



XX July 2021

**URGENT: FIELD SAFETY NOTICE – MDS-21-4144**

**BD SmartSite™ Needle Free Valve**

**REF & Lot Numbers:** See Appendix 1

**Type of Action:** Advisory

**Attention: Clinical Personnel, Risk Managers, Biomedical Personnel**

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is issuing an advisory Field Safety Notice for specific lots of BD SmartSite™ Needle Free Valve products, as listed in Appendix 1, and according to our distribution records your organisation may have received the impacted product, which was shipped from 23<sup>rd</sup> January 2020.

**Description of the Problem**

Based on customer feedback, BD has identified potential issues with the valve of the Needle-free Connector for the products listed in Appendix 1 resulting in difficulty to flush, flow issues, and partial or total occlusions on the Extension Sets with SmartSite™ and Standalone SmartSite™ connectors. Only the lot numbers listed in Appendix 1 are affected by this issue.

BD has an online tool to support the identification of impacted lot numbers <https://www.bd.com/MDS-21-4144>.

**Clinical Impact**

The health consequences associated with the use of an occluded connector is a delay in therapy that can potentially lead to an injury that requires medical intervention.

BD has not identified any reports of serious adverse events to date that could be associated with this Field Safety Corrective Action. No specific patient follow-up activities are required if the product has already been used or already safely connected to the female luer of connecting device.

**Advice for Clinical Users**

As a result of this feedback and to mitigate the occurrence of the connector occluding, BD is recommending the following steps be followed prior to clinical use of the needle-free connector

- Depress the syringe plunger whilst the syringe is still attached to the needle-free connector.
- If unable to depress the plunger, pull back on the syringe plunger and depress the syringe plunger again. Repeating this step may assist in opening the needle-free connector valve.



- If the valve still is not open; without disconnecting the syringe male luer tip from the BD SmartSite™ valve surface, carefully unthread and rethread the syringe to partially disengage and reengage the syringe.
- Repeating this step up to three times may assist in opening the needle-free valve.  
*Note: To maintain sterility, do not allow the syringe and needle-free valve to completely disconnect*
- If previous steps do not open the valve, then replace with another BD SmartSite needle-free connector.
- After the steps above, proceed with the existing instructions for use for product.

**Actions by BD:**

1. BD has identified the root cause and initiated corrective actions to prevent recurrence of this issue.

**Actions for Customers to take:**

1. Circulate this Field Safety Notice to all those within your organisation that may use the BD SmartSite™ Needle Free Valve devices listed in Appendix 1.
2. Where a potential delay in therapy cannot be clinically tolerated (e.g., in an emergency situation) consideration should be given to administering the critical drug directly into the catheter hub or through a different route.
3. If you have further distributed the product, please identify those users and notify them at once of this Field Safety Notice.
4. If you continue to experience issues with the BD SmartSite™ Needle Free Valve report as a complaint to BD per your normal process.
5. Complete the customer response form on page 3 and return it to <<insert contact details here>> as soon as possible or no later than <<xx August 2021>>. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

**There is no requirement for customers to return any BD SmartSite™ Needle Free Valve devices to BD. These products can continue to be used in accordance with the guidance in this safety notice.**

**Contact Reference Person**

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may



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cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

**SIGNED**



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## Customer Response Form – MDS-21-4144

### BD SmartSite™ Needle Free Valve

REF & Lot Numbers: See Appendix 1

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Please read in conjunction with Field Safety Notice MDS-21-4144 and return the completed and signed form as soon as possible or **no later than <<xx August 2021>>** to <<insert fax/email address here>>.

**By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

<b>Account/Organisation Name:</b>	
<b>Department (if applicable):</b>	
<b>Address:</b>	
<b>Postcode:</b>	<b>City:</b>
<b>Contact Name:</b>	
<b>Job Title:</b>	
<b>Contact Telephone Number:</b>	<b>Contact E-mail Address:</b>
<b>Signature:</b>	<b>Date:</b>

*This form must be returned to BD before this action can be considered closed for your account.*

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**Row Labels**

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**2000E-04**

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**SMARTSITE NEEDLE-FREE CO**

21035775  
21035776  
21035777  
21035778  
21036842

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**2000E7D**

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**7-DAY LL VLV ADPT(STAND**

1015511  
1016651  
1016663  
1016664  
1016761  
1016762  
1017045  
1017152  
1017153  
1017154  
1017306  
1017679  
1017680  
1017681  
1017964  
1018010  
1018316  
1018317  
1018575  
1018576  
1018577  
1018578  
1018579  
1018583  
1018584  
1019392  
1019393  
1019582  
1019583  
1019584  
1019886  
1019892  
1019925  
1020131  
1020967  
1021008  
1021015

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**20019E7D**

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**Y EXT W/VLV PORTS & 2 SL**

