



Two-Layer Compression System

INSTRUCTIONS FOR USE

Compression therapy is essential to improve the healing rates of venous ulcers and other lower limb lesions. Multi-layer high compression systems has been shown unequivocally to provide highly effective treatment for most patients with uncomplicated lower limb venous ulceration, oedemas and other indications.

Global Health and Safety Flexy/Two® multi-layer compression bandaging systems are mainly used for the management of venous leg ulcers, reduction of associated chronic venous oedema and other associated conditions.

I. Main Components

Ankle Size; 18-32 cm	Flexy ^{LAYER*1}	Flexy ^{LAYER*2}
Size	10 cm x 6.5 (stretched)	10 cm x 8.2 m (stretched)
Type	Padding compression bandage	Cohesive compression bandage with pressure indicator
Ref no	10037	10038
Material	91.8 % Polyester 8.2 % Elastane	85% Polypropylene 15% Elastane
Weight	108 g/m ² (+/-15)	48 g/m ² (+/-7)
Shelf Life	3 Years	
Latex Free	Yes	

II. Indications

Chronic Venous Diseases

Prevention and treatment of venous oedema. Prevention and treatment of venous skin changes, eczema and pigmentation, lipodermatosclerosis and atrophie blanche. Treatment of venous leg ulcers, varicose veins. Functional venous insufficiency (associated with obesity, jobs that involve sitting or standing). Venous malformations.

Thromboembolic Venous Diseases

Superficial venous thrombosis. Deep arm and leg venous thrombosis, post-thrombotic syndrome. Thrombosis prophylaxis in mobile patients.

Oedema

Lymphoedema. Oedema in pregnancy, post-traumatic oedema. Post-operative oedema. Post-operative reperfusion oedema. Idiopathic cyclic oedema. Lipoedema from stage II. Congestive states as a result of immobility (arthrogenic congestive syndrome, paresis, and partial paresis of the extremities) Drug induced oedema if not possible to switch.

Other Indications

Obesity with functional venous insufficiency. Inflammatory dermatosis of the legs. Congestive conditions in pregnancy.

III. Precautions and Contraindications

- Read the recommended application directions before using.
- The bandaging system should only be used after consultation with a doctor or specialist and checked regularly the appropriateness of the therapy.
- A full holistic assessment, including Doppler, should be carried out prior to application (refer to local guidelines).
- The Flexy Two Compression bandaging system is designed to be used in patients with and ABPI of 0.8 – 1.3.
- Should not be used on patients with an ankle brachial pressure index (ABPI) of less than 0.8, or on diabetic patients with advanced small vessel disease.

- The bandaging system should be performed by a trained, experienced health care professional and should be treated as per local clinical protocols.
- The system must be applied on intact skin only. Open wounds must be treated with an appropriate dressing before treatment.
- In case of peri-ulcer infectious dermatosis, treat infection before starting treatment with the compression system.
- If the patient develops pain in the foot or toes, or pale, cool, or numb toes, the bandage should be promptly removed.
- If the patient has a very thin ankle or very prominent tibial crest, care should be taken, and extra padding should be applied to these areas to prevent pressure necrosis.
- Failure to detect significantly reduced arterial flow may lead to further complications and may result in pressure necrosis, amputation or even death.
- The sub bandage pressure may bruise or harm unpadding skin especially over bony parts.
- May cause dry and itchy skin.
- The bandages of Flexy/Two® Bandaging System may be left in place for up to 7 days.
- Store in a cool dry place, away from sun light and heat.
- Single Use Only.
- Non-Sterile.

Other Contraindications

- Advanced peripheral arterial occlusive disease if any of the following parameters applies;

ABPI Ankle	Blood Pressure	Toe Blood Pressure	TcPO2
< 0.8	< 60 mmHg	< 30mmHg	< 20 mmHg instep

- De-compensated heart failure (NYHA III + IV)
- Septic phlebitis
- Phlegmasia coerulea dolens
- Severe exuding dermatosis
- Intolerance to compression material
- Severe sensory disturbances of the extremity
- Advanced peripheral neuropathy
- Primary chronic polyarthritis

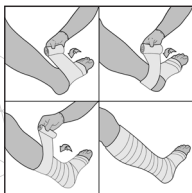
V. Recommended Application Directions

Before Bandaging

- Determine ABPI by using Doppler ultrasound testing and make certain the Ankle Brachial Pressure Index (ABPI) is above 0.8.
- Wounds must be cleaned and covered with an appropriate dressing before compression bandaging.
- Examine the shape of limb ensure the suitability for Flexy/Two kit and identify any areas at risk of excessive pressure including bony prominences.
- Measure the ankle circumference (Flexy/Two System can be used on patients between 18 to 32 cm ankle circumference).
- An ankle circumference may diminish during the treatment and may require additional padding.
- It is recommended to apply the compression kit after the patient's legs have been elevated for an hour to minimize any orthostatic oedema.
- It is recommended to wash and dry the leg and apply medical skin care to the unbroken and stressed skin before applying the Flexy/Two bandaging.
- Patient's foot should remain at a 90° throughout the application.

Application

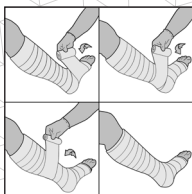
1. Flexy/Layer#1 - Padding Compression Bandage



Start applying Flexy/Layer#1 from the base of the toes (*metatarsophalangeal joint*). After two fixing turns guide the bandage over the back of the foot including the heel using figure of eight technique. Do not stretch or apply tension. Wrap the bandage using spiral technique around the leg above the ankle at full stretch and 50 % overlap to the knee (around 2 cm below the head of fibula). If necessary, cut off any excess bandage.

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2. Flexy/Layer#2 - Cohesive Compression Bandage



Start applying Flexy/Layer#2 from the base of the toes (*metatarsophalangeal joint*). After two fixing turns guide the bandage over the back of the foot including the heel using figure of eight technique. Do not stretch or use the guidance marker while applying the bandage to the foot. Wrap the bandage using spiral technique around the leg above the ankle at 50 % overlap to the knee. For optimal pressure, stretch the bandage until the marker displays a regular square shape with all sides at equal length (*see illustration*).

Following the application press down gently to ensure that bandage adheres to itself. If necessary, cut off any excess bandage.



Additional Information

- It may be necessary to adjust the application technique to suit the anatomical or pathophysiological characteristics of the patient.
- The application technique may need to be changed according to the medical prescription.

- During the application be sure that the bandages are evenly stretched and kept parallel in order to achieve even distribution of pressure and to avoid constriction.
- After application, check the toes, ensure of good circulation.
- During the treatment the patient should be encouraged to move to support the therapeutic effect.
- The bandage can be removed by unwinding or by cutting with the help of bandage scissors.
- During the therapy with Flexy / Two® system, bathing and showering should be avoided.
- If any serious incident has occurred while using this device, please report to national authority and to the manufacturer.

IV. Labelling Symbols

	Conformité Européenne		PP (Polypropylene)
	UK Conformity Assessed		Mobius Loop
	Medical Device		Keep away from sunlight
	Consult instructions for use		Upper limit of temperature
	Caution		Manufacturer
	Non-sterile		Use-by date
	Do not re-use		Catalogue number
	Keep dry		Batch code
	Authorised representative in the European Community		

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