Reprocessed by

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# Instructions for Use
# Hygia Reprocessed Kendall Express Sleeves IFU
## Reprocessed Device for Single Use.

**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

**NON-STERILE NOT MADE WITH NATURAL RUBBER LATEX**

**Sleeves Description**
Hygia Reprocessed Kendall Express SCD

**Indications for Use**
The Hygia Health Services Reprocessed Kendall SCD Express knee/thigh length sleeves are designed to increase venous blood flow in at-risk patients in order to prevent deep vein thrombosis. The sleeves are a non-invasive therapeutic method for prevention of deep vein thrombosis. The sleeves are also used in the treatment of venous leg/foot ulcers and edema which are disorders associated with venous insufficiency.

**Warnings**
- Proper sleeve positioning must be assured to avoid the potential for pressure points on the limb.
- Ensure proper connections to the SCD Controller and sleeves.
- Kinked or twisted tubing may restrict air flow.
- Sleeves should be removed if patient experiences numbness, tingling, or leg pain.
- To minimize local air movement when using sleeves in operating room, cuff cooling should be turned off, if available.

**Directions for Use**
1. Remove SCD sleeves from plastic bag.
2. Place side of sleeve with printed instructions against patient's leg. Position the sleeve so that the blue arrows printed on the sleeve are centered directly behind the patient's leg.
3. Wrap the sleeve securely around the patient's leg, beginning with the side without the hook tape.
4. Holding the ankle section of the sleeve against the patient's ankle, wrap the sleeve securely around the ankle and calf, attaching the hook edge securely to the sleeve. For thigh sleeves, repeat this procedure on the calf and then on the thigh section of the sleeve. The sleeve should fit securely, but not tightly, around all sections of the patient's leg. **Note:** *Do not position the sleeve such that the tubing can form pressure points on the patient's limb. This may be particularly important in certain prone, kneeling or side lying positions. In these cases, the SCD sleeves can be rotated around the limb with no reduction in efficacy.*
   **(a)** SINGLE LEG APPLICATION SCD EXPRESS CONTROLLER: A single sleeve with corresponding tubing may be utilized.
   **(b)** SINGLE LEG APPLICATION: When only one leg is to be compressed utilizing an SCD 5325, SCD SEQUEL, or SCD RESPONSE controller, an unused sleeve must be attached to the second sleeve connector. **The sleeve should remain in the plastic bag to produce proper compression.**
5. Plug the white sleeve connector into a mating connector on the tubing leading to the SCD controller. Be sure the tubing is not twisted. Be sure the appropriate tubing set is being used (see table below).

| SCD CONTROLLER | SCD TUBING SET |
|---|---|
| **SCD 5325** | **9508** |
| **SCD SEQUEL** or **SCD RESPONSE** | **9918** |
| **SCD EXPRESS** | **9528** |

6. To properly engage the connectors, align the arrows and push the white mating connectors together firmly. To uncouple the white connectors, firmly pull the mating connectors apart.

7. Turn the SCD controller to the **ON** position, after ensuring the tubing is correctly attached to the SCD sleeves and the controller.
8. Refer to original equipment manufacturer manual for further instructions.

**Contraindications:**
Sleeves may not be recommended for the patients with the following:

1. Any local leg condition in which sleeves would interfere such as dermatitis, vein ligation (immediate postoperative), gangrene, or recent skin graft
2. Severe arteriosclerosis or other ischemic vascular disease
3. Massive edema of legs or pulmonary edema from congestive heart failure
4. Extreme deformity of leg
5. Suspected existing deep venous thrombosis
6. Congestive heart failure

**Precautions:**

1. One must assure that the device is properly applied and correctly connected to the air controller.
2. If the patient experiences numbness, tingling, or leg pain, the sleeves should be removed

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

This product and its packaging have been exposed to ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, proposition 65, a State of California voter initiative, requires the following notice:

Warning: this product and its packaging have been exposed to ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.