Device Description and Specification, including Variants and Accessories

Device Description and Specification

1.1.1. Product Name

Pneumatic tourniquet cuff

1.1.2. General Device Description

The Pneumatic tourniquet cuff is composed of prickly surface adhesive belt, hairy surface adhesive belt, air pipe, air seat, belt body, streamer, TPU film, PE plate.The Pneumatic tourniquet cuff mainly used for patients with limbs operation, does not apply to femoral artery hemostasis. The product is controlled by the air pressure of the tourniquet cuff, blocking blood flow to get the purpose of hemostasis.

1.1.3. Product Pictures

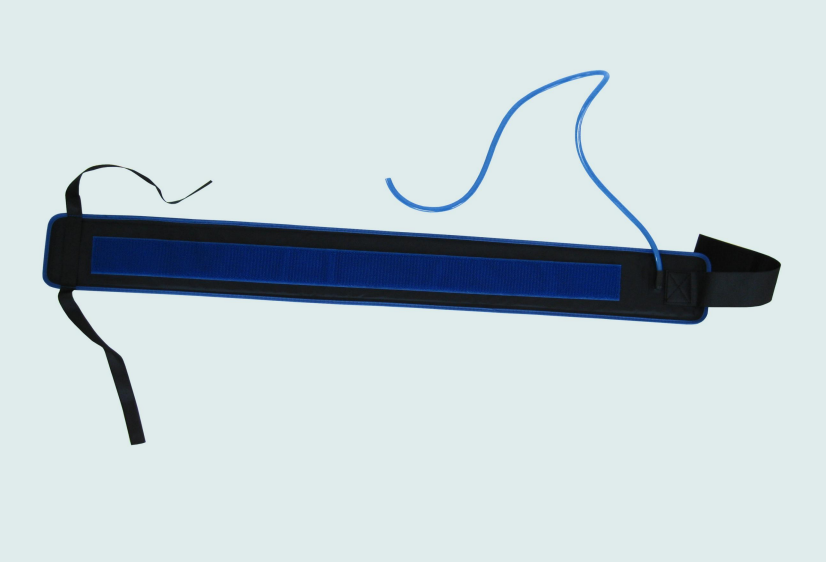


Diagram of Pneumatic tourniquet cuff-1



Diagram of Pneumatic tourniquet cuff-2

1.1.4. Raw materials and Supplier information

Materials Name	Manufacturer	Address
HDPE board	Nanjing HeTai Plastic Products Co., Ltd	No. 11 Jiuci Road, Nanjing, Jiangsu Province
Transparent TPU membrane	Xionglin New Material Technology Co., LTD	Nanya Village Industrial Zone, Daojiao Town, Dongguan City
Carton	Sanwa Packing Co., LTD	Tiantai County Tiantong Road
Nylon compound TPU membrane	Zhejiang Yousheng Composite Fabric Co., LTD	Building 1, No.183, Hengxing Road, Weitang Street, Jiashan County
Sticking band	Wuxi Baihe Weaving Co., LTD	No.18, Hexin Road, Xishan Economic Development Zone, Wuxi city
Transparent TPU tube	Fenghua Xikou Hemei Plastic Industry Co., LTD	No.21, Yongan Road, Xikou Industrial Zone, Fenghua City
Air mouth, Air seat	Yuyao City Wenyun Hardware Factory	Yuyao City, Sanqi Town, Happy Village

1.1.5. Basic Unique Device Identifier and SRN

Basic-UDI：697521819TF01MA

SRN：CN-MF-000018938

1.1.6. Intended Purpose

The Pneumatic tourniquet cuff mainly used for patients with limbs operation, does not apply to femoral artery hemostasis. The product is controlled by the air pressure of the tourniquet cuff, blocking blood flow

to get the purpose of hemostasis.

1.1.7. Contraindications

None.

1.1.8. Cautions

1.The product should be stored in clean environment with non-corrosive gases and good ventilation.

2.Inspect the device and package before opening. Do not use the product if any damage is noted.

3.Do not inflate the cuff before wrapping around the limb.

4.Wrap the cuff around the patient’s limb more than a circle, otherwise the tourniquet cuff will not work properly.

5.A too high pressure will cause limb tissue necrosis, and will result in the patient having pain.

6.The cuff tubing should be positioned on or near the lateral part of the extremity to avoid pressure on nerves and kinking of the tubing.

7.Do not use the cuff when airleak happens in connecting with the automatic tourniquet system.

1.1.9. Qualification of the Product as a Device

The principle, intended use, structure and materials of all models and specifications are the same. The difference is the size.The difference in size does not affect the safety and effectiveness of the product.Therefore, all models and specifications belong to one product family and can be used as a medical device to evaluate and analyze.

According to Annex II + Annex III of Medical Device REGULATION (EU) 2017/745, the product is a medical device.

1.1.10. Risk Class of the Device

According to classification requirements in ANNEX VIII of Medical Device REGULATION (EU) 2017/745:

The Pneumatic tourniquet cuff’s correctly classified is class Is, rule 1.

1.1.11. Conformity assessment

Annex II＋Annex III

1.1.12. Novel Features / Changes to Predecessor

The Pneumatic tourniquet cuff has similar functions with the products already on the market, and there is no Novel Features / Changes to Predecessor.

1.1.13. Accessories and Device Combinations

NA.

1.1.14. Technical Specifications

1.Physical property

1.1 Appearance

1.1.1 The stitching foot of the tourniquet body should be controlled at 2.5 stitches /cm. The stitching must be uniform and there is no floating wire jumper.

1.1.2 The edge is uniform and the wool button is basically the same color.

1.1.3 The distance between the left and right sides of the horizontal bar should not be greater than 0.5cm.

1.1.4 Clean surface, no stains, no damage.

1.2 Dimension

The length of the trachea should not be less than 900 mm, and the connecting parts matching the hemostat should be provided.The size of the belt body should meet the requirements.

1.3 Air nozzle

The four sides of the air nozzle and the belt body are connected by high frequency heat sealing to ensure that the heat sealing is firm and without damage.

1.4 PE Board

PE plate should be able to roll round and not break.

1.5 Connection firmness

The joints of the tourniquet should be able to withstand 25N static tension, and should not break and fall off for 30 seconds.

1.6 Peel strength

The stripping force of the adhesive strap of the tourniquet should not be less than 10N after adhesion.

1.7 Pressure bear

The inner cavity of the tourniquet can withstand 0.12MPa gas pressure for 60 seconds without leakage, and should be able to withstand 350N static external pressure for 30 seconds without rupture.

2.Chemical properties

2.1 Sensitization

Tourniquet skin sensitization should not be greater than grade I.

2.2 Stimulation

Tourniquet skin irritation index should not be greater than 1.0.

2.3 Initial contamination bacteria

The initial contaminated bacteria should be less than 10cfu/g.

2.4 Pathogenic Bacteria

Tourniquet should be free of pathogenic bacteria.

3. Ethylene oxide residue

When the product is disinfected by ethylene oxide, the EO residue is not more than 4mg, and the ECH residue is not more than 10mg.

1.1.15. Shelf Life

3 years.

1.1.16. Sterilization Method

Sterilized by EO.

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