Dossier d'information Euro Pharmat

DISPOSITIF MEDICAL

Nom : Laboratoires 3M Santé
Dénomination commune : **Bande Cohésive Contention**
Nom commercial : 3M Coban avec ou sans latex, stérile ou non stérile

4. Conditions de conservation et de stockage	
	Conditions normales de conservation & de stockage : 10°C à 30°C avec 30 à 60% HR **Précautions particulières : non applicable** **Durée de la validité du produit : 5 ans dans des conditions de stockage normales** **Présence d'indicateurs de température s'il y a lieu : non applicable**
5. Sécurité d'utilisation	
5.1	**Sécurité technique** : le cas échéant, renvoyer à la notice d'utilisation ou notice d'information. Pour les DM implantables : passage possible à l'IRM, radiodétectabilité ?
5.2	**Sécurité biologique (s'il y a lieu) :**
6. Conseils d'utilisation :	
6.1	**Mode d'emploi : Annexe 2**
6.2	**Indications :** (destination marquage CE) **La bande 3M Coban est conçue pour la réalisation de compressions, de contentions ainsi que pour le maintien de pansements et attelles.**
6.3	**Précautions d'emploi :** Se rapporter à la notice en annexe (s'il y a lieu) - **Le coban avec latex ne doit jamais être mis :** **- sur un patient allergique au latex** **- directement sur une plaie ouverte.** - **Toujours dérouler 20 à 30 cm de bande avant d'être appliquée.** - **Doit être posée avec la tension souhaitée car la bande ne se détend pas après application.** - **Vérifier que la compression exercée est sans danger pour le patient(effet garrot) c'est à dire, qu'il faut vérifier que la peau est non décolorée, non refroidie, sans troubles sensitifs(fourmillement).**
6.4	**Contre- Indications : Ce produit n'est pas conçu pour d'autres usages que ceux indiqués.** Absolues et relatives. Se rapporter à la notice en annexe (s'il y a lieu)
7. Informations complémentaires sur le produit	
	Bibliographie, rapport d'essais cliniques, ou d'études pharmaco-économiques, amélioration du service rendu : recommandations particulières d'utilisation (restrictions de prise en charge, plateau technique, qualification de l'opérateur, etc) … : **Voir annexe 4**
8. Liste des annexes au dossier (s'il y a lieu)	

Laboratoires 3M Santé
Boulevard de l'Oise
95029 Cergy-Pontoise Cedex
Tél : 01.30.31.58.44
Fax : 01.30.31.85.51

Fiche Technique

3M™ Coban™

Marquage CE - Classe I non stérile

Bande de contention élastique cohésive avec ou sans latex

I - Indications

La bande élastique cohésive 3M Coban est une bande conçue pour la contention en traumatologie bénigne, en phlébologie, en médecine du sport, et pour le maintien de pansements ou de dispositifs médicaux.

II - Caractéristiques du produit

La bande 3M Coban est perméable à l'air et à l'eau, mais ne perd pas ses caractéristiques au contact de l'eau car elle est hydrophobe ; il existe une version stérile.

- **Composition :** ***(contient du latex)***

  - Fibres de polyester non tissées liées avec un copolymère acrylique.
  - Fibres élastiques longitudinales en spandex.
  - Substance cohésive à base de caoutchouc naturel et de composants spécifiques hypoallergéniques.

- **Caractéristiques physiques :**

  - Allongement : Longitudinal : 125%
Transversal : 24%
  - Charge minimale de rupture : Longitudinale : 1 430 g /cm
Transversale : 1 200 g / cm
  - M.V.T.R. : 7 000 g / m2 / 24 h

- **Tests de biocompatibilité :**

  - Présence de latex

- **Date d'expiration du produit et conservation :**

  - 5 ans dans des conditions de stockage normales soit une température moyenne de 10°C à 30°C, avec 30 à 60% HR.

- **Mode de stérilisation possible :**

  - La bande cohésive 3M Coban existe en version stérile.

Élimination des déchets :

- Incinération

- **Lieu de fabrication :**

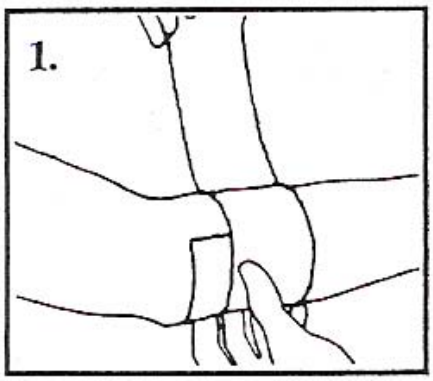
  - 3M Medical Manufacturing Kamen Germany, Edisonstrasse 6, 59157 Kamen Germany

III - Présentations commerciales :

