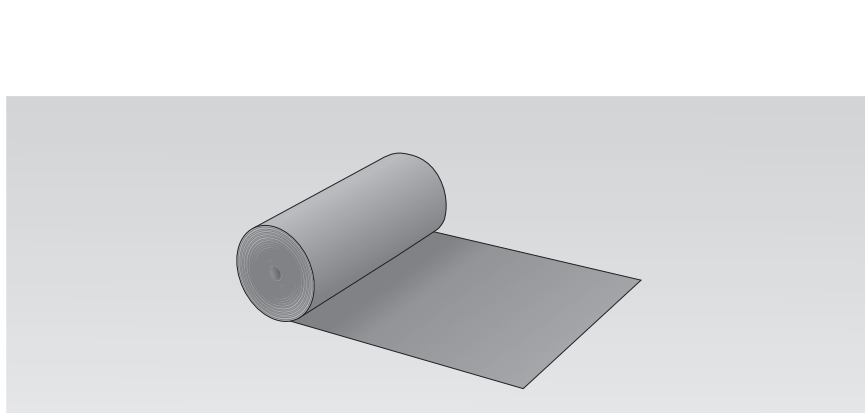


VBM Medizintechnik



Esmarch Bandage for single use

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VERWENDUNG/ZWECK
Die Esmarch Bandage wird zur Blutentleerung der oberen oder unteren Extremität eines Patienten vor der Anwendung einer Tourneiquet Manschette verwendet.
Klinischer Nutzen: Die Esmarch Bandage erzeugt in Kombination mit einer Tourneiquet Manschette ein blutleeres Feld. Patientenzielgruppe: Patienten, die eine Operation an der oberen oder unteren Extremität mit einer Tourneiquet Manschette benötigen.
Verwendungsort: Räume, die für chirurgische Eingriffe geeignet sind.
INDIKATIONEN
• Operationen im blutleeren Feld
Weitere Indikationen sind nicht bekannt.
KONTRAINDIKATIONEN
• Offene Frakturen der Extremitäten
• Schwere Quetschverletzungen
• Schwere Bluthochdruck
• Hauttransplantation - beeinträchtigte Durchblutung (z. B. periphere arterielle Verschlusskrankheit)
Weitere Kontraindikationen sind nicht bekannt.
SICHERHEITSHINWEISE
• Gebrauchsanweisung vor der Anwendung des Produktes sorgfältig lesen, beachten und zum späteren Nachschlagen aufbewahren.
• Das Produkt darf nur von einem Arzt oder von medizinisch ausgebildetem Personal unter Anleitung eines Arztes verwendet werden.
• Der Anwender und/oder der Patient muss alle im Zusammenhang mit dem Produkt aufgeführten schwerwiegenden Vorfälle dem Hersteller und der zuständigen Behörde des EU-Mitgliedsstaats melden (bzw. der zuständigen Behörde des jeweiligen Landes, wenn ein Vorkommnis außerhalb der EU eintritt), in dem der Anwender und/oder der Patient niedergelassen ist.
• Vor der Anwendung das Produkt einer Sichtkontrolle und einer Funktionskontrolle unterziehen (siehe Kapitel „Sichtkontrolle“). Ein mangelhaftes Produkt darf nicht verwendet werden.
• Maximale Anwendungsdauer: 15 min
Es dürfen keine Änderungen am Produkt vorgenommen werden.
• Das Produkt ist zum Einmalgebrauch bestimmt und darf nicht wiederverwendet und/oder aufbereitet werden. Die Funktion des Produktes wird durch die Aufbereitung beeinträchtigt. Eine Wiederverwendung birgt das Gefährdungspotenzial einer Infektion.
• Das Produkt ist steril (Ethylenoxid).

