Regulatory information

CE Marking	Index of classification	~~PHTALATES~~	~~LATEX~~
CE	I		

Manual pneumatic tourniquets are made up of :

Pressure gauge 0-300 mmHg with hand inflator
Disposable arm cuff and lower limb cuff without bladder.

The pressure gauge is graduated from 0 to 300 mmHg.

These devices are intended to be used in emergency situations, only once. However, the design of these devices is very reliable but adapted for a single use.

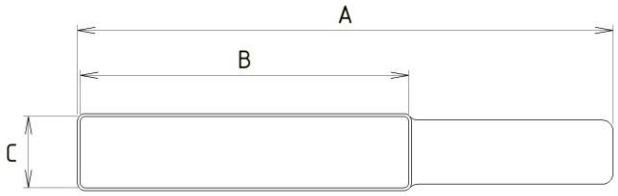
To minimize the risks associated with the installation of a tourniquet (pressure), the maximum pressure possible the device is limited to 300 mmHg, controlled by a mechanical valve.
The device is packaged individually – no sterile.

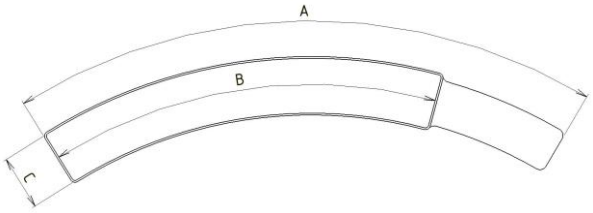
1 – Device identification

Manual tourniquet with disposable arm cuff

2 - References

Reference	Designation	Dimensions of bladders in cm		Overall dimensions in cm
		Lenght	Width	
GMBU01	Manual tourniquet arm cuff New born	29	3.5	48
GMBU02	Manual tourniquet arm cuff Child	35	4.5	48
GMBU04	Manual tourniquet arm cuff Adult	46	8	67
GMCU05	Manual tourniquet conical lower limb cuff Adult L	76	10	90
KGMBU1	Kit with : 1 x child, 1x adult, 1 x conical lower limb cuff adult L			





3 – Use of the device – Operating instructions

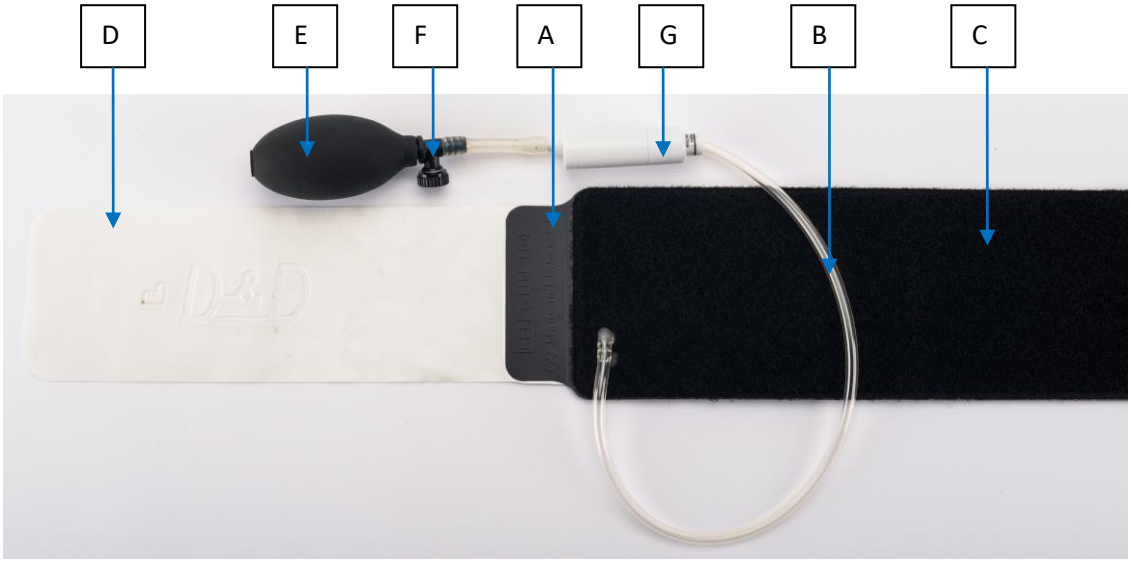
<u>Application of the arm cuff or lower limb cuff on the limb</u> :

- Before fitting the tourniquet:
  - check that the tourniquet to be fitted is of the correct size for the limb
  - check that the pocket of the tourniquet is sealed
  - check the quality of the Velcro and seams on the arm cuff / lower limb cuff

- Position the arm cuff or lower limb cuff by wrapping the device around the limb upstream of bleeding area.
- The device must be tightened up on the member prior to pressure.
- The maximum pressure must be greater than 100 mmHg with respect to the blood pressure of the patient.
- Without taking possible blood pressure, taking into account these indications on the labels of the devices.
- Secure the whole by making a knot with the ribbon.
- Record the date and time of tourniquet placed on the provided label
- The maximum duration of tourniquet use is one hour (référence : J-P Estèbe / Annales Françaises d'Anesthésie et de réanimation 25 (2006) 330 - 332)

4 - Identification and characteristics of different subsets

Identifier	Denomination	Characteristics
A	Arm cuff / lower limb cuff monobloc	Fabric Coating TPU latex free
B	Connecting tube	Medical PVC - FTA805RT100
C	Velcro	Loop High-Frequency welding Astrakan soudé
D	Velcro	Hook High-Frequency welding
E	Bulb	PVC phtalates free
F	Bulb's valve	ABS
G	Pressure gauge	ABS



5 - Cleaning and disinfection

Arm cuff and lower limb cuff are not to be reused, it is not expected protocol for cleaning and disinfection.

It is for the institution to ensure that the device is not used again after use. Reuse, reprocessing or re-sterilization may compromise the integrity of the device and / or contaminate it, which can lead to injury, illness for the patient.

6-Packaging

Reference	Packaging unit
GMBU02	1
GMBU04	1
GMCU05	1
KGMBU1	1

7 - Storage

Type of packaging	Storage area	Temperature	Humidity	Atmospheric pressure
Original packaging	Medically clean	-10° à 40° C	30 à 40 %	500 to 1060 hpA