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**B. Braun Melsungen AG**
**Division Hospital Care**
**Safety Officer Medical Devices**

34209 Melsungen

Our Reference FSCA-2022-12-07
Amendment 2 - Scope Extension

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Date: Apr 11, 2023

# URGENT Field Safety Corrective Action – PROSET INFUSION SET - leakage

## Amendment 2 - Scope Extension

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to recall additional article/batch combinations of PROSET INFUSION SETs with Discofix C as a scope extension of Field Safety Corrective Action FSCA-2022-12-07 from the market. The scope extension refer to position 1 to position 63 and are marked in **green**. All other position have been recalled earlier and are only listed for completeness:

| Position | Article Number | Article Name | Batch |
|---|---|---|---|
| 1. | 4085086 | PROSET DISCOFIX C-HAHNBANK SET 3-FACH | 22K10F0000 |
| 2. | 4092539 | PROSET SPIRALLEITUNG 2X3,2 500CM M DWH | 22K02F0000 |
| 3. | 4180306 | PROSET DISCOFIX C HB 5 / INTRAPUR PLUS | 22K27F0000 |
| 4. | 4180350 | PROSET INTRAPUR 0,2µM | 22K10F0000 |
| 5. | 4180351 | PROSET INTRAPUR 1,2µM | 22H29F0000 |
| 6. | 4180438 | PROSET DISCOFIX C-DREIWEGEHAHN SET | 22K12F0000 |
| 7. | 4180438 | PROSET DISCOFIX C-DREIWEGEHAHN SET | 22K16F0000 |
| 8. | 4180439 | PROSET DISCOFIX C-DREIWEGEHAHN SET | 22K24F0000 |
| 9. | 4181027 | PROSET DISCOFIX C HB 3 / INTRAPUR PLUS | 22K09F0000 |
| 10. | 4181028 | PROSET DISCOFIX C HB 3 / INTRAPUR PLUS | 22K15F0000 |
| 11. | 4181778 | PROSET DISCOFIX C -HAHNBANK-SET 5-FACH | 22K27F0000 |
| 12. | 4182182 | PROSET DISCOFIX-DREIWEGEHAHN SET | 22K14F0000 |
| 13. | 4182308 | PROSET DISCOFIX C-HAHNBANK SET 5-FACH | 22K26F0000 |
| 14. | 4182633 | PROSET DISCOFIX C-HAHNBANK SET 3-FACH | 22K06F0000 |
| 15. | 4182633 | PROSET DISCOFIX C-HAHNBANK SET 3-FACH | 22K10F0000 |

