



CALIFORNIA DEVICE RECALL INFORMATION SHEET

B. Braun Medical Recall Infusomat Administration Sets For Tubing Length And Diameter

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|--|--|--|
| 12/13/2023 | <p>Infusomat Administration Sets 362031 Infusomat Space Pump Set with Caresite Injection Site; 362032 15 drops/mL, priming volume: 22mL, length: 119in, SafeLine; 362033 UNIV. 15 DR PUMP SET, 1.2 FIL, 2 CRSITE; 362034 Priming volume: 19mL, length: 120in, SafeLine; 362035 INFUSOMAT SPACE PUMP IV SET; 362043 Priming volume: 39mL, length: 120in, SafeLine; 362050 15 drops/mL, priming volume: 26mL, length: 124in, SafeLine; 362420 SPACE PUMP SET 15 DROP W/2 SAFEDAY; 362432 15 drops/mL, priming volume: 21mL, length: 118in, ULTRASITE; 362911 Priming volume: 14mL, length: 84in, CARESITE, Spin-Lock; 363010 Priming volume: 21mL, length: 121in, SafeLine; 363019 Priming volume: 40mL, length: 123in, SafeLine; 363030 15 drops/mL, priming volume: 22mL, length: 119in, SafeLine; 363032 20 drops/mL, priming volume: 20mL, length: 119in, SafeLine; 363230 15 drops/mL, priming volume: 22mL, length: 123in,</p> | <p>B. BRAUN MEDICAL, INC. Allentown, Pennsylvania</p> | <p>In affected products, the tubing outer diameter may vary in size or the length of tubing may be too short. Both issues may lead to false air-in-line alarms, which will stop the infusion and interrupt therapy. Interruptions or delays in medication administration may result in serious injury to patients which may be life-threatening (e.g. interruption of a vasopressor to a hemodynamically unstable patient) or may lead to death.</p> |

ULTRASITE;
363410 15 drops/mL, priming
volume: 23mL, length: 119in,
CARESITE;
363419 Priming volume:
41mL, length: 120in,
CARESITE;
363420 15 drops/mL, priming
volume: 24mL, length: 120in,
CARESITE;
363421 15 drops/mL, priming
volume: 22mL, length: 120in,
CARESITE;
363422 Priming volume:
21mL, length: 130in,
CARESITE;
363423 60 drops/mL, priming
volume: 21mL, length: 118in,
CARESITE;
363424 UNIV. 15 DR PUMP
SET, 1.2FIL, 2CRSTE ASV;
363430 15 drops/mL, priming
volume: 23mL, length: 123in,
CARESITE;
363433 UNIV. 15 DROP
PUMP SET, 3 CARESITE,
ASV;
363901 60 drops/mL, priming
volume: 11mL, length: 129in;
363902 Priming volume:
25mL, length: 130in;
363904 UNIV. 15 DROP
PUMP SET, ASV;
470119 15 drops/mL, priming
volume: 23mL, length: 119in,
CARESITE;
480254 SPACE PUMP IV
SET 15D, 110 IN.;
480255 SPACE PUMP IV
SET, 127 IN;
480257 60 DROP NITRO
SPACE SET, 88 IN.;
480258 15 DROP PUMP SET
1 SAFEDAY 0.2 FILTER;
480263 SPACE PUMP IV
SET 15D, 90 IN.;
480264 SPACE PUMP IV
SET, 15 DRPS/ML, 95 IN.;
490037 Priming volume:
25mL, length: 136in;
490038 60 drops/mL, priming
volume: 11mL, length: 129in;
490100 15 drops/mL, priming
volume: 22mL, length: 120in,

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| | <p>CARESITE; 490101 Priming volume: 19mL, length: 120in, CARESITE; 490102 15 drops/mL, priming volume: 22mL, length: 120in, CARESITE; 490103 15 drops/mL, priming volume: 24mL, length: 120in, CARESITE; 490104 60 drops/mL, priming volume: 21mL, length: 115in, CARESITE; 490105 Priming volume: 39mL, length: 120in, CARESITE</p> | | |
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| Recall Class | Product Identification | Distribution | Affected Dates |
|--------------|--|---|-------------------------------------|
| I | <p>Infusomat Administration Sets 362031 Infusomat Space Pump Set with Caresite Injection Site; 362032 15 drops/mL, priming volume: 22mL, length: 119in, SafeLine; 362033 UNIV. 15 DR PUMP SET, 1.2 FIL, 2 CRSITE; 362034 Priming volume: 19mL, length: 120in, SafeLine; 362035 INFUSOMAT SPACE PUMP IV SET; 362043 Priming volume: 39mL, length: 120in, SafeLine; 362050 15 drops/mL, priming volume: 26mL, length: 124in, SafeLine; 362420 SPACE PUMP SET 15 DROP W/2 SAFEDAY; 362432 15 drops/mL, priming volume: 21mL, length: 118in, ULTRASITE; 362911 Priming volume: 14mL, length: 84in, CARESITE, Spin- Lock; 363010 Priming volume: 21mL, length: 121in, SafeLine; 363019 Priming volume: 40mL, length: 123in, SafeLine; 363030 15 drops/mL, priming volume: 22mL, length: 119in, SafeLine;</p> | <p>33,820,976 Units Nationwide</p> | <p>December 2023 and prior</p> |

363032 20 drops/mL, priming volume: 20mL, length: 119in, SafeLine;

363230 15 drops/mL, priming volume: 22mL, length: 123in, ULTRASITE;

363410 15 drops/mL, priming volume: 23mL, length: 119in, CARESITE;

363419 Priming volume: 41mL, length: 120in, CARESITE;

363420 15 drops/mL, priming volume: 24mL, length: 120in, CARESITE;

363421 15 drops/mL, priming volume: 22mL, length: 120in, CARESITE;

363422 Priming volume: 21mL, length: 130in, CARESITE;

363423 60 drops/mL, priming volume: 21mL, length: 118in, CARESITE;

363424 UNIV. 15 DR PUMP SET, 1.2FIL, 2CRSTE ASV;

363430 15 drops/mL, priming volume: 23mL, length: 123in, CARESITE;

363433 UNIV. 15 DROP PUMP SET, 3 CARESITE, ASV;

363901 60 drops/mL, priming volume: 11mL, length: 129in;

363902 Priming volume: 25mL, length: 130in;

363904 UNIV. 15 DROP PUMP SET, ASV;

470119 15 drops/mL, priming volume: 23mL, length: 119in, CARESITE;

480254 SPACE PUMP IV SET 15D, 110 IN.;

480255 SPACE PUMP IV SET, 127 IN.;

480257 60 DROP NITRO SPACE SET, 88 IN.;

480258 15 DROP PUMP SET 1 SAFEDAY 0.2 FILTER;

480263 SPACE PUMP IV SET 15D, 90 IN.;

480264 SPACE PUMP IV SET, 15 DRPS/ML, 95 IN.;

490037 Priming volume: 25mL, length: 136in;

490038 60 drops/mL, priming volume: 11mL, length: 129in;

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| | <p>490100 15 drops/mL, priming volume: 22mL, length: 120in, CARESITE;</p> <p>490101 Priming volume: 19mL, length: 120in, CARESITE;</p> <p>490102 15 drops/mL, priming volume: 22mL, length: 120in, CARESITE;</p> <p>490103 15 drops/mL, priming volume: 24mL, length: 120in, CARESITE;</p> <p>490104 60 drops/mL, priming volume: 21mL, length: 115in, CARESITE;</p> <p>490105 Priming volume: 39mL, length: 120in, CARESITE</p> | | |
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FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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