



Health Solutions



HEELIFT
AFO Ultra



HEELIFT
Glide Ultra



HEELIFT
Classic



HEELIFT
Glide

HEELIFT
AFO



HEELIFT
Traction



HEELIFT® SUSPENSION BOOT
HEEL PROTECTOR



Instructions for Use (Note: Review cautions and warnings related to HEELIFT® device before selection and use.)

1. Determine appropriate size.

- Measure calf circumference. (see exhibit A.)
- Correlate the size of the calf circumference with the appropriate size of the HEELIFT® offloading boot on sizing chart and determine the proper size.
- Open the boot by undoing straps. (see exhibit B.)
- Set extra foam pad aside for optional customization. (Note: Customization should only be performed by your healthcare provider)
- Place foot in boot. (see exhibit C.)
- Place the lower extremity in the boot with the leg resting on the fixed elevation pad and the back of heel hanging off the fixed elevation pad over the heel opening so that no pressure is on heel. (see exhibit D.)



2. Secure the straps.

- Secure each strap. (see exhibit E.)
- Pull each strap over the foam pad of the boot over the leg and feed through the respective D-ring and then fasten the strap Velcro back onto itself. (see exhibit E.)
- Start with the top strap and work your way downwards with each strap. (see exhibit E.)
- Straps should never be in contact with the skin. (see exhibit E.)
- Make sure each strap is fastened back onto itself with the Velcro closure so that the hook & loop side of the strap is not exposed. (see exhibit F.)
- Use the Two-Finger Test to check to make sure each strap is fastened appropriately to ensure the boot is not too tight or not too loose and does not contact the skin. (see exhibit F.)



3. Check to make sure the heel is completely offloaded by:

- Lifting the leg and looking in the heel opening to ensure heel is completely offloaded and no pressure is on the back of the heel.(see exhibit G.)
- Put hand through heel opening and cup heel to ensure heel is completely offloaded and no pressure is on the back of the heel.(see exhibit H.)



1

4. Use of the Forefoot strap **(Note: Use of forefoot strap should only be performed by your healthcare provider)**

- The additional forefoot strap is only available on the Glide, Glide Ultra, AFO, and AFO Ultra HEELIFT® boot.
- The forefoot strap should only be used on people with good skin integrity.
- If not using the forefoot strap: Wrap strap around the underside of the boot, pull the strap through the D-ring, and secure the hook & loop to itself. (see exhibit I.)
- If using the forefoot strap: Secure the forefoot strap. (see exhibit J.)
- Pull the strap over the top of the forefoot portion of the boot and feed through its respective D-ring and secure the Velcro to itself. (see exhibit J)
- The forefoot strap should never be in contact with the skin. (see exhibit J)
- Make sure each hook & loop strap is fastened back onto itself with the D-ring closure so that the hook & loop side is not exposed. (see exhibit J.)
- Use the Two-Finger Test to check to make sure each strap is fastened appropriately to ensure the boot is not too tight or not too loose and does not touch the skin. (see exhibit J.)



2

Indications for Use of HEELIFT® Classic, HEELIFT® Glide, HEELIFT® Glide Ultra, and HEELIFT® Traction Boots.

- Any person who is immobile or who has limited mobility who has an area at-risk for a pressure ulcer to develop on the foot or ankle.
- Any person who is immobile or who has limited mobility who has a preexisting pressure ulcer on their heel and/or ankle.
- Any person who has a Braden Score of less than or equal to 18 (<18).

3

Cautions

- The HEELIFT® offloading boot is a medical device used for the prevention and treatment of pressure ulcers. It should only be used under the guidance of your healthcare provider.
- A HEELIFT® offloading boot with a convoluted interior should only be used on a person with good skin integrity. If used on a person with poor skin integrity the convoluted texture can lead to compromise of the skin.
- Make sure the HEELIFT® boot is of the appropriate size before applying. Always measure the calf circumference and correlate the measurement of the calf circumference to the sizing chart to determine the appropriate size of the HEELIFT® boot.
- Note: It is important to determine the appropriate size of the HEELIFT® boot for each individual person so that the boot is not too small causing pressure on the skin leading to a pressure ulcer and so that the boot is not too loose causing shear and friction forces on the skin leading to a pressure ulcer.
- Make sure straps never touches the skin to not cause pressure, shear, or forces on the skin which could cause a pressure ulcer.
- Use the 2-finger test after securing the straps to make sure the boot is not too tight or too loose.
- The HEELIFT® offloading boot is a single patient only – limited multiple use medical device.

