

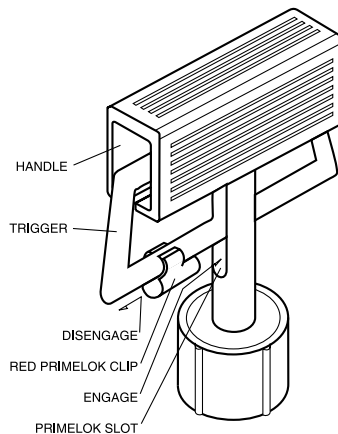
INSTRUCTIONS FOR USE

DESCRIPTION:

The Merit basixCOMPAK Inflation Syringe is a 20ml disposable device fitted with a threaded plunger and lock / release bar, capable of producing a maximum pressure of 30 ATM/BAR, a flexible high pressure extension tube, and a three-way medium pressure stopcock. The basixCOMPAK is designed to generate and monitor pressures over a range of -1 to +30 ATM/BAR (-14.7 to +441 PSI) with accuracy of ±1 ATM/BAR (14.7 PSI).

PRODUCT INTRODUCTION:

The product includes a series of models based upon operational purpose. The model name and components for each are as follows:



IN4130: 30 ATM analog inflation device with 13" (35.5cm) extension tubing and angled gauge, 3-way stopcock included. Packaged 5 units per box, 4 boxes per case.

IN4230: 30 ATM analog inflation device with angled gauge, 13" (35.5cm) extension tubing, Access-9™ and Merit Angioplasty Pack™ (MAP). MAP includes large bore hemostasis valve, metal guide wire insertion tool and torque device. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

IN4530: 30 ATM analog inflation device with angled gauge, 13" (35.5cm) extension tubing, AccessPlus™ and Merit Angioplasty Pack™ (MAP). MAP includes large bore hemostasis valve, metal guide wire insertion tool and torque device. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

IN4430: 30 ATM analog inflation device with angled gauge, 13" (35.5cm) extension tubing, MBA™ and Merit Angioplasty Pack™ (MAP). MAP includes large bore hemostasis valve, metal guide wire insertion tool and torque device. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

IN4330: 30 ATM analog inflation device with angled gauge, 13" (35.5cm) extension tubing, Honor® and Merit Angioplasty Pack™ (MAP). MAP includes large bore hemostasis valve, metal guide wire insertion tool and torque device. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

IN4352: 30 ATM analog inflation device with angled gauge, 13" (35.5cm) extension tubing, Honor® (20cm tubing extension) and Merit Angioplasty Pack™ (MAP). MAP includes large bore hemostasis valve, metal guide wire insertion tool and torque device. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

K05-00807: 30 ATM analog inflation device with 13" (35.5cm) extension tubing and with 10ml Red Nitro & 10ml Yellow Heparin Medallion® Syringes. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

K05-01840: 30 ATM analog inflation device with angled gauge, 13" (35.5cm) extension tubing and Merit Angioplasty Pack™ (MAP). MAP includes the AccessPlus™ large bore hemostasis valve, metal guide wire insertion tool, torque device and RXP® - rapid exchange prep syringe. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

K05-00812: 30 ATM analog inflation device with 13" (35.5cm) extension tubing and 20ml VacLok® syringe. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

K05-00892: 30 ATM analog inflation device with 13" (35.5cm) extension tubing, includes Access-9™ large bore hemostasis valve. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

K05-00808: 30 ATM analog inflation device with 13" (35.5cm) extension tubing and 10ml red NITRO Medallion® syringe. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

K05-00842: 30 ATM analog inflation device with 13" (35.5cm) extension tubing, Merit Angioplasty Pack™ (MAP) and 10ml red NITRO Medallion® syringe. MAP includes Access-9™ large bore hemostasis valve, metal guide wire insertion tool and torque device. 3-way stopcock included. Packaged 5 kits per box, 4 boxes per case.

INDICATIONS AND USAGE:

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

INSTRUCTIONS FOR USE:

Before use, inspect the device and packaging to verify that no damage has occurred as a result of shipping.

PRIMING WITH PRIMELOK™:

The PrimeLok allows purging of air and excess fluid without squeezing the trigger. The basixCOMPAK is packaged with the PrimeLok and with the lock/release mechanism in the disengaged position.

