Emergency Compression Bandage

Presentation, Catalogue and Certificate (FDA, CE, ISO and CDSCO)



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medihelpindia.in

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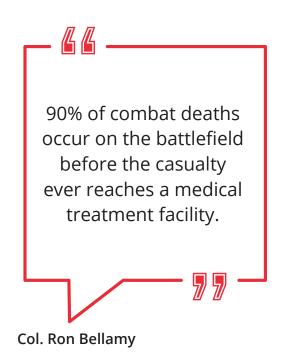
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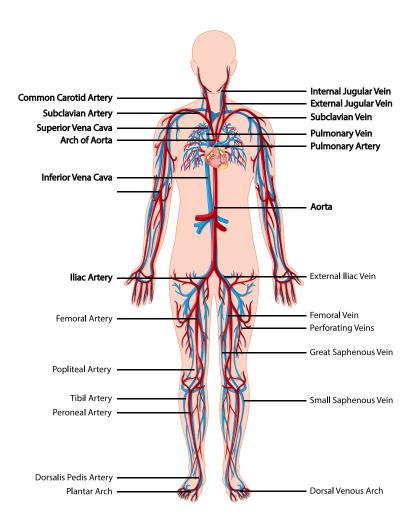
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Persys Medical Group Specializes in Manufacturing, Marketing & Distributing Innovative Lifesaving Medical Devices Worldwide Over 20 Years

WHAT IS HEMORRHAGE?

In medical terms, loss of blood from damaged blood vessels. A hemorrhage may be internal or external, and usually involves a lot of bleeding in a short time.







THE GOLDEN HOURE

In Emergency medicine, the Golden hour refers to a time period lasting from a few minutes to several hours following traumatic injury being sustained by a casualty, during which there is the highest likelihood that prompt medical treatment will prevent death.

Hemorrhage and Shock

What happens when you start to Bleed ?

Normal Adult Blood Volume is 5 Liter Hemorrhage is the quantity of blood loss from the normal that determins the criticality of the injured person.



Recognizing Shock

- Shock is defined as a failure to deliver adequate oxygen to tissues. In the case of blood loss this occurs both due to loss of blood volume and hemoglobin which carries oxygen in the blood.
- Adults have approximately 5 liters of blood.
- As blood loss increases, physiologic changes will become more prominent and more severe

Stages of Shock

Stages 1

- Loss of <15 %</p>
- Symptoms :-
- Normal BP
- Normal Heart rate
- Anxiety can be variable

Stages 2

- 15-30% volume loss (750-1500 ml)
- Symptoms and Signs:
- Elevated heart rate (> 100 BPM)
- Normal blood pressure
- Increased respirations
- Anxious or restless
- Mental status maintained



Stages 3

- 30-40% volume loss (1500-2000 ml)
- Systolic BP begins to fall but can be variable
- Pronounced heart rate increases > 120 BPM
- Pronounced increase in respiration >30 RPM
- Sweating and cool skin



Stages 4

- >40% Volume loss (>2000 ml)
- Symptoms and Signs
- Marked decrease in systolic BP
- Marked increase in heart rate >140 BPM
- Lethargy , loss of consciousness.
- Cardiac arrest

HISTORY

- First Care Products (FCP) was established in 1995 in Israel
- 1998 French & Belgian NATO Forces in Bosnia
- Golden Standard in military emergency car was established



Emergency Compression Bandage

Working with NATO & EU Leading militaries worldwide (USA, UK, Germany, France and many others) Saves time, saves costs, saves lives Fast and Easy to use by professional and non professional (and self use)



Special Features

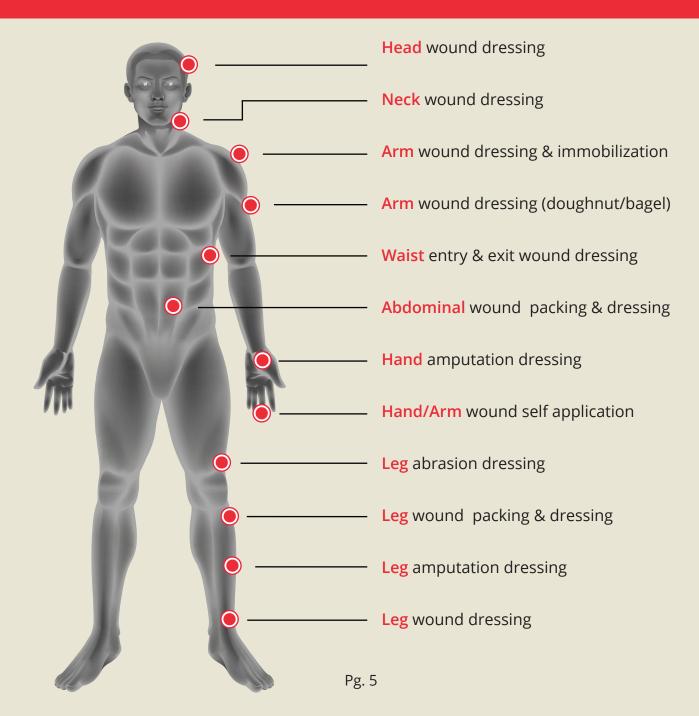
- Compact, Light-Weight, Waterproof, Vacuum-sealed packaging
- Simple to open
- Outer packaging (and nylon FCP09+) can be used as a sterile surface (e.g. as a work surface, exposed brain, to keep wound dry/rain)
- Pressure Bar
 - Immediate direct pressure to the wound site
 - Used to easily change directions
- Stop & Go Release
- Closure Bar, 'pen in a pocket'
- Loop self application

