

AnastoClip® Atraumatic Tissue Everting Forceps English — Instructions for Use

显微组织镊 AnastoClip Atraumatic Tissue Everting Forceps 使用说明书

AnastoClip® Atraumatic Tissue Everting

Forceps (Model Number 4001-06) English — Instructions for Use

Rx only

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

Indications

The AnastoClip Atraumatic Tissue Everting Forceps are intended to aid in the everting of the tissue edges during clip placement.

Instructions For Use

The tissue everting forceps are packaged with instrument guards to protect the tip of the forceps during shipment. Remove the protective guard prior to cleaning, sterilization and use.

2. Symmetrically evert all tissue layers for secure nonpenetrating clip placement. Evert the tissue edges of the vessel with the tissue everting forceps.

Ensure that all tissue edges are symmetrically everted prior to applying the clip. Failure to symmetrically evert the tissue edges prope

evert the tissue edges properly can result in possible bleeding or leakage.

3. Inspect the vessel wall to ensure that

the forceps do not damage vessel during manipulation.

NOTE: Atraumatic Tissue Everting Forceps are designed to minimize potential damage to tissue or other small tubular structures.

Warnings

- 1. THE TISSUE EVERTING FORCEPS MUST BE CLEANED AND STERILIZED PRIOR TO USE! (REFER TO CLEANING AND STERILIZATION METHOD).
- 2. Do not evert the tissue by grasping one tissue edge with one pair of forceps and the other tissue edge with another pair of forceps and pulling them together to evert and apply the clips. This may result in asymmetrical eversion of tissue, which could result in possible bleeding or leakage.
- 3. Do not use the tissue everting forceps if the tips scissor when they are closed.

Cleaning and Sterilization Method

Caution: The tissue everting forceps are packaged NONSTERILE and must be cleaned and sterilized prior to use.

Cleaning

Using a clean towel, wipe all visible soil from the forceps. Prepare an enzymatic detergent per the manufacturer's recommendations. Allow the forceps to soak in the enzymatic detergent for a minimum of one minute. Using a soft bristled brush remove any remaining soil paying particular attention to the inside of the forceps hinge, serration grips and pin. Thoroughly rinse in fresh running water and/or distilled water to remove all traces of detergents and soil. Forceps should be inspected for cleanliness and damage, ensure they function correctly and are clean prior to sterilization.

Sterilization

Sternization
The tissue everting forceps may be steam sterilized in a gravity displacement or prevacuum autoclave).] It is recommended that the tissue everting forceps be sterilized in accordance with one of the following sterilization times and temperatures:

Gravity-Displacement Steam Sterilization Wrapped Forceps Temperature: 270-275°F (132-135°C) Exposure Time: 10 minutes

Gravity-Displacement Flash Cycle Unwrapped Forceps Temperature 270-275°F (132-135°C) Exposure Time: 10 minutes

Pre-Vacuum Steam Sterilization Wrapped Forceps Temperature: 270-275°F (132-135°C) Exposure Time: 4 minutes

Pre-Vacuum Flash Cycle Unwrapped Forceps Temperature 270-275°F (132-135°C) Exposure Time: 4 minutes

Notices: Limited Product Warranty; Limitation Of Remedies LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. LeMaitre Vascular makes no representation regarding the suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR
BE LIABLE FOR ANY DIRECT, INDIRECT,
CONSEQUENTIAL, SPECIAL, PUNITIVE, OR
EXEMPLARY DAMAGES. IN NO EVENT WILL THE
AGGREGATE LIABILITY OF LEMAITRE VASCULAR
WITH RESPECT TO THIS DEVICE, HOWEVER
ARISING, UNDER ANY THEORY OF LIABILITY,
WHETHER IN CONTRACT, TORT, STRICT LIABILITY,
OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS
(US\$1,000), REGARDLESS OF WHETHER LEMAITRE
VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY
OF SUCH LOSS, AND NOTWITHSTANDING THE
FAILURE OF THE ESSENTIAL PURPOSE OF ANY
REMEDY, THESE LIMITATIONS APPLY TO ANY
THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

显微组织镊 (AnastoClip Atraumatic Everting Forceps)

适用范围 用于显微手术时夹 持、分离组织。



示意图和命名 显微组织镊见 右图。

型号、规格 4001-06-4001-07

显微组织镊尺寸和款式

	长度	显微显微组织镊
Ì	18 cm	✓
Ì	20 cm	✓

结构及组成

由一对尾部叠合的叶片组成。采用不锈钢材料制成。可重复使用。

注意事项

- 注意事项
 1. 不要用一把显微组织镊翻转一侧组织,而用另一把显微组织镊翻转另一组织,将其拉到一起进行翻转。这可能导致非对称地组织翻转,可能会导致组织出血。
 2. 当显微组织镊的两尖端在闭合时相互交叉,请不要使用该显微组织镊来翻转组
- 织。 该显微组织镊为"非无菌"包装,所以在使 用前应先清洗与消毒。 3.

警告 为了在搬运过程中保护显微组织镊,显微组织镊的外面有保护套,在清洗、消毒及使用前,先拆下保护套。

温微组织领的清洗和消毒办法 清洗办法 使用一条清洁的毛巾擦洗所有可见的污迹,准 备制造商推荐的酶洗涤剂。将镊子放入酶 清洗剂中至少一分钟。用软毛刷清除剩余 的赃物,特别注意镊子内侧的铰链、锯齿状 的夹具和头端。用清洁流动水和/或蒸馏水 冲洗洗涤剂和污染,检查镊子是否清洗干 净,是否被损坏,确保镊子在消毒之前能正 常工作且洁净。

消毒杀菌 显微组织镊可在常态或真空中消毒,在进行 消毒杀菌时,建议按照以下时间和温度执 行操作:

非真空蒸汽灭菌 被包裹的镊子

温度: 270-275°F(132-135℃) 灭菌时间: 10分钟

非真空蒸汽灭菌 未被包裹的镊子 温度: 270-275°F (132-135℃) 灭菌时间: 10分钟

真空蒸汽灭菌 被包裹的镊子 温度: 270-275° F(132-135° C) 灭菌时间: 4分钟

真空蒸汽灭菌 未被包裹的镊子 温度: 270-275° F (132-135° C) 灭菌时间: 4分钟

生产日期及使用期限请见包装。

注意:有限产品保证;补数局限性 LeMaitre Vascular, Inc. 认为,在生产该设备的过程中已经相当谨慎了。除明确规定外,LeMaitre Vascular, Inc. (如用于在本条中,此类条款包括LeMaitre Vascular, Inc. 及其关联公司及其各自的雇员,官员,董事、经理和代理商)均不会以法律或任何其他方式做出任何关于此器械的明确或暗商油用途保证(包括但不限于对一个特定用途的商品用途保证或适当性的暗示性保证)

,并谨此声明。

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显微组织镊(AnastoClip® Atraumatic Tissue Everting Forceps)

产品备案凭证编号,国械备 20160264号

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