3M™ Coban™ 2 and 3M™ Coban™ 2 Lite Two Layer Compression Systems

Coban 2 catalog numbers	2092, 2094, 2094, 2094N, 2094XL, 20012, 20014, 20016, 20018, 20022, 20024
Coban 2 Lite catalog numbers	2794, 2794E, 2794N, 20721, 20723, 20724, 20726, 20713, 20714, 20716, 20751, 20793, 20795, 20796

General Description

This technical data sheet covers both 3M™ Coban™ 2 Compression System and 3M™ Coban™ 2 Lite Compression System. Where the data is appropriate for both products, the name Coban 2 (Lite) will be used otherwise the individual Coban 2 Compression System names will apply.
Coban 2 (Lite) is designed to provide sustained therapeutic compression through a thin, conformable and flexible compression bandage which is comfortable in use and facilitates the wearing of normal shoes and clothing.
Coban 2 (Lite) 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) is CE marked as a Class I medical device and fulfils the essential requirements of the Medical Device Directive 93/42/EEC. **Note:** This Document is valid for the European Union only. The registration status in other geographies must be confirmed.

3M™ Coban™ 2 (Lite) Two-Layer Compression System with tan compression layer (layer 2) and white comfort layer (layer 1). Examples of kits and bulk packs are shown (not to scale).

Product Composition

Product Family	Material
Coban 2 (Lite) Comfort Layer – layer 1 (inner layer)	• Flexible Polyurethane Foam • Synthetic Rubber Copolymer • Polyester (PET) • Hydrocarbon Resin Tacifier • Polyurethane • Acrylic Copolymer • Zinc Oxide
Coban 2 (Lite) Compression Layer – layer 2 (outer layer)	• Synthetic Rubber Copolymer • Polyethylene Terephthalate • Hydrocarbon Resin Tacifier • Polyurethane • Acrylic Copolymer • Zinc Oxide

Packaging Composition

Each roll is packaged into a pouch (immediate wrapper). Several pouches are packaged into a primary box. Then several primary boxes are placed in a corrugated shipper box.

Packaging Level	Material
Pouch:(Immediate Wrapper)	High Density Polyethylene Printed Film
Carton:	Paperboard
Shipper:	Corrugated box

Intended 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 > 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 > 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.

Product Range

Coban 2 Compression System

Reference Number*	Size / Dimension / Contents per primary	Name / Descriptor	Primary /Shipper
2092	Comfort Layer: 5 cm x 1,2 m Compression Layer: 5 cm x 2,7 m 1 roll each/primary box	3M™ Coban™ 2 2 Layer Compression System	8
2094	Comfort Layer: 10 cm x 2,7 m Compression Layer: 10 cm x 3,5 m 1 roll each/primary box	3M™ Coban™ 2 2 Layer Compression System	8
2094	*Comfort Layer: 10 cm x 2,7 m* *Compression Layer:* *10 cm x 3,5 m* *1 roll each/primary box*	*3M™ Coban™ 2* *2 Layer Compression System* *(distributed by Fresenius; for Germany only)*	*8*
2094N	Comfort Layer: 10 cm x 2,7 m Compression Layer: 10 cm x 3,5 m 1 roll each/primary box Kit includes a stocking	3M™ Coban™ 2 2 Layer Compression System	8
2094XL	Comfort Layer: 10 cm x 3,5 m Compression Layer: 10 cm x 4,5 m 1 roll each/primary box Kit includes a stocking	3M™ Coban™ 2 2 Layer Compression System	8
20012	5 cm x 1,2 m (2 in x 1,3 yd) 32 rolls/primary box	3M™ Coban™ 2 Comfort Foam Layer	4
20014	10 cm x 3,5 m (4 in x 3,8 yd) 18 rolls/primary box	3M™ Coban™ 2 Comfort Foam Layer	2
20016	15 cm x 3,5 m (6 in x 3,8 yd) 10 rolls/primary box	3M™ Coban™ 2 Comfort Foam Layer	4
20018	20 cm x 3,5 m (8 in x 3,8 yd) 9 rolls/primary box	3M™ Coban™ 2 Comfort Foam Layer	2
20022	5 cm x 2,7 m (2 in x 2,9 yd) 32 rolls/primary box	3M™ Coban™ 2 Compression Layer	4
20024	10 cm x 4,5 m (4 in x 4,9 yd) 32 rolls/primary box	3M™ Coban™ 2 Compression Layer	2
20026	15 cm x 4,5 m (6 in y 4,9 yd) 15 rolls/primary box	3M™ Coban™ 2 Compression Layer	4
20095	1x ref 20012 1x ref 20022 1x ref 20014 1x ref 20024 1x ref 20016 1x ref 20026	3M™ Coban™ 2 2 Layer Compression System Leg Kit	1
20096	1x ref 20016 1x ref 20026 2rolls/primary	3M™ Coban™ 2 2 Layer Compression System	8
20097	1x ref 20012 1x ref 20022 1x ref 20014 1x ref 20024 2x ref 20016 2x ref 20026	3M™ Coban™ 2 2 Layer Compression System XL Leg Kit	1

