

# 3M™ Coban™ 2 Compression System

Lymphoedema



Maintain  
Mobility  
While Reducing Oedema



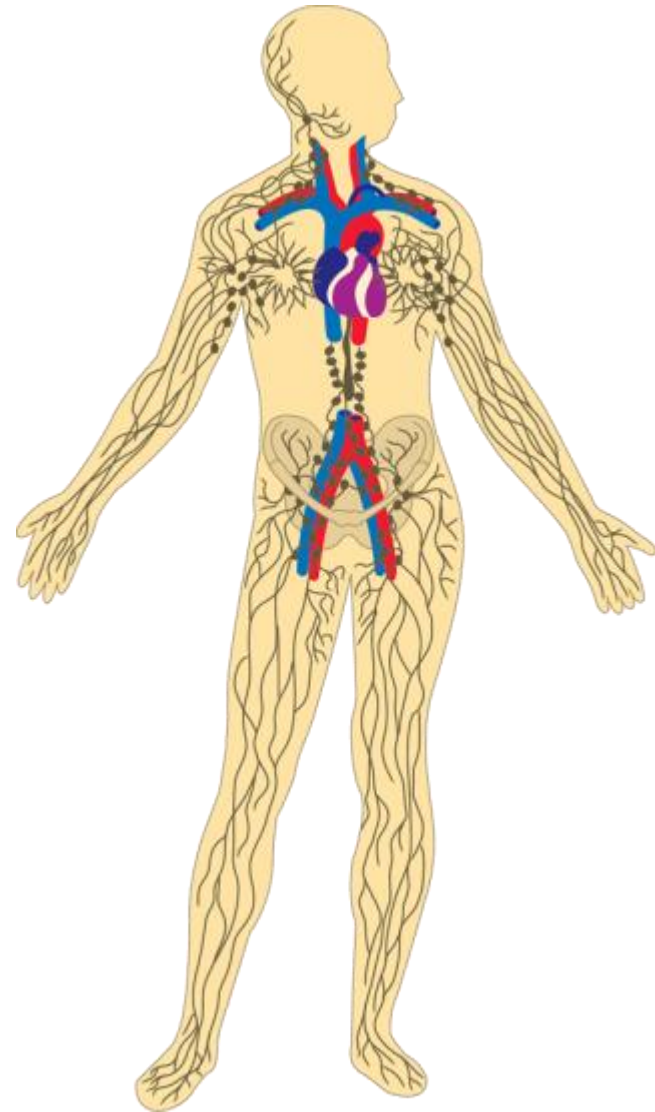
# Bandaging as Part of Intensive Therapy

- Compression is one of the most critical aspects of treatment for Lymphoedema
  - *Is most effective when inelastic materials are used.*
- Different mechanisms may explain the efficacy of compression therapy:
  - *reduction in capillary filtration,*
  - *shift of fluid into non-compressed parts of the body,*
  - *increase in lymphatic reabsorption and stimulation of lymphatic transport,*
  - *improvement in the venous pump in patients with veno-lymphatic dysfunction and breakdown of fibrosclerotic tissue.*
- The Coban 2 Compression Systems have been designed to create
  - *a comfortable inelastic sleeve,*
  - *have been proven to support the muscle functional dynamics that support normal venous and lymphatic return and reducing edema.*
- Results of a multi-centre, prospective, open label, randomized controlled study showed that Coban 2 Layer Compression System renewed twice weekly is effective to reduce lymphoedema.

# How Compression Bandaging Works to Move Lymph

***“In obstructive lymphedema, lymphatic wall muscular fibers become damaged and the spontaneous contractility becomes ineffective in lymph transport because of low generated pressures and lymphatic valve insufficiency.”***

***“The lymph propelling task is taken over by leg muscle contractions.”***



From: Olszewski W. *Contractility Patterns of Human Leg Lymphatics in Various Stages of Obstructive Lymphedema.* Ann. N.Y. Acad. Sci. 1131: 110–118 (2008)

# The Ideal Compression system....

*“ Is an inelastic, conformable, low profile sleeve with an anatomical fit around a subjects leg that allows functional activities, that does not slip, which provides in rest a safe and tolerated pressure but generates effective working pressures, is easy to reproduce and apply by clinicians.”*

JAN SCHUREN - Inventor



# How Coban 2 Compression System provides short stretch benefits

- The Coban 2 Compression System has been designed with materials that work together to create a comfortable inelastic sleeve and have been proven to support the muscle functional dynamics that support normal venous and lymphatic return and reducing edema.
- Results of a multi-centre, prospective, open label, randomized controlled study showed that Coban 2 Layer Compression System renewed twice weekly is effective to reduce lymphedema.



# Traditional Bandaging Materials



Short stretch, inelastic bandages with a variety of padding materials to normalize the limb shape believed to provide a pressure gradient according to Laplace's Law.

Rigid sleeve that supports intermittent peak pressures of muscle activity to achieve the massaging effect that stimulates lymph

Thick, stiff and bulky so that wearing normal clothing and footwear is difficult.

Restrict mobility, reduce flexibility & limit function for activities of daily living.



# 3M Breakthrough in Materials

Coban™ 2 Layer Compression Systems provide ideal properties

- *Enable innovative application methods to provide comfortable, sustained compression*
- *Create an inelastic sleeve with ideal stiffness to support all the muscular movements of the patient within the bandage.*

Layer 1, the Comfort Foam Layer, a laminate of medical grade polyurethane foam with cohesive, non-woven backing

- *applied with the foam side towards the skin*
- *provides comfortable cushion, protection and mechanical grip to reduce slippage during wear.*

Layer 2, the Compression Layer, a cohesive bandage with spandex filaments modified to be be short stretch, with specific numbers and denier to provide optimal stiffness

- *short stretch properties ---designed to be applied at full stretch to eliminate the guesswork*

Two layers **cohere** creating a comfortable inelastic sleeve that conforms to the anatomy and grips the skin to reduce potential for uncomfortable slipping and bunching.

