

“法斯樂舒順” 蘭斯頓雙腔導管

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 023106 號

產品英文名稱：“Vascular Solutions” Langston Dual Lumen Catheter

受影響規格/型號/批號：

型號	批號 (國內無進口受影響批號)
5515	635806, 640206, 644140, 648701, 654143, 658252, 659635, 661470, 665301, 670376,
5540	654130, 672728, 656020, 638111, 677058, 643376, 633647, 639516, 645032, 649315,
5545	650991, 656191, 658151, 659443, 660590, 666438, 670586, 672660, 635207, 636898,
5550	643051, 644573, 645360, 645482, 648481, 649729, 650018, 650873, 651457, 653053, 655645, 655738, 657627, 658250, 658824, 659122, 659217, 660910, 661139, 663039, 663344, 665098, 665099, 666559, 668703, 671743, 671948, 672894, 633211, 635208, 635542, 636901, 637832, 644015, 646106, 649078, 650765, 654190, 657517, 657680, 660717, 662903, 663138, 665303, 667164, 669190, 647786, 671427, 634423, 634247, 648043, 648963, 651920, 653863, 660823, 662493, 661257, 650369, 638953, 669199, 658438, 668701, 636284, 640938, 641222, 641543, 641679, 642031, 650023, 654010, 655128, 657030, 660075, 663281, 663790, 663854, 635805, 659362, 668303, 666966, 632018, 635209, 643835, 645118, 646247, 647482, 649456, 652176, 653319, 656554, 659630, 661863, 662824, 665234, 669602, 647370, 648337, 672813, 664087, 657243, 652097, 668095, 636471, 640676, 642373, 642520, 644650, 654890, 655460, 657866, 658018, 661474, 662053, 662133, 664449, 667465, 668934, 670503, 672130, 663791, 635280, 669402, 632020, 638198, 639892, 640034, 648603, 653565, 654889, 658984, 662642, 671202, 643542, 645481, 672349, 635541, 661707, 666332, 670144, 654514, 654657, 671004, 671633, 637388, 645031, 646641, 650606, 670299, 642928, 670865, 639414, 642178, 646110, 651524, 660199, 668094, 669591, 641060, 647014, 651163, 655869, 656727, 647697, 635861, 640459, 666067, 667936, 632019, 638323, 643874, 646108, 648210, 649584, 654340, 658541, 664236, 633929, 646640, 653443, 668305, 668771, 655287, 662265, 637384, 651829, 669737, 648780, 652777, 653776, 658671, 667832, 637945, 651278, 652628, 660288, 667151, 656801, 646879, 650560, 652459, 659855, 660397, 667835, 636709, 647206, 673021, 649315, 634357, 645111, 649740, 650126, 655647, 657411, 661790, 666866, 673313, 638819, 650127, 659802, 672219, 675001, 638547, 668503, 637973, 640204, 659555, 660597, 633668, 663767, 669593, 659856, 644096, 676528, 672481, 632704, 656792, 658273, 666755, 635885

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)

受影響產品在加壓注射過程中，導管的內腔可能會與導管接頭分離。

國內矯正措施：

經查，國內未進口受影響產品，故台灣泰利福醫療產品有限公司無須執行回收行動。

廠商聯絡資訊：

公司名稱：台灣泰利福醫療產品有限公司

聯絡電話：02-2656-5965

聯絡人電子郵件：Teleflex.Taiwan@teleflex.com

相關警訊來源(網址)：

美國 FDA：

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=183703>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=183704>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=183705>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=183706>