Product Data Sheet

1.0 Name of the product	JOBST® Comprifore LF & JOBST® Comprifore lite LF
2.0 Product description	
2.1 Description *[RA]*	JOBST® Comprifore LF and JOBST® Comprifore® lite LF are multilayer compression bandage systems used for the management of venous leg ulcers and associated conditions. JOBST® Comprifore LF is designed to provide a compression pressure of 40 mmHg for the healing of venous leg ulcers for patients with an ABPI over 0.8. Comprifore® lite LF is designed to easier provide a reduced compression pressure for mixed leg ulcers for patients with an ABPI from 0.6 to 0.8. The JOBST® Comprifore LF system contains 4 bandages, whereas the JOBST® Comprifore lite LF system contains 3 bandages. The first padding layer (JOBST® Comprifore #1) is applied to protect bony prominences and to give a more cone-shaped form to the limb. The second layer (JOBST® Comprifore #2) is a crepe bandage applied for fixation of the padding and is followed by a third layer (JOBST® Comprifore #3 LF - not included in JOBST® Comprifore lite) consisting of an elastic long-stretch bandage. The last fourth layer (JOBST® Comprifore #4 LF) is a cohesive bandage used to keep all previous layers in place. The final compression pressure applied is the cumulative pressure of all the bandages combined. Since the pressure achieved depends mainly on the pressure applied during bandaging, the actual compression pressure must always be checked by a doctor and adapted to the individual needs of the patient.
2.2 Intended purpose *[RA]*	JOBST® Comprifore LF Sets multilayer compression bandage systems are used for the management of venous leg ulcers and associated conditions such as CVD, post-sclerotherapy, DVT, PTS prevention, and lymphedema.
2.3 Instructions for use *[MA]*	Yes

2.4 Warnings and precautions for use *[MA]*	• If the patient develops pain in the foot or toes, or cool, numb toes, the bandage should be promptly removed. • Very thin bony legs or legs with a prominent calf bone should be protected with extra padding. The pressure under the bandage could bruise and harm unprotected/unpadded skin especially over bony parts of the leg. • The risk of having arterial as well as venous disease rises with age. • Failure to detect significantly reduced arterial flow can result in pressure necrosis, amputation or even death. • In case of decreased arterial flow the bandaging should be performed by an experienced health care professional and pressure should be controlled after bandaging. • Open wounds must be covered with an appropriate dressing before compression bandaging. • Where the product is used on infected wounds the infection should be inspected and treated as per local clinical protocols. • Dependent on the amount of wound exudate and chosen wound dressing(s) wound drainage may soak through the bandages completely. This can happen during the initial phase of therapy. In this case, remove JOBST® Comprifore LF or JOBST® Comprifore lite LF and apply another. • Special cautions are required in case of cutaneous infection, weeping dermatosis, severely compromised skin sensibility, advanced peripheral neuropathy or impaired sensitivity of the limb (e.g. in diabetes mellitus). • The attending physician decides whether compression in general can be applied in patients suffering from the following diseases: rheumatoid arthritis, complex regional pain syndrome, CRPS (M. Sudeck), malignant lymphedema, gangrene. • Conditions in which increased venous and lymphatic return is not desired. • Medical compression garments should only be used after consultation with your doctor or therapist and checked regularly by them on the appropriateness of your therapy, also considering age and health status. Do not use if the package is already open or damaged as the sterility of the dressing is guaranteed only when the package is unopened and undamaged prior to use.