Available Bandages

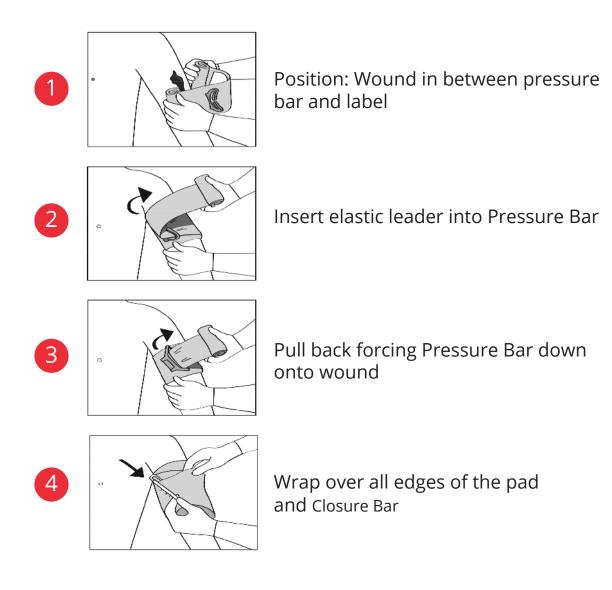
5 available FCP Emergency Bandages:

- FCP-01 10cm x 450cm (when stretched) Direct Pressure Dressing
- FCP-02 15cm x 450cm Direct Pressure Dressing x 450cm Direct Pressure Dressing
- FCP-05 15cm x 450cm Direct Pressure Dressing w/ 2nd mobile pad
- FCP-09 30cm x 600cm Abdominal/Large Area Wound Dressing, 'The Multi Bandage
- FCP-T3 4" (10.16cm) customizable bandage with expandable pad and additional

Areas to use the Emergency Bandage?



Bandage Application



Training Tips

- Work Close
- Ensure bandaging is done above and below PB to ensure pressure and sterility of wound
- Closure Bar Like a pen in a pocket one side is enough
- Blood on edges, use Additional Pressure (3 stages)
 - 1. Standard, if bleeding continues
 - 2. Optional: Single/candy twist, if bleeding continues
 - 3. Twists tourniquet effect

Summary

Applies immediate pressure on the wound to stop bleeding

Flexible - used on difficult wound sites

Increase pressure when needed (3 stages)

