

# Clinical evaluation of a novel, non-electromechanical single-use Negative Pressure Wound Therapy (NPWT) system for the management of closed surgical incisions

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## 1. Background

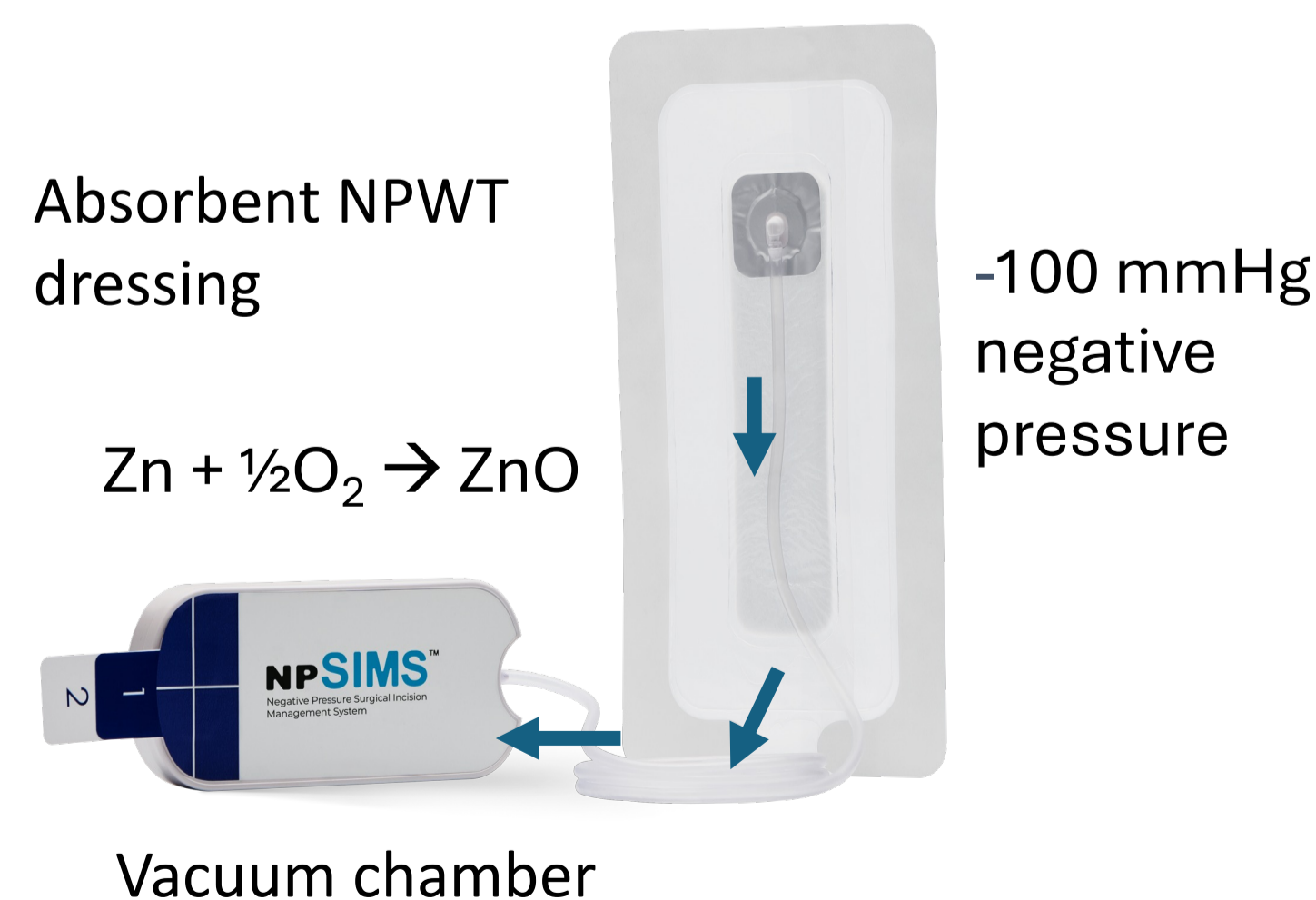
Closed incision negative pressure wound therapy (ciNPWT) has been shown to reduce SSI by around 40%: N = 44 trials N = 5693 patients (Shiroky et al (2020)). However, adoption is limited by the cost of electromechanical devices. This study describes the first clinical evaluation of a low cost of manufacture non-electromechanical single-use NPWT system for the management of closed surgical incisions.

## 2. Materials & Methods

The novel solid-state device\* has no electrical or mechanical components. Activation of a chemical reaction generates negative pressure in the rigid vacuum chamber by removal of oxygen which is 21% of atmospheric pressure.

