

Notice of Field Safety Corrective Action (FSCA)

26th August 2016

To whom may it concern,

M.I. Tech Co., Ltd. Is initiating a voluntarily recall of selected Esophagus STENT and TracheaBronchium STENT as follows device list.

Device List: See the attachment

1. Description of the Problem:

M.I.Tech Co., Ltd. is initiating a voluntary recall of selected HANAROSTENT products following defects found during an internal final releasing inspection. During the inspection we have noticed some longitudinal cracks in the outer-sheath on the delivery device. There have been no reports of any issues or problems that have been notified associated with the affected products, but we have decided to on-go with the voluntary recall for all products that have used the same batch of outer-sheath materials.

2. Potential Patient Risk:

If the faulty product is noticed before the procedure is taken place, the user will not be able to implant the stent, since the delivery device will not function properly. However if the crack of the delivery device ruptures during the procedure, the patient might have severe bleeding to the internal anatomy, and not limit to, and might need surgical operations to remove the device. If the listed device has already been used without any complications extra attention will not be necessary.

3. Action to be taken:

Although no report has been filed of the same issue mentioned above, the stent must be removed from end-users and institutions that can or will use the products. If the listed stents have not been used they must be returned immediately to our office or distributor to prevent any potential risk. Please communicate with your corresponding employee or quality control manager at M.I.Tech to the details of this voluntary recall protocol.

4. FSCA

1) Background information and reason for the recall:

During the final release inspection for the Esophagus stent, we found damage of outer sheath (6mm PTFE tube).

This kind of non-conformity is new and we proceeded comparison test with the outer sheath of this lot and the previous lot. We expect difference in the two different lots.

We had taken the risk analysis for the damage of outer sheath and we assumed that this non-conformity had a potential patient risk in which damage of outer sheath during the stent insertion procedure, it may cause bleeding or may need surgical operation.

Therefore we would like to voluntary recall all products using the same lot with damage one.

At present, we have not received any customer complaint related to outer sheath damage during/before stent insertion procedure or during final release inspection.

2) Description and justification of the action (corrective / preventive)

(1) Analysis of root case for the outer sheath damage

- a. Material: Compared to Lot used in previous, there may difference in a property of material
- b. Manufacturing process: The deviation was not found in manufacturing process
- c. Human: The worker didn't have the factors which may cause to damage of product during the manufacturing process on the site.
- d. Machine: The process compliance with the manual and there's no effect cause due to equipment.
- e. Stent: Stent ensured conformity to standard

(2) Corrective Action

- a. The entire lot of PTFE tube(6mm) used in deficiency outer sheath has been collected and isolated
- b. The entire lot of PTFE tube(6mm) used in deficiency outer sheath has been discontinued to release, attach label "DO NOT USE" and isolated.
- c. Request CAPA of PTFE tube supplier.

(3) Preventive Action

- a. Revise of SOP for the in-coming inspection process
- b. Training the inspectors and workers about the possibility of the product damage during the manufacturing process.
- c. Additional actions: Additional review expected regarding to CAPA from provider

3) Advice on action to be taken by the distributor and user

Requesting distributors to stop supplying products related to recall to customers and to collect them in separated warehouse. If they have already been supplied to customers, they must be requested not to be used but to be returned as soon as possible. If the products have been used without incidents, the products will be safe with patients so the patients will not be treated after.

4) Progress of FSCA, together with reconciliation date (Planning)

- (1) Requesting distributors not to use the products related to recall
(Sending letters to distributors): ~ 16-08-31
- (2) Counting and checking out product quantities which customers have used: ~ 16-09-02
- (3) Requesting distributors to return all products related to recall: ~ 16-09-09
- (4) Completion of product return: ~ 16-09-13
- (5) Investigation on all of returned products: ~ 16-09-23

(6) Discard of all of returned products: ~ 16-09-30

5) Time schedule for the implementation of the different action

- (1) PTFE tube supplier CAPA: ~ 16-09-30
- (2) Revise of incoming inspection SOP: ~ 16-09-09
- (3) Training the inspectors and workers: ~ 16-09-02
- (4) Investigation on all of internally collected products with M.I.Tech: ~ 16-09-09
- (5) Discard of all of internally collected products with M.I.Tech: ~ 16-09-30

