

«Hospital_Name»

«Users_Name» - «Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 92552660-FA>

«Date_notif_sent»

Cover letter for Distributors – Urgent Medical Device Recall "Name of the Product"

Dear «Users_Name»,

Boston Scientific Corporation is conducting a Medical Device Recall of specific lots/batches of IceFORCE 2.1 CX and IcePearl 2.1 CX Cryoablation Needles on behalf of Galil Medical Ltd.. Please find more information in the attached Field Safety Notice.

You are kindly requested to follow the below instructions:

- 1- Check your Inventory for the products affected by this Field safety Notice.**
- 2- Please segregate and do not distribute any of the affected products found in your inventory.**
- 3- Please notify all your customers that have received affected product of the below Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this Field Action to the medical facility level.
- 4- Have all affected product returned to your facility** and held in quarantine for reconciliation.
- 5- Please complete the attached Verification Form, even if you do not have any product to return.**
- 6- When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **26 June 2020**.
- 7- If you have products to return,** please package them in an appropriate shipping box and **contact «Customer_Service_Tel» of your local Boston Scientific office,** to arrange return.

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

xxx
Quality Department
Boston Scientific International S.A.

Attachment: - Field Safety Notice
- Distributor Verification Form

Betref: 92552660-FA

«Date_notif_sent»

Dringende kennisgeving veiligheid - Dringende terugroeping van medisch product "Name of the Product"

Geachte «Users_Name»,

Boston Scientific begint met de verwijdering van specifieke lots/batches IceFORCE 2.1 CX- en IcePearl 2.1 CX-cryoablatienaalden namens Galil Medical Ltd., de wettelijke fabrikant van deze producten. Deze maatregel wordt getroffen naar aanleiding van een melding van ernstig letsel van een patiënt tijdens een ingreep vanwege een lekkage van hogedrukgas vanuit een naald tijdens het elektrisch ontdooien. Uit het initiële onderzoek is gebleken dat het oppervlak van de naald is verslechterd vanwege onverwachte elektrolyse tijdens de ingreep. De elektrolyse duurde lang genoeg om perforatie van de schachtwand te veroorzaken.

Er is geconstateerd dat dit probleem is veroorzaakt door een significante hoeveelheid retroperitoneaal gas en veneus gas, dat werd verholpen met conservatieve maatregelen zonder klinische gevolgen. Er bestaat echter een mogelijkheid dat potentieel levensbedreigende verwondingen kunnen ontstaan uit lekkages van hogedrukgas. Er zijn tot op heden geen dodelijke ongevallen gemeld.

Uit onze gegevens blijkt dat uw instelling een aantal van de betrokken producten heeft ontvangen. **Onderstaande Bijlage 1 geeft een compleet overzicht van alle betrokken producten**, inclusief productomschrijving, materiaalnummer (UPN), GTIN, lotnummers en uiterste gebruiksdatum. Alleen de materiaalnummers en lotnummers genoemd in onderstaande tabel zijn betrokken. **Geen enkel ander Boston Scientific product is betrokken bij deze kennisgeving veiligheid.**

Verdere distributie of gebruik van overgebleven producten waarop deze terugroepingsactie betrekking heeft, dient onmiddellijk gestopt te worden.

INSTRUCTIES :

1- U dient het gebruik van alle vermelde Boston Scientific productpartijen onmiddellijk te stoppen en alle betrokken producten uit uw inventaris te verwijderen, ongeacht waar deze units zich bevinden in uw organisatie. Bewaar de producten afzonderlijk op een veilige plaats alvorens ze naar Boston Scientific terug te sturen.

2- U wordt verzocht het bijgesloten verificatieformulier in te vullen, zelfs als u geen producten hebt die u wilt retourneren.

3- Nadat u het verificatieformulier ingevuld heeft, kunt u het op of vóór 26 juni 2020, naar uw plaatselijke Boston Scientific-klantenservice sturen, ter attentie van «Customer_Service_Fax_Number».

