Reprocessed by

HYGIA
HEALTH SERVICES
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Instructions for Use
Hygia Reprocessed Huntleigh Foot Cuff 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 Huntleigh Foot Garment

Indications for Use
The Hygia Health Services Reprocessed Huntleigh Foot Garments Clinical applications for the FP5000 system are as follows:

- Prevention of deep vein thrombosis (DVT).
- Enhancement of venous and arterial circulation.
- Prevention of venous stasis.
- Assistance in healing of cutaneous ulcers, including venous ulcers.
- Reduction of acute and chronic edema.
- Reduction of lower limb pain due to trauma or surgery.
- Reduction of compartmental pressures.

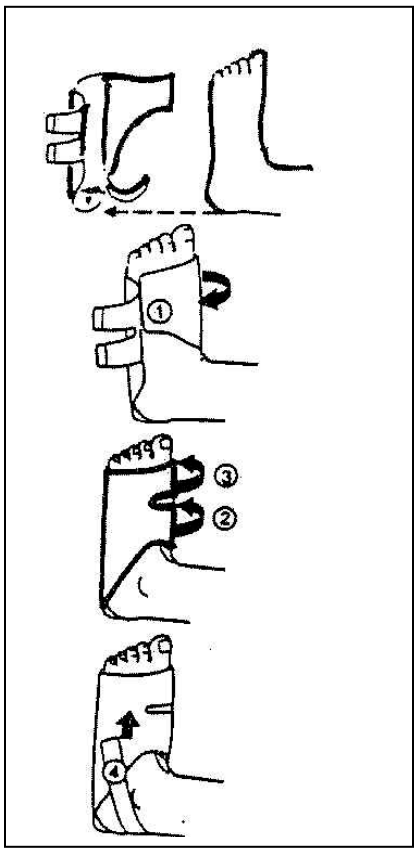
Warnings/Precautions:

- Proper garment application and connection to the pump is essential. One must ensure that the wrap is properly applied, correctly connected to the pump and that the connection is secure.
- Garments should be removed immediately if the patient experiences tingling, numbness, or leg pain and the physician should be notified.
- Continuous external pneumatic compression is recommended until the patient is fully ambulatory when used for DVT prevention. Any interruption of therapy for a substantial length of time should be at the discretion of the physician.
- The patient's skin integrity should be checked at least once every shift.

Directions for Use
Please refer to FP5000 Pump System Protocol before application of garments.

1. Plug the FP5000 pump into a suitable electrical outlet. DO NOT TURN THE PUMP ON AT THIS TIME.
2. Remove the garment from the sealed bag. The garment may be used on either foot.

The foot garment is fitted as follows:



Place foot in the center of garment.

Ensure the back of garment is in line with
The heel as indicated.

Bring flap (1) over the top of foot and hold in place.

Bring flap (2) over the foot and secure.

Bring flap (3) over the foot and secure.

The fit should be snug but comfortable.

Bring strap (4) around back of heel and fix in place as indicated.

Tension strap so garment is secure and comfortable.

3. Attach the air tubing to the FP5000 pump, ensuring that a “click” is heard with each snap-lock connection.
4. Turn the pump on. Check the garment after a few inflations and, if necessary, re-adjust for comfort and security of fit.
5. The pump will automatically adjust to the default settings. If settings other than the default settings are ordered by the physician, refer to the Original Equipment Manufacturer operating manual for complete information on how to adjust the settings.
6. Refer to the FP5000 pump operating manual, supplied by the Original Equipment Manufacturer, for complete information on the use of the system.
7. Sizing:

Catalog	Description	Size
FG100-R	Regular Foot Garment	Female shoe size up to 9 (US); Male shoe size up to 7 (US)
FG200-R	Large Foot Garment	Female shoe size 9.5 or above (US); Male shoe size 7.5 or above (US)

Contraindications:
The FP5000System should NOT be used in the following conditions:

1. Severe arteriosclerosis or other ischemic vascular disease.
2. Congestive heart failure.
3. Pulmonary edema.
4. Known or suspected acute deep vein thrombosis or phlebitis.
5. Any local condition in which the garments would interfere:
    - Gangrene
    - Untreated infected wounds
    - Recent skin graft
    - Dermatitis

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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.