

Reprocessed by



HEALTH SERVICES

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Instructions for Use
Hygia Reprocessed Huntleigh 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 Huntleigh Flowtron® Compression Sleeves

Indications for Use

The DVT calf/thigh sleeves are recommended for use in patients for whom external compression therapy using the Huntleigh Flowtron® System is indicated for the prevention of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombus formation. Intra-operative compression therapy is frequently indicated, sometimes adjunctively with medical measures, during orthopedic, trauma, urologic and general surgery, particularly in patients over the age of 40.

Warnings/Precautions

- Check that the sleeve is properly applied and that connection to the pump is correctly connected and secure.
- Remove the sleeve if patient experiences tingling, numbness, or leg pain.

Directions for Use

1. Plug the Flowtron® pump into a suitable electrical outlet. **DO NOT TURN PUMP ON AT THIS TIME.**
2. Remove the garments from the sealed bag. The garments may be used on either leg.
3. Calf garments: Unfold the garment and position the inflatable bladder directly behind the patient's calf. **SNUGLY** wrap the garment around the patient's leg and secure the fastener tabs.
4. Thigh garments: Unfold the garment and position the square opening labeled "this section behind the knee" behind the patient's knee. (popliteal fossa). **SNUGLY** wrap the garment around the patient's leg, making sure the inflatable bladder is directly behind the patient's calf and thigh respectively. Secure the fastener tabs in the calf section first, then secure the fastener tabs in the thigh area. The sleeve should fit securely, but not tightly, around all section of the patient's leg.
5. Repeat for the other leg. In case of single leg application, refer to the Original Equipment Manufacturer Operation Manual for instructions.
6. Attach the garments to the air tubing using the snap-lock connectors. Ensure that a "click" is heard.
7. Attach the air tubing to the Flowtron® pump, ensuring that a "click" is heard with each snap-lock connection.
8. Adjust the pump pressure regulator dial to the recommended pressure unless otherwise ordered by the physician.
9. Turn the pump on. The on/off switch should be illuminated.
10. Refer to the Flowtron® pump operating manual for complete information on the use of the system.

Contraindications

Sleeves may not be recommended for patients with the following:

1. Severe arteriosclerosis or other ischemic vascular disease
2. Congestive heart failure
3. Pulmonary edema
4. Known or suspected deep vein thrombosis or phlebitis
5. Any local leg condition in which the garments would interfere such as gangrene, untreated infected wounds, recent skin graft, dermatitis or vein ligation (immediate postoperative)
6. Deformity of the leg

Huntleigh Flowtron® Compression Sleeves

Sizing

DVT 10 L501M	Standard Calf garment - up to 17" calf circumference
DVT 20	Large Calf garment - up to 23" calf circumference
DVT 30	Standard Thigh garment - up to 28" thigh circumference
DVT 40	Large Thigh garment - up to 35" thigh circumference

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.