Ref. No. ASO/JPNATC/Proprietary/2014-15  
Dated: 24.06.2014

Subject: Purchase of Single use negative pressure wound therapy system

The request is received from faculty of J.P.N.A. Trauma Centre, AIIMS for the purchase of subject cited item from M/s Smith & Nephew on proprietary basis. The proposal submitted by M/s Smith & Nephew and PAC certifications are attached and uploaded on website.

Specifications of Single use negative pressure wound therapy system are as follows:

- A portable sterile pump operated on 2 lithium batteries, should be of pocket size.
- 2 Sterile dressings and 10 fixations strips.
- Maintains negative pressure wound therapy (NPWT) at 80mmHg (Nominal) +/- 20mmHg to the wound surface.
- Manages exudates through a combination of absorption and evaporation of moisture through the outer film.
- Intended for use in wound sizes (surface area x depth) up to 400 c.c. which are considered to be low to moderately exuding.
- Intended to be used for a maximum of 7 days on low exuding wounds and 6 days on moderately exuding wounds.
- No canister must be required.
- Must be light weighed.

Technical specifications

- Maximum vacuum – 100mmHg, Operating environment – 5-35 degree celcius, 10-95% RH
- Storage: 5-25 degree celcius, 10-75% RH, 700 to 1060 mbar atmospheric pressure.
- Pump is protected by overflow filter in the dressing.
- Pressure controls- Micropressure controlled. Must use pressure sensor to control the action of an electric pump to maintain vaccum within specified range.

The above documents are being uploaded for open information to submit objections, comments, if any, from manufacturer regarding proprietary nature of the item within 15 days from the date of issue/uploading of the notification giving reference ASO/JPNATC/ proprietary/2014-15. The comments should be sent to Asstt. Stores Officer, JPNA Trauma Centre at AIIMS on or before 11.07.2014 up to 12:30 PM., failing which it will be presumed that any other vendor is having no comments to offer and case will be decided on merits.

Your's faithfully

[Signature]

Asstt. Stores Officer (JPNATC)

Encl: Related documents enclosed

1. PAC Certificate
Exclusivity Certificate

From our knowledge, PICO, a proprietary product of Smith & Nephew, is the first and only single-use, battery powered, canister-less negative pressure therapy system. While it provides the known clinical benefits as traditional negative pressure wound therapy, the unique dressing technology allows the system to manage low to moderate amount of exudate\(^1\) without having to use a canister while keeping a moist wound healing environment\(^1,2,3,4\) and providing patient with comfort\(^5\) and greater freedom\(^6\).

PICO System presents the following technical specificities:

- The unique fluid management capability of the dressing technology enables the system to work without canister;
  - The combined mechanisms of the absorbent layer and the high moisture vapor transmission top film enables the dressing to manage fluid to optimize wound healing conditions without the need for a canister;
  - Silicone adhesive helps to minimize trauma and pain to the peri wound area at dressing removal\(^6\) and will not adhere to newly formed tissue\(^3\);
  - "Airlock" layer creating an air pocket enabling consistent and uniform NPWT delivery\(^1,2\) across the wound;
  - Super absorbent layer ensure exudate is held away from the wound bed and peri wound area\(^1\) minimizing the risk of maceration\(^1,2,6\);
  - High moisture vapor transmission rate permeable polyurethane film acts as a bacterial barrier\(^7\) is waterproof\(^8\) and enables optimal exudate evaporation.

- PICO system is provided with 2 dressing kits to support first application and dressing change;
- The quiet battery powered pump (2 lithium AA batteries provided in kit) is compact and discreet (7cm x 6cm x 2cm and weight inferior to 120g), has a pre-defined life of 7 days\(^8,9\) and delivers pressure 80mmHg\(^7\).
- The pump has visual safety indicators for low vacuum to alert the user when vacuum level is low or when there may be a leak in the system as well as for low battery\(^9\).

While PICO provides important and exclusive patient and clinician advantages and benefits, its unique technology enables payers to provide a renown wound therapy to increased amount of patients while its advantageous value provides more predictable cost when compared to other disposable and conventional negative pressure therapy systems.

The table below summarizes some of the particular characteristics, advantages and benefits associated with PICO.

\(^*\) Trademark of Smith & Nephew
### Table: features & benefits comparison between conventional NPWT and PICO®

<table>
<thead>
<tr>
<th>Feature</th>
<th>PICO Single Use Device</th>
<th>Other disposable NPWT systems</th>
<th>Conventional NPWT</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compact Canister-free system</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>Lightweight Product design, quiet, discreet, and portable, for greater patient freedom and comfort⁷.</td>
</tr>
<tr>
<td>Unique &quot;Airlock&quot;, super absorbent dressing with high MVTR polyurethane film.</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>Easy to apply &amp; holds exudate away from the wound and peri wound skin minimizing the risk of maceration¹.².³.⁶ even in the event where the pump would stop and no negative pressure would be applied.</td>
</tr>
<tr>
<td>Use with or without filter</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>Enables clinician flexibility in therapy application for optimized system performance.</td>
</tr>
<tr>
<td>7-days system provided with multiple dressings</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>One dressing could last up to 7 days depending on levels of exudate.².⁶. Two dressings are provided to ensure that the clinician has sufficient dressings to last up to 7 days.</td>
</tr>
<tr>
<td>No service requirements between uses in different patients</td>
<td>✓ (single patient use)</td>
<td>✓ (single patient use)</td>
<td>X</td>
<td>No costs related to maintenance and management of the asset.</td>
</tr>
</tbody>
</table>

The PICO single-use negative pressure therapy system is unique and while it is already patent protected in many countries around the world, the following pending applications are a selection of the applications filed to protect the product in India:

**Patents**
- IN09654DN2008 A
- IN09655DN2008 A

**Designs**
- IN236121 S
- IN236127 S
- IN236128 S

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International Marketing Manager  
Advanced Wound Devices, PICO  
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