GIMA
PROFESSIONAL MEDICAL PRODUCTS

# *BRACCIALI PER TOURNIQUET*
# *TOURNIQUET CUFFS*
# *BRASSARDS POUR GARROT TOURNIQUET*
# *MANGUITOS PARA TORNIQUETES*

**Manuale d'uso - User Manual - Notice d'utilisation - Manual del usuario**

***ATTENZIONE:*** *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto. -* ***ATTENTION:*** *The operators must carefully read and completely understand - the present manual before using the product. -* ***AVIS:*** *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit. -* ***ATENCIÓN:*** *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*

- È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.
- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.
- Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.
- Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

| GIMA | REF |
|---|---|
| **33113** | AVR-CUFF S012 |
| **33114** | AVR-CUFF S018 |
| **33115** | AVR-CUFF S024 |
| **33116** | AVR-CUFF S038 |
| **33117** | AVR-CUFF S044 |
| **33118** | AVR-CUFF 2XD026 |

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CE

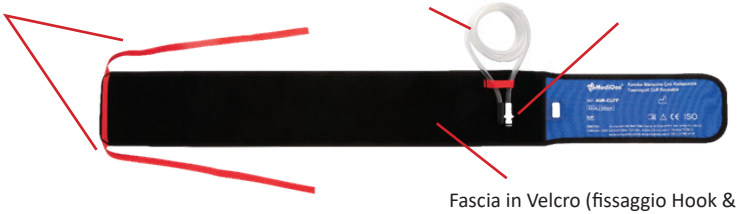
MD

M33113-M-Rev.0-04.25

Lacci di fissaggio (lacci di sicurezza)
Fastening Strap (Safety Strap)
Sangle de fixation (sangle de sécurité)
Correa de sujeción (correa de seguridad)

Tubo
Hose
Tube
Tubo

Connettore di collegamento del tubo
Hose Connection Connector
Connecteur de raccordement du tube
Conector de conexión de tubo



Fascia in Velcro (fissaggio Hook & Loop)
Velcro Band (Hook & Loop Fastener)
Bande Velcro (Fermeture Velcro)
Banda de velcro (cierre autoadherente)

# INSTRUCTIONS FOR USE (IFU)
# TOURNIQUET CUFFS

## 1. Product Description and Application
Tourniquet cuffs are medical accessories used in conjunction with automatic tourniquet devices. They are used to stop blood flow during surgical procedures, allowing for better visibility of the surgical site, reducing operation time, and minimizing blood loss.

## 2. Usage Conditions and Application
- Should only be used by trained medical personnel.
- The device must be compatible with single or dual-hose systems.
- Before use, the cuff should be tested up to 300 mmHg to check for any leaks.
- The cuff should be placed as proximally (closest to the body) as possible or at the widest diameter of the extremity.
- A gauze pad or protective sleeve should be used before applying the cuff.
- The cuff's tubes should be positioned either on the side or front.
- The cuff should be secured with a Velcro system and should not be too tight (there should be enough space for a finger to pass through).
- After securing with Velcro, a fastening strap (safety strap) should be tied over the cuff to prevent loosening.
- The cuff should overlap by at least 1/4 but should not exceed 1/2 of its width.
- To ensure venous drainage, the extremity should be elevated for at least 30 seconds before cuff inflation.
- Cuff pressure should be approximately 50-70 mmHg above the patient's systolic blood pressure, and about twice the systolic pressure for lower extremities.
- The maximum usage time is 120 minutes, with a recommended break of 20 minutes. In elderly and diabetic patients, this duration should not exceed 60 minutes.

## 3. Contraindications (Usage Restrictions)
- Peripheral artery disease, severe atherosclerosis.
- Sickle cell disease.
- Open fractures or areas with skin grafts.
- Severe traumatic injuries and circulatory disorders.
- Should be used with caution in elderly, diabetic, and alcohol-dependent patients.

## 4. Warnings and Precautions
- Improper positioning of the tourniquet cuff may result in nerve damage or paralysis.
- The tourniquet should not be twisted or folded on the skin.
- Excessively low or high pressure may cause intraoperative bleeding.
- Special caution is needed for patients at risk of vascular occlusion.
- After use, the cuff should be fully deflated before removal.

