basixTOUCH™

Inflation Device

English

INSTRUCTIONS FOR USE

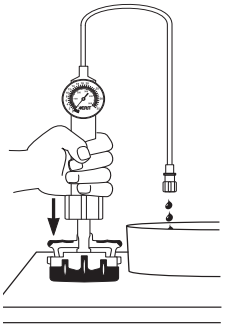
DESCRIPTION:
The basixTOUCH™ Inflation Device by Merit Medical is a 30mL disposable device with a threaded plunger assembly, a flexible high pressure extension tube. The basixTOUCH™ is designed to generate positive and negative pressure, and monitor positive pressures over a range of zero to +35ATM/BAR (zero to 514 PSI).

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

INDICATIONS FOR 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.

NOTE: This device has not been cleared for dispensing fluids into the body.

INSTRUCTIONS FOR USE:
Before use, inspect the device and packaging to verify that no damage has occurred as a result of shipping. If the pressure gauge needle is not resting within the "0" box, do not use.



DEVICE PREPARATION:
1. To prepare inflation device, turn the device with gauge facing down and aspirate up to 30 mL of contrast solution or other fluid into the syringe by squeezing the trigger and pulling back on the handle.
2. Push handle against table or other solid surface to remove air in syringe.

CAUTION: Inspect the inflation device tubing and stopcock (if used) to ensure that there is no air in the system.

ATTACHING THE INFLATION DEVICE TO THE BALLOON:
NOTE: Refer to the manufacturer's directions accompanying the balloon dilatation 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 directions for use.
2. Create a fluid-fluid connection between the balloon and the inflation device extension tube, connect the luer connectors securely.
3. Squeeze the trigger and pull back on the plunger handle to apply a vacuum to the balloon.

BALLOON INFLATION AND DEFLATION:
1. To inflate the balloon, squeeze the trigger to allow the plunger to return to a resting position (0 ATM/BAR or PSI). Release grip on the trigger, which will lock the plunger into position. To increase pressure, rotate handle clockwise until the desired pressure is achieved.

NOTE: Loss of pressure may indicate a leak in the system.
CAUTION: If applied pressure does not indicate on gauge display, discontinue use immediately and replace it with a new unit
2. To deflate balloon, squeeze the trigger and pull back to generate a negative pressure. Release grip to lock the plunger in a negative pressure position.

CAUTION: To protect the threads of the lock release handle, the pressure must be reduced to 25 ATM or lower before the quick release mechanism is used to deflate the angioplasty balloon.

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 crossinfection, 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.

Users should follow local guidelines and practices regulating the disposal of infected waste products.

② Use once and destroy

STERILE EO EtO Sterilized

Non-pyrogenic
Sterile if package is unopened and undamaged.
For Patent Coverage, see www.merit.com/patents

MERIT MEDICAL®

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1-801-253-1600 • U.S.A. Customer Service 1-800-356-3748

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

400350003ZHP_001 ID 01-31-2023

basixTOUCH™

充盈压力泵系统

Chinese

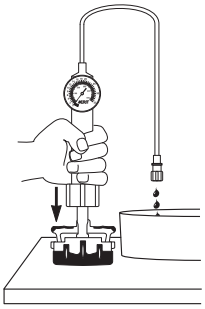
使 用 说 明

产品描述：
该产品由压力泵、止血阀、导引导丝插入工具、转矩器械、三通阀等部件组成，接触人体的材质为聚碳酸酯及聚亚胺酯。

℞ only 仅限处方使用警告：美国联邦法律要求本器械仅凭医嘱销售。

适用范围：
该产品适用于扩张和缩小血管成形术球囊或者其它介入设备，并测试球囊内的压力。

禁忌症：此装置不得用于向人体内注入液体。



使用说明：
使用前，请检查装置和包装，以确认是否发生因运输导致的损坏。如果压力计指针并非显示在"0"框内，请勿使用。

装置准备：
1. 要准备压力泵，转动装置使压力计朝下，通过扣动扳机和向后拉手柄将30毫升造影剂或其它液体吸入压力泵。
2. 垂直于桌面或其它固体表面推动手柄，以去除注射器中的空气。

警告：请检查压力泵管和旋塞（如果使用的话），以确保装置中没有空气。

将充盈装置连接至球囊：
注意：关于装置的特殊使用信息、最大充盈压力、注意事项和警告，请参阅随球囊扩张导管或其它介入装置附的制造商使用说明书。
1. 按照导管制造商的使用说明书准备和测试球囊导管。
2. 搭建好球囊和充盈压力泵延长管之间的液体连接，牢固地连接鲁尔接头。
3. 扣动扳机，向后拉柱塞手柄为球囊施加负压。

球囊充盈和缩瘪：
1. 要充盈球囊，扣动扳机，使柱塞返回到静止位置（0 ATM/BAR 或 PSI）。松开扳机将锁定柱塞到位。要增加压力，顺时针旋转手柄直至达到所需压力。

注意：压力损失可能表明装置泄漏。
警告：如果压力计不能显示施加的压力，请立即停止使用，并更换新的装置

2. 要使球囊缩瘪，扣动扳机，拉回柱塞以产生负压。松开扳机将柱塞锁定在负压位置。

警告：为了保护锁定释放手柄，在利用快速释放机制为血管成形术球囊缩瘪之前，压力必须降至25 ATM 或更低。

重复使用注意事项声明
仅用于单个患者。不能重复使用、再加工或灭菌。重复使用、再加工或再灭菌可能会危害器械的结构完整性，导致器械运转不良，对患者造成伤害、致病或死亡。重复使用，再加工或再灭菌还可能造成器械污染，引起患者感染或交叉感染，包括但不限于从一个患者到另一个患者的感染性疾病传播。器械的污染还可能导致患者受到伤害、致病或死亡。

使用者应当按照当地准则和规范处置感染废弃产品。

② 不得二次使用

STERILE EO 经环氧乙烷灭菌

无热原
未开封和包装完好时保持无菌。
专利相关信息请见： www.merit.com/patents

产品名称：充盈压力泵系统
型号、规格：IN8100、IN8130、IN8352、IN8353、IN8112、IN8152、IN8302、IN8403、H3SNC
结构及组成：该产品由压力泵、止血阀、导引导丝插入工具、转矩器械、三通阀等部件组成，接触人体的材质为聚碳酸酯及聚亚胺酯。产品经环氧乙烷灭菌，一次性使用，货架有效期3年。
注册证编号：国械注进20183032068
产品技术要求编号：国械注进20183032068
有效期：3年
储存条件：贮存在通气良好，无腐蚀性气体的室内。
运输条件：按合同规定进行。
注册人及生产企业名称：美国麦瑞通医疗设备有限公司Merit Medical Systems, Inc.
注册人及生产企业住所：1600 West Merit Parkway, South Jordan, Utah 84095
注册人及生产企业联系方式：1-801-253-1600
生产地址：

IN8100 IN8130 IN8352 IN8353 IN8112 IN8152 IN8302 IN8403	1600 West Merit Parkway, South Jordan, Utah 84095; Avenida Sor Juana Ines de la Cruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California MEXICO 22630
H3SNC	1600 West Merit Parkway, South Jordan, Utah 84095

中国境内代理人及售后服务单位名称：麦瑞通医疗器械（北京）有限公司
中国境内代理人及售后服务单位住所： 北京市朝阳区东大桥路9号楼2单元801室内B01、B02及B03单元
中国境内代理人及售后服务单位电话：010-85610788
中国境内代理人及售后服务单位传真：010-85616981
生产日期和失效日期：见产品标签
说明书编制或修订日期：2023年5月