# THE IMPORTANCE OF **COMPLIANCE** IN **COMPRESSION** THERAPY

AMER® HEALTH CARE X

# Introduction

Compression therapy is key to the management of edema and critical to boosting healing rates in Venous Leg Ulcers (VLUs). Compression acts to reduce venous hypertension and improve the flow of fluids in the lower extremities; however, compliance challenges have been well documented with the use of standard compression devices. Oftentimes, these challenges are brought about due to difficulty with proper device application and/or discomfort while wearing the garment. Noncompliance leads to longer healing times, reduced healing rates and increased recurrence of VLUs which can have potentially serious complications. Recently introduced compression garments utilizing the newest in compression materials and technology show promise toward resolving these compliance challenges.

Chronic Venous Insufficiency (CVI) is a condition involving lower leg edema leading to an imbalance between capillary filtration into and lymphatic drainage from the interstitial space.[1] The prevalence of edema increases as people age and can dramatically reduce mobility; increase discomfort, swelling, tension, and pain; and result in potentially serious complications and diminished quality of life. An estimated 25 million Americans suffer from venous insufficiency, with 7 million of those patients exhibiting symptoms of edema and venous ulcers.[2] Obesity, sedentary lifestyle with little to no exercise, smoking, use of alcohol and aging contribute to CVI.

As CVI progresses, lower extremity edema acts to weaken veins and create valvular incompetency leading to dysfunction in venous return and allowing the backflow of blood and fluid to collect at the ankles and lower legs. Venous hypertension is the hallmark of CVI. Left untreated, progressive changes to skin and subcutaneous tissues occur leading to skin breakdown and the potential formation of VLUs. Venous ulcers typically form between the malleoli and lower calf or gaiter area of the leg.[3] These can be very difficult to treat and carry risk of serious complications including infection, amputation and death.[4] An estimated 1% of individuals with chronic venous insufficiency suffer from VLUs during their lifetime.[5,6]

Venous Leg Ulcers often require extended, costly treatment - averaging 12-13 months of treatment - and have a high frequency of recurrence in up to 60-70% of patients.[7] Common features of these ulcers include prolonged or excessive inflammation, persistent infections, formation of drug-resistant microbial biofilms, and the inability of dermal and/or epidermal cells to respond to reparative stimuli; resulting in the failure to heal.[8]

Understanding management options is critical to improving the healing rates of VLUs and reducing complications and recurrence. Effective treatment begins with dressings to protect and maintain a moist wound bed, promote autolytic debridement, control exudate, and manage infection,[9] used in conjunction with compression. Compression therapy is believed to exert its positive effect on venous ulcers by increasing fibrinolysis, reducing venous hypertension and improving the cutaneous microcirculation.[10] Long-term use of compression to prevent recurrence[11] follows, as compression assists venous function while standing and walking. Comfort and the acceptability of the compression system is essential for compliance with the protocol, and patients need to be included in treatment decisions.

# Why and When Compression is Necessary

Considered the gold standard for treatment of edema, compression has repeatedly shown to improve healing rates, promote good circulation, reduce edema and decrease recurrence.[12] Compression therapy exerts a controlled pressure on the limb, measured in millimeters of mercury (mmHg). The action of compression devices is mechanical and has two mechanisms of action: a static effect or resting pressure and a dynamic effect due to the changing circumference of the leg during walking.

Short-stretch systems (inelastic) are thought to be more effective at aiding venous return than long-stretch (elastic) systems.[13] Long-stretch bandaging has a low static stiffness index (SSI) and exerts less pressure during standing/walking as well as at rest. Compression therapy using short-stretch bandaging with a high SSI creates an unyielding (rigid) closed system whereby external pressure applied to the leg is transmitted equally in all directions within the contained area using the principal known as Pascal's Law. When pressure is applied at one point it creates a pressure wave that is distributed evenly throughout the lower limb according to Pascal's Law and assists the calf muscle in improving venous return.[14] Short-stretch bandaging provides low pressure during rest and high pressure while standing and/or walking.[14] It is generally acknowledged that movement and exercise are positive predictors of outcomes in VLUs.[15]