The thin profile allows use of more normal footwear so the patient can remain as active as possible.

Maintaining function & activity will promote reduction of oedema and lymphatic return.



# Summary of Clinical Evidence

3M has recently completed studies in partnership with leading clinicians

- Randomized control trial on 82 patients with arm and leg lymphoedema from which application frequency, clinical outcomes and cost of total treatment were captured
- Observational case series on use of the new materials on 24 patients, and report of clinician and patient experiences
- Proof of concept study of effective volume reduction over 24 hours on 30 leg lymphoedema patients

*Six manuscripts are currently being prepared for publication in peer-reviewed journals*

## Summary of Clinical Program to Support Use of 3M™ Coban™ 2 Compression Systems for Lymphoedema Bandaging

To espouse the evidence to support use of 3M™ Coban™ 2 Compression Systems for lymphoedema treatment, 3M has recently completed a number of clinical and economic studies in partnership with leading clinicians. The body of work includes:

- Randomised control trial on 82 patients with arm and leg lymphoedema from which application frequency, clinical outcomes and cost of total treatment were captured
- Observational case series on use of the new materials on 24 patients, and report of clinician and patient experiences
- Proof of concept study of effective volume reduction over 24 hours on 30 leg lymphoedema patients

### Randomised Controlled Trial

A randomised control trial was conducted to investigate the efficacy and safety of the Coban 2 Compression System compared to traditional short stretch multi-layer bandaging. This multi-center, prospective study was performed with 82 patients suffering from lymphoedema stage II or late stage II, either as secondary arm lymphoedema or as primary or secondary leg lymphoedema. All patients were randomly allocated to treatment regimen and the study duration was 10 days. Limb volume as well as adverse events, were recorded at each study visit. Mobility was assessed at the end of each week. The % volume reduction of the study limb was the primary endpoint.

### Observational Case Series

- A qualitative study has been conducted to explore the experience of patients who have undergone a period of Complete Decongestive Therapy using the Coban 2 Compression System. Qualitative data were collected from 12 patients from the UK and 8 from Canada with a range of presentations of lymphoedema. Single semi-structured interviews were used and participants were asked questions relating to their experience of diagnosis, the impact of lymphoedema on their lives, previous treatment using multi-layer lymphoedema bandaging and their experiences of the 3M System.
- Quantitative data were collected from the clinicians and patients involved in the qualitative study above. In total 24 patients were entered into this prospective study (12 from UK, 12 from Canada) with a variety of clinical indications. Bandages were replaced according to clinical need and the protocol of the center undertaking this study. Efficacy parameters and patient reported symptom relief was measured.

### Proof of Concept Study

A prospective randomised study to demonstrate proof of concept for the Coban 2 Compression System was conducted. This study included 30 patients hospitalized for conventional treatment of moderate to severe lymphoedema (Stage II-III) of the leg. Patients were treated with Coban 2 Compression Systems or traditional bandages used in this facility. In both groups initial bandages were removed after 2 hours, and replaced by new bandages for the following 22 hours. No other therapeutic intervention was performed. Leg volume and inter-tissue pressures were measured.

Six manuscripts are currently being prepared for publication in peer-reviewed journals and the detail results will be available once the studies have been published.



#### Skin Health Products

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“The cumulative results from these research studies support that ‘Coban 2 Compression System’ is clinically effective and is set to fundamentally change the field of Lymphoedema.”



*Christine Moffatt CBE PhD  
Lead Researcher, Derby Hospitals  
Honorary Professor in Nursing & Health Care Glasgow University*



Reduces oedema effectively!

We are confident to recommend 2 x / week applications of Coban 2 Compression systems during intensive therapy.

Lymphoedema

# Conformability without additional padding

- Coban 2 Layer Compression System materials were designed to provide the required “stiffness” with two, thin layers that conform directly to the patients limb contours.
- Clinical effectiveness has been proven as seen by volume and skin fibrosis reduction.



## Mobility and Function



- The thin, low profile of the Coban 2 Layer Compression System materials has been proven to improve patients Health Related Quality of Life Physical Symptoms and Daily Living Scores.
- Patients with lymphoedema also reported an extremely positive experience wearing Coban 2 layer compression systems with the key advantages of lightness, neatness and flexibility enabling mobility and improving quality of life.



# Lightness & Comfort

- Traditional bandages are heavy and bulky and interfere with the patients function, flexibility and mobility.
- In new research awaiting publication patients reported an extremely positive experience wearing Coban 2 layer compression systems
- Key advantages of lightness, neatness and flexibility enabling mobility and improving quality of life.

*Ms G, breast cancer survivor shows the flexibility and lightness*



# Proven Safe for Skin

- Maintenance of skin integrity with careful management of skin problems is important to minimize the risk of infection.
- 3M Coban 2 comfort foam layer is a laminate of medical grade foam with a latex-free cohesive backing. The hypoallergenic foam side is applied to the skin and has been proven to be safe, non irritating, non sensitizing and can be left in place up to 7 days when clinically appropriate.
- Clinical experience using Coban 2 Compression system for patients with lymphoedema has demonstrated effective compression for up to 4 days with high skin tolerance.
  - *During this same study, a wide array of skin products were used in conjunction with the Coban 2 bandage and were found to be well tolerated and did not promote bandage slippage.*



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