4- Als u producten heeft die geretourneerd moeten worden, verpak deze alstublieft in een passende doos en neem dan contact op met uw plaatselijke Boston Scientific klantenservice door te bellen met: «Customer_Service_Tel», om de retournering te regelen.

5- Breng alle gezondheidszorgdeskundigen in uw organisatie van dit bericht op de hoogte, als zij dit moeten weten, evenals alle instellingen waar de mogelijk betrokken producten aan zijn doorgegeven (indien van toepassing). Geef aan Boston Scientific de gegevens door van eventueel betrokken producten die aan andere organisaties zijn doorgeleverd (indien van toepassing).

De bevoegde overheidsinstantie is van deze kennisgeving inzake veiligheid op de hoogte gebracht.

We betreuren het ongemak dat deze actie voor u veroorzaakt, maar stellen uw begrip voor onze maatregelen voor patiëntveiligheid en klantentevredenheid op prijs.

Als u vragen of hulp nodig heeft bij deze kennisgeving inzake veiligheid, neem dan contact op met uw plaatselijke vertegenwoordiger.

Hoogachtend,

xxx
Quality Department
Boston Scientific International S.A.

Bijlage: Verificatieformulier

Bijlage 1: Lijst van betrokken producten

Lijst van betrokken producten voor IceFORCE™ 2.1 CX- en IcePearl™ 2.1 CX-cryoablatienaalden

UPN-nr.	UPN- beschrijving	GTIN	Batch	Periode van uiterste gebruiksdatum
FPRPR3601	IcePearl 2.1 CX 90° Needle	07290104830990	A0735, A0736, A0749, A0750, A0798, A0799, A0817, A0818, A0840, A0841, A0874, A0875, A0888, A0889, A0898, A0899, A0945, A0946, A0950, A0951, A0992, A0993, A1003, A1004, A1005, A1006, A1012, A1027, A1028, A1078, A1079, A1090, A1091, A1096, A1097, A1098, A1099, A1111, A1112, A1143, A1144, A1155, A1156, A1168, A1169, A1190, A1191, A1192, A1204, A1205, A1223, A1224, A1232, A1233, A1268, A1271, A1272, A1296, A1297, A1299, A1300, A1302, A1303, A1343, A1344, A1348, A1349, A1369, A1370, A1393, A1394, A1408, A1409, A1417, A1418, A1438, A1439, A1440, A1441, A1454, A1455, A1499, A1500, A1509, A1510, A1516, A1517, A1520, A1538, A1539, A1540, A1541, A1546, A1547, A1553, A1554, A1580, A1581, A1599, A1600, A1603, A1604, A1606, A1617, A1618, A1619, A1649, A1650, A1651, A1652, A1665, A1666, A1674, A1675, A1680, A1681, A1686, A1687, A1734, A1735, A1749, A1750, A1772, A1773, A1797, A1798, A1809, A1810, A1828, A1829, A1853, A1854, A1869, A1870, A1885, A1886, A1893, A1894, A1911, A1912, A1922, A1923, A1926, A1927, A1929, A1930, A1971, A1972, A1982, A1983, A2038, A2039, A2058, A2059, A2107, A2108, A6655, A6656, A6716, A6717, A6733, A6749, A6750, A6794, A6795, A6821, A6822, A6844, A6845, A6852, A6853, A6865, A6866, A6879, A6880, A6884, A6885, A6940, A6941, A6984, A6985, A7067, A7068, A7076, A7077, A7101, A7102, A7111, A7112, A7124, A7125, A7136, A7137, A7161, A7162, A7163, A7164, A7172, A7173, A7175, A7176, A7181, A7182, A7186, A7187, A7193, A7194, T0032, T0033, T0040, T0041, T0061, T0062, T0066, T0067, T0078, T0079, T0130, T0131, T0132, T0133, T0182, T0187, T0202, T0213, T0214, T0233, T0234, T0245, T0246, T0249, T0250, T0251, T0252, T0253, T0254, T0266, T0267, T0293, T0295, T0296, T0297, T0324, T0325, T0345, T0346, T0380, T0381, T0407, T0408, T0409, T0410, T0475, T0476, T0522, T0523, T0537, T0538, T0555, T0556, T0590, T0606, T0607, T0608, T0609, T0610, T0611, T0620, T0621, T0696, T0705, T0706, T0707, T0762, T0763, T0764, T0767, T0768, T0769, T0770, T0771, T0772, T0773, T0777, T0778, T0779, T0784, T0804, T0805, T0806, T0807, U0019, U0020, U0070, U0071, U0072, U0073, U0074, U0075, U0091, U0092, U0112, U0113, U0130, U0131, U0132, U0133, U0134, U0135, U0185, U0186	14-jun-2020 tot 27-feb-2022

