

## California Device Recall Information Sheet

### Food and Drug Branch – Device Recalls

Medline Industries, LP-Northfield Recalls Procedure Kits Containing Medtronic Aortic Root Cannula, Neonatal/Pediatrics Intubation Trays, and Newborn Resuscitation Kits

| Recall Date | Product Description                                                                                                                                                                                                                                                                    | Recalling Firm                      | Recall Reason                                                                                                                                                      |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 04/04/2025  | Medline medical procedure kits, containing Medtronic Aortic Root Cannula, labeled as follows: TOL DR R Pack                                                                                                                                                                            | Medline Industries, LP - Northfield | Medical convenience kits containing Medtronic Aortic Root Cannula are being recalled due to the potential excess material in the male lures on the aortic cannula. |
| 04/04/2025  | Medline medical procedure kits, containing Medtronic Aortic Root Cannula, labeled as follows: CPB Adjunct Pack, DR. C Pack, PK Cust CV A&B C CO, TOL DR R Pack, TOL DR. C Pack, TOL DR. M Pack.                                                                                        | Medline Industries, LP - Northfield | Medical convenience kits containing Medtronic Aortic Root Cannula are being recalled due to the potential excess material in the male lures on the aortic cannula. |
| 04/04/2025  | Medline medical procedure kits, containing Medtronic Aortic Root Cannula, labeled as follows: CABG OPNHRT S HSP, Cardiac CABG, Cardiac Pack, DR D AC Pack, Heart Basin Pack-LF, K OH Component Pack, Open Heart Adult Part 1 CDS, Open Heart B Pack-LF, Open Heart Pack, Z Open Heart. | Medline Industries, LP - Northfield | Medline medical procedure kits, containing Medtronic Aortic Root Cannula                                                                                           |
| 04/04/2025  | Medline medical procedure kits, containing Medtronic Aortic Root Cannula, labeled as follows: Heart Basin Pack-LF                                                                                                                                                                      | Medline Industries, LP - Northfield | Medical convenience kits containing Medtronic Aortic Root Cannula are being                                                                                        |

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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                     | recalled due to the potential excess material in the male lures on the aortic cannula.                                                     |
| 04/10/2025 | Medline medical convenience kits labeled as: Neonatal Intubation Tray, REF ACC010371C; Newborn Resuscitation Kit, REF ACC010381A; Newborn Resuscitation Kit, REF ACC010381B; Newborn Resuscitation Kit, REF ACC010381C; Peds Grey-Pink-Red, REF ACC010395; Peds Purple, REF ACC010397; Neonatal Intubation Tray, REF ACC010541A; Neonatal Intubation Tray, REF ACC010541B; Neonatal Intubation Tray, REF ACC010541C; Pediatrics Intubation Tray, REF DYNJAA252. | Medline Industries, LP - Northfield | Specific Medline Kits were manufactured using Intubation ORAL/NASAL Endotracheal Tubes which were subsequently recalled by Smiths Medical. |

| Recall Class | Product Identification                                                                                                                                                                                                                                                                                                 | Distribution | Affected Dates          |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-------------------------|
| I            | TOL DR R PACK, UDI/DI 10195327166304 (ea) 40195327166305 (case), Lot Numbers 22GBL197, 22JBG283; TOL DR R PACK, UDI/DI 10195327273484 (ea) 40195327273485 (case), Lot Numbers 23ABO787, 23EBT153, 23HBB950; TOL DR R PACK, UDI/DI 10195327503390 (ea) 40195327503391 (case), Lot Numbers 24CBL126, 24EBV315, 24EBW136. | 468 units    | February 2025 and Prior |
| I            | TOL DR R PACK, UDI/DI 10198459054242 (ea) 40198459054243 (case), Lot Number 24IBV027; TOL DR. C PACK, UDI/DI 10195327176914 (ea) 40195327176915 (case), Lot Number 22HBX339; TOL DR. CRESCENZO PACK, UDI/DI                                                                                                            | 1247 units   | February 2025 and Prior |

