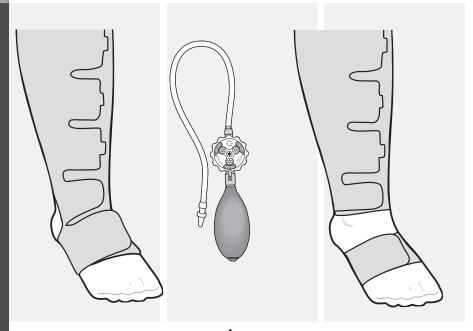


#### Aero-Wrap™ Compression Systems

Aero-Wrap™ Aero-Wrap™ Flex

# User Guide and Instructions for Use





#### Life Science Solutions

by SUN SCIENTIFIC

### **Table of Contents**

Chapter 1 Before You Get Started 1
1.1 Aero-Wrap™ Product Introduction & Components1
1.2 How to Contact Sun Scientific2
1.3 Safety Precautions3
1.4 Explanation of Symbols
1.5 Indications for Use
1.6 Contraindications
1.7 Precautions and Warnings4
Chapter 2 Operating Instructions 6
2.1 Applying Aero-Wrap™6
2.2 Applying Aero-Wrap™ Flex
2.3 Inflating Aero-Wrap™ and Aero-Wrap™ Flex
2.4 Deflating Aero-Wrap™ and Aero-Wrap™ Flex 14
2.5 Removing Aero-Wrap™ and Aero-Wrap™ Flex 14
2.6 Optional: Using the Extension Panel
2.7 Optional: Attaching the Under-Sock
Chapter 3 System Cleaning and Care 16
Chapter 4 Warranty and Service Information

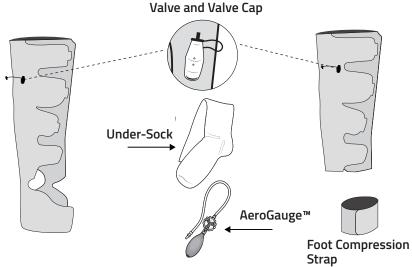
#### **Before You Get Started**



Know your device. Read the manual carefully and learn the device's operation and limitations before use.

# 1.1 Aero-Wrap™ Systems Product Introduction and Components.

- Aero-Wrap™ and Aero-Wrap™ Flex are single-patient, reusable compression systems designed to provide static pneumatic compression to the lower-leg to treat a number of different conditions as identified in section 1.5.
- Aero-Wrap™ and Aero-Wrap™ Flex come in unilateral (single leg) and bilateral (two leg) configurations.
- Each Aero-Wrap™ system contains:
  - Inflatable Wrap(s): Lower-leg compression sleeve with attached foot portion.
  - Under-Sock(s): Comfort liner to be worn under the sleeve.
  - AeroGauge™: Hand pump that provides adjustable static pneumatic compression.
- Each Aero-Wrap™ Flex system contains:
  - Inflatable Flex Wrap(s): Lower-leg compression sleeve without attached foot portion.
  - Under-Sock(s): Comfort liner to be worn under the sleeve.
  - AeroGauge™: Hand pump that provides adjustable static pneumatic compression.
  - Foot Compression Strap(s): Separate elastic foot strap, allowing for maximum ankle mobility.



#### 1.2 How to Contact Sun Scientific.

If you have questions about your Aero-Wrap™ please contact Sun Scientific:

Customer Service: Toll-free (U.S. only) at 855.656.5656

Monday-Friday, 9:00 a.m. - 5:00 p.m. EST.

You may also email us at info@sun-scientific.com.

Or contact your local distributor.

#### 1.3 Safety Precautions.

- Should the upper or lower leg develop pain or the foot become pale, cool or numb, remove Aero-Wrap™.
- Take caution while using in a pressurized environment, such as an airplane, as compression within the sleeve is likely to change. If you feel a noticeable change in compression, deflate and re-inflate to proper levels.
- Care should be taken to use proper footwear when using Aero-Wrap™ while walking/doing activities. Failure to do so can cause damage to the bottom of Aero-Wrap™ and could be a potential slipping hazard to the user.