- **Hôpital**

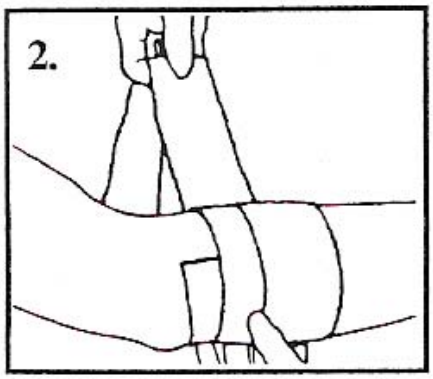
Identification	Code	Numéro d' identification	Largeur mm	Longueur m	Rouleaux /Boîtes
				étire	
Coban chair (brown)	1581	DH-9999-7880-1	25	4,5	30
Coban chair (brown)	1582	DH-9999-7881-9	50	4,5	36
Coban chair (brown)	1583	DH-9999-7882-7	75	4,5	24
Coban chair (brown)	1584	DH-9999-7883-5	100	4,5	18
Coban chair (brown)	1586	DH-9999-7884-3	150	4,5	12
Coban chair (brown)	1584 L	DH-9999-7885-0	100	6	18
Coban chair (brown)	1584 L	DH-9999-7898-3	100	6	128
Coban blanc (white)	1583 W	DH-9999-7887-6	75	4,5	24
Coban blanc (white)	1584 W	DH-9999-7888-4	75	4,5	18
Coban bleu (blue)	1581 B	DH-9999-7889-2	25	4,5	30
Coban bleu (blue)	1582 B	DH-9999-7890-0	50	4,5	36
Coban bleu (blue)	1583 B	DH-9999-7891-8	75	4,5	24
Coban bleu (blue)	1584 B	DH-9999-7892-6	10	4,5	18
Coban rouge (red)	1583 R	DH-9999-7893-4	75	4,5	24
Coban vert (green)	1583 G	DH-9999-7896-7	75	4,5	24
Coban vert (green)	1584 G	DH-9999-7897-5	100	4,5	18
Coban blanc (white)	6910	DH-9999-7921-3	50	4,5	200
Coban blanc (white)	6910	DH-9999-7926-2	75	4,5	200

Conseils D'Utilisation:



1. Dérouler environ 30 cm de bande et relâcher la tension de celle-ci.

2. Sans étirer la bande, effectuer un tour complet et recouvrir d'un second tour. Presser doucement la surface pour assurer une bonne tenue.



3. Poursuivre le bandage en maintenant la tension nécessaire pour obtenir la compression souhaitée. Toujours relâcher la bande après l'avoir déroulée avant de l'appliquer afin de ne pas exercer une tension trop forte.

4. Une fois l'application terminée, couper l'excédent de bande. Une légère pression de la main sur le bandage assure une bonne tenue.

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1: Lymphology. 2002 Mar;35(1):23-7. Related

Erratum in:
- Lymphology 2002 Jun;35(2):96.

Limb volume reduction after physical treatment by compress and/or massage in a rodent model of peripheral lymphedema

Kriederman B, Myloyde T, Bernas M, Lee-Donaldson L, Preciado S, Stea B, Summers P, Witte C, Witte M.

Department of Surgery, The University of Arizona, Tucson 85724-5063, lymph@u.arizona.edu

Lack of a standardized experimental counterpart of peripheral lymphedem small animal has hampered research into treatment of this debilitating cor recently refined a rodent model consisting of radical unilateral lymphatic/ excision in conjunction with a circumferential integumental gap, followe regional irradiation of the groin to reproduce stable unilateral hindlimb L current study, Wistar-Fuzzy rats with established right hindlimb LE, were subdivided into five groups and subjected to one of the following daily pl regimens over a 5-day period: pneumatic compression pumping at 30 torr low-stretch multi-layered compressive bandaging using Coban (CB); mar lymphedema drainage (MLD) or a light massage consisting of stationary motions using the fingertips; combined physiotherapy (CPT consisting of CB); and a no treatment or control group (CTRL). Hindlimb and LE volu serially measured before and after treatment. Whereas CTRL showed pro worsening of hindlimb swelling, PCP, CB, CPT and MLD each produced and substantial edema reduction over the 5 day interval, PCP, CB and CP vacillating edema reduction which, however, exceeded rebound swelling basis. MLD, on the other hand, showed a steady gradual daily decline in l

PMID: 11939569 [PubMed]

2: Clin Physiol. 1998 Mar;18(2):117-24. Related

Full text blackwell-synergy.com

Compression-induced pulsatile blood flow changes in human

Mayrovitz HN.

Miami Heart Research Institute, Miami Beach, Florida 33140, USA.