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|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|----------------------------|
|   | 10195327273750 (ea)<br>40195327273751 (case), Lot<br>Numbers 22LBC389, 23EBQ439,<br>23HBG138; TOL DR. C PACK,<br>UDI/DI 10195327513818 (ea)<br>40195327513819 (case), Lot<br>Numbers 23KBS878, 24CBB191,<br>24EBD828; TOL DR. C PACK,<br>UDI/DI 10198459054259 (ea)<br>40198459054250 (case), Lot<br>Numbers 24FBO426, 24HBP282,<br>24JBL545, 24LBR173; TOL DR. M<br>PACK, UDI/DI 10195327513825<br>(ea) 40195327513826 (case), Lot<br>Numbers 23KBC932, 24CBP602,<br>24EBV519; TOL DR. M PACK,<br>UDI/DI 10198459054266 (ea)<br>40198459054267 (case), Lot<br>Numbers 24GBI558, 24GBX898,<br>24IBE173, 24IBE173A, 25ABG352.                                                                                                                                                                                       |            |                            |
| I | CABG OPNHRT S HSP, UDI/DI<br>10195327449650 (EA)<br>40195327449651 (case), Lot<br>Numbers 23IBH906, 24EBC446,<br>24FMC989, 24GME639; CABG<br>OPNHRT S HSP, UDI/DI<br>10198459089503 (EA)<br>40198459089504 (case), Lot<br>Numbers 24KMB217, 25AMG162;<br>CARDIAC CABG, UDI/DI<br>10195327490362 (EA)<br>40195327490363 (case), Lot<br>Numbers 23LBV500, 24DBS178,<br>24EBK724, 24FBL825; CARDIAC<br>PACK, UDI/DI 10195327490355<br>(EA) 40195327490356 (case), Lot<br>Numbers 24CBN830, 24DBS177;<br>DR D AC PACK, UDI/DI<br>10195327298258 (EA)<br>40195327298259 (case), Lot<br>Numbers 23HBD834, 23IBF066;<br>HEART BASIN PACK-LF, UDI/DI<br>10195327047573 (EA)<br>40195327047574 (case), Lot<br>Numbers 22GMD767, 22JMD290,<br>23GMC713, 23IMA561,<br>23KMC902; K OH COMPONENT<br>PACK, UDI/DI 10195327659684 | 1310 units | February 2025 and<br>Prior |

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|   | (EA) 40195327659685 (case), Lot Numbers 24EBT996, 24IBR766, 24KBJ595, 24LBQ493; OPEN HEART ADULT PART 1 CDS, UDI/DI 10195327034726 (EA) 40195327034727 (case), Lot Number 24CBG813; OPEN HEART B PACK-LF, UDI/DI 10195327206383 (EA) 40195327206384 (case), Lot Numbers 22IMH938, 22KMC295, 23AMD800, 23DME198, 23GMD603, 23GMI093, 23HMG457, 23IMG457, 23KMJ484, 24AMG704, 24AMI684, 24BMG042, 24GMA506, 24GMA897; OPEN HEART PACK, UDI/DI 10889942934164 (EA) 40889942934165 (case), Lot Number 23JBD049; Z OPEN HEART, UDI/DI 10195327659882 (EA) 40195327659883 (case), Lot Numbers 24EBT606, 24IBE093, 24JBV568, 24KBR945. |            |                         |
| I | HEART BASIN PACK-LF, UDI/DI 10195327563561 (ea) 40195327563562 (case), Lot Numbers 24BMB798, 24DMH381, 24EMF949, 24GMF161, 24IMB237.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 320 units  | February 2025 and Prior |
| I | REF ACC010371C: UDI/DI 10193489268188 (ea) 40193489268189 (case); REF ACC010381A: UDI/DI 10193489800944 (ea) 40193489800945 (case); REF ACC010381B: UDI/DI 10193489457803 (ea) 401934894578049 (case); REF ACC010381C: UDI/DI 10193489922127 (ea) 40193489922128 (case); REF ACC010395: UDI/DI 10193489218152 (ea) 40193489218153 (case); REF ACC010397: UDI/DI 10193489218169 (ea) 40193489218160 (case); REF ACC010541A: UDI/DI                                                                                                                                                                                               | 1550 units | February 2025 and Prior |

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| 10195327036980 (ea)<br>40195327036981 (case);<br>REF ACC010541B: UDI/DI<br>10195327153649 (ea)<br>40195327153640 (case);<br>REF ACC010541C: UDI/DI<br>10198459155765 (ea)<br>40198459155766 (case);<br>REF DYNJAA252: UDI/DI<br>10193489297980 (ea)<br>40193489297981 (case),<br>Lot Numbers: 20DDA921-<br>22IBP405 |  |  |
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For additional information, please visit this [FDA Website Medtronic Aortic Root Cannula \(TOL DR R PACK\)](#), this [FDA Website Medtronic Aortic Root Cannula \(CPB Adjunct Pack, DR. C Pack, PK Cust CV A&B C CO, TOL DR R Pack, TOL DR. C Pack, TOL DR. M Pack \)](#), this [FDA Website Medtronic Aortic Root Cannula \(CABG OPNHRT S HSP, Cardiac CABG, Cardiac Pack, DR D AC Pack, Heart Basin Pack-LF, K OH Component Pack, Open Heart Adult Part 1 CDS, Open Heart B Pack-LF, Open Heart Pack, Z Open Heart\)](#), this [FDA Website Medtronic Aortic Root Cannula \(Heart Basin Pack-LF\)](#) and this [FDA Website Neonatal/Pediatrics Intubation Tray, and Newborn Resuscitation Kits](#).