Instruction for Use

PRESSURE CUFFS

GREY FUSE®, CLEAR FUSE® & EASY FUSE®

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FABRIQUÉ EN FRANCE

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Created in 1949 by Lucien Dessillons. Since its inception, DESSILLONS & DUTRILLAUX has been developing and manufacturing equipment for medical diagnosis, orthopedic surgery and medical resuscitation.

1. Summary

2. Device identification

The DDM pressure cuff is a non-sterile medical device consisting of an inflatable bladder, a pressure gauge or indicator and an inflation bulb.

It is a manual infusion accelerator, an accessory of the gravity infusion line. It compresses the flexible serum bag (pressure up to 300 mmHG) to accelerate the infusion rate.

It is used when gravity alone does not achieve desired flow rates.

GREY FUSE	**LATEX-FREE | REUSABLE | NOT STERILE | 3 SIZES**				
	**Reference**	**Size**	**Pocket dimensions in mm**	**UDI**	**Lifetime**
	M20500	500cc	250x162	3700468211518	2 years
	M21000	1000cc	365x170	3700468211501	
	M25000	3000cc	561x350	3700468207276	

CLEAR FUSE	**LATEX-FREE | REUSABLE | NOT STERILE| 3 SIZES**				
	**Reference**	**Size**	**Dimensions of the pocket in mm**	**UDI**	**Lifetime**
	M30500	500cc	220x191	3700468203933	2 years
	M31000	1000cc	333x222	3700468203940	
	M34000	3000cc	420x440	3700468206866	

EASY FUSE	**LATEX-FREE | SINGLE USE | NOT STERILE| 3 SIZES**				
	**Reference**	**Size**	**Dimensions of the pocket in mm**	**UDI**	**Lifetime**
	M10500	500cc	250x162	3700468203810	Disposable
	M11000	1000cc	365x170	3700468203841	
	M13000	3000cc	338x235	3700468203872	

- is class IIa .
- The lifetime is conditioned by the use of the device and the cleaning/decontamination cycles.
- Device intended to be used with other devices: the size of the cuff must be adapted to the size of the solution bag or blood bag (500 cc, 1000 cc, 3000 cc). The cuff/pocket assembly hangs from a bracket.
- For the single-use EASY FUSE cuff: The device must only be used if its original packaging is preserved, do not reuse.

3. Device Destination

<table>
<tr><td>Destination/indication</td><td>Indications: The manual infusion accelerator or pressure cuff is an accessory of the gravity infusion line.
It compresses the flexible serum bag (pressure up to 300 mmHG) to speed up the infusion rate.
It is used when gravity alone does not achieve desired flow rates.

The size of the cuff must be adapted to the size of the solution bag or blood bag (500 cc, 1000 cc, 3000 cc).

Performance :
This medical device belongs to the group of manual infusion accelerators.
The maximum pressure obtained is 300 mmHg .
As the solution bag empties, it is necessary to re-inflate the pressure cuff to maintain constant pressure.

Accuracy of measuring instruments:
Accuracy of ± 3 mm guaranteed over the entire measurement range for CLEAR FUSE and GREY FUSE pressure gauges</td></tr>
<tr><td>Area of use</td><td>For use by qualified healthcare professionals.
There is no specific target medical indication for these devices.
The most common medical uses are :
filling ,
transfusion (Limited to class I hemorrhages or in an emergency, pending assembly of the accelerator-heater)
when inserting an arterial catheter, in order to avoid reflux of arterial blood into the tubing.</td></tr>
<tr><td>Patient population</td><td>Infants, pediatric and adult patients</td></tr>
<tr><td>Users</td><td>Medical staff trained in intravenous injection technique.
User Profile:<table><tr><td>Occupation</td><td>IDE, IBODE, surgeon</td></tr><tr><td>Sex</td><td>M/F</td></tr><tr><td>Age</td><td>>18</td></tr><tr><td>Study level</td><td>Graduate studies in the medical field</td></tr><tr><td>Special knowledge)</td><td>Infusion technique training</td></tr></table></td></tr>
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4. Contraindication, complication and precautions

Contraindications	There are no known contraindications.
Complications	Side effect directly related to the cuff: none.
Precautions to take	**<u>Precautions to be taken before use:</u>** The size of the cuff must be adapted to the size of the solution bag or blood bag (500cc, 1000cc, 3000cc). Serum bags, blood bags and transfusers used with the pressure cuff must be designed to withstand a pressure of 300mm HG. Read the manufacturer's instructions. A check of the equipment is necessary before any use: visually check its general condition, and mainly the presence of the pressure gauge, the valve, and the inflation bulb. If the device has a malfunction (leak at the level of the bag, the manometer or the pressure indicator) it must not be used. It is necessary to verify the absence of air in the IV bag before using the pressure cuff. **<u>Precautions during and after use:</u>** If the device leaks, reinflate the cuff or change the device. Be careful not to puncture the cuff. For single-use cuffs: do not reuse. For reusable cuffs: follow the cleaning and disinfection instructions, check the device after disinfection.

