered to be that of the first name listed.

Secure Your Tax Records From Identity Theft

Identity theft occurs when someone uses your personal information, such as your name, SSN, or other identifying information, without your permission to commit fraud or other crimes. An identity thief may use your SSN to get a job or may file a tax return using your SSN to receive a refund.

To reduce your risk:

- Protect your SSN,
- Ensure your employer is protecting your SSN, and
- Be careful when choosing a tax return preparer.

If your tax records are affected by identity theft and you receive a notice from the IRS, respond right away to the name and phone number printed on the IRS notice or letter.

If your tax records are not currently affected by identity theft but you think you are at risk due to a lost or stolen purse or wallet, questionable credit card activity, or a questionable credit report, contact the IRS Identity Theft Hotline at 800-908-4490 or submit Form 14039.

For more information, see Pub. 5027, Identity Theft Information for Taxpayers.

Victims of identity theft who are experiencing economic harm or a systemic problem, or are seeking help in resolving tax problems that have not been resolved through normal channels, may be eligible for Taxpayer Advocate Service (TAS) assistance. You can reach TAS by calling the TAS toll-free case intake line at 877-777-4778 or TTY/TDD 800-829-4059.

Protect yourself from suspicious emails or phishing schemes. Phishing is the creation and use of email and websites designed to mimic legitimate business emails and websites. The most common act is sending an email to a user falsely claiming to be an established legitimate enterprise in an attempt to scam the user into surrendering private information that will be used for identity theft.

The IRS does not initiate contacts with taxpayers via emails. Also, the IRS does not request personal detailed information through email or ask taxpayers for the PIN numbers, passwords, or similar secret access information for their credit card, bank, or other financial accounts.

If you receive an unsolicited email claiming to be from the IRS, forward this message to *phishing@irs.gov*. You may also report misuse of the IRS name, logo, or other IRS property to the Treasury Inspector General for Tax Administration (TIGTA) at 800-366-4484. You can forward suspicious emails to the Federal Trade Commission at *spam@uce.gov* or report them at *www.ftc.gov/complaint*. You can contact the FTC at *www.ftc.gov/idtheft* or 877-IDTHEFT (877-438-4338). If you have been the victim of identity theft, see *www.IdentityTheft.gov* and Pub. 5027.

Go to *www.irs.gov/IdentityTheft* to learn more about identity theft and how to reduce your risk.

Privacy Act Notice

Section 6109 of the Internal Revenue Code requires you to provide your correct TIN to persons (including federal agencies) who are required to file information returns with the IRS to report interest, dividends, or certain other income paid to you; mortgage interest you paid; the acquisition or abandonment of secured property; the cancellation of debt; or contributions you made to an IRA, Archer MSA, or HSA. The person collecting this form uses the information on the form to file information returns with the IRS, reporting the above information. Routine uses of this information include giving it to the Department of Justice for civil and criminal litigation and to cities, states, the District of Columbia, and U.S. commonwealths and territories for use in administering their laws. The information may also be disclosed to other countries under a treaty, to federal and state agencies to enforce civil and criminal laws, or to federal law enforcement and intelligence agencies to combat terrorism. You must provide your TIN whether or not you are required to file a tax return. Under section 3406, payors must generally withhold a percentage of taxable interest, dividends, and certain other payments to a payee who does not give a TIN to the payor. Certain penalties may also apply for providing false or fraudulent information.