

MADE IN FRANCE 

Regulatory information

CE Marking	Index of classification	PHTHALATES	LATEX
CE	I		

These arm cuffs and lower limb cuffs of very robust design are composed of a single monobloc assembly, which facilitates their maintenance and decontamination. Owing to their impervious connector, it is possible to immerse them in a decontaminating solution. To ensure secure Velcro fixing, a ribbon to tie keeps the whole.

1 – Device identification

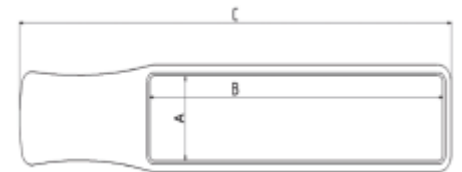
Illustration of the assembly



Optional fastening strap



Internal protection



A : Width of the bladder
 B : Length of the bladder
 C : Length overall



Cap on the tubing for easy cleaning


2 - References

Arm cuff with 1 bladder :

Reference	Optional : fastening	Designation	Color of tube	Dimensions in cm		
				A	B	C
GBDM101	GBDMS101	Cuff new born straight	White	3.5	29	38
GBDM102	GBDMS102	Cuff child straight	Pink	4.5	35	48
GBDM103	GBDMS103	Cuff small adult straight	Parma	6	46	61
GBDM104	GBDMS104	Cuff adult straight	Blue sky	8	46	67
GBCM105	GBCMS105	Conical cuff adult large	Turquoise	10	47	70
GCDM103	GCDMS103	Lower limb cuff adult straight	Yellow	8	76	97
GCDM104	GCDMS104	Lower limb cuff adult straight	Purple	10	62	76
GCDM105	GCDMS105	Lower limb cuff adult straight L	Green	10	76	90
GCDM106	GCDMS106	Lower limb cuff adult straight XL	Grey	10	82	100
GCDM107	GCDMS107	Lower limb cuff adult straight XXL	Red	10	107	122
GCCM104	GCCMS104	Conical lower limb cuff adult	Purple	10	62	76
GCCM105	GCCMS105	Conical lower limb cuff adult L	Green	10	76	90
GCCM106	GCCMS106	Conical lower limb cuff adult XL	Grey	10	82	100
GCCM107	GCCMS107	Conical lower limb cuff adult XXL	Red	10	107	122

Arm cuff with 2 bladders :

Reference	Optional : fastening strap	Designation	Dimensions in cm		
			A	B	C
GBDM204	GBDMS204	Cuff adult straight	6	46	67
GBDM202	GBDMS202	Cuff child straight	4.5	35	48
GCCM204	GCCMS204	Lower limb cuff adult conical	8	62	76

	TECHNICAL CHARACTERISTICS	CT 010
	Monobloc arm cuff and lower limb cuff	Index 19

3 – Use of the device – Operating instructions

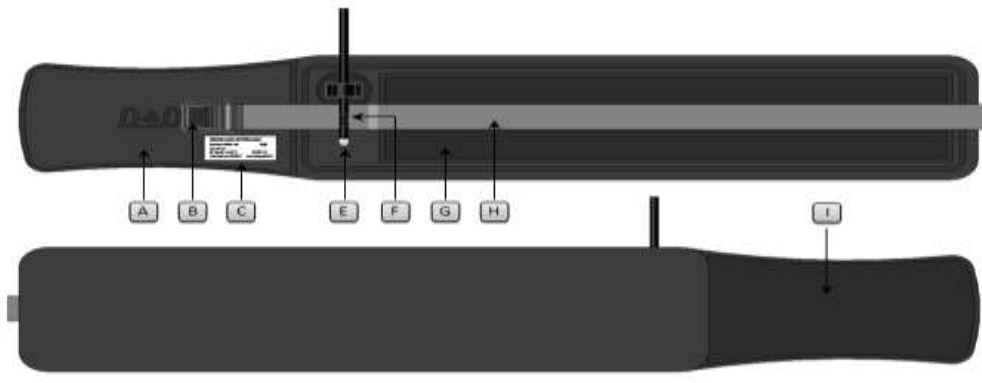
- Exsanguinate the limb using an Esmarch bandage or by elevating at 45° for 5 to 8 min.
- Before fitting the tourniquet:
 - check that the tourniquet to be fitted is of the correct size for the limb
 - check that the pocket of the tourniquet is sealed
 - check the quality of the Velcro and seams on the arm cuff / lower limb cuff
- Position the arm cuff or lower limb cuff on a protective bandage, previously applied on the skin of the limb on which the tourniquet is to be fitted.
- Secure the whole with by making a knot with the ribbon (or with fastening strap optional : secure the whole by fitting the strap into the buckle).
- Insert the connecting tube fully (click) in the quick coupler.
- Before applying pressure, pull gently on the tube to check for perfect connection of the 2 parts.