A wide variety of compression devices exist, including dynamic pneumatic pumps, sleeves and tapes, static compression stockings, tubular elastic devices, multi-layered bandages (bandage systems), and compression wraps and garments. Graduated compression garments that achieve 30-40 mmHg for mild leg edema and 40-50 mmHg for moderate leg edema are the mainstay of treatment in the long-term management phase of chronic edema. The most effective level of compression to overcome venous hypertension has been determined to be around 40 mmHg at the ankle.[16] To achieve true graduated compression, the bandage should be applied at a consistent tension and be able to keep its shape over time.[17]


**> 30-40 mmHg for mild edema**
**> 40-50 mmHg for moderate edema**

# Increasing Compliance: The Key to Success

Ehmann noted a shift in practice, moving away from management using traditional compression garments to using made-to-measure compression garments and Velcro wrapping devices as first-line treatments. The movement away from the use of traditional compression garments is, in part, because they are often found to be difficult to apply and uncomfortable to wear for prolonged periods of time.[18] A critical success factor in ulcer healing and recurrence is whether the patient will wear the wrap for the prescribed length-of-time and maximize the therapy.[19]

The Cochrane review[20] confirmed the critical importance of compression therapy for successful treatment of venous stasis disease. For compression to be effective, the garment must be comfortable while providing sustained, consistent therapeutic compression. The garment must be easy to use with simple, quick application and removal; must stay in place while being worn; and must be air permeable to allow for the movement and transfer of air, heat and moisture to encourage longer wear.

Use of compression in compliant patients can increase the ulcer-healing rate and significantly reduce recurrence. Studies have documented that healing rates as high as 97% can be achieved in those who are compliant with therapy.[21] A 7-year cohort review of 3,144 patients showed only 33% of patients are compliant with compression garments.[22] By addressing the concerns of application and comfort challenges, studies such as one conducted by Lambert et al. have demonstrated the potential for Health Care Providers (HCP) to increase compliance with compression protocols to a much as 61%.[23]

# Overcoming Application Difficulties

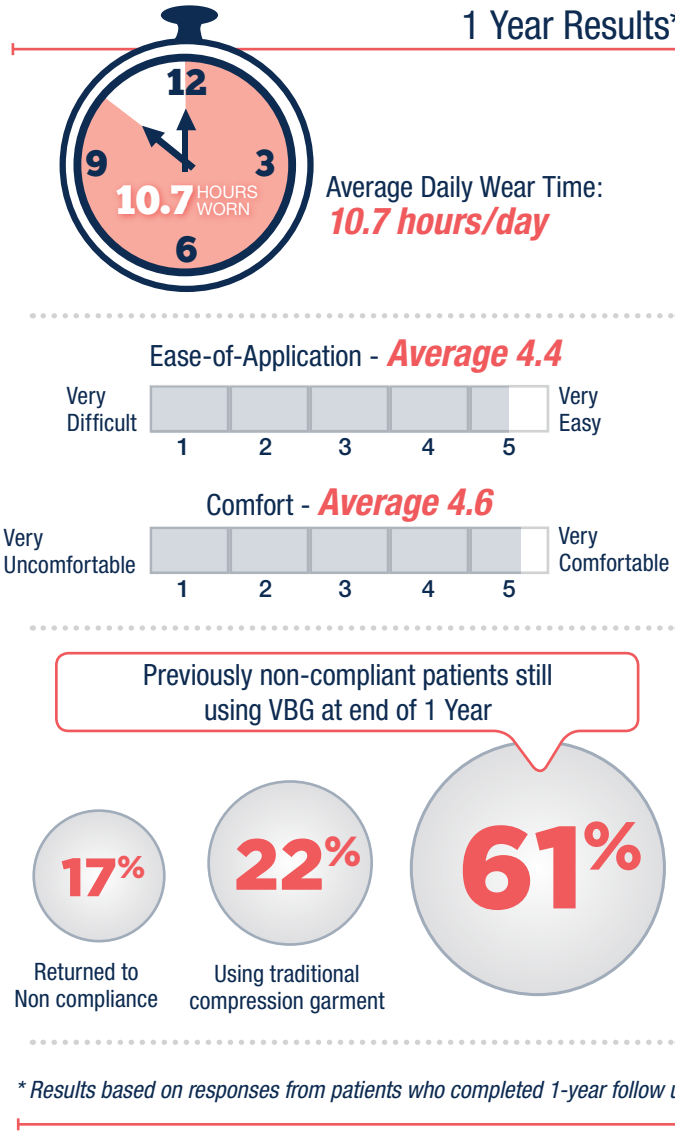
A cross-sectional study by Shashi and Gogia highlighted the exceptional effectiveness of compression therapy. The study discusses user variation; concluding technique does matter and pointing out the importance of adequate training. It is essential that HCPs who treat patients for lower extremity venous ulcerations educate patients regarding the need for long-term use of compression and proper application to achieve appropriate compression levels. This is especially important when using a multilayer bandaging system which uses a specific technique that must be learned.[24]