5. Technical characteristics

	Cuff / materials	Pressure reading	Foot attachment system	Visualization of the liquid in the pocket
GREY FUSE	TPU coated fabric, HF welded	Graduated manometer 0 - 300 mmHg , Accuracy ± 3 mmHg	Wrist strap to hang the device on the infusion stand. Hook to hold IV bag on M25000 only	Transparent fabric composed of a weft and a mesh in polyamide allowing visualize the solute pocket.
CLEAR FUSE	Cuff made of TPU membrane by high frequency welding	Graduated manometer 0 - 300 mmHg , Accuracy ± 3 mmHg	Eyelet for hanging the device on the infusion stand. Hook to hold the IV bag	The device wraps around the pocket of liquid; visualization of the liquid by transparency.
EASY FUSE	TPU coated fabric, HF welded	Graduated pressure indicator 0 - 300 mmHg with a safety zone	Wrist strap to hang the device on the infusion stand and hold the solute bag	Transparent fabric composed of a weft and a mesh in polyamide allowing the solute pocket to be seen.

Subsets	EASY FUSE materials	Materials GREY FUSE	Materials CLEAR FUSE
Cuff only	PU coated fabric + polyamide monofilament	PU coated fabric + polyamide monofilament	Polyurethane
Pressure indicator	ABS		
Manometer		ABS PC + PC glass + TPU protector	ABS PC + PC glass + TPU protector
Pear	Phthalate-free PVC	Phthalate-free PVC	Phthalate-free PVC
pear faucet	ABS	Aluminum + chrome brass	Aluminum + chrome brass
Tubing	PVC	PVC	PVC
Female coupler		ACETAL	
Male acetal fitting		ACETAL-EPDM	
Clip connectors		TPU	
Clamp	Polyoxymethylene		
3-way valve	Polycarbonate + Polyethylene		
Ganse		Polyester	
hand strap		Polyester	

6. Maintenance and Calibrations (GREY FUSE and CLEAR FUSE)

Calibration of pressure gauges: every 12 months.
Calibration must be carried out by a duly authorized technician and using a verified and approved measuring instrument.

Before any calibration operation, the device must be decontaminated to avoid any risk of contamination with the operator.

List of spare parts : They must be replaced by a biomedical technician.

Denomination	GREY FUSE	CLEAR FUSE
Cuff only 500 cc	M20511	MS3050
Cuff only 1000 cc	M20011	MS3100
Cuff only 3000cc	M25011	MS3400
Manometer	A10808	A10807
Pressure gauge protector	PM50B	PM50B
pear faucet	A10259M	A10259M
whole pear	A10226M	A10226M

7. Device Use, Performance, Cleaning, Storage and Disposal

Manual	1. Visually check the general condition of the device before using it. 2. Position the bag to be infused in the cuff: Lying flat, position the bag to be infused under the transparent mesh, outlet tubes oriented towards the manometer. Slide the cuff strap into the opening of the bag to be irrigated, then into the passage made on the cuff. 3. Using the bulb, inject the necessary pressure to ensure that the pocket is held in the cuff. 4. Suspend the assembly on the infusion stand by the wrist strap. 5. Inflate the cuff until the desired pressure is obtained (max: 300 mmHg). 6. As the irrigated product flows, the pressure displayed on the pressure gauge gradually drops it must be restored to ensure complete emptying of the liquid. 7. At the end of the infusion, decompress the cuff using the bulb valve.
Essential performance	The cuff exerts pressure on the IV bag up to 300 mmHg without leakage. By regularly inflating the cuff, the pressure on the bag can be maintained until the bag is empty of solute. The cuff is compatible with all flexible infusion/transfusion bags on the market (pressure resistant).
Cleaning operation CLEAR FUSE and GREY FUSE range	Surface cleaning: Disinfection with disinfectant solution by spraying the entire device. (Disinfectant solutions without strong acid; type Anios spray or Surfa'Safe from ANIOS) The EASY FUSE range is for single use.
Safe disposal of the device	The medical device must be discarded after being decontaminated and following the practices in force in your establishment. It must be disposed of in a specific container DAOM (waste assimilated to household waste), DIB (ordinary industrial waste), DIV (recoverable industrial waste)
Storage	Ventilated room; Temperature: -10 to 40°C; Humidity: 30-40%; Atmospheric pressure. For the single-use device: keep it in its packaging.

8. Information in the event of a serious incident

Any serious incident occurring in connection with the device should be notified to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

9. Guarantee

Guarantee	DDM replaces or repairs any device that does not work as indicated in the instructions. The duration of this warranty is 24 months.
Warranty limit	The product must be used in accordance with the instructions and for the indications provided; it must not have been modified or accidentally damaged before use.

10. Symbols used

Information	Symbol
Maker	
Medical device	
Catalog reference	

Information	Symbol
Date of manufacture	
Lot	
Serial No	

Information	Symbol
Temperature limit	
Humidity limitation	
Atmospheric pressure limitation	

Information	Symbol
THIS	
Consult the instructions for use	
Single-use device