For more information, refer to the file "Use of monobloc arm cuffs and lower limb cuffs".

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4 - Identification and characteristics of different subsets

Identifier	Designation	Characteristics
A	Fabric	Coatings TPU
B	Buckle (optional)	ABS
C	Label	Refer "Label Informations"
E	Angled connecting tube	Molded PU , High-Frequency welding, angle 90 °
F	Connecting hose	Compound vinylique without phtalates 58 shore A
G	Velcro	Loop High-Frequency welding
H	Strap (optional)	Polyester
I	Velcro	Hook High-Frequency welding
J	Metal male connector with-O-ring A11008M	METAL
K	O-ring for connector A11322	EPDM


















Label informations :

Identifier	Designation
A	Manufacturer identification
B	Reference Product
C	Dimensions of the bladder
D	Batch number
E	Original product marking
F	Date of manufacture
G	CE marking
H	Reference to the manual



Connectors

Clip system connection with O-ring			
Reference	Design	Material	Designation
A11012		ACETAL	Female coupler online fluted 4.8 mm
A11016		ACETAL	Female end online fluted 4,8 mm with sealing valve
A11008M		METAL	Metal male coupler online fluted 4.8 mm
A11008		ACETAL EPDM	Male coupler online fluted 4.8 mm
A11010		ACETAL EPDM	Male end online fluted 4,8 mm with sealing valve
A11322		EPDM	O-ring for acetal male connector
A20001 A20006		SILICONE + ACETAL	Blue extension 3 m + male and female connectors Red extension 3 m + male and female connectors
A20003 A20005		SILICONE + ACETAL	Blue autoclavable, underwater extension 3 m + male and female connectors. Red autoclavable, underwater extension 3 m + male and female connectors.

Connection with clip system			
Reference	Design	Material	Designation
A11305		Chrome plated brass	Female connector with clip system
A11313		Chrome plated brass	Male connector with clip system
A11352		Chrome plated brass	Male / female with clip system
Standard luer lock connection			
Reference	Design	Material	Designation
A11312		Chrome plated brass	Luer lock female connection
A11311		Chrome plated brass	Luer lock male connection
A11354		Chrome plated brass	Male / female luer lock connection
A20021		Silicone	Extension 3 m + male and female connectors

5 - Cleaning and disinfection

Upon immersion of the device, take care to maintain the connector (on the tube) out of the water

N°	Step	Objective	Products used	Duration	Appropriate conditions	Instructions for use
1	Pre-treatment	Facilitate the cleaning step	ANIOSYME DD1	5 min	Dose of 25 ml to 5 liters of cold or lukewarm water	1-1 Prepare a dip tank
						1-2 Submerge the medical device keeping the tube out of the water
						1-3 Rinse with tap water
2	Cleaning	Pre-disinfection	ANIOSYME DD1	5 min	Dose of 25 ml to 5 liters of cold or lukewarm water	2-1 Prepare a dip tank
						2-2 Submerge the medical device keeping the tube out of the water
						2-3 Cleaning with a soft brush or towels
						2-4 Rinse with tap water
						2-5 Wipe with a clean towels
3	Chemical disinfection	Disinfection	STERANIOS 2 %	15 min	No dilution solution ready	3-1 Prepare a dip tank
						3-2 Submerge the medical device and cover the dip tank
						3-3 Rinse the device with sterile or filtered
						3-4 Wipe with a clean towels
5	Storage area	Conservation of the device to use new	Package for use in the operating room	6 months	Disposable packaging	Keep the medical device as aseptically as possible

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Page 6 / 7

6 - Packaging

Reference	Reference	Reference	Reference	Packaging unit
GBDM101	GBDMS101	GBDM201	GBDMS201	1
GBDM102	GBDMS102	GBDM202	GBDMS202	1
GBDM103	GBDMS103	GBDM203	GBDMS203	1
GBDM104	GBDMS104	GBDM204	GBDMS204	1
GBCM105	GBCMS105	GBCM205	GBCMS205	1
GCDM103	GCDMS103	GCDM203	GCDMS203	1
GCDM104	GCDMS104			1
GCDM105	GCDMS105	GCDM205	GCDMS205	1
GCDM106	GCDMS106	GCDM206	GCDMS206	1
GCDM107	GCDMS107	GCDM207	GCDMS207	1
GCCM104	GCCMS104	GCCM204	GCCMS204	1
GCCM105	GCCMS105	GCCM205	GCCMS205	1
GCCM106	GCCMS106	GCCM206	GCCMS206	1
GCCM107	GCCMS107	GCCM207	GCCMS207	1

7 - Storage

Type of packaging	Storage area	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.

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Page 7 / 7