



HEALTH SERVICES

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Instructions for Use
Hygia Reprocessed Kendall Express Foot Cuffs 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 Express Foot Cuff (5897 & 5898)

Indications for Use

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

Warnings

- Do not attempt to repair or replace broken tubing connectors as hazardous inflation of the cuff may occur.

Directions for Use

1. The SCD Express Foot Cuffs are designed to accommodate either right or left feet. Select foot size of patient and corresponding SCD Express Foot Cuff size according to the following chart.

	REF HHS-5897 Regular	REF HHS-5898 Large
Women's Shoe Size	9 (US) 7½ (UK) or smaller	9½ (US) 8 (UK) or larger
Men's Shoe Size	7½ (US) 7(UK) or smaller	8 (US) 7½ (UK) or larger

2. Place foot in the designated area of the foot cuff. For best fit, insure heel is aligned with edge of cuff.
3. Wrap the foot cuff around the foot and attach the hook securely to the cuff. The cuff should fit snug, but not too tight.
4. Plug the white cuff connector into the mating connector on the tube leading to the SCD Express Controller. Ensure tubing is not kinked or twisted. The cuff connector is compatible only with the SCD Express Controller and SCD Tubing Set 9528. The cuff will not connect to, and is not for use with, the SCD 5325, SCD Sequel, or SCD Response.
5. To properly align the connectors, align the arrows and push the white mating connectors together firmly. To uncouple the connectors, firmly pull the mating connectors apart.
6. Turn the SCD Express Controller to the on position after insuring the tubing is attached correctly to the foot cuff.
7. Refer to original equipment manufacturer manual for further instructions.

Contraindications

Foot Cuffs may not be recommended for the patients with the following:

1. Any local leg condition in which foot cuffs 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 cuffs 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.