Coban 2 Lite Compression System

Reference Numbers*	Size / Dimension / Contents	Name/Descriptor	Primary /Shipper
2794 2794E	Layer 1: 10 cm x 2,7 m (4 in x 2.9 yd) Layer 2: 10 cm x 3,2 m (4 in x 3.4 yd) Two rolls per primary box (one each)	3M™ Coban™ 2 Lite 2 Layer Compression System	8
2794N	Layer 1: 10 cm x 2,7 m (4 in x 2.9 yd) Layer 2: 10 cm x 3,2 m (4 in x 3.4 yd) Two rolls per primary box (one each) Kit includes a stocking	3M™ Coban™ 2 Lite 2 Layer Compression System	8
20721	2,5 cm x 3,5 m (1 in x 3,8 yd) 36 rolls per primary box	3M™ Coban™ 2 Lite Compression Layer	4
20723	7,5 cm x 3,5 m (3 in x 3,8 yd) 32 rolls per primary box	Coban 2 Lite Compression Layer	4
20724	10 cm x 3,5m (4 in x 3,8 yd) 32 rolls per primary box	3M™ Coban™ 2 Lite Compression Layer	2
20726	15 cm x 3,5 m (6 in x 3,8 yd) 15 rolls per primary box	3M™ Coban™ 2 Lite Compression Layer	4
20713	7,5 cm x 2,7 m (3 in x 3 yd) 17 rolls per primary box	3M™ Coban™ 2 Lite Comfort Foam Layer	4
20714	10 cm x 2,7 m (4 in x 3 yd) 18 rolls per primary box	3M™ Coban™ 2 Lite Comfort Foam Layer	2
20716	15 cm x 2,7 m (6 in x 3 yd) 10 rolls per primary box	3M™ Coban™ 2 Lite Comfort Foam Layer	4
20751	2,5 cm x 3,5 m (1 in x 3,8 yd) 2 rolls per primary	3M™ Coban™ 2 Lite 2 Layer Compression System	8
20793	Layer 1: 7,5cm x 2,7m (3in x 3yd) Layer 2: 7,5cm x 3,5m (7,5in x 3,8yd) Two rolls per primary (one each)	3M™ Coban™ 2 Lite 2 Layer Compression System	8

GENERAL CHARACTERISTICS

Parameter	Product Performance	Test Method	Results
Coban 2-Sustained therapeutic compression	Pressure under the bandage is maintained over the wear-time	Sub-bandage pressure bench test	3M Bandage system provides sustained compression over 7 days wear-time
	Pressure under the bandage is maintained over the wear-time and despite functional activity	2 hour "in function" In-house panel to evaluate sub-bandage pressures during two hours of controlled functional activities of the 3M Coban 2 Layer Compression System when compared to various currently marketed competitive systems."	3M Bandage system provides sustained compression
	Pressure under the bandage is maintained over the wear-time	7 day wear-time In-house panel with volunteers	Minimal slippage - Bandage system does not slip more than 5cm in average during 7 days wear-time
Coban 2 Lite-Sustained Therapeutic compression	**Venous Leg Ulcer:** Pressure under the bandage is maintained over the wear-time	In House Clinical Study Report:	3M Bandage system provides sustained compression over 7 days wear-time

