General Use

Product Description

3M[™] Coban[™] 2 Layer Compression System has been designed to achieve sustained, therapeutic compression.

3M Coban 2 Compression System consists of two latex-free roll bandages. The inner comfort layer is a lamination of polyurethane foam and a cohesive bandage. The outer compression layer is a cohesive bandage, designed to provide compression levels shown to be effective in the treatment of venous leg ulcers in patients exhibiting an ABPI equal to 0.8 or greater. After application, the inner and outer roll cohere to each other and reduce slippage during wear. This compression system is intended for single use only and may be worn up to seven days. 3M Coban 2 Compression System is not designed, sold or intended for use except as indicated.

Indications for Use

3M Coban 2 Compression System is indicated for the management of venous leg ulcers, lymphoedema and other clinical conditions where compression is appropriate. It can be used for patients with an ABPI equal to 0.8 or greater.

Contraindications

- ABPI less than 0.8.
- Decompensated heart insufficiency NYHA Class IV, ACC/AHA Stage D.

Warnings

- Wrapping too tightly may impair circulation. Monitor the area of application frequently for signs of discoloration, pain, numbness, tingling or other changes in sensation and swelling. If
 these symptoms occur, remove 3M Coban 2 Compression System promptly and contact your health care provider.
- 3M Coban 2 Compression System should not be used in arms or anatomical regions with small circumferences as full stretch application may be too tight. For arms and these
 anatomical regions 3M™ Coban™ 2 Lite Compression System may be used.
- Do not reuse. Reuse may result in compromising product integrity or lead to device failure.

Precautions

- 1. 3M Coban 2 Compression System should be used under the supervision of a licensed health care professional. Patients with known arterial insufficiency, decompensated heart insufficiency or diabetes with advanced small vessel disease may not tolerate compression.
- 2. 3M Coban 2 Compression System is not designed as a wound dressing. Wounds should be managed with dressings appropriate to the wound condition.
- 3. It is important to ensure adequate arterial blood flow before applying 3M Coban 2 Compression System. If inadequate arterial blood flow is suspected, assess an ankle-brachial pressure index (ABPI). If the ABPI is < 0.8, 3M Coban 2 Compression System should not be used. If the ABPI is between 0.5 and 0.8, 3M Coban 2 Lite Compression System can be used.
- 4. In diabetic patients, 3M Coban 2 Compression System should be used with caution due to the possibility of microvascular disease.

Considerations

- 1. Patients new to compression therapy may not initially tolerate the pressure level provided. For these patients, 3M Coban 2 Compression System may be initially applied with less than full stretch or 3M Coban 2 Lite Compression System can be used.
- 2. Effective compression is intended to reduce oedema. 3M Coban 2 Compression System should be changed if it becomes loose fitting, or when it no longer conforms to the shape of the leg.
- 3. Patients should be advised to keep Coban 2 Compression System dry. If the bandage becomes wet, patients should contact their healthcare provider to determine if it should be replaced.
- 4. Patients should be advised to promptly contact their health care provider if they experience pain, numbness, tingling, discoloration or swelling.

Directions for Use

General Instructions:

- 1. Follow facility or agency guidelines for infection control.
- 2. Apply 3M Coban 2 Compression System with the foot in a dorsiflexed position (foot at a 90° angle).

Layer 1: The Inner Comfort Layer

- 1. Apply this layer with the foam side against the skin, using just enough tension to conform to the shape of the leg with minimal overlap. This ensures a thin application that promotes patient comfort and joint articulation where needed.
- 2. Start the application with a circular winding at the base of the toes, beginning at the fifth metatarsal head (figure 1).
- 3. The second circle of winding should come across the top of the foot so that the middle of the bandage width approximately covers the articulating aspect of the ankle joint (figure 2).
- 4. The next winding runs over the heel (figure 3). In most cases, the plantar surface of the foot is not completely covered. However, this is not needed and an extra winding over the ankle joint would make the completed application unnecessarily thick.
- 5. The comfort layer does not conform completely over the Achilles tendon area. The excess material will be smoothed down without causing pain or discomfort when covered by the compression layer (figure 9).
- 6. Proceed up to the knee with minimal overlap, using just enough tension to conform to the shape of the leg (figures 4 and 5). Cut off excess material. Light pressure applied at the end of the bandage ensures that it stays in place during application of the compression layer.

Layer 2: The Outer Compression Layer

The compression layer is designed to be applied at full stretch throughout its application. For reduced compression, 3M Coban 2 Compression System can be applied with less than full stretch or 3M Coban 2 Lite Compression System can be used.

- 1. Start the application with a circular winding at the base of the toes, beginning at the fifth metatarsal head (figure 6).
- 2. Complete up to three figures of eight around the ankle ensuring the entire heel is covered with at least two layers (figures 7-10).
- 3. Proceed up the leg with 50% overlap to cover the entire inner comfort layer. Maintain consistent stretch throughout the bandaging process (figure 11).
- 4. Following the application, press lightly on the entire surface of the application to guarantee an optimal conformability and to ensure that the bandage adheres to itself and to the inner comfort layer.



Removing 3M Coban 2 Compression System

3M Coban 2 Compression System may be removed with bandage scissors or by unwrapping.

Storage/ Shelf Life/Disposal

For best performance, store 3M Coban 2 Compression System at room temperature in its individual package until use. Avoid excessive heat and humidity. For shelf life, refer to the date printed on each box (see explanation of symbols below).

Coban 2 can be disposed as normal hospital/household waste or according to facility procedures for waste handling.

How Supplied

3M Coban 2 Compression System is supplied in boxes of individually packaged rolls.

If you have any questions or comments, please contact your local 3M subsidiary or 3M representative. For details see www.3M.com and select your country.

Lot Code Explanation

The following code is used:

LOT / Hourglass YYYY-MM ZZ with

YYYY: the year in which the shelf life will run out

MM: the end of the month in which the shelf life will run out (01=January; 02=February; 03=March etc.)

ZZ: running LOT-No. in the month (AA=first Lot; AB=second Lot; AC=third Lot etc.)

Example: \Box 2020-05 AC = product expires end of May 2020

Explanation of Symbols

This product and package do not contain natural rubber latex.

A Caution, see instructions for use

(2) Do not reuse

Vise by date

LOT Batch code

Manufacturer

----- Stretched

----- Un-stretched

CE

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a 3M Health Care 2510 Conway Ave. St. Paul, MN 55144 1-800-228-3957 www.3M.com/SkinWoundCare www.3M.com/Patents

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