

**MADE IN FRANCE** 

**Regulatory information**

CE Marking	Index of classification	Notified body	<del>PHTALATES</del>	<del>LATEX</del>
CE 0459	Ila	G-MED		

Simple and robust design, these pressures are economical. However the safety and reliability have been preserved :

- High quality technical fabric
- Presence of a pressure gauge used to control the pressure
- The transparent monofilament view window tear-proof to view the liquid
- Disposable

## 1 – Device identification

Visual face



Rear view



## 2 - References

Reference	Designation	Size	Dimensions in mm	
			Length	Width
M10500	Disposable pressure cuff	500 cc	250	162
M11000	Disposable pressure cuff	1000cc	365	170
M13000	Disposable pressure cuff	3000cc	338	235

### 3 – Use of the device - Operating instructions

Visual inspection : before use the medical device.

- On a horizontal plane, positioned under the transparent fabric, the pocket to press, output tubes oriented to pressure gauge.
- Insert the fastening system of pressure cuff in the opening of the pocket to be irrigated, before slipping into the opening made on the pressure cuff.
- Using the bulb, breathe the pressure required to maintain the cuff around the bag to irrigate, suspend all on a drip stand. Inflate the pressure cuff until the desired pressure (max : 300 mmHg). In case of exceeding pressure greater than 300 mmHg, the red zone will appear and the pressure will be regulated automatically.
- As to the flow of product irrigated, the pressure displayed by the pressure gauge falls gradually : it is necessary to restore order to ensure complete emptying of the liquid.

### 4 - Identification and characteristics of different subsets

Reference	Denomination	Characteristics
M10511	Pressure cuff only 500 cc	PU coated fabric+ polyamide monofilament
M10011	Pressure cuff only 1000 cc	PU coated fabric+ polyamide monofilament
M13011	Pressure cuff only 3000 cc	PU coated fabric+ polyamide monofilament
A55003	Pressure gauge	ABS
A55004	Bulb	PVC phthalates free
A10259	Valve bulb	ABS
A55005	Complete bulb	PVC phthalates free

### 5 - Packaging

Reference	Packaging units	Dimensions of the packaging in mm	Weight of the packaging (gr)
M10500	10	200X135X400	1126
M11000	10	200X135X400	1216
M13000	5	200X135X400	909

### 6 - Storage

Type of packaging	Storage	Temperature	Humidity	Atmospheric pressure
Original packaging	Ventilated area	-10° to 40 ° c	30 to 40 %	500 to 1060 hpA