**Chairwoman of the Supervisory Board:**
Dr. Annette Beller

**Executive Board:**
Markus Strotmann
(Chairman)
Priv.-Doz. Dr. Stefan Ruppert
Jürgen Stihl

**Corporate Office: Melsungen**
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| Position | Article Number | Article Name | Batch |
|---|---|---|---|
| 16. | 4182638 | PROSET DISCOFIX C HB 3 / INTRAPUR PLUS | 22K08F0000 |
| 17. | 4182737 | PROSET DISCOFIX C-HAHNBANK SET 5-FACH | 22K28F0000 |
| 18. | 4183255 | PROSET INTRAPUR 0,2µM | 22K14F0000 |
| 19. | 4183455 | PROSET INTRAFIX SAFESET 230CM | 22K06F0000 |
| 20. | 4183455 | PROSET INTRAFIX SAFESET 230CM | 22K16F0000 |
| 21. | 4183455 | PROSET INTRAFIX SAFESET 230CM | 22K23F0000 |
| 22. | 4183852 | PROSET DISCOFIX C-HAHNBANK SET 3-FACH | 22K09F0000 |
| 23. | 4183925 | PROSET ORIGINAL PERFUSOR LEITUNG | 22K20F0000 |
| 24. | 4183969 | PROSET PERFUSOR LEITUNG | 22K08F0000 |
| 25. | 4184005 | PROSET INFUSIONS-SET M. 1,2MM | 22K22F0000 |
| 26. | 4184006 | PROSET ORIGINAL PERFUSOR LINE | 22K27F0000 |
| 27. | 4184007 | PROSET PERFUSOR LEITUNG | 22H29F0000 |
| 28. | 4184491 | PROSET DISCOFIX C-HAHNBANK SET 5-FACH | 22L05F0000 |
| 29. | 4184963 | PROSET DISCOFIX C-HAHNBANK SET 3-FACH | 22K14F0000 |
| 30. | 4185928 | PROSET DISCOFIX C-HAHNBANK SET 3-FACH | 22K27F0000 |
| 31. | 4186109 | PROSET INTRAFIX SAFESET | 22H30F0000 |
| 32. | 4186109 | PROSET INTRAFIX SAFESET | 22K07F0000 |
| 33. | 4186168 | PROSET INTRAFIX PRIMELINE | 22K16F0000 |
| 34. | 4186980 | PROSET INTRAFIX SAFESET | 22K05F0000 |
| 35. | 4186981 | PROSET INTRAFIX SAFESET | 22K24F0000 |
| 36. | 4187008 | PROSET INTRAFIX PRIMELINE | 22K12F0000 |
| 37. | 4187010 | PROSET INTRAFIX PRIMELINE | 22K27F0000 |
| 38. | 4187105 | PROSET INTRAFIX PRIMELINE | 22K06F0000 |
| 39. | 4187113 | PROSET INTRAFIX SAFESET | 22K21F0000 |
| 40. | 4187113 | PROSET INTRAFIX SAFESET | 22K26F0000 |
| 41. | 4187202 | PROSET DISCOFIX-C HAHNBANK-SET 3-FACH | 22K02F0000 |
| 42. | 4187823 | PROSET INFUSIONS-SET M. 0,2MM | 22K26F0000 |
| 43. | 4187834 | PROSET DISCOFIX HAHNBANK C 3-FACH SET | 22K06F0000 |
| 44. | 4188030 | PROSET INTRAFIX SAFESET | 22K15F0000 |
| 45. | 4188072 | PROSET DISCOFIX C-HAHNBANK SET 8-FACH | 22K12F0000 |
| 46. | 4188117 | PROSET INTRAFIX SAFESET | 22K06F0000 |
| 47. | 4188120 | PROSET INTRAFIX SAFESET | 22H29F0000 |
| 48. | 4188120 | PROSET INTRAFIX SAFESET | 22K08F0000 |
| 49. | 4188120 | PROSET INTRAFIX SAFESET | 22K13F0000 |
| 50. | 4188120 | PROSET INTRAFIX SAFESET | 22K17F0000 |
| 51. | 4188530 | PROSET INTRAFIX SAFESET | 22K02F0000 |
| 52. | 4188530 | PROSET INTRAFIX SAFESET | 22K13F0000 |
| 53. | 4188530 | PROSET INTRAFIX SAFESET | 22K23F0000 |
| 54. | 4188540 | PROSET INTRAFIX SAFESET | 22K22F0000 |
| 55. | 4189109 | PROSET INTRAFIX SAFESET | 22H27F0000 |
| 56. | 4189847 | PROSET DISCOFIX HB SET 5-F. M. 0,2MM F. | 22L04F0000 |

