

Medical Device Recall Reporting Form

《医疗器械召回事件报告表》

Product name 产品名称	Max-Core Disposable Core Biopsy Instrument 一次性活检针（商品名：Max-Core）	Registration license Number 注册证号码	CFDA(I)20143150789, which was effective from Jan.28,2014 to Jan.27, 2018. 国食药监械（进）字 2014 第 3150789 号,有效期自 2014 年 1 月 28 日至 2018 年 1 月 27 日
Manufacturer 生产企业	Bard Peripheral Vascular, Inc.		
Responsible company, person and contact in China 中国境内负责单位、负责人及联系方式	Bard Healthcare Science (Shanghai) Co., Ltd 巴德医疗科技（上海）有限公司 Weiwei Sun/+86 21 61950999 孙薇薇 021-61950999 Cher Liu/+86 21 61950998 刘月 021-61950998		
Person and contact information of recall 召回工作联系人和联系方式	Weiwei Sun/+86 21 61950999 孙薇薇 021-61950999 Cher Liu/+86 21 61950998 刘月 021-61950998		
Indication 产品的适用范围	The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone. 该活检器械拟定用于获得肝、肾、前列腺、脾、淋巴结和各软组织瘤的活检组织。不适用于骨骼。		
Recalling region and country 涉及地区和国家	Australia, China, EU, Japan, Korea, Mexico, Panama, Singapore, Taiwan, and the U.S. 澳大利亚、中国、欧盟、日本、韩国、墨西哥、巴拿马、新加坡、台湾和美国	Product Model and Code 涉及产品型号、规格	MC1820
Quantity of recall product including manufacture or import 涉及产品生产（或进口中国）数量	50 EA. 50 件	Quantity of recall product be distributed in China market 涉及产品在中国的销售数量	50EA 50 件
Identification info Such as Lot 识别信息(如批号)	REYC2853		



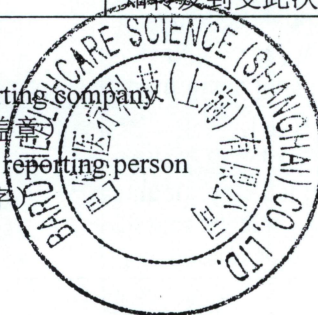
Recall reason 召回原因简述	Bard Peripheral Vascular (BPV) became aware that a user experienced a needlestick injury after Max-Core Disposable Core Biopsy Instrument self-activated during cleaning of the needle shaft. An increase in Max-Core Core Biopsy Instrument complaints for self-activation led to the opening of a Quality Event to investigate the increase in failures. Users of the device are at risk of injury if the device inadvertently self-activated during handling or cleaning while the needle is in place. Bard Peripheral Vascular (BPV) has confirmed that the above product code / lot number may be at risk of having self-activation-related issues. 巴德BPV公司收到投诉显示一个用户在对Max-Core一次性活检针针杆进行清洗时，活检针自激发，导致该用户被针刺伤。Max-Core一次性活检针自激发的相关抱怨逐步增多，因此我公司自发进行了质量核查以调查原因。用户在使用或清洗产品时，可能存在因自激发被刺伤的风险。巴德BPV公司确认以上产品型号/批号可能存在自激发相关问题的风险。
Recall actions 纠正行动简述	For all affected products, stop to distribute and use and place in quarantine immediately, send this recall notification to relevant distributors or hospitals and getting the affected product returned. 将相应召回批次的产品立即停止销售和使用，并将召回产品隔离、将本召回通知转发到受此次召回影响的下级经销商或医院，要求其将受影响产品退回。

Seal of the reporting company

报告单位：（盖章）

Signature of the reporting person

报告人：（签字）



Signature of

负责人：（签字）

Reporting date

报告日期：2015-4-20

孙凤娟

