

Flexy//TWO[®]

Global health  safety[®]

TWO LAYER COMPRESSION SYSTEM

LATEX FREE

**MEDICAL DEVICE CLASS I
PRODUCT CARD**

ENGLISH 

GHS_PC_10039_VSEP21

I. PRODUCT OVERVIEW

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 a safe and 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.



II. TECHNICAL SPECIFICATION

| | Flexy LAYER#1 | Flexy LAYER#2 |
|------------|--|--|
| Ankle Size | 18 - 32 cm | |
| Size | 10 cm x 6.5 m (stretched) | 10 cm x 8.2 m (stretched) |
| Type | Padding compression bandage | Cohesive Compression bandage with pressure indicator |
| Ref no. | 10037 | 10038 |
| Material | 85 % polyester, 8% elastane, 7% synthetic rubber | 62% polyester, 22% elastane, 16% synthetic rubber |
| Weight | 108 g/m ² (+/- 15) | 49 g/m ² (+/- 7) |
| Shelf Life | 3 Years | 3 Years |
| Latex Free | Yes | Yes |



III. 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;

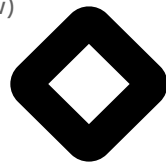
Flexy/Layer#1 - Padding Compression Bandage

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.



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 display a regular square shape with all sides at equal length. (See the illustration below)

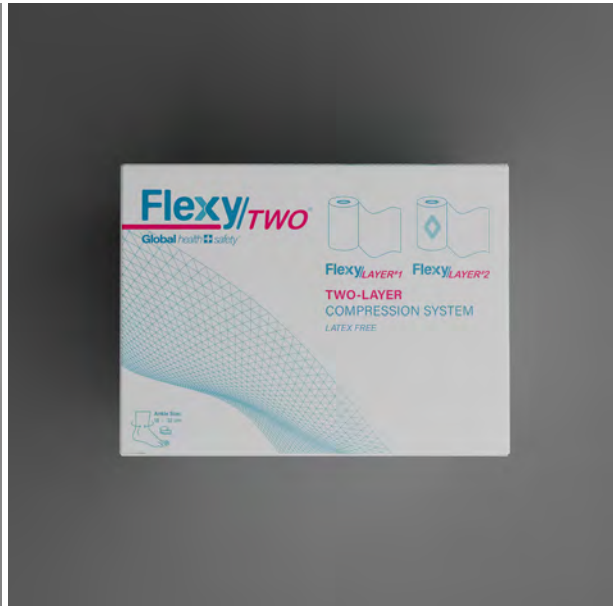


Following the application press down gently to ensure that bandage adheres to itself. If necessary, cut off any excess bandage.

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.
- Flexy Two Bandaging System may be left in place for up to 7 days.

IV. PACKAGING



V. WARNINGS

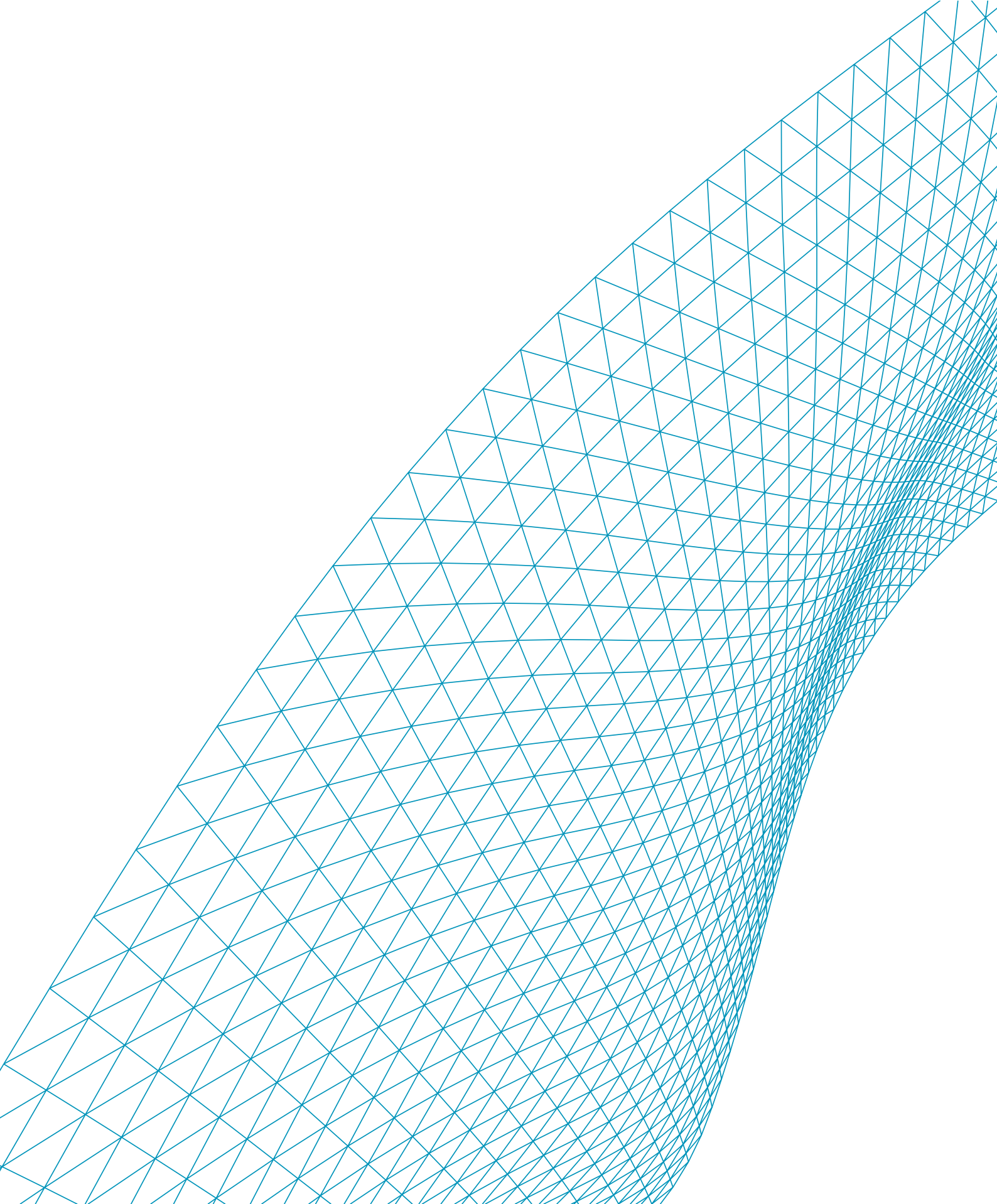
- Flexy Two system should only be used after consultation with a doctor or specialist and checked regularly
- the appropriateness of the therapy.
- The bandaging system should be performed by a trained health care professional.
- Flexy Two system is designed to be used in patients with and ABPI of 0.8 - 1.3.
- In case of peri ulcer infectious dermatosis, treat infection before starting treatment .
- If the patient develops pain in the foot or toes, or pale, cool, or numb toes, the bandages should be promptly removed.
- Failure detect significantly reduced arteriel flood may lead to further complications and may result in pressure necrosis amputation or even death.
- May cause dry and itchy skin.
- Read the recommended application directions before using.
- Single Use Only.
- Non - Sterile.

VI. STORAGE CONDITIONS

Store under ambient temperature and dry conditions. Avoid excessive heat.

VII. PACKAGING SYMBOLS





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