M.I.Tech

Date: *April 2022*

URGENT FIELD SAFETY NOTICE (FSN)

RECALL OF CERTAIN M.I.TECH STENTS DUE TO MISSING CE MARK

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

Dear Valued Customer,

We, M.I.Tech, are conducting a Field Corrective Action concerning the certain EPBA stent products mentioned in the Table 1 "Products relevant for recall" of this letter.

Explanation of the issue

M.I.Tech is the legal manufacturer of metal stents for the Gastroenterology and Respiratory fields. According to our investigation, certain EPBA stent products (listed below), distributed in European market, have not undergone EU CE conformity assessment.

Material	Material Description	Lot Numbers
E0422292	EPBA-18-060-230	All lot numbers distributed since September 2020 Please refer to the table below.
E0422293	EPBA-18-080-230	
E0422294	EPBA-18-100-230	
E0422295	EPBA-18-120-230	
E0422296	EPBA-18-150-230	

Table 1: products relevant for recall

<Lot Numbers of EPBA stents relevant for product recall>

EPBA-18-060-230 14 units	EPBA-18-080-230 43 units	EPBA-18-100-230 23 units	EPBA-18-120-230 26 units	EPBA-18-150-230 17 units
20091349-1	20090454-1	20091350-1	20091351-1	21020873-1
20091349-2	20090454-2	20091350-2	20091351-2	21020873-2
21010696-1	20090454-3	20101209-1	21011107-1	21020873-3
21010696-2	20090454-4	20101209-2	21011107-2	21020873-4
21010696-3	20090455-1	20120457-1	21011107-3	21020874-1
21010696-4	20091233-1	21030091-1	21011107-4	21020874-2
21030089-1	20091233-2	21030091-2	21011108-1	21020874-3
21030821-1	20091233-3	21020841-1	21011108-2	21060503-1
21030821-2	20091233-4	21020841-2	21011108-3	21070347-1
21041129-1	20091233-5	21020841-3	21011108-4	21070347-2
22011045-1	20101208-1	21020841-4	21011109-1	21070347-3
21020117-1	20101208-2	21020842-1	21011109-2	21070347-4
21020117-2	20101208-3	21050567-1	21011109-3	21090734-1
21020117-3	20101208-4	21070345-1	21011109-4	21090734-2
	20120456-1	21070345-2	21011110-1	21091300-1
	21010664-1	21070345-3	21011436-1	21091300-2
	21010664-2	21070345-4	21011436-2	21091300-3

	21020855-1 21020855-2 21020855-3 21020855-4 21020856-1 21020856-2 21050562-1 21050562-2 21090693-1 21090693-2 21090693-3 21090693-4 21090694-1 21090694-2 21090694-3 21091319-1 21091319-2 21091370-1 21091370-2 21091370-3 21091370-4 21091371-1 21100561-1 21111388-1 22010942-1 22010942-2	21070346-1 21090683-1 21090683-2 21091368-1 21100549-1 22010810-1	21011436-3 21011436-4 21011437-1 21020115-1 21020115-2 21020115-3 21020115-4 21020116-1 21020116-2	

The Covered Esophagus (EPBA) Stent is used for application in palliative treatment of esophageal stricture and/or trachea-esophageal fistula caused by malignant tumors. The product consists of a stent and a delivery device, an accessory that is used to deliver and place the stent. The delivery device is not a permanent implant product. It goes through the endoscope channel and the patient contact area and time is very small.

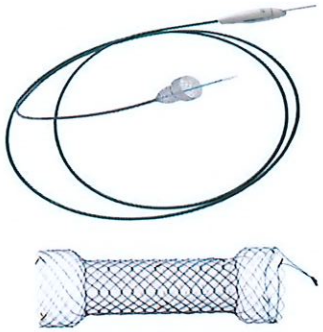

Figure 1: Delivery device and stent

There are various combinations of stents of different diameters and delivery devices of several lengths available for the European market and thus having the CE mark.

Unfortunately, the combination to which this recall is applicable is not CE marked. The reason is that this combination was originally not foreseen for the European market.

However, the stent itself is the same and the raw material of the delivery device is also the

same. There have been no clinical complaints or accident reports related to these products for 2 years.
Therefore, the possibility of clinical harm and risk for the patients is considered as very low

Investigation of the root cause of the issue is in progress. All devices have been identified.

Corrective Actions in progress:
Sales block has been implemented on M.I.Tech side. Product recall will be initiated.

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

Our primary objectives are patient safety and user safety. We are conscious to have undertaken a conservative approach to this issue, while issuing this FCA.

We trust your understanding and full support to our actions and apologize for the inconvenience this situation may cause to you and your clients.

Thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

We remain at your disposal for any further recommendation or request.

Yours faithfully

25 April, 2022

Chang-Hwon, Oh

Quality Management Representative