1 – Device identification

CE Marking	Index of classification	~~PHTALATES~~	~~LATEX~~
CE	I		

.**Manual tourniquet with autoclavable arm cuff**

Manual pneumatic tourniquet is used in orthopaedic surgery in order to stop bloodstream on limb.

Manual pneumatic tourniquets are made up of :

Manometer 0-600 mmHg with hand inflator
Autoclavable arm cuff and lower limb cuff with silicone bladder.

The manometer is graduated from 0 to 600 mmHg with a graduated measuring range every 10 mmHg, and an accuracy of ± 5 mmHg.
The manometer made up of a membrane aneroid beryllium copper treated with quality watch-making mechanism.

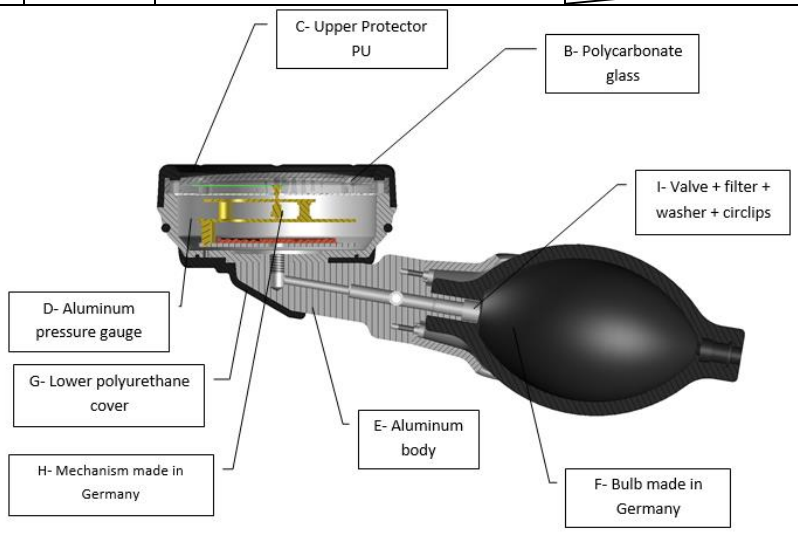
Owing to their special, robust design, it is possible to autoclave these arm cuffs and lower limb cuffs. They are composed of an envelope and a removable silicone bladder, makes it easier to maintain

2 - References

Reference	Designation
G20154	Manual tourniquet arm cuff/lower limb cuff New born
G20153	Manual tourniquet arm cuff Child
G20155	Manual tourniquet arm cuff Small Adult
G20152	Manual tourniquet arm cuff Adult
G20150	Manual tourniquet lower limb cuff Adult
G20151	Manual tourniquet lower limb cuff Adult L
G20156	Manual tourniquet lower limb cuff Adult XL
G20157	Kit manual pneumatic tourniquet

3 – Technicals characteristics

Identifier	Reference	Designation	Characteristic
B	A10362	Glass	Polycarbonate
C	A10363	Upper protector	Polyurethan
D	A10364	Pressure gauge	Aluminium
E	A10365	Body	Aluminium
F	A10226	Bulb	Phtalates - free PVC
G	A10366	Lower cover	Polyurethane
H	A10374	Mechanism 0-600 mmHg	Brass
I	A10368	Valve + filter + washer + circlips	



4 – Operating instructions

- Position the cuff or shorts on the limb:
  - Exsanguinate the limb using an Esmarch bandage or by elevating the limb at 45° for 5 to 8 minutes.
  - Before applying the tourniquet:
- Ensure that the tourniquet is the correct size for the limb (outside the operating field),
  - Make sure the tourniquet bag is watertight,
  - Check the quality of the Velcro system on the cuff/shorts,
  - Position the cuff or shorts on a sterile protective strip, previously applied to the skin of the limb to be tourniqueted.

- Connecting the cuff to the pressure gauge :
- Connect the pneumatic extension of the cuff or shorts to the connector on the manometer.

5 - Maintenance :

Control calibration every 12 months for the manometer.

6 - Cleaning :

Important: Before using for the first time and for any cleaning operation, remove the bag from its envelope.

PRE-DISINFECTION
Envelope: Immerse the envelope in disinfectant solutions suitable for textiles (detergents, decontaminants).
Pouch: Use disinfectant solutions validated for elastic materials. Do not use disinfectants containing components such as phenols or alkylamines (do not immerse the pouch).

CLEANING

Envelope: Wash the envelope by hand, or in a machine at 40°, in the closed position (to prevent different envelopes from sticking together).
PH-neutral detergents are recommended for cleaning.
Rinse and dry. Machine drying is not recommended.
Pouch: Wash the pouch by hand without letting water penetrate through the end of the connector.
PH-neutral detergents are recommended for cleaning. It is essential to rinse the devices thoroughly with demineralised water to remove residues of disinfectants and detergents (do not immerse the bag).
Rinse-Dry.

AUTOCLAVABLE
The repackaged envelope and pouch are autoclavable (up to 100 cycles).

Autoclave at 134° for 18 minutes; the presence of detergent or disinfectant residues may cause the silicone elastomer and the fabric to harden or deteriorate.

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 Spengler product that should the product fail to function to Spengler published specifications during the term of this warranty, will either replace or repair.

The warranty 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- Materiovigilance

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

Symbols used:

MD	Medical device	Packaging label
REF	Product catalogue	Packaging label
LOT	Batch number	Packaging label
	Manufacturing date	Packaging label
CE	Medical device compliant with European regulation in force	Packaging label
	Manufacturer: Spengler SAS 30 rue Jean de Guiramand 13290 Aix-en-Provence-Fr	Packaging label
	Consult instructions manual	Packaging label
	Atmospheric limitation	Packaging label
	Temperature limitation	Packaging label
%	Humidity limitation	Packaging label