(vervolgd op de volgende pagina)

UPN-nr.	UPN-beschrijving	GTIN	Batch	Periode van uiterste gebruiksdatum
FPRPR3602	IceFORCE 2.1 CX 90° Needle	07290104831003	A0754, A0755, A0758, A0759, A0770, A0771, A0782, A0783, A0788, A0789, A0794, A0795, A0803, A0804, A0827, A0828, A0833, A0834, A0844, A0845, A0856, A0857, A0871, A0872, A0880, A0881, A0894, A0895, A0905, A0906, A0907, A0908, A0922, A0923, A0925, A0926, A0930, A0931, A0939, A0940, A0941, A0942, A0952, A0953, A0956, A0957, A0958, A0959, A0972, A0973, A0974, A0975, A0996, A0997, A0999, A1000, A1010, A1011, A1017, A1018, A1034, A1035, A1036, A1037, A1042, A1043, A1045, A1073, A1074, A1076, A1077, A1088, A1089, A1093, A1094, A1100, A1101, A1127, A1128, A1172, A1173, A1129, A1130, A1131, A1132, A1135, A1136, A1214, A1215, A1228, A1229, A1243, A1244, A1246, A1247, A1258, A1259, A1266, A1267, A1659, A1660, A1661, A1662, A1670, A1671, A1676, A1677, A1696, A1697, A1698, A1699, A1702, A1703, A1704, A1705, A1708, A1709, A1736, A1737, A1740, A1741, A1742, A1743, A1269, A1270, A1289, A1290, A1315, A1316, A1330, A1331, A1332, A1333, A1338, A1339, 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A1940, A1941, A1931, A1932, A1952, A1953, A1957, A1958, A1963, A1964, A1969, A1970, A1980, A1981, A1992, A1993, A1995, A1996, A2004, A2005, A2014, A2015, A2027, A2028, A2031, A2032, A2046, A2047, A2051, A2052, A2056, A2057, A2084, A2085, A2111, A2112, A2125, A2126, A2134, A2135, A2139, A2140, A6636, A6637, A6638, A6639, A6651, A6652, A6674, A6675, A6683, A6684, A6703, A6704, A6724, A6725, A6728, A6759, A6760, A6763, A6764, A6765, A6766, A6783, A6784, A6803, A6804, A6805, A6806, A6841, A6842, A6850, A6851, A6858, A6859, A6862, A6863, A6868, A6869, A6874, A6875, A6876, A6877, A6881, A6882, A6887, A6888, A6894, A6895, A6904, A6905, A6909, A6910, A6919, A6920, A6921, A6922, A6934, A6935, A6936, A6937, A6938, A6939, A6946, A6947, A6954, A6955, A6959, A6973, A6974, A6996, A6997, A7023, A7024, A7041, A7047, A7054, A7050, A7051, A7055, A7056, A7057, A7058, A7059, A7060, A7096, A7097, A7080, A7081, A7086, A7087, A7089, A7090, A7092, A7093, A7094, A7095, A7098, A7099, A7107, A7108, A7109, A7128, 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U0110, U0111, U0138, U0139, U0140, U0141, U0142, U0143, U0144, U0145, U0162, U0163, U0170, U0171, U0190, U0191	18-jun-2020 tot 01-mrt-2022