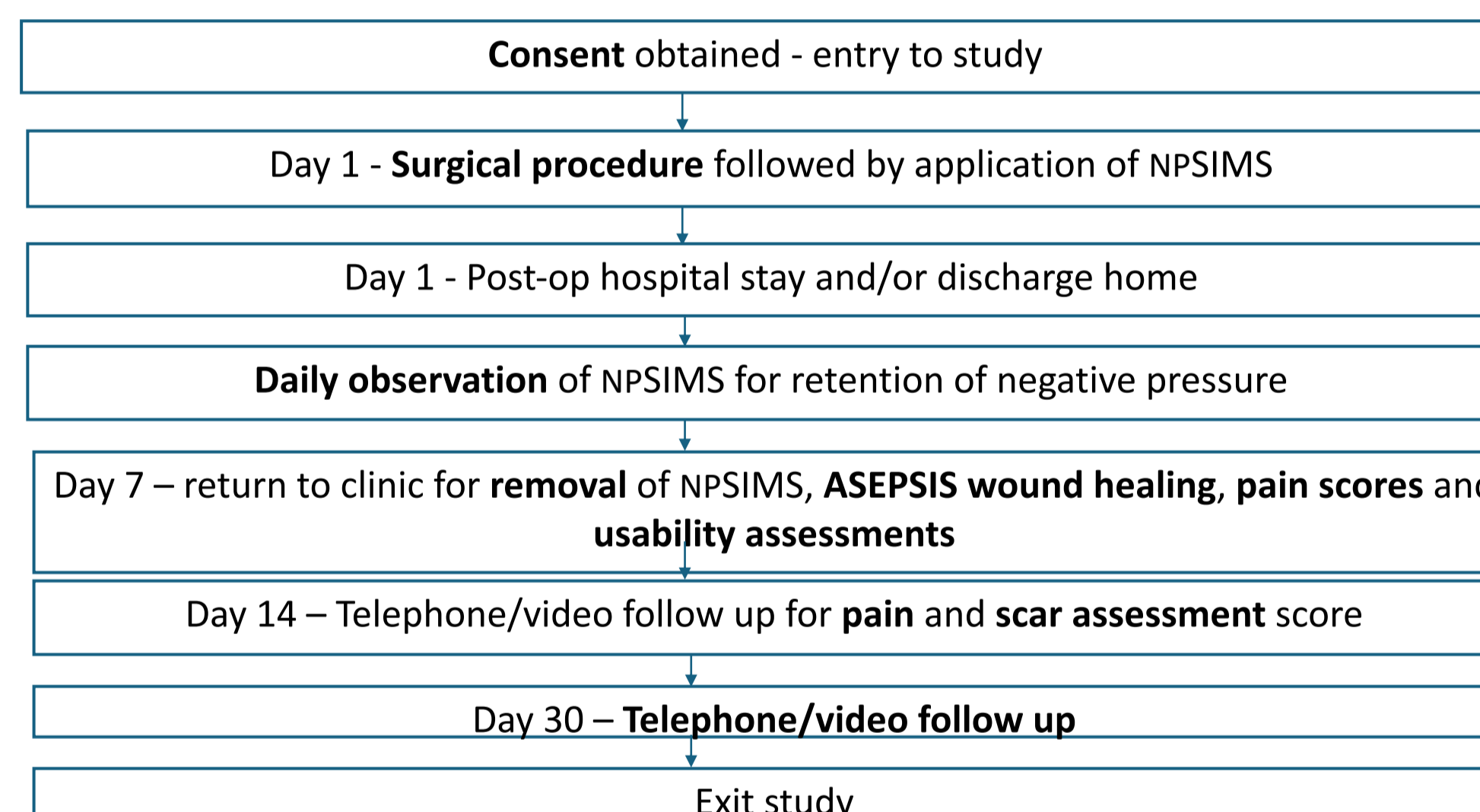
If all oxygen was removed the negative pressure would be 21% x 760 mmHg = -159.6 mmHg.

In practice an initial pressure of -100±5mmHg gradually declines over 7 days to -60mmHg (nominally 80mmHg ± 20mmHg) as air diffuses in through the dressing's permeable outer membrane.



