Regulatory Information Summary

Regulatory Information - Prospera PRO-II / PRO-III NPWT

The **Prospera PRO-II / PRO-III NPWT System** is a FDA cleared Class II Device under 510K Number K112458. DeRoyal has exclusivity rights to market the system across global geographies. The FDA clearance includes the NPWT PRO-II/PRO-III devices, compatible canisters, and wound dressing kits. Wound dressing kits include the foam or gauze, drape/film and a device interface dome with tubing.

Intended Use - These negative pressure wound therapy systems are indicated for patients that would benefit from a suction device particularly as the device may promote wound healing by removal of wound exudate, debris, and infectious material or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from the patient's airway or respiratory support system. These devices may be used during surgery or at the patient's bedside and are indicated for home use.

Indications:

- Chronic wounds
- Acute
- Sub-acute
- Traumatic wounds
- Dehisced wounds
- Partial thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps
- Grafts

Contraindications:

The PRO-II and PRO-III devices are contraindicated for the following applications:

- Necrotic tissue with eschar present
- Unexplored or non-enteric fistulas
- Untreated osteomyelitis
- Wounds containing malignant tissue
- Exposed arteries, nerves (including vagus nerve), blood vessels, veins, or internal organs
- Exposed anastomotic site

See Instructions For Use for Contraindications, Safety Information, Warnings and other important information.

For Healthcare Professionals requesting dressings which are not available in NPWT kits, appropriate testing will be performed to determine performance compatibility. These dressings are to be used at clinician discretion.

Additional Regulatory Information - For more information visit DeRoyal.com or contact DeRoyal directly.

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