

ACHIEVE®

Coaxial Programmable Automatic Biopsy System

English

INSTRUCTIONS FOR USE

Intended for use in obtaining core biopsy samples from soft tissue such as breast, kidney, liver, prostate and various soft tissue masses.

Not intended for use in bone.

Do not use if package is damaged.

WARNING: Test firing the needle may damage the cutting cannula and/or stylet tip. Keep fingers or other objects from in front of the needle as it will advance 2.5 cm very rapidly when activated. Never test fire the instrument in an unsafe direction.

STEP 1: COAXIAL INTRODUCER PLACEMENT

During the pre-procedure set-up, insert the biopsy device through the coaxial introducer needle to verify compatibility.

Adjust sliding skin stopper on coaxial introducer needle to desired calibration and lock in place. Insert introducer needle until sliding stopper rests on skin surface. Image coaxial needle, if desired, to make sure the tip is at or near the edge of the region to be sampled. Remove inner stylet.

STEP 2: PREPARATION OF ACHIEVE FOR USE

To charge the Achieve biopsy device, simply pull back on the charging arm and release twice; first to charge the cutting cannula, the second to charge the inner stylet.

STEP 3: INSERT ACHIEVE

Insert charged Achieve biopsy device into coaxial introducer and press fit firmly onto Luer taper.

STEP 4: FIRE THE INSTRUMENT

Two firing sequence methods are available once the Achieve biopsy device is charged.

1. Delay Mode–Depression of the D button releases the inner stylet into the sample area. The operator uses this delay firing method to verify the position of the sample notch in the target area prior to depressing the A button which activates the cutting cannula, capturing the tissue sample.
2. Automatic Mode–The operator can choose the fully sequential mode, omitting the delay feature, simply by depressing the A button first. This releases the stylet and cutting cannula in sequence, capturing the tissue sample.

A = Automatic mode
D = Delay mode (Stylet Only)

STEP 5: BIOPSY SPECIMEN

Withdraw the Achieve needle from the coaxial introducer. To retrieve the tissue sample, hold the instrument with the A and D firing buttons facing up, and pull back and release the charging arm once. This action will retract the outer cutting cannula exposing the stylet notch with the tissue sample.

STEP 5: OBTAINING MULTIPLE SAMPLES

After the tissue sample is removed, additional samples from the same patient may be obtained by pulling the charging arm a second time, which will retract the stylet within the cutting cannula, placing the Achieve biopsy device once again in a fully charged position. Repeat Steps 3-5.

In the automatic mode, the Achieve automatic biopsy device is designed to fire the cannula and stylet in rapid succession. Please exercise caution before proceeding as the device will advance 2.5 cm when activated.

CAUTION: For single use only. Re-use may result in a non-functional product or contribute to cross contamination.

Only clinicians who have been properly trained in this procedure, including patient preparation, sample preservation and the use of image guidance for percutaneous biopsy, should use this device.

	Use By: YYYY-MM-DD
	Lot Number
	Catalog Number
	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged
	Single Use
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service.
	Medical Device
Sterile Package	Sterile Package
	Manufacturer
	Date of Manufacture: YYYY-MM-DD



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



Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland
EU Customer Service +31 43 358 82 22

组织活检针

使用說明

该说明书适用于自动活检针套装。型号规格为CA1411, CA1415, CA1420, CA1611, CA1615, CA1620, CA1811, CA1815, CA1820, CA2011, CA2015, CA2020。

适用范围：本产品用于从软组织如乳房、肾脏、肺、前列腺和甲状腺获取活检样本。其中，自动活检针用于从软组织如乳房、肾脏、肝脏、前列腺获取活检样本；半自动活检针用于从软组织如乳房、肾脏、肺和甲状腺获取活检样本；手动活检针用于从软组织如肾脏、肝脏取活检样本；导引针用于协助活检针从软组织如乳房、肾脏、肝脏、肺、前列腺和甲状腺获取活检样本。

- 不适用于骨活检
- 如包装破损,请勿使用。
- 。
- 警告：对活检针进行发射检测会损伤到切割套管和/或管心针针头。因为在激发时活检针会快速向前推进2.5 cm，所以在发射前把手指或者其他物体从针的前方移开。不要在不安全的方向对活检装置进行发射检测。
- 第1步：导引针放置
- 将导引针上的限位器调至预期的校准位置并固定。然后，插入导引针，直至限位器接触皮肤表面。必要时，使同轴针成像，以确保针尖位于或接近取样区边缘。拔出内置衬芯。
- 第2步：对Achieve的使用前准备
- 只需要简单的把获能拉杆向后拉动，就可以使Achieve活检针获得发射所需的能量，回拉期间放松两次，第一次是使针管获能，第二次是使内部的衬芯获能。
- 第3步：插入Achieve
- 将Achieve活检针插入同轴导引针，并将其紧按在鲁尔接头上。
- 第4步：装置的发射
- 在Achieve活检设备获得发射能量后，有两种序列的发射方式可供选择。
1. 延迟模式—按下按钮D后，会把衬芯释放入取样区域内。操作者使用延迟发射方式可以首先确认样本凹槽是否在目标区之内，然后再按下按钮A发射针管来获取组织标本。
 2. 自动模式—操作者可以选择全序列模式，把延迟模式的步骤省略，直接按下按钮A即可。这将会使衬芯和针管依次释放并获取组织样本。
A=自动模式
D=延迟模式（仅释放衬芯）
- 第5步：活检样本
- 从同轴导引针中退出Achieve针。使发射按钮A和D朝上并握住装置，回拉一次获能拉杆然后放松，此时即可得到组织样本。这个动作会使针管回缩，以便暴露出带有组织样本的衬芯凹槽。
- 第6步：获取多个样本
- 在取走组织样本后，如果需要对同一患者获取另外的样本，只需要再次回拉获能拉杆使管心针再次回缩入针管内，此时的Achieve活检装置再次处于获得全部发射能量的待发射状态。重复步骤3-5。
- 警告：一次性使用，重复使用会造成交叉感染。
- 只有经过培训（包括病人准备、样品保存和影像导引经皮活检）的医生，才可用此器械。