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| Position | Article Number | Article Name | Batch |
|---|---|---|---|
| 57. | 4182002A | PROSET INTRAFIX SAFESET 3XDISCOFIX C | 22K02F0000 |
| 58. | 4182189SP | PROSET DISCOFIX C HB 3-FACH/SPACE LTG. | 22K15F0000 |
| 59. | 4182189SP | PROSET DISCOFIX C HB 3-FACH/SPACE LTG. | 22K23F0000 |
| 60. | 4182191SP | PROSET INFUSOMAT SPACE LEITUNG | 22K19F0000 |
| 61. | 4187789SP | PROSET INFUSOMAT SPACE LEITUNG | 22K27F0000 |
| 62. | 4188166SP | PROSET DISCOFIX C HB 5-FACH M. 0,2MM | 22K20F0000 |
| 63. | 4189981SP | PROSET INFUSOMAT SPACE LEITUNG | 22K26F0000 |
| 64. | 4187113 | PROSET INTRAFIX SAFESET | 22H30F0000 |
| 65. | 4087930 | PROSET DISCOFIX C-MANIFOLD SET 3-GANG | 22K08F0000 |
| 66. | 4168894 | PROSET CERTOFIX QUATTRO S830 | 22L19A8001 |
| 67. | 4180038 | PROSET INTRAFIX PRIMELINE | 22K05F0000 |
| 68. | 4180120 | PROSET DISCOFIX C MANIFOLD 3-GANG | 22H30F0000 |
| 69. | 4183450 | PROSET INTRAFIX SAFESET | 22H30F0000 |
| 70. | 4183925 | PROSET ORIGINAL PERFUSOR LINE | 22H31F0000 |
| 71. | 4183927 | PROSET INFUSIONS-SET M. 0,2MM | 22K07F0000 |
| 72. | 4183945 | PROSET INFUSION-SET | 22K05F0000 |
| 73. | 4185687 | PROSET INFUSION SET FOR INFUSION THERAPY | 22K06F0000 |
| 74. | 4187006 | PROSET INTRAFIX SAFESET | 22K01F0000 |
| 75. | 4187008 | PROSET INTRAFIX PRIMELINE | 22K05F0000 |
| 76. | 4187010 | PROSET INTRAFIX PRIMELINE | 22H31F0000 |
| 77. | 4187527 | PROSET DISCOFIX C-STOPCOCK-SET | 22K07F0000 |
| 78. | 4187879 | PROSET DISCOFIX C-MANIFOLD SET 3-GANG | 22H30F0000 |
| 79. | 4187879 | PROSET DISCOFIX C-MANIFOLD SET 3-GANG | 22K14F0000 |
| 80. | 4187911 | PROSET DISCOFIX C-STOPCOCK-SET | 22K14F0000 |
| 81. | 4188110 | PROSET INTRAFIX SAFESET | 22H26F0000 |
| 82. | 4188110 | PROSET INTRAFIX SAFESET | 22H30F0000 |
| 83. | 4188114 | PROSET INTRAFIX SAFESET | 22H31F0000 |
| 84. | 4188116 | PROSET INTRAFIX SAFESET | 22K06F0000 |
| 85. | 4188120 | PROSET INTRAFIX SAFESET | 22H29F0000 |
| 86. | 4188120 | PROSET INTRAFIX SAFESET | 22K08F0000 |
| 87. | 4800362 | PROSET VITREKTOMIE SET | 22L05A7001 |
| 88. | 4182189SP | PROSET DISCOFIX C 3GANG/SPACELINE | 22K02F0000 |

Reason for the Recall

In the course of our Post Market Surveillance activities, we identified the risk for leakages on the Discofix C in the above mentioned article batch combinations.

The potential leakage is indicated on the picture below:

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Whilst no injuries to patients, users, or third parties have been reported to date, the deviation might harbour the risk for the patient of microbial contamination, under supply, open patient access, or air infusion. A potential consequence for the healthcare worker is given by contact to hazardous drugs.

In view of the identified risks, we decided to recall all affected devices from the market.

Based on internal controls and available post market data, the effect can be limited to the above mentioned article batches combinations. **The extension has become necessary after further investigations revealed, that additional article batch combinations of finished goods are affected.**

Actions to be taken

Our records have shown that your institution has received one or more of the affected article batch combinations.

We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned product in your organization and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine and return affected articles.
- Do not use affected devices anymore.
- It is recommended to exchange devices from the above mentioned batches, which are currently in use.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.

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If more information is needed or you require devices for replacement, please contact

Local contact 1
Name
Title
Email
telephone

Local contact 2

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

Yours sincerely,