

附件 1

医疗器械召回事件报告表

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

产品名称	覆膜支架系统	注册证或备案 凭证编码	国械注进 20153132422 国械注进 20173137035
生产企业名称	Medtronic Inc. 美敦力公司		
代理人名称	美敦力（上海）管理有限公司		
召回单位负责人和联系方式，经办人和联系方式	负责人：吴 懿 021-20325954 经办人：祝 易 021-20325241		
产品的适用范围	国械注进 20153132422：该产品适用于肾下腹主动脉瘤或主髂动脉瘤的血管内治疗。 国械注进 20173137035：该产品适用于肾下腹主动脉或主髂动脉瘤的血管内治疗。		
涉及地区和国家	全球	召回级别	2 级
涉及产品生产（或进口中国）批次、数量	2603 个	涉及产品 型号、规格	见附页 1
识别信息 （如批号）	见附页 1	涉及产品在中 国的销售数量	1998 个
召回原因简述	美敦力通过投诉调查发现，特定型号下的特定批号的覆膜支架系统的锥形头端可能会与输送系统分离。进一步调查表明，该问题是由于我司供应商在制造锥形头端组件的过程中，制造人员的操作不规范导致，锥形头端分离的发生率预计为 0.002%。由于锥形头端分离只能发生在手术中支架释放的过程中，对于术中使用了受影响的支架且已经成功地释放，不会有额外的风险，也无需采取其他的措施。截至 2021 年 12 月 9 日，我司在全球范围内共收到 5 起锥形头端与输送系统分离的投诉，在中国市场上未发生过与该问题相关的投诉和不良事件。		
纠正行动简述（包括召回要求和处理方式等）	美敦力将向所有受影响的平台商及下游经销商和医院发送医疗器械主动召回通知函，阐明此轮召回的背景并要求经销商和医院确认收到通知函，立即停止经营或使用上述受影响产品，同时退回其持有的未使用的受影响产品。退回的产品将会被隔离在美敦力上海仓库，根据最终处置决定退回原厂或进行销毁。		





报告单位：美敦力（上海）管理有限公司
报告人：祝易

负责人：吴懿
报告日期：2022年1月18日

附页 1：受影响产品名称、注册证、型号和批号

产品名称：覆膜支架系统 注册证：国械注进20173137035	
型号	批号（一个批号仅对应一个产品）
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