

Suzhou Yaxin Medical Products Co.,Ltd CE Technical File		Document Number
Product	Drainage Tube	SZYX/9.1-02(B)-05-2013
Title	Description of the Product	Page 1 of 3

1 Overview

The Drainage Tube is intended for clinical use in biliary drainage and surface wound drainage procedures, and has been widely utilized in medical practice.

Shelf life is three years. ETO sterilization.

2 The models of Drainage Tube

2.0mm(F6)、2.7mm(F8)、3.3mm(F10)、4.0mm(F12)、4.7mm(F14)、5.3mm(F16)、6.0mm(F18)、6.7mm(F20)、7.3mm(F22)、8.0mm(F24)、8.7mm(F26)、9.3mm(F28)、10.0mm(F30)、10.7mm(F32)、11.3mm(F34)、12.0mm(F36)

3 Components of the Product main suppliers

Drainage Tube consists of PVC tube and connector.

Components	Main suppliers
PVC	Shanghai Xinshanhua Polymer material Co., Ltd.
Paper packaging(inner packaging)	Suzhou Zhongying Paper and Plastics Co., Ltd.
Film packaging(inner packaging)	Suzhou Xiangcheng Culture and Education Medical plastic Packaging Factory
EO	Wuxi Meihu liquefied Gas Co., Ltd.

4 The basic sizes of the product and tolerance

Table 1 basic sizes of drainage tube

						Unit: mm	
Spec	External Diameter (D / D1 / D2)	Tube Wall Thickness (B / B1 / B2)	Length (L / L1 / L2)	Spec	External Diameter (D / D1 / D2)	Tube Wall Thickness (B / B1 / B2)	Length (L / L1 / L2)
2.0mm (F6)	2.0±0.35	≥0.3	≥110	7.3mm (F22)	7.3±0.5	≥0.6	≥110
2.7mm (F8)	2.7±0.35			8.0mm (F24)	8.0±0.5		
3.3mm (F10)	3.3±0.40			8.7mm (F26)	8.7±0.6		
4.0mm (F12)	4.0±0.40	≥0.4		9.3mm (F28)	9.3±0.6	≥0.7	
4.7mm (F14)	4.7±0.40			10.0mm (F30)	10.0±0.6		
5.3mm (F16)	5.3±0.50			10.7mm (F32)	10.7±0.6		
6.0mm (Fr18)	6.0±0.50	≥0.5		11.3mm (F34)	11.3±0.6		
6.7mm (Fr20)	6.7±0.50			12.0mm (F36)	12.0±0.6		

5 Product requirements

1. The basic dimensions (D, B, L) and tolerances of the drainage tube shall comply with the requirements specified in Table 1.
2. The surface of the drainage tube shall be smooth, free from sharp edges and burrs.
3. If the drainage tube is provided with graduation marks, the marks shall be clear and complete.

Suzhou Yaxin Medical Products Co.,Ltd CE Technical File		Document Number
Product	Drainage Tube	SZYX/9.1-02(B)-05-2013
Title	Description of the Product	Page 2 of 3

4. The tip of the drainage tube shall be smooth. If side holes are present, their surfaces shall also be smooth.
5. The inner lumen of the drainage tube shall be free of foreign matter and impurities.
6. The anti-deformation performance of the drainage tube under a negative pressure of 30 kPa shall comply with the requirements of YY0489-2004, Clause 4.2.
7. The tensile strength of the drainage tube shall comply with the requirements of YY0489-2004, Clause 4.3.
8. The drainage tube shall be flexible and resistant to bending.
9. The biocompatibility of the drainage tube shall be evaluated as follows: Cytotoxicity \leq Grade 1; Sensitization reaction \leq Grade 1; No irritation reaction shall occur on the skin.
10. Drainage tube should be sterilized.
11. After sterilization, the number of remained ethylene oxide is not more than 10 μ g/g.