PREPARATION PRIOR TO USE
• Select suitable Esmarch Bandage.
VISUAL INSPECTION
• Check the packaging for damage.
• Check the product for damage.
• A faulty product must be disposed of (see "Disposal").
• The product is sterile (ethylene oxide).
• The product must not be used if the packaging is damaged or the expiration date has expired.
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VERBODINGEN VAN DE AANWENDING
• Geschikte Esmarch Bandage auswählen.
SICHTKONTROLLE
• Verpackung auf Beschädigungen prüfen.
• Produkt auf Beschädigungen untersuchen.
Ein mangelhaftes Produkt muss entsorgt werden (siehe Kapitel „Entsorgung“).
ANWENDUNG
Die Blutentleerung wird durch Hochhalten der Extremität unterstützt.
• Esmarch Bandage um die Extremität des Patienten, von distal nach proximal bis zur Tourneiquet Manschette wickeln (Bild 1).
• Tourneiquet Manschette belüften, um den Blutfluss zu unterbrechen.
• Esmarch Bandage entfernen.
LEBENSDAUER
Verwendbar bis: siehe Etikett des Produktes
LAGER- UND TRANSPORTBEDINGUNGEN
VORSICHT
• Vor Hitze schützen und trocken lagern.
• Vor Sonnenlicht und Lichtquellen schützen.
• In der originalen Verpackung lagern und transportieren.

ENTSORGUNG
Das gebrauchte oder mangelhafte Produkt muss gemäß den anwendbaren nationalen und internationalen gesetzlichen Regelungen entsorgt werden.
PRODUKTSPEZIFIKATIONEN

REF	20-21-060-1	20-21-080-1	20-21-100-1	20-21-150-1
Länge	365 cm	365 cm	365 cm	365 cm
Breite	6 cm	8 cm	10 cm	15 cm
Gewicht (inkl. Verpackung)	1160 g	1320 g	1760 g	2580 g
Verpackungseinheit	10	10	10	10

MATERIALDATEN
Polyisopren (IR)

EN ESMARCH BANDAGE FOR SINGLE USE
Instructions for use
The Esmarch Bandage is used to exsanguinate a patient's upper or lower extremity before using a Tourneiquet Cuff. Clinical benefit: The Esmarch Bandage creates a bloodless field in combination with a Tourneiquet Cuff. Patient target group: Patients who require a surgery at upper or lower extremities using a Tourneiquet Cuff. Place of use: Rooms which are suitable for surgical interventions.
INDICATIONS
• Surgeries in bloodless field
No other indications are known.
KONTRAINDICATIONS
• Open fractures of the extremities
• Severe crushing injuries
• Severe hypertension
• Skin transplant - impaired circulation (e.g. peripheral arterial disease)
No other contraindications are known.

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SAFETY INSTRUCTIONS
• Read and follow the instructions for use carefully, using the product and keep them for future reference.
• This product must only be used by a physician, or by medically trained personnel working under the instruction of a physician.
• The user and/or patient must report any serious adverse events that occurred in connection with the product to the manufacturer and competent authorities of the EU Member State (or report to the competent authorities of the country if an event occurs outside of the EU) in which the user and/or patient is located.
• Before use, the product must be inspected visually for damages (see "Visual inspection").
• A faulty product must not be used.
• Maximum application time: 15 min.
• No changes may be made to the product.
• The product is intended for single use and must not be reused and/or reprocessed.
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• A faulty product must not be used.
• Maximum application time: 15 min.
• No changes may be made to the product.
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ANVENDELSER
Fjernelsen af blodet fra ekstremiteten lettes ved at holde den oppe.
• Esmarch-bandagen vikles rundt om patientens ekstremitet, indtil den når punkt 1 (se figur 1).
• Beluft åndedrættet for at afbryde blodgennemstrømningen.
• Fjern Esmarch-bandagen.
LEVELID
Skal anvendes: for et enkelt brug på produktet
OPBEVARELINGS- OG TRANSPORTBETINGELSER
FORSIGTIG
• Skal opbevares på et tørt sted og beskyttes mod varme.
• Skal beskyttes mod sollys og skildris.
• Skal opbevares og transporteres i den originale emballage.
BORTSKAFFELSE
Det brugte eller defekte produkt skal bortskaffes i overensstemmelse med gældende nationale og internationale lovestemmelser.
PRODUKTSPECIFIKATIONER

REF	20-21-060-1	20-21-080-1	20-21-100-1	20-21-150-1
Længde	365 cm	365 cm	365 cm	365 cm
Bredde	6 cm	8 cm	10 cm	15 cm
Vægt (inkl. emballage)	1160 g	1320 g	1760 g	2580 g
Emballeringsenhed	10	10	10	10

MATERIALER
Polyisopren (IR)

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