Initial and sustained (7-h) impacts of foot-to-knee compression bandagin arterial pulsatile blood flow were assessed by nuclear magnetic resonanc in eight healthy supine subjects. A widely used bandaging method (zinc i gauze + Coban) and a slight variant (Coban only) were applied one week one leg. Blood flow was measured on each day of bandage application be after bandaging and after 7 h of normal activity. Initial mean sub-bandag (lateral gaiter) were between 28.4 and 28.9 mmHg but were significantly after 7 h to 16.3-19.4 mmHg. Overall below-knee pulsatile blood perfusi initially significantly increased by both methods mainly due to increased blood flow. Bandaging was also associated with a decrease in blood perf nonbandaged control leg mainly due to a decrease in distal blood flow. N these effects were sustained after 7 h. The fact that neither sub-bandage p blood flow was sustained may indicate a causal linkage, a concept consis the finding of a linear relationship between afternoon blood flow and sub pressure reductions. The implications of the present findings for venous u therapy are speculative and based on the concept that arterial pulsatile flo augmentation is a positive feature. If so, more frequent bandage changes transient flow stimulation or use of bandages to better maintain sub-band pressure to sustain flow increases may be useful.

PMID: 9568350 [PubMed]

☑ **3:** Int J Dermatol. 1993 Apr;32(4):304-6. Related

Fibrin cuff lysis in chronic venous ulcers treated with a hydr dressing.

Mulder G, Jones R, Cederholm-Williams S, Cherry G, Ryan T.

Wound Healing Institute, Denver, Colorado 80014.

BACKGROUND. Pericapillary fibrin cuffs (PFC) are a recognized part c pathology of venous stasis ulcers. A hydrocolloid dressing capable of lysi surface fibrin was tested in venous ulcers for its capacity to lyse pericapil below the wound surface. METHODS. Tissue biopsies from the rims of 1 ulcers were evaluated for thickness of shallow and deep dermal PFCs bef after treatment with DuoDERM covered by Unna's boot and a compressi (DD+UB; n = 9) versus the same treatment without the hydrocolloid dres = 10). Frozen sections of all biopsies were stained with an immunofluore antibody to fibrin for rating of PFC thickness. Separate sections were stai hematoxylin and eosin to assess capillary frequency, histopathology, and inflammation. All ratings and pathology assessments were performed blir treatment conditions. RESULTS. Both deep and shallow PFCs were redu of ulcers treated with DD+UB versus 40% of ulcers treated with UB (alp No other significant differences in inflammation, histopathology, or capil frequency were observed. CONCLUSIONS. Treatment with DD+UB red in twice the number of ulcers than UB alone in 1 week. This is the first sc documentation that a topical wound dressing could reduce the pathophysi associated with venous ulcers, beyond the known beneficial effect of grac

compression. Not all hydrocolloid dressing are fibrinolytic, so this effect generalize to other dressings.

Publication Types:
- Clinical Trial

PMID: 8486467 [PubMed]

☑ **4:** J Vasc Surg. 1992 Mar;15(3):480-6. Related

Comment in:
- J Vasc Surg. 1992 Sep;16(3):500-1.

J Vasc Surg

A prospective, randomized trial of Unna's boot versus Duode hydroactive dressing plus compression in the management of leg ulcers.

Cordts PR, Hanrahan LM, Rodriguez AA, Woodson J, LaMorte WV Menzoian JO.

Section of Vascular Surgery, Boston University School of Medicine, MA

Leg ulcers caused by chronic venous insufficiency plague an estimated 5(Americans, but there have been few improvements in conservative treatm century, and Unna's boot continues to be a mainstay of therapy. A recent suggests that Duoderm CGF dressing provides greater patient comfort an compliance, but Duoderm alone (without compression) resulted in slowe compared with Unna's boot. We enrolled 30 patients (30 ulcers) in a clini compare Duoderm CGF plus compression (Coban wrap) to Unna's boot. significant difference was observed between the two groups with respect initial ulcer area, ulcer duration, or extent of venous insufficiency by dup Eight of 16 ulcers (50%) in the Duoderm group healed completely versus ulcers (43%) in the Unna's boot group (p = 0.18). Healing rates (square c per week) correlated significantly with initial ulcer area and initial ulcer p for both groups but best correlated with initial ulcer perimeter (r = 0.88 w Duoderm, p less than 0.0001; r = 0.80 with Unna's boot, p less than 0.002 adjusting for differences in initial ulcer perimeter, healing rates were sign faster for patients on Duoderm than patients on Unna's boot during the fir of therapy (0.384 +/- 0.059 cm2/wk/cm perimeter for Duoderm versus 0. 0.043 cm2/wk/cm perimeter for Unna's boot; p = 0.002). At 12 weeks pat Duoderm again appeared to heal faster than those on Unna's boot, althoug did not reach statistical significance (0.049 +/- 0.007 cm2/wk/cm perimet Duoderm versus 0.020 +/- 0.017 for Unna's boot, p = 0.11).(ABSTRACT TRUNCATED AT 250 WORDS)

Publication Types:
- Clinical Trial
- Randomized Controlled Trial

PMID: 1538504 [PubMed]

☑ **5:** J Ir Med Assoc. 1972 Jun 10;65(11):290-3. Related

The use of Coban bandages in compression sclerotherapy.

Kline AL, Fegan WG.

Publication Types:
- Clinical Trial
- Controlled Clinical Trial

PMID: 5030910 [PubMed]

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