

## **3M™ Coban™ 2 and 3M™ Coban™ 2 Lite**

### **Two-Layer Compression Systems**

#### **INSTRUCTIONS FOR USE**

##### **GENERAL DESCRIPTION**

These instructions cover the use of both 3M™ Coban™ 2 Two-Layer Compression System and 3M™ Coban™ 2 Lite Two-Layer Compression System. Where the instructions are appropriate for both products, the name Coban 2 (Lite) Compression System will be used otherwise individual Coban 2 systems will be italicized and underlined.

Coban 2 (Lite) Compression System should only be used under the supervision of a health care professional and it is important that both patients and professionals read the following information carefully, prior to using either product.

Coban 2 (Lite) Compression System is designed to provide a thin, conformable and flexible compression bandage which is comfortable in use and facilitates the wearing of normal shoes and clothing.

##### **PRODUCT DESCRIPTION**

Coban 2 (Lite) Compression System consists of a Comfort Foam Layer (Layer 1) and a Compression Layer (Layer 2). It is available in various sizes either as kits (both layers) or bulk (single layer) boxes. Coban 2 (Lite) products are not made with natural rubber latex.

The Comfort Foam Layer (Layer 1) is a lamination of polyurethane foam and a cohesive bandage. It is intended to be used as the first, inner layer of the two-layer system.

The Compression Layer (Layer 2) is a cohesive bandage. It is intended to be used as the second, outer layer of the two-layer system.

Both have been designed to be applied together to achieve sustained, therapeutic compression. After application, the Comfort Foam Layer and the Compression Layer cohere to each other to form a thin, conformable application which is comfortable and resistant to slippage during wear.

The system and its components are intended for single use and may be worn up to seven days. Coban 2 (Lite) Compression System is not designed, sold or intended for use except as indicated.

##### **INDICATIONS FOR USE**

Coban 2 (Lite) Compression System is indicated for the management of venous leg ulcers, lymphedema and other clinical conditions where compression is appropriate.

Coban 2 Compression System is indicated for use in patients with an **ABPI (Ankle Brachial Pressure Index)  $\geq 0.8$**  and is used mainly for the leg and the foot.

Coban 2 Lite Compression System is indicated for use in patients with an **ABPI  $\geq 0.5$**  or for those limbs with small circumferences. It is used mainly for the arms, fingers, toes and lower extremities of patients with mixed disease or poor tolerance of high compression.

##### **CONTRAINDICATIONS – COBAN 2 (LITE) COMPRESSION SYSTEM**

1. Decompensated heart insufficiency NYHA Class IV, ACC/AHA Stage D
2. Septic phlebitis
3. Phlegmasia coerulea dolens and other conditions contraindicated according to established guidelines or local procedures.
4. Known hypersensitivity to any of the component materials
5. Coban 2 Compression System
  - Severe arterial occlusive disease with an ABPI of less than **0.8**
6. Coban 2 Lite Compression System
  - Severe arterial occlusive disease with an ABPI of less than **0.5**

##### **GENERAL CONSIDERATIONS AND WARNINGS**

1. Coban 2 (Lite) 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. 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, patients should be advised to remove Coban 2 (Lite) Compression System and promptly contact their health care provider.
3. Patients new to compression therapy may not initially tolerate the pressure level provided. For these patients, the Compression Layer may be initially applied with less than full stretch or Coban 2 Lite Compression System can be used.
4. Coban 2 (Lite) Compression System is not designed as a wound dressing. Wounds should be managed with dressings appropriate to the wound condition.

5. Coban 2 (Lite) Compression System should be changed if it becomes loose fitting, or when it no longer conforms to the shape of the bandaged area. The patient should contact their health care professional to determine if it should be replaced.
6. Patients should be advised to keep Coban 2 (Lite) Compression System dry. If the bandage becomes wet, patients should contact their health care provider to determine if it should be replaced.
7. For thorax applications, *Coban 2 Lite Compression System* may be more comfortable for some patients.
8. Do not reuse. Reuse may result in compromising product integrity or lead to device failure.
9. At the discretion of the health care professional, patients or their care providers can be trained to apply the bandage for subsequent applications.

### GENERAL DIRECTIONS FOR USE

1. Follow facility or agency guidelines for infection control.
2. Maintain consistent stretch throughout the bandaging process.
3. Cut off excess material.

One of the most common applications in compression therapy is the lower leg application used for, but not only, the treatment of venous leg ulcers. For the use of Coban 2 (Lite) Compression System in other anatomical areas please contact your local 3M subsidiary or 3M representative to receive information on all application techniques.

### DIRECTIONS FOR USE

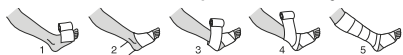
(example Lower Leg)

Apply the Compression System with the foot in a dorsiflexed position (foot at 90° angle).

#### LAYER 1: THE INNER COMFORT LAYER

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 breathable and thin application that promotes patient comfort and joint articulation.

1. Start the application with a circular winding at the base of the toes, beginning at the fifth metatarsal head (figure 1).
2. 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).
3. Bring the next winding low, around the back of the heel leaving the plantar aspect of the heel uncovered. Covering the plantar heel is not needed and an extra winding over the ankle may make the completed application unnecessarily thick (figure 3).
4. The comfort layer may not conform completely over the Achilles tendon area. The excess material will be smoothed down without discomfort when covered by the compression layer (figure 9).
5. 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.

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.



#### APPLICATION TIP:

A lightweight, stretchable nylon stocking is provided in some individual kits of Coban 2 (Lite) Compression System to cover the bandage.

#### REMOVING COBAN 2 (LITE) COMPRESSION SYSTEM

The compression system may be removed with bandage scissors or by unwrapping. When removing a lower leg application with scissors, it is advised to cut on the medial side of the leg and ensure cutting behind the medial malleoli.

#### STORAGE, SHELF LIFE AND DISPOSAL

Store Coban 2 (Lite) 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 (Lite) Compression System can be disposed as normal hospital/household waste or according to facility procedures for waste handling.

## HOW SUPPLIED


Coban 2 (Lite) Compression System is supplied as individual kits (containing the number of rolls needed for an average application) and in bulk boxes with individually packaged rolls of Comfort Foam Layer or Compression Layer. Individual kits may also contain a nylon stocking. Please contact your local 3M subsidiary or 3M representative for details on the product offerings available in your country.

If you have any questions or comments, please contact your local 3M subsidiary or 3M representative. For details see [www.3M.com](http://www.3M.com) and select your country.


## SHELF LIFE AND LOT NUMBER EXPLANATION

The following coding is used:


Shelf Life: the hourglass symbol is used followed by Year-Month represented by YYYY-MM


Example:  2020-05 product will expire at the end of May 2020

LOT Number description: the lot-code symbol is used followed by a 9 character code

Example:  2020-05AC


## EXPLANATION OF SYMBOLS:

 Do not reuse

 Use by date

 Batch code

 Catalogue Number


 Caution, see instructions for use

 Manufacturer

 Date of manufacture

 CE-Mark

 Not Made With Natural Rubber Latex

 Un-stretched

 Stretched

Made in U.S.A.

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