ENDOTEK BIG60®

60ml Inflation Device

INSTRUCTIONS FOR USE

DESCRIPTION:
The BIG60® Inflation Device is a 60ml disposable inflation device capable of producing a maximum pressure of 12 ATM/BAR, fitted with a threaded plunger assembly with a lock/release bar, a flexible high pressure tube, and a three-way medium pressure stopcock. The BIG60 Inflation Device is designed to generate and monitor inflation pressures over a range of -.68 to 12ATM/BAR (-10 to 176 psi) with an accuracy of 3% ATM/BAR.

INTENDED USE:
This inflation device is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon.

PRECAUTIONS:
- Inspect the BIG60 Inflation Device and packaging for damage prior to use. Do not use product if opened or damaged. Confirm the product is consistent with the package label. Contact Customer Service to report and replace damaged product.
- 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 product 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 product may lead to injury, illness, or death of the patient.
- Graduations on device barrel are for reference only and are not intended for exact measurement.

INSTRUCTIONS FOR USE:
1. Prior to use, free the plunger tip by twisting the device plunger/handle 360 degrees clockwise.
2. To prep device, simply aspirate up to 60ml of contrast solution into the syringe by pulling back on the device handle.
CAUTION: Inspect the device tubing and stopcock (if used) to ensure there is no air in the system.
3. Remove any excess air by orienting the device upwards, squeezing the trigger located on the device handle and pushing the handle forward. Push forward until the device plunger tip is oriented with the black arrow printed on the device barrel (approximately 35ml).

ATTACHING THE INFLATION DEVICE TO THE BALLOON:
NOTE: Refer to the manufacturer's directions accompanying the balloon dilation catheter, or other interventional device, for specific information on use, maximum inflation pressure, precautions, and warnings for that device.
1. Prepare and test the balloon catheter according to the catheter manufacturer's instructions for use.
2. Create a fluid-fluid connection between the balloon and the inflation device extension tube and connect the luer connectors securely.
3. Squeeze the trigger and pull back on the handle to apply vacuum to the balloon.

BALLOON INFLATION AND DEFLATION:
1. To inflate the balloon, squeeze the trigger allowing the plunger to return to the resting position (0 ATM/BAR). Release grip on the trigger, locking the plunger into position.
2. To increase pressure, rotate the handle clockwise until the desired inflation pressure is reached. The locking mechanism maintains the pressure.
CAUTION: Do not exceed 12 ATM.
NOTE: Loss of pressure may indicate a leak in the system.
3. To deflate the balloon (rotate the handle counter-clockwise to relieve pressures above 6 ATM) squeeze the trigger and pull the handle back to generate the desired negative pressure. Release the grip on the trigger to lock the plunger in the negative pressure position.

STORAGE: Store in a cool, dry place.

WARRANTY
The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is exclusive and manufacturer makes no other representations or warranties of any kind to customers, its end users, or to any third parties with respect to the device and hereby expressly disclaims any and all other warranties, express or implied, statutory or otherwise, including, but not limited to, infringement and the implied warranties of merchantability and fitness for a particular purpose, even if manufacturer is aware of such purpose. Handling and storage of this device, as well as other factors relating to the patient, diagnosis, treatment, implant procedures, and other matters beyond the control of the manufacturer, directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of the device. Under no circumstances shall manufacturer be liable to customer or any other person or entity for any punitive, special, incidental or consequential damages directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty shall not apply, and manufacturer assumes no liability with respect to, devices that have been (i) modified, changed, altered, misused, mishandled, repaired, reused, reprocessed, refurbished or resterilized; (ii) subjected to improper maintenance, testing or storage, accident, tampering, or inadequate protection against shock, vibration, excessively high or low temperatures, overpressure, or physical, environmental or electrical stress; (iii) been used outside the approved "Indications for Use" as cleared by the relevant competent authority, used contrary to the use outlined in the device specifications, or in an application or environment for which such device was not designed or contemplated; or (iv) distributed or used contrary to applicable federal, state, local or regulatory standards.

RX only: CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Single Use

Caution: Consult accompanying document

STERILE EO

Sterile if package is unopened or undamaged
Non-pyrogenic

MERIT MEDICAL ENDOTEK®

Manufacturer: www.merit.com
Merit Medical Systems, Inc. South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A. Customer Service 1-800-356-3748

EC REP Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West,
Galway, Ireland

401997002/C ID 031513

ENDOTEK BIG60®

60ml 充盈压力泵

使用说明

说明：
BIG60® 充盈压力泵是一种容量 60ML、能够产生最大压力为 12 ATM/BAR 的一次性充盈装置，装配有带锁／解锁条的螺纹活塞组件、柔韧高压管以及中等压力三通阀。BIG60 充盈压力泵旨在产生及监测范围介于 -.68 至 12ATM/BAR（-10 至 176 PSI）的充盈压力，准确度达到 3% ATM/BAR。

