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URGENT: FIELD SAFETY NOTICE

Medical Device Safety Advisory Notice

Châteaubriant, Date

ATTENTION: Pharmacist/Risk Manager responsible for medical device vigilance and the Biomedical/Engineering Department

Security information for infusion sets, transfusion sets and associated accessories with luer lock included in Medline's Caresets and Sterile Procedure Trays

Medline Reference: FSN-25/01
MoH Reference: N/A
Product description: Infusion sets, transfusion sets and associated accessories with luer lock included in Medline's Caresets and Sterile Procedure Trays
Legal Manufacturer SRN: FR-MF-000000176
Action type: Field Safety Notice
Product codes: See Appendix 1 (pages 5 & 6)

Dear Customer,

This letter is to advise you that Didactic has initiated a Field Safety Notice regarding infusion sets, transfusion sets and associated accessories with luer lock manufactured by Didactic, which are included in the Medline's Caresets and Sterile Procedure Trays listed in the table in Appendix 1 (pages 5 & 6).

Medline has decided to notify all customers who have received and customers who might receive these impacted Caresets and Sterile Procedure Trays.

The Didactic Field Safety Notice is available on the French Competent Authority (ANSM) website under reference R2501409.

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REASON FOR THE FSN:

Please find the description of the problem announced by Didactic:

“The purpose of this letter is to inform you that Didactic has decided, following several reports of medical device vigilance, to publish this safety information due to a risk of solute leakage or air ingress induced by a cracking of the connectors of INFINEED brand infusion devices (extenders and infusion accessories) during prolonged contact with a solution of chlorhexidine solution 2% in 70° isopropyl alcohol.

DIDACTIC recommends not to use chlorhexidine 2% solutions in 70° iso propyl alcohol.”

POTENTIAL RISKS:

Please find the potential risks announced by Didactic:

“The weakening of the connections induced by these cracks ("cracking of plastic materials") has exposed, in a certain number of cases, to serious clinical consequences, such as leakage of drug solutions, risks of infection and even risks of air embolism.

The tests carried out following these cases confirm that the possible associated risk is amplified, especially the greater the quantity of solution and the longer the contact is prolonged.”

RECOMMENDATIONS:

Please find the recommendations from Didactic:

“The SF2H recommendations recommend 70° ethyl alcohol for the disinfection of infusion connections, which has the same antiseptic power but presents much less risk of cracking. Finally, it is important to allow a time for any alcoholic derivatives to evaporate before proceeding with the connection itself; Indeed, cracking phenomena are described as resulting from a double constraint, both chemical and mechanical.”

ACTIONS REQUIRED:

Step 1: Please take note of this safety information and inform all users in your facility.

Step 2: Please note that this safety notice concerns previous and future deliveries.

Step 3: Please complete and return the acknowledgement of receipt (page 4) by email as soon as possible, **but no later than February 21st, 2025.**





Thank you for your cooperation; Medline apologizes for the inconvenience caused.

The relevant competent authorities have been informed of this safety notice.

Please proceed to the following page to acknowledge receipt of this notice.

Please contact us at the email provided below if you have any questions.

Yours sincerely,

Audrey Barraud,
Quality Director, Medline Europe

This urgent safety information is only addressed to facilities that have received the products concerned.



Please email the Acknowledgement Receipt to the following email address:
GMB-EU-FSN-FSCA-CHBT@medline.com

Medline Reference: FSN-25/01

Please complete the Acknowledgement Receipt and send it back by email as soon as possible, **but no later than February 21st, 2025.**

The Medline’s Caresets and Sterile Procedure Trays including the infusion sets, transfusion sets and associated accessories with luer lock Didactic, are listed in the table in **Appendix 1** (pages 5 & 6).

By completing and signing the document, I confirm that I have read and I understood the instructions provided. I acknowledge receipt of the FSN-25/01 by signing this document and returning it to Medline. I also agree to further distribute and communicate this important information within my facility as required.

If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

If you are a **dealer, wholesaler, distributor/reseller**, that distributed any affected products to other facilities: per Medical Device Regulation 2017/745, Article 14, part 4, please distribute this notification to your customers and provide confirmation to Medline that your customers have been notified by completing the information below and returning it to Medline at the address listed above.

Date: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

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Appendix 1 - Samples concerned

