

Reprocessed by



HEALTH SERVICES

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**Instructions for Use**  
**Hygia Kendall SCD Comfort Sleeve 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 SCD Comfort

**Indications for Use**

The Hygia Health Services Reprocessed Kendall SCD Comfort Sleeves are designed to increase venous blood flow in at-risk patients that are non-ambulatory patients in order to prevent deep vein thrombosis. The sleeves are also used in the treatment of venous leg ulcers and edema which are disorders associated with venous insufficiency.

**Warnings**

- One must assure that the device is properly applied.
- 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.
- Avoid freezing and excessive heat.
- **DANGER: DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.**
- Do not attempt to repair or replace broken tubing connectors as hazardous inflation of the sleeves may occur.

**Directions for Use**

1. Read instructions prior to use.
2. Remove SCD sleeves from plastic bag. Unfold sleeves.
3. Place patient's leg on the inside of the sleeve.
4. Wrap the sleeve securely around the patient's leg, beginning with the side without the hook tape.
5. 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 section of the patient's leg.  
Note: Do not position the sleeve such that the tubing can form pressure points on the patient's limb.
6. **SINGLE LEG APPLICATION:** See original equipment manufacturer instructions.
7. Plug the sleeve connector into a mating connector on the tubing leading to the SCD controller. Be sure the tubing is not kinked or twisted.
8. Align the blue arrows and push the white mating connectors together firmly. The connectors will be properly engaged. To uncouple the white connectors, firmly pull the mating connectors apart.
9. The Comfort sleeves are compatible with the SCD 700 Series controller.
10. Turn the SCD controller to the ON position, after ensuring the tubing is correctly attached to the SCD sleeves and the controller.
11. Refer to the SCD Operator's Instruction Manual for further detailed instructions and information.

### **Contraindications**

The compression sleeves may not be recommended for patients with the following:

1. Any local leg condition in which sleeves would interfere, such as (a) dermatitis, (b) vein ligation (immediate post-operative), (c) gangrene, or (d) 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 pre-existing deep venous thrombosis

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.