

«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

Reference: 92552660-FA

«Date_notif_sent»

Urgent Field Safety Notice - Urgent Medical Device Recall "Name of the Product"

Dear «Users_Name»,

Boston Scientific is initiating a removal of specific lots/batches of IceFORCE 2.1 CX and IcePearl 2.1 CX Cryoablation Needles on behalf of Galil Medical Ltd., the legal manufacturer of the products. This action is being taken following one report of a serious injury in a patient during a procedure due to a high-pressure gas leak from a needle during the electrical thawing operation. The initial investigation has found that the needle surface deteriorated due to unexpected electrolysis during the procedure. The duration of the electrolysis was long enough to cause a perforation in the shaft wall.

The injury that resulted from this issue was the observation of a significant amount of retroperitoneal gas and venous gas that was resolved with conservative measures without clinical sequelae. However, there is a possibility that potentially life-threatening injuries could result from high pressure gas leaks. No deaths have been reported to date.

Our records indicate that your facility received some of the concerned product. The **Attachment 1 below provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN and Lot/Batch numbers and expiry date. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.** **Further distribution or use of any remaining product affected by this action should cease immediately.**

INSTRUCTIONS:

1- Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- Please complete the attached Verification Form even if you do not have any product to return.

3- 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**.

4- **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.

5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

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: Verification Form

Attachment 1 : Affected Product Listing

Affected Product Listing for IceFORCE™ 2.1 CX and IcePearl™ 2.1 CX Cryoablation Needles

UPN #	UPN Description	GTIN	Batch	Expiration Date Range
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 to 27-Feb-2022

(continued on next page)

UPN #	UPN Description	GTIN	Batch	Expiration Date Range
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, A1345, A1346, A1350, A1351, A1352, A1353, A1354, A1355, A1357, A1358, A1359, A1360, A1361, A1362, A1365, A1366, A1371, A1372, A1375, A1376, A1380, A1381, A1383, A1384, A1385, A1386, A1387, A1388, A1389, A1390, A1397, A1398, A1406, A1407, A1414, A1415, A1425, A1426, A1431, A1432, A1445, A1446, A1452, A1453, A1462, A1463, A1467, A1468, A1469, A1470, A1491, A1492, A1493, A1494, A1503, A1504, A1536, A1537, A1542, A1543, A1557, A1558, A1570, A1571, A1584, A1585, A1594, A1595, A1597, A1598, X6924, A1608, A1609, A1622, A1623, A1624, A1625, A1630, A1631, A1637, A1638, A1641, A1642, A1744, A1745, A1751, A1752, A1770, A1771, A1777, A1778, A1783, A1784, A1787, A1788, A1789, A1790, A1795, A1796, A1805, A1806, A1814, A1815, A1826, A1827, A1835, A1836, A1840, A1841, A1842, A1843, A1849, A1850, A1851, A1852, A1855, A1856, A1859, A1860, A1862, A1863, A1867, A1868, A1881, A1882, A1887, A1888, A1899, A1900, A1903, A1904, A1907, A1908, A1913, A1914, A1916, A1917, A1918, A1919, A1920, A1921, A1938, A1939, 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 to 01-Mar-2022

(continued on next page)

UPN #	UPN Description	GTIN	Batch	Expiration Date Range
FPRPR3603	IcePearl 2.1 CX Needle	07290104831010	A1564, A1521, A6723, A6908, A6929, A7015, T0025, T0056, T0137, T0138, T0269, U0041	08-Dec-2020 to 23-Nov-2021
FPRPR3604	IceFORCE 2.1 CX Needle	07290104831027	A1203, A1549, A6734, A6916, A6928, A6931, A7083, T0156, T0166, U0042	13-Oct-2020 to 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 to 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 to 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-Oct-2020 to 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 to 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 to 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 to 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