Sung-Gun Kim

Quality Manager

M. I. Tech Co., Ltd

26th August 2016

[Attachment] Device List

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
1	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16050256	1	2016-05-20	France
2	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16050257	1	2016-05-20	
3	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16050212	3	2016-05-20	
4	NES-18-170-070	HANAROSTENT® Esophagus BS (CCC)	16050213	1	2016-05-20	
5	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16050214	1	2016-05-20	
6	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16050220	1	2016-05-20	
7	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16050221	4	2016-05-20	
8	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16050222	2	2016-05-20	
9	NTS-14-060-090	HANAROSTENT® TracheaBronchium (CCC)	16050528	2	2016-06-01	
10	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16050490	4	2016-06-01	
11	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050491	4	2016-06-01	
12	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050492	1	2016-06-01	
13	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16050493	2	2016-06-01	
14	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16050500	2	2016-06-01	
15	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16050501	1	2016-06-01	
16	NTS-14-040-090	HANAROSTENT® TracheaBronchium (CCC)	16050722	1	2016-06-07	
17	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16050681	4	2016-06-07	
18	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16050682	4	2016-06-07	
19	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16050683	1	2016-06-07	
20	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16050684	4	2016-06-07	
21	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16050685	4	2016-06-07	
22	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050686	4	2016-06-07	
23	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050687	4	2016-06-07	
24	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050688	4	2016-06-07	
25	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050689	1	2016-06-07	
26	NES-18-170-070	HANAROSTENT® Esophagus BS (CCC)	16050690	1	2016-06-07	
27	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16050691	4	2016-06-07	
28	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16050699	4	2016-06-07	
29	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16050700	3	2016-06-07	
30	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16050701	4	2016-06-07	
31	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16050702	3	2016-06-07	
32	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16050939	4	2016-06-14	
33	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16050940	4	2016-06-14	
34	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16050941	1	2016-06-14	
35	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16050942	3	2016-06-14	

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
37	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050944	4	2016-06-14	France
38	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050945	1	2016-06-14	
39	NES-18-170-070	HANAROSTENT® Esophagus BS (CCC)	16050946	4	2016-06-14	
40	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16050955	4	2016-06-14	
41	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16050956	4	2016-06-14	
42	NTS-14-040-090	HANAROSTENT® TracheaBronchium (CCC)	16060200	2	2016-06-22	
43	NTS-16-060-090	HANAROSTENT® TracheaBronchium (CCC)	16060201	1	2016-06-22	
44	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060164	3	2016-06-22	
45	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060165	4	2016-06-22	
46	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060166	3	2016-06-22	
47	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060172	4	2016-06-22	
48	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060173	3	2016-06-22	
49	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060174	4	2016-06-22	
50	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060175	4	2016-06-22	
51	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16060619	1	2016-06-24	
52	NTS-14-040-090	HANAROSTENT® TracheaBronchium (CCC)	16060446	1	2016-06-30	
53	NTS-16-040-090	HANAROSTENT® TracheaBronchium (CCC)	16060447	1	2016-06-30	
54	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060391	4	2016-06-30	
55	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060392	4	2016-06-30	
56	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060393	4	2016-06-30	
57	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060394	4	2016-06-30	
58	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060395	4	2016-06-30	
59	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060396	4	2016-06-30	
60	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060397	4	2016-06-30	
61	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060398	3	2016-06-30	
62	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16060399	4	2016-06-30	
63	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16060411	4	2016-06-30	
64	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16060412	3	2016-06-30	
65	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060413	4	2016-06-30	
66	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060414	4	2016-06-30	
67	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060415	1	2016-06-30	
68	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060622	4	2016-07-11	
69	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060626	4	2016-07-11	
70	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060627	4	2016-07-11	
71	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060628	2	2016-07-11	
72	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16060629	3	2016-07-11	
73	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060623	4	2016-07-11	

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
74	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16060624	2	2016-07-11	France
75	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16060625	4	2016-07-11	
76	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16060630	1	2016-07-11	
77	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16060631	1	2016-07-11	
78	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16060641	4	2016-07-11	
79	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16060642	4	2016-07-11	
80	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16060643	2	2016-07-11	
81	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060644	4	2016-07-11	
82	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16060645	1	2016-07-11	
83	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16050836	4	2016-07-12	
84	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16060853	1	2016-07-12	
85	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16060856	3	2016-07-12	
86	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16050837	4	2016-07-19	
87	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070074	4	2016-07-19	
88	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070079	3	2016-07-19	
89	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070080	4	2016-07-19	
90	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070081	1	2016-07-19	
91	NES-18-170-070	HANAROSTENT® Esophagus BS (CCC)	16070082	1	2016-07-19	
92	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070083	4	2016-07-19	
93	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070084	3	2016-07-19	
94	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050840	4	2016-07-25	
95	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16050841	4	2016-07-25	
96	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070235	4	2016-07-25	
97	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070236	4	2016-07-25	
98	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070237	4	2016-07-25	
99	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070238	4	2016-07-25	
100	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070243	4	2016-07-25	
101	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070244	4	2016-07-25	
102	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070245	4	2016-07-25	
103	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070246	4	2016-07-25	
104	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070247	3	2016-07-25	
105	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070248	4	2016-07-25	
106	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070249	4	2016-07-25	
107	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070250	4	2016-07-25	
108	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070251	4	2016-07-25	
109	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070252	1	2016-07-25	