Parameter	Product Performance	Test Method	Results
	Lymphoedema: Pressure under the bandage is maintained over the wear-time	Clinical Trial	Can stay in place for up to 4 days with effective compression Low slippage allows effective treatment for up to 4 days
	Compression dynamics compared with Coban 2	In House Clinical Study Report:	Product provides the same compression dynamics (SSI, amplitude) as Coban 2L combined with a reduced resting pressure.
Minimal slippage- Stays in Place	The bandage stays in place over the wear-time	7 day wear-time In-house panel with volunteers	Minimal slippage - Bandage system does not slip more than 5cm in average during 7 days wear-time
Bandage wear-time	Coban 2- Long wear-time (up to 7 days)	Sub-bandage pressure bench test “Pressure Measurement under Medical Bandages"	3M Bandage system provides sustained compression over 7 days wear-time
	Coban 2 Lite Long wear-time (up to 7 days)	7 day wear-time In-house panel	Minimal slippage - Bandage system does not slip more than 5cm in average during 7 days wear-time
Pain reduction	Patient wearing Coban 2 feel less pain	Randomised controlled trials in Leg ulcer and Lymphedema	Clinical research study shows pain decrease of 50% within 1-2 weeks in venous leg ulcer patients using Coban 2**
Coban 2- leg ulcer healing	Designed to provide effective therapeutic compression for the treatment of venous leg ulcers	Randomised controlled trial	Product promotes healing and reduces wound size of venous leg ulcers
Coban 2- Reduces Edema	Designed to provide effective therapeutic compression for the treatment of venous leg ulcers and chronic oedema, such as lymphoedema	Clinical Study	Bandage system results in oedema reduction during 24h wear-time Product successfully reduces chronic edema For lymphedema: significant improvement of thickened and firm skin (symptoms of fibrosis)
Coban 2 Lite- designed to provide therapeutic compression effective in healing leg ulcers	Designed to provide therapeutic compression that has shown to be effective in healing leg ulcers.	Compression profile matches treatment guidelines	Compression profile matches treatment guidelines
Coban 2 Lite- Reduces Edema	Designed to provide effective therapeutic compression for the treatment of venous leg ulcer and chronic oedema, such as lymphoedema	Clinical Study	Bandage system results in oedema reduction during wear. Product successfully reduces chronic edema In Lymphedema: Provides significant improvement of thickened and firm skin (symptoms of fibrosis)

Parameter	Product Performance	Test Method	Results
Anatomic Fit	Permits good anatomic fit	Clinical study	Can be used on difficult shapes and sizes
Dynamic Pressure Profiles	Has high stiffness, i.e. the pressure generated is effective during mobilization and is well tolerated during rest	Pico Press sub bandage pressure measurement device	High Static Stiffness Index (SSI) throughout wear time.
	High standing pressure	Pico Press sub bandage pressure measurement device	High standing pressure throughout wear time
Thickness of applied bandage	Low profile	Clinical study	allows patient to wear their usual footwear
Good Cohesive properties	Good cohesiveness to ensure easier application and that the bandage stays in place	Cohesive Strength	Cohesive strength - comfort layer: > 17,8 N/inch² - compression layer: min. 84,5 N/inch² (min. 19 lbs/inch²);
Latex free	No natural rubber latex in product	Inhibition ELISA (test on final product)	Raw- / input materials must not contain natural rubber latex No contamination by natural rubber latex during manufacturing process of product above detection limit.
Breathable	Moisture vapor transmission rate provides information on breathability	"Water Vapour Transmission Rate of Sheet Materials" (ASTM test method)	MVTR min. 900g/m²/24h (entire system, no overlap)
Patient compliance	Is associated with high patient compliance	Clinical Study	High patient compliance of patients wearing Coban 2
Coban 2- Ease and reproducibility of application	Product is easy to apply and variability of performance between clinicians is minimised	Kikuhime small probe, Pressure measurement device, Measurement of pressure reproducibility with 5 compression systems	Product can be applied in a manner, which reproducibly achieves consistent levels of compression.
Dimensional Data	Manufacturing tolerance ensures greater than 95% of declared dimension	Physical measurement	Guarantee a manufacturing tolerance of greater than 95%
Sterility	Not Sterile	N/A	N/A
Shelf Life	Comfort Layer 2 year shelf life Compression Layer 3 year shelf life	Bench Study	Pass

