

OA 165
2023.2.23

提交: 企业所在地省级食品药品监督管理部门

器械注册/备案部门

医疗器械召回事件报告表

产品名称	主动脉内球囊反搏泵 (商品名: CARDIOSAVE) 主动脉内球囊反搏泵 Intra- Aortic Balloon Pump	注册证或备案凭 证编码	国食药监械(进)字 2014 第 3214542 号 国械注进 20193082223
生产企业名称	德塔斯康医疗股份有限公司 Datascope Corp.		
代理人名称	迈柯唯(上海)医疗设备有限公司		
召回单位负责人和 联系方式, 经办人 和联系方式	负责人: 胡文仙 联系方式: 021-61973999 经办人: 楼雨晴 联系方式: 021-61973999		
产品的适用范围	该产品临床适用于成人患者, 对主动脉球囊进行充气 and 排气, 通过反搏原理为左心室提供暂时支持。主动脉球囊放置于下行主动脉, 位于左锁骨动脉分支末端。放置球囊后, 将反搏泵调整为心电图(ECG)或动脉压力波形同步触发, 确保在心动周期的相应位置进行充气 and 排气。		
涉及地区和国家	全球	召回级别	一级
涉及产品生产(或 进口中国)批次、 数量	507 (其中 5 台样机)	涉及产品型号、 规格	CARDIOSAVE Hybrid
识别信息(如批 号)	序列号信息详见附件 UDI: 10607567108421	涉及产品在中国 的销售数量	502 台
召回原因简述	原因 1: 此召回为“沪药监械主召 2023-001”的更新, 仅变更召回级别为一级, 纠正行动不做调整。生产企业内部调查发现, 若治疗时使用的主动脉内球囊导管发生穿孔, 血液进入主动脉内球囊反搏泵主机可能导致意外停机。 原因 2: 生产企业内部调查发现: ①显示屏连接线和背板-连接线组件之间可能出现连接故障, 从而导致 IABP (主动脉内球囊反搏泵) 意外停机 (该问题仅限于 2017 年 7 月 24 日之前发货的产品)。②主机和视频显示板之间可能出现通信中断, 从而导致 IABP 意外停机, 生产企业没有收到相关的不良事件报告。 本着对客户负责的态度, 确保产品使用安全、有效, 企业决定对其进行召回。本次召回仅涉及附件所列型号批次, 其他型号批次不受影响。		
纠正行动简述(包 括召回要求好处理 方式等)	1. 识别受影响客户并发送客户通知, 要求客户遵循通知中的警示信息和临床指导建议。 2. 更新产品说明书, 增加警示及临床指导措施。 对受影响设备的显示连接线进行更换 (该问题仅限于 2017 年 7 月 24 日之前发货的产品)。 对受影响设备的软件进行升级。		



报告人: (盖章)

报告人:

负责人: 胡文仙

报告日期: 2023/2/20



序列号					
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