Skill and training can be a determining factor in the efficacy of compression. A cross-sectional study was conducted to determine if home care nurses were regularly able to achieve therapeutic levels of sub-bandage pressure using various systems. Results showed a substantial variation in exerted pressures achieved, ranging from 11 mmHg to 80 mmHg (30-50 mmHg considered optimal). Sixty-three percent of participants achieved pressures within the optimal range when applying a two-component bandage while 41% achieved optimum pressure when applying an elastic bandage and 40% when applying an inelastic bandage. The study demonstrated difficulty achieving desired sub-bandage pressure when home care nurses applied the bandage, indicating a substantial proportion of patients do not receive adequate compression therapy.[25]

In addition to confusion over the proper application of compression devices, elderly or obese patients may also be unable to reach and bend sufficiently to apply the device. Mullins and Bock's study points out that many patients have extreme difficulty putting on compression devices and hosiery due to dexterity and strength issues.[26] When patients do not clearly understand the application process or have physical difficulty with donning their garment, the resulting frustration often leads to non-compliance.

Lambert et al. evaluated the ease of application, comfort and compliance of traditional compression garments compared with the use of the EXTREMIT-EASE® Compression Garment—a Velcro-Bungee Garment (VBG) system. Study participants included patients previously demonstrating poor compliance with standard compression stockings or multilayer compression therapy. Patients and family were instructed in the application and use of the VBG garment in the office setting with follow-up at 1-2 weeks to ensure proper use. Study participants completed questionnaires at 6-8 weeks and again at one year. Participants who had not been compliant with traditional compression garments demonstrated increase in both compliance and length of utilization. Of the 18 participants who completed the study, eleven or 61% of previously non-compliant patients were still using the Velcro-Bungee garment at one year. Patients reported wearing the garment an average of 10.1 hours per day at 6 weeks and 10.7 hours at one year. When asked to rate Ease of Placement on a 1 (very difficult) to 5 (very easy) scale, the average response at 6 weeks was 4.6 and 4.4 at one year. Comfort (1 very uncomfortable to 5 very comfortable) was rated at an average 4.7 at 6 weeks and 4.6 at one year. Results concluded a majority of previously non-compliant patients remained compliant at one year with an average daily time utilization of 10.7 hours.[23]