20015114  
20015115  
20015116  
20015117  
20036259  
20036260  
20036328  
20036329  
20037133  
20046569

20046570  
20046615  
20046616  
20046617  
20055967  
20055968  
20055984  
20055985  
20055986  
20055987  
20055988  
20055989  
20056365  
20056366  
20056452  
20056453  
20056565  
20056566  
20057064  
20075235  
20075616  
20075617  
20085526  
20085775  
20086097  
20086098  
20086099  
20086100  
20086101  
20086102  
20086427  
20086429  
20095126  
20095127  
20095128  
20095129  
20095130  
20095146  
20095150  
20095151  
20097045  
20097046  
20097047  
20105605  
20105606  
20105607  
20106572  
20106573  
20106678  
20115001  
20115002  
20115006  
20115007  
20115008  
20115009  
20115010  
20115011  
20115012  
20116408

20116409  
20116410  
20116411  
20116815  
20116830  
20116831  
20116832  
20116961  
20117063  
20117064  
20125036  
20125037  
20125245  
20125246  
20125247  
20125248  
20125249  
20125250  
21015733  
21015735

**20021E7D**

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**J-LOOP MICRO EXT SET, 7**

20026035  
20056670  
20056671  
20066232  
20066233  
20066234  
20115389  
20115390  
20115391  
20125048  
20125313

**20037E7D**

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**SMALLBORE 7 INCH W/ VLV,**

20026037  
20026038  
20026039  
20045035  
20097181  
20097182

**20039E7D**

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**SMALLBORE 6 INCH EXT VLV**

20027157  
20027158  
20027159  
20027160  
20035250  
20035251  
20035685  
20035686  
20035687  
20036089  
20067218  
20067220  
20067221  
20067223  
20067224  
20067227

20075225  
20075226  
20075228  
20075229  
20085511  
20115320  
20115321  
20115322  
20115323  
20115325  
20115326  
20115327  
20115329  
20115330  
20115331  
20115332  
20115333  
20115335  
20115351  
20116509  
20116510  
20116511  
20125315  
20125458  
21016036  
21016037  
21016233  
21016235  
21016310  
21016311  
21016313  
21016314  
21016316  
21025040  
21025041  
21025042  
21025043  
21025512  
21025513  
21025514  
21025515

**20049E7D**

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**12 INCH SMARTSITE HEP L/**

20026042

**20061E7D**

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**LGE BORE Y EXT W/VP 3 SL**

20125787

21016498

**20062E7D**

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**TRI-PORT EXT CHK VLV W/3**

20116554

20116555

20125592

20125593

**20159E**

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**EXT SET W/MACROBORE 2VPS**

20096455

**20159E7D**

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**EXT SET W/MACROBORE 2VPS**



20105459

**2300E**

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**BAG ACCESS DEVICE**

20066503  
20066504  
20076251  
20076352  
20086483  
20086484  
20086485  
20086486  
20096280  
20096281  
20096282  
20096283  
20097163  
20105074  
20105075

**2309E**

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**BAG ACCESS DEVICE W/CKV**

20035697  
20066399  
20076260

**2309E-0006**

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**BAG ACCESS DEVICE W/CKV**

20095374  
20095375  
20096302  
20105754  
20105755  
20105756  
20105757  
20105758  
20115470

**2441-0007**

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**GEM V/NV MC 4SS 60DP DEH**

20056757  
20065191  
20065192  
20065282  
20065298  
20075258  
20076104  
20076847  
20076848  
20076872  
20076873  
20097101  
20097102  
20097157

**60103E**

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**GP SERIES BURETTE SET, 1**

20026728  
20026729  
20026730  
20026852  
20026853  
20026865  
20026866

20026882  
20026883  
20037109  
20037110  
20037111  
20066210  
20066351  
20066482  
20066549  
20066582  
20076167  
20076187  
20076306  
20076307  
20076319  
20076320  
20076321  
20076322  
20076400  
20076401  
20076507  
20076508  
20105324  
20105670  
20116236  
20116237  
20116238  
20116270  
20116271  
20116369  
20117006  
20117007  
20117008  
20125276  
20125277  
20125465  
20125466  
20125490  
20125547  
20125598  
21015686  
21035102  
21035103  
21035268  
21035269  
21035387  
21035388  
21035522

**72103E-0006**

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**SE BURETTE SET, 1 SS Y.**

20025345  
20025483  
20037040  
20037041  
20037042  
20086605  
20086606  
20086696  
20095927

20096020  
20105323  
20125599  
20125695  
20125709  
21015395

**82113E-0006**

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**V/NV BURETTE SET**

20066405  
20075901  
20075902  
20076376  
20076377  
21016459  
21016460  
21016690  
21016691  
21035306  
21035418  
21035419  
21035420  
21035421  
21035423

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**Grand Total**