拟定用途：
此充盈装置用于血管成形术中对球囊或其他介入装置进行充盈和撤压，以及测量球囊内的压力。

注意事项：
- 使用前请检查 BIG6O 充盈压力泵及包装是否有破损。如果产品包装已打开或有破损，请勿使用。确认产品与包装标签一致。联系客户服务，报告并更换受损的产品。
- 仅可用于一名患者。请勿重复使用、重新处理或重新消毒。重复使用、重新处理或重新消毒可能破坏装置的结构完整性，及／或导致装置故障，从而可能导致患者受伤、患病或死亡。重复使用、重新处理或重新消毒也存在产品污染的风险，及／或导致患者感染或交叉感染，包括但不限于在患者间传播传染病。产品污染可能导致患者受伤、患病或死亡。
- 压力泵筒壁上的刻度仅供参考，并非用于精确测量。

使用说明：
1. 使用前，将压力泵活塞／手柄按顺时针方向旋转 360 度，以松开活塞头。
2. 为准备压力泵，只需简单地后拉压力泵手柄将 60ML 造影剂吸入压力泵即可。

警示：检查 压力泵前端延长管内及旋塞阀（如果使用），以确保系统内没有空气。

3. 通过调整压力泵至头端朝上、按压位于 压力泵手柄上的扳柄及向前推动手柄，排出空气。直至 压力泵活塞头位于压力泵筒壁上印有的黑色箭头处（约 35ML）。

将充盈压力泵连接在球囊上：
注意：请参阅球囊扩张导管或其他介入装置随附的制造商使用说明，了解有关该装置的使用、最大扩张压力、注意事项及警告等具体信息。
1. 根据制造商的使用说明准备并测试球囊导管。
2. 紧密连接鲁尔接头，使球囊与充盈压力泵延长管之间建立一个液体-液体的连接。
3. 按压扳柄并向后拉手柄使球囊成为真空。

球囊充盈和撤压
1. 为对球囊充盈，按压扳柄使活塞回到静止位置。松开扳柄，将活塞锁定到位。
2. 为增加压力，顺时针旋转手柄直至达到期望的扩张压力 。锁定装置可以帮助维持压力。

警示：切勿超过 12 ATM。
注意：压力减小可能表明系统存在泄露。

3. 对球囊撤压（逆时针旋转手柄以释放压力至 6 ATM 以上），按压扳柄并向后拉以产生 所需的负压力。松开扳柄，将活塞锁定在负压力位置。

存放：储存在阴凉、干燥的地方。

保证
制造商保证，在设计及制造该装置时已采取合理的谨慎措施。此保证具有排他性，且制造商概未就该装置向其客户、终端用户或任何第三方作出任何其他类型的陈述或保证，并特此明确放弃任何及所有其他保证，无论是明示或默示、法定或其他方面的保证，包括但不限于侵权及对适销性和某种特定用途的适用性的默示保证，即使制造商了解该用途亦如此。该装置的处理及存放，以及与患者、诊断、治疗、植入操作及制造商控制范围之外的其他事宜相关的其他因素，会对该装置及其使用时获得的结果产生直接影响。制造商在此保证下的义务仅限于更换该装置。在任何情况下，制造商均无须就使用该装置而直接或间接产生的任何惩罚性、特殊性、偶然性或后果性损害，对客户或任何其他人士或实体承担责任。制造商不承担，也未授权任何其他人士代其承担与该装置相关的任何其他或额外的法律责任或责任。此保证在下述情况下不适用，且制造商概不就装置的下述情况承担任何法律责任：(I) 修改、改变、更改、误用、错误操、维修、重复使用、重新处理、翻新或重新消毒；(II) 遭受不当维护、测试或存放、意外、干扰或者对于震动、震荡、过高或过低的温度、超压或物理、环境或电应力采取的保护不足；(III) 在相关主管当局批准用于核准的“适应症”范围之外，违背装置规格所列明的用途而加以使用，或用于该装置并非设计或预期使用的应用或环境中；或 (IV) 违背适用的联邦、州、地方或监管标准而加以分发或使用。

仅凭处方销售：
警示：联邦（美国）法律限定本装置仅可由医师或凭医师处方销售。

一次性使用

警示：请查阅随附文件

STERILE EO

仅在包装未打开且无损坏的情况下才无菌
无热原

产品有效期：3 年
储存条件：室温，通风，干燥，避光；
运输条件：运输过程中，避免接触高温潮湿；

注册证号：SFDA (I) 20132660778
标准号：YZB/USA 6606-2012
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MERIT MEDICAL ENDOTEK®

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