

明字86号  
2023年1月20日

# 医疗器械召回事件报告表

提交: 企业所在地省级药品监督管理部门

器械注册/备案部门

|                        |   |                |                                       |
|------------------------|---|----------------|---------------------------------------|
| 产品名称                   | 腔镜下自动缝合器线匣 V-loc<br>180 Absorbable Reload/ V-loc<br>PBT Non-Absorbable Reload   | 注册证或备案<br>凭证编码 | 国械注进 20153651978;<br>国械注进 20153021978 |
| 生产企业名称                 | Covidien llc  |                |                                       |
| 代理人名称                  | 柯惠医疗器材国际贸易(上海)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<br>经办人: 魏梦舒 021-38986698   |                |                                       |
| 产品的适用范围                | 用于内窥镜手术中组织的缝合。  |                |                                       |
| 涉及地区和国家                | 澳大利亚, 爱尔兰, 美国等国家/地区   | 召回级别           | 二级                                    |
| 涉及产品生产(或进口中国)批次、数量     | 0   | 涉及产品型号、规格      | 见附页                                   |
| 识别信息(如批号)              | 见附页   | 涉及产品在中国的销售数量   | 0                                     |
| 召回原因简述                 | 美敦力全球通过投诉监控报告识别到特定型号特定批次的该产品在外科手术过程中存在缝针断裂的故障模式, 经查导致缝针出现断裂的根本原因在于制造过程中使用的相关模具没有很好的对齐, 用这种未对齐的模具冲压针孔时会致使缝针出现细微裂纹, 降低缝针强度。考虑到这一潜在问题可能导致手术时间延长, 异物掉入患者体内、意外辐射暴露等问题, 美敦力全球决定发起自主召回。我司中国境内尚未收到任何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)   | 不适用, 受影响产品未进口至中国, 无需采取纠正行动  |                |                                       |

报告单位: 柯惠医疗器材国际贸易(上海)有限公司

负责人: 吴懿

报告人: 魏梦舒

报告日期: 2023年1月17日





| 注册证编号  | 产品型号      | 识别信息: 批号/序列号   |
|--|-----------|--|
| 国械注进<br>20153651978<br>国械注进<br>20153021978<br>(延续后注<br>册证编号) | VL0CA004L | NI G0268Y; N9M0756Y  |
|  | VL0CA006L | NDD0586Y; NOH0178Y; NIA0817Y; NIB0531Y; NIE0104Y; NIE0747Y; NIF0714Y; NIH0583Y;<br>NI J0848Y; N2D0068Y; N2D0077Y; N2D0240Y   |
|  | VL0CA008L | NOA0577Y; NOCC0316Y; NDD0001Y; NDD0106Y; NDD0397Y; NDD0398Y; NOE0682Y; NOF0368Y;<br>NOF0758Y; NOF0969Y; NOG0972Y; NOJ11022Y; NOJ11023Y; NOK0723Y; NOK1031Y; NOL0127Y;<br>NOL0128Y; NOM0360Y; NOM0513Y; NIA0199Y; NIA0660Y; NIA0816Y; NIA0958Y; NIB0110Y;<br>NIB0750Y; NIC0088Y; NIC0398Y; NIC0495Y; NID0528Y; NID0697Y; NID0853Y; NIE0102Y;<br>NIE0103Y; NIF0035Y; NIF0182Y; NIG0107Y; NIG0404Y; NIG0628Y; NIH0234Y; NIH0677Y;<br>NI J0440Y; NIK0248Y; NIK0306Y; NIK0867Y; NIL0592Y; NIL0766Y; NIM0720Y; NIM0731Y;<br>N2A0468Y; N2B0095Y; N2B0188Y; N2B0289Y; N2C0008Y; N2C0009Y; N2C0032Y; N2C0495Y;<br>N2C0683Y; N2D0813Y; N2D0814Y; N9K1167Y; N9K1169Y; N9L0102Y; N9L0103Y; N9L0503Y;<br>N9L0966Y; N9M0077Y |
|  | VL0CA204L | NOC0212Y; NO J0294Y  |
|  | VL0CA206L | NOC0307Y; NOD0105Y; NOD0326Y; NOD0327Y; NOD0587Y; NOE0718Y; NOE0979Y; NIA0502Y;<br>NIE0748Y; NIF0701Y; NIF0915Y; NIG0759Y; NIH0058Y; NIH0803Y; NIK0185Y; NIM0276Y;<br>N2C0524Y; N2D0233Y; N2D0444Y; N2D0445Y   |
|  | VL0CA208L | NOA0201Y; NOC1103Y; NOD0498Y; NOD0506Y; NOF0759Y; NOG0279Y; NOG0280Y; NOH0960Y;<br>NOK0671Y; NOK0672Y; NOM0315Y; NOM0393Y; NIA0156Y; NIA0501Y; NIB0084Y; NIB0263Y;<br>NIB0560Y; NIC0728Y; NIE0462Y; NIE0508Y; NIF0048Y; NIF0556Y; NIG0123Y; NIG0442Y;<br>NIH0056Y; NIH0257Y; NIH0666Y; NIH0901Y; NI J0216Y; NI J0510Y; NI J0850Y; NIK0164Y;<br>NIL0069Y; NIL0494Y; NIL0672Y; N2A0110Y; N2B0148Y; N2E0299Y; N9J0737Y; N9K1182Y;<br>N9L0093Y; N9L0502Y; N9L0737Y; N9L0738Y; N9L0761Y; N9M0758Y   |
|  | VL0CA304L | NOB0409Y; NOD0405Y; NOF1041Y; NO J0293Y; N9J0918Y  |
|  | VL0CA306L | NOA0239Y; NOA0527Y; NOF0833Y; NOH1087Y; NIF0811Y; NIG0287Y; NIG0763Y; NIK0247Y;<br>N2B0322Y; N2C0682Y; N2D0302Y; N2D0552Y; N2E0113Y; N9J0258Y; N9M0757Y  |





附页 1：受影响产品的注册证编号、型号和批号/序列号

| 注册证编号 | 产品型号      | 识别信息：批号/序列号  |
|-------|-----------|--|
|       | VLOCN308L | N0A0383Y;N0K0988Y;N1G0106Y;N1G0551Y;N1L0085Y;N1L0162Y;N2C0509Y;N2C0748Y;N9J0919Y   |
|       | VLOCN004L | N0B0834Y;N0J0895Y  |
|       | VLOCN006L | N0B0660Y;N0J0042Y;N0J0896Y;N1A0931Y;N1C0644Y;N1L0438Y;N2E0205Y;N2E0350Y  |
|       | VLOCN008L | N0B0787Y;N0E0302Y;N1C0706Y;N1G0856Y  |
|       | VLOCN204L | N0B0001Y;N0E0552Y;N0G0568Y;N0J0894Y;N1F0108Y   |
|       | VLOCN206L | N0B0957Y;N0G0569Y;N0J0933Y;N0L0198Y;N0M0714Y;N1A0932Y;N1C0558Y;N1C0770Y;N1F0047Y;N1F0796Y;N1G0758Y;N1K0184Y;N2E0270Y;N2E0298Y;N9L0954Y |
|       | VLOCN208L | N0B0772Y;N0E0990Y;N0G0570Y;N0J0870Y;N1C0557Y;N1F0109Y;N1F0132Y;N1G0101Y;N1J0032Y;N9J0311Y  |
|       | VLOCN304L | N0B0833Y;N0G0487Y  |
|       | VLOCN306L | N0B0851Y;N0E0558Y;N0G0719Y   |
|       | VLOCN308L | N0G0324Y   |

--结束--