1. To engage PrimeLok, squeeze trigger and slide PrimeLok into slot in plunger.

CAUTION: RX Only – Federal (USA) law restricts this device to sale by or on the order of a physician.

2. To prep syringe, simply aspirate up to 20ml of contrast solution into the inflation syringe by pulling back on the handle.

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

3. Push handle against table to remove air in syringe.

4. To disengage PrimeLok, squeeze handle and slide PrimeLok out of slot. This will allow the trigger to lock in position and the device is now ready for use.

CAUTION: The PrimeLok must be disengaged before pressure can be maintained by the lock/release mechanism.

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 syringe extension tube and connect the luer connectors securely.

3. Squeeze the trigger and pull back on the handle to apply a 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. To increase pressure, rotate the handle clockwise until the desired inflation pressure is reached. The lock mechanism maintains the pressure.

NOTE: Loss of pressure may indicate a leak in the system.

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

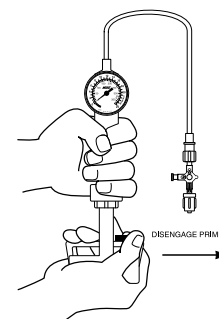
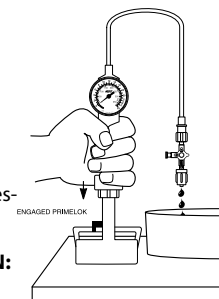
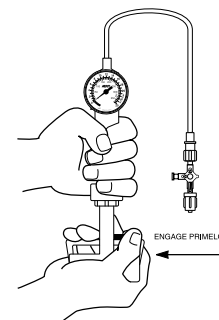
2. To deflate the balloon, squeeze the trigger and pull back to generate a negative pressure. Release grip on the trigger to lock the plunger in the negative pressure position.

Shelf Life:	30 Months
Storage Conditions:	Well-Ventilated, Dry, Room Temperature
Shipping Conditions:	Refer to Shipping Contract
Certificate No:	SFDA (I) 20112210006
Registration Standards No.:	YZB/USA 3145-2010
Name of After Sales	
Service Provider:	Jyton & Emergo (Beijing) Medical Technology Co., Ltd.



Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A.

Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland
401961001/B ID 051911



使用说明

描述:

Merit basixCOMPAK Inflation Syringe是一种能够产生最大压力为30ATM/bar的20mL的一次性设备, 装配有螺纹柱塞和锁/解锁条, 可变高压伸缩管, 三通阀。basixCOMPAK设计产生和控制压力-1到+30 ATM/BAR(-14.7到+441PSI)精确到±1 ATM/BAR (14.7 PSI)。

产品说明

产品包含一系列以可操作的型号。这些产品的名称和型号如下:

IN4130: 30 ATM压力泵带有13英寸(35.5cm)延长管和扭矩仪, 三通阀。每盒5个包装单位, 每个包装4盒。

IN4230: 30 ATM压力泵带有扭矩仪, 13英寸(35.5cm)延长管, Access-9™ and Merit Angioplasty Pack™ (MAP)。MAP包含长止血真空管、金属导丝插入和扭转装置和三通阀。每盒5个配套元件, 每个包装4盒。

IN4530: 30 ATM压力泵, 13英寸(35.5cm)延长管、长止血真空管、金属导丝、扭矩仪、Access-PLUS止血真空管和三通阀。每盒5个配套元件, 每个包装4盒。

IN4430: 30 ATM压力泵带有扭矩仪, 13英寸(35.5cm)延长管, MBA™ and Merit Angioplasty Pack™ (MAP)。MAP包括长止血真空管, 金属导丝插入和扭转装置和三通阀。每盒5个配套元件, 每个包装4盒。

IN4330: 30 ATM压力泵带有扭矩仪, 13英寸(35.5cm)延长管, Honor® and Merit Angioplasty Pack™ (MAP)。MAP包括长止血真空管, 金属导丝插入和扭转装置和三通阀。每盒5个配套元件, 每个包装4盒。

IN4352: 30 ATM压力泵带有扭矩仪, 13英寸(35.5cm)延长管, Honor(20cm延长管)and Merit Angioplasty Pack™ (MAP)。MAP包括长止血真空管, 金属导丝插入和扭转装置和三通阀。每盒5个配套元件, 每个包装4盒。

K05-00807: 30 ATM压力泵带有扭矩仪, 13英寸(35.5cm)延长管和10mL红色硝基和10mL黄色肝磷脂Medallion®注射筒和三通阀。每盒5个配套元件, 每个包装4盒。

