

一次性皮肤牵开器

使用说明书

Instructions for use of Disposable Skin Retractor

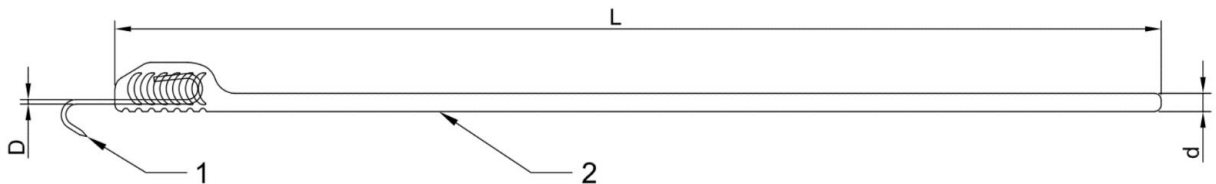
【产品名称】 Product Name

一次性皮肤牵开器 Disposable Skin Retractor

【产品组成结构】 Product Structure

一次性皮肤牵开器共有 H 和 R 两种型号。H 型产品由钩子和硅胶杆组成，R 型产品由支撑板、螺柱和卡扣组成，两种型号的结构组成示意图如图 1、图 2 所示：

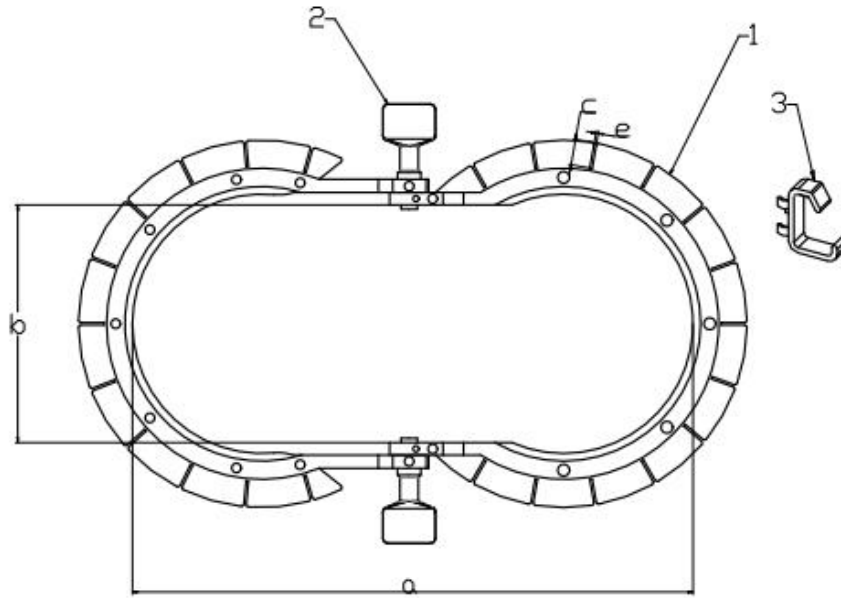
There are two models for Disposable skin retractor, model H and model R respectively. H model is composed of hook and silicone rod, R model is composed of support plate,stud and buckle.The structure of two models are shown in Fig.1. and Fig.2:



1 钩子 hook 2 硅胶杆 silicone rod

图 1 H 型结构组成示意图

Fig.1 Diagram of H model-skin hook



1 支撑板 Support plate 2 螺柱 Locking screw 3 卡扣 Buckle

图 2 R 型结构组成示意图

Fig.2 Diagram of R model-retractor ring

【型号规格】Product Model

H 型一次性皮肤牵开器型号规格列表

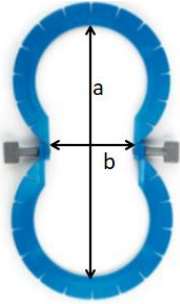
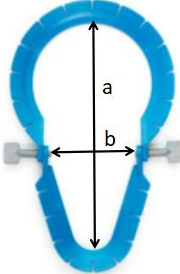
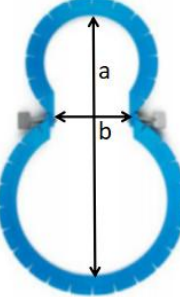
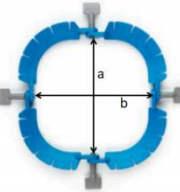
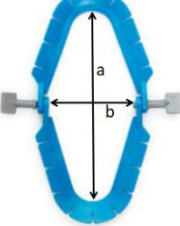
The specifications of R model of Disposable skin retractor

