

1 – Device identification

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

The pressure cuffs are medical devices used to pressurize, under control of a manometer, a bladder of product to be infused or transfused quickly.

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
- The transparent monofilament view window tear-proof to view the liquid

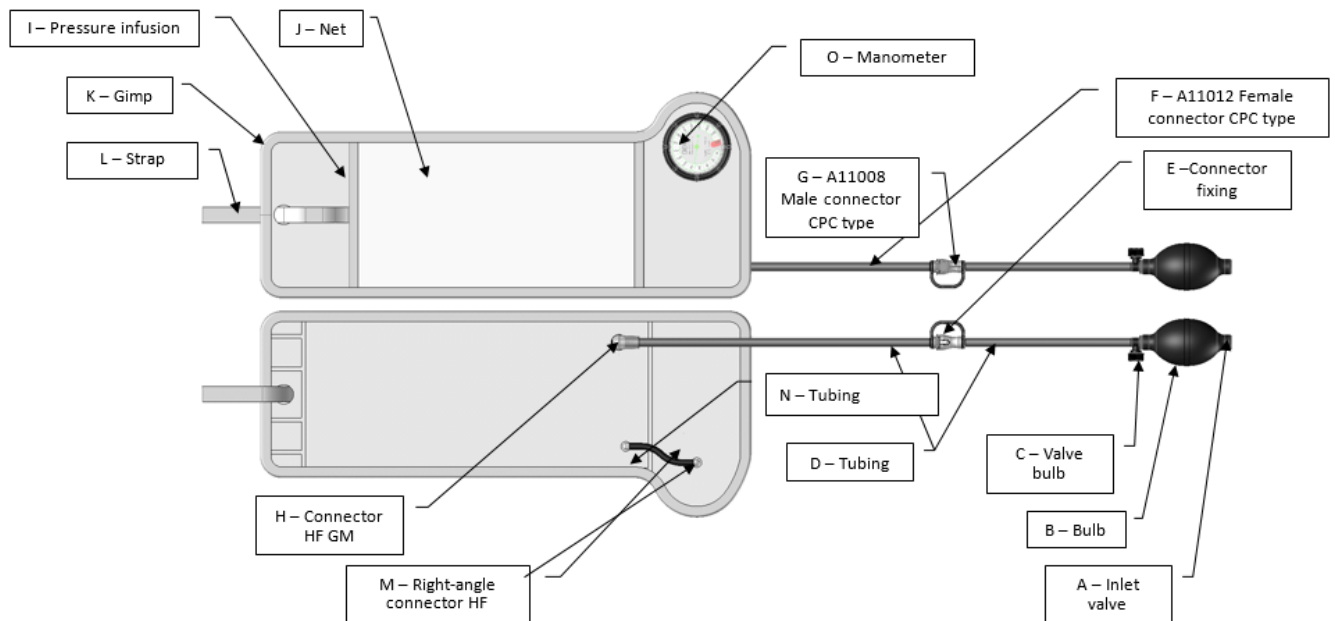


2 – References :

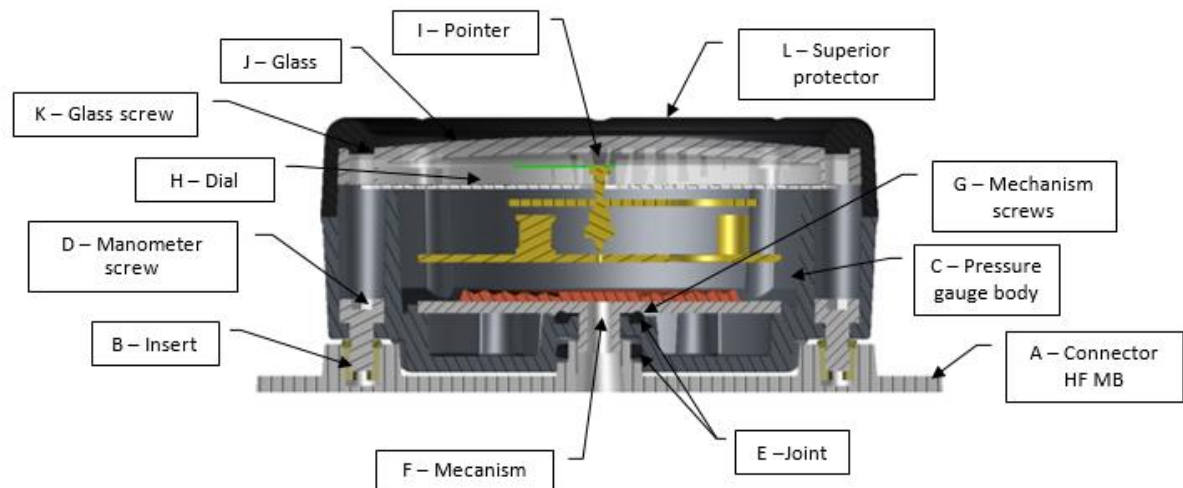
Reference	Designation	Size	Dimensions in mm	
			Lenght	Width
M20500	Monobloc pressure infusion cuff	500 cc	250	162
M21000	Monobloc pressure infusion cuff	1 000 cc	365	170
M25000	Monobloc pressure infusion cuff	3 000 to 5 000	561	350

3 – Technicals characteristics :

Identifier	Reference	Denomination	Characteristics
I	M20511	Pressure cuff only 500 cc	PU coated fabric+ poyamide monofilament
I	M20011	Pressure cuff only 1000 cc	PU coated fabric+ poyamide monofilament
I	M25011	Pressure cuff only 3000 - 5000 cc	PU coated fabric+ poyamide monofilament
O	A10808	Pressure gauge	ABS PC +glass PC + TPU
C	A10259	Valve bulb	ABS
A-B-C	A10226	Complete bulb	PVC phtalates free
F	A11012	Female coupler online fluted 4.8 mm	ACETAL
G	A11008	Male coupler online fluted 4.8 mm	ACETAL EPDM
E	A10130	Connectors fastener (A11012 + A11008)	TPU



Identification of the pressure gauge components :



4 – Operating instructions :

Visual inspection : before use the medical device.

- On a horizontal plane, positioned under the transparent fabric, the bladder 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 flaw 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 clip connectors.

5 - Maintenance :

- Calibration control of the manometer : every 12 months
- Visual inspection : before use the medical device.
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6 - Cleaning :

Surface cleaning	Disinfection with decontamination solution
Complete device	Complete device

7 - Storage conditions :

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

8 - Warranty :

This warranty provides assurance for the 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.

9 - Warning :

After several uses and for signs of damage to the mesh or tear the seams, it is recommended not to use the device.

This failure could result in a risk of complications for the patient.