	失效日期
	批号
	产品编码
	经环氧乙烷灭菌
	如包装破损切勿使用
	不得二次使用
	查阅使用说明书
	医疗设备
	无菌包装
	制造商
	生产日期

产品名称：组织活检针

型号、规格：见附页

结构及组成：本产品分为自动活检针、半自动活检针、手动活检针和导引针。自动活检针和半自动活检针由衬芯、针管、弹簧、把手和针座组成，采用环氧乙烷灭菌。手动活检针由衬芯、针管、衬芯座和针座组成，采用射线灭菌。导引针由衬芯、针管、衬芯座、针座和限位器组成，采用环氧乙烷灭菌。本产品一次性使用。

注册证编号：国械注进20162142774

产品技术要求编号：国械注进20162142774

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 USA

注册人及生产企业联系方式：1-801-253-1600

生产地址：Avenida Sor Juana Ines De La Cruz, 19970 Interior B, Edificio 2, Parque Industrial Frontera, Tijuana, Baja California, C.P. 22630 MEXICO

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

储存条件：应储存在阴凉、干燥、清洁、通风良好和无腐蚀性气体的环境中

有效期：5年

生产日期和失效日期：见产品标签

说明书编制或修订日期：2021年9月

规格型号附页

组织活检针型号表

自动活检针型号表

型号	长度 L	外径
A146	60	2.1(14G)
A149	90	2.1(14G)
A1411	110	2.1(14G)
A1415	150	2.1(14G)
A1420	200	2.1(14G)
A166	60	1.6(16G)
A169	90	1.6(16G)
A1611	110	1.6(16G)
A1615	150	1.6(16G)
A1620	200	1.6(16G)
A186	60	1.2(18G)
A189	90	1.2(18G)
A1811	110	1.2(18G)
A1815	150	1.2(18G)
A1820	200	1.2(18G)
A1825	250	1.2(18G)
A206	60	0.9(20G)
A209	90	0.9(20G)
A2011	110	0.9(20G)
A2020	200	0.9(20G)

Temno evolution半自动活检针型号表

型号	长度 L	外径
TT146	60	2.1(14G)
TT1411	110	2.1(14G)
TT1415	150	2.1(14G)
TT1420	200	2.1(14G)
TT166	60	1.6(16G)
TT1611	110	1.6(16G)
TT1615	150	1.6(16G)
TT1620	200	1.6(16G)
TT186	60	1.2(18G)
TT1811	110	1.2(18G)
TT1815	150	1.2(18G)
TT1820	200	1.2(18G)
TT206	60	0.9(20G)
TT2011	110	0.9(20G)
TT2015	150	0.9(20G)
TT2020	200	0.9(20G)

Temno半自动活检针型号表

型号	长度 L	外径
T146	60	2.1(14G)
T149	90	2.1(14G)
T1411	110	2.1(14G)
T1415	150	2.1(14G)
T1420	200	2.1(14G)
T166	60	1.6(16G)
T169	90	1.6(16G)
T1611	110	1.6(16G)
T1615	150	1.6(16G)
T1620	200	1.6(16G)
T186	60	1.2(18G)
T189	90	1.2(18G)
T1811	110	1.2(18G)
T1815	150	1.2(18G)
T1820	200	1.2(18G)
T1915	150	1.1(19G)
T206	60	0.9(20G)
T209	90	0.9(20G)
T2011	110	0.9(20G)
T2015	150	0.9(20G)
T2020	200	0.9(20G)
T226	60	0.7(22G)
T229	90	0.7(22G)
T2215	150	0.7(22G)

手动活检针型号表

型号	长度 L	外径
2N2711X	76	1.2(18G)
2N2712X	114	1.2(18G)
2N2713X	152	1.2(18G)
2N2700X	76	2.1(14G)
2N2702X	114	2.1(14G)
2N2704X	152	2.1(14G)

导引针型号表

型号	长度 L	外径
PP13510	100	2.4(13.5G)
PP1356	60	2.4(13.5G)
PP156	60	1.8(15G)
PP1510A	100	1.8(15G)
PP1515A	150	1.8(15G)
PP176	60	1.4(17G)
PP1710	100	1.4(17G)
PP1715	150	1.4(17G)
PP196	60	1.1(19G)
PP1910	100	1.1(19G)
PP1915	150	1.1(19G)
PP206	60	0.9(20G)
PP2010	110	0.9(20G)
PP2015	150	0.9(20G)

自动活检针套装型号表

型号	组成型号	
	自动活检针	导引针
CA1411	A1411	PP1356
CA1415	A1415	PP13510
CA1420	A1420	PP13515
CA1611	A1611	PP156
CA1615	A1615	PP1510A
CA1620	A1620	PP1515A
CA1811	A1811	PP176
CA1815	A1815	PP1710
CA1820	A1820	PP1715
CA2011	A209	PP196
CA2015	A2011	PP1910
CA2020	A2020	PP1915

清单结束