



Guard Medical Announces FDA 510k clearance for increased wear time of its novel NPseal™, the first all-in-one NPWT surgical dressing

Miami, May 24, 2021 – Privately-held company [Guard Medical Inc.](http://www.guard-medical.com) today announces FDA 510k clearance of a wear time extension **from 3 to 6 days** for its next generation Negative Pressure Wound Therapy (NPWT) dressing **NPseal™** for the treatment of closed surgical incisions. Guard Medical's simple, innovative and cost-effective NPWT **NPseal™** is a wearable dressing with an integrated pump that establishes and maintains negative pressure with just a few pinches.

"In a go-to-market study commissioned by Guard Medical, Fletcher Spaght Inc. encountered high receptiveness amongst surgeons of the **NPseal™** but observed that surgeons would prefer a longer wear time. Receiving FDA clearance for the **NPseal™** wear time extension to 6 days is a significant step forward to become the NPWT device of choice for the treatment of a wide variety of surgical wounds," stated **Machiel van der Leest**, CEO of Guard Medical. "NPseal's ease-of-use and cost effectiveness makes, for the first time, prophylactic use of NPWT for all eligible closed surgical wounds possible."

FSI conducted in-depth interviews with 65 surgeons in Guard Medical's targeted surgical specialties of Colorectal Surgery, Plastic & Reconstructive Surgery, Orthopedic Surgery, Obstetrics & Gynecology and General Surgery, as well as Dermatology. These surgical specialties were selected on the basis of the incidence of surgical site infection and specific procedure volumes. The surgeons were drawn from both academic and community hospitals.

NPWT has been shown to reduce Surgical Site Infections (SSI) in a large number of peer reviewed articles but is in limited use due to its high cost and complexity. While being easy-to-use, **NPseal™** delivers the same NPWT as current more expensive and complex NPWT devices.

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Guard Medical Inc. (www.guard-medical.com), a privately-held company, is developing easy-to-use and cost-effective solutions that enables prophylactic Negative Pressure Wound Therapy (NPWT) wound care of closed surgical incisions. Guard Medical's simple NPWT technology originated with NewYork-Presbyterian and Weill Cornell Medicine in response to physician's identification of unmet needs related to Surgical Site Infections (SSI). Current investors include Bpifrance and Matignon Investissement et Gestion.

Guard Medical's vision is to develop NPWT solutions for use on a wide range of surgical wound types and sizes with broad applications for infection prevention, scar mitigation and enhanced cosmesis.

For further information please contact: Dr. Frederick Cornhill
Chief Scientific Officer, Guard Medical
E: j.cornhill@guard-medical.com