6 Packing form

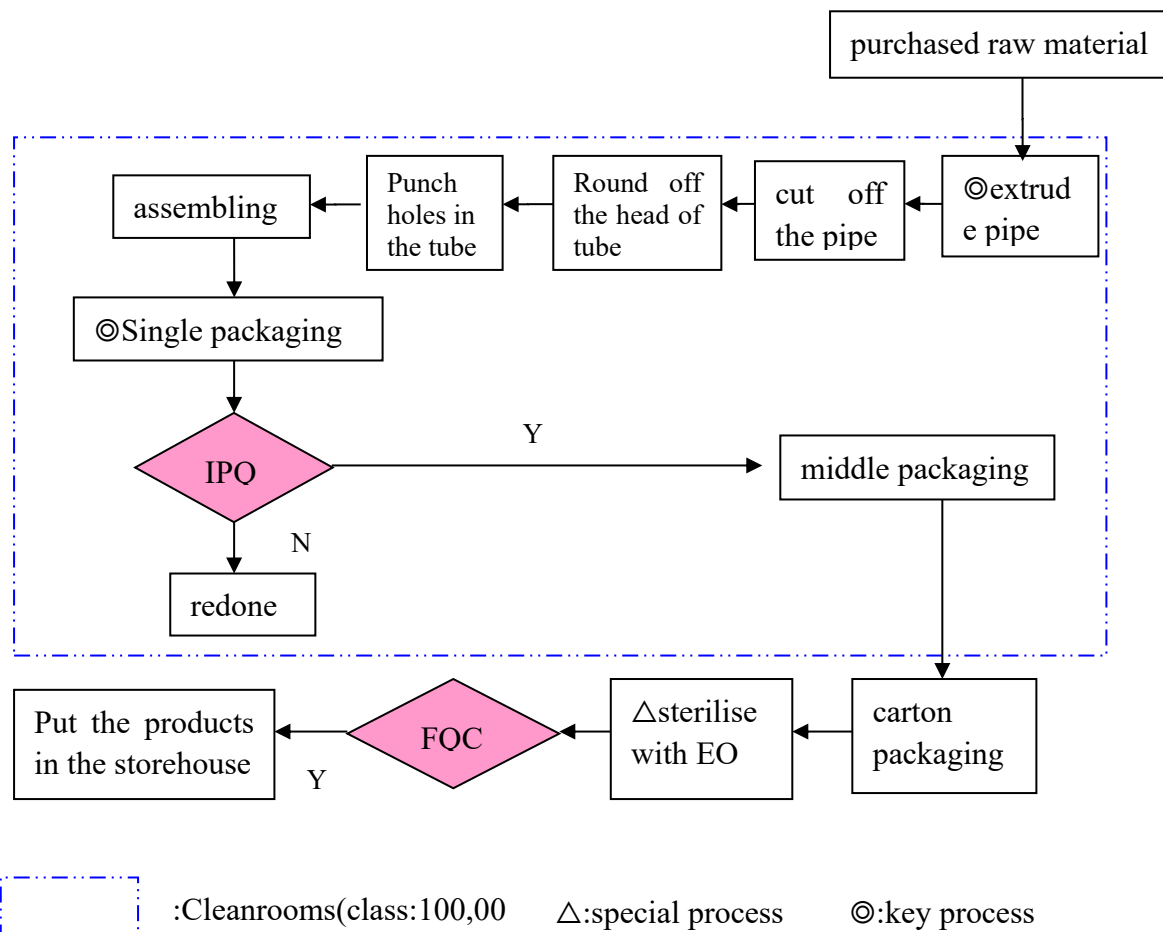
Drainage tube uses single packaging and carton packaging. Each middle packaging contents 10 inner packagings, and each carton packaging is made of 10 middle packagings.

7 Auxiliary materials of production

Drainage tube is made of polyvinyl chloride according to GB15593-1995.

Suzhou Yaxin Medical Products Co.,Ltd CE Technical File		Document Number
Product	Drainage Tube	SZYX/9.1-02(B)-05-2013
Title	Description of the Product	Page 3 of 3

8 Manufacturing process



9 Classification

According to Medical Devices Directives 93/42/EEC Rule 7, Drainage tube belongs to Class II a sterile.

10 Selection of Evaluation of the Product

We select certification channels according to Medical Devices Directives 93/42/EEC Annex V and VII.

11 Contraindication

Allergy to device materials PVC.