4 Warning

- All customization of the HEELIFT® boot should only be performed by the healthcare provider. If the boot is not customized appropriately to properly offload an at-risk area or area of pre-existing wound undue pressure can occur on the skin therefore leading to development of a pressure ulcer or worsening of a pre-existing wound.
- Forefoot strap on HEELIFT® Glide boot is only recommended for people with good skin integrity. If used on a person with poor skin integrity can cause pressure or shear and friction force on underlying skin resulting in a pressure ulcer. Please seek opinion of healthcare provider before using.
- The leg should never move within the boot. If the leg moves within the boot, the boot is not applied appropriately and injury to the skin from shear and friction forces against the skin from the boot can cause injury to the skin.
- Make sure adhesive side of extra foam pad never touches the skin to avoid any reaction from the adhesive on the skin, or any compromise of the skin from the adhesive.
- SCD tubing should always carefully be placed into the groove built into the boot so that it never touches the skin, to avoid compromise of the skin from the tubing.
- Ventilation holes are meant for air circulation within the boot. Do not place any tubing through the ventilation holes in the boot.
- As per standard of care, remove HEELIFT® boot and inspect skin every 8 hours to ensure no compromise of the skin has occurred.
- Discontinue the HEELIFT® offloading boot if you experience any pain, compromise of the skin or skin break down, redness or other changes in skin color, abnormal swelling, or other issue while wearing the boot and contact your healthcare provider immediately or go to your nearest emergency room for immediate care and attention.

5 Customization (Note: Customization should only be performed by your healthcare provider. If using the HEELIFT® Ultra boots pull back the removable elevation cover first.)

The HEELIFT® offloading boot can be customized to offload other at-risk areas in addition to the back of the heel including the Achilles Tendon, Malleolar Decubitus, Foot Drop, hip and/or foot rotation, and SCD Tubing.

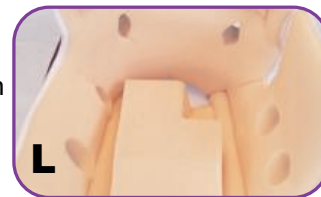
1. Achilles Tendon. (see exhibit K)

- Make an upside-down V cut or an upside-down U cut as determined appropriate by your healthcare provider in the bottom of the fixed elevation pad to appropriately offload the Achilles tendon.



2. Malleoli (ankle bones) (see exhibit L)

- Make an oblique cut or an upside-down hockey stick cut as determined appropriate by your healthcare provider on the side of the elevation pad starting from a point just above the ankle bone and cutting downward through the bottom of the fixed elevation pad so that the ankle bone is completely offloaded.
- If further offloading is required as determined by your healthcare provider place the extra foam pad in the groove on the side of the ankle bone needing to be offloaded with the bottom of the pad just above the ankle bone and cut the top of the extra foam pad flush with the top of the boot. Attach the extra foam pad to the side of the boot once appropriately positioned in the groove by peeling the adhesive backing off the extra foam pad. Make sure the adhesive side never touches the skin.



3. Foot Drop (see exhibit M)

- Measure the extra foam pad from the tip of the toes to the area where the arch meets the heel.
- Cut the extra foam pad at the area where the arch meets the heel and bevel the edge.
- Peel the adhesive backing off the extra foam pad.
- Position the extra foam pad vertically under the patient's foot so that the beveled edge is under the area where the arch meets the heel, and the adhesive side of the pad, is against the bottom of the boot to not touch the skin (make sure adhesive never touches the skin).



4. Hip and/or Foot Rotation (see exhibit N.)

- Use the optional Anti-Rotation Wedge to prevent hip and/or foot rotation. See instructions included with the wedge.
- The Anti-Rotation Wedge gives you the flexibility needed to stop rotation in immobile patients. The easy to apply, reusable wedge attaches to either side of the boot, and prevents rotation.
- Works for both external and internal rotation.



5. SCD Tubing Placement (see exhibit O)

- Place SCD tubing in the groove built into the boot along the side of the boot, between the elevation pad and the side of the boot opposite the side with the attached D-rings. This allows the tubing to lay flat and to exit the boot without touching the skin.
- SCD tubing should always carefully be placed into the groove, built into the boot, so that it never touches the skin to avoid compromise of the skin from the tubing.
- Ventilation holes are meant for air circulation within the boot. Do not place any tubing through the ventilation holes in the boot.



