DIRECTIONS

PRO-II® Canisters For Suction

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IMPORTANT INFORMATION

This document contains pertinent safety and instructional information pertaining to the Prospera® PRO-II device and PRO-II Canister when used 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.

BEFORE USING TO ASPIRATE, CONFIRM:

1. Pressure (mmHg) settings on home screen match prescribed pressure (mmHg).
2. Sensitivity settings are set to 5/L as shown.

PRO-II Canisters are for use with the Prospera PRO-II only. PRO-II canisters are prescription medical devices for use under the direction of a licensed and trained clinician. Read and understand all accompanying documentation including all indications, contraindications, warnings, cautions, precautions and instructions for use completely and carefully before use.

For additional copies of any Prospera PRO-II instructional or safety documentation, please contact DeRoyal Customer Service (within the US: 1-800-251-9864). Some documents may also be downloaded from the DeRoyal website at www.deroyal.com.

Licensed clinicians should receive adequate training before operating device. Clinicians should have sufficient clinical knowledge of the device's capabilities and thorough understanding of its safe and effective operation before determining if suction application is clinically appropriate. Failure to receive adequate training may result in serious injury to the patient or user.

INTENDED USE

The Propsera PRO-II device is 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.

SINGLE USE

The Prospera PRO-II 250cc and 450cc canister is intended for use by a single patient. Do not reuse or reprocess any part of the canister. Reuse, reprocessing, or sterilization may damage the canister, may lead to contamination, and may result in user or patient injury or patient infection.

DISPOSABLE EXUDATE CANISTER FOR PRO-II DEVICE

This disposable exudate canister is for use with the PRO-II device only when performing aspiration or suction and consists of a canister with a connected suction tube. The disposable exudate canister has an integrated bacterial filter and may be available with and without solidifier. The integrated bacterial filter helps to prevent an overflow in the event of an operational error. If the liquid reaches this filter, (1) suction is no longer possible, (2) an error message "System closed" appears on the display, and (3) suction is discontinued. If this occurs, the disposable exudate canister must be replaced.

The disposable exudate canister, including the suction tube, is intended for single use only. Replace the disposable exudate canister in accordance with applicable facility protocol when full, prior to each new patient, or every 3-5 days.

POSITIONING OF THE PRO-II DEVICE

Ensure the device is operating in a safe environment, place upright on a stable surface.

CONNECTING THE DISPOSABLE EXUDATE CANISTER OF THE PRO-II® DEVICE

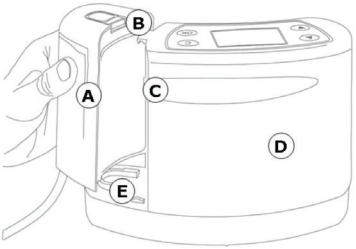

Fig.1 Connecting the disposable exudate canister

A Disposable exudate canister including suction tube
B Locking mechanism for canister
C Aspiration port
D PRO-II® device
E Guiding rail

1. Remove the disposable exudate canister (fg. 1 (A)) from packaging.
2. Slide canister onto guiding rails (fg. 1 (E)) of the PRO-II device until the disposable exudate canister clicks into place in the locking mechanism (fg. 1 (B)).
3. To remove from device after use, press the “Press Here” button on the top of the canister prior to sliding back along the guiding rails.

REPLACEMENT OF THE DISPOSABLE CANISTER OF THE PRO-II DEVICE

1. Ensure the PRO-II device is turned off.
2. Separate the suction tubing from the canister tubing and close the connector with the protective cap.
3. Press on the “Push Here” button on the top of the canister (fig. 5 (B)) and keep it pressed while pulling the disposable exudate canister horizontally away from the device.
4. Dispose of the disposable exudate canister and the integrated suction tube in accordance with facility protocol.
5. Connect a new disposable exudate canister to the device. Ensure that the disposable exudate canister is properly attached to the device.
6. Connect the suction tubing to the canister tubing.
7. Press “OK” to start suction.

STORAGE AND TRANSPORT CONDITIONS

Store at room temperature and avoid excessive heat and humidity.

KEEP DRY KEEP AWAY FROM SUNLIGHT

WARRANTY

DEROYAL® PRODUCTS ARE WARRANTED FOR NINETY (90) DAYS FROM THE DATE OF SHIPMENT FROM DEROYAL AS TO PRODUCT QUALITY AND WORKMANSHIP. DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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