Reference	Lot number	Reference	Lot number	Reference	Lot number
1450442-12	960345	1491015-5	981880	1500506-4	981057
1450442-9	914753	1491398-11	975868	1500626-4	979424
1451215-10	908179	1491400-8	975183	1501485-2	981085
1456135-13	947114	1491548-7	982785	ST01-BGCAN007	47320405
1466649-5	884968	1491548-7	982786	ST01-BGCGS007	44111652
1467911-6	896016	1492334-10	972009	ST01-BGCGS010	47320406
1471305-7	910749	1492482-4	251047	ST01-DGFUR099	43252128
1472390-4	902333	1492482-5	251048	ST01-FGRAN001	45478736
1478501-5	930078	1492918-2	961350	ST01-FGRAN016	48278004
1479402-5	941348	1492931-3	961962	ST01-FGRAN017	49135856
1479773-4	922371	1492949-16	977399	ST01-FGUGS151	47339747
1480028-5	958782	1492949-18	980261	ST01-HGGAN194	42710113
1480356-10	934780	1492949-18	980262	ST01-HGGAN204	42888183
1480365-9	934767	1492949-18	981058	ST01-HGGAN205	42901313
1483034-10	946214	1492949-18	981059	ST01-HGGAN206	42955312
1483491-3	237839	1492949-18	981781	ST01-HGGAN218	43462816
1483491-4	237917	1492949-9	973931	ST01-HGGAN247	43860487
1483491-5	237853	1493212-3	967950	ST01-HGGAN273	45816441
1483608-5	949950	1493217-6	965825	ST01-HGGAN320	46447909
1484045-11	948944	1493389-2	250535	ST01-HGGAN321	46447910
1484046-6	948682	1493634-5	976800	ST01-HGGAN322	46447911
1484407-6	953478	1493635-7	976809	ST01-HGGCV157B	47772812
1484407-8	958986	1493654-9	971283	ST01-KER71852	296590
1485378-4	976275	1493724-10	969218	ST01-KER71944	48161665
1485737-5	944326	1493813-2	968764	ST01-KER71944	48595054
1486479-5	952717	1493816-2	963632	ST01-LGTGS078	48075357
1487884-11	968807	1494771-9	978696	ST01-PGSAN182	49256869
1488018-12	980917	1495698-8	970517	ST01-PGSGS120	45498796
1488791-11	971395	1495875-7	977360	ST01-ZGZGS255	44919888
1488907-7	974572	1496553-2	975248	ST02-COMPABD03	45302894
1488944-4	957192	1496554-2	975186	ST02-HGGAN204	46395073
1488944-4	957195	1499582-5	980918	ST02-HGGAN320	48017652
1489679-3	956516	1499963-4	978758	ST02-KER71944	48920899
1490706-9	965219	1500006-3	978572	ST02-NCOMPABD03	44403559

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Appendix 1 – Sets and Trays concerned

Reference	Reference	Reference	Reference	Reference
AGBAN077C	AGBOR021	FGUCV043	HGGAN192A	HGGUR084B
AGBBA007A	AGBOR033	FGUMA257	HGGAN194	KER70044
AGBBA131B	BGCAN007	FGUOR108	HGGAN234	KER70658A
AGBBA137C	COMPABD01	FGUOR207	HGGAN238	KER70845
AGBBS093C	COMPABD02	FGUUR016B	HGGAN239	KER71082A
AGBBS093D	COMPABD03	FGUUR032	HGGAN264	KER71135A
AGBBS103H	DGFAN302B	HGGAN063B	HGGAN278A	KER71183
AGBBS103I	DGFAN440K	HGGAN063C	HGGAN300	KER71185
AGBBS331C	DGFAN557B	HGGAN078A	HGGAN354	KER71185A
AGBBS331D	DGFAN557C	HGGAN078B	HGGAN357	KER71805
AGBCV009I	DGFAN587A	HGGAN090	HGGAN360	LGTAN055B
AGBCV026G	DGFAN590	HGGAN101	HGGBA358D	LTBA206E
AGBCV069	DGFAN590A	HGGAN101A	HGGBA477B	LGTGS025
AGBEN035C	DGFAN660B	HGGAN101B	HGGBA477C	LGTGS025B
AGBEN099	DGFCV098B	HGGAN103	HGGCV054I	LGTGS029
AGBEN099A	DGFCV133C	HGGAN113	HGGCV054J	LGTNE046
AGBEY023B	DGFCV133D	HGGAN114	HGGCV078D	NCOMPABD03
AGBEY064A	DGFCV336	HGGAN115	HGGCV100B	PGSAN109B
AGBGS002A	DGFGS228	HGGAN115A	HGGCV100C	PGSAN135A
AGBGS003D	DGFTH160A	HGGAN116	HGGCV100D	PGSBA157A
AGBGS031	EGEAN001B	HGGAN116A	HGGCV154	PGSBA157B
AGBGS031A	EGIGS025	HGGAN125	HGGCV154A	PGSBA157C
AGBGS031B	FGRAN013	HGGAN125A	HGGCV157B	PGSEN004D
AGBGS033	FGRBA023D	HGGAN133A	HGGCV166	PGSTH014A
AGBGS033A	FGRUR009	HGGAN145	HGGCV204	PGSUR024
AGBGS057	FGUAN039	HGGAN154	HGGGS065	SGPAN017A
AGBGS057A	FGUBA248	HGGAN156	HGGGS216	SGPAN030
AGBMA049D	FGUBS173J	HGGAN156A	HGGGS216A	VGCAN004
AGBMA049E	FGUBS173K	HGGAN166	HGGMA066I	WGHEY030K
AGBMA049F	FGUBS173L	HGGAN179	HGGMA476	WGHEY030L
AGBMA085B	FGUBS174K	HGGAN180	HGGMA476A	WGHEY030M
AGBNE032B	FGUBS174L	HGGAN180A	HGGNS006	WGHEY041
AGBNE032C	FGUBS174M	HGGAN182	HGGUR084	WGHNE024
AGBNE032D	FGUBS411A	HGGAN192	HGGUR084A	ZGZTH008D

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