## 5. Sterilization and Maintenance
- Single-use cuffs should not be reused.
- Reusable cuffs should be inspected before each use, and any damaged cuffs should be replaced.

- Cuffs should not be autoclaved or sterilized at high temperatures.
- Mild disinfectant solutions should be used for cleaning, and the cuff should be thoroughly dried afterward.
- During storage, the cuff should be kept in a dry and cool environment.

## 6. Side Effects

- Pain, stiffness, and weakness in the extremity.
- Skin discoloration (reactive hyperemia).
- In rare cases, paralysis, vascular occlusion, or embolism.
- Severe adverse effects may occur in IVRA/Bier block procedures.

## 7. Model Variations

| Model Code | Size (Inches) | Size (Cm) ~ | Chamber Count |
|---|---|---|---|
| AVR-CUFF S008 | 8”L x 2”W | 20 cm x 5 cm | Single Chamber |
| AVR-CUFF S012 | 12”L x 3”W | 30 cm x 8 cm | Single Chamber |
| AVR-CUFF S015 | 15”L x 4”W | 38 cm x 10 cm | Single Chamber |
| AVR-CUFF S018 | 18”L x 4”W | 46 cm x 10 cm | Single Chamber |
| AVR-CUFF S024 | 24”L x 4”W | 61 cm x 10 cm | Single Chamber |
| AVR-CUFF S030 | 30”L x 5”W | 76 cm x 13 cm | Single Chamber |
| AVR-CUFF S034 | 34”L x 5”W | 86 cm x 13 cm | Single Chamber |
| AVR-CUFF S038 | 38”L x 5”W | 97 cm x 13 cm | Single Chamber |
| AVR-CUFF S044 | 44”L x 6”W | 112 cm x 15 cm | Single Chamber |
| AVR-CUFF 2XD014 | 14”L x 4”W | 36 cm x 10 cm | Dual Chamber |
| AVR-CUFF 2XD020 | 20”L x 6”W | 51 cm x 15 cm | Dual Chamber |
| AVR-CUFF 2XD026 | 26”L x 6”W | 66 cm x 15 cm | Dual Chamber |

For more information, please contact your authorized distributor or manufacturer.

**GIMA WARRANTY TERMS**
The Gima 12-month standard B2B warranty applies

**Indice dei simboli - Symbol index - Index des symboles - Índice de símbolos**

| | |
|---|---|
|  | **IT -** Data di fabbricazione **GB -** Date of manufacture **FR -** Date de fabrication **ES -** Fecha de fabricación |
|  | **IT -** Fabbricante **GB -** Manufacturer **FR -** Fabricant **ES -** Fabricante |
|  | **IT -** Dispositivo medico **GB -** Medical Device **FR -** Dispositif médical **ES -** Producto sanitario |
|  | **IT -** Numero di lotto **GB -** Lot number **FR -** Numéro de lot **ES -** Número de lote |
|  | **IT -** Codice prodotto **GB -** Product code **FR -** Code produit **ES -** Código producto |
|  | **IT -** Dispositivo medico conforme al regolamento (UE) 2017/745 **GB -** Medical Device compliant with Regulation (EU) 2017/745 **FR -** Dispositif médical conforme au règlement (UE) 2017/745 **ES -** Producto sanitario conforme con el reglamento (UE) 2017/745 |
|  | **IT -** Identificatore univoco del dispositivo **GB -** Unique device identifier **FR -** Identifiant unique de l'appareil **ES -** Identificador de dispositivo único **PT -** Identificador exclusivo do dispositivo |
|  | **IT -** Leggere le istruzioni per l'uso **GB -** Consult instructions for use **FR -** Consulter les instructions d'utilisation **ES -** Consultar las instrucciones de uso |
|  | **IT -** Attenzione - Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB -** Caution - read instructions (warnings) carefully **FR -** Attention - lisez attentivement les instructions (avertissements) **ES -** Precaución - lea las instrucciones (advertencias) cuidadosamente |
|  | **IT -** Distribuito da **GB -** Distributed by **FR -** Distribué par **ES -** Distribuido por |