## Velcro-Bungee Garment System Compliance Study among Previously Non-Compliant Patients[23]



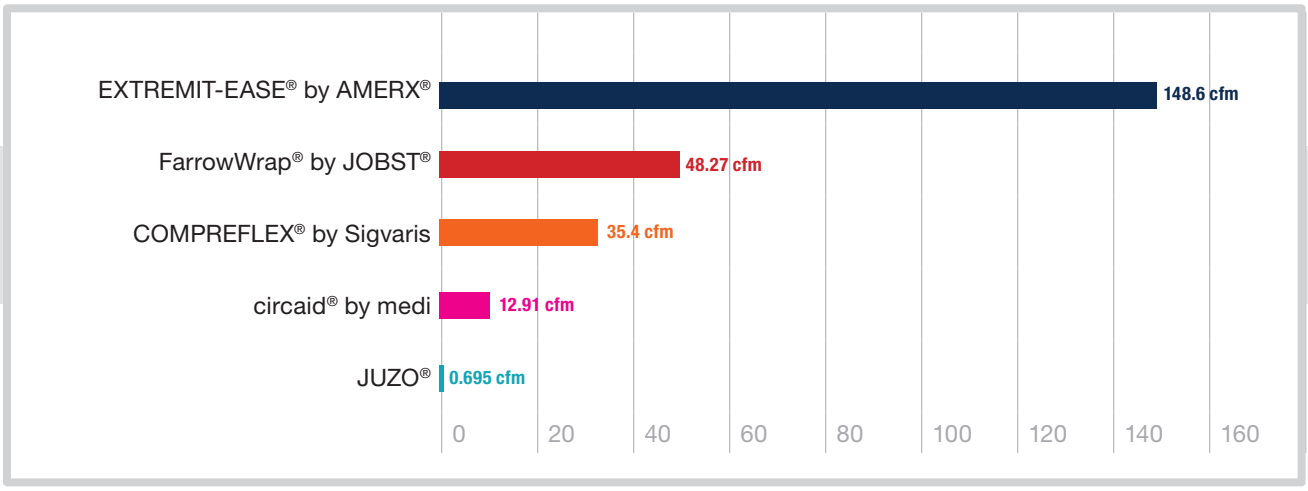
# Overcoming Discomfort Challenges

Poor tolerability to wearing compression garments may contribute to reduced compliance, which reduces healing rates and may double the time to complete healing.[27, 28] Multi-layer compression systems, such as four-layer bandages, are often used for extended periods of time with minimum dressing changes. This may cause overheating of the underlying tissues and, perhaps, excessive sweat production due to poor moisture exchange between the body and the surroundings.[29] Multilayer compression wraps can lose compression or creep, resulting in slippage and bunching. They can also be occlusive and prevent skin respiration, resulting in potential skin maceration. Other factors that impact compliance include sensorial or tactile comfort which is related to the mechanical contact of the fabric with the skin.[30]

Fabrics used in the construction of compression garments vary widely. Properties of the fabric that influence thermal comfort include air permeability, moisture vapor permeability/transportation and heat transmission.[31] Among all comfort characteristics, the most important factor is the movement of heat and moisture through padding to maintain the thermal equilibrium between the human body and the environment. Thermal equilibrium, and thus thermo-physiological comfort, is determined by heat and moisture transmission characteristics through fabrics.[32]

A study at an independent testing laboratory utilizing the ASTM Standard D737, 2004 (reapproved 2016), "Standard Test Method for Air Permeability of Textile Fabrics"; compared the air permeability and thermo-physiological effects of five compression garments used for the management of lymphedema. Air permeability is expressed in the amount of air in cubic feet per minute (cfm) that passes through a sample of a given area in one minute. The EXTREMIT-EASE Compression Garment allowed a significantly higher amount of air-flow—149 cfm (cubic feet per minute)—than other compression garments in the study. The study illustrated the differences in average amount of air-flow for each compression garment, suggesting the thermo-physiological effect of providing greater transfer of heat and moisture or vapor transmission. This results in greater thermal equilibrium between the human body and the environment and can have a positive impact on comfort and overall compliance.[33]

## Air Permeability Comparison of Five Leading Compression Garments

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# In Conclusion

The benefits of compression for healing venous leg ulcers and reducing recurrence rates have been well-documented in medical literature, but this therapy can only work when patients comply with the protocol. By prescribing compression garments that address and reduce the two primary barriers to compliance—application difficulties and discomfort—health care providers can significantly increase compliance rates leading to reduced edema, improved wound care outcomes, and a better quality of life for patients.