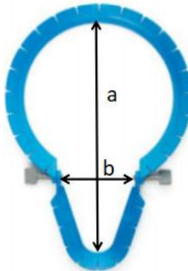
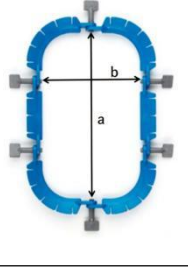
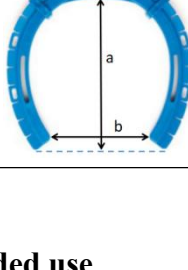
单位 Unit: mm

型号规格 Model&Specifi cation	REF	钩子外形 Appearance of hook	钩子直径 (D) Diameter of hook (mm)	硅胶杆直径 (d) Diameter of silicone rod (mm)	硅胶杆长度 (L) Length of silicone rod (mm)
SG1601-H-1	SG1601-H-1	3mm 尖钩 sharp hook	0.5 ± 0.05	2.3 ± 0.1	150 ± 5
SG1601-H-2	SG1601-H-2				
SG1601-H-6	SG1601-H-6				
SG1602-H-1	SG1602-H-1	5mm 尖钩 sharp hook	0.7 ± 0.05	2.8 ± 0.1	163 ± 5
SG1602-H-2	SG1602-H-2				
SG1602-H-6	SG1602-H-6				
SG1603-H-1	SG1603-H-1	12mm 钝钩 blunt hook	1.0 ± 0.05	2.8 ± 0.1	163 ± 5
SG1603-H-2	SG1603-H-2				
SG1603-H-6	SG1603-H-6				
SG1604-H-1	SG1604-H-1	12mm 双钝钩 Two-Bifurcate Hook	1.0 ± 0.05	3.1 ± 0.1	155 ± 5
SG1604-H-2	SG1604-H-2				
SG1604-H-4	SG1604-H-4				

R 型一次性皮肤牵开器型号规格列表
The specifications of R model of Disposable skin retractor

单位 Unit: mm

型号规格 Model& Specification	REF	支撑板外形 Appearance of Support plate	长 (a) Length	宽 (b) Width	卡槽深度 (c) Slot depth	卡槽宽度 (e) Slot width	卡扣数量 With buckle numbers
SG1601-R	SG1601-R		234 ± 5	99 ± 5	11.0 ± 0.5	1 ± 0.1	无卡扣 NA
SG1602-R	SG1602-R		210 ± 5	99 ± 5	11.0 ± 0.5	1 ± 0.1	2 个 2 pieces
SG1603-R	SG1603-R		304 ± 5	99 ± 5	11.0 ± 0.5	1 ± 0.1	2 个 2 pieces
SG1604-R	SG1604-R		141 ± 5	141 ± 5	11.5 ± 0.5	1 ± 0.1	无卡扣 NA
SG1605-R	SG1605-R		188 ± 5	99 ± 5	11.0 ± 0.5	1 ± 0.1	2 个 2 pieces

SG1606-R	SG1606-R		323 ± 5	99 ± 5	11.0 ± 0.5	1 ± 0.1	无卡扣 NA
SG1607-R	SG1607-R		245 ± 5	141 ± 5	11.5 ± 0.5	1 ± 0.1	无卡扣 NA
SG1608-R	SG1608-R		185 ± 5	117 ± 5	8.0 ± 0.5	1 ± 0.1	2 个 2 pieces

【预期用途】 Intended use

产品用于在外科手术时牵开组织，显露手术视野。

It is indicated for use to provide incision retraction and to aid in visualization during surgical procedures.

【适用范围】 Indications

产品用于在外科手术时牵开组织，显露手术视野。

It is indicated for use to provide incision retraction and to aid in visualization during surgical procedures.

【用户】 Intended users

能严格按使用说明书进行操作的医务人员。

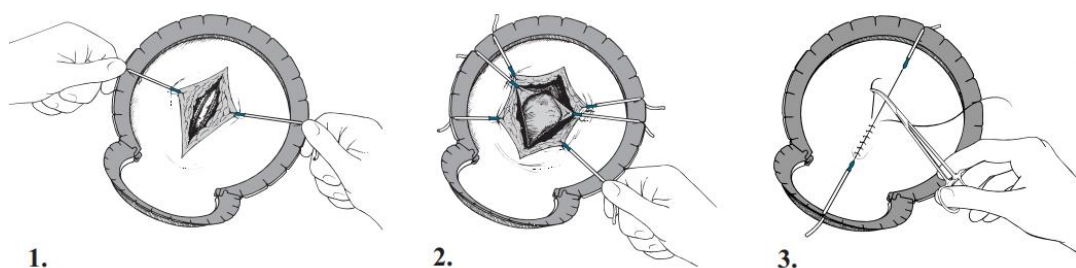
It is used by healthcare professionals who can strictly follow the instructions for use.

【患者人群】 Intended patient group

需要进行外科手术牵开组织的患者。

It is intended to be used on human patients with no restriction on age or gender.

