December 4, 2020

To whom it may concern,

Company: Japan Lifeline Co., Ltd.
Representative: Keisuke Suzuki, President and CEO
(Code: 7575 TSE 1st Section)
Contact person: Kenji Yamada, Senior Vice President,
Corporate Administration Headquarters
(TEL. +81-3-6711-5200)

Announcement on Recall (Patient Monitoring Class I) of S-ICDs

Regarding EMBLEM™ MRI S-ICD, a subcutaneous cardioverter defibrillator ("S-ICD") which Japan Lifeline Co., Ltd. ("the Company") sells, the Company announced today that Boston Scientific Japan K.K. ("Boston Scientific"), a market authorization holder of said product in Japan, has determined to conduct monitoring of patients[*1] implanted with S-ICDs.

The Company will cooperate with Boston Scientific and promptly implement measures. The Company sincerely apologizes for the inconvenience and concern this has caused implanted patients and medical professionals who deliver treatment.

[*1] The term patient monitoring refers to the observation of patients using a medical device, etc., without extracting it from the patient's body, typically conducted by the market authorization holder of the concerned product.

1. Patient monitoring outline

   Globally, six instances of damage to internal header parts due to electrical overstress related to delivery of defibrillation therapy in S-ICDs (events) have been identified. If this event occurs, it is possible that necessary therapy is not provided, and because it cannot be categorically denied the possibility of a serious health hazard, Boston Scientific has determined to request medical institutions to confirm treatment strategy as well as provide periodic follow-up to all patients implanted with S-ICD devices in which this event may possibly occur.

   It is expected that early S-ICD replacement would be necessary should the event occur, however, there has been no serious health events reported as of this time. In addition, all of the 102 units subject to patient monitoring in Japan have been identified. In cooperation with Boston Scientific, the Company has already requested all the target medical institutions to provide periodic follow-up to patients implanted with the target units. In addition, there is no danger of this event occurring in product currently in the market and no impacted devices are still available for future implants.

   For more detail, please refer to the attached press release by Boston Scientific "Notification regarding Monitoring of Patients with Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Class 1)" (A translation by the Company)

2. Impact on business performance

After careful examination, the Company will promptly disclose any material impact on business performance should there be any.

Attachment: Press release by Boston Scientific Japan (translation by the Company)

NOTICE: This document has been translated by the Company from the Japanese original for the reference purpose only. In the event of any discrepancy between this translated document and the Japanese original, the original shall prevail. The Company assumes no responsibility for this translation or for direct, indirect or any other forms of damages arising from the translation.

December 4, 2020

Notification regarding Monitoring of Patients with Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs)
(Class 1)

This is to inform you that Boston Scientific Japan will conduct monitoring (follow-up observation) of patients implanted with our subcutaneous implantable cardioverter defibrillator pulse generators (S-ICD).

The devices requiring monitoring have all been identified, and we promptly contacted medical institutions to request that they monitor patients implanted with said devices. While it is possible that early S-ICD replacement would be necessary should the event described in the Patient Monitoring Outline below occur, we note that no serious health events related to the described device behavior have been reported as of this time.

We apologize for the inconvenience and concern this has caused implanted patients and medical professionals who deliver treatment.

1. Patient Monitoring Outline:

Globally, six instances of damage to internal header parts due to electrical overstress related to delivery of defibrillation therapy in S-ICDs (events) have been identified. If this event occurs, it is possible that necessary therapy is not provided, and because we cannot categorically deny the possibility of a serious health hazard, we have requested medical institutions to confirm treatment strategy as well as provide periodic follow-up to all patients implanted with S-ICD devices in which this event may occur.

2. Name of the company conducting patient monitoring

1. Boston Scientific Japan
2. Address: 4-10-2 Nakano, Nakano-ku, Tokyo
3. Business Category: Type I Medical Device Manufacturer/Distributor
4. License: 13B1X00043

3. Description of Medical Device Subject to Patient Monitoring

1. Product Name: S-ICD Pulse Generator
2. Generic name: Automatic Implantable Cardioverter-Defibrillator
3. Approval Number: 22700BZX00132000
4. Country of Manufacture: USA

This device is an implantable cardioverter defibrillator (ICD), implanted in the body to treat ventricular tachycardias, providing atrial/ventricular and/or ventricular sensing and pacing as well as anti-

tachycardia pacing and defibrillation, and is used in patients who are at high risk of sudden cardiac death.

4. Targeted products for Patient Monitoring

1. Model Numbers:

Model：A209
Serial：

105118	107001	109935	110448	110930	111418	111532	111969	112133	112312
112429	112816	113015	114312	114700	116022	117494	117566	117603	117621
117662	117670	117672	117686	117698	117835	117836	117838	117932	118041
118187	118301	118373	118416	118420	118492	118493	118521	118545	118548
118624	118670	118674	118800	118985	119016	119093	119150	119176	119182
119194	119197	119206	119381	119600	119659	119666	120066		

Model：A219
Serial：

203403	203605	206007	206042	206409	206439	210763	210830	210845	211780
212093	214570	214599	214626	214627	214631	214633	214639	214643	214644
214646	214655	214685	214798	214873	215317	215365	215369	215391	215470
215483	215576	215692	215697	218076	218110	218140	218262	218370	218719
219404	219409	219675	219808						

2. Shipment period: January 27, 2016 through February 23, 2018
3. Number of products shipped: 102
4. Patient monitoring start date: December 3, 2020

5. Background

Globally, six instances of damage to internal header parts due to electrical overstress related to delivery of defibrillation therapy in S-ICDs (events) have been identified. Confirmation with the foreign manufacturing facility has confirmed that due to variations in headers built during a specific time frame, a very small pathway may develop in the header which allows moisture ingress, enabling a shorting condition to occur during delivery of high voltage therapy. If this event occurs, it is possible that necessary therapy is not provided, and because we cannot categorically deny that a serious health event may occur, we have requested medical institutions to confirm treatment strategy as well as provide periodic follow-up to all patients implanted with S-ICD devices in which this event may occur.

This event may occur in a subset of product manufactured between May 2015 and December 2017. There is no danger of this event occurring in product currently in the market and no impacted devices are still available for future implants. There have been no reports of this event occurring in Japan.

6. Possible Health Hazards

If this event occurs, the potential exists for life-threatening harm due to an inability to provide defibrillation therapy. This event would manifest clinically by the subsequent inability to interrogate the device using the programmer or the LATITUDE remote monitoring system or by display of device-based errors/alerts. In the six instances confirmed to date, Boston Scientific Technical Services recommended device replacement in

each instance, and no serious patient injury or death has been reported. There have been no reports of this event occurring in Japan.

7. Other

Boston Scientific Japan has confirmed all hospitals to which affected product has been shipped and is providing information regarding confirmation of treatment strategy and recommendations regarding patient management to these hospitals.

8. Contact information

Reiko Kawabata, Corporate Communications and Branding
Boston Scientific Japan
4-10-2 Nakano, Nakano-ku, Tokyo
Phone: 070-1446-2442
Email: reiko.kawabata@bsci.com

Atsushi Ikeda, Corporate Communications and Branding
Phone: 080-4207-8857
Email: atsushi.ikeda@bsci.com