#### 1.4 Explanation of Symbols.



To indicate the maximum and minimum temperature limits at which the item shall be stored, transported



Refer to instruction manual



Warning Caution: see instructions for use

#### 1.5 Indications for Use.

Aero-Wrap™ Compression systems are designed to provide static compression therapy, in the inpatient and outpatient setting to provide treatment for:

- 1. Venous stasis ulcers
- 2. Leg ulcers
- 3. Chronic venous insufficiency
- 4. Lymphedema

#### 1.6 Contraindications.

Aero-Wrap™ should not be used if you have one or more of the following conditions:

- Decompensated acute heart failure
- Severe peripheral arterial disease (critical limb ischemia including ischemic rest pain, arterial wounds, or gangrene)
- Acute thrombophlebitis, acute deep venous thrombosis
- Existing pulmonary edema
- Existing pulmonary embolisms
- Infection in the lower leg
- Where increased venous or lymphatic return is undesirable
- Allergy to materials

\*\*Attention people with diabetes: We recommend you speak with your physician before use of this product. An ABI ankle pressure of at least 0.5 is necessary for safe use of compression therapy.\*\*

#### 1.7 Precautions and Warnings.



- No side effects are currently known. However, if a negative result should occur (i.e. skin irritations) from the use of Aero-Wrap™ or Aero-Wrap™ Flex, please discontinue use of the product and consult with a medical professional.
- Use of Aero-Wrap™ directly against the skin without use of the Under-Sock or liner of your choice may cause irritation.
- Compression to a leg which already has a partially blocked blood supply

- could lead to potentially serious complications. Do not use Aero-Wrap™ if you have compromised blood flow. If you have a question, please consult a physician before using this product.
- The compression applied by Aero-Wrap™ should never be painful or be uncomfortable. If you experience discomfort, reduce the compression level or remove Aero-Wrap™ systems.
- Caution should be used on patients with neuropathy or limbs insensitive to pain.
- Ensure no abrasive material is in contact with the skin.
- Follow all wound care instructions provided by your clinician.
- Not made or processed with natural rubber latex.
- Do not use in an MRI environment or hyperbaric chamber.
- Do not use any other inflation source other than those provided in Aero-Wrap™.
- Disconnect prior to defibrillation.
- To prevent strangulation or choke hazards keep Aero-Wrap™ products away from babies and children.
- Sun Scientific is not liable for damage or injuries which have been caused by improper handling or misuse.

## **Operating Instructions**

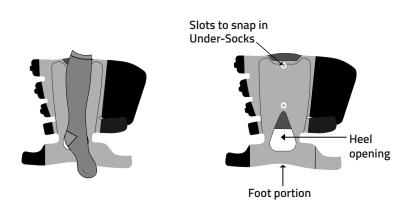
Follow the steps outlined below for Applying, Inflating, Deflating, and Removing Aero-Wrap™.

#### 2.1 Applying Aero-Wrap™.

Attached Under-Sock

Aero-Wrap™ sleeves can be worn with the detachable Under-Sock provided or with a liner of your choice.

Detached Under-Sock



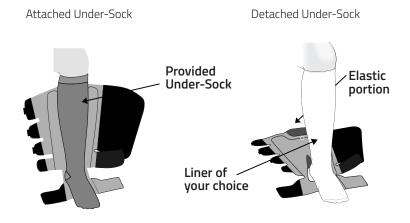
Aero-Wrap™ inside view

1. From a comfortable seated position hold Aero-Wrap $^{\rm m}$  so that the hook and loop straps are open.

With the attached Under-Sock - Pull the Under-Sock up so that it reaches to the junction below your knee, positioning Aero-Wrap<sup>M</sup> as shown below.

