Reprocessed by

HYGIA
HEALTH SERVICES
434 Industrial Lane Birmingham, AL 35211
1-866-943-6670

Instructions for Use
Hygia Kendall SCD 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 Sleeves

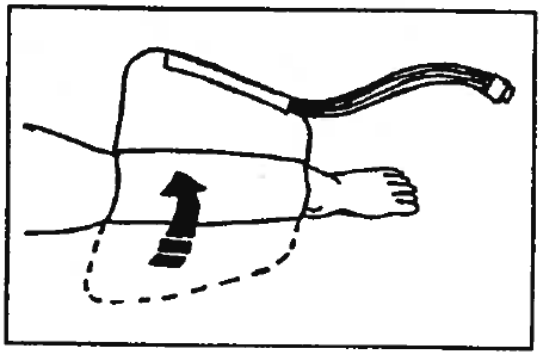
Indications for Use
The Hygia Health Services Reprocessed Kendall SCD knee/thigh length sleeves are designed to increase venous blood flow in at-risk patients that are non-ambulatory patients in order to prevent deep vein thrombosis. The sleeves are also used in the treatment of venous leg ulcers and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

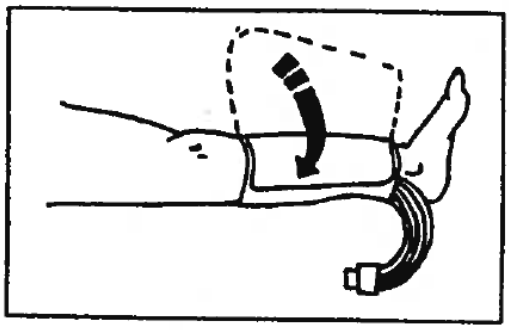
Warnings
- One must assure that the device is properly applied.
- Proper sleeve positioning must be assured to avoid the potential for pressure points on the limb.
- Ensure proper connections to the SCD controller and sleeves.
- Kinked or twisted tubing may restrict air flow.
- Sleeves should be removed if patient experiences numbness, tingling, or leg pain.
- To minimize local air movement when using sleeves in operating room, sleeve 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. COMPATIBILITY: This product is designed for use with SCD Controller models 5315, 5320, 5325, 6325, and 7325.
3. Remove SCD sleeves from plastic bag. Unfold sleeves.
4. Place patient's leg on the inside of the sleeve.
5. Wrap the sleeve securely around the patient's leg, beginning with the side without the hook tape.
6. 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.

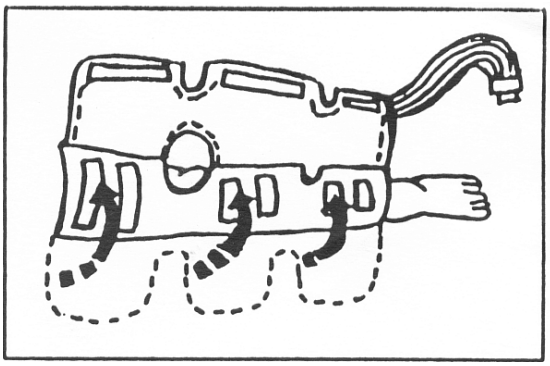
   Do not position the sleeve such that the tubing can form pressure points on the patient's limb. This may be particularly important in certain prone and kneeling surgical positions. In these cases, the SCD sleeves can be rotated around the limb with no reduction in efficacy.

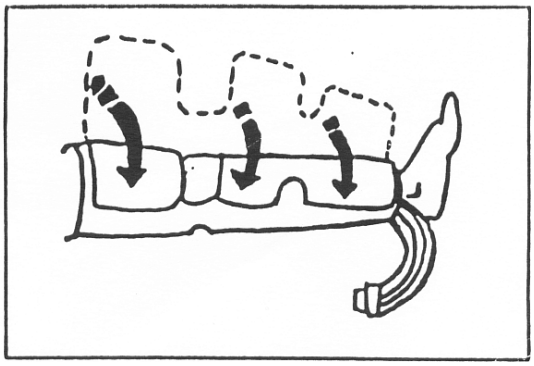
CALF Pictorial



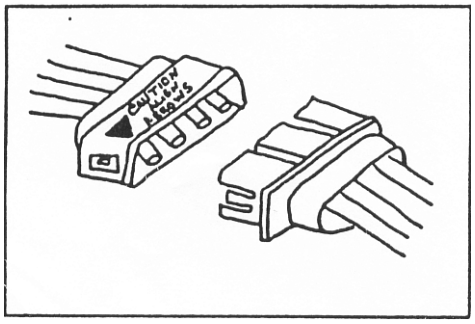


THIGH Pictorial





7. SINGLE LEG APPLICATION: When only one leg is to be compressed, an unused sleeve must be attached to the second sleeve connector. The sleeve should remain in the plastic bag to produce proper compression.
8. Plug the white sleeve connector into a mating connector on the tubing leading to the SCD controller. Be sure the tubing is not kinked or twisted.
9. 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.



10. Turn the SCD Controller to the ON position, after ensuring the tubing is correctly attached to the SCD sleeves and the controller.
11. Depress sleeve cooling button if cooling is desire. A light will indicate sleeve cooling is operative.
12. One complete cycle consists of 11 seconds of gradient compression followed by a decompression period.
13. Recommended pressure is 35-55 mmHG.

    For Controller Model 5320, pressure can be attained by turning the pressure adjust knob counterclockwise to increase pressure or clockwise to decrease pressure. One full turn of the control knob will increase or decrease the pressure by approximately 6 mmHG.

    For controller models 5325, 6325, and 7325, pressure is automatically preset at 45 mmHg.
14. Refer to the SCD Operator's Instruction Manual for further detailed instructions and information.
15. To ensure product safety and efficacy, the Kendall SCD Compression System must only be used with SCD sleeves and tubing assemblies compatible with the system.
16. Refer to original equipment manufacturer manual for further instructions.

17. Sizing

Catalog	Description	Circumference
5329	SCD Knee	Up to 21"
5489	SCD Large Knee	Up to 26"
5490	SCD Extra-Large Knee	Up to 32"
5345	SCD Small Thigh	Up to 22"
5330	SCD Medium Thigh	Up to 28"
5480	SCD Large Thigh	Up to 36"

Suggested Use

1. When treating leg edema, sleeves may be used while the patient is in a sitting or supine position for 30 minutes to 2 hours, once or twice daily. The sleeves should only be sued while the patient is awake. Treatment should be continued until swelling is at an acceptable level as determined by a physician.
2. When treating venous leg ulcers, sleeves may be used while the patient is in a sitting or supine position for 2 to 4 hours daily. Treatments should be conducted on patients while they are awake.
3. The frequency and duration of treatment periods may vary according to a physician's recommendation or the progress of the patient in response to compression therapy.
4. To prevent deep vein thrombosis, compression should be used constantly during times in which the patient is stationary.

Contraindications

The Kendall SCD Compression System 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.