SAFETY AND SKIN TOLERABILITY (1)
All tests conducted according to GLP (good laboratory practice)
as described by the FDA (21CFR Part 58)and according respective EU standards

Parameter	Product Performance	Test Method	Results
Basic safety	Safe for intended use Coban 2 (Lite) compression systems are categorized as a surface devices having permanent (> 30 days) contact duration with breached or compromised surfaces. As such, the guidance suggests that cytotoxicity, sensitization, irritation, subacute/sub chronic toxicity, and genotoxicity studies be conducted on patient contacting materials.	ISO 10993-Part 1 (biological evaluation of medical devices- evaluation and testing) ISO 14971 (application of risk management to medical devices)	In compliance In compliance- All documentation completed
Basic safety/Skin irritation	Gentle to skin/Minimal irritation	ISO 10993-10 HCIPT (Human Cumulative Irritation Patch Test)	In compliance Pass
Skin tolerability	Weak sensitizing potential	Guinea Pig Maximisation Test (Magnussen Klingman)	0% of respondents
Comfortable to wear	Comfortable resting pressure	Pico Press sub bandage pressure measurement device	Comfortable resting pressure over 24h
Basic safety/ absence of toxic compounds	Contains No health hazard chemical compounds Free of: - PVC - Natural rubber latex - Colophony No antimicrobial compounds intentionally added.	ISO 10993-18 Biological evaluation of medical devices- Part 18: chemical characterization of materials Raw Material Information, Formulation, Composition, LCM Raw Material Information, Formulation, Composition, LCM	Negative- no health hazard compound materials were detected Confirmed Confirmed
Basic safety/ absence of Substances of Very High Concern	The substances of the REACH SVHC candidate list as of 15th June 2015 are not present at or above 0,1%	Raw Material Information, Formulation, Composition	Confirmed

PACKAGING RELATED INFORMATION

Packaging standards

Parameter	Product Performance	Norm	Status
Labeling information supplied by manufacturer	Legally correct labeling	EN1041	In compliance
Symbols used for labeling of medical devices	Legally correct symbols used	EN980 and ISO 15233	In compliance
Undesirable components of packaging	Free of substances of very high concern (SVHCs) in >0,1% in weight concentration	EC Regulation 1907/2006 (REACH) for any packaging article as described in directive 94/62/EC from the EU	Stated in supplier contracts
Undesirable components of packaging	Free of PVC (polyvinylchloride) Free of silica gel Totally Chlorine Free bleaching	3M internal standards	Stated in supplier contracts
Undesirable components of packaging	Sum concentration level of Lead, Cadmium, Mercury and Hexavalent Chromium not to exceed 100ppm (by weight)	Article 9 of EC directive 94/62/EC	Stated in supplier contracts

CERTIFICATIONS

Type of Certification	3M Company Certifications	Certifying Body	Results
ISO 13485 (Design, Development, Manufacture, Sales & Marketing and Distribution)	3M Neuss in Germany	Certified by DQS (CE0297)	Legal Manufacturer
ISO 13485 (Manufacture)	Kamen in Germany	Certified by DQS (CE0297)	Manufacturing Site

Additional information:

The information provided in this technical data sheet related to material content represents 3M's knowledge and belief as of the date it is provided, which may be based in whole or in part on information provided by suppliers to 3M.

This Technical Data Sheet is approved by 3M Regulatory Affairs:
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