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
110	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16070253	4	2016-07-25	France
111	NES-18-170-070	HANAROSTENT® Esophagus BS (CCC)	16070254	3	2016-07-25	
112	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070255	2	2016-07-25	
113	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070256	4	2016-07-25	
114	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070257	4	2016-07-25	
115	NTS-14-040-090	HANAROSTENT® TracheaBronchium (CCC)	16070506	1	2016-08-01	
116	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070512	4	2016-08-01	
117	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070513	4	2016-08-01	
118	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070514	1	2016-08-01	
119	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16070515	4	2016-08-01	
120	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070533	2	2016-08-01	
121	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070534	2	2016-08-01	
122	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070523	4	2016-08-01	
123	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070524	4	2016-08-01	
124	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070525	2	2016-08-01	
125	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070526	4	2016-08-01	
126	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070527	4	2016-08-01	
127	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070528	3	2016-08-01	
128	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16070529	4	2016-08-01	
129	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16070530	4	2016-08-01	
130	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16070531	2	2016-08-01	
131	NES-18-170-070	HANAROSTENT® Esophagus BS (CCC)	16070532	3	2016-08-01	
110	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16070253	4	2016-07-25	
111	NES-18-170-070	HANAROSTENT® Esophagus BS (CCC)	16070254	3	2016-07-25	
112	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070255	2	2016-07-25	
113	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070256	4	2016-07-25	
114	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070257	4	2016-07-25	
115	NTS-14-040-090	HANAROSTENT® TracheaBronchium (CCC)	16070506	1	2016-08-01	
116	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070512	4	2016-08-01	
117	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070513	4	2016-08-01	
118	EPW-20-100-070	HANAROSTENT Esophagus BS (NCN)	16070514	1	2016-08-01	
119	EPW-20-150-070	HANAROSTENT Esophagus BS (NCN)	16070515	4	2016-08-01	
120	NESA-18-090-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070533	2	2016-08-01	
121	NESA-18-110-070	HANAROSTENT® Esophagus Asymmetric (CCC)	16070534	2	2016-08-01	
122	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070523	4	2016-08-01	

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
123	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070524	4	2016-08-01	France
124	NES-18-080-070	HANAROSTENT® Esophagus BS (CCC)	16070525	2	2016-08-01	
125	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070526	4	2016-08-01	
126	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070527	4	2016-08-01	
127	NES-18-110-070	HANAROSTENT® Esophagus BS (CCC)	16070528	3	2016-08-01	
128	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16070529	4	2016-08-01	
129	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16070530	4	2016-08-01	
130	NES-18-140-070	HANAROSTENT® Esophagus BS (CCC)	16070531	2	2016-08-01	
131	NES-18-170-070	HANAROSTENT® Esophagus BS (CCC)	16070532	3	2016-08-01	
132	MECE1812X	CHOOSTENT® Esophagus (CCC)	16045035	4	2016-06-09	
133	MECE1812X	CHOOSTENT® Esophagus (CCC)	16045036	4	2016-06-09	
134	MECE1812X	CHOOSTENT® Esophagus (CCC)	16045037	2	2016-06-09	
135	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045023	4	2016-06-09	
136	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045024	4	2016-06-09	
137	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045025	4	2016-06-09	
138	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045026	4	2016-06-09	
139	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045027	4	2016-06-09	
140	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045028	4	2016-06-09	
141	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045029	4	2016-06-09	
142	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045030	4	2016-06-09	
143	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045031	4	2016-06-09	
144	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045032	4	2016-06-09	
145	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045033	4	2016-06-09	
146	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045034	1	2016-06-09	
147	MECJ1810X	CHOOSTENT® Esophagus Upper (CCC)	16045038	3	2016-06-09	
132	MECