

Enforcement Report - Week of October 8, 2025

Class I Devices Event

Event ID:

97495

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/08/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/26/2025

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Medline Industries, LP
3 Lakes Dr
Northfield, IL 60093-2753
United States

Distribution Pattern:

US Distribution to States of: FL, MD, NJ, TN

Associated Products

Product Description:

Sterile Medline Convenience Kits: 1) MAJOR PACK L-F, Model Number: DYNJ0382730O; 2) LB BASIC CUSTOM PACK, Model Number: DYNJ61038B

Product Quantity:

22 units

Reason for Recall:

Convenience kits labeled as sterile have not gone through the sterilization process.

Recall Number:

Z-2592-2025

Code Information:

1) DYNJ0382730O, UDI-DI: 10198459117992(each), 40198459117993(case), Lot Number: 25GBC583; 2) DYNJ61038B, UDI-DI: 10195327596316(each), 40195327596317(case), Lot Number: 25GBF720;

Product Description:

Sterile Medline Convenience Kits: 1) EXTREMITY PACK, Model Number: DYNJ45701B

Product Quantity:

88 units

Reason for Recall:

Convenience kits labeled as sterile have not gone through the sterilization process.

Recall Number:

Z-2593-2025

Code Information:

1) DYNJ45701B, UDI-DI: 10193489856279(each), 40193489856270(case), Lot Number: 25GBF686

Class I Devices Event

Event ID:

97496

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

07/31/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/26/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Medline Industries, LP
3 Lakes Dr
Northfield, IL 60093-2753
United States

Distribution Pattern:

Domestic US distribution nationwide. International distribution pending. No international distribution.

Associated Products

Product Description:

Reprocessed Livewire Steerable Electrophysiology Catheter Item Numbers 401575RH 401582RH 401600RH 401603RH 401606RH 401652RH 401653RH 401654RH 401904RH 401905RH 401908RH 401914RH 401915RH 401918RH 401932RH 401933RH 401934RH 401938RH 401939RH 401940RH 401941RH 401991RH

Product Quantity:

7913 eaches

Reason for Recall:

Specific lots of reprocessed electrophysiology and ultrasound catheters may contain small residual particulates. If devices with residual particulates on patient-contacting surfaces are used, there is a potential risk of an inflammatory response or systemic infection, and if particulate were to dislodge during use and contact circulating blood and/or the heart, it may produce a granulomatous reaction or thrombus formation, which may lead to cerebral or pulmonary embolism, or deep vein thrombosis.

Recall Number:

Z-2610-2025

Code Information:

Item Number/UDI (ea)/UDI(case): 401575RH 10888277407497 20888277407494; 401582RH 10888277407510 20888277407517; 401600RH 10888277407541 20888277407548; 401603RH 10888277407558 20888277407555; 401606RH 10888277407565 20888277407562; 401652RH 10888277407572 20888277407579; 401653RH 10888277407589 20888277407586; 401654RH 10888277407596 20888277407593; 401904RH 10888277407602 20888277407609; 401905RH 10888277407619 20888277407616; 401908RH 10197344020966 20197344020963; 401914RH 10888277407527 20888177407524; 401915RH 10888277407626 20888277407623; 401918RH 10888277407640 20888277407647; 401932RH 10888277407671 20888277407678; 401933RH 10888277407688 20888277407685; 401934RH 10888277407695 20888277407692; 401938RH 10888277407701 20888277407708; 401939RH 10888277407718 20888277407715; 401940RH 10888277407480 20888277407487; 401941RH 10888277407725 20888277407722; 401991RH 10888277407756 2088277407753; LOTS EP230724 EP230731 EP230803 EP230816 EP230914 EP231017 EP231116 EP240108 EP240122 EP240212 EP240227 EP240311 EP240322 EP240411 EP240415 EP240422 EP240429 EP240507 EP240514 EP240520 EP240528 EP240607 EP240611 EP240710 EP240715 EP240723 EP240805 EP240812 EP240820 EP240829 EP240911 EP240923 EP240930 EP241008 EP241030 EP241125 EP250108

Product Description:

Reprocessed Webster CS Catheter 10 Electrodes for electrophysiological mapping of cardiac structures. Medline Item Numbers BD710DF282CRH BD710DF282RRH BD710FJ282CRH BD710FJ282RRH

Product Quantity:

7913 eaches

Reason for Recall:

Specific lots of reprocessed electrophysiology and ultrasound catheters may contain small residual particulates. If devices with residual particulates on patient-contacting surfaces are used, there is a potential risk of an inflammatory response or systemic infection, and if particulate were to dislodge during use and contact circulating blood and/or the heart, it may produce a granulomatous reaction or thrombus formation, which may lead to cerebral or pulmonary embolism, or deep vein thrombosis.

Recall Number:

Z-2611-2025

Code Information:

Item Number/UDI-DI BD710DF282CRH 10197344044023; BD710DF282RRH 10197344044030; BD710FJ282CRH 10197344044047; BD710FJ282RRH 10197344044054; LOTS EP241216 EP241218 EP241226 EP241231 EP250110 EP250121 EP250210

Product Description:

Reprocessed Inquiry Steerable Diagnostics Catheter for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies;

Medline Item Numbers 81102RH 81104RH 81107RH 81174RH 81402RH 81404RH 81405RH 81472RH 81473RH 81474RH 81531RH 81532RH

Product Quantity:

7913 eaches

Reason for Recall:

Specific lots of reprocessed electrophysiology and ultrasound catheters may contain small residual particulates. If devices with residual particulates on patient-contacting surfaces are used, there is a potential risk of an inflammatory response or systemic infection, and if particulate were to dislodge during use and contact circulating blood and/or the heart, it may produce a granulomatous reaction or thrombus formation, which may lead to cerebral or pulmonary embolism, or deep vein thrombosis.

Recall Number:

Z-2612-2025

Code Information:

Item Number/UDI-DI 81102RH 10197344133239; 81104RH 10197344133246; 81107RH 10197344133260; 81174RH 10197344133291; 81402RH 10197344133352; 81404RH 10197344133376; 81405RH 10197344133383; 81472RH 10197344133413; 81473RH 10197344133420; 81474RH 10197344133437; 81531RH 10197344133512; 81532RH 10197344133529; LOTS EP250212 EP250214

Product Description:

Reprocessed ViewFlex Xtra ICE Catheter to visualize cardiac structures; blood flow and other devices within the heart. Medline Item Numbers D087031RH

Product Quantity:

7913 eaches

Reason for Recall:

Specific lots of reprocessed electrophysiology and ultrasound catheters may contain small residual particulates. If devices with residual particulates on patient-contacting surfaces are used, there is a potential risk of an inflammatory response or systemic infection, and if particulate were to dislodge during use and contact circulating blood and/or the heart, it may produce a granulomatous reaction or thrombus formation, which may lead to cerebral or pulmonary embolism, or deep vein thrombosis.

Recall Number:

Z-2613-2025

Code Information:

Item Number/UDI-DI D087031RH 10197344019557 LOTS EP240731 EP240814 EP240826 EP240903 EP240916 EP241003 EP241014 EP241028 EP241104 EP241112 EP241202 EP241209A EP241219 EP241224 EP250114 EP250116 EP250204 EP250219

Product Description:

Reprocessed ACUSON AcuNav Ultrasound Catheter for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. For imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures. Medline Item Numbers 10135910RH 10135936RH

Product Quantity:

7913 eaches

Reason for Recall:

Specific lots of reprocessed electrophysiology and ultrasound catheters may contain small residual particulates. If devices with residual particulates on patient-contacting surfaces are used, there is a potential risk of an inflammatory response or systemic infection, and if particulate were to dislodge during use and contact circulating blood and/or the heart, it may produce a granulomatous reaction or thrombus formation, which may lead to cerebral or pulmonary embolism, or deep vein thrombosis.

Recall Number:

Z-2614-2025

Code Information:

Item Number/UDI-DI 10135910RH (for use on GE Systems) 10197344026500; 10135936RH (For use on Siemens Systems) 10197344026517; LOTS EP241021 EP241114 EP241226 EP250213 LOTS EP240731 EP240814 EP240826 EP240903 EP240916 EP241003 EP241014 EP241028 EP241104 EP241112 EP241202 EP241209A EP241219 EP241224 EP250114 EP250116 EP250204 EP250219

Class I Devices Event

Event ID:

97525

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

09/09/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/01/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Draeger, Inc.
3135 Quarry Rd
Telford, PA 18969-1042
United States

Distribution Pattern:

Devices were imported from Draegerwerk Ag and Co. KGaA and distributed in the following states: AL, AZ, CA, CT, FL, GA, ID, IL, IN, KS, KY, MA, MN, MO, NC, NE, NM, NV, NY, OH, PA, TX, UT, VA, WI. Devices were direct shipped from Draegerwerk Ag and Co. KGaA to the following countries: Argentina, Australia, Belgium, Brazil, Chili, China, Croatia, Denmark, Ecuador, France, Georgia, Germany, Greece, Hungary, India, Indonesia, Italy, Japan, Jordan, Kuwait, Lithuania, Mexico, Netherlands, Peru, Poland, Romania, Russian Federation, Saudi Arabia, Serbia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, Vietnam.

Associated Products

Product Description:

Brand Name: Atlan Product Name: Atlan A350 Model/Catalog Number: 8211500 Software Version: Not applicable Product Description: The Atlan is an anesthesia workstation intended for use in anesthetizing adults, pediatrics, and neonates. The device can be used for mechanical ventilation, manual ventilation, pressure-supported spontaneous breathing, and spontaneous breathing. The device is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions Component: Not applicable

Product Quantity:

530

Reason for Recall:

The device either indicated a failure of the piston ventilator before use or suffered a failure of the mechanical ventilation during use.

Recall Number:

Z-2616-2025

Code Information:

Lot Code: UDI-DI Number: 04048675556176 Serial Numbers Distributed in the US: ASTB-0181 ASTC-0005,ASTC-0006,ASTC-0007 ASTD-0244,ASTD-0259 ASTE-0180,ASTE-0254,ASTE-0255 ASTH-0083,ASTH-0464 ASUA-0479,ASUA-0482 ASUB-0012,ASUB-0013,ASUB-0015,ASUB-0017,ASUB-0018,ASUB-0292 ASUC-0065,ASUC-0084,ASUC-0085,ASUC-0086,ASUC-0087,ASUC-0088,ASUC-0090,ASUC-0091,ASUC-0092,ASUC-0096,ASUC-0097,ASUC-0099,ASUC-0100,ASUC-0101,ASUC-0102,ASUC-0103, ASUC-0104,ASUC-0105,ASUC-0107,ASUC-0108,ASUC-0109,ASUC-0110,ASUC-0111,ASUC-0112, ASUC-0113,ASUC-0116,ASUC-0117,ASUC-0118,ASUC-0119,ASUC-0120,ASUC-0121,ASUC-0122, ASUC-0123,ASUC-0125,ASUC-0126,ASUC-0127,ASUC-0128,ASUC-0129,ASUC-0130,ASUC-0131, ASUC-0132,ASUC-0133,ASUC-0134,ASUC-0135,ASUC-0136,ASUC-0137,ASUC-0138,ASUC-0139, ASUC-0140,ASUC-0141,ASUC-0142,ASUC-0143,ASUC-0143,ASUC-0144,ASUC-0145,ASUC-0162, ASUC-0163,ASUC-0164,ASUC-0165,ASUC-0166,ASUC-0167,ASUC-0168,ASUC-0169,ASUC-0170,ASUC-0171,ASUC-0172,ASUC-0173,ASUC-0203,ASUC-0204,ASUC-0205,ASUC-0206,ASUC-0207, ASUC-0208,ASUC-0209,ASUC-0210,ASUC-0218,ASUC-0219,ASUC-0220,ASUC-0221,ASUC-0222, ASUC-0223,ASUC-0224,ASUC-0225,ASUC-0235,ASUC-0236,ASUC-0237,ASUC-0340,ASUC-0341 ASUD-0244,ASUD-0261,ASUD-0262,ASUD-0263,ASUD-0267,ASUD-0281,ASUD-0282,ASUD-0283 Serial Numbers Distributed OUS ASUA-0353,ASUA-0441,ASUA-0447,ASUA-0472,ASUA-0478,ASUA-0496,,SUA-0497,ASUA-0500, ASUB-0004,ASUB-0024,ASUB-0025,ASUB-0030,ASUB-0033,ASUB-0034,ASUB-0035,ASUB-0038, ASUB-0039,ASUB-0040,ASUB-0041,ASUB-0043,ASUB-0044,ASUB-0046,ASUB-0048,ASUB-0063, ASUB-0064,ASUB-0066,ASUB-0067,ASUB-0069,ASUB-0073,ASUB-0074,ASUB-0075,ASUB-0076, ASUB-0077,ASUB-0095,ASUB-0096,ASUB-0097,ASUB-0098,ASUB-0099,ASUB-0100,ASUB-0101, ASUB-0102,ASUB-0104,ASUB-0105,ASUB-0107,ASUB-0108,ASUB-0109,ASUB-0112,ASUB-0113, ASUB-0114,ASUB-0115,ASUB-0116,ASUB-0118,ASUB-0120,ASUB-0121,ASUB-0122,ASUB-0123, ASUB-0124,ASUB-0128,ASUB-0129,ASUB-0130,ASUB-0136,ASUB-0137,ASUB-0139,ASUB-0140, ASUB-0141,ASUB-0143,ASUB-0144,ASUB-0145,ASUB-0146,ASUB-0147,ASUB-0148,ASUB-0149, ASUB-0150,ASUB-0151,ASUB-0152,ASUB-0153,ASUB-0154,ASUB-0155,ASUB-0156,ASUB-0157, ASUB-0158,ASUB-0159,ASUB-0160,ASUB-0161,ASUB-0162,ASUB-0163,ASUB-0177,ASUB-0178,ASUB-0188,ASUB-0189,ASUB-0190,ASUB-0191,ASUB-0192,ASUB-0193,ASUB-0194,ASUB-0195, ASUB-0196,ASUB-0197,ASUB-0198,ASUB-0199,ASUB-0201,ASUB-0202,ASUB-0203,ASUB-0204, ASUB-0205,ASUB-0206,ASUB-0207,ASUB-0208,ASUB-0209,ASUB-0210,ASUB-0211,ASUB-0223, ASUB-0224,ASUB-0225,ASUB-0226,ASUB-0227,ASUB-0229,ASUB-0230,ASUB-0231,ASUB-0232, ASUB-0233,ASUB-0234,ASUB-0235,ASUB-0236,ASUB-0237,ASUB-0238,ASUB-0240,ASUB-0243, ASUB-0245,ASUB-0252,ASUB-0253,ASUB-0254,ASUB-0255,ASUB-0256,ASUB-0257,ASUB-0258, ASUB-0260,ASUB-0261,ASUB-0262,ASUB-0263,ASUB-0264,ASUB-0265,ASUB-0271,ASUB-0272,ASUB-0273,ASUB-0276,ASUB-0278,ASUC-0001ASUC-0004,ASUC-0016,ASUC-0017,ASUC-0018, ASUC-0019,ASUC-0020,ASUC-0022,ASUC-0024,ASUC-0026,,ASUC-0028,,ASUC-0030,ASUC-0031, ASUC-0032,ASUC-0033,ASUC-0034,ASUC-0035,ASUC-0036,ASUC-0039,ASUC-0061,ASUC-0062, ASUC-0063,ASUC-0226,ASUC-0227,ASUC-0228,ASUC-0229,ASUC-0230,ASUC-0232,ASUC-0233, ASUC-0234,ASUC-0247,ASUC-0248,ASUC-0249,ASUC-0250,ASUC-0251,ASUC-0252,ASUC-0253, ASUC-0254,ASUC-0255,ASUC-0256,ASUC-0257,ASUC-0262,ASUC-0263,ASUC-0264,ASUC-0265, ASUC-0266,ASUC-0267,ASUC-0269,ASUC-0272,ASUC-0273,ASUC-0274,ASUC-0275,ASUC-0276,

ASUC-0277,ASUC-0278,ASUC-0279,ASUC-0284,ASUC-0286,ASUC-0287,ASUC-0288,ASUC-0289, ASUC-0290,ASUC-0291,ASUC-0292,ASUC-0293,ASUC-0294,ASUC-0295,ASUC-0296,ASUC-0300, ASUC-0301,ASUC-0302,ASUC-0303,ASUC-0304,ASUC-0305,ASUC-0306ASUC-0307,ASUC-0308, ASUC-0309,ASUC-0310,ASUC-0311,ASUC-0314,ASUC-0315,ASUC-0316,ASUC-0319,ASUC-0320, ASUC-0321,ASUC-0322,ASUC-0323,ASUC-0339,ASUC-0342,ASUC-0343,ASUC-0344,ASUC-0345, ASUC-0346,ASUC-0348,ASUC-0349,ASUC-0350,ASUC-0351,ASUC-0352,ASUC-0353,ASUC-0354, ASUC-0355,ASUC-0356,ASUC-0357,ASUC-0358,ASUC-0359,ASUC-0360,ASUC-0361,ASUC-0362,ASUC-0363,ASUC-0364,ASUC-0365,ASUC-0366,ASUC-0367,ASUC-0380,ASUC-0381,ASUC-0382, ASUC-0383,ASUC-0384,ASUC-0385,ASUC-0386,ASUC-0387,ASUC-0391,ASUC-0392,ASUC-0393, ASUC-0394,ASUC-0395,ASUC-0396,ASUC-0397,ASUC-0398,ASUC-0399,ASUC-0400,ASUC-0401, ASUC-0402,ASUC-0403,ASUC-0404,ASUC-0405,ASUC-0406,ASUC-0407,ASUC-0408,ASUC-0409, ASUC-0410,ASUC-0416,ASUD-0001,ASUD-0002,ASUD-0004,ASUD-0005,ASUD-0006,ASUD-0007, ASUD-0008,ASUD-0009,ASUD-0010,ASUD-0011,ASUD-0012,ASUD-0013,ASUD-0014,ASUD-0015, ASUD-0016,ASUD-0018,ASUD-0019,ASUD-0020,ASUD-0022,ASUD-0023,ASUD-0041,ASUD-0042,ASUD-0043,ASUD-0044,ASUD-0046,ASUD-0047,ASUD-0048,ASUD-0049,ASUD-0050,ASUD-0051, ASUD-0057,ASUD-0059,ASUD-0060,ASUD-0061,ASUD-0062,ASUD-0063,ASUD-0064,ASUD-0065, ASUD-0066,ASUD-0074,ASUD-0075,ASUD-0077,ASUD-0078,ASUD-0079,ASUD-0080,ASUD-0081, ASUD-0098,ASUD-0099,ASUD-0100,ASUD-0101,ASUD-0102,ASUD-0103,ASUD-0104,ASUD-0105, ASUD-0106,ASUD-0107,ASUD-0108,ASUD-0109,ASUD-0126,ASUD-0127,ASUD-0128,ASUD-0129, ASUD-0130,ASUD-0131,ASUD-0133,ASUD-0135,ASUD-0136,ASUD-0140,ASUD-0141,ASUD-0150, ASUD-0168,ASUD-0173,ASUD-0174,ASUD-0175,ASUD-0181,ASUD-0182,ASUD-0183,ASUD-0184,ASUD-0185,ASUD-0186,ASUD-0196,ASUD-0198,ASUD-0199,ASUD-0200,ASUD-0201,ASUD-0202, ASUD-0203,ASUD-0204,ASUD-0205,ASUD-0206,ASUD-0219,ASUD-0220,ASUD-0221,ASUD-0222, ASUD-0223,ASUD-0224,ASUD-0225,ASUD-0226,ASUD-0227,ASUD-0228,ASUD-0238,ASUD-0239, ASUD-0245,ASUD-0246,ASUD-0247,ASUD-0248,ASUD-0249,ASUD-0250,ASUD-0251,ASUD-0252, ASUD-0253,ASUD-0258,ASUD-0259,ASUD-0260,ASUD-0273,ASUD-0274

Product Description:

Brand Name: Atlan Product Name: Atlan A350XL Model/Catalog Number: 8621600 Software Version: Not Applicable Product Description: The Atlan is an anesthesia workstation intended for use in anesthetizing adults, pediatrics, and neonates. The device can be used for mechanical ventilation, manual ventilation, pressure-supported spontaneous breathing, and spontaneous breathing. The device is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions Component: Not applicable

Product Quantity:

223

Reason for Recall:

The device either indicated a failure of the piston ventilator before use or suffered a failure of the mechanical ventilation during use.

Recall Number:

Z-2617-2025

Code Information:

Lot Code: UDI-DI Number: 04048675556183 Serial Numbers Distributed in the US: ASTA-0307,ASTA-0309,ASTA-0311,ASTA-0349,ASTA-0350,ASTA-0409 ASTB-0048 ASTC-0244,ASTC-0245 ASTD-0008,ASTD-0009,ASTD-0010,ASTD-0011,ASTD-0013,ASTD-0014,ASTD-0212,ASTD-0239 ASTH-0307,ASTH-0308,ASTH-0309,ASTH-0310,ASTH-0311,ASTH-0332,ASTH-0333,ASTH-0334, ASTH-0335,ASTH-0336,ASTH-0383,ASTH-0384 ASTJ-0014 ASUA-0469,ASUA-0483,ASUA-0484,ASUA-0486,ASUA-0488 ASUB-0093,ASUB-0169,ASUB-0170,ASUB-0171,ASUB-0172,ASUB-0173,ASUB-0174,ASUB-0175, ASUB-0176,ASUB-0183,ASUB-0184,ASUB-0185,ASUB-0186,ASUB-0187,ASUB-0215,ASUB-0216, ASUB-0217,ASUB-0218,ASUB-0219,ASUB-0221,ASUB-0222,ASUB-0250,ASUB-0251,ASUB-0266, ASUB-0267, ASUB-0268,ASUB-0269,ASUB-0270 ASUC-0067,ASUC-0068,ASUC-0069,ASUC-0072,ASUC-0114,ASUC-0115,ASUC-0146,ASUC-0148, ASUC-0149,ASUC-0150,ASUC-0151,ASUC-0153,ASUC-0155,ASUC-0156,ASUC-0157,ASUC-0158, ASUC-0174,ASUC-0175,ASUC-0176,ASUC-0178,ASUC-0179,ASUC-0180,ASUC-0181,ASUC-0182, ASUC-0183,ASUC-0184,ASUC-0185,ASUC-0186,ASUC-0187,ASUC-0188,,ASUC-0189,ASUC-0190, ASUC-0191,ASUC-0192,ASUC-0193,ASUC-0194,ASUC-0196,ASUC-0197,ASUC-0198,ASUC-0199, ASUC-0200,ASUC-0201,ASUC-0202,ASUC-0211,ASUC-0212,ASUC-0213,ASUC-0214,ASUC-0215, ASUC-0216,ASUC-0217,ASUC-0238,ASUC-0239,ASUC-0285,ASUC-0368,ASUC-0369,ASUC-0370, ASUC-0371,ASUC-0372,ASUC-0373 ASUD-0142,ASUD-0142,ASUD-0143,ASUD-0143,ASUD-0144,ASUD-0145,ASUD-0146,ASUD-0147, ASUD-0164,ASUD-0165,ASUD-0165,ASUD-0165,ASUD-0165,ASUD-0187,ASUD-0188,ASUD-0189,ASUD-0190,ASUD-0191,ASUD-0192,ASUD-0193,ASUD-0207,ASUD-0208,ASUD-0209,ASUD-0210, ASUD-0211,ASUD-0212,ASUD-0212,ASUD-0275,ASUD-0276,ASUD-0277,ASUD-0294 Serial Numbers Distributed OUS (Direct shipped from Draegerwerk AG & Co., KGaA): ASUB-0094,ASUB-0279,ASUB-0280,ASUB-0281,ASUB-0282,ASUB-0284,ASUB-0285,ASUB-0286, ASUC-0005,ASUC-0006,ASUC-0007,ASUC-0008,ASUC-0010,ASUC-0011,ASUC-0012,ASUC-0013, ASUC-0014,ASU-0042,ASUC-0043,ASUC-0044,ASUC-0045,ASUC-0046,ASUC-0047,ASUC-0048, ASUC-0049,ASUC-0050,ASUC-0051,ASUC-0052,ASUC-0053,ASUC-0054,ASUC-0057,ASUC-0060, ASUC-0073,ASUC-0074,ASUC-0075,ASUC-0076,ASUC-0077,ASUC-0078,ASUC-0079,ASUC-0080, SUC-0081,ASUC-0082,ASUC-0331,ASUC-0377,ASUC-0378,ASUC-0379,ASUD-0067,ASUD-0068, ASUD-0088,ASUD-0089,ASUD-0091,ASUD-0092,ASUD-0093,ASUD-0094,ASUD-0095,ASUD-0096,ASUD-0097,ASUD-0112,ASUD-0113,ASUD-0114,ASUD-0115,ASUD-0116,ASUD-0117,ASUD-0118, ASUD-0119,ASUD-0120,ASUD-0121,ASUD-0122,ASUD-0160,ASUD-0166

Class I Devices Event**Event ID:**

97530

Product Type:

Devices

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/30/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Siemens Medical Solutions USA, Inc
40 Liberty Blvd
Malvern, PA 19355-1418
United States

Distribution Pattern:

Worldwide distribution - US Nationwide and the countries of Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahrain, Bangladesh, Belgium, Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Canada, Chile, China, Colombia, Croatia, Cyprus, Czechia, Denmark, Ecuador, Egypt, Estonia, Ethiopia, Finland, France, Georgia, Germany, Great Britain, Greece, Hong Kong, Hungary, India, Indonesia, Iran, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Korea, Kosovo, Kuwait, Latvia, Lebanon, Lithuania, Luxembourg, Macao, Malaysia, Malta, Mexico, Moldova, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Nepal, Netherlands, New Zealand, Nigeria, Norway, Oman, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Qatar, Republic of North Macedonia, Reunion, Romania, Russian Federation, Saudi Arabia, Senegal, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Syrian Arab Republic, Taiwan, Tanzania, Thailand, Trinidad and Tobago, Turkey, Turkmenistan, Ukraine, United Arab Emirates, Uzbekistan, Viet Nam.

Associated Products

Product Description:

Biograph mMR. Model Number: 10433372.

Product Quantity:

23 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2654-2025

Code Information:

Model Number: 10433372. UDI Number: (01)04056869006741(21)151032, (01)04056869006741(21)151057, (01)04056869006741(21)1510535, (01)04056869006741(21)151034, (01)04056869006741(21)151003, (01)04056869006741(21)151021, (01)04056869006741(21)151055, (01)04056869006741(21)151013, (01)04056869006741(21)151064, (01)04056869006741(21)151044, (01)04056869006741(21)151038, (01)04056869245188(21)151006, (01)04056869006741(21)151030, (01)04056869006741(21)151004, (01)04056869006741(21)151022, (01)04056869006741(21)151049, (01)04056869006741(21)151045, (01)04056869006741(21)151032, (01)04056869006741(21)151025, (01)04056869006741(21)151048, (01)04056869006741(21)151062, (01)04056869006741(21)151010, (01)04056869006741(21)151051. Serial Numbers: 151032, 151057, 51053, 151034, 51003, 151021, 51055, 151013, 51064, 151044, 51038, 51006, 51030, 151004, 51022, 151049, 151045, 51032, 151025, 51048, 51062, 51010, 51051.

Product Description:

BIOGRAPH One (DE). Model Number: 11689172.

Product Quantity:

1 unit

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2655-2025

Code Information:

Model Number: 11689172. UDI Numbers: (01)4068151020472(21)238008. Serial Numbers: 238008.

Product Description:

MAGNETOM Cima.X (DE). Model Number: 11647158.

Product Quantity:

9 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2656-2025

Code Information:

Model Number: 11647158. UDI Numbers: (01)04056869975221(21)213043, (01)04056869975221(21)213041, (01)04056869975221(21)213034, (01)04056869975221(21)213028, (01)04056869975221(21)213061, (01)04056869975221(21)213005, (01)04056869975221(21)213056, (01)04056869975221(21)213057, (01)04056869975221(21)213020. Serial Numbers: 213043, 213041, 213034, 213028, 213061, 213005, 213056, 213057, 213020.

Product Description:

MAGNETOM Connectom.X. Model Number: 11371480.

Product Quantity:

1 unit

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2657-2025

Code Information:

Model Number: 11371480. UDI Numbers: N/A. Serial Numbers: 237551.

Product Description:

MAGNETOM Lumina (DE). Model Number: 11344916.

Product Quantity:

71 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2658-2025

Code Information:

Model Number: 11344916. UDI Numbers: (01)04056869230740(21)196591, (01)04056869230740(21)196655, (01)04056869230740(21)196355, (01)04056869230740(21)196733, (01)04056869230740(21)196553, (01)04056869230740(21)196519, (01)04056869230740(21)196782, (01)04056869230740(21)196684, (01)04056869230740(21)196280, (01)04056869230740(21)196796, (01)04056869230740(21)196551, (01)04056869230740(21)196741, (01)04056869230740(21)196611, (01)04056869230740(21)196544, (01)04056869230740(21)196724, (01)04056869230740(21)196776, (01)04056869230740(21)196752, (01)04056869230740(21)196372, (01)04056869230740(21)196350, (01)04056869230740(21)196508, (01)04056869230740(21)196753, (01)04056869230740(21)196738, (01)04056869230740(21)196765, (01)04056869230740(21)196409, (01)04056869230740(21)196737, (01)04056869230740(21)196604, (01)04056869230740(21)196362, (01)04056869230740(21)196619, (01)04056869230740(21)196261, (01)04056869230740(21)196415, (01)04056869230740(21)196391, (01)04056869230740(21)196529, (01)04056869230740(21)196414, (01)04056869230740(21)196778, (01)04056869230740(21)196308, (01)04056869230740(21)196768, (01)04056869230740(21)196791, (01)04056869230740(21)196832, (01)04056869230740(21)196606, (01)04056869230740(21)196240, (01)04056869230740(21)196730, (01)04056869230740(21)196831, (01)04056869230740(21)196789, (01)04056869230740(21)196780, (01)04056869230740(21)196779, (01)04056869230740(21)196405, (01)04056869230740(21)196376, (01)04056869230740(21)196703, (01)04056869230740(21)196828, (01)04056869230740(21)196422, (01)04056869230740(21)196800, (01)04056869230740(21)196775, (01)04056869230740(21)196795, (01)04056869230740(21)196514, (01)04056869230740(21)196326, (01)04056869230740(21)196463, (01)04056869230740(21)196359, (01)04056869230740(21)196750, (01)04056869230740(21)196354, (01)04056869230740(21)196557, (01)04056869230740(21)196688, (01)04056869230740(21)196818, (01)04056869230740(21)196772,

(01)04056869230740(21)196651, (01)04056869230740(21)196687, (01)04056869230740(21)196799, (01)04056869230740(21)196717, (01)04056869230740(21)196367, (01)04056869230740(21)196823, (01)04056869230740(21)196830, (01)04056869230740(21)196815. Serial Numbers: 196591, 196655, 196355, 196733, 196553, 196519, 196782, 196684, 196280, 196796, 196551, 196741, 196611, 196544, 196724, 196776, 196752, 196372, 196350, 196508, 196753, 196738, 196765, 196409, 196737, 196604, 196362, 196619, 196261, 196415, 196391, 196529, 196414, 196778, 196308, 196768, 196791, 196832, 196606, 196240, 196730, 196831, 196789, 196780, 196779, 196405, 196376, 196703, 196828, 196422, 196800, 196775, 196795, 196514, 196326, 196463, 196359, 196750, 196354, 196557, 196688, 196818, 196772, 196651, 196687, 196799, 196717, 196367, 196823, 196830, 196815.

Product Description:

MAGNETOM Prisma. Model Number: 10849582.

Product Quantity:

39 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2659-2025

Code Information:

Model Number: 10849582. UDI Numbers: (01)04056869006727(21)66104, (01)04056869006727(21)66109, (01)04056869006727(21)166242, (01)04056869006727(21)166047, (01)04056869006727(21)166037, (01)04056869006727(21)166003, (01)04056869006727(21)66102, (01)04056869006727(21)166074, (01)04056869006727(21)166281, (01)04056869006727(21)166220, (01)04056869006727(21)166160, (01)04056869006727(21)166310, (01)04056869006727(21)66028, (01)04056869006727(21)166034, (01)04056869006727(21)66106, (01)04056869006727(21)166235, (01)04056869006727(21)166201, (01)04056869006727(21)166345, (01)04056869006727(21)166009, (01)04056869006727(21)166188, (01)04056869006727(21)166046, (01)04056869006727(21)166296, (01)04056869006727(21)66057, (01)04056869006727(21)166326, (01)04056869006727(21)166327, (01)04056869006727(21)166017, (01)04056869006727(21)166311, (01)04056869006727(21)166133, (01)04056869006727(21)166162, (01)04056869006727(21)66096, (01)04056869006727(21)166082, (01)04056869006727(21)66059, (01)04056869006727(21)166084, (01)04056869006727(21)166090, (01)04056869006727(21)166033, (01)04056869006727(21)166010. Serial Numbers: 66104, 66109, 166242, 166047, 166037, 166003, 66102, 166074, 166281, 166220, 166160, 166310, 66028, 166034, 66106, 166235, 166201, 166345, 166009, 166188, 166046, 166296, 66057, 166326, 166327, 166017, 166311, 166133, 166162, 66096, 166082, 66059, 166084, 166090, 166315, 166313, 166307, 166033, 166010.

Product Description:

MAGNETOM Skyra (DE). Model Number: 10432915. 510(k) Numbers: K101347, K111242, K123510, K133435, K140253, K141977, K142515, K153343, K173592, K202014, K231560.

Product Quantity:

182 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2660-2025

Code Information:

Model Number: 10432915. UDI Numbers: (01)04056869006703(21)145760, (01)04056869006703(21)145549, (01)04056869006703(21)146110, (01)04056869006703(21)146093, (01)04056869006703(21)146082, (01)04056869006703(21)145124, (01)04056869006703(21)145390, (01)04056869006703(21)146182, (01)04056869006703(21)145008, (01)04056869006703(21)145473, (01)04056869006703(21)145095, (01)04056869006703(21)145664, (01)04056869006703(21)145200, (01)04056869006703(21)146086, (01)04056869006703(21)145812, (01)04056869006703(21)146220, (01)04056869006703(21)145253, (01)04056869006703(21)146103, (01)04056869006703(21)146123, (01)04056869006703(21)146147, (01)04056869006703(21)146124, (01)04056869006703(21)145890, (01)04056869006703(21)145306, (01)04056869006703(21)145905, (01)04056869006703(21)146171, (01)04056869006703(21)145148, (01)04056869006703(21)145152, (01)04056869006703(21)145119, (01)04056869006703(21)146207, (01)04056869006703(21)145549, (01)04056869006703(21)145681, (01)04056869006703(21)146067, (01)04056869006703(21)145140, (01)04056869006703(21)145635, (01)04056869006703(21)146282, (01)04056869006703(21)145496, (01)04056869006703(21)145314, (01)04056869006703(21)146268, (01)04056869006703(21)145423, (01)04056869006703(21)145706, (01)04056869006703(21)145990, (01)04056869006703(21)145062, (01)04056869006703(21)145128, (01)04056869006703(21)145750, (01)04056869006703(21)145150, (01)04056869006703(21)145115, (01)04056869006703(21)145672, (01)04056869006703(21)145526, (01)04056869006703(21)145041, (01)04056869006703(21)145403, (01)04056869006703(21)145799, (01)04056869006703(21)145658, (01)04056869006703(21)146203, (01)04056869006703(21)145414, (01)04056869006703(21)145301,

(01)04056869006703(21)145384, (01)04056869006703(21)45881, (01)04056869006703(21)45942, (01)04056869006703(21)145685, (01)04056869006703(21)145674, (01)04056869006703(21)145862, (01)04056869006703(21)45095, (01)04056869006703(21)46044, (01)04056869006703(21)45537, (01)04056869006703(21)145026, (01)04056869006703(21)146117, (01)04056869006703(21)146092, (01)04056869006703(21)145631, (01)04056869006703(21)45940, (01)04056869006703(21)146114, (01)04056869006703(21)145666, (01)04056869006703(21)145380, (01)04056869006703(21)45120, (01)04056869006703(21)145710, (01)04056869006703(21)145367, (01)04056869006703(21)145187, (01)04056869006703(21)145164, (01)04056869006703(21)46176, (01)04056869006703(21)45399, (01)04056869006703(21)145334, (01)04056869006703(21)145633, (01)04056869006703(21)145610, (01)04056869006703(21)46048, (01)04056869006703(21)145667, (01)04056869006703(21)145104, (01)04056869006703(21)46161, (01)04056869006703(21)46020, (01)04056869006703(21)145541, (01)04056869006703(21)145259, (01)04056869006703(21)46149, (01)04056869006703(21)45149, (01)04056869006703(21)45944, (01)04056869006703(21)46189, (01)04056869006703(21)45201, (01)04056869006703(21)45116, (01)04056869006703(21)145148, (01)04056869006703(21)45346, (01)04056869006703(21)145179, (01)04056869006703(21)46127, (01)04056869006703(21)45435, (01)04056869006703(21)46047, (01)04056869006703(21)45526, (01)04056869006703(21)45117, (01)04056869006703(21)145454, (01)04056869006703(21)45249, (01)04056869006703(21)145110, (01)04056869006703(21)145012, (01)04056869006703(21)145061, (01)04056869006703(21)145533, (01)04056869006703(21)146105, (01)04056869006703(21)145113, (01)04056869006703(21)46191, (01)04056869006703(21)45681, (01)04056869006703(21)145886, (01)04056869006703(21)145491, (01)04056869006703(21)145632, (01)04056869006703(21)45107, (01)04056869006703(21)46007, (01)04056869006703(21)45018, (01)04056869006703(21)146102, (01)04056869006703(21)146100, (01)04056869006703(21)45019, (01)04056869006703(21)145521, (01)04056869006703(21)145323, (01)04056869006703(21)145325, (01)04056869006703(21)45906, (01)04056869006703(21)146115, (01)04056869006703(21)145020, (01)04056869006703(21)145728, (01)04056869006703(21)145447, (01)04056869006703(21)45099, (01)04056869006703(21)45349, (01)04056869006703(21)46150, (01)04056869006703(21)145089, (01)04056869006703(21)145209, (01)04056869006703(21)45835, (01)04056869006703(21)145302, (01)04056869006703(21)46239, (01)04056869006703(21)46140, (01)04056869006703(21)145293, (01)04056869006703(21)45556, (01)04056869006703(21)145486, (01)04056869006703(21)145485, (01)04056869006703(21)145403, (01)04056869006703(21)145245, (01)04056869006703(21)46034, (01)04056869006703(21)145443, (01)04056869006703(21)145297, (01)04056869006703(21)146090, (01)04056869006703(21)45074, (01)04056869006703(21)45239, (01)04056869006703(21)145386, (01)04056869006703(21)46222, (01)04056869006703(21)45948, (01)04056869006703(21)145718, (01)04056869006703(21)145282, (01)04056869006703(21)45056, (01)04056869006703(21)46102, (01)04056869006703(21)145320, (01)04056869006703(21)45220, (01)04056869006703(21)45424, (01)04056869006703(21)145522, (01)04056869006703(21)145230, (01)04056869006703(21)145636, (01)04056869006703(21)145598, (01)04056869006703(21)146078, (01)04056869006703(21)45982, (01)04056869006703(21)46145, (01)04056869006703(21)46298, (01)04056869006703(21)145169, (01)04056869006703(21)45237, (01)04056869006703(21)145662, (01)04056869006703(21)45087, (01)04056869006703(21)45409, (01)04056869006703(21)45130, (01)04056869006703(21)146120, (01)04056869006703(21)145197, (01)04056869006703(21)145794, (01)04056869006703(21)146122, (01)04056869006703(21)146121, (01)04056869006703(21)46294. Serial Numbers: 145760, 45549, 146110, 146093, 146082, 45124, 145390, 46182, 145008, 145473, 145095, 145664, 45200, 146086, 45812, 46220, 45253, 146103, 146123, 46147, 146124, 45890, 45306, 145905, 46171, 45148, 45152, 45119, 46207, 145549, 145681, 146067, 45140, 145635, 46282, 45496, 45314, 46268, 145423, 145706, 45990, 145062, 145128, 145750, 145150, 145115, 145672, 145526, 145041, 45403, 145799, 145658, 46203, 145414, 145301, 145384, 45881, 45942, 145685, 145674, 145862, 45095, 46044, 45537, 145026, 146117, 146092, 145631, 45940, 146114, 145666, 145380, 45120, 145710, 145367, 145187, 145164, 46176, 45399, 145334, 145633, 145610, 46048, 145667, 145104, 46161, 46020, 145541, 145259, 46149, 45149, 45944, 46189, 45201, 45116, 145148, 45346, 145179, 46127, 45435, 46047, 45526, 45117, 145454, 45249, 145110, 145012, 145061, 145533, 146105, 145113, 46191, 45681, 145886, 145491, 145632, 45107, 46007, 45018, 146102, 146100, 45019, 145521, 145323, 145325, 45906, 146115, 145020, 145728, 145447, 45099, 45349, 46150, 145089, 145209, 45835, 145302, 46239, 46140, 145293, 45556, 145486, 145485, 145403, 145245, 46034, 145443, 145297, 146090, 45074, 45239, 145386, 46222, 45948, 145718, 145282, 45056, 46102, 145320, 45220, 45424, 145522, 145230, 145636, 145598, 146078, 45982, 46145, 46298, 145169, 45237, 145662, 45390, 145087, 45409, 45130, 146120, 145197, 145794, 146122, 146121, 46294.

Product Description:

MAGNETOM Skyra fit. Model Number: 10849580.

Product Quantity:

30 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2661-2025

Code Information:

Model Number: 10849580. UDI Numbers: (01)04056869006710(21)170068, (01)04056869006710(21)70022, (01)04056869006710(21)170018, (01)04056869006710(21)170039, (01)04056869006710(21)170023, (01)04056869006710(21)170030, (01)04056869006710(21)170004, (01)04056869006710(21)170077, (01)04056869006710(21)170058, (01)04056869006710(21)170002, (01)04056869006710(21)170010, (01)04056869006710(21)70026, (01)04056869006710(21)170056, (01)04056869006710(21)170061, (01)04056869006710(21)170017, (01)04056869006710(21)170101, (01)04056869006710(21)170100, (01)04056869006710(21)170060, (01)04056869006710(21)170007, (01)04056869006710(21)70020, (01)04056869006710(21)170112, (01)04056869006710(21)70023, (01)04056869006710(21)70027,

(01)04056869006710(21)170095, (01)04056869006710(21)170075, (01)04056869006710(21)170011, (01)04056869006710(21)170081, (01)04056869006710(21)170044, (01)04056869006710(21)70028, (01)04056869006710(21)70008. Serial Numbers: 170068, 70022, 170018, 170039, 170023, 170030, 170004, 170077, 170058, 170002, 170010, 70026, 170056, 170061, 170017, 170101, 170100, 170060, 170007, 70020, 170112, 70023, 70027, 170095, 170075, 170011, 170081, 170044, 70028, 70008.

Product Description:

MAGNETOM Skyra Fit BioMatrix. Model Number: 11516217.

Product Quantity:

18 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2662-2025

Code Information:

Model Number: 11516217. UDI Numbers: (01)04056869299273(21)212018, (01)04056869299273(21)212023, (01)04056869299273(21)212030, (01)04056869299273(21)212032, (01)04056869299273(21)212034, (01)04056869299273(21)212035, (01)04056869299273(21)212038, (01)04056869299273(21)212039, (01)04056869299273(21)212047, (01)04056869299273(21)212063, (01)04056869299273(21)212065, (01)04056869299273(21)212068, (01)04056869299273(21)212087, (01)04056869299273(21)212088, (01)04056869299273(21)212090, (01)04056869299273(21)212096, (01)04056869299273(21)212097, (01)04056869299273(21)212098. Serial Numbers: 212018, 212023, 212030, 212032, 212034, 212035, 212038, 212039, 212047, 212063, 212065, 212068, 212087, 212088, 212090, 212096, 212097, 212098.

Product Description:

MAGNETOM Spectra (CN). Model Number: 10655588.

Product Quantity:

1 unit

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2663-2025

Code Information:

Model Number: 10655588. UDI Numbers: (01)04056869006796(21)56069. Serial Numbers: 56069.

Product Description:

MAGNETOM Verio. Model Number: 10276755.

Product Quantity:

69 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2664-2025

Code Information:

Model Number: 10276755. UDI Numbers: N/A. Serial Numbers: 40649, 40243, 40408, 40628, 40848, 40473, 40497, 40564, 40389, 40523, 40283, 40331, 40744, 40821, 40433, 40502, 40179, 40246, 40766, 40753, 40313, 40670, 40131, 40466, 40292, 40161, 40745, 40268, 40877, 40640, 40665, 40264, 40420, 40727, 40328, 40156, 40800, 40441, 40859, 40220, 40858, 40779, 40233, 40629, 40681, 40200, 40277, 40378, 40714, 40715, 40423, 40204, 40486, 40251, 40488, 40109, 40157, 40440, 40140, 40237, 40312, 40235, 40398, 40368, 40562, 40671, 40376, 40686, 40116.

Product Description:

MAGNETOM Verio Dot. Model Number: 10684333.

Product Quantity:

30 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2665-2025

Code Information:

Model Number: 10684333. UDI Numbers: (01)04056869006673(21)160021, (01)04056869006673(21)60108, (01)04056869006673(21)160019, (01)04056869006673(21)60091, (01)04056869006673(21)160043, (01)04056869006673(21)60126, (01)04056869006673(21)60047, (01)04056869006673(21)160003, (01)04056869006673(21)160042, (01)04056869006673(21)160024, (01)04056869006673(21)160035, (01)04056869006673(21)60099, (01)04056869006673(21)160007, (01)04056869006673(21)160006, (01)04056869006673(21)160009, (01)04056869006673(21)160033, (01)04056869006673(21)160027, (01)04056869006673(21)160012, (01)04056869006673(21)160016, (01)04056869006673(21)160032, (01)04056869006673(21)160013, (01)04056869006673(21)160018, (01)04056869006673(21)160031, (01)04056869006673(21)160011, (01)04056869006673(21)160015, (01)04056869006673(21)60054, (01)04056869006673(21)160034, (01)04056869006673(21)60063, (01)04056869006673(21)60079, (01)04056869006673(21)160041. Serial Numbers: 160021, 60108, 160019, 60091, 160043, 60126, 60047, 160003, 160042, 160024, 160035, 60099, 160007, 160006, 160009, 160033, 160027, 160012, 160016, 160032, 160013, 160018, 160031, 160011, 160015, 60054, 160034, 60063, 60079, 160041.

Product Description:

MAGNETOM Verio Dot Upgrade. Model Number: 10684334.

Product Quantity:

46 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2666-2025

Code Information:

Model Number: 10684334. UDI Numbers: (01)04056869006680(21)162012, (01)04056869006680(21)162055, (01)04056869006680(21)162039, (01)04056869006680(21)162002, (01)04056869006680(21)162014, (01)04056869006680(21)162069, (01)04056869006680(21)162083, (01)04056869006680(21)162028, (01)04056869006680(21)162060, (01)04056869006680(21)162054, (01)04056869006680(21)162088, (01)04056869006680(21)62032, (01)04056869006680(21)162077, (01)04056869006680(21)162025, (01)04056869006680(21)162082, (01)04056869006680(21)162085, (01)04056869006680(21)162040, (01)04056869006680(21)162032, (01)04056869006680(21)162037, (01)04056869006680(21)162043, (01)04056869006680(21)162047, (01)04056869006680(21)62019, (01)04056869006680(21)62050, (01)04056869006680(21)162061, (01)04056869006680(21)62018, (01)04056869006680(21)162004, (01)04056869006680(21)162013, (01)04056869006680(21)162007, (01)04056869006680(21)162049, (01)04056869006680(21)62025, (01)04056869006680(21)162048, (01)04056869006680(21)162081, (01)04056869006680(21)162044, (01)04056869006680(21)162076, (01)04056869006680(21)162003, (01)04056869006680(21)62023, (01)04056869006680(21)162021, (01)04056869006680(21)162074, (01)04056869006680(21)162017, (01)04056869006680(21)162029, (01)04056869006680(21)162022, (01)04056869006680(21)62035, (01)04056869006680(21)62039, (01)04056869006680(21)162001, (01)04056869006680(21)162018, (01)04056869006680(21)62042. Serial Numbers: 162012, 162055, 162039, 162002, 162014, 162069, 162083, 162028, 162060, 162054, 162088, 62032, 162077, 162025, 162082, 162085, 162040, 162032, 162037, 162043, 162047, 62019, 62050, 162061, 62018, 162004, 162013, 162007, 162049, 62025, 162048, 162081, 162044, 162076, 162003, 62023, 162021, 162074, 162017, 162029, 162022, 62035, 62039, 162001, 162018, 62042.

Product Description:

MAGNETOM Vida (DE). Model Number: 11060815. 510(k): K170396, K173617, K181433, K183254, K192924, K203443, K213693, K213805, K220425, K231560.

Product Quantity:

237 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2667-2025

Code Information:

Model Number: 11060815. UDI Numbers: (01)04056869039176(21)176636, (01)04056869039176(21)177211, (01)04056869039176(21)175728, (01)04056869039176(21)175685, (01)04056869039176(21)177298, (01)04056869039176(21)177295, (01)04056869039176(21)177349, (01)04056869039176(21)176757, (01)04056869039176(21)175935, (01)04056869039176(21)176371, (01)04056869039176(21)177012, (01)04056869039176(21)177146, (01)04056869039176(21)176755, (01)04056869039176(21)176781, (01)04056869039176(21)176036, (01)04056869039176(21)177151, (01)04056869039176(21)177299, (01)04056869039176(21)177352, (01)04056869039176(21)177354, (01)04056869039176(21)176779, (01)04056869039176(21)175838, (01)04056869039176(21)177359, (01)04056869039176(21)175977, (01)04056869039176(21)177244, (01)04056869039176(21)176686, (01)04056869039176(21)177096, (01)04056869039176(21)177034, (01)04056869039176(21)176639, (01)04056869039176(21)175805, (01)04056869039176(21)176358, (01)04056869039176(21)176293, (01)04056869039176(21)176118, (01)04056869039176(21)177088, (01)04056869039176(21)176189, (01)04056869039176(21)177337, (01)04056869039176(21)177333, (01)04056869039176(21)176094, (01)04056869039176(21)176736, (01)04056869039176(21)177105, (01)04056869039176(21)175787, (01)04056869039176(21)177381, (01)04056869039176(21)177144, (01)04056869039176(21)176665, (01)04056869039176(21)176577, (01)04056869039176(21)176559, (01)04056869039176(21)176696, (01)04056869039176(21)176452, (01)04056869039176(21)177033, (01)04056869039176(21)177124, (01)04056869039176(21)175897, (01)04056869039176(21)177329, (01)04056869039176(21)176567, (01)04056869039176(21)176529, (01)04056869039176(21)176709, (01)04056869039176(21)176059, (01)04056869039176(21)176374, (01)04056869039176(21)177258, (01)04056869039176(21)177162, (01)04056869039176(21)176661, (01)04056869039176(21)177371, (01)04056869039176(21)176829, (01)04056869039176(21)177213, (01)04056869039176(21)176570, (01)04056869039176(21)176532, (01)04056869039176(21)177257, (01)04056869039176(21)176319, (01)04056869039176(21)176332, (01)04056869039176(21)177265, (01)04056869039176(21)177332, (01)04056869039176(21)177356, (01)04056869039176(21)176288, (01)04056869039176(21)176350, (01)04056869039176(21)176751, (01)04056869039176(21)177319, (01)04056869039176(21)177347, (01)04056869039176(21)176828, (01)04056869039176(21)176814, (01)04056869039176(21)177086, (01)04056869039176(21)176414, (01)04056869039176(21)177178, (01)04056869039176(21)177238, (01)04056869039176(21)176211, (01)04056869039176(21)177102, (01)04056869039176(21)176843, (01)04056869039176(21)177366, (01)04056869039176(21)176483, (01)04056869039176(21)177209, (01)04056869039176(21)176906, (01)04056869039176(21)175964, (01)04056869039176(21)175843, (01)04056869039176(21)177324, (01)04056869039176(21)176203, (01)04056869039176(21)177309, (01)04056869039176(21)176084, (01)04056869039176(21)177312, (01)04056869039176(21)175661, (01)04056869039176(21)177289, (01)04056869039176(21)177283, (01)04056869039176(21)177293, (01)04056869039176(21)175819, (01)04056869039176(21)176948, (01)04056869039176(21)176637, (01)04056869039176(21)177143, (01)04056869039176(21)176733, (01)04056869039176(21)177214, (01)04056869039176(21)176238, (01)04056869039176(21)177346, (01)04056869039176(21)177345, (01)04056869039176(21)176667, (01)04056869039176(21)177210, (01)04056869039176(21)176328, (01)04056869039176(21)176333, (01)04056869039176(21)177237, (01)04056869039176(21)177136, (01)04056869039176(21)176811, (01)04056869039176(21)176312, (01)04056869039176(21)175915, (01)04056869039176(21)176537, (01)04056869039176(21)177149, (01)04056869039176(21)177216, (01)04056869039176(21)177217, (01)04056869039176(21)175639, (01)04056869039176(21)177276, (01)04056869039176(21)176449, (01)04056869039176(21)176677, (01)04056869039176(21)176652, (01)04056869039176(21)176927, (01)04056869039176(21)177339, (01)04056869039176(21)175701, (01)04056869039176(21)175671, (01)04056869039176(21)176259, 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(01)04056869039176(21)177270, (01)04056869039176(21)177267, (01)04056869039176(21)177239, (01)04056869039176(21)176815, (01)04056869039176(21)175894, (01)04056869039176(21)176735, (01)04056869039176(21)176994, (01)04056869039176(21)177055, (01)04056869039176(21)175993, (01)04056869039176(21)175775, (01)04056869039176(21)177032, (01)04056869039176(21)176545, (01)04056869039176(21)177220, (01)04056869039176(21)177285, (01)04056869039176(21)177145, (01)04056869039176(21)175746, (01)04056869039176(21)177189, (01)04056869039176(21)175689, (01)04056869039176(21)177338, (01)04056869039176(21)176178, (01)04056869039176(21)176759, (01)04056869039176(21)176689, (01)04056869039176(21)177280, (01)04056869039176(21)177229, (01)04056869039176(21)177230, (01)04056869039176(21)176502, (01)04056869039176(21)176058, (01)04056869039176(21)175738, (01)04056869039176(21)177054, (01)04056869039176(21)177386, (01)04056869039176(21)177255, (01)04056869039176(21)177256, (01)04056869039176(21)177164, (01)04056869039176(21)176438, (01)04056869039176(21)176157, (01)04056869039176(21)176995, (01)04056869039176(21)177323, (01)04056869039176(21)176410, (01)04056869039176(21)176680, (01)04056869039176(21)176518. Serial Numbers: 176636, 177211, 175728, 175685, 177298, 177295, 177349, 176757, 175935, 176371, 177012, 177146, 176755, 176781, 176036, 177151, 177299, 177352, 177354, 176779, 175838, 177359, 175977, 177244, 176686, 177096, 177034, 176639, 175805, 176358, 176293, 176118, 177088, 176189, 177337, 177333, 176094, 176736, 177105,

175787, 177381, 177144, 176665, 176577, 176559, 176696, 176452, 177033, 177124, 175897, 177329, 176567, 176529, 176709, 176059, 176374, 177258, 177162, 176661, 177371, 176829, 177213, 176570, 176532, 177257, 176319, 176332, 177265, 177332, 177356, 176288, 176350, 176751, 177319, 177347, 176828, 176814, 177086, 176414, 177178, 177238, 176211, 177102, 176843, 177366, 176483, 177209, 176906, 175964, 175843, 177324, 176203, 177309, 176084, 177312, 175661, 177289, 177283, 177293, 175819, 176948, 176637, 177143, 176733, 177214, 176238, 177346, 177345, 176667, 177210, 176328, 176333, 177237, 177136, 176811, 176312, 175915, 176537, 177149, 177216, 177217, 175639, 177276, 176449, 176677, 176652, 176927, 177339, 175701, 175671, 176259, 176877, 176880, 176876, 176683, 177203, 177383, 177104, 177234, 176393, 177160, 176299, 177331, 177170, 177336, 177334, 177303, 175876, 176004, 177184, 177181, 175990, 177150, 176524, 177361, 177374, 176326, 175830, 176169, 177205, 177286, 176546, 177384, 176246, 176020, 177318, 175761, 176184, 176251, 177348, 176120, 177363, 177292, 177172, 177173, 176731, 176194, 176700, 177279, 176563, 177368, 177380, 176790, 176445, 177133, 176651, 176377, 176376, 176196, 176195, 175807, 176068, 176064, 177275, 177273, 175772, 177278, 177270, 177267, 177239, 176815, 175894, 176735, 176994, 177055, 175993, 175775, 177032, 176545, 177220, 177285, 177145, 175746, 177189, 175689, 177338, 176178, 176759, 176689, 177280, 177229, 177230, 176502, 176058, 175738, 177054, 177386, 177255, 177256, 177164, 176438, 176157, 176995, 177323, 176410, 176680, 176518.

Product Description:

MAGNETOM Vida Fit. Model Number: 11410481.

Product Quantity:

27 units

Reason for Recall:

There is a potential for an ice blockage to form or currently exist within the magnet venting system. In the event of a quench, helium gas may be unable to escape through the designed venting paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

Recall Number:

Z-2668-2025

Code Information:

Model Number: 11410481. UDI Numbers: (01)04056869245188(21)202129, (01)04056869245188(21)202025, (01)04056869245188(21)202139, (01)04056869245188(21)202016, (01)04056869245188(21)202051, (01)04056869245188(21)202055, (01)04056869245188(21)202114, (01)04056869245188(21)202119, (01)04056869245188(21)202013, (01)04056869245188(21)202050, (01)04056869245188(21)202127, (01)04056869245188(21)202123, (01)04056869245188(21)202031, (01)04056869245188(21)202110, (01)04056869245188(21)202108, (01)04056869245188(21)202101, (01)04056869245188(21)202093, (01)04056869245188(21)202028, (01)04056869245188(21)202142, (01)04056869245188(21)202125, (01)04056869245188(21)202084, (01)04056869245188(21)202151, (01)04056869245188(21)202135, (01)04056869245188(21)202121, (01)04056869245188(21)202006, (01)04056869245188(21)202146, (01)04056869245188(21)202145. Serial Numbers: 202129, 202025, 202139, 202016, 202051, 202055, 202114, 202119, 202013, 202050, 202127, 202123, 202031, 202110, 202108, 202101, 202093, 202028, 202142, 202125, 202084, 202151, 202135, 202121, 202006, 202146, 202145.

Class I Devices Event

Event ID:

97555

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/21/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/01/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Medline Industries, LP
3 Lakes Dr
Northfield, IL 60093-2753
United States

Distribution Pattern:

US Nationwide distribution in the state of CA.

Associated Products

Product Description:

Medline Kits: 1) VALVE PACK-LF, Model Number: DYNJ0415366P; 2) VALVE PACK-LF, Model Number: DYNJ0415366Q

Product Quantity:

828 units

Reason for Recall:

The kits contain certain lots of cannula products where the catheter may not retain its shape.

Recall Number:

Z-2670-2025

Code Information:

1) DYNJ0415366P, UDI-DI: 10195327177966(each), 40195327177967(case), Lot Number: 24DMG366; 2) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 25EMD672; 3) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 25GMD016; 4) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 25AMB610; 5) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 25BMJ241; 6) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 25CMI425; 7) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 24DMC189; 8) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 24EMC463; 9) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 24GMJ353; 10) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 24IMB824; 11) DYNJ0415366Q, UDI-DI: 10195327678227(each), 40195327678228(case), Lot Number: 24KME116

Class II Devices Event

Event ID:

96745

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

05/07/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/02/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Medtronic MiniMed, Inc.
18000 Devonshire St
Northridge, CA 91325-1219
United States

Distribution Pattern:

US: No distribution OUS: Austria, Belgium, Italy, Spain, Switzerland, United Kingdom

Associated Products

Product Description:

Medtronic, Simplera Sensor, REF: MMT-5100JD1

Product Quantity:

1,440 units

Reason for Recall:

The device cap label may not adhere to the sensor, compromising the sterility of the sensor, and increasing the risk of infection.

Recall Number:

Z-0033-2026

Code Information:

Lot # HG81GLZ/ GTIN: 20763000649580

Class II Devices Event

Event ID:

97269

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

06/26/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/29/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

bioMerieux, Inc.
100 Rodolphe St
Durham, NC 27712-9402
United States

Distribution Pattern:

International distribution in the countries of Albania, Armenia, Australia, Austria, Belgium, Bosnia, Bulgaria, China, Croatia, Cyprus, Czech Republic/Slovakia, France, Germany, Greece, Iberia, India, Israel, Italy, Japan, Lithuania, Macedonia, Malaysia/Brunei, Moldova, Netherlands, Pakistan, Poland, Portugal, Romania, Russia, Serbia, South Korea, Spain, Switzerland, Taiwan, Thailand, and Turkey.

Associated Products

Product Description:

VITEK₂ 2 Gram-negative AST Test Kits (Cards) containing Colistin formulation cs02n. VITEK₂ is an automated system consisting of instruments, software and reagent cards designed for the identification and antimicrobial susceptibility testing of bacteria and yeast. Export only

Product Quantity:

235269 cards

Reason for Recall:

Potential for false resistant results for Colistin (cs02n) with multi-drug-resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii* complex used in specific cards

Recall Number:

Z-2671-2025

Code Information:

Material Number/Material Description/Batch Number: 423936 AST-N412 TEST KIT 20 CARDS 0143139204 423936 AST-N412 TEST KIT 20 CARDS 0143254504 423936 AST-N412 TEST KIT 20 CARDS 0143303504 424196 AST-N427 TEST KIT 20 CARDS 0542849204 424196 AST-N427 TEST KIT 20 CARDS 0543190104 424196 AST-N427 TEST KIT 20 CARDS 0543266504 424196 AST-N427 TEST KIT 20 CARDS 0542951404 424196 AST-N427 TEST KIT 20 CARDS 0543190104 424196 AST-N427 TEST KIT 20 CARDS 0543289404 424499 AST-N438 TEST KIT 20 CARDS 0703181504 424499 AST-N438 TEST KIT 20 CARDS 0703218104 424499 AST-N438 TEST KIT 20 CARDS 0703273104 424499 AST-N438 TEST KIT 20 CARDS 0703125104 424501 AST-N439 TEST KIT 20 CARDS 0723192104 424501 AST-N439 TEST KIT 20 CARDS 0723048404 424501 AST-N439 TEST KIT 20 CARDS 0722971504 424501 AST-N439 TEST KIT 20 CARDS 0723237504 424501 AST-N439 TEST KIT 20 CARDS 0722860204 424502 AST-N440 TEST KIT 20 CARDS 0733170404 424502 AST-N440 TEST KIT 20 CARDS 0733317504 424502 AST-N440 TEST KIT 20 CARDS 0733170404 424541 AST-N443 TEST KIT 20 CARDS 0773230404 424541 AST-N443 TEST KIT 20 CARDS 0773247404 424541 AST-N443 TEST KIT 20 CARDS 0772911104 424587 AST-N444 TEST KIT 20 CARDS 0802553214 424587 AST-N444 TEST KIT 20 CARDS 0802553204 424620 AST-N447 TEST KIT 20 CARDS 0853198104 424620 AST-N447 TEST KIT 20 CARDS 0853247204 424633 AST-N448 TEST KIT 20 CARDS 0862971204 424633 AST-N448 TEST KIT 20 CARDS 0863202504 424633 AST-N448 TEST KIT 20 CARDS 0863296504 424839 AST-N462 TEST KIT 20 CARDS No Lots 424840 AST-N463 TEST KIT 20 CARDS No Lots 424842 AST-N465 TEST KIT 20 CARDS No Lots 424891 AST-N475 TEST KIT 20 CARDS 1703184204 424891 AST-N475 TEST KIT 20 CARDS 1703225504 424934 AST-N476 TEST KIT 20 CARDS 1713192504 425019 AST-N477 TEST KIT 20 CARDS 1733184104 425019 AST-N477 TEST KIT 20 CARDS 1733205204 425019 AST-N477 TEST KIT 20 CARDS 1733205214 424197 AST-XN21 TEST KIT 20 CARDS 0493174204 424197 AST-XN21 TEST KIT 20 CARDS 0493310504 424199 AST-XN22 TEST KIT 20 CARDS 0552981204 424199 AST-XN22 TEST KIT 20 CARDS 0553156204 424351 AST-XN24 TEST KIT 20 CARDS 0653042204 424351 AST-XN24 TEST KIT 20 CARDS 0653217504 424394 AST-XN25 TEST KIT 20 CARDS 0662155104 424394 AST-XN25 TEST KIT 20 CARDS 0662553204 424586 AST-XN28 TEST KIT 20 CARDS 0793210504 424586 AST-XN28 TEST KIT 20 CARDS 0793265504 424586 AST-XN28 TEST KIT 20 CARDS 0793295504 424586 AST-XN28 TEST KIT 20 CARDS 0793210504 424604 AST-XN29 TEST KIT 20 CARDS 0822932204 424604 AST-XN29 TEST KIT 20 CARDS 0823262504 424810 AST-XN35 TEST KIT 20 CARDS 1323087204 424888 AST-XN37 TEST KIT 20 CARDS 1693079204 AST-XN25 424394 Australia AST-N412 423936 Thailand AST-XN21 424197 Turkey AST-XN22 424199 Iberia AST-N427 424196 Iberia AST-XN24 424351 Germany AST-N439 424501 Italy AST-N440 424502 Italy AST-XN28 424586 France AST-N443 424541 France, Spain & Portugal AST-N444 424587 Russia AST-N447 424620 Netherlands AST-N448 424633 Israel AST-XN35 424810 Poland AST-N462 424839 Taiwan AST-N463 424840 Taiwan AST-N465 424842 Taiwan AST-XN37 424888 Japan AST-N475 424891 Pakistan AST-N476 424934 Pakistan AST-N477 425019 India AST-N438 424499 Italy AST-XN29 424604 Japan

Class II Devices Event

Event ID:

97308

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

07/01/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/26/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

North American Rescue LLC.
35 Tedwall Ct
Greer, SC 29650-4791
United States

Distribution Pattern:

Worldwide - US Nationwide distribution in the states of SC, OK, ID, KY, VA, NV, IL, TX, CA, FL, LA, NY, LA, ME, PA, AR, AZ, AL, DE, MA, MS, HI, WA, MI, GA, NJ, UT, MD, OR, NC, NC, AL and the countries of KOR, JPN, BWA, SAU, BEL.

Associated Products

Product Description:

JUNCTIONAL EMERGENCY TREATMENT TOOL (JETT), REF: 30-0088, a component inside kits: KIT, TCCC Training- Complete (Modules 1-3), REF: 85-0550; KIT, TCCC MODULE ONE - SKILLS, REF: 85-0519; KIT, MULTI MISSION EXPEDITIONARY RESPONSE - MMERK, REF: 85-2420; KIT, TCCC SKILLS/IFAK COMBO, REF: 85-0740, KIT, TCCC/TECC MODULE ONE SKILLS REFILL, REF: 85-1900

Product Quantity:

552

Reason for Recall:

Device used for unilateral or bilateral occlusion of blood flow to the lower limbs has a potential manufacturing defect that may compromise the structural integrity of the device and device performance during use.

Recall Number:

Z-2637-2025

Code Information:

JETT: REF: 30-0088 UDIs: (01)00842209100002(11)240426(10)0212241, (01)00842209100002(11)240515(10)817221, (01)00842209100002(11)240530(10)817222, (01)00842209100002(11)240618(10)817222, (01)00842209100002(11)240701(10)817222, (01)00842209100002(11)240712(10)1213231. REF: 30-0088: Lots: 021224-1, 81722-1, 81722-2, 121323-1. Kits: REF/UDI-DI/Lot: 85-0550/00842209110711/85-0550091824, 85-0550090424, 85-0550030725, 85-0550052925, 85-0550052325, 85-0550082324, 85-0550080624, 85-0550062624, 85-0550052124, 85-0550111424, 85-0550102924; 85-0519/00842209110742/85-0519090324, 85-0519081924; 85-2420/00842209113910/85-2420041725, 85-2420042125, 85-2420100324; 85-0740/00842209110599/85-0740042925, 85-0740050625, 85-0740052925, 85-0740081224, 85-0740082924, 85-0740011325, 85-0740122324, 85-0740121724, 85-0740112024, 85-0740110424, 85-0740102524; 85-1900/00842209110810/85-1900082124, 85-1900031125

Class II Devices Event

Event ID:

97312

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/21/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/26/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Bard Peripheral Vascular Inc
1625 W 3rd St Bldg 1 850 W. Rio Salado Prkwy.
Tempe, AZ 85281-2438
United States

Distribution Pattern:

Worldwide - US Nationwide distribution including in the states of NJ, NY, FL, LA, VA, CA, TX, NV, PA, NE, TN, IL, AZ, SC, AK, GA, CO, HI, OH, NC,

WI, WV, MD, MO, AL, OK, MS, PR, KS, UT, CT, IA, MI, IN, MA, KY, WA, MT, MN, SD, ME, DE, NM, AR and the country of Malaysia.

Associated Products

Product Description:

Venclose digiRF Generators, Model VCRFG1, with software 3.35 designed to identify internal wiring anomalies in the Venclose EVSRF Ablation Catheter prior to use. The Venclose digiRF Generator is a sophisticated multi-voltage energy delivery system featuring touchscreen control that automatically configures non-adjustable treatment parameters (including time and temperature) for compatible catheters connected via a triaxial connector port. Designed for use with Venclose RF Catheters (either the EVSRF or Maven variants) as an integrated system, the device employs resistive radiofrequency ablation to deliver temperature-controlled RF energy that heats incompetent vein walls, inducing irreversible luminal occlusion followed by progressive fibrosis and eventual vein resorption. The 510(k) submission K250068 encompasses solely the Venclose digiRF Generator due to software modifications with no alterations to the cleared Venclose Catheters (EVSRF and Maven variants, cleared under K160754 and K211806, respectively).

Product Quantity:

1,725

Reason for Recall:

Software version 3.35 of the Venclose digiRF Generator incorporates a catheter verification feature specifically designed to detect internal wiring anomalies in Venclose EVSRF Ablation Catheters prior to clinical use. This automated diagnostic check is executed immediately upon catheter connection to the generator, occurring before the procedure interface becomes accessible. When a catheter fails this verification process, the generator displays a Red X indicator on the screen without accompanying error codes, effectively disabling catheter functionality. However, BD has determined that software version 3.35 generates false positive failures due to temperature-dependent verification parameters, incorrectly flagging properly functioning Venclose EVSRF Ablation Catheters as defective when the catheter temperature is not at steady state during the check initiation.

Recall Number:

Z-2638-2025

Code Information:

UDI-DI: 00858254006022. Generator Software Version 3.35

Class II Devices Event

Event ID:

97390

Status:

Ongoing

Recall Initiation Date:

08/04/2025

Center Classification Date:

10/02/2025

Recalling Firm:

Beckman Coulter Inc.
250 S Kraemer Blvd
Brea, CA 92821-6232
United States

Distribution Pattern:

Internationally distribution to the countries of Poland, India, Dominican Republic, Lebanon, Italy, Brazil, El Salvador, Saudi Arabia, Germany, France, Nepal, Canada, Chile, Spain, Malaysia, Switzerland, Morocco, Philippines, Curacao, Qatar, United Arab Emirates, Hungary, Czechia, Oman, New Zealand, Thailand, Indonesia, Algeria, United Kingdom of Great Britain and Northern Ireland, Namibia, Turkey, Republic of Korea

Product Type:

Devices

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

DxC 500 AU Module w/ISE, DxC 500i, With ISE, REF: C63522 and DxC 500 AU Module, DxC 500i, Without ISE, REF: C6352; part of the DxC 500i Clinical Analyzer

Product Quantity:

116

Reason for Recall:

On a clinical analyzer, when ordering a Clinical Chemistry (CC) combination test simultaneously with an Immunoassay (IA) test, if the IA test is

processed between the CC tests, CC sample status will remain In Progress with no errors, may cause processing delays.

Recall Number:

Z-0032-2026

Code Information:

REF/UDI-DI: C63522/14987666545089, C63521/14987666545072. Software Versions: SW 1.3.3 and 1.3.4

Class II Devices Event

Event ID:

97413

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

07/25/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/26/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Zap Surgical Systems
590 Taylor Way
San Carlos, CA 94070-6307
United States

Distribution Pattern:

Worldwide - US Nationwide distribution in the states of FL, CO, NJ, NY and the countries of Germany, France, Spain, Poland, Republic of Korea, Türkiye, Paraguay.

Associated Products

Product Description:

ZAP-X Radiosurgery System, Model: 300150

Product Quantity:

17

Reason for Recall:

If the radiosurgery system triggers a proximity error message during a long gantry move (greater-than 180 degrees), and a subsequent proximity error message occurs after the automatic reduction of speed, a software defect could potentially lead the collimator to collide with patient shoulders or the patient table.

Recall Number:

Z-2639-2025

Code Information:

UDI-DI: 00860183001504, Serial Numbers: ZUC17153, ZUC20156, ZUC20157, ZUC20159, ZUC21162, ZUC21164, ZUC22166, ZUC22169, ZUC22170, ZUC22171, ZUC22173, ZUC22174, ZUC23176, ZUC23177, ZUC24179, ZUC24180, ZUC24181. Software version: TDS V1.10.1

Class II Devices Event

Event ID:

97451

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/08/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/29/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Schiller, Ag

Altgasse 68
Baar
Switzerland

Distribution Pattern:

US Nationwide distribution in the states of MT, WI, IL.

Associated Products

Product Description:

Argus PB-3000, Reference Numbers: 1A.701307,3.921002, 3.921030,3.921031, 3.921006

Product Quantity:

266 units

Reason for Recall:

Vital sign monitoring instrument may trigger an error message during blood pressures measurements, Specifically, when the initial inflation pressure is set in the high-pressure range.

Recall Number:

Z-2672-2025

Code Information:

REF: 1A.701307: UDI- 07613365003024 REF: 3.921002, UDI: 07613365001914 REF: 3.921030, UDI: 07613365003468 REF: 3.921031: UDI: 07613365003475 REF: 3.921006, UDI: 07613365000115 Affected Serial Numbers: 7010.000160 and lower, 7012.000356 and lower, 7013.000256 and lower, 7014.000152 and lower

Class II Devices Event

Event ID:

97474

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/26/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/02/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

W L Gore & Associates, Inc.
1505 N 4th St
Flagstaff, AZ 86004-5867
United States

Distribution Pattern:

US: OR, AL, OH, MD, VA, CA, FL, NC, OK, MA, MO, AZ, TX, IL, GA, PA, NH, HI, MN, MS, KY, ID, LA, NJ, TN, DE, IN, MI, WI, NY, DC, SC, CT, NE, IA, WA, AR, NV, WV, AK, UT, ND, KS, CO, ME, MT, NM, SD, PR, WY, RI. OUS: PANAMA, CANADA, CHINA, TAIWAN, GERMANY, SLOVENIA, NORWAY, UNITED KINGDOM, ITALY, SPAIN, FINLAND, NETHERLANDS, SWEDEN, FRANCE, UNITED ARAB EMIRATES, DENMARK, PORTUGAL, AUSTRIA, SWITZERLAND, BELGIUM, TURKIYE, SLOVAK REPUBLIC, CYPRUS, SAUDI ARABIA, SOUTH AFRICA, LUXEMBOURG, FRENCH GUIANA, ANDORRA, IRELAND, NEW CALEDONIA, POLAND, ISRAEL, GREECE, GUADELOUPE, CROATIA, REUNION, BAHRAIN, HUNGARY, JAPAN

Associated Products

Product Description:

GORE ACUSEAL Vascular Graft, REF: ECH050020J, ECH050020W, ECH050050J, ECH050050W, ECH060010A, ECH060020A, ECH060020J, ECH060020W, ECH060040A, ECH060040W, ECH060050A, ECH060050J, ECH460045A, ECH460045J, ECH470045, ECH470045A; used with Instructions for Use.

Product Quantity:

52,306

Reason for Recall:

Reports of vascular graft delamination, which may lead to reduced access flow; cannulation difficulties; bleeding or bruising; and harms related to

reintervention procedures, so Instructions for Use will be updated to modify existing warning to 1) further clarify techniques that may contribute to the risk of delamination, 2) Addition of delamination to device-related adverse event section.

Recall Number:

Z-0036-2026

Code Information:

REF/UDI-DI: ECH050020J/04993024010758, ECH050020W/00733132635450, ECH050050J/04993024010772, ECH050050W/00733132635474, ECH060010A/00733132622573, ECH060020A/00733132622597, ECH060020J/04993024009967, ECH060020W/00733132634729, ECH060040/00733132605347, ECH060040A/00733132605354, ECH060040W/00733132619719, ECH060050A/00733132626960, ECH060050J/04993024009981, ECH460045A/00733132634811, ECH460045J/04993024010789, ECH470045/00733132626977, ECH470045A/00733132634811. Product with a serial number that includes and falls within the range of 6597081PP001 and 9853822PP024.
Instructions for Use MD183888 Revision 4

Class II Devices Event

Event ID:

97502

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

09/03/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/01/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

PHILIPS MEDICAL SYSTEMS NEDERLAND B.V.

Veenpluis 4-6

Best

Netherlands

Distribution Pattern:

Worldwide distribution - US Nationwide and the countries of Albania, Algeria, Argentina, Australia, Austria, Azerbaijan, Bangladesh, Belarus, Belgium, Bolivia, Bosnia and Herzegovina, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Curacao, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, Estonia, Finland, France, Georgia, Germany, Greece, Guinea, Honduras, Hungary, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Korea, South, Kosovo, Latvia, Lebanon, Libya, Lithuania, Macedonia, Malaysia, Malta, Mauritius, Mexico, Mongolia, Morocco, Nepal, Netherlands, New Zealand, Norway, Palestine, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Syrian Arab Republic, Taiwan, Tanzania, Thailand, Trinidad and Tobago, Tunisia, Turkey, Türkiye, Ukraine, United Arab Emirates, United Kingdom, Uruguay, Utd.Arab.Emir., Uzbekistan, Venezuela, Vietnam, Yemen.

Associated Products

Product Description:

Allura Xper FD10C; Model Number: 722001; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

2 units (US only)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0001-2026

Code Information:

Model Number: 722003; UDI-DI: N/A; Serial Numbers: 19, 21;

Product Description:

Allura Xper FD10; Model Numbers: (1) 722003, (2) 722010, (3) 722026; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

2317 units (497 US, 1820 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0002-2026

Code Information:

Model Numbers: (1) 722003, (2) 722010, (3) 722026; UDI-DI: (1) N/A, (2) 00884838059030, (3) 00884838054189; Serial Numbers: (1) 1343, 1349, 1153, 1154, 1472, 257, 1694, 746, 745, 1599, 501, 503, 1360, 959, 1138, 490, 1188, 1532, 940, 1214, 401, 1627, 1031, 1728, 1189, 285, 1311, 1700, 998, 1187, 1222, 305, 1353, 939, 1326, 445, 1223, 700, 657, 527, 1634, 1023, 917, 1043, 994, 995, 945, 521, 590, 591, 855, 491, 1615, 1732, 1761, 1078, 367, 690, 1529, 385, 997616, 1085, 1663, 653, 1667, 928, 1449, 968, 1286, 72, 1622, 1621, 472, 1799, 463, 619915, 696, 1525, 1514, 574, 306, 1114, 1584, 447, 1950, 1647, 406, 1555, 1482, 1489, 1443, 1444, 1072, 1954, 1704, 1232, 749, 1266, 1089, 259, 1259, 1787, 345, 640, 37, 1714, 546, 1133, 1135, 1032, 1512, 892, 684, 857, 1084, 1067, 2936, 1411, 947, 197, 392, 1271, 1807, 1805, 1575, 963, 1430, 8198, 1869, 1594, 467, 1551, 1947, 390, 342, 368, 912, 913, 8091, 1471, 1474, 1446, 1001, 1092, 1718, 1637, 453, 833, 430, 1738, 1749, 1491, 1605, 1130, 5, 639, 674, 797, 1033, 1357, 1632, 1744, 281, 391, 1535, 350, 452, 629, 732, 754, 1038, 1045, 1536, 1056, 599, 1331, 756, 1351, 1611, 1610, 1804, 1122, 1413, 644, 545, 1059, 1327, 513, 1163, 1204, 1193, 1549, 418, 1778, 955, 1199, 2933, 517, 1597, 1585, 1063, 1596, 1341, 337, 1746, 1747, 1619, 288, 988, 535, 1717, 319, 411, 412, 413, 414, 415, 1395, 1338, 1706, 1572, 1916, 1282, 789, 790, 614, 763, 728, 605, 622, 492, 1612, 192, 1613, 1648, 1568, 1569, 1570, 1685, 1314, 948, 505, 566, 1297, 895619, 1108, 1277, 239, 1216, 328, 1492, 863, 1616, 370, 359, 388, 1169, 1118, 1416, 1260, 1609, 115, 1337, 1107, 519, 1155, 13, 1478, 1090, 1662, 1818, 1094, 1142, 1730, 1463, 1752, 1215, 1558, 1578, 1083, 1378, 985, 1014, 1231, 356, 310, 777, 307, 308, 309, 778, 780, 1127, 1167, 1186, 742, 1653, 1051, 898, 1689, 715, 716, 423, 1571, 1101, CV.615, 1399, 1931, 1149, 753, 377, 1255, 424, 1733, 606, 1247, 1293, 548, 813, 1524, 1457, 321, 1421, 1979, 1487, 249, 1509, 937, 1016, 1857, 676, 875, 373, 313, 314, 1923, 1161, 1160, 1162, 1919, 1712, 1723, 1328, 750, 1396, 1582, 1445, 1511, 1576, 1680, 1104, 560, 1735, 1664, 4.5161E+15, 1173, 1064, 1458, 949, 1592, 1121, 1295, 265, 1708, 1709, 374, 1119, 369, 1176, 1230, 1925, 1246, 1755, 1756, 339, 861, 1606, 1649, 990, 1823, 1325, 1633, 596, 1527, 1784, 1834, 464, 1456, 796, 1273, 1110, 1751, 1726, 1928, 468, 935, 839, 1702, 807, 1025, 272, 1109, 1593, 1743, 538, 1684, 1198, 292, 1669, 1065, 1697, 1022, 770, 708, 1053, 1, 744, 1141, 329, 1125, 1661, 344, 1760, 1567, 1495, 782, 1132, 1452, 1603, 1407, 669, 1207, 1409, 1412, 1500, 1501, 1748, 1414, 1692, 1595, 1203, 1764, 1058, 1027, 961, 1172, 346, 255, 1469, 1077, 1112, 1278, 354, 416, 363, 582, 1518, 1666, 2674, 1352, 205, 899, 883, 161, 1280, 569, 922, 1691, 667, 578, (2) 662, 905, 480, 833, 787, 365, 169, 1336, 839, 1048, 1011, 343, 637, 917, 108, 677, 671, 468, 1132, 1025, 1226, 1108, 274, 1043, 1302, 160, 1309, 638, 1436, 527, 1442, 1109, 679, 119, 42, 467, 987, 986, 1112, 175, 968, 791, 1084, 1440, 505, 286, 636, 946, 214, 755, 1365, 809, 763, 992, 521, 932, 1123, 218, 1176, 67, 979, 1064, 931, 127, 764, 1210, 1209, 624, 1298, 290, 190, 605, 604, 1126, 1173, 422, 1170, 882, 1128, 646, 648, 395, 1396, 1233, 1234, 1236, 1235, 698, 690, 478, 1041, 1042, 592, 1214, 780, 158, 1395, 1432, 830, 252, 873, 818, 1230, 1263, 69, 1370, 1369, 999, 728, 485, 488, 1310, 673, 683, 890, 641, 1373, 1040, 308, 65, 360, 1297, 1397, 1398, 209, 500, 914, 1149, 794, 423, 1118, 878, 920, 1005, 1292, 1275, 1144, 453, 1425, 792, 1283, 902, 1424, 229, 651, 240, 788, 1312, 838, 1391, 1183, 611, 939, 921, 1344, 572, 970, 585, 1181, 1078, 1279, 656, 668, 896, 531, 342, 177, 33, 344, 1308, 1069, 1287, 477, 1261, 241, 1009, 1441, 694, 107, 714, 785, 414, 777, 608, 666, 654, 1122, 601, 301, 924, 426, 265, 1198, 577, 1047, 1187, 494, 447, 1250, 1147, 1034, 1421, 1258, 193, 626, 652, 1016, 1015, 1017, 1018, 1423, 1332, 578, 1106, 980, 1169, 1438, 868, 383, 782, 125, 52, 697, 523, 707, 708, 566, 589, 593, 594, 891, 1146, 1267, 1278, 861, 1321, 1096, 906, 1366, 374, 1363, 243, 524, 1428, 812, 225, 813, 857, 555, 598, 95, 844, 1285, 1161, 212, 96, 139, 1055, 1202, 928, 1185, 1374, 102, 410, 58, 786, 276, 126, 1050, 37, 1361, 1153, 1166, 915, 951, 884, 544, 146, 121, 1113, 803, 802, 769, 540, 1385, 192, 62, 529, 1305, 1007, 1306, 612, 1093, 1203, 1216, 620, 300, 1058, 528, 559, 1334, 600, 1006, 141, 740, 828, 1192, 715, 635, 1134, 1135, 520, 570, 90, 811, 53, 901, 223, 1095, 552, 1326, 973, 596, 45, 712, 1148, 1349, 323, 825, 402, 713, 313, 195, 900, 277, 176, 806, 907, 967, 795, 816, 1154, 1439, 273, 1431, 1404, 29, 63, 346, 157, 1427, 692, 270, 655, 610, 895, 762, 888, 936, 50, 990, 665, 1444, 603, 1003, 1617, 220, 1152, 819, 613, 614, 634, 136, 944, 255, 817, 1140, 793, 393, 518, 568, 842, 563, 330, 367, 473, 515, 1315, 952, 866, 1002, 1429, 1430, 1426, 418, 778, 954, 781, 720, 911, 49, 354, 186, 719, 978, 46, 831, 789, 1067, 1129, 940, 83, 123, 516, 586, 1193, 166, 501, 758, 64, 1056, 1004, 1403, 1141, 86, 111, 1241, 1171, 909, 548, 506, 1393, 1371, 1036, 597, 653, 1086, 88, 1180, 381, 1389, 776, 115, 219, 959, 533, 801, 498, 1402, 1053, 997, 116, 579, 211, 404, 428, 503, 493, 1120, 1121, 753, 606, 226, 1452, 495, 1244, 945, 1088, 1245, 996, 137, 72, 1177, 1178, 128, 525, 960, 625, 1221, 607, 744, 71, 400, 20, 1434, 1392, 984, 1105, 1266, 615, 130, 923, 1208, 1051, 1206, 975, 1168, 253, 398, 1211, 320, 1039, 97, 703, 526, 1237, 650, 427, 496, 1286, 772, 680, 1232, 649, 401, 1194, 774, 963, 876, 660, 885, 800, 1012, 264, 228, 699, 1356, 475, 1331, 759, 722, 1100, 1384, 1352, 350, 1357, 1090, 1098, 1099, 748, 1220, 657, 658, 659, 854, 1325, 565, 736, 734, 737, 735, 642, 1255, 1360, 1054, 490, 391, 425, 513, 1381, 1163, 1164, 1342, 898, 1364, 424, 1368, 1367, 105, 993, 732, 580, 1256, 704, 261, 695, 696, 1353, 1379, 1378, 238, 1254, 1394, 1390, 706, 1253, 1327, 1165, 1032, 319, 1223, 1252, 469, 739, 1380, 541, 731, 1019, 1023, 1215, 247, 1191, 856, 1375, 51, 1350, 971, 1345, 356, 877, 164, 1125, 272, 989, 340, 35, 34, 249, 1196, 1294, 114, 80, 1445, 380, 1276, 1200, 935, 1242, 224, 106, 104, 103, 1401, 622, 371, 162, 333, 927, 1022, 1000, 930, 1197, 1116, 903, 1435, 91, 1346, 602, 245, 535, 230, 231, 232, 991, 248, 1111, 742, 1029, 222, 797, 254, 416, 1010, 957, 92, 687, 1304, 187, 502, 1124, 174, 537, 1199, 941, 553, 1339, 1001, 1351, 1307, 173, 134, 1137, 282, 483, 847, 1068, 760, 1008, 1213, 1092, 1151, 1083, 1268, 955, 711, 1145, 514, 1273, 66, 1157, 1119, 702, 860, 1446, 685, 686, 942, 181, 357, 1190, 961, 287, 948, 509, 619, 185, 1104, 887, 394, 304, 863, 799, 1224, 1225, 1021, 1422, 1033, 1136, 998, 733, 154, 834, 1150, 1091, 832, 311, 142, 388, 1451, 599, 1188, 235, 236, 1031, 1030, 850, 250, 1097, 904, 199, 328, 182, 294, 1066, 77, 122, 810, 184, 474, 471, 962, 771, 138, 1182, 549, 1065, 1376, 1433, 1355, 689, 163, 631, 1303, 1155, 558, 804, 1044, 822, 852, 880, 476, 862, 1280, 1300, 1077, 858, 362, 1207, 1076, 874, 1218, 1130, 972, 1313, 710, 934, 645, 855, 583, 178, 94, (3) 765, 156, 253, 287, 825, 394, 713, 74, 462, 192, 191, 204, 155, 1132, 967, 205, 1246, 122, 259, 185, 618, 531, 855, 235, 805, 725, 832, 368, 646, 663, 653, 965, 602, 908, 959, 221, 1129, 973, 664, 778, 109, 110, 116, 284, 115, 389, 841, 223, 694, 222, 374, 634, 622, 436, 878, 1192, 102, 914, 396, 704, 370, 782, 1210, 201, 774, 696, 838, 344, 563, 731, 233, 1126, 543, 1072, 93, 796, 601, 245, 234, 1340, 604, 627, 190, 935, 560, 11, 562, 297, 98, 99, 100, 101, 1338, 1248, 544, 561, 1100, 1239, 1293, 648, 1038, 1231, 1215, 215, 683, 142, 1268, 728, 1050, 600, 843, 391, 877, 224, 73, 608, 1051, 1052, 324, 969, 323, 444, 1189, 931, 265, 431, 114, 654, 786, 617, 130,

990, 378, 1101, 558, 738, 1287, 942, 75, 688, 985, 220, 781, 78, 845, 614, 151, 559, 79, 1205, 770, 1000, 909, 319, 633, 458, 381, 400, 826, 716, 966, 432, 335, 1068, 244, 957, 484, 485, 121, 612, 998, 986, 534, 807, 961, 962, 1049, 707, 866, 759, 1115, 638, 830, 271, 813, 775, 1316, 343, 406, 252, 748, 616, 1278, 1104, 446, 557, 1368, 358, 310, 497, 977, 471, 334, 65, 423, 461, 1001, 806, 769, 143, 711, 257, 771, 881, 581, 576, 1127, 1128, 1258, 1307, 311, 90, 1092, 276, 722, 1188, 809, 1326, 1067, 404, 729, 894, 477, 18, 1018, 126, 164, 542, 978, 566, 455, 1201, 1202, 1204, 564, 541, 1227, 1349, 1134, 326, 231, 77, 1220, 1221, 746, 448, 650, 401, 794, 146, 69, 681, 690, 545, 1228, 1321, 1071, 189, 188, 174, 387, 1341, 897, 619, 1107, 1033, 804, 677, 678, 424, 1271, 587, 1347, 584, 578, 454, 1037, 355, 354, 709, 1203, 356, 930, 172, 911, 134, 294, 609, 569, 141, 596, 177, 979, 452, 928, 924, 1093, 161, 182, 960, 717, 1313, 1054, 1233, 388, 720, 721, 1117, 96, 1146, 510, 858, 745, 744, 420, 1272, 508, 55, 494, 459, 193, 364, 1091, 1064, 863, 7, 697, 159, 536, 535, 692, 756, 628, 237, 512, 197, 749, 385, 968, 586, 768, 611, 249, 1148, 1121, 17, 273, 43, 203, 1108, 40, 1265, 1264, 132, 217, 507, 662, 754, 478, 1031, 997, 375, 426, 884, 1123, 1356, 450, 503, 1026, 228, 270, 425, 472, 1305, 1360, 1362, 1363, 1029, 1364, 269, 372, 428, 427, 449, 751, 902, 687, 1113, 753, 1366, 1199, 1329, 1355, 1361, 546, 527, 1301, 322, 944, 136, 179, 373, 104, 64, 1196, 314, 1147, 441, 938, 44, 686, 402, 1019, 31, 430, 580, 439, 440, 15, 599, 1276, 927, 592, 1245, 304, 575, 1173, 589, 763, 180, 594, 359, 723, 700, 1195, 521, 285, 658, 657, 656, 857, 803, 585, 854, 382, 779, 632, 1165, 183, 91, 418, 28, 342, 209, 403, 511, 330, 1218, 71, 525, 730, 915, 303, 526, 1229, 125, 726, 505, 846, 128, 637, 300, 429, 119, 792, 348, 435, 810, 995, 1028, 453, 1277, 2, 572, 1005, 1106, 360, 488, 620, 293, 14, 296, 206, 747, 266, 783, 1275, 1118, 689, 540, 1186, 351, 166, 571, 1250, 516, 1034, 631, 1230, 1372, 178, 365, 570, 1046, 1047, 573, 1306, 975, 577, 313, 626, 25, 1255, 1184, 917, 695, 780, 1179, 468, 1208, 480, 23, 913, 1152, 341, 1170, 184, 840, 764, 936, 274, 1053, 635, 606, 302, 1371, 390, 895, 630, 899, 734, 337, 129, 502, 1308, 298, 719, 523, 13, 152, 851, 593, 392, 171, 1303, 727, 349, 383, 353, 520, 1163, 133, 413, 118, 903, 327, 661, 261, 460, 528, 1014, 1015, 1177, 1016, 347, 1012, 1013, 33, 871, 880, 299, 24, 1187, 213, 1008, 27, 137, 1011, 226, 940, 1191, 139, 496, 1216, 214, 739, 624, 489, 1185, 1353, 1296, 740, 1044, 1240, 625, 1190, 932, 491, 1070, 148, 487, 1096, 943, 1243, 393, 1097, 836, 1021, 1006, 761, 1241, 1242, 421, 1359, 1194, 476, 666, 1098, 649, 598, 597, 301, 818, 958, 1048, 916, 703, 345, 1289, 812, 325, 1280, 1281, 405, 951, 328, 1171, 1175, 762, 1343, 1327, 610, 395, 941, 1286, 416, 470, 1145, 509, 167, 1065, 773, 1320, 912, 153, 1138, 1078, 814, 530, 529, 1234, 76, 42, 150, 490, 292, 399, 1174, 1136, 789, 672, 640, 641, 642, 154, 1119, 410, 873, 868, 816, 1086, 898, 551, 847, 766, 888, 445, 699, 1150, 574, 22, 92, 519, 208, 1155, 1213, 970, 1352, 500, 332, 1226, 988, 994, 1169, 210, 362, 752, 732, 659, 956, 1120, 1022, 901, 187, 539, 815, 1133, 1354, 1318, 1261, 1315, 1314, 1116, 1217, 1282, 1009, 1302, 1076, 1346, 833, 1331, 1337, 1062, 1154, 989, 1336, 1319, 1310, 1309, 891, 1262, 1334, 1339, 1252, 708, 1342, 1335, 987, 1159, 1266, 1153, 1063, 1292, 1135, 1259, 1260, 981, 948, 590, 859, 579, 1007, 1328, 1010, 1332, 1351, 760, 1256, 984, 1161, 636, 1294, 1122, 939, 1274, 1176, 767, 1269, 1214, 1348, 1270, 1283, 1164, 1312, 1209, 1109, 735, 225, 227, 992, 844, 463, 1317, 498, 621, 147, 434, 433, 493, 62, 1219, 236, 464, 39, 875, 937, 157, 971, 537, 714, 742, 1224, 361, 591, 1137, 785, 651, 1168, 701, 777, 776, 515, 1149, 1207, 1206, 1330, 919, 741, 1279, 1066, 808, 922, 567, 1125, 84, 149, 1024, 277, 715, 338, 333, 565, 1156, 457, 1222, 95, 82, 85, 673, 603, 835, 379, 737, 811, 1144, 377, 1143, 306, 89, 97, 517, 867, 869, 702, 918, 1140, 790, 447, 660, 1370, 357, 1045, 376, 824, 712, 41, 1027, 582, 1020, 81, 200, 684, 279, 736, 652, 1225, 363, 758, 504, 724, 950, 29, 492, 583, 346, 682, 549, 250, 506, 819, 251, 262, 263, 755, 821, 983, 921, 1311, 1158, 1157, 1105, 275, 772, 289, 288, 194, 1023, 456, 199, 784, 216, 900, 315, 1004, 255, 887, 886, 1102, 1002, 107, 308, 414, 1058, 896, 366, 710, 524, 290, 1151, 706, 532, 443, 442, 547, 417, 1357, 38, 870, 1365, 889, 412, 862, 1369, 398, 1090, 305, 163, 411, 466, 105, 1273, 788, 419, 1035, 170, 384, 1344, 1345, 247, 481, 827, 212, 318, 316, 317, 1030, 1178, 1131, 675, 1358, 256, 336, 1322, 623, 1130, 1172, 892, 588, 291, 1257, 743, 408, 286, 1H071046, 1162, 70, 1323, 1325, 260, 106, 83, 876, 211, 655, 568, 198, 268, 495, 974, 793, 160, 907, 486, 1251, 469, 669;

Product Description:

Allura Xper FD10/10; Model Numbers: (1) 722005, (2) 722011, (3) 722027; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

585 units (145 US, 440 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0003-2026

Code Information:

Model Numbers: (1) 722005, (2) 722011, (3) 722027; UDI-DI: (1) N/A, (2) 00884838059047, (3) 00884838054196; Serial Numbers: (1) 361, 212, 233, 321, 435, 285, 384, 388, 343, 399, 392, 128, 355, 51, 367, 348, 160, 271, 530, 112, 70, 520, 323, 49, 329, 365, 269, 270, 523, 490, 346, 129, 258, 298, 316, 485, 261, 169, 427, 352, 474, 497, 251, 100, 456, 360, 305, 419, 405, 489, 306, 307, 467, 234, 333, 533, 209, 369, 543, 332, 328, 366, 339, 389, 538, 394, 378, 379, 237, 165, 2724, 238, 415, 473, 482, 397, 53, 385, 52, 447, 96, 429, 159, 531, 58, 499, 229, 374, 25, 354, 440, 441, 54, 403, 55, 342, 272, 80, 351, 371, 85, 75, 276, 26, 561, 511, 478, 428, 500, 464, 463, 14, 459, 416, 359, 487, 564, 469, 72, 125, 494, 76, (2) 157, 83, 268, 308, 380, 95, 107, 34, 59, 23, 319, 49, 170, 137, 173, 101, 84, 155, 133, 234, 345, 332, 102, 270, 177, 132, 325, 15, 79, 76, 17, 87, 255, 171, 362, 168, 22, 275, 344, 324, 163, 375, 103, 82, 40, 154, 215, 273, 222, 203, 214, 220, 242, 166, 71, 156, 36, 189, 186, 118, 119, 300, 213, 372, 12, 55, 41, 100, 190, 278, 258, 299, 260, 280, 32, 89, 199, 194, 108, 75, 307, 301, 18, 302, 303, 304, 305, 306, 293, 294, 184, 266, 146, 116, 68, 310, 272, 238, 152, 286, 309, 43, 334, 338, 165, 80, 112, 233, 188, 141, 139, 77, 99, 277, 313, 223, 27, 26, 29, 340, 69, 374, 328, 228, 251, 231, 323, 224, 145, 66, 117, 153, 6, 129, 355, 91, 227, 202, 114, 274, 21, 86, 378, 376, 377, 257, 265, 127, 180, 259, 211, 206, 217, 314, 98, 201, 341, 318, 347, 261, 178, 183, 271, 230, 317, 198, 321, 204, 94, 104, 290, 244, 333, 287, 38, 39, 176, 282, 216, 158, 329, 246, 295, 56, 337, 292, 125, (3) 203, 335, 123, 133, 134, 284, 280, 183, 169, 106, 107, 234, 42, 101, 307, 265, 306, 267, 209, 153, 40, 332, 156, 112, 305, 1, 104, 263, 342, 71, 255, 351, 298, 175, 120, 116, 174, 241, 240, 29, 50, 288, 56, 152, 43, 49, 202, 178, 266, 127, 319, 39, 164, 187, 321, 328, 282, 184, 53, 146, 35, 337, 357, 213, 293, 292, 170, 346, 211, 95, 144, 238, 247, 154, 188, 347, 196, 159, 339, 343, 256, 167, 338, 334, 162, 273, 5, 160, 246, 61, 36, 299, 294, 345, 76, 94, 350, 348, 349, 172, 323, 324, 151, 7, 44, 99, 189, 85, 102, 78, 212, 126, 81, 268, 356, 244, 221, 55, 86, 254, 6, 117,

113, 362, 271, 186, 259, 236, 201, 275, 135, 277, 3, 58, 249, 149, 148, 38, 47, 316, 27, 165, 274, 80, 64, 205, 223, 270, 181, 245, 46, 352, 358, 361, 60, 228, 142, 57, 100, 70, 214, 145, 30, 114, 115, 204, 225, 297, 182, 48, 110, 84, 132, 177, 300, 79, 130, 210, 82, 260, 261, 103, 322, 128, 360, 310, 125, 68, 291, 180, 287, 264, 272, 59, 155, 207, 122, 45, 166, 158, 239, 33, 31, 137, 308, 243, 242, 131, 218, 66, 147, 197, 168, 118, 73, 235, 278, 250, 227, 96, 119, 233, 329, 296, 193, 143, 219, 276, 326, 312, 304, 311, 199, 75, 121, 87, 91, 192, 289, 217, 355, 232, 67, 315, 69, 19, 34, 141, 18, 138, 309, 51, 171, 136, 191, 269, 62, 206, 330, 90, 195, 215, 88, 139, 220, 198, 150, 208, 28, 163, 286, 23, 24, 21, 20, 65;

Product Description:

Allura Xper FD10 OR Table; Model Numbers: 722033; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

2 units (1 US, 1 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0004-2026

Code Information:

Model Numbers: 722033; UDI-DI: 00884838059078 Serial Numbers: 1, 6;

Product Description:

Allura Xper FD20; Model Numbers: (1) 722006, (2) 722012, (3) 722028; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

5067 units (1626 US, 3441 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0005-2026

Code Information:

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1291, 2244, 602, 523, 1051, 1951, 2200, 2366, 2017, 623, 1971, 2144, 1320, 1855, 2708, 2944, 1238, 180, 1376, 2107, 2882, 139, 583, 350, 628, 1865, 1240, 550, 2169, 2406, 1464, 1494, 491, 2208, 167, 2921, 385, 2646, 2220, 1930, 2477, 1551, 1794, 2091, 1233, 2554, 1463, 2854, 514, 294, 2443, 921, 2665, 1227, 955, 2832, 2007, 1706, 609, 2087, 1698, 972, 2298, 2802, 1064, 2128, 1958, 1068, 1703, 2761, 2347, 1907, 2544, 1135, 2053, 2870, 2799, 266, 1748, 1490, 1870, 658, 1828, 621, 1574, 603, 910, 1988, 1425, 557, 138, 1452, 262, 2627, 1620, 2754, 2652, 1180, 354, 1813, 2918, 2011, 373, 1121, 421, 1844, 1385, 834, 2000, 2388, 2591, 2743, 2790, 890, 236, 870, 1835, 2391, 2748, 2356, 2344, 2182, 1223, 2911, 1288, 2121, 2008, 2714, 398, 1234, 850, 965, 2688, 2604, 662, 868, 2501, 1483, 1489, 2780, 2439, 1528, 1820, 2618, 1232, 2675, 2823, 2583, 2175, 2491, 1984, 2695, 2791, 393, 592, 1371, 1125, 1031, 1085, 1864, 645, 1565, 179, 946, 1372, 945, 1449, 1517, 1186, 2078, 1557, 1318, 1264, 1351, 1821, 2077, 1867, 1198, 1840, 1812, 2066, 212, 933, 1676, 1634, 536, 1541, 1338, 1520, 1955, 178, 249, 2497, 1418, 1251, 1176, 1417, 2625, 1899, 1454, 1055, 1962, 1015, 1124, 1547, 2663, 2266, 1230, 2772, 1543, 956, 1744, 2110, 1553, 2498, 2505, 2922, 2090, 1639, 657, 2499, 2141, 1619, 143, 1368, 1149, 292, 887, 113, 2458, 105, 1742, 1949, 1850, 1901, 845, 2100, 273, (3) 819, 1598, 774, 316, 1946, 945, 541, 565, 647, 864, 674, 1041, 710, 949, 946, 880, 961, 447, 237, 238, 236, 356, 1188, 1189, 696, 1098, 793, 656, 618, 313, 329, 274, 1214, 1846, 1978, 1649, 1256, 1024, 2192, 904, 284, 242, 1397, 1957, 167, 207, 208, 526, 1820, 1756, 1677, 991, 2348, 479, 2641, 431, 2020, 2760, 734, 601, 869, 377, 1454, 1629, 1984, 275, 2933, 900, 66, 52, 1340, 539, 1, 272, 1103, 1311, 494, 80, 1639, 1136, 282, 1408, 1232, 990, 262, 1275, 522, 1956, 1017, 406, 548, 586, 530, 136, 137, 1441, 1130, 1657, 940, 938, 1656, 1736, 1076, 929, 251, 731, 989, 1834, 981, 350, 125, 368, 971, 499, 261, 211, 2647, 1424, 1856, 1261, 924, 934, 1854, 721, 1142, 1002, 1651, 1385, 2174, 1930, 1463, 2846, 1508, 892, 1111, 779, 519, 518, 590, 1058, 452, 453, 811, 1370, 543, 680, 1074, 668, 1191, 1212, 11, 318, 1211, 118, 343, 437, 424, 435, 205, 340, 481, 806, 1837, 805, 468, 906, 1811, 1774, 317, 2502, 1132, 1081, 982, 592, 655, 143, 1405, 1482, 1413, 140, 1448, 2103, 464, 1213, 139, 552, 476, 303, 419, 521, 531, 1201, 1014, 861, 580, 1327, 256, 1266, 917, 1472, 2083, 2007, 2008, 1652, 1129, 1646, 818, 1394, 1396, 254, 326, 122, 1116, 1824, 324, 1716, 2295, 130, 2906, 1288, 896, 995, 987, 877, 1755, 928, 267, 759, 866, 1310, 895, 1407, 1187, 128, 1171, 273, 888, 1264, 1222, 2843, 336, 375, 887, 449, 516, 533, 408, 373, 154, 956, 496, 1549, 376, 744, 1034, 1054, 473, 808, 630, 785, 379, 553, 2261, 110, 983, 627, 903, 1099, 1909, 654, 1481, 784, 2061, 422, 525, 363, 1690, 23040202, 260, 1233, 2206, 1122, 2275, 2310, 2506, 2200, 339, 781, 1850, 1331, 809, 365, 571, 204, 203, 1538, 678, 528, 560, 310, 743, 445, 161, 189, 2635, 292, 1466, 1200, 1374, 720, 1836, 173, 620, 1085, 361, 281, 475, 1004, 669, 1049, 456, 315, 2335, 908, 672, 1522, 1723, 1350, 132, 145, 180, 141, 127, 570, 1001, 463, 1484, 1835, 1244, 1022, 1004, 1456, 538, 2173, 210, 564, 558, 407, 1751, 1050, 2284, 697, 364, 2070, 1000, 582, 1349, 1351, 879, 932, 930, 882, 129, 218, 451, 485, 1393, 176, 1920, 257, 962, 1809, 556, 1353, 998, 691, 215, 279, 459, 976, 1011, 1267, 889, 729, 1149, 1279, 1095, 2253, 1870, 1556, 1498, 1650, 952, 160, 540, 1569, 966, 306, 234, 692, 213, 925, 1202, 1566, 222, 596, 994, 1269, 131, 138, 133, 1855, 224, 48, 1783, 2834, 490, 968, 2645, 67, 1570, 1100, 2249, 1352, 1869, 638, 1447, 631, 637, 2151, 2601, 529, 493, 534, 1326, 2710, 491, 2110, 891, 867, 2745, 31, 206, 2196, 751, 2293, 1890, 561, 1822, 1880, 825, 209, 1461, 2707, 2709, 579, 1634, 1077, 1875, 498, 462, 677, 1948, 1043, 142, 280, 159, 1373, 169, 1949, 2922, 535, 2252, 386, 158, 922, 185, 184, 1154, 489, 1826, 466, 671, 978, 1499, 1708, 1710, 217, 197, 227, 195, 194, 402, 1483, 967, 559, 1069, 1032, 1068, 973, 454, 918, 1705, 821, 914, 698, 1387, 1988, 854, 1051, 675, 741, 768, 910, 666, 1889, 1983, 1845, 1980, 1568, 550, 547, 416, 1168, 428, 394, 1828, 1446, 901, 636, 1368, 426, 1035, 1995, 1333, 684, 1457, 1514, 190, 842, 840, 625, 1630, 166, 346, 2615, 1156, 632, 1633, 71, 1567, 2407, 2422, 1395, 1428, 382, 2071, 121, 874, 549, 229, 228, 333, 372, 151, 695, 371, 911, 1619, 1030, 1155, 717, 265, 1343, 1439, 1600, 878, 1572, 663, 231, 742, 905, 758, 1039, 942, 763, 1056, 2347, 1271, 1363, 2317, 2139, 2220, 760, 2322, 2589, 1843, 1193, 1873, 1915, 1280, 1814, 1830, 1255, 546, 36, 816, 575, 149, 2818, 713, 1583, 659, 660, 183, 2273, 1709, 1718, 1928, 2194, 1914, 770, 1687, 935, 49, 2545, 2958, 801, 2048, 856, 335, 2418, 824, 277, 1362, 884, 883, 1400, 800, 826, 1462, 767, 1021, 1235, 1329, 2314, 1416, 2475, 2021, 1295, 1844, 2155, 2708, 1810, 1635, 1636, 10, 2178, 2002, 2758, 1726, 2421, 588, 616, 748, 658, 505, 524, 400, 232, 777, 1332, 2233, 443, 972, 370, 1911, 413, 2659, 2172, 2663, 2480, 2093, 2608, 480, 2350, 788, 870, 235, 2778, 2352, 2204, 2205, 2927, 2701, 433, 2098, 1786, 2568, 2924, 1165, 410, 1195, 1955, 1785, 244, 2482, 438, 2797, 1321, 1877, 792, 32, 1559, 1601, 2671, 2897, 460, 1571, 1551, 168, 178, 1604, 812, 1287, 35, 1979, 1247, 1857, 730, 2489, 511, 1061, 964, 187, 302, 2578, 862, 287, 1006, 2572, 545, 997, 1242, 830, 1682, 780, 1059, 1060, 2427, 91, 1325, 360, 1173, 247, 182, 2839, 188, 2859, 1314, 504, 2915, 1157, 1861, 2538, 2090, 193, 1831, 352, 852, 893, 611, 2547, 79, 1199, 2887, 2594, 1924, 753, 1603, 2850, 1864, 1821, 412, 551, 665, 2025, 266, 2107, 170, 171, 790, 1558, 1621, 835, 1540, 1120, 2532, 2212, 1679, 2587, 2877, 2086, 2814, 1789, 2364, 1688, 963, 157, 1878, 1866, 322, 1562, 937, 527, 1613, 1421, 1713, 1389, 2099, 980, 1669, 765, 986, 754, 1893, 2217, 881, 1378, 2372, 2373, 1112, 523, 2751, 2351, 2481, 2483, 278, 1328, 2095, 689, 135, 434, 766, 1695, 1694, 64, 1007, 1704, 432, 635, 501, 794, 200, 405, 423, 1148, 1675, 1293, 965, 2334, 1460, 1775, 348, 153, 1819, 1865, 396, 984, 1952, 1815, 642, 912, 738, 993, 1386, 850, 1925, 436, 827, 1186, 1730, 894, 506, 2066, 2676, 2953, 685, 1895, 2612, 617, 1458, 2079, 510, 1493, 1382, 330, 514, 233, 813, 621, 1529, 2918, 2901, 670, 2028, 2466, 2755, 687, 2041, 1218, 38, 1700, 1067, 1313, 1254, 536, 1205, 441, 2408, 2833, 2024, 201, 555, 853, 1178, 439, 612, 323, 248, 1151, 1152, 319, 309, 362, 2168, 578, 1079, 614, 126, 1082, 694, 1172, 2451, 1527, 2668, 2921, 264, 77, 2759, 2821, 2874, 2810, 2187, 2379, 2152, 2912, 2911, 1347, 589, 718, 1046, 430, 388, 2609, 2463, 725, 2478, 2570, 2618, 2621, 327, 2255, 1719, 2658, 803, 2374, 2820, 2555, 1437, 2362, 338, 773, 2605, 2700, 2258, 1008, 728, 469, 775, 1516, 1578, 1579, 1947, 2400, 367, 1702, 2713, 1881, 2455, 2320, 2690, 2527, 2222, 1812, 2873, 2779, 2403, 2404, 2336, 2019, 1686, 1632, 2513, 2425, 2424, 2889, 2673, 2732, 181, 221, 374, 164, 112, 2929, 939, 782, 2328, 2824, 442, 1391, 2126, 562, 1953, 2764, 1070, 1781, 2867, 1089, 2383, 119, 2000, 492, 411, 1693, 899, 1797, 2765, 198, 640, 863, 1863, 2939, 2500, 1066, 2302, 23, 1587, 1128, 2132, 2112, 783, 381, 1018, 1113, 1734, 2562, 1994, 1769, 341, 1813, 290, 2259, 810, 1418, 795, 1545, 2344, 328, 2262, 1505, 933, 465, 955, 1940, 2838, 1506, 2702, 214, 99, 1364, 1219, 1285, 776, 2559, 1766, 1354, 1699, 2306, 2304, 2305, 2461, 1586, 2417, 2245, 607, 1959, 2823, 2954, 2625, 2774, 2115, 2140, 2298, 1449, 2569, 711, 2089, 2827, 192, 2672, 2001, 1776, 1932, 2085, 602, 472, 954, 1125, 115, 600, 1317, 2798, 2237, 1459, 2195, 1894, 2456, 414, 1337, 1433, 1515, 2292, 1612, 2614, 249, 2038, 1597, 2391, 2311, 2087, 1471, 2706, 1294, 2045, 2501, 1848, 2553, 1477, 2788, 2721, 2511, 2720, 2697, 2698, 37, 2177, 2837, 270, 1605, 1616, 1141, 1231, 609, 1610, 1618, 1417, 1479, 1626, 544, 970, 1582, 1092, 1617, 921, 1404, 2426, 1525,

1399, 1608, 81, 2059, 2603, 297, 944, 1743, 212, 855, 2891, 628, 2677, 2790, 701, 2825, 114, 165, 2623, 574, 295, 745, 985, 2153, 1210, 199, 1419, 1488, 1487, 13, 219, 676, 1584, 1071, 1075, 1063, 1040, 444, 2105, 230, 1907, 2617, 2430, 2675, 123, 1207, 1307, 1308, 87, 1517, 2145, 724, 1735, 2246, 502, 1038, 1228, 2250, 389, 799, 585, 651, 2934, 2952, 2666, 2639, 733, 1180, 1369, 1383, 661, 2135, 2133, 54, 857, 2951, 2033, 1411, 1717, 2714, 2444, 1181, 1029, 1384, 2248, 29, 2324, 1898, 1042, 2355, 1388, 875, 714, 2534, 2460, 321, 1027, 1622, 2945, 2340, 2121, 2416, 1576, 2433, 1580, 2826, 1047, 1902, 1577, 2215, 1301, 843, 712, 2491, 286, 820, 2575, 1065, 1623, 1624, 1425, 2084, 2218, 1772, 1315, 2043, 931, 2602, 1117, 1724, 1534, 2388, 2484, 2438, 2522, 2157, 1300, 2197, 2319, 2097, 2012, 2851, 838, 1511, 2312, 2747, 837, 708, 604, 603, 2081, 2646, 2111, 1341, 2016, 2186, 2034, 1357, 1520, 2415, 2576, 1422, 2361, 2470, 1887, 2243, 2479, 1489, 1166, 2734, 1127, 2345, 2849, 1832, 2368, 507, 508, 1728, 1490, 2113, 2655, 1163, 2473, 2349, 2528, 1588, 2723, 2318, 1107, 2091, 2327, 2332, 988, 2221, 1316, 1732, 2719, 2669, 915, 1662, 2792, 2763, 948, 2649, 2940, 2858, 186, 1970, 1496, 1026, 1973, 2487, 2229, 1252, 2515, 2242, 1324, 2063, 2741, 487, 2624, 2591, 2213, 1900, 1753, 2296, 2910, 1376, 2051, 2736, 1805, 2619, 2616, 2120, 1745, 2183, 2560, 2518, 2129, 2767, 1410, 2216, 876, 2535, 2626, 1747, 2339, 2036, 2100, 1431, 2771, 2044, 2405, 1647, 736, 737, 735, 2631, 2680, 2643, 1470, 2804, 2271, 1537, 2784, 2459, 2832, 2892, 2193, 2803, 1497, 2227, 1581, 1208, 2130, 2712, 2777, 2477, 2476, 2661, 1987, 1892, 2860, 2018, 2127, 2223, 1194, 2656, 2064, 1760, 2780, 1298, 1564, 1589, 2279, 2822, 2188, 2881, 2042, 2556, 1806, 2366, 1055, 2367, 2627, 2696, 1474, 1096, 2387, 2536, 1336, 2896, 2685, 2359, 2363, 2565, 2516, 1561, 2717, 2032, 1057, 2125, 2863, 2464, 2931, 1770, 1048, 848, 2072, 2845, 1885, 2137, 2201, 2744, 1167, 2521, 1512, 1777, 2644, 2369, 2432, 2358, 2693, 2542, 2147, 2031, 1531, 2816, 2210, 2566, 2396, 1106, 1767, 1121, 1941, 2159, 2287, 2323, 2756, 1790, 2783, 2162, 1377, 1681, 1780, 2812, 1289, 2894, 1906, 2705, 1936, 2517, 2660, 2504, 2592, 2505, 2166, 2441, 1131, 2942, 2865, 2428, 2040, 2600, 2094, 1969, 2571, 1974, 2389, 2552, 2300, 2131, 2411, 2882, 1804, 1674, 1245, 2950, 2886, 2219, 1867, 2684, 1711, 2439, 2254, 1696, 2947, 2795, 2557, 2730, 2512, 2138, 2393, 1536, 2257, 1541, 1240, 1939, 1402, 815, 1990, 2757, 2793, 1138, 1801, 2167, 2392, 1229, 2442, 2728, 1903, 2265, 2836, 2234, 1882, 2285, 2880, 1803, 2796, 2397, 2114, 2297, 2856, 1916, 2068, 2738, 2588, 2737, 1998, 1764, 831, 1217, 2436, 936, 2613, 2458, 2346, 2409, 1778, 2802, 2904, 2567, 2465, 2775, 2670, 1455, 1921, 2488, 1468, 1871, 1091, 2161, 2468, 2075, 2182, 2715, 2165, 2333, 2735, 2023, 1360, 2228, 1908, 1196, 1752, 1478, 2509, 2370, 1427, 2214, 2731, 2303, 1962, 2523, 2184, 2628, 2027, 2175, 2956, 2606, 2749, 1250, 1942, 2868, 2941, 2888, 1899, 2648, 2069, 2762, 2794, 2633, 2283, 2454, 1862, 1574, 2301, 2857, 2146, 2117, 1929, 2092, 2208, 2679, 1876, 907, 2634, 1664, 2691, 2704, 2378, 2847, 1599, 2148, 2930, 2854, 2492, 1765, 1739, 2742, 2651, 1725, 2607, 2022, 2203, 1290, 2586, 2776, 2899, 2142, 2549, 2913, 503, 162, 2457, 2202, 2440, 2574, 2748, 1935, 2185, 1415, 1683, 1912, 2688, 2687, 2872, 2288, 2141, 2640, 1542, 2593, 2486, 1991, 2264, 1528, 1744, 2164, 2326, 2844, 2835, 2325, 1594, 2469, 2420, 2419, 1888, 2453, 2914, 2309, 1976, 2497, 1192, 2564, 2548, 2584, 2291, 1905, 2870, 2650, 2282, 2841, 2154, 1742, 2251, 2329, 2321, 2629, 1185, 1796, 2394, 943, 1793, 2903, 2902, 2014, 2343, 2013, 2498, 1678, 796, 1161, 2381, 2909, 2773, 1504, 2109, 2128, 2307, 2499, 2786, 1090, 2785, 2526, 2733, 2096, 1910, 2923, 2769, 2878, 1841, 1643, 2052, 1944, 2937, 2406, 1727, 2750, 2337, 1465, 2382, 2313, 2209, 2768, 2754, 1923, 2766, 1216, 2596, 1642, 1573, 2462, 1575, 2160, 1761, 2540, 1680, 755, 1665, 715, 2448, 1530, 2494, 2530, 1965, 2554, 2597, 1904, 2599, 2782, 2781, 2116, 1552, 1469, 2524, 1019, 2611, 2118, 2365, 1473, 1544, 1253, 1808, 1543, 1963, 2360, 2943, 2531, 1153, 2864, 2925, 1795, 2852, 2412, 1933, 2067, 1762, 1738, 2561, 1958, 1355, 1593, 2341, 1223, 2260, 1158, 2722, 1661, 1849, 2119, 1663, 1521, 2800, 1847, 2449, 2829, 2395, 2595, 2746, 1375, 1464, 2270, 1992, 2230, 2232, 2580, 999, 1518, 2740, 1997, 2225, 2683, 2136, 2871, 2399, 1981, 2919, 1773, 1659, 1401, 2884, 1409, 2801, 2866, 1276, 2890, 2686, 2272, 2437, 2739, 2474, 2278, 2062, 2808, 2268, 1510, 2156, 2908, 2817, 2263, 2543, 2948, 2653, 2875, 1961, 2520, 2003, 1943, 1251, 2525, 2452, 2401, 2932, 2787, 1502, 2828, 2144, 2848, 2331, 2011, 1653, 2689, 1954, 1763, 1697, 1162, 1398, 2582, 1746, 2289, 2508, 2630, 2269, 2861, 1671, 1670, 2226, 2308, 1227, 2431, 2678, 2544, 2299, 624, 2716, 2944, 2563, 1668, 2807, 337, 2869, 1443, 2471, 690, 1097, 797, 747, 845, 844, 846, 573, 1720, 1258, 802, 104, 1555, 1292, 817, 778, 764, 369, 2667, 1302, 2078, 2380, 150, 941, 380, 2830, 1044, 1451, 320, 2102, 353, 1159, 1025, 762, 1638, 839, 1645, 814, 1088, 63, 116, 1312, 2207, 1403, 484, 2632, 1134, 1135, 1359, 1802, 2485, 1342, 2938, 1535, 2900, 2529, 1146, 639, 1703, 179, 2077, 398, 2495, 1539, 2390, 1206, 1986, 1438, 1087, 1086, 851, 2770, 1937, 9, 2831, 105, 111, 2076, 951, 2035, 2256, 2519, 1816, 1817, 652, 467, 2169, 1945, 1818, 2104, 926, 709, 440, 2398, 823, 1532, 822, 2445, 2163, 1184, 2726, 392, 2037, 1442, 1596, 568, 2410, 1972, 2772, 2450, 1123, 1124, 2809, 101, 2353, 1879, 1977, 2692, 107, 124, 225, 1660, 1891, 1968, 1654, 113, 832, 415, 727, 387, 2108, 2743, 1851, 608, 1554, 576, 577, 30, 1105, 1346, 1309, 716, 14, 726, 723, 722, 2585, 1361, 613, 1689, 1792, 191, 1209, 1500, 299, 298, 300, 1221, 1884, 1825, 2546, 2503, 2681, 2853, 2236, 1913, 2238, 1064, 1320, 2895, 2840, 2928, 1960, 2472, 2879, 2015, 1595, 1768, 1901, 1692, 662, 650, 175, 2357, 2356, 1073, 1839, 2274, 1602, 1390, 1372, 702, 834, 606, 1045, 2101, 1037, 557, 593, 594, 301, 732, 98, 156, 1548, 2598, 1426, 919, 2620, 2467, 1265, 1268, 2622, 43, 2496, 2082, 1547, 1546, 2143, 395, 1432, 2294, 679, 483, 1858, 1304, 1429, 1101, 2898, 1553, 1971, 1926, 641, 1145, 2957, 2694, 2695, 1791, 975, 2006, 2558, 41, 1757, 40, 163, 1367, 27, 2907, 1356, 1358, 2514, 615, 2049, 2198, 2682, 2004, 2936, 2267, 1886, 2386, 2799, 1627, 2413, 2122, 1164, 2423, 1503, 2338, 2158, 2080, 2657, 1838, 2354, 2429, 2811, 791, 969, 1784, 1874, 2149, 1585, 2946, 1615, 1246, 2935, 1934, 2046, 2718, 2577, 1868, 2893, 1896, 2434, 2330, 1104, 868, 455, 1712, 259, 1982, 314, 355, 847, 269, 643, 705, 34, 860, 1118, 1183, 756, 2189, 1918, 1625, 623, 1715, 2150, 2029, 703, 1684, 2074, 296, 226, 1788, 2073, 704, 429, 707, 1685, 1731, 1799, 458, 311, 2170, 291, 1102, 1557, 974, 2171, 1170, 2026, 1740, 597, 1241, 2190, 1297, 103, 120, 512, 482, 693, 599, 947, 1996, 673, 2065, 74, 2949, 633, 648, 657, 2199, 1550, 1453, 276, 403, 517, 1975, 1714, 245, 649, 334, 898, 285, 605, 427, 752, 622, 1257, 354, 653, 366;

Product Description:

Allura Xper FD20 Biplane; Model Numbers: (1) 722008, (2) 722013; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

501 units (212 US, 289 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0006-2026

Code Information:

Model Numbers: (1) 722008, (2) 722013; UDI-DI: (1) N/A, (2) 00884838059061; Serial Numbers: (1) 491, 489, 360, 325, 142, 125, 312, 319, 82, 192, 244, 453, 306, 116, 124, 18270, 524, 106, 224, 463, 197, 264, 100, 294, 246, 357, 212, 287, 154, 459, 71, 112, 472, 483, 465, 419, 38, 454, 2470, 441, 460, 369, 407, 102, 231, 94, 437, 420, 1178, 108, 270, 442, 521, 372, 113, 34, 187, 254, 365, 390, 413, 52, 18, 19, 239, 288, 424, 279, 115, 481, 141, 304, 267, 361, 415, 178, 245, 445, 23, 296, 487, 349, 456, 470, 386, 69, 1236, 37, 59, 455, 217, 446, 272, 160, 406, 350, 167, 247, 416, 435, 48, 447, 179, 410, 196, 458, 525, 480, 476, 370, 327, 169, 121, 259, 266, 128, 186, 290, 385, 253, 450, 359, 391, 283, 323, 205, 425, 346, 388, 376, 150, 394, 123, 339, 513, 337, 93, 268, 200, 87, 110, 46, 542, 530, 334, 122, 468, 250, 482, 63, 305, 213, 546, 273, 433, 475, 398, 31, (2) 505, 313, 217, 492, 34, 410, 153, 360, 290, 74, 83, 241, 404, 126, 244, 106, 383, 346, 461, 307, 1, 442, 435, 293, 253, 297, 46, 289, 638, 342, 69, 267, 402, 214, 86, 603, 149, 424, 140, 254, 255, 266, 475, 519, 518, 303, 194, 115, 150, 129, 496, 599, 441, 124, 151, 179, 550, 377, 575, 631, 562, 178, 330, 309, 601, 327, 308, 264, 78, 268, 141, 175, 357, 85, 40, 216, 637, 422, 174, 109, 72, 218, 228, 511, 389, 152, 479, 561, 262, 626, 61, 164, 497, 170, 379, 84, 125, 564, 573, 426, 556, 42, 100, 495, 500, 96, 515, 105, 428, 427, 531, 375, 316, 278, 347, 462, 249, 205, 246, 43, 639, 304, 634, 147, 15, 567, 168, 607, 283, 52, 171, 66, 36, 585, 271, 117, 443, 107, 343, 223, 385, 165, 453, 370, 22, 367, 108, 352, 291, 71, 259, 455, 468, 368, 239, 315, 325, 532, 598, 440, 172, 193, 301, 415, 540, 62, 299, 184, 185, 187, 188, 437, 189, 183, 186, 190, 413, 191, 560, 490, 300, 295, 81, 448, 444, 400, 632, 110, 111, 624, 65, 633, 630, 361, 549, 417, 449, 506, 177, 629, 48, 476, 527, 276, 247, 156, 499, 50, 167, 132, 302, 618, 608, 265, 70, 457, 547, 312, 321, 366, 390, 544, 236, 157, 243, 144, 525, 238, 570, 161, 349, 359, 454, 613, 623, 222, 335, 445, 538, 416, 628, 619, 47, 206, 620, 384, 526, 332, 358, 509, 470, 378, 296, 227, 31, 58, 589, 616, 447, 530, 232, 324, 311, 176, 181, 554, 134, 163, 104, 403, 478, 459, 17, 2266, 528, 318, 29, 28, 237, 559, 372, 256, 374, 487, 405, 380, 434, 130, 473, 551, 557, 294, 412, 128, 388, 207, 258, 429, 95, 411, 353, 542, 533, 622, 182, 574, 139, 137, 250, 563, 502, 450, 436, 406, 524, 354, 510, 395, 458, 261, 503, 348, 595, 586, 535, 569, 425, 334, 344, 355, 465, 345, 501, 522, 64, 396, 408, 208, 555, 394, 57, 493, 201;

Product Description:

Allura Xper FD20 Biplane OR Table; Model Numbers: (1) 722020, (2) 722025; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

4 units (2 US, 2 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0007-2026

Code Information:

Model Numbers: (1) 722020, (2) 722025; UDI-DI: (1) N/A, (2) 00884838059108; Serial Numbers: (1) 4, (2) 2, 3, 6;

Product Description:

Allura Xper FD20 OR Table; Model Numbers: (1) 722015, (2) 722023, (3) 722035; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

298 units (72 US, 226 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0008-2026

Code Information:

Model Numbers: (1) 722015, (2) 722023, (3) 722035; UDI-DI: (1) N/A, (2) 00884838059085, (3) 00884838054240; Serial Numbers: (1) 12, 2, 16, 8, 23, 3, 13, (2) 27, 116, 12, 175, 98, 35, 72, 142, 179, 46, 64, 110, 124, 66, 117, 109, 42, 138, 83, 82, 127, 75, 118, 41, 146, 33, 165, 121, 3, 169, 101, 103, 129, 10, 105, 90, 107, 100, 47, 159, 137, 119, 164, 70, 95, 177, 2, 158, 86, 34, 132, 9, 108, 31, 112, 173, 114, 170, 172, 4, 14, 85, 13, 88, 25, 67, 94, 87, 57, 125, 73, 106, 16, 96, 58, 99, 38, 141, 32, 84, 68, 134, 79, 52, 56, 69, 37, 21, 53, 123, 157, 102, 126, 145, 144, 15, 135, 152, 149, 60, 150, (3) 243, 123, 38, 85, 101, 117, 212, 21, 172, 183, 252, 236, 88, 57, 143, 125, 145, 161, 244, 119, 100, 165, 47, 126, 127, 52, 247, 131, 124, 89, 169, 46, 245, 246, 242, 74, 30, 192, 60, 59, 196, 216, 187, 121, 34, 222, 72, 111, 128, 227, 174, 144, 28, 84, 130, 263, 132, 25, 98, 134, 35, 226, 190, 3, 6, 1, 249, 109, 251, 232, 207, 158, 160, 237, 163, 79, 248, 253, 94, 80, 250, 154, 69, 97, 148, 170, 195, 26, 122, 96, 107, 142, 58, 166, 235, 230, 265, 83, 53, 32, 164, 56, 40, 11, 10, 62, 221, 257, 255, 229, 256, 254, 261, 260, 238, 113, 258, 241, 188, 259, 267, 167, 204, 43, 33, 37, 104, 233, 114, 108, 153, 70, 65, 191, 77, 110, 225, 75, 76, 193, 185, 186, 129, 103, 71, 92, 151, 201, 208, 149, 205, 19, 50, 51, 61, 211, 99, 12, 15, 198, 82, 105, 136, 194, 23, 200, 116, 48, 13, 106, 95, 206, 168, 203, 146, 81, 156, 45, 173, 49, 64, 171, 184, 102, 17, 215, 29, 231, 16, 202;

Product Description:

Allura Xper FD20/10; Model Numbers: 722029; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

87 units (21 US, 66 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0009-2026

Code Information:

Model Numbers: 722029; UDI-DI: 00884838054219; Serial Numbers: 71, 91, 7, 94, 62, 88, 36, 97, 21, 100, 30, 63, 60, 129, 95, 126, 110, 56, 55, 57, 31, 26, 49, 114, 128, 108, 103, 107, 81, 43, 52, 119, 118, 80, 78, 47, 106, 123, 96, 122, 14, 127, 101, 116, 102, 115, 19, 109, 120, 92, 69, 27, 46, 93, 51, 50, 124, 87, 20, 29, 32, 104, 34, 45, 59, 79, 24, 70, 39, 66, 82, 75, 40, 33, 23, 25, 85, 37, 44, 58, 38, 61, 98, 53, 89, 35, 48;

Product Description:

Allura Xper FD20/15; Model Numbers: 722058; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

300 units (69 US, 231 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0010-2026

Code Information:

Model Numbers: 722058; UDI-DI: 00884838059115; Serial Numbers: 337, 178, 249, 22, 202, 279, 254, 285, 71, 186, 82, 85, 162, 138, 24, 365, 203, 167, 146, 168, 304, 172, 200, 123, 129, 149, 259, 4, 197, 134, 38, 290, 171, 56, 264, 238, 199, 61, 156, 99, 65, 59, 109, 100, 305, 319, 215, 278, 124, 196, 405, 325, 265, 378, 277, 274, 94, 182, 366, 340, 190, 219, 373, 239, 23, 205, 257, 212, 111, 110, 399, 72, 332, 92, 142, 67, 106, 335, 360, 415, 11, 114, 151, 93, 232, 395, 292, 380, 183, 349, 261, 15, 375, 161, 78, 368, 9, 372, 288, 252, 320, 213, 293, 389, 169, 97, 336, 25, 143, 133, 192, 49, 412, 201, 89, 66, 163, 170, 77, 273, 35, 222, 229, 248, 334, 384, 40, 268, 240, 258, 289, 269, 226, 244, 48, 141, 391, 241, 164, 381, 281, 154, 246, 127, 315, 256, 233, 348, 204, 396, 7, 185, 95, 131, 377, 60, 68, 206, 101, 150, 333, 84, 398, 313, 3, 39, 344, 376, 382, 370, 387, 419, 394, 407, 413, 392, 411, 358, 409, 385, 416, 367, 379, 331, 418, 356, 421, 369, 420, 397, 357, 408, 393, 388, 108, 211, 126, 125, 301, 12, 30, 355, 354, 159, 139, 128, 81, 58, 96, 343, 177, 115, 19, 18, 311, 220, 386, 291, 327, 214, 145, 223, 137, 136, 119, 103, 404, 27, 32, 350, 400, 422, 423, 347, 73, 43, 55, 194, 189, 237, 230, 221, 247, 116, 242, 29, 37, 276, 345, 166, 179, 53, 87, 303, 90, 112, 245, 148, 41, 234, 208, 117, 193, 76, 236, 266, 130, 235, 251, 86, 31, 195, 144, 330, 63, 295, 70, 187, 79, 10, 33, 75, 361, 153, 284, 102, 21, 64, 45, 36, 181, 351, 272, 210, 243, 20, 98, 34, 16, 218;

Product Description:

Allura Xper FD20/15 OR Table; Model Numbers: 722059; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

8 units (2 US, 6 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0011-2026

Code Information:

Model Numbers: 722059; UDI-DI: 00884838059122; Serial Numbers: 7, 33, 35, 40, 38, 41, 37, 2;

Product Description:

Allura Xper FD20/20; Model Numbers: 722038; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

115 units (34 US, 81 OUS)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0012-2026

Code Information:

Model Numbers: 722038; UDI-DI: 00884838054226; Serial Numbers: 39, 63, 42, 55, 67, 99, 60, 71, 141, 115, 7, 78, 108, 106, 167, 118, 130, 49, 119, 126, 173, 38, 37, 48, 62, 35, 137, 120, 157, 41, 131, 96, 70, 46, 102, 169, 11, 89, 117, 40, 105, 113, 110, 5, 134, 88, 64, 112, 143, 94, 109, 73, 133, 166, 147, 31, 3, 127, 92, 135, 32, 69, 121, 123, 98, 129, 79, 14, 148, 153, 164, 111, 160, 171, 172, 159, 155, 144, 163, 152, 168, 161, 122, 158, 156, 138, 162, 132, 95, 116, 45, 9, 150, 146, 90, 27, 91, 154, 104, 124, 30, 136, 72, 93, 66, 140, 75, 50, 68, 58, 54, 47, 36, 28, 29;

Product Description:

Allura Xper FD20/20 OR Table; Model Numbers: 722039; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

5 units (OUS only)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0013-2026

Code Information:

Model Numbers: 722039; UDI-DI: 00884838054271; Serial Numbers: 2, 4, 5, 6, 8;

Product Description:

Allura Xper CV20; Model Numbers: 722031; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

53 units (OUS only)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0014-2026

Code Information:

Model Numbers: 722031; UDI-DI: N/A; Serial Numbers: 29, 77, 23, 18, 45, 90, 164, 30, 76, 32, 75, 33, 40, 13, 113, 111, 46, 25, 130, 26, 61, 78, 42, 167, 49, 64, 41, 71, 20, 17, 63, 39, 9, 55, 36, 73, 48, 53, 31, 96, 28, 154, 166, 15, 84, 47, 35, 24, 148, 50, 79, 62, 66;

Product Description:

Cardio Vascular-Allura Centron; Model Numbers: 722400; Associated 510(k)s: K102005, K130638, K130842, K133292, K141979, K162859, K161563;

Product Quantity:

313 units (OUS only)

Reason for Recall:

The BIOS battery may deplete faster than initially anticipated during the design phase. When the battery is depleted, the start-up process of the system will be halted, and the system will not start. No user messages are shown before the battery is low on power or depleted.

Recall Number:

Z-0015-2026

Code Information:

Model Numbers: 722400; UDI-DI: N/A; Serial Numbers: 282, 91, 206, 472, 187, 486, 480, 71, 322, 280, 506, 429, 413, 497, 507, 502, 222, 103, 53, 510, 43, 439, 489, 55, 176, 76, 364, 209, 382, 178, 243, 16, 74, 158, 113, 303, 4, 101, 131, 334, 93, 156, 347, 552, 482, 414, 112, 60, 42, 82, 407, 338, 33, 184, 153, 189, 424, 201, 245, 122, 273, 228, 79, 307, 476, 57, 196, 533, 217, 225, 314, 432, 81, 458, 491, 361, 2, 308, 89, 321, 525, 519, 511, 148, 100, 258, 63, 62, 22, 130, 221, 135, 159, 352, 49, 143, 31, 254, 363, 434, 223, 174, 137, 257, 232, 269, 161, 471, 470, 155, 150, 136, 440, 545, 279, 6, 149, 346, 317, 369, 119, 495, 547, 348, 110, 86, 380, 61, 341, 438, 437, 513, 459, 379, 355, 64, 485, 503, 290, 186, 168, 400, 498, 278, 283, 512, 487, 236, 455, 276, 173, 448, 92, 83, 251, 139, 160, 109, 522, 319, 381, 68, 291, 199, 67, 233, 539, 504, 190, 535, 116, 479, 423, 473, 296, 285, 449, 329, 508, 292, 398, 230, 548, 523, 299, 494, 286, 300, 488, 541, 543, 427, 447, 542, 262, 536, 469, 430, 529, 554, 555, 546, 375, 534, 521, 419, 344, 433, 463, 443, 483, 357, 374, 277, 530, 337, 549, 441, 320, 445, 287, 556, 446, 527, 526, 532, 418, 51, 544, 444, 69, 23, 250, 272, 252, 106, 224, 37, 90, 267, 229, 202, 393, 218, 550, 524, 540, 284, 557, 316, 121, 77, 147, 353, 553, 376, 132, 133, 389, 496, 368, 454, 315, 34, 240, 97, 531, 28, 9, 297, 538, 197, 415, 21, 151, 227, 528, 259, 256, 152, 330, 264, 193, 386, 44, 188, 220, 462, 356, 551, 396, 460, 249, 412, 157, 244, 78, 395, 212, 478, 499, 515, 271, 306, 435, 501, 518, 140, 226, 114, 360, 370, 477;

Class II Devices Event

Event ID:

97507

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/18/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/02/2025

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Aesculap AG
Am Aesculap-Platz 1
Tuttlingen
Germany

Distribution Pattern:

US distribution to Missouri. OUS International distribution to Norway, Portugal, France, Great Britain, Czech Republic, Germany, Turkey, Brazil, Japan, Chile, China, Hong Kong, Indonesia, India, Iran, Mexico, Malaysia, Philippines, Saudi Arabia, Thailand.

Associated Products

Product Description:

AESCULAP ELAN 4 FIXED DURAGUARD STANDARD. Model Number: GB942R.

Product Quantity:

1 unit

Reason for Recall:

Mislabeled. The ELAN 4 FIXED DURAGUARD STANDARD was labeled as "Long" and the ELAN 4 FIXED DURAGUARD LONG was labeled as "Standard."

Recall Number:

Z-0026-2026

Code Information:

Model Number: BG942R, UDI-DI Number: 04046963805777. Serial Number: 8157.

Product Description:

AESCULAP ELAN 4 FIXED DURAGUARD LONG. Model Number: GB943R.

Product Quantity:

3 units

Reason for Recall:

Mislabeled. The ELAN 4 FIXED DURAGUARD STANDARD was labeled as "Long" and the ELAN 4 FIXED DURAGUARD LONG was labeled as "Standard."

Recall Number:

Z-0027-2026

Code Information:

Model Number: GB943R, UDI-DI Number: 04046963805784. Serial Numbers: 4519, 4528, 4533.

Class II Devices Event

Event ID:

97509

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

09/09/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/30/2025

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

MedicalCommunications GmbH
Max-Jarecki-Str. 8
Heidelberg
Germany

Distribution Pattern:

US Nationwide distribution.

Associated Products

Product Description:

Ashvins variant HEYEX 2 / HEYEX PACS. Software Version: Version 2.6.0 (Build 2088) to 2.6.8 (Build 2220). Device Type: Software (Medical Image Management, Picture Archiving and Communication System)

Product Quantity:

474 units

Reason for Recall:

Potential that the measured value may be smaller than the actual area.

Recall Number:

Z-2673-2025

Code Information:

Model Name: Ashvins variant HEYEX 2 / HEYEX PACS. UDI-DI: 4260648620046. Software Version: 2.6.0 (Build 2088) to 2.6.8 (Build 2220).

Class II Devices Event

Event ID:

97518

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

09/02/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/02/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

LeMaitre Vascular, Inc.
206 N Center Dr
North Brunswick, NJ 08902-4246
United States

Distribution Pattern:

US Nationwide distribution in the states of CA, CT, FL, GA, IL, MA, MS, NC, ND, NJ, NY, OK, PA, TN, TX, VA, WA.

Associated Products

Product Description:

Artegraft Collagen Vascular Grafts Model Numbers: (1) AG 616, (2) AG 630, (3) AG 636, (4) AG 640, (5) AG 645, (6) AG 715, (7) AG 730, (8) AG 735, (9) AG 740, (10) AG 745, (11) AG 750, (12) AG 830, (13) AG 840, (14) AG 1015, (15) AG 1030;

Product Quantity:

28 units

Reason for Recall:

The bovine carotid arteries used to produce the impacted grafts from affected lots were sourced using raw material from a supplier that had not been reviewed and approved by the appropriate regulatory authority.

Recall Number:

Z-0034-2026

Code Information:

Model Numbers: (1) AG 616, (2) AG 630, (3) AG 636, (4) AG 640, (5) AG 645, (6) AG 715, (7) AG 730, (8) AG 735, (9) AG 740, (10) AG 745, (11) AG 750, (12) AG 830, (13) AG 840, (14) AG 1015, (15) AG 1030; UDI-DIs: (1) 00316837000213, (2) 00316837000220, (3) 00316837000237, (4) 00316837000244, (5) 00316837000251, (6) 00316837000268, (7) 00316837000275, (8) 00316837000282, (9) 00316837000299, (10) 00316837000305, (11) 00316837000312, (12) 00316837000367, (13) 00316837000329, (14) 00316837000343, (15) 00316837000350; Serial Numbers: (1) 23DD203-019, 23DD203-046, (2) 23DD203-024, 23DD203-029, (3) 23DD203-045, (4) 23DD203-018, (5) 23DD203-004, (6) 23DD203-021, 23DD203-044, 23DD203-038, 23DD203-039, 23DD203-011, 23DD203-032, 23DD203-031, 23DD203-043, (7) 23DD203-040, 23DD203-030, 23DD203-037, (8) 23DD203-035, 23DD203-033, (9) 23DD203-034, (10) 23DD203-036, (11) 23DD203-022, 23DD203-023, (12) 23DD203-017, (13) 23DD203-027, (14) 23KK498-014, (15) 23DD203-026;

Class II Devices Event

Event ID:

97524

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/29/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/02/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Northeast Scientific Inc.
2142 Thomaston Ave
Waterbury, CT 06704-1013
United States

Distribution Pattern:

US Nationwide distribution to CA, FL, IL, KS, LA, MD, MI, MO, NC, NJ, NM, NV, NY, PA, TN, TX, VA.

Associated Products

Product Description:

NES Reprocessed 0.9mm OTW Turbo Elite Laser Atherectomy Catheter. Model Number: R-410-152. The NES Reprocessed Turbo-Elite Laser Atherectomy Catheter is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions.

Product Quantity:

561 units

Reason for Recall:

Potential for breaches in the sterile barrier packaging, compromising sterility assurance.

Recall Number:

Z-0018-2026

Code Information:

Model No R-410-152; UDI-DI 00850044399055; All Lot Numbers that are within their labeled shelf life with expiration dates prior to 29AUG2026

Product Description:

NES Reprocessed 1.4mm OTW Turbo Elite Laser Atherectomy Catheter. Model Number: R-414-151. The NES Reprocessed Turbo-Elite Laser Atherectomy Catheter is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. This model is not cleared for marketing in the US.

Product Quantity:

173 units

Reason for Recall:

Potential for breaches in the sterile barrier packaging, compromising sterility assurance.

Recall Number:

Z-0019-2026

Code Information:

Model No R-414-151; UDI-DI 00850044399116; All Lot Numbers that are within their labeled shelf life with expiration dates prior to 29AUG2026

Product Description:

NES Reprocessed 1.7mm OTW Turbo Elite Laser Atherectomy Catheter. Model Number: R-417-152. The NES Reprocessed Turbo-Elite Laser Atherectomy Catheter is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. This model is not cleared for marketing in the US.

Product Quantity:

165 units

Reason for Recall:

Potential for breaches in the sterile barrier packaging, compromising sterility assurance.

Recall Number:

Z-0020-2026

Code Information:

Model No R-417-152; UDI-DI 00850044399093; All Lot Numbers that are within their labeled shelf life with expiration dates prior to 29AUG2026

Product Description:

NES Reprocessed 2.0mm OTW Turbo Elite Laser Atherectomy Catheter. Model Number: R-420-006. The NES Reprocessed Turbo-Elite Laser Atherectomy Catheter is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. This model is not cleared for marketing in the US.

Product Quantity:

199 units

Reason for Recall:

Potential for breaches in the sterile barrier packaging, compromising sterility assurance.

Recall Number:

Z-0021-2026

Code Information:

Model No R-420-006; UDI-DI 00850044399079; All Lot Numbers that are within their labeled shelf life with expiration dates prior to 29AUG2026.

Product Description:

NES Reprocessed 0.9mm RX Turbo Elite Laser Atherectomy Catheter. Model/Catalog Number: R-410-154. The NES Reprocessed Turbo-Elite Laser Atherectomy Catheter is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. This model is not cleared for marketing in the US.

Product Quantity:

795 units

Reason for Recall:

Potential for breaches in the sterile barrier packaging, compromising sterility assurance.

Recall Number:

Z-0022-2026

Code Information:

Model No R-410-154; UDI-DI 00850044399062; All Lot Numbers that are within their labeled shelf life with expiration dates prior to 29AUG2026.

Product Description:

NES Reprocessed 1.4mm RX Turbo Elite Laser Atherectomy Catheter. Model Number: R-414-159. The NES Reprocessed Turbo-Elite Laser Atherectomy Catheter is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. This model is not cleared for marketing in the US.

Product Quantity:

1,019 units

Reason for Recall:

Potential for breaches in the sterile barrier packaging, compromising sterility assurance.

Recall Number:

Z-0023-2026

Code Information:

Model No R-414-159; UDI-DI 00850044399123; All Lot Numbers that are within their labeled shelf life with expiration dates prior to 29AUG2026.

Product Description:

NES Reprocessed 1.7mm RX Turbo Elite Laser Atherectomy Catheter. Model Number: R-417-156. The NES Reprocessed Turbo-Elite Laser

Atherectomy Catheter is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. This model is not cleared for marketing in the US.

Product Quantity:

616 units

Reason for Recall:

Potential for breaches in the sterile barrier packaging, compromising sterility assurance.

Recall Number:

Z-0024-2026

Code Information:

Model No R-417-156; UDI-DI 00850044399109; All Lot Numbers that are within their labeled shelf life with expiration dates prior to 29AUG2026.

Product Description:

NES Reprocessed 2.0mm RX Turbo Elite Laser Atherectomy Catheter. Model Number: R-420-159. The NES Reprocessed Turbo-Elite Laser Atherectomy Catheter is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. This model is not cleared for marketing in the US.

Product Quantity:

141 units

Reason for Recall:

Potential for breaches in the sterile barrier packaging, compromising sterility assurance.

Recall Number:

Z-0025-2026

Code Information:

Model No R-420-159; UDI-DI 00850044399086; All Lot Numbers that are within their labeled shelf life with expiration dates prior to 29AUG2026.

Class II Devices Event

Event ID:

97535

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/29/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/01/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Getinge Disinfection Ab
Ljungadalsgatan 11
Vaxjo
Sweden

Distribution Pattern:

Worldwide - US Nationwide distribution in the states of Colorado, Massachusetts, New Mexico, New Hampshire and the countries of Algeria, Australia, Belgium, Brazil, Canada, Chile, China, Colombia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hong Kong, Hungary, India, Iraq, Ireland, Israel, Italy, Japan, Kenya, Korea, Republic of, Kuwait, Lithuania, Mexico, Netherlands, New Zealand, Norway, Poland, Qatar, Romania, Saudi Arabia, Singapore, Spain, Sweden, Thailand, Turkey, United Arab Emirates, United Kingdom.

Associated Products

Product Description:

Getinge 88-Series Washer- Disinfector. Model Number: 88-5.

Product Quantity:

788 units

Reason for Recall:

Potential for device to overheat during operation if the circulation pressure calibration was not performed or had been performed incorrectly, and the

low-pressure alarm is not triggered.

Recall Number:

Z-0016-2026

Code Information:

Model Number: 88-5. UDI-DI Numbers: 07340153700109, 07340153700116. Software Version: GD 14080 Rev A. All Lot Numbers with electrical heating.

Class II Devices Event

Event ID:

97545

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/13/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/02/2025

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

CHANGE HEALTHCARE CANADA COMPANY
10711 Cambie Rd Suite 130
Richmond
Canada

Distribution Pattern:

Worldwide - US Nationwide distribution in the states of AR, WI, NJ, IN, AL, CA, WA, FL, MA, LA and the country of Canada.

Associated Products

Product Description:

Change Healthcare Radiology Solutions software version 14.2.2

Product Quantity:

12 programs

Reason for Recall:

Due to software issue, radiology reports may not be fully displayed when viewing.

Recall Number:

Z-0030-2026

Code Information:

Version 14.2.2/UDI: (01)17540262030068

Class II Devices Event

Event ID:

97553

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

07/30/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/01/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

S.I.N. Implant System Ltda
Rua Soldador Ocimar Guimaraes da Silva 421 Jardim Analia Franco

Sao Paulo
Brazil

Distribution Pattern:

US Nationwide distribution including in the states of TX, IL, KY, NC, TN, CO, CA, MO, MD, AL, FL, PA, UT, NE, ID, AZ, WA, OK, OR, NV, NJ, VA, NY, LA, CT, SD, SC, HI, KS, MA, MI, NM, OH, MT, WI, MN, ME.

Associated Products**Product Description:**

IMPLANT EPIKUT PLUS MT16 3,5X10,0MM, REF: ILM 3510N; IMPLANT EPIKUT PLUS MT16 3,8X11,5MM, REF: ILM 3511N; IMPLANT EPIKUT PLUS MT16 3,5X13,0MM, REF: ILM 3513N; IMPLANT EPIKUT PLUS MT16 3,5X15,0MM, REF: ILM 3515N; IMPLANT EPIKUT PLUS MT16 3,8X10,0MM, REF: ILM 3810N; IMPLANT CM16 3,8 X 11MM, REF: ILM 3811N; IMPLANT EPIKUT PLUS MT16 3,8X15,0MM, REF: ILM 3815N; IMPLANT EPIKUT PLUS MT16 4,0X10,0MM, REF: ILM 4010N; IMPLANT EPIKUT PLUS MT16 4,0X11,5MM, REF: ILM 4011N; IMPLANT EPIKUT PLUS MT16 4,0X13,0MM, REF: ILM 4013N; IMP EPIKUT PLUS LONG MT16 4,0X20,0MM, RES: ILM 4020N; IMPLANT EPIKUT PLUS MT16 4,0X8,5MM, RES: ILM 4085N; IMPLANT EPIKUT PLUS MT16 4,5X13,0MM, REF: ILM 4513N; IMPLANT EPIKUT PLUS MT16 4,5X15,0MM, REF: ILM 4515N; IMPLANT EPIKUT PLUS MT16 4,5X8,5MM, REF: ILM 4585N; IMPLANT EPIKUT PLUS MT16 5,0X10,0MM, REF: ILM 5010N; IMPLANT EPIKUT PLUS MT16 5,0X11,5MM, REF: ILM 5011N; IMPLANT EPIKUT PLUS MT16 4,5X10,0MM, REF: ILM 4510N; IMPLANT EPIKUT PLUS MT16 5,0X13,0MM, RES: ILM 5013N; IMPLANT EPIKUT PLUS MT16 5,0X15,0MM, REF: ILM 5015N; IMPLANT EPIKUT PLUS MT16 5,0X8,5MM, REF: ILM 5085N; IMP EPIKUT PLUS LONG MT16 4,0X18,0MM, REF: ILM 4018N; IMP EPIKUT PLUS LONG MT16 3,8X18,0MM, REF: ILM 3818N; IMPLANT EPIKUT PLUS MT16 4,5X11,5MM, REF: ILM 4511N; IMPLANT EPIKUT MT16 4,5X15,0MM, REF: ILM 4515; IMPLANT EPIKUT MT16 4,5X8,5MM, REF: ILM 4585; IMPLANT EPIKUT MT16 3,8X13,0MM, REF: ILM 3813; IMPLANT EPIKUT MT16 3,8X15,0MM, REF: ILM 3815; IMPLANT EPIKUT MT16 5,0X8,5MM, REF: ILM 5085; IMPLANT EPIKUT MT16 3,8X11,5MM, REF: ILM 3811; IMPLANT EPIKUT PLUS MT16 3,8X20,0MM, REF: ILM 3820N; IMPLANT EPIKUT PLUS MT16 4,5X18,0MM, REF: ILM 4518N; IMPLANT UNITITE MORSE COMPACT 6.0X7MM, REF: UCMC 6007N

Product Quantity:

4,367

Reason for Recall:

Dental implants were imported under temperature and storage conditions that do not comply with the instructions for use and product labeling so there may be packaging damage, which could compromise product quality and performance.

Recall Number:

Z-0017-2026

Code Information:

REF/UDI-DI/Lot(Expiration): ILM 3510N/7899995277558/X010469795(9/12/2026); ILM 3511N/7899995274342/X020477141(7/11/2027), X040490928(1/3/2028), X030483330(1/2/2028), X030482747(9/2/2027), X030482813(10/10/2027), W100457486(2/9/2027), X030482750(9/2/2027), W020415041(10/12/2026), X020477137(3/4/2027); ILM 3513N/7899995274335/W080447571(2/4/2028), X010469706(3/4/2028), X010471894(4/11/2028), W020415045(1/3/2028), X120531584(6/5/2028), X040490953(5/11/2028), Y010537386(6/12/2028); ILM 3515N/7899995280893/W020420816(6/12/2028), X030484303(10/2/2028), X010472646(9/12/2028), X010472644(8/10/2028), X120531182(10/5/2028); ILM 3810N/7899995274274/X120531775(10/5/2028); ILM 3811N/7899995274229/X010471364(10/12/2028), X080513064(12/2/2028), X100521415(12/2/2028), X120531368(2/2/2029), X070504152(11/5/2028), X020478981(10/12/2028), X120531376(3/2/2029), X020478983(11/2/202), X010471356(10/12/2028), X100523193(1/2/2029); ILM 3815N/7899995274168/X120531820(11/2/2029), X120531267(11/2/2029), X010473617(11/2/2029), V110406564(10/2/2029); ILM 4010N/7899995274137/Y020538716(14/12/2028), X120530744(14/12/2028), X120530266(14/01/2029); ILM 4011N/7899995274113/W100458406(15/12/2028), V110406330(15/12/2028), X120531292(16/05/2028), V110404633(15/12/2028), X090516009(16/01/2029); ILM 4013N/7899995274106/W080449448(16/08/2027), X120531842(17/12/2028), X120530728(17/12/2028), X120530726(17/01/2029), X120530724(16/12/2028), X120530730(17/12/2028), Y010537900(17/12/2028), W090454924(16/09/2028), X010473946(16/12/2028), W100458876(16/09/2028), X120531618(17/12/2028), X090517847(16/12/2028), X120530300(16/12/2028), X120531930(17/12/2028), X010472967(16/12/2028), X090517840(16/12/2028), X090515626(16/12/2028), X090515638(16/12/2028); ILM 4020N/7899995273499/X120530786(17/12/2028); ILM 4085N/7899995274144/X120531822(18/06/2028); ILM 4513N/7899995274038/X120530720(20/03/2028), Y010538078(22/09/2028), X120530722(20/10/2027), X120530849(22/06/2028); ILM 4515N/7899995274021/X120530902(23/10/2028), X120530716(23/07/2028), X120530340(23/03/2028); ILM 4585N/7899995274076/X110529195(25/11/2028), X110529193(25/10/2027); ILM 5010N/7899995273970/X040490644(26/12/2028), X040490886(26/12/2028); ILM 5011N/7899995273963/X120530851(26/12/2028); ILM 4510N/7899995274069/Y010537208(18/12/2028); ILM 5013N/7899995273956/X100522628(27/06/2027); ILM 5015N/7899995273932/X120530844(28/12/2028), X040490872(27/12/2028); ILM 5085N/7899995274007/X120530511(28/12/2028), X120530714(29/01/2029), X120530338(28/12/2028), Y010536031(30/05/2028); ILM 4018N/7899995273529/Y010537853(17/12/2028); ILM 3818N/7899995280886/Y010536867(13/12/2028); ILM 4511N/7899995274045/X120531860(18/12/2028), X120531935(18/12/2028), X120530732(18/12/2028); ILM 4515/7899995280169/X060497920(23/02/2028), X060497915(23/01/2028); ILM 4585/7899995280251/X040490690(24/01/2028), X120529433(24/01/2029), X120529450(24/01/2029); ILM 3813/7899995280527/Y020539359(6/2/2029); ILM 3815/7899995280473/Y010535029(7/2/2029); ILM 5085/7899995280091/X090516829(28/12/2028); ILM

3811/7899995280534/X110528601(10/10/2028); ILM 3820N/7899995273642/V110406210(13/12/2028), X020479077(X020479077); ILM 4518N/7899995273437/W060438138(24/01/2028), X120531278(24/01/2028); UCMC 6007N/7899995215895/Y010536358(30/10/2028);

Class II Devices Event

Event ID:

97559

Product Type:

Devices

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

08/28/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/26/2025

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Howmedica Osteonics Corp.

325 Corporate Dr

Mahwah, NJ 07430-2006

United States

Distribution Pattern:

International distribution in the country of United Kingdom.

Associated Products

Product Description:

1. EXETER V40 STEM 44MM NO 2, Model/Catalog Number: 0580-1-442; 2. EXETER V40 STEM 37.5MM NO 0, Model/Catalog Number: 0580-1-352;

Product Quantity:

55 units (all OUS)

Reason for Recall:

a potential product mix where the package labeled as Catalog Number 0580-1-442, lot A00976, may contain Catalog Number 0580-1-352, lot G8754849, and vice versa. Patient labels may also be impacted.

Recall Number:

Z-2640-2025

Code Information:

1. Model/Catalog Number: 0580-1-442, UDI-DI: 04546540153319, Lot Number: A00976; 2. Model/Catalog Number: 0580-1-352, UDI-DI: 04546540153241, Lot Number: G8754849;