

# TRU-CUT®

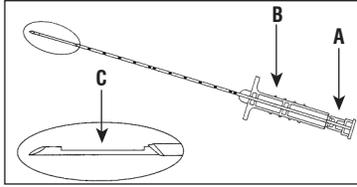
English

## Soft Tissue Biopsy Needles

### INSTRUCTIONS FOR USE

Intended for use in obtaining core biopsy samples from soft tissue such as breast, kidney, liver, lymph nodes and soft tissue masses. Not intended for use in bone.

**WARNING:** This needle is not designed for puncturing the skin.



A. Obturator Handle  
B. Cannula Handle  
C. Specimen Notch

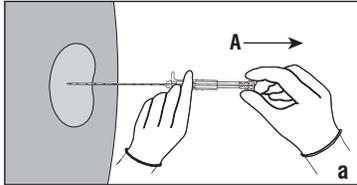
Excessive force or resistance when the needle is extended may result in a bent specimen notch. A bent specimen notch will interfere with needle function and possibly cause tissue tearing. Excessive lateral force applied against the obturator handle of the needle may interfere with the function of the stop mechanism and may result in deeper tissue penetration than is desired with the potential for tissue or organ damage.

#### INSTRUCTIONS FOR USE

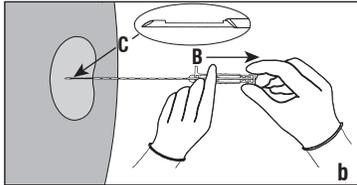
- Using sterile technique, prepare the biopsy site.
- Remove packaging. Remove protective sheath.
- Test for proper function and alignment by sliding the cannula over the obturator several times. If the parts do not move easily, the unit should be discarded.

#### BIOPSY PROCEDURE (except Breast Biopsy)

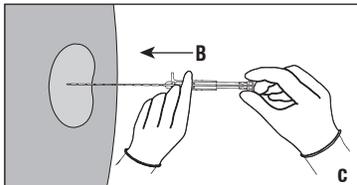
- 4A. Retract the obturator to cover the specimen notch. Hold the cannula handle and insert the needle assembly so that the specimen notch is within the tissue to be biopsied (a).



- 5A. Retract the cannula to expose the specimen notch.  
**NOTE:** Do not move the obturator (b).

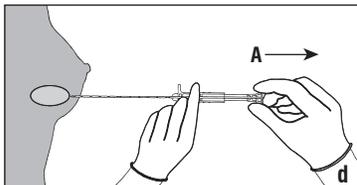


- 6A. To cut the tissue, quickly advance the cannula handle (c). If another biopsy of the same tissue is required, leave the cannula positioned at the target biopsy site and follow instructions for multiple biopsy samples.

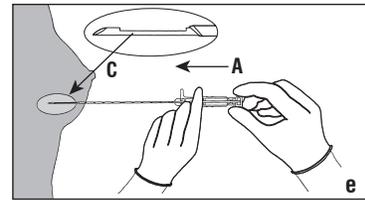


#### INSTRUCTIONS FOR THE BREAST BIOPSY

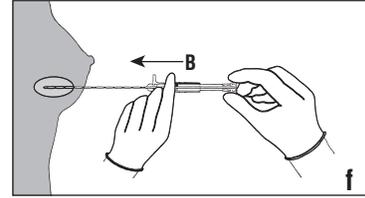
- 4B. Retract the obturator to cover the specimen notch. Hold the cannula handle and insert the needle assembly to the edge of the biopsy site (d).



- 5B. Hold cannula handle firmly. Quickly advance the obturator as far as permitted to position the specimen notch in the tissue to be biopsied (e).



- 6B. To cut the tissue, quickly advance the cannula handle (f). If another biopsy of the same tissue is required, leave the cannula positioned at the target biopsy site and follow instructions for multiple biopsy samples.



#### FOR MULTIPLE BIOPSY SAMPLES

- Hold the cannula handle in a fixed position.
  - Lift the obturator shaft slightly to clear the stop mechanism.
  - Pull the obturator back to remove it from the cannula.
  - Remove the sample from the specimen notch.
  - To reinsert the obturator into the cannula, align the obturator shaft with the open side of the cannula handle and the specimen notch facing up. Slide the obturator forward until the obturator shaft locks into the handle.
  - Follow one of the sampling procedures described to take additional biopsies.
- Withdraw the needle assembly with the cannula still advanced over the obturator.
  - Advance the obturator to remove the biopsy specimen from the specimen notch.

Do not use if package is damaged.