Can be used to change direction

Saves time, saves money, saves live



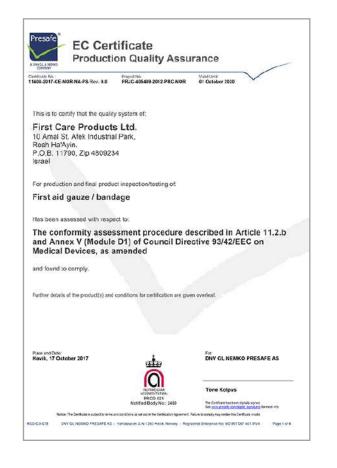




CERTIFICATIONS

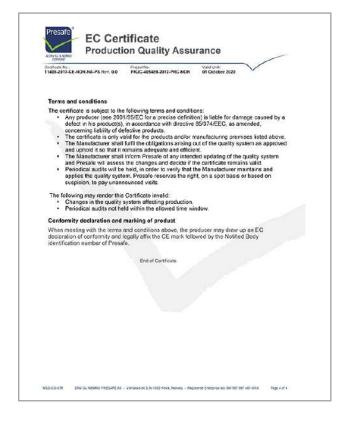




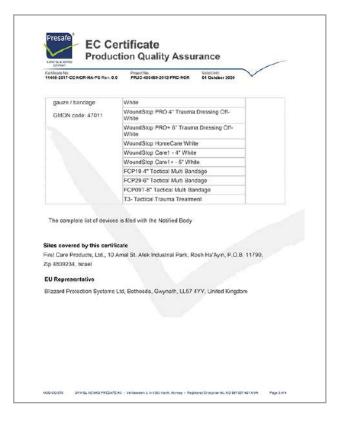








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Jurisdiction					
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Certificate his	lory:				
Revision	Description		Issue Date		
0.0	following tra	Replaces certificate EU 1009413 rev 3.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presate AS (NB 2460)			
Product Description		Product Name	Class		
Product Description		Product Name	Class		
		FCP01 - 4" Emergency Bandage Green			
		FCP02 - 6" Emergency Bandage Green			
		FCP03 - 4" Emergency Bandage White			
		FCP05 - 6" Emergency Bandage w/2nd Mobil Pad Green	9		
		FCP06 - 6" Emergency Bandage White			
First aid		FCP07 - 4" Emergency Bandage w/2nd Mobil Pad Green	¢:		
gauze / bandage GMDN code: 47D11		FCP09 - 8" Abdominal Emergency Bandage Green	IS		
		FCP10 - 8" Abdominal Emergency Bandage White			
		FCP11 - 4" Emergency Bandage w/2nd Mobile Pad White	9		
		FCP12 - 6" Emergency Bandage w/2nd Mobil Pad White	9		
		FCP09+ Multi Bandage Green			
		FCP10+ Multi Bandage White			









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Central Drugs Standard Com Directorate General of Hea Ministry of Health & Fam (Medical Device & Diagnost	FORM MD-15 [Sesub-rule (1) of rule 36] Licence to Import Medical Device Licence No. : IMP/MD/2020/00283				
(Medical Device & Diagnosti File No. : HQMD/2019/001507 To,	FDA Bhawan, Kotla Road New Delhi-110002 Phone No-011-23236965 Fax: 23236973	1. M/s ME New Delt	EDIHELP HEALTHCARE PVT. LTD., G-10 (Gr ii , New Delhi, Delhi (India) - 110019 Telepho o import the medical device(s) manulactured by	D., G-10 (Ground Floor) Apgarwal Bhawan, 35-36. Nehru Place, 19 Tetephone No.: 987155932 FAX: 911146055020 is hereby ulactured by overseas manufacturer having manufacturing site as	
 My MEDIHELP HEALTHCARE PVT. LTD., G-10 (Ground Floor) Aggarval Bhawan, 35-36, Nehra Place, New Delhi, New Delhi, Delhi (India) - 110019 Telephone: New SW1585932 FAX: 9111146052020 Sub:- Import Licence under the Medical Device Rules, 2017 thereu Sir, Import Licence vander the Medical Device Rules, 2017 thereu Sir, In per theorem No. JMPMID/20201002581 in beneby forsamled to you van for the time being in force and as such the licencely insuod under E and distinct from any licence(s) which may be necessary under Government of Italas, Ministry of Commerce. The import licencely methics of input (Jassev vill not accer import of Medical Devices covered by that / these licence(s) of nude Ministry separate licencely are required for import of such Medical Therefore, it is advised to obtain, where necessary licence(s) for the Ministry separate licencely on engine for import of such Medical Therefore, and advised to obtain, where necessary licence(s) for in trade Courted Regulations. Any literature or pucking accompanying the Medical Devices or provisions of the Drugs and Maga: Remedies (Digectionalbe Advis 1: The products and premises overed under this licence(s) are subject regained. 	which is subjected to the following conditions: der are in addition to and not derogation of any other law page and Connector and rule with the in addition to r the Import Trade Control Regulations made of the diringly to itself ' themselves be sufficient autority' for the Import Trade Control Regulations of the Commerce Devices. Import of Modeal Devices in question unior the Import ay matter stated on the Iabala should not contravene the tritement) Ad.	S.No 1 3. Details S.No 1 1	Generic Name :Surgical Dressings Brand Name(if registered under the Trade Ma Class of Madical Device :Class C Solars of Madical Device :Class C Shoft Life:8 years Shoft Life:8 years Shoft Life:8 years Intended to be used as a mechanical barrier, for for absorption of blood from open vounds. In ac bandage with an optional plastic barrier, making wounds and wounds requiring moisture contrain	Name and Address of Manufacturing Site Actual Manufacturing Site : M/s First Care Products Ltd., 40 Abu Yosil, Kfar Tuba-Zangariyye, 12310, Israel, Country: Israel Telephone No.: 97299517444 FAX: 97299517444 E-Mail : INFO@PERSYSMEDICAL.COM Device Details ints Act, 1999):Emergency Bandage atil Bandages and WoundStop Bandages are compression to increase hemorrhage control and ktition, The Multi-Bandages are a large sized it applicable for treating addominal/ozgosed organ ment at the wound site. ton and polyamide; Pad-fluff pulp and hydrophilic d Polyamide.	
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	 The authorised agent M/s MEDIHELP HEAL 35-36, Nehru Place, New Delhi . New Delhi 911146052020will be responsible for the buy resports. This licence is subject to the provisions of therein. Place: New Delhi CDSCO	I, Deihi (India) - 110019 T. ssines activities of the over I the Medical Devices Rules disc disc LSØ Central	elephone No.: 9871555932 FAX: seas manufacturer, in India in all		
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Saves time, saves costs, saves lives

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