## Discover Where **COMPRESSION** Meets **COMPLIANCE®** with the **EXTREMT-EASE®** Compression Garment

Providing 30-50 mmHg therapeutic compression, the innovative design of the EXTREMT-EASE Compression Garment features a combination of zipper and bungees with large tabs, making independent application and adjustment easy for patients to achieve—even if they suffer from dexterity issues.

Patients appreciate the lightweight, air permeable fabric which allows for hours of comfortable wear with less sweat, hot spots, and pistoning. EXTREMIT-EASE is available in Regular and Tall heights for sizes ranging from XS-XXL and available in black and tan. Each EXTREMIT-EASE Compression Garment system comes complete with a mesh laundry bag and one garment liner. Additional Garment Liners are also available in tan and dark gray.

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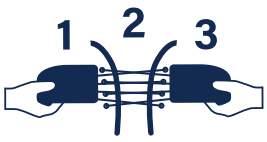
EXTREMIT-EASE

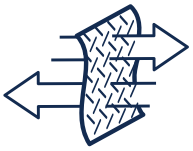
COMPRESSION GARMENT

# WHERE **COMPRESSION** MEETS **COMPLIANCE**®

## Increase Compliance, Reduce Edema, and Improve Wound Care Outcomes with the NEW EXTREMIT-EASE® Compression Garment




Easy Application and Adjustment



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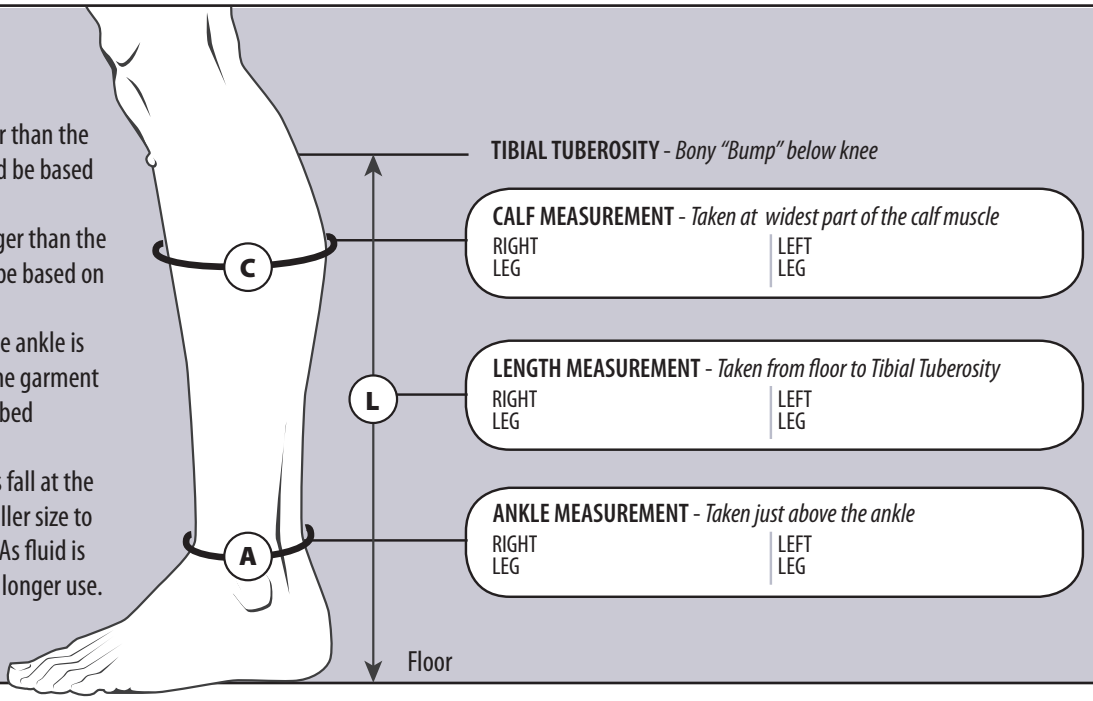
EXTREMIT-EASE COMPRESSION GARMENT

# MEASUREMENT/FITTING GUIDE

Patient Name: _____ Date: _____

## FITTING TIPS

- If the calf measurement is one size larger than the ankle on the fitting chart, the size should be based on the measurement of the calf.
- If the ankle measurement is one size larger than the calf on the fitting chart, the size should be based on the measurement of the ankle.
- If the difference between the calf and the ankle is more than one size in either direction, the garment should not be used and a custom prescribed compression wear should be utilized.
- If both the ankle and calf measurements fall at the mid-point between sizes, select the smaller size to avoid quickly sizing out of the garment. As fluid is dispersed, the smaller size will allow for longer use.