**Without the attached Under-Sock** - Step your heel into the triangular opening as shown below.

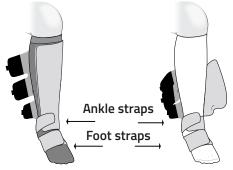
(Aero-Wrap™ should not be worn directly on your skin. If your physician has provided any wound care instructions, they should be followed first).



 $\textit{Aero-Wrap} \, {}^{\text{\tiny{M}}} \, \textit{proper orientation}$ 

2. Secure the straps from **bottom to top**. This will align the elastic portion with the back of your calf. Continue up the leg securing the remaining straps. The straps may require readjustment later in the fitting process. When securing the straps, you should feel as though the sleeve is snug but not tight. Adjust the straps if necessary so they do not bunch.

# Attached Under-Sock Detached Under-Sock



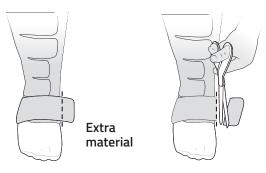


Aero-Wrap™ being secured

Fully Applied Sleeve

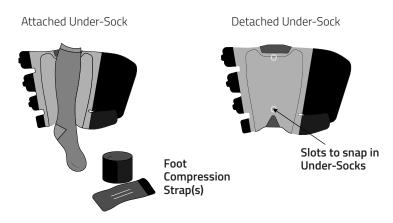
- 3. **Optional: Trim the foot strap.** Aero-Wrap<sup>™</sup> has a long foot strap to accommodate different foot sizes. If the foot strap is too long it can be trimmed to reduce excess material by following the instructions below:
- 1. Apply Aero-Wrap™ per instructions.
- 2. With the foot straps secured, check to see if there is extra material that extends beyond the hook and loop pad.
- 3. Use scissors to carefully trim the extra material that extends beyond the hook and loop pad on the top of your foot.

(see diagram on next page)



#### 2.2 Applying Aero-Wrap™ Flex.

Aero-Wrap™ Flex sleeves can be worn with or without the detachable Under-Sock and Foot Compression Strap.

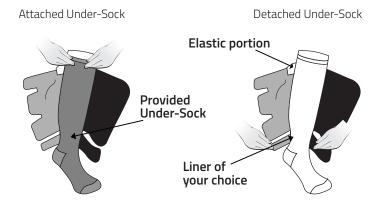


 $\textit{Aero-Wrap} \, ^{\scriptscriptstyle{\mathsf{TM}}} \, \textit{Flex inside view}$ 

1. From a comfortable seated position hold Aero-Wrap™ Flex so that the hook and loop straps are open.

With the attached Under-Sock - Pull the Under-Sock up so that it reaches to the junction below your knee, positioning Aero-Wrap™ Flex as shown below.

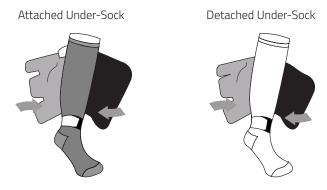
Without the attached Under-Sock - Start by wrapping the lower portion around your leg and securing the bottom strap. Work your way up by securing each strap with the elastic portion hugging the back of your calf. (Aero-Wrap™ Flex should not be worn directly on your skin. If your physician has provided any wound care instructions, they should be followed first).



Aero-Wrap™ Flex proper orientation

2. Secure the straps from **bottom to top**. This will align the elastic portion with the back of your calf. Continue up the leg securing the remaining straps. The straps may require readjustment later in the fitting process. When securing the straps, you should feel as though the

sleeve is snug but not tight. Adjust the straps if necessary so they do not bunch.



Aero-Wrap™ Flex proper orientation

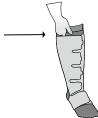
3. Optional: Foot Compression Strap(s). Aero-Wrap™ Flex includes an optional elastic Foot Compression Strap(s). To apply: Over the included Under-Sock or your chosen liner, open the strap with the writing face up and position it under the arch of your foot. Pull and secure the hook and loop tabs to apply compression.