**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 Irradiation
	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 <a href="http://www.merit.com/ifu">www.merit.com/ifu</a> 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

**EC REP 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

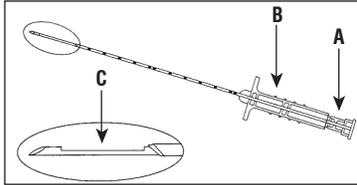
### 使用說明

该说明书适用于手动活检针。型号规格为2N2700X, 2N2702X, 2N2704X, 2N2711X, 2N2712X, 2N2713X。

适用范围：本产品用于从软组织如乳房、肾脏、肝脏、肺、前列腺和甲状腺获取活检样本。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、肝脏、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、肝脏获取活检样本；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

警告：本活检针的设计不适用于皮肤穿刺。



A 衬芯座

B 针座

C 衬芯样本凹槽

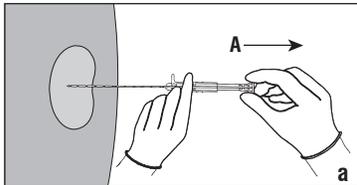
当穿刺针处于伸出状态时，过度用力或者出现阻力能够引起样本凹槽的弯曲。样本凹槽弯曲会妨碍穿刺针的功能，并可能导致组织撕裂。对穿刺针的衬芯座过度侧向用力会妨碍制动机械装置的功能，并可能会使穿刺深度深于标记深度，有损伤组织或者器官的可能。

使用指导

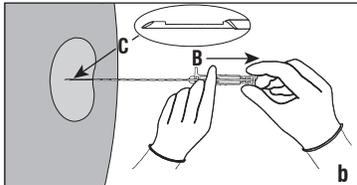
1. 使用无菌技术，对活检部位做好准备。
2. 拆开包装，移除保护鞘。
3. 检查功能是否正常，把针管套入衬芯直线滑动数次。如果有部件移动不畅，那么整套装置不应继续使用。

穿刺步骤（乳房穿刺除外）

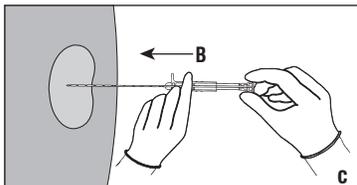
- 4A. 回拉衬芯使样本凹槽处于遮盖状态。握住针座，把组合后的穿刺针整体插入，使样本凹槽处于活检组织内部 (a)。



- 5A. 回拉针管使样本凹槽处于暴露状态。注意：不要移动衬芯 (b)。

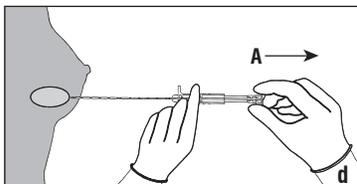


- 6A. 快速推进针座以切割组织 (c)。如果需要同一组织进行再次活检，则把针管放置于穿刺目标位置并按照多次穿刺取样的指导继续进行操作。

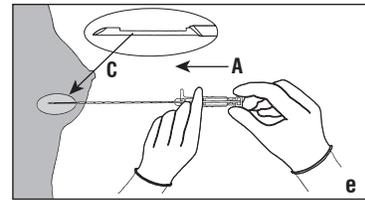


乳房穿刺的指导

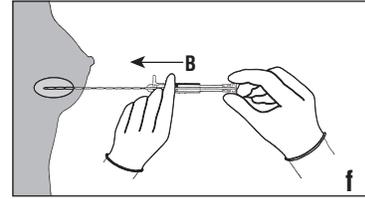
- 4B. 回拉衬芯使样本凹槽处于遮盖状态。握住针管手柄，把组合后的穿刺针插入到活检位置边缘 (d)。



- 5B. 稳定的握住针座。快速推进衬芯，距离尽可能的长以便使样本凹槽处于待穿刺的组织内部 (e)。



- 6B. 快速推进针座以切割组织 (f)。如果需要同一组织进行再次活检，则把针管放置于穿刺目标位置并按照多次穿刺取样的指导继续进行操作。



多次穿刺取样的指导

- 握住针座使其处于一个固定位置。
- 轻轻抬起衬芯杆以清除制动机械装置。
- 回拉衬芯并把衬芯移出针管。
- 把样本从样本凹槽中移出。
- 使样本凹槽向上，把衬芯从针管开口处直线插入，以便使衬芯重新插入针管。把衬芯一直向前滑动推进，直到衬芯杆锁入手柄。
- 按照上述取样步骤中相应的程序继续操作以进行再次活检。

7. 把穿刺针组件撤出，撤出时要使针管相对于衬芯始终处于推进状态以防组织样本暴露。
8. 推进衬芯，把活检样本从样本凹槽中移出。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

	失效日期
	批号
	产品编码
	经射线灭菌
	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

如包装破损，请勿使用。

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

说明书编制或修订日期：2021年9月

生产日期和失效日期：见产品标签

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