## EXTREMIT-EASE® COMPRESSION GARMENT

| | LEG CIRCUMFERENCE MEASUREMENTS | | | | | | LENGTH MEASURMENTS | |
|---|---|---|---|---|---|---|---|---|
| | X-SMALL | SMALL | MEDIUM | LARGE | X-LARGE | 2X-LARGE | REG | TALL |
| **A** = ANKLE | 21 -25 cm<br>8.5 - 10 in | 25 - 30 cm<br>10 - 11.5 in | 30 - 33 cm<br>11.5 - 13 in | 33 - 37 cm<br>13 - 14.5 in | 37 - 41 cm<br>14.5 - 16 in | 39 - 43 cm<br>15.5 - 17 in | 37 - 44 cm<br>14.5 - 17.5 in | 44 - 51 cm<br>17.5 - 20 in |
| **C** = CALF | 37 - 42 cm<br>14.5 - 16.5 in | 42 - 47 cm<br>16.5 - 18.5 in | 47 - 52 cm<br>18.5 - 20.5 in | 52 - 57 cm<br>20.5 - 22.5 in | 57 - 62 cm<br>22.5 - 24.5 in | 62 - 67 cm<br>24.5 - 26.5 in | | |

## EXTREMIT-EASE® COMPRESSION GARMENT/LINER ORDER:

*One Garment Liner and mesh laundry bag are included with each EXTREMIT-EASE® COMPRESSION GARMENT*

Indicate number/size needed:
NO product substitutions

**COMPRESSION GARMENT(S)**

**SIZE**
___ QTY - XS
___ QTY - S
___ QTY - M
___ QTY - L
___ QTY - XL
___ QTY - XXL

**LENGTH**
___ REG
___ TALL

**COLOR**
___ BLACK
___ TAN

**ADDITIONAL GARMENT LINERS**

**SIZE**
___ QTY - M
___ QTY - L

**COLOR**
___ GRAY
___ TAN

## EXTREMIT-EASE® LINER

| | MEDIUM | LARGE |
|---|---|---|
| MALE SHOE SIZE | 7 - 9 | 10 - 12 |
| FEMALE SHOE SIZE | 8 - 10 | 11 - 13 |

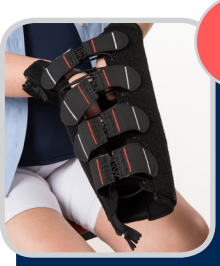
**SPECIFIC INSTRUCTIONS:** _____

# EXTREMIT-EASE®
## COMPRESSION GARMENT

# APPLICATION INSTRUCTIONS

## 1 APPLY LINER

Apply the EXTREMIT-EASE® Liner as if you are putting on a sock. Be sure to place toes all the way to the end of the liner and work out any extra space or wrinkles throughout the liner to avoid discomfort after compression is applied.



## 2 RELEASE & LOOSEN

Completely release all four sets of bungees/tabs and reattach the tabs as close to the center opening as possible.

Loosen the garment by pulling against the fabric to open and increase the center gap.

## 3 UNZIP & OPEN

Unzip and open the garment, ensuring the tongue is pressed against the bungees.

## 4 SLIDE & ZIP

Slide your foot into the garment and zip it up to secure the garment in place. **Upon initial application, the garment may feel snug.**

Rotate the garment to align the bungees with the front of the leg, position the garment just below the knee, and double-check the garment tongue to make certain there are no folds or wrinkles.

## 5 COMPRESS

Starting from the bottom set of bungees, grasp the tabs using your index finger and thumb and pull the bungees away from the garment, contracting the space between the eyelets.