Foot Compression Strap

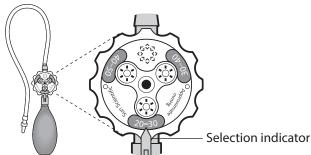
#### 2.3 Inflating Aero-Wrap™ and Aero-Wrap™ Flex.

**IMPORTANT INSTRUCTION:** Prior to inflating the sleeve, you should be able to easily slide one finger between the liner-layer and the sleeve. Having this space allows the chambers to appropriately inflate to provide air compression. If you intend to wear a shoe while wearing Aero-Wrap™, put the shoe on prior to inflating the sleeve.



Aero-Wrap™ and Aero-Wrap™ Flex are inflated with the AeroGauge™ Hand Pump for static compression.

1. Turn the dial on the AeroGauge™ so the desired compression level is selected. You should feel a soft click when the dial is appropriately set at the compression level.

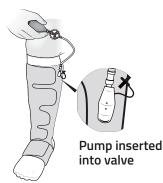


IMPORTANT INSTRUCTION: It's recommended to start gradually with the compression level. Begin at the 20–30 mmHg option and check your leg(s) for any reaction after two hours of use. Gradually increase the duration and compression level, if desired. Consider if your physician or health care professional may have advised you on the desired compression level for you and your condition. You should follow your health care professionals recommendations.

Walking, exercising or other vigorous activities engage the calf muscles, creating a natural pumping action; this may help reduce swelling and you may be required to adjust the hook and loop straps or add air to the sleeve.

2. Remove the valve cap located on the sleeve and insert the tip of the AeroGauge™ pump into the valve. Slowly squeeze the bulb approximately 15 times to inflate the chambers. When squeezing the pump, make sure your fingers do not cover the dial area where the compression levels are displayed.

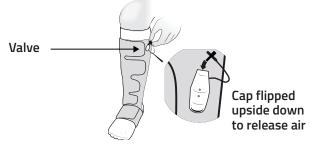
NOTE: You may hear a "hiss" until the selected compression is attained. The pump is designed to release excess air to prevent filling the wrap above the selected level.



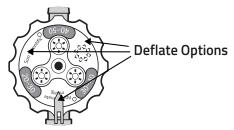
#### 2.4 Deflating Aero-Wrap™ and Aero-Wrap™ Flex.

#### There are two ways to deflate:

1. The first way is to locate the valve cap on the side of the sleeve on both Aero-Wrap™ and Aero-Wrap™ Flex (the same place you inserted the pump to inflate the chambers). Flip the cap upside down and press the tip of the cap into the valve until the compression has been released.



2. The second way is to insert the AeroGauge™ into the valve. Position the dial so that the arrow is in between two of the inflation values.

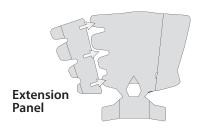


#### 2.5 Removing Aero-Wrap™ and Aero-Wrap™ Flex.

1. Once deflated, carefully peel each hook tab from its loop pad. Take care to not pull any tab too far as this can cause a rip.

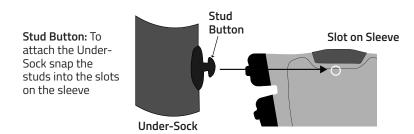
#### 2.6 Optional: Using the Extension Panel

Aero-Wrap™ and Aero-Wrap™ Flex can be adjusted with an Extension Panel (purchased separately) which can adjust the shape or width of the sleeve for patients who do not fit within the traditional product measurements. The Extension Panel is attached with hook to the sleeve and can be angled to provide extra width where required.



#### 2.7 Optional: Attaching/Detaching the Under-Sock

Aero-Wrap™ and Aero-Wrap™ Flex have detachable Under-Sock(s) that can be snapped into and out of the slots on the sleeve.



## **System Cleaning Instructions**

CAREFULLY REMOVE THE UNDER-SOCK, AEROGAUGE, EXTENSION PANEL etc. BEFORE CLEANING AND INSPECTION.