【使用方法】 Directions for use



1. 在手术部位周围放置牵开环，用相同的拉力向 4 个不同的方向拉皮肤拉钩，以使牵开环位置固定。Place retractor ring around surgery site. Pull the skin hook in 4 directions with equal tension to hold retractor ring in place.
2. 随着解剖的进展，拉钩的前端停留到更深的组织。增加或重新定位拉钩到所需的角，以平衡收缩。As dissection progresses, advance position of hook into deeper tissue. Add or reposition hook to desired angle for balanced retraction.
3. 在缝合时保持拉钩的恒定张力。Maintain constant tension of hook while suturing.

【注意事项】 Precaution

1、本产品应由能严格按使用说明书进行操作的医务人员使用，并了解手术的并发症、危害、风险和益处。The product should be used by healthcare professionals who can strictly follow the instructions for use and understand the potential complications, hazards, risks and benefits of the procedure.

2、包装破损，严禁使用。核实包装上的有效期，超过有效期，严禁使用。Do not use if package is damaged. Check the expiration date on the package, and do not use if the date is beyond the expiration date.

3、本产品不能被用作适用范围外的其他目的。The product cannot be used for any other purpose out of the indications.

4、SG1602-R、SG1603-R、SG1605-R 和 SG1608-R 四个规格配有附件卡扣，此附件联用导管规格为外径 24-38Fr，超过规格，严禁使用。SG1602-R, SG1603-R, SG1605-R and SG1608-R, these four specifications are with buckles in inner package. The buckle is used in combination with a catheter in 24-38Fr. It is forbidden to use if the catheter is not the specification as required.

【警示】 Warning

- 1、本产品为一次性使用，不得反复使用、反复处理、反复灭菌。反复使用、反复处理、

反复灭菌可能导致产生污染或引起患者交叉感染的危险，从而导致患者受伤、产生疾病、严重时甚至死亡。 For single use products only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization may create a risk of contamination or cross-infection of patient which may lead to injury, illness or even death of the patient when in severe cases.

2、本产品经环氧乙烷灭菌，如果包装袋破损，请勿使用。The product is sterilized by EO. Do not use if package is damaged.

3、单包装破损、零部件脱落、单包装内有异物禁止使用，并销毁。If the inner package is damaged, the parts fall off, and there is foreign body in the inner package, do not use and destroy it.

4、使用后，设备应作为废物隔离和管理，而不是随意储存。应当按照当地的法律法规予以销毁和处置。不要随意丢弃，以免感染或微生物危害。After use, the device shall be isolated and managed as waste, not stored at will. It shall be destroyed and disposed of in accordance with local laws and regulations. Do not discard at will to avoid infection or microbial damage.

5、与该产品有关的任何严重事故应向制造商和确定使用者和(或)患者所在的会员国主管当局报告。Any serious accident related to the product shall be reported to the manufacturer and to the competent authorities of the Member State in which the identified users and/or patients are located.

【禁忌症】 Contraindications

产品无已知的禁忌症。No known contraindications.

【副作用】 Side-effect

无 None

【贮存和运输】 Transportation & Storage

产品应存放在相对湿度不超过 80%、无腐蚀性气体、防鼠、防火、防虫、通风良好、洁净的室内。过期后请勿使用。

运输过程中应注意产品的防护，使用常规运输工具运输，防止重压、尖物碰撞、日晒雨淋。

The device shall be stored in a room with relative humidity no more than 80%, no corrosive gas and good ventilation. Do not use after expiry date.

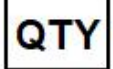
Pay attention to the protection of products during transportation, and use conventional transportation tools to prevent heavy pressure, sharp object collision, sun and rain.

Shelf life

有效期为三年

3 years

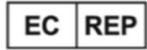
The symbols on the package labels

No.	Symbol	Title	No.	Symbol	Title
1		COUNTRY AND DATE OF MANUFACTURE	2		BATCH CODE
3		DO NOT RE-USE	4		MEDICAL DEVICE
5		CAUTION	6		CONSULT INSTRUCTIONS FOR USE
7		MANUFACTURER	8		USE BY
9		CATALOGUE NUMBER	10		DO NOT USE IF PACKAGE IS DAMAGED
11		THE PRODUCT HAS PASSED CE CERTIFICATION	12		DOES NOT CONTAIN NATURAL RUBBER LATEX
13		UNIQUE DEVICE IDENTIFIER	14		QUANTITY
15		DO NOT RESTERILIZE	16		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/ EUROPEAN UNION
17		STERILIZED USING ETHYLENE OXIDE SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE	18		HUMIDITY LIMITATION
19		KEEP AWAY FROM SUNLIGHT	20		KEEP DRY
21		NON-PYROGENIC			



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