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Technical Data

Contents of Package

- HEELIFT® offloading boot
- Single patient-Multiple use
- Extra foam pad for optional customization of boot (should only be performed by your healthcare provider)
- Instructions for use
- Anti-Rotation Wedges (optional)
 - HEELIFT® Ultra models include an Anti-Rotation Wedge

Size: Calf Circumference

- Petite: 15-25 cm (6-10 inches)
- Standard: 25-38 cm (10-15 inches)
- Bariatric: 38-58 cm (15-23 inches)

Interior

- Smooth
- Convoluted (should only be used by people with good skin integrity and without comorbidity)
- Ultra (lined with water repellent liner indicated for draining wounds)



7

Cleaning **(Caution: Clean or disinfect using a nonbleach gentle detergent or a nonbleach disinfectant. As with any medical device, bleach can breakdown the integrity of the material of the HEELIFT® offloading boot. To maintain the integrity of the HEELIFT® we recommend sanitizing or hand washing.)**

1. To sanitize

- Use a nonbleach disinfectant wipe or spray.

2. To hand wash

- Wash in warm water with a mild nonbleach detergent.

3. To machine wash and dry

- Secure all straps.
- Remove traction device if using HEELIFT® traction boot.
- Place in mesh HEELIFT® brand, regular mesh laundry bag, or pillowcase.
- Machine wash in warm water (40°C/105°F) gentle cycle with a mild nonbleach detergent.
- Machine dry on low heat.

Instructions for Traction Boot (Note: Review indications, cautions, and warnings related to HEELIFT® device before use.)

- PRE-OPERATIVE - the HEELIFT® Traction Boot for extension helps to stabilize femur fractures prior to surgery and enables to apply straight skin traction with up to 4.5 kg/ 10 lbs. (Buck's traction).
- POST-OPERATIVE - without traction device mechanism converts to suspension boot to aid in the prevention of pressure injuries/ulcers during rehabilitation.

PRE-OPERATIVE

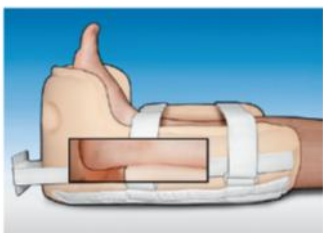
A. Application of the suspension boot

- Open the HEELIFT® Traction Boot. Remove the spare foam pad. Please keep the spare pad available; see optional customization instructions.
- Place the patient's foot into the extension boot and ensure that the heel is positioned directly above the heel suspension opening. The heel should hang over the bottom elevation pad. See photo 1.
- For closing pull the hook and loop fastener straps over the leg towards the D-rings. Thread the straps through the D-rings. Use the hook and loop fastener closures to secure the straps. See photo 2.
- Test for the proper fit by trying to remove the closed extension boot. Test the fit under straps and heel opening using the "Two-Finger" test. See photo 3. The boot should not be placed neither too loose nor too tight around the leg. The hook and loop fastener straps should not be in contact with the skin.
- To prevent rotation of the foot use the Anti-Rotation Wedge (available separately) and place it on the left or right side along with the tibia.
- To prevent foot drop, see Section 5 for customization instructions.



B. Application of traction device

- Remove the long hook and loop fastener attached traction straps (D) from the sides of the traction boot.
- Unravel the traction rope (A) and double knot one end to the rope attachment bar (B).
- Fix the rope attachment bar with the hook and loop fastener traction straps to both sides of the HEELIFT® Traction Boot. Place the plate for the traction bar to be outside.
- Pass the unknotted end of the traction rope through the prepositioned traction pulley on the cross bar attached to the frame at the foot of the bed.
- Pull firmly on the rope and create a short 2.5 cm (1-inch) large loop in the rope and secure with the appropriate knot (not a slip knot) just beyond the pulley.
- Attach a weight hanger with the prescribed weight (max. 4.5 kg/10 lbs.).
- Elevate the extension boot together with the traction bar so that the HEELIFT® Traction Boot and the leg are 0.6 cm (0.24 in) above the bed. You should be able to fit your finger between the heel opening and the bed.
- If the leg is externally rotated, apply the Anti-Rotation Wedge (available separately) beneath the traction straps on the outside of the traction boot.
- To avoid foot drop, secure the extra pad in a vertical position behind the sole of the foot. see Section 5 for customization instructions.



POST-OPERATIVE

A. Convert HEELIFT Traction boot to suspension boot

1. Remove the side traction straps, traction bar and rope.
2. Follow application instructions, pre-operative number 1 to 5.
3. Follow customization instructions for the spare foam pad (see Section 5 - Customization).

