

产品规格书

Product Specification

规格书编号:	LT201401001
Specification No:	LT201401001
产品名称:	硅凝胶敷料
Production Name:	Silicone foam dressing
版本号码:	02
Revision No:	02
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生效日期:	2017/01/01
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Zhejiang Longterm Medical Technology Co., Ltd

1. 产品规格要求 Product specification:

1.1 材料描述 MATERIAL DESCRIPTION:

硅凝胶泡沫敷料由 PU 膜、PU 泡沫、硅凝胶和 PE 隔离膜组成

Silicone foam dressing consists of PU film, PU foam, silicone gel and PE release film.

1.2 产品组成 PRODUCT CONTENTS:

代号 Product No	产品图片 Photo	组成 Product contents
Silicone foam dressing		表层：厚度为 0.022mm--0.028mm 的肤色 PU 膜 Surface: thickness 0.022mm--0.028mm Complexion polyurethane film 第一层：PU 泡沫，厚度 2mm。吸水倍率不小于自身重量 5 倍 The first layer: PU foam, thickness 2 mm, the weight which PU foam pad absorb seepage fluid from the wound ≥ 5 times original pad weight 第二层：硅凝胶，涂胶克重为每平方米不小于 100g。 The second layer: silicone gel, Adhesive $\geq 100\text{g}/\text{M}^2$ 底纸：PE 隔离膜，厚度 0.09-0.11mm。 Back: PE release film, thickness 0.09-0.11mm.

1.2 产品尺寸 Product size

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Item	Dressing Length	Dressing Width	Pad Length	Pad Width	Fold Length
	(A)	(B)	(C)	(D)	(E)
Sample	(17.5±0.5)cm	(17.5±0.5)cm	/	/	/

Note: The product specifications can be available at clients' option.

2 产品性能 Product performance

2.1 物理性能: PHYSICAL PROPERTIES

2.1.1 180°剥离力度: 室温下不小于 0.3N/25mm

180°peel strength. Be required ≥ 0.3 N/25mm at room temperature

2.1.2 液体吸透量: 不小于 3000g/m²/24h/37℃

Fluid handling capacity: Be no less than 3000g/m²/24h/37℃

2.1.3 吸水率: 不小于自身重量的 5 倍

Absorption: Be no less than 5 times of its weight

2.2 产品外观要求 Appearance

片材必须裁切整齐, 涂胶均匀.

Each finished dressing should be neatly cut, even adhesive coated.

每片产品整洁, 无毛边, 无污点, 不受污染。

All finished dressings to be clean and neat, be free of dirt, burr, and other pollutions.

3 灭菌 Sterilization

3.1 产品经 EO 灭菌。

All finished products to be sterilized by EO.

4. 包装要求: PACKAGING

每片产品放入纸塑袋中密封, 然后密封好产品的纸袋包装装入白色内盒, 最后用出口专 用 5 层瓦楞纸箱打包。

Each dressing is to be packaged in Paper/Poly closed pouch, and then put several packs to be packaged in one white inner box. Finally, the several inner cases packed by export-use 5 layers

carton.

5. 贮存条件 Storage Condition

产品应贮存在相对湿度不大于80%，无腐蚀性气体通风良好的室内。Products should be stored in a well-ventilated clean room with relative humidity less than 80% and no corrosive gas .

6. 有效期 The period of validity

在规定的贮存条件下，自灭菌日起有效期3年

The product shall valid for 3 years from the sterilization date, provided that it is kept under the stipulated storage conditions.