## 3. Results

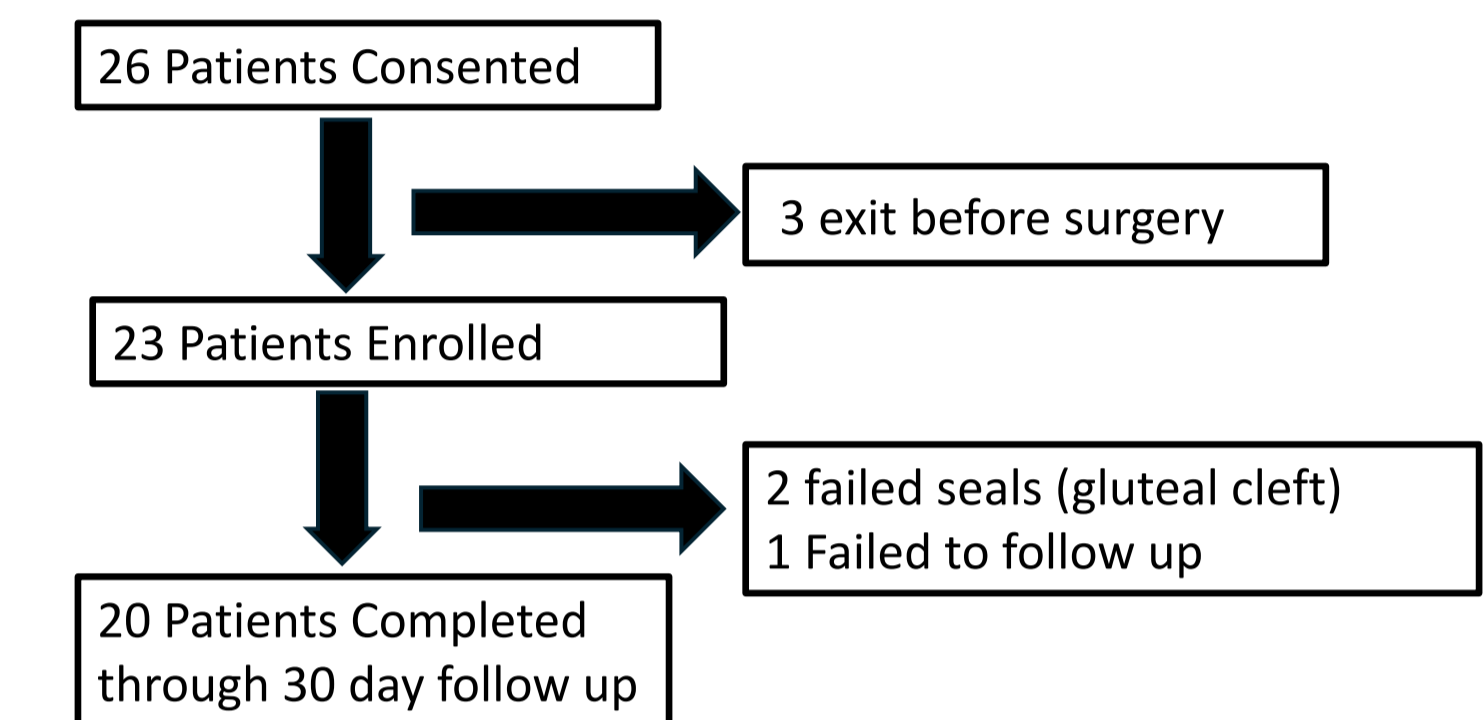
ClinicalTrials.gov (NCT04488666) registered 27th July 2020. New Zealand HDEC approved (20/STH/144) on 9<sup>th</sup> November 2020 for up to 30 patients. First patient recruited on 26<sup>th</sup> January 2021- last patient 26<sup>th</sup> August 2023. Primary endpoint was the number of days of delivery of negative pressure to the wound.



	Total enrolled (n=23)	Plastic surgery (n=10)	Spinal surgery (n=10)
Age (years)	65.0 ± 11.9	70.7 ± 10.2 (10)	60.9 ± 11.9 (10)
Female	10/23 (43.5%)	3/10 (30.0%)	5/10 (50.0%)
BMI (kg / m <sup>2</sup> )	30.9 ± 6.8 (23)	28.3 ± 3.9 (10)	33.2 ± 8.1 (10)

Length of incisions (cm)

Mean ± SD	7.6 ± 2.6	6.0 ± 1.5	8.4 ± 2.5
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Endpoints mean	Total (n=23)	Skin surgery n=10	Spinal surgery n=10
Median [min, max]			
Days of negative pressure delivery per incision	6.3 7.0 [1.0, 9.0]	6.4 7.0 [4.0, 7.0]	6.0 6.5 [1.0, 9.0]
Number of devices used per subject	1.2 1.0 [1.0, 3.0]	1.0 1.0 [1.0, 1.0]	1.4 1.0 [1.0, 3.0]
Days of negative pressure delivered per device	5.9 7.0 [0.3, 8.0]	6.4 7.0 [4.0, 7.0]	5.3 7.0 [0.3, 8.0]

A total of 9 adverse events were recorded – 2 were attributed to the device.

## 4. Conclusion.

A first-in-man clinical study has shown that a novel, low cost, closed incision NPWT device, in which vacuum is provided by an oxygen-consuming chemical reaction, is able to generate and maintain negative pressure for a mean of 5.9 days of negative pressure delivered per device. The device was used on a range of closed incisions at different anatomical locations. The device was well tolerated, silent, and shown to be convenient and easy to use.

## 5. References.

Shiroky et al (2020). "The Impact of Negative Pressure Wound Therapy for Closed Surgical Incisions on Surgical Site Infection: A Systematic Review and Meta-Analysis." *Surgery* 167(6):1001–9.

\*NPSIMS – Negative Pressure Surgical Incision Management System (Aatru Medical, LLC, USA)  
The NPSIMS device has received 510(k) FDA regulatory clearance in the USA (K201400)

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