Intended Use Statement

HEELFIT® Traction boot is a medical device used for stabilizing fractures prior (pre-operative) to surgery (resembling Bucks Traction) and provides leg elevation after surgery (post-operative) to prevent pressure injuries/ulcers.

Indications

- **Pre-operative** for preparing the extension or
- **Post-operative** for prevention of pressure injuries/ulcers
- Disease or condition:
 - Patients with lower extremity fractures
 - Post-operative patient requiring elevation
 - Patients at risk for pressure injuries/ulcers
 - Patients with fracture and pain
 - Patients with displaced fracture

Contraindications

- Open fractures because contaminated bone can go back into wound
- Bleeding wounds
- Elderly patients' skin is fragile and may be injured from the traction
- Osteoporosis

Cautions

- Make sure top of the HEELIFT® Traction boot is below fibular lead.
- The HEELIFT® Traction Boot for extension is only designed for the use with bedridden patients and intended for inpatient use.
- In case of improper handling, the function and maximum safety of the product can no longer be guaranteed.
- This aid is intended for single patient – multiple use only.

Warnings

- The HEELIFT® Traction boot should be removed every 8 hours to inspect skin.
- Do not use over open wounds; the HEELIFT® Traction Boot is to be used on patients with intact skin only.
- Do not use this device if it was damaged and/or packaging has been opened.
- All customization of the HEELIFT® boot should only be performed by the healthcare provider. If the boot is not customized appropriately to properly offload an at-risk area or area of pre-existing wound undue pressure can occur on the skin therefore leading to development of a pressure ulcer or worsening of a pre-existing wound.
- The leg should never move within the boot. If the leg moves within the boot, the boot is not applied appropriately and injury to the skin from sheer and friction forces against the skin from the boot can cause injury to the skin.
- Make sure adhesive side of extra foam pad never touches the skin to avoid any reaction from the adhesive on the skin, or any compromise of the skin from the adhesive.
- SCD tubing should always carefully be placed into the groove built into the boot so that it never touches the skin, to avoid compromise of the skin from the tubing.
- Ventilation holes are meant for air circulation within the boot. Do not place any tubing through the ventilation holes in the boot.

- Discontinue the HEELIFT® Traction boot if you experience any pain, compromise of the skin or skin break down, redness or other changes in skin color, abnormal swelling, or other issue while wearing the boot and contact your healthcare provider immediately or go to your nearest emergency room for immediate care and attention.
- If you develop an allergic reaction and/or experience itchy, red skin after coming into contact with any part of this device, please stop using it and contact your healthcare professional immediately.

Technical Data

Contents of Package

- HEELIFT® Traction offloading boot
- Traction metal bar with nylon hook-and-loop fastener
- Traction nylon rope
- Extra foam pad
- Anti-Rotation Wedges (optional)
- Application and Fit Instructions

Size: Calf Circumference

Standard: 25-38cm (10-15 inches)

Color:

Beige

Interior:

Smooth

Maintenance:

The product does not require maintenance.

Cleaning Instructions

- **Cleaning:** Remove traction device before cleaning.
To hand wash: Use non-bleach, mild cleaner and warm water.
- **To machine wash and dry:** Secure straps and place in net laundry bag or pillowcase. Wash with mild detergent (40C/105F), do not use bleach, and dry on low temperature. Allow to dry completely before reapplying boot to patient.
- **To sanitize:** Wipe with sanitizing wipes or spray, dry completely before using.

Anti-Rotation Wedge:



Consult Instructions for Use



EN-English



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Heel Protector

| | |
|----|------------------------|
| ES | Protector de talón |
| DE | Fersenschutz |
| DA | Haelbeskytter |
| FR | Protecteur de talon |
| IT | Protezione del tallone |
| LT | Kulno gynėjas |
| NL | Hielbeschermer |
| NO | Haelbeskytter |
| PL | Ochraniacz pięty |
| PT | Protetor de calcanhar |
| RO | Protector pentru toc |
| SV | Hälskydd |
| SK | Chráníč päty |
| TR | Cok koruyucu |

Suspension Boot

| | |
|----|------------------------|
| ES | Bota de suspensión |
| DE | Aufhängungstiefel |
| DA | Affjedring støvle |
| FR | Botte de suspension |
| IT | stivale di sospensione |
| LT | Pakabos bagažinė |
| NL | verende laars |
| NO | fjæring støvel |
| PL | bagażnik zawieszania |
| PT | Bota de Suspensão |
| RO | Cizmă suspendată |
| SV | upphängnings stövel |
| SK | Zavesenie topánok |
| TR | süspansiyonlu çizme |



