“亞諾”經皮穿刺去除血栓裝置
回收警訊
(國內無進口受影響產品)

許可證字號：衛署醫器輸字第 022037 號

產品英文名稱： “Arrow” Trerotola PTD (Percutaneous Thrombolytic Device)

受影響規格/型號/批號：

型號	批號
PT-12709-WC PT-65709-HFWC PT-65709-W PT-65709-WC PT-45509 PT-65509-HFC PT-65509	13F20C0094, 13F20G0284, 13F20L0282, 13F21A0497, 13F21A0718, 13X21E0008, 13F21F1187, 13F20A0323, 13F20B0139, 13F20C0594, 13F20F0083, 13F20F0230, 13F20F0577, 13F20H0756, 13F20K0849, 13F20L0283, 13F20M0182, 13F21A0498, 13F21B0158, 13F21C0747, 13F21E0555, 13F19M0129, 13F20B0053, 13F20C0595, 13F20F0231, 13F20G0361, 13F20K0632, 13F21A0353, 13F21C0748, 13F21D0721, 13F21E0823, 13F21F1189, 13F20C0596, 13F20F0081, 13F20F0229, 13F20F0509, 13F20F0578, 13F20G0177, 13F20G0566, 13F20H0531, 13F20J0379, 13F20L0514, 13F21A0354, 13F21C0081, 13F21C0749, 13F21D0870, 13F21E0415, 13F21F1188, 13F20A0209, 13F20B0054, 13F20B0527, 13F20C0427, 13F20D0127, 13F20D0402, 13F20F0390, 13F20G0285, 13F20J0545, 13F20J0933, 13F20K0851, 13F20M0174, 13F21A0662, 13F21C0079, 13F21C0751, 13X21D0027, 13F21F0399, 13F21G0226, 13F21G1343, 13F21H0639, 13F21H1272, 13F21L0900, 13F20A0359, 13F20A0519, 13F20B0140, 13F20B0423, 13F20C0223, 13F20C0593, 13F20D0128, 13F20D0386, 13F20F0576, 13F20G0176, 13F20J0139, 13F20J0547, 13F20K0212, 13F20L0160, 13F20M0183, 13F21B0224, 13F21C0080, 13F21C0366, 13F21D0106, 13X21D0026, 13F21E0078, 13F21E0557, 13F21G1344, 13F21H0213, 13F21H0659, 13F21J0455, 13F21K0897, 13F21L0901, 13F20A0286, 13F20A0426, 13F20A0640, 13F20B0141, 13F20B0276, 13F20B0353, 13F20B0424, 13F20C0352, 13F20C0425, 13F20C0426, 13F20D0122, 13F20D0123, 13F20D0124, 13F20D0403, 13F20E0204, 13F20F0232, 13F20F0389, 13F20G0353, 13F20H0729, 13F20J0378, 13F20J0546, 13F20J0771, 13F20K0503, 13F20K0504, 13F20K0630, 13F20K0631, 13F20M0175, 13F20M0176, 13F20M0177, 13F20M0178, 13F20M0181, 13F21A0352, 13F21B0159, 13F21B0222, 13F21B0519, 13F21C0364, 13F21C0365, 13F21D0462, 13F21E0079, 13F21E0259, 13F21E0260, 13F21E0556, 13F21F0641, 13F21G0227, 13F21G0401, 13F21G0772, 13F21H0447, 13F21K0827, 13F21K0898, 13F21L0227, 13F21L0507, 13F21L0898

發布對象：醫療從業人員/醫療器材專業人員

警訊說明：(回收/矯正原因描述)

原廠接獲有關經皮穿刺去血栓裝置(Percutaneous Thrombolytic Device)於使用時，尖端可能與籃網(basket)分離的通報，因此啟動矯正行動。若發生上述情況，臨床人員可依照其專業判斷，以異物夾取器(snare device)或以小手術從血管內取出，或者在確認分離的尖端過小且不具活性的尖端栓塞相較嘗試取出的傷害較小情況下，可選擇不取出。這樣的事件可能導致異物進入動脈/靜脈循環的部分或完全栓塞，引發潛在的血管併發症，包括但不限於動脈或靜脈的機械性阻塞 (mechanical obstruction)、動脈或靜脈血栓、局部缺血或動脈阻塞及血栓形成(包括肺栓塞和梗塞)所造成血管覆蓋區域的梗塞，以及血管內的感染(可能性較小)。異物栓塞或其組成進入周邊或肺循環所將造成的後果，主要取決於栓塞大小。臨床人員亦可選擇將栓塞擷取於新放置的支架外，進而將栓塞從循環中排除。

國內矯正措施：

經查，台灣泰利福醫療產品有限公司未進口警訊受影響產品。

廠商聯繫資訊：

公司名稱：台灣泰利福醫療產品有限公司

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相關警訊來源(網址)：

美國 FDA：

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=191575

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=191576

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=191573

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=191468

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=191470

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=191574

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=191469

https://www.fda.gov/medical-devices/medical-device-recalls/arrow-international-llc-subsidiary-teleflex-inc-recalls-arrow-trerotola-percutaneous-thrombolytic

英國 MHRA：https://mhra-gov.filecamp.com/s/JMuZDZcEfJ2uCvp8/d

加拿大 Canada：https://recalls-rappels.canada.ca/en/alert-recall/arrow-trerotola-products