

Pressure infusion cuff reusable Grey Fuse

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MADE IN FRANCE



Regulatory information

CE Marking	Index of classification	Notified body	PHTALATES LATEX
CE 0459	lla	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
- 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	3000 to 5 000 cc	561	350

Date of first EC marking certificate: 2004



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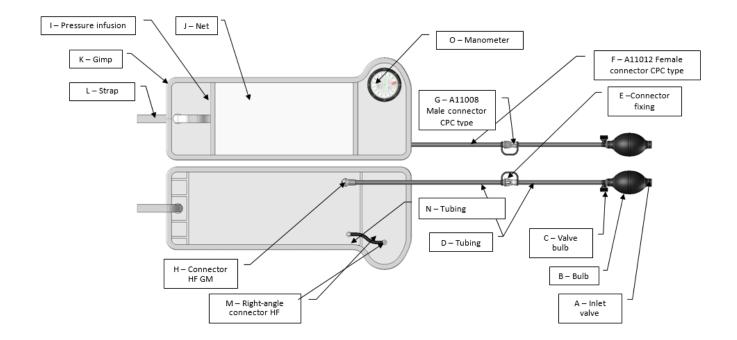
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3 - Use of the device - Operating instructions

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 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.

4 - Identification and characteristics of different subsets



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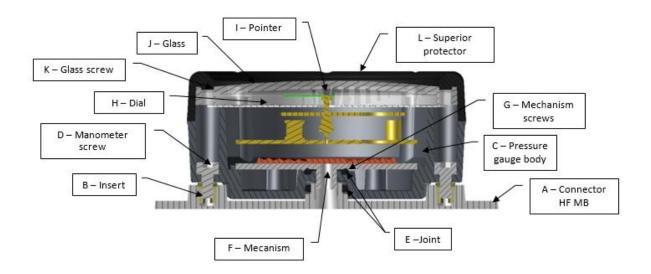


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Identifier	Reference	Denomination	Characteristics	
I	M20511	Pressure cuff only 500 cc	PU coated fabric+ poyamide monofilament	
I	M20011	Pressure cuff only 1000 cc	PU coated fabric+ poyamide monofilament	
I	M25011	Pressure cuff only 3000 - 5000 cc	PU coated fabric+ poyamide monofilament	
0	A10808	Pressure gauge	ABS PC +glass PC + TPU	
С	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	
Е	A10130	Connectors fastener (A11012 + A11008)	TPU	

Identification of the pressure gauge components:





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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, accident or improper handling.

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