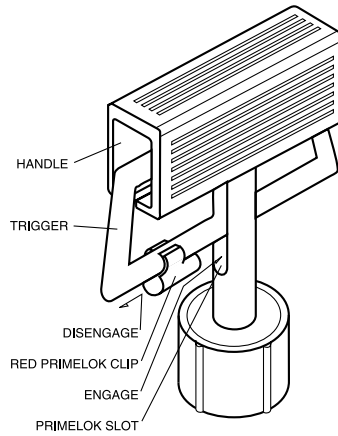
K05-01840: 30 ATM压力泵带有扭矩仪, 13英寸(35.5cm)延长管和Merit Angioplasty Pack™ (MAP)。MAP包括AccessPlus™止血真空管和长止血真空管, 金属导丝插入工具, 金属环和RXP®更换注射器包含三通阀。每盒5个配套元件, 每个包装4盒。

K05-00812: 30 ATM压力泵带有13英寸(35.5cm)延长管和20mL Vaclok®注射器包含三通阀。每盒5个配套元件, 每个包装4盒。

K05-00892: 30 ATM压力泵带有13英寸(35.5cm)延长管, 包括Access-9™长止血真空管。包含三通阀。每盒5个配套元件, 每个包装4盒。

K05-00808: 30 ATM压力泵带有13英寸(35.5cm)延长管和10mL红色硝基Medallion®注射筒和三通阀。每盒5个配套元件, 每个包装4盒。

K05-00842: 30 ATM压力泵带有13英寸(35.5cm)延长管, Merit Angioplasty Pack™ (MAP)和10mL红色硝基Medallion®注射筒。MAP包括Access-9™长止血真空管, 金属导丝插入工具, 金属环和三通阀。每盒5个配套元件, 每个包装4盒。



用法和说明

此设备用于血管成型球的充气 and 放气或者其他干预设备, 以及测量球体内部的压力。

使用说明

使用之前, 检测设备和包装确认购买之前没有损坏。

启动PRIMELOK™

PRIMELOK™允许空气和多余液体的排除而不用推挤扳柄。

basixCOMPAK与PrimeLok

和加锁/解锁装置在空闲状态包装在一起。

1. 启动PrimeLok, 推压扳机并且滑动PrimeLok到柱塞的狭缝。

注意: 仅仅RX, 美国法律限制医生等销售。

2. 准备注射筒, 通过后拉手柄吸入20mL对比溶液
注意: 检查注射筒管和阀(如果使用)保证系统没有空气。

3. 抵住桌子推动手柄排空注射筒中的空气。

4. 分离PrimeLok, 推挤手柄并且将PrimeLok滑出狭缝, 这将使得扳机在适当的位置锁定并且设备开始准备投入使用。

注意: PrimeLok必须在加锁/解锁装置能够维持压力之前分离。

将压力泵连接在球囊上

注意: 参见生产厂商相关球囊扩张导管或其他介入设备具体使用、最大膨胀压的信息。

1. 按球囊导管厂商的使用指南准备并测试球囊导管。

2. 在球囊和注射筒延长管之间建立一个液体-液体的连接, 安全的接好鲁尔接头。

3. 推挤扳柄并而后拉活手柄使球囊真空。

球囊充气 and 放气

1. 为使球囊充气, 推挤扳柄使活手柄回到平衡位置(0 ATM/BAR)。松开扳柄, 锁定活手柄位置。为增加压力, 顺时针转动手柄直至达到期望压力。锁闭装置维持压力。

注意: 压力损失将会指示系统的泄露。

警告: 为保护锁/松阀门手柄上的螺纹, 在快速释放装置被用于血管成形球囊的放气时, 设备必须显示25 ATM或者更低。

2. 为使球囊放气, 逆时针旋转手柄释放压力到25 ATM或更低。推挤扳柄并而后拉以产生一个负压力。

储存条件: 室温、干燥、通风

运输条件: 按合同规定的运输条件。

产品有效期: 30个月

注册证号: SFDA(I) 20112210006

标准号: YZB/USA 3145-2010

售后服务单位名称: 捷通埃默高(北京)医药科技有限公司

售后服务单位地址: 北京市海淀区苏州街18号院2号楼12A08室

售后服务电话: 010-85875188 售后服务传真: 010-85875198



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