(vervolgd op de volgende pagina)

UPN-nr.	UPN-beschrijving	GTIN	Batch	Periode van uiterste gebruiksdatum
FPRPR3603	IcePearl 2.1 CX Needle	07290104831010	A1564, A1521, A6723, A6908, A6929, A7015, T0025, T0056, T0137, T0138, T0269, U0041	08-dec-2020 tot 23-nov-2021
FPRPR3604	IceFORCE 2.1 CX Needle	07290104831027	A1203, A1549, A6734, A6916, A6928, A6931, A7083, T0156, T0166, U0042	13-okt-2020 tot 05-dec-2021
FPRPR3605	IceFORCE 2.1 CX Prostate Kit/VL	07290104831034	A1105, A1193, A1291, A1435, A1550, A1565, A1776, A1781, A6758, A6930, A7062, A7061, T0153	03-sep-2020 tot 08-sep-2021
FPRPR3606	IcePearl 2.1 CX Prostate Kit/VL	07290104831041	A1148, A1171, A1248, A1460, A1561, A1582, A1936, A2121, A6702, A6743, A6856, A6925, A7013, A7026, A7088, A7148, T0054, T0136, T0141, T0224, T0236, T0237, T0268, T0437, T0592, U0082, U0027, U0093, U0226, U0227	14-sep-2020 tot 22-feb-2022
FPRPR3607	3 IceFORCE® 2.1 Prostate Kit/VL	07290104831058	A1194, A1298, A1436, A1569, A1567, A1782, A6754, A6757, A6848, A6849, A6915, T0154, T0163, T0552, U0083	13-okt-2020 tot 23-jan-2022
FPRPR3608	3 IcePearl® 2.1 Prostate Kit/VL	07290104831065	A1170, A1583, A1937, A6710, A6744, A6857, A6900, A6913, A6926, A7014, A7027, A7122, T0055, T0144, T0181, T0211, T0212, T0238, T0270, T0816, T0815	14-sep-2020 tot 17-jan-2022
FPRPR3617	IcePearl™ 2.1 CX L 90° Needle	07290104831072	A0904, A1085, A1177, A1178, A6681, A6682, A6962, A6963, A6977, A7113, U0084	19-jul-2020 tot 07-feb-2022
FPRPR3618	IceFORCE™ 2.1 CX L 90° Needle	07290104831089	X2073, X6812, A0815, A0994, A1044, A1046, A1188, A1189, A1544, A1545, A1774, A1775, A2029, A2030, A6677, A6678, A7032, A7033, A7082, T0134, T0135, T0142, T0143, T0275, T0278, U0160, U0161	4-jun-2020 tot 21-feb-2022

Please Complete the form even if you do not have any affected product & send it to Your Local Office:
«Customer_Service_Fax_Number»

Distributor's Verification Form – Urgent Medical Device Recall
"Name of the Product"
92552660-FA

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date_notif_sent».
2. **Boston Scientific records indicate you have received the following affected product** (*additionally please check inventory against complete list of affected product provided*).

Material N° (UPN)	Lot / Batch N° / Serial N°	Customer PO	Qty Sent	Qty to return (Units)

3. We confirm that all areas where affected product could be located, **including at our customers' location**, have been checked.

4. **TICK ONE OF THESE STATEMENTS***, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»:

- We do not have any affected product.
- We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch number /Serial number and the quantity to return.***

TO RETURN PRODUCTS:

1. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product.
2. Prepare the package.
3. Follow the instructions given by your Local Office about collection of the package.

NAME* _____ Title _____

Telephone _____ Email _____

Distributor SIGNATURE* _____ DATE* _____
* Required field dd/mm/yyyy