

MADE IN FRANCE 

Regulatory information

CE Marking	Index of classification	Notified body	PHTHALATES	LATEX
CE 0459	Ila	G-MED		

1 – Device identification

The Grey Fuse pressure infusion cuffs are made from one set :

- robust design
- High quality technical fabric
- cleaning and decontamination facilities
- strap for hanging the pressure infusion cuff (on M25000 only)
- hook to keep the infusion bag on M25000 due of weight of fluid bags
- transparent fabric composed of a weft and a polyamide mesh allowing the solute bag to be seen.



2 – References

:

Reference	Designation	Size	Dimensions in mm	
			Lenght	Width
M20500	Monobloc pressure infusion cuff	500 cc	250	162
M21000	Monobloc pressure infusion cuff	1 000 cc	365	170
M25000	Monobloc pressure infusion cuff	3000 to 5 000 cc	561	350

Dessillons & Dutrillaux

Zone Industrielle La Tuque

Tél : +33 5 53 48 30 66

technique@ddmedical.fr

47240 CASTELCULIER

Fax : +33 5 53 47 24 64

www.ddmedical.fr

Date of first EC marking certificate:
2004

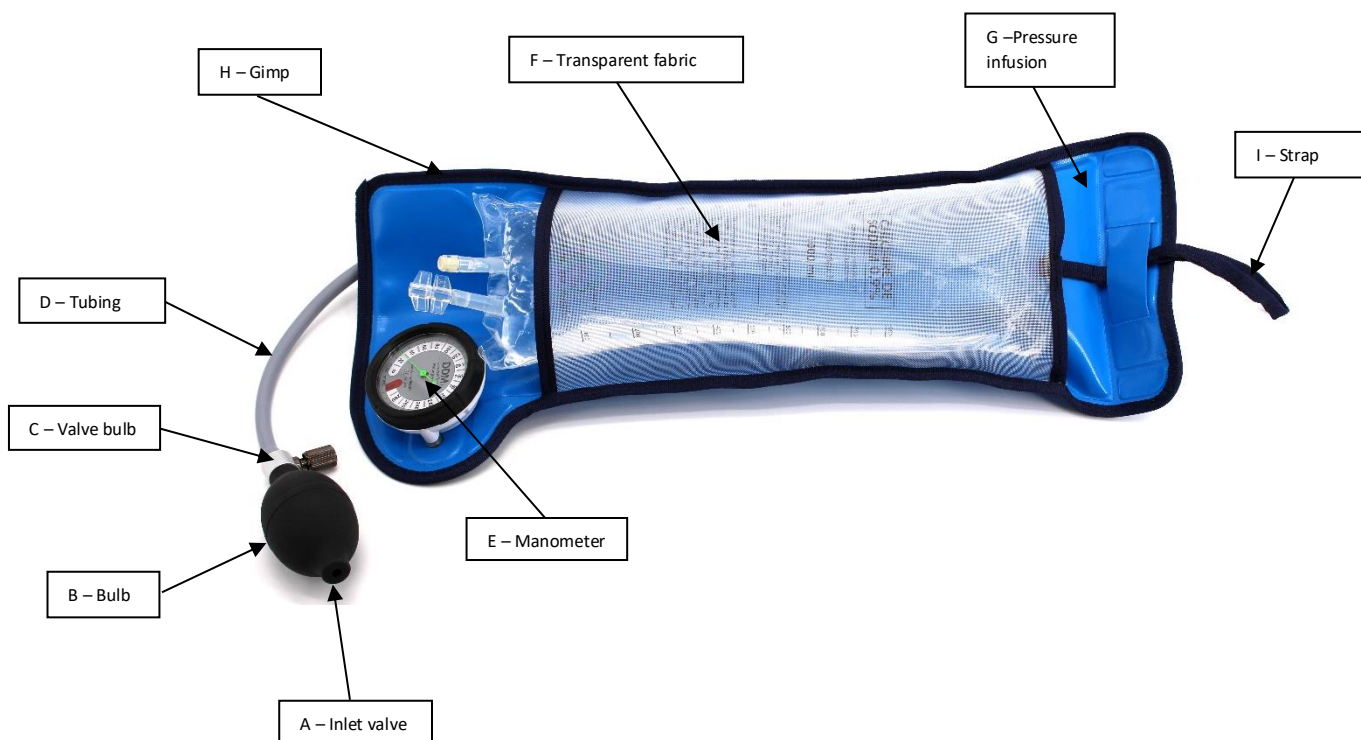
Page 1 / 4

3 – Use of the device - Operating instructions

Visual inspection: before use the medical device.