#### CAUTION: Avoid the following for the Aero-Wrap™



- Do not submerge.
- Do not disassemble.
- Do not machine dry.
- Do not iron.
- Do not machine wash

Do not swim or

bathe with wrap.

- Do not dry clean.
- Do not autoclave.

Aero-Wrap ™ and Aero-Wrap™ Flex can be cleaned, as needed, using a damp cloth and mild household soap or laundry detergent, and hung to dry.

**Under-Sock(s)** can be cleaned in the washing machine with laundry detergent. Remove the Under-Sock from the Aero-Wrap before washing the Under-Sock. Air dry.

AeroGauge™ can be cleaned, as needed, using a damp cloth and mild household dish washing soap. Don't submerge in water or fluid as this will damage the pump.

**Foot Compression Strap** can be cleaned in the washing machine with laundry detergent. Air dry.

# Warranty and Service Information

Our warranty service to the system offers the following coverage

■ Aero-Wrap™ and Aero-Wrap™ Flex: 90 Days

Sun Scientific Inc. warrants its Aero-Wrap™ systems to be free from defects in workmanship and materials for the periods listed above from the date Device is delivered to the original purchaser ("Warranty Period"). This Limited Warranty is extended only to the original purchaser and is non-transferable. Sun Scientific's sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device which is defective in either workmanship or material. This is the sole remedy of the Purchaser. In addition, this Limited Warranty does not cover any Device which may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of Sun Scientific instructions including, without limitation, the instructions contained in this document.

 THERE ARE NO WARRANTIES OTHER THAN THOSE EXPRESSLY STATED HEREIN.

- TO THE EXTENT PERMITTED BY LAW, SUN SCIENTIFIC DOES NOT MAKE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS TO ANY PRODUCT OR DEVICE, WHETHER OR NOT THAT PRODUCT OR DEVICE IS COVERED BY ANY EXPRESS WARRANTY CONTAINED HEREIN.
- IN NO EVENT SHALL SUN SCIENTIFIC BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, USE OR TIME INCURRED BY PURCHASER OR END USER). IN ADDITION, SUN SCIENTIFIC SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

#### Maintenance and Replacement Parts.

• Aero-Wrap™ contains no user serviceable parts inside: Opening or tampering with this device will void the warranty and could be dangerous. In the event Aero-Wrap™ requires repairs, a Return Merchandise Authorization (RMA) should be requested from the medical equipment company who supplied the product or from Sun Scientific.



#### REF.

Aero-Wrap™ Flex, Unilateral, Small Kit MS-SF Aero-Wrap™ Flex, Unilateral, Medium Kit MS-MF Aero-Wrap™ Flex, Unilateral, Large Kit MS-LF Aero-Wrap™ Flex, Unilateral, XLarge Kit MS-XLF Aero-Wrap™ Flex, Bilateral, Small Kit MSB-SF Aero-Wrap™ Flex, Bilateral, Medium Kit MSB-MF Aero-Wrap™ Flex, Bilateral, Large Kit MSB-LF Aero-Wrap™ Flex, Bilateral, XLarge Kit MSB-XLF Aero-Wrap™, Unilateral, Small Kit AW-LSB Aero-Wrap™, Unilateral, Medium Kit AW-LMB Aero-Wrap™, Unilateral, Large Kit AW-LLB Aero-Wrap™, Unilateral, XLarge Kit AW-LLBX Aero-Wrap™, Bilateral, Small Kit AWB-LSB Aero-Wrap™, Bilateral, Medium Kit AWB-LMB Aero-Wrap™, Bilateral, Large Kit AWB-LLB Aero-Wrap™, Bilateral, XLarge Kit AWB-LLBX

#### Visit us at:

www.aero-wrap.com www.sun-scientific.com

For Instructional videos please visit our You-Tube channel by searching "Sun Scientific" or following this QR code:

#### Visit our YouTube Channel!







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