Reprocessed by

HYGIA
HEALTH SERVICES
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Instructions for Use
Hygia Kendall Impad Rigid Sole Cover 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 Impad Rigid Sole Foot Cover

Indications for Use
The Hygia Health Services Reprocessed Novamedix Impad is designed to enhance circulation of blood in the venules and arterioles. It is to be used by the patients in both the home and institutional settings as a non-invasive therapeutic method to prevent deep vein thrombosis, reduce wound healing time, treat and assist healing of venous leg ulcers, and reduce edema caused by venous insufficiency in the lower extremities.

For full Impad Foot Cover Life:
- Do not walk or bear weight on the ImPad
- Only inflate when fitted to foot

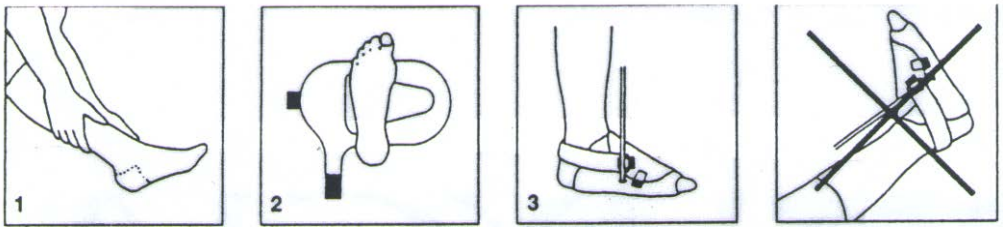
DANGER:
- DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
- AVOID FREEZING AND EXCESSIVE HEAT.

Warnings
Special attention, additional padding and checking every shift change should be given to patients with poor circulation, fragile skin, insensitive extremities, diabetes, and those who may be predisposed to tissue viability problems including those receiving anticoagulation therapy. To minimize skin pressure effects reduce the IMPULSE PRESSURE and set the IMPULSE DURATION to 1 second. Check for skin reddening and any early signs which may lead to tissue viability problems and use additional padding or discontinue treatment according to clinical judgment.
For further detailed instructions and information, refer to the Operator's Instruction Manual.

Precautions:
1. One must ensure that the wrap is applied properly.
2. One must ensure that the wrap is correctly connected to the pump and that the connection is secure.
3. If the patient experiences numbness, tingling, or leg pain, the wrap should be removed.

Directions for Use
1. Apply T.E.D. graduated compression stocking or stockinette over the foot and ankle as required. Avoid wrinkles.
2. Select the appropriate ImPad foot cover (Regular or Large, Left or Right).Red Graphics = LEFT. Blue graphics = RIGHT. Place foot centrally on top of inflation pad as shown by the graphics on the ImPad. The inlet tube should be on the medial side (inside) of the foot. **CAUTION: The inflation pad must be placed directly under the arch of the foot.**
3. Wrap the medial side (inside) of the foot cover over the top of the foot and then over the lateral side (outside) of the cover and secure with the fastener strap. Next, wrap the rear strap around the back of the heel and secure with the fastener tab. Check that the foot cover is fitted snugly and the patient is comfortable.
4. For best results make sure the foot is *BELOW* the level of the heart (never elevated).
5. Refer to original equipment manufacturer manual for further instructions.
6. Sizing:

Catalog	Description	Size
5065	Impad Pair, Regular	Men: 4.5-8 US; Women 5.5-9 US
5075	Impad Pair, Large	Men: 8.5-12.5 US; Women 9.5-11.5 US



CONTRAINDICATIONS: The A-V Impulse System is contraindicated for patients with conditions where an increase of fluid to the heart may be detrimental, including some patients with congestive heart failure and those with pre-existing deep vein thrombosis, thrombophlebitis or pulmonary embolism. The device should be used with caution on the infected or insensitive extremity. Wraps may not be recommended for patients with the following: Congestive heart failure or where an increase of fluid to the heart might be detrimental, known of suspected deep vein thrombosis, pre-existing deep vein thrombosis, thrombophlebitis, or pulmonary embolism, severe arteriosclerosis or other ischemic vascular disease, or any local leg condition in which the wrap would interfere such as dermatitis, gangrene, recent skin graft, or untreated infected wounds.

PATIENT & SKIN CARE:
As with any treatment technique it is important to check regularly for patient comfort and compliance and to pay particular attention to skin care and hygiene.
It is recommended that after a few hours of use that foot cover is checked to ensure that the impulse is felt directly under the arch of the foot, that it fits snugly and is comfortable, and that there are no skin pressure problems. If appropriate, make the necessary corrections.
Regularly remove the foot cover and T.E.D. graduated compression stocking or stockinette to check skin condition.

PATIENT INFORMATION:
Why do I need the A-V Impulse System foot pump? In the early 1980s, Doctors Fox and Gardner discovered a pump in the bottom of your foot which empties when you walk. This “foot pump” helps to increase blood flow in your leg and returns the blood back to your heart. Knowing this, Doctors Fox and Gardner decided to develop the A-V Impulse System to artificially activate the natural “foot pump”. This device becomes important when you are confined to bed because the blood flow in your legs may slow down and cause a blood clot to form or your legs to swell. When you wear the A-V Impulse System, blood flow in your leg is increased, and blood clots and leg swelling are reduced.
Do I have to wear the A-V Impulse System foot pump day and night? It is important that you wear the system at all times until your doctor determines you no longer need the device. However, you must remove the ImPad foot cover when you walk, bathe, or leave your room for tests or physical therapy.
How should the Impad foot cover fit? The ImPad should fit snugly, but not too tight. It should not slip or move on your foot. If the ImPad foot cover is too loose or tight, ask your nurse to adjust it.
Is there a correct position I should be in? The device works best when the foot is below the heart as this helps the veins to refill. Try to maintain this position whenever possible.
How can I help my doctor or nurse to monitor the A-V Impulse System during my hospital stay?

- DO NOT WALK WITH THE FOOT COVERS ON YOUR FEET
- DO NOT ADJUST THE CONTROLS ON THE PUMP YOURSELF
- LET THE NURSE KNOW IF THE PUMP BEEPS OR TURNS OFF AUTOMATICALLY
- AVOID TWISTING OR KINKING OF THE TUBING.

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.