Secure each set of tabs to the garment evenly on opposing sides.

Use the white and red guidelines sewn into the tabs and the white seam line sewn into the garment to achieve desired compression levels. For lower compression, align the white guideline with the white seam line. Adjust the red guideline closer to the white seam line to increase compression levels. **It is not recommended to compress beyond the red guideline.**


To check that your level of compression is set properly, insert two fingers between the garment and your leg. Your fingers should fit snugly, but without difficulty. If the garment is too tight, simply loosen the bungees/tabs and test again.

As treatment progresses, the center opening under the bungees will become smaller. **If no gap is visible on the front of the garment, it is time to switch to a smaller garment for effective compression.**

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# EXTREMIT-EASE®
## COMPRESSION GARMENTS & LINERS

# ORDER FORM

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PHYSICIAN NAME(S)

ADDRESS

CITY | STATE | ZIP CODE

PHONE NUMBER | FAX NUMBER

EMAIL ADDRESS

OFFICE MANAGER / PURCHASING | PURCHASING EMAIL

| EXTREMIT-EASE® COMPRESSION GARMENT PRICING | | | |
|---|---|---|---|
| UNIT | 12 UNITS | 36 UNITS | 72 UNITS |
| $55.00/EA | $53.00/EA | $50.00/EA | $47.00/EA |

| EXTREMIT-EASE® GARMENT LINER PRICING | | | |
|---|---|---|---|
| UNIT | 12 UNITS | 36 UNITS | 72 UNITS |
| $10.00/EA | $9.50/EA | $9.00/EA | $8.50/EA |

### EXTREMIT-EASE® COMPRESSION GARMENT — BLACK, REGULAR

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | = 0 | $0.00 |
| XS (E10140) | S (E10141) | M (E10142) | L (E10143) | XL (E10144) | 2XL (E10140) | TOTAL UNITS | EXTENDED PRICE |

### EXTREMIT-EASE® COMPRESSION GARMENT — BLACK, TALL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | = 0 | $0.00 |
| XS (E20140) | S (E20141) | M (E20142) | L (E20143) | XL (E20144) | 2XL (E20140) | TOTAL UNITS | EXTENDED PRICE |

### EXTREMIT-EASE® COMPRESSION GARMENT — TAN, REGULAR

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | = 0 | $0.00 |
| XS (E10240) | S (E10241) | M (E10242) | L (E10243) | XL (E10244) | 2XL (E10240) | TOTAL UNITS | EXTENDED PRICE |

### EXTREMIT-EASE® COMPRESSION GARMENT — TAN, TALL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | = 0 | $0.00 |
| XS (E20240) | S (E20241) | M (E20242) | L (E20243) | XL (E20244) | 2XL (E20240) | TOTAL UNITS | EXTENDED PRICE |

### PAYMENT METHOD

PAYMENT METHOD

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AMERX ACCOUNT NUMBER | P.O. NUMBER

CREDIT CARD NUMBER

EXPIRATION DATE | SECURITY CODE

NAME ON CARD

BILLING ADDRESS

☐ Same as Above ☐ Billing Address Below

BILLING STREET ADDRESS

CITY | STATE | ZIP CODE

Save Card On File? ☐ YES ☐ NO

(Office Use Only) Credit Card Auth. #

SIGNATURE | DATE

### EXTREMIT-EASE® GARMENT LINER — TAN

| | | | |
|---|---|---|---|
| | | = 0 | $0.00 |
| MED (E90002) | LG (E90003) | TOTAL UNITS | EXTENDED PRICE |

### EXTREMIT-EASE® GARMENT LINER — GRAY

| | | | |
|---|---|---|---|
| | | = 0 | $0.00 |
| MED (E90012) | LG (E90013) | TOTAL UNITS | EXTENDED PRICE |

| | |
|---|---|
| SHIPPING & HANDLING $8.95<br>Free S & H with 12 Unit Purchase | $8.95 |
| Special Shipping & Handling | $ |
| TOTAL | $8.95 |

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