

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Abbott Vascular Inc. Recalls 20/30 Priority Pack Accessory Kit w/Copilot, 20/30 Priority Pack Accessory Kit, 20/30 Indeflator, and 20/30 Priority Pack Kit

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|---|---------------------|--|
| 12/20/2024 | 20/30 Priority Pack Accessory Kit w/Copilot, REF: 1003327, used for cardiovascular procedures. | Abbott Vascular Inc | Inflation Device used during cardiovascular procedures may leak in the indeflator at the hose rotating luer or at the gauge, which could lead to air embolism. |
| 12/20/2024 | 20/30 Priority Pack Accessory Kit/.096 RHV, REF: 1000186, or use during vascular procedures in conjunction with interventional and / or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices). | Abbott Vascular Inc | Inflation Device used during cardiovascular procedures may leak in the indeflator at the hose rotating luer or at the gauge, which could lead to air embolism. |
| 12/20/2024 | 20/30 INDEFLATOR, REF: 1000184, for use during cardiovascular procedures in conjunction with interventional devices such as balloon dilatation catheters to create and monitor pressure in the balloon. | Abbott Vascular Inc | Inflation Device used during cardiovascular procedures may leak in the indeflator at the hose rotating luer or at the gauge, which could lead to air embolism. |
| 12/20/2024 | 20/30 Priority Pack Kit/.115 RHV, REF: 1000186-115, used for cardiovascular procedures. | Abbott Vascular Inc | Inflation Device used during cardiovascular procedures may leak in the indeflator at the hose rotating luer or at the gauge, which could lead to air |

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| | | | embolism. |
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| Recall Class | Product Identification | Distribution | Affected Dates |
|--------------|--|----------------------------|-------------------------|
| II | UDI-DI: 08717648013973, Lots: 60516923, 60553232, 60553233, 60556003, 60556008, 60556009, 60556011, 60556012, 60556014, 60557297, 60559370, 60559371, 60559374, 60559375, 60559376, 60561751, 60561752, 60561753, 60561754, 60561755 | 2056 Shipped to California | November 2024 and Prior |
| II | UDI-DI: 08717648013614, Lots: 60538750, 60538751, 60539113, 60545329 | 55 Shipped to California | November 2024 and Prior |
| II | UDI-DI: 08717648013591, Lots: 60418466, 60418467, 60418468 | 266 Shipped to California | November 2024 and Prior |
| II | UDI-DI: 08717648015274, Lots: 60564920, 60564933, 60566431, 60566432, 60566433, 60566667 | 0 Shipped to California | November 2024 and Prior |

For additional information, please visit this FDA website [20/30 Priority Pack Accessory Kit w/Copilot](#), this FDA Website [20/30 Priority Pack Accessory Kit](#), this FDA Website [20/30 Indeflator](#), and this FDA Website [20/30 Priority Pack Kit](#).