

REVOLUTION™

CATHETER SECUREMENT DEVICE

INSTRUCTIONS FOR USE

DESCRIPTION:

Revolution catheter securement device.

INDICATIONS FOR USE:

The Revolution catheter securement device is designed to secure a non-vascular catheter placed in a patient to help minimize catheter movement and accidental removal.

CONTRAINDICATIONS:

The Revolution catheter securement device is not intended to be used on vascular catheters.

CAUTIONS:

- Read instructions prior to use.
- **Rx Only - Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.
- Contents of unopened, undamaged package are sterile.

REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

INSTRUCTIONS FOR USE:

Inspect the Revolution catheter securement device prior to use to verify that no damage has occurred during shipping.

- Remove the shower lid and Revolution catheter securement device from the packaging. Use caution to ensure that you do not pull the finger rings prematurely and activate strings.
- Before placing the Revolution catheter securement device, ensure that the skin where the device will be placed is clean and dry.
- Position Revolution catheter securement device & secure catheter
- If desired, place the supplied lid over the Revolution catheter securement device to cover the catheter and puncture site while showering.

The Revolution catheter securement device is designed to secure catheters from 6F - 24F and to remain secure up to 7 days.

CAUTION: In order to secure the catheter, verify that the blue ring is rotated sufficiently. Under-tightening may allow the catheter to move. Over-tightening may compress the catheter and restrict or stop fluid flow.

CAUTION: Verify that the catheter is not kinked after deployment.

CAUTION: The Revolution catheter securement device can get wet and can be worn while showering. Merit Medical recommends having the device lid in place when showering. Avoid soaking the device for long periods of time.

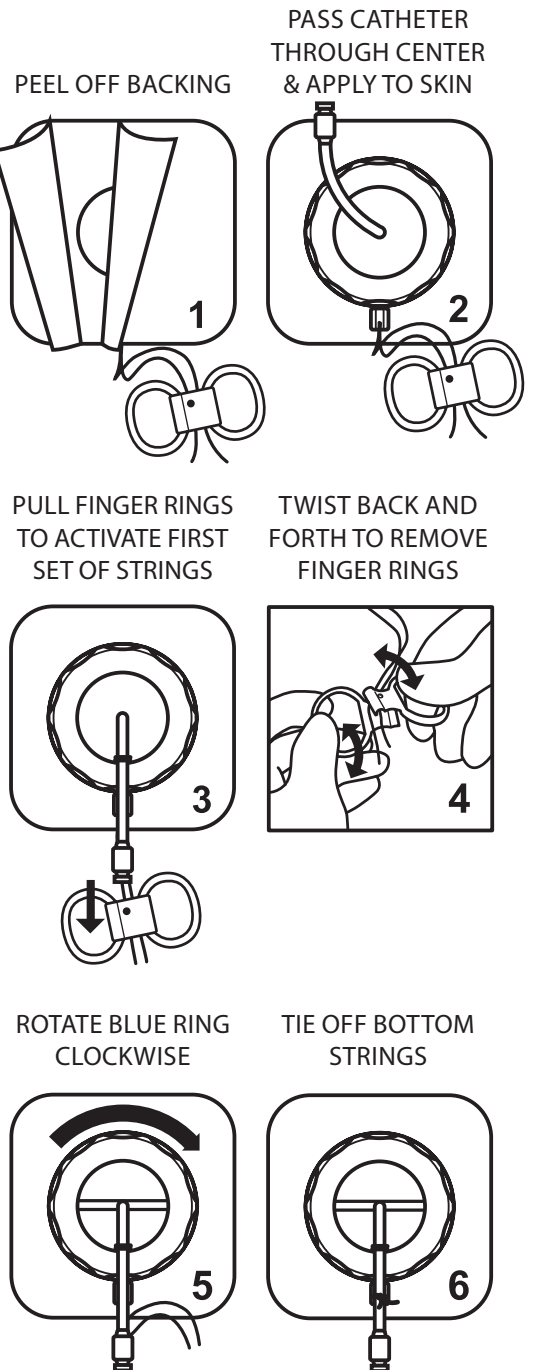
CAUTION: Avoid using alcohol or acetone based solutions when cleaning around or in the center ring of the Revolution. These substances may weaken the device's adhesive.

To remove the Revolution catheter securement device, remove the lid if applicable, cut the strings holding the catheter, and carefully peel the Revolution catheter securement device from the patient's skin.

Storage Requirements: Store in a cool, dry place.

Transportation Conditions: Do not expose to excessive heat or humidity

Shelf-life: 3 years



使用说明书

产品名称：导管固定系统

适用范围：用于确保非血管性导管放入患者体内，协助减少导管移动及偶发性的脱移。

禁忌症：导管固定系统不得用于血管性导管。

警告：

- 使用前请阅读使用说明书。
- 只可用作处方药-警告：此系统仅限于由医生销售或订购。
- 包装未打开和未损坏的情况下，本产品为无菌产品。

不得重复使用的警示：

本产品仅为单个病人使用。不得重复使用、重复加工或重复灭菌。重复使用、重复加工或重复灭菌可能危及产品结构的完善性和/或导致器械失效，从而导致病人受伤，生病或死亡。重复使用、重复加工或重复灭菌也可能产生污染产品的风险和/或导致病人感染或交叉感染，包括（但不限于）：病人之间传染性疾病的传播。被污染的产品可能导致病人受伤，生病或死亡。

使用说明：使用前需检查并确认导管固定系统在运输过程中没有被损坏。

- 将洗浴保护盖和导管固定系统从包装袋中取出。使用者需小心操作，确保不要提前将指环拉出，激活绳扣。
- 放置导管固定系统前，须确保所要放置部位的皮肤清洁、干燥。
- 将导管固定系统定位，放置好并将导管固定。
- 如需要，洗浴时可将随附的保护盖放在导管固定系统上以遮住导管和穿刺部位。

导管固定系统可用于固定6F-24F的导管并可持续固定7天。

注意：为将导管固定住，请检查蓝色环是否旋转充分。
 不够紧可能会使导管移动。
 过紧可能会压迫导管并阻碍或中断液体流动。

注意：需确定导管在固定后没有纽结。

注意：洗浴时导管固定系统可能被淋湿和损坏。MERIT MEDICAL 建议洗浴时加盖保护盖。避免长时间浸泡该产品。

注意：不得使用酒精溶液或丙酮溶液清洗导管固定系统的周边或环中心。这些物质可能会减弱产品的粘性。

取下导管固定系统，如需要，可先取下保护盖，握住导管并剪断绳子，小心将导管固定系统从病人的皮肤上撕下。

储存条件：存储于阴凉干燥处。

运输条件：在运输过程中，不能放置在高温或潮湿的地方。

有效期：3年

生产日期和失效日期：见产品标签

生产证编号：国械注进20192142011

产品技术要求编号：国械注进20192142011

中国境内代理人及售后服务单位名称：美瑞通医疗器械（北京）有限公司

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注册人及生产企业名称：美国美瑞通医疗设备有限公司 Merit Medical Systems, Inc.

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注册人及生产企业联系方式：1-801-253-1600

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结构及组成：导管固定系统由接触人体的胶粘剂贴和不接触人体的旋转环、旋转环保护盖、固定线和固定把手组成，射线灭菌，产品一次性使用。

型号、规格：CFG624