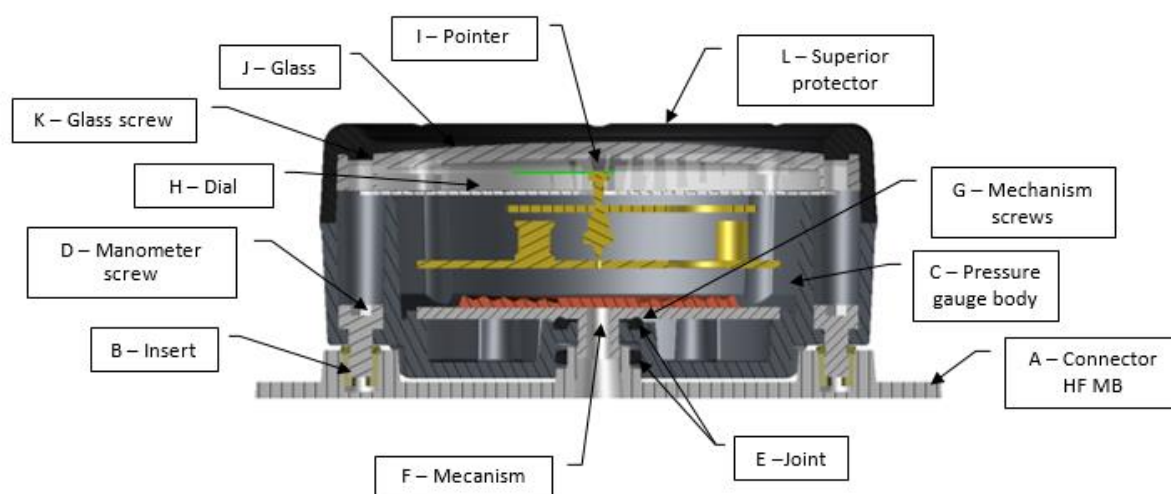
- On a horizontal plane, positioned under the transparent fabric, the pocket to press, output tubes oriented to pressure gauge.
- Insert the fastening system of pressure cuff in the opening of the pocket to be irrigated, before slipping into the opening made on the pressure cuff.
- Using the bulb, breathe 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.
- The decompression of the cuff is facilitated by the valve bulb.

4 - Identification and characteristics of different subsets



Identifier	Reference	Denomination	Characteristics
G	M20511	Pressure cuff only 500 cc	PU coated fabric+ poyamide transparent fabric
G	M20011	Pressure cuff only 1000 cc	PU coated fabric+ poyamide transparent fabric
G	M25011	Pressure cuff only 3000 - 5000 cc	PU coated fabric+ poyamide transparent fabric
E	A10808	Pressure gauge	ABS +glass PC + TPU
C	A10259M	Valve bulb	Aluminum and chromed brass
A-B-C	A10226M	Complete bulb + metal flow control valve	PVC phtalates free + metal
D		Tubing	PVC phtalates free
F		Transparent fabric	Polyamide
H		Gimp	Polyester
I		Strap	Polyester

Identification of the pressure gauge components:



5 – Cleaning and disinfection:

Surface cleaning	Disinfection with decontamination solution
Complete device	Complete device

6 - Maintenance:

Visual inspection / watertight: before each use.
Calibration test: every 12 months.

7 - Packaging

Reference	Packaging units
M20500	1
M21000	1
M25000	1

8 - Storage

Type of packaging	Storage area	Temperature	Humidity	Atmospheric pressure
Original packaging	Ventilated area	-10°C à 40 ° C	30 à 40 %	500 à 1060 hPa

9 - Warranty:

This warranty provides assurance for customer who purchases a D & D product that should the product fail to function to D & D published specifications during the term of this warranty, will either replace or repair.

The guarantee period is 2 (two) years from the date of purchase.

The product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.