2.5 Indications and Contraindications *[MA]*	**Indications** JOBST® Comprifore LF and JOBST® Comprifore lite LF multilayer compression bandage systems are used for the management of venous leg ulcers and associated conditions. **Contraindications** JOBST® Comprifore LF or any similar compression bandaging system SHOULD NOT BE USED on patients with advanced peripheral arterial disease and an Ankle Brachial Pressure Index (ABPI) of less than 0.8. JOBST® Comprifore lite LF or any similar compression bandaging system SHOULD NOT BE USED on patients with advanced peripheral arterial disease and an Ankle Brachial Pressure Index (ABPI) of less than 0.6. Your physician or other licensed healthcare provider can determine the ankle brachial pressure index. An ABPI of less than 0.8 may mean that the ulcer may not be simply a venostasis ulcer. Compression bandaging of a leg which already has a partially blocked blood supply could completely stop the flow of blood into the leg and lead to the death of the skin and muscle of the leg. Death of the muscle and skin of the leg could lead to further complications and possibly amputation of the leg. JOBST® Comprifore LF and JOBST® Comprifore lite LF or any similar compression bandaging system SHOULD NOT BE USED on diabetic patients with advanced small vessel disease. Diabetics may have false ABPI due to calcification of peripheral arterial vessel. Always assess diabetics with additional clinical measures. JOBST® Comprifore LF and JOBST® Comprifore lite LF SHOULD NOT BE USED in case of uncontrolled congestive heart failure, untreated septic phlebitis or incompatibility to fabric.
2.6 Transport Precautions *[R&D/ Packaging]*	not applicable
2.7 Duration of application *[MA] Period of use*	A wearing period of up to 7 days is recommended. The product is single use only. That means it is only meant to be used for a maximum time of 7 days.
2.8 Information on reusable/ washable products (delete if not applicable) [R&D]	The product is single use only and not washable.

2.9 Composition
[drawing optional]
[including w%]

Can be done alphabetically in complex products. Source is spec (delivery or internal)

[R&D]

JOBST® Comprifore #1	JOBST® Comprifore #2	JOBST® Comprifore #3 LF	JOBST® comprifore #4 LF
natural absorbent padding bandage	light conforming bandage	light compression bandage (only available in JOBST® Comprifore)	flexible cohesive compression bandage
100 % viscose	70% cotton, 30% polyamide	88.5% viscose, 6.5% spandex, 5.0% polyamide	62.5% synthetic rubber compound, 35.3% polyamide/ polypropylene, 2.2% polyurethane

2.10 Product range
[Packaging] as described in PFD

Component	Components per folding box	Folding box per shipper	Product code	Product name
Jobst Comprifore # 1	1 pc	8	**72661-00005-01**	JOBST® Comprifore LF
Jobst Comprifore # 2	1 pc			
Jobst Comprifore # 3 LF	1 pc			
Jobst Comprifore # 4 LF	1 pc			
IFU	1 pc			
Jobst Comprifore # 1	1 pc	8	**72661-00007-01**	JOBST® Comprifore lite LF
Jobst Comprifore # 2	1 pc			
Jobst Comprifore # 4 LF	1 pc			
IFU	1 pc			

2.11 Sizing Chart *[Ortho and Compression] [R&D] (delete if not applicable)*

Dimension	JOBST® Comprifore #1	JOBST® Comprifore #2	JOBST® Comprifore #3	JOBST® comprifore #4
Length unstretched [m]	3.5	3	3.1	2.5
Length stretched [m]	Not applicable	4.5	8.7	5.25
Width [cm]	10	10	10	10

2.12 Storage conditions *[R&D]*	Dry, clean, and without exposure to direct sunlight. Max. storage condition: 30°C / 86F.
2.13 Shelf life/ Storage time *[R&D]*	The Supplier seeks to achieve a remaining shelf life of at least 2 years.
2.14 Sterilization *[R&D]*	Not applicable (non-sterile)
2.15 Reimbursement Information *(delete if not applicable) [commercial] e.g. HiMi, HCPCS, LPPR, PZN*	Not applicable
2.16 Key quality parameters *(delete if not applicable) Source is spec (delivery or internal, apply test standards e.g. RAL GZ, DIN 61632) [R&D]*	Compression system is inelastic according to definition of Hugo Partsch (SSI >10mmHg)

3.0 Chemical substances of special concern to Essity

Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link www.essity.com/gss

Deviations are covered in 3.1 Components.

3.1 Components *[R&D & Packaging]*

Raw materials used in product formulation

Substance	Included in formulation
natural rubber Latex	Not intentionally added
Lanolin and its derivatives	Not intentionally added
Colophony	Not intentionally added

Colophony derivatives	Not intentionally added
Bisphenol A (BPA)	No
Polyvinylchloride (PVC)	No
Methylmethacrylate	No
Butylacrylate	No
Microplastics (<5 mm)	No
Nanoparticles	No
Fragrance/parfum	No
Antibiotics	No
Triclosan	No
Chlorhexidine	No
Polyhexanide	No

Type of cotton used in the product: Standard Cotton

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	Yes (folding boxes) and partly in shippers

Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch *BSN medical GmbH* cannot provide proof of absence.

History

Version / Date	Page / Item	Description of Change
01 / 13.01.2022	All	Set up new document