Single Patient - Multiple Use

| | |
|----|--|
| ES | Un solo paciente – uso múltiple |
| DE | Einzelner Patient – mehrfach anwendbar |
| DA | Enkelt patient – flergangsbrug |
| FR | Un seul patient - à usage multiple |
| IT | Singolo paziente – uso multiplo |
| LT | Vienas pacientas – daugkartinis naudojimas |
| NL | Eén patiënt – meervoudig gebruik |
| NO | Kun til bruk på én pasient – flergangsbruk |
| PL | Wielokrotne użycie u jednego pacjenta” |
| PT | Paciente único – várias utilizações |
| RO | Un singur pacient – utilizare multiplă |
| SV | En patient – flera användningar |
| SK | Jeden pacient – viacnásobné použitie |
| TR | Tek hasta - coklu kullanim |



Consult Instructions for Use

| | |
|----|--|
| ES | Consultar instrucciones de uso |
| DE | Konsultieren Sie die Gebrauchsanweisung lesen |
| DA | Se brugsanvisningen |
| FR | Consulter les instructions d'utilisation |
| IT | Consultare le istruzioni per l'uso |
| LT | Pasikonsultuokite naudoti naudojimą instrukcijas |
| NL | Raadpleeg de instructies voor gebruik |
| NO | Kontakt instruksjonene for bruk |
| PL | Skonsultuj się z instrukcjami do użycia |
| PT | Consulte as instruções de uso |
| RO | Consultați instrucțiunile de utilizare |
| SV | Konsultera bruksanvisningen |
| SK | Konzultujte pokyny na použitie |
| TR | Kullanım için talimatlara danışın |



Medical Device

| | |
|----|---|
| ES | Dispositivo médico |
| DE | Medizinprodukt |
| DA | Medicinsk udstyr |
| FR | Dispositif médical |
| IT | Dispositivo medico |
| LT | Medicinos priemonė |
| NL | Medisch hulpmiddel |
| NO | Medisinsk utstyr |
| PL | Wyrób medyczny |
| PT | Dispositivo médico |
| RO | Dispozitiv medical |
| SV | Medicinteknisk produkt |
| SK | Zdravotnícke zariadenie zdravotnícky prístroj |
| TR | Tıbbi cihaz |



Latex-Free

| | |
|----|------------------|
| ES | Sin látex |
| DE | Latexfrei |
| DA | Latex fri |
| FR | Sans latex |
| IT | Senza latex |
| LT | Be latekso |
| NL | Latex vrij |
| NO | Uten latex |
| PL | Bez lateksu |
| PT | Látex grátis |
| RO | Fără latex |
| SV | Latex fri |
| SK | Bez latexu |
| TR | Lateks içermeyiz |



Unique Device Indicator

| | |
|----|--|
| ES | Identificador de dispositivo único |
| DE | Eindeutige Gerätekenung |
| DA | Unikt enheds Identifikator |
| FR | Identifiant unique de l'appareil |
| IT | Identificatore univoco del dispositivo |
| LT | Unikalus įrenginio identifikatorius |
| NL | Unieke apparaatindicator |
| NO | Unik enhetsidentifikator |
| PL | Unikalny identyfikator urządzenia |
| PT | Identificador Único de Dispositivo |
| RO | Identificator unic de dispozitiv |
| SV | Unik enhetsidentifierare |
| SK | Jedinečný identifikátor zariadenia |
| TR | Benzersiz Cihaz Tanımlayıcı |



Keep Dry and Away from Direct Sunlight

| | |
|----|--|
| ES | Manténgase seco y alejado de la luz solar directa |
| DE | Trocken und vor direkter Sonneneinstrahlung schützen |
| DA | Hold dig tør og væk fra direkte sollys |
| FR | Garder sèche et loin de la lumière directe du soleil |
| IT | Mantieniti asciutto e lontano dalla luce solare diretta |
| LT | Laikykite sausas ir toli nuo tiesioginių saulės spindulių |
| NL | Droog en uit de buurt van direct zonlicht houden |
| NO | Hold deg tørr og vekk fra direkte sollys |
| PL | Przechowywać w suchym miejscu i z dala od bezpośredniego światła słonecznego |
| PT | Mantenha-se seco e longe da luz solar direta |
| RO | Păstrați uscarea și departe de lumina directă a soarelui |
| SV | Håll torr och bort från direkt solljus |
| SK | Uchovávať v suchu a mimo dosahu priameho slnečného svetla |
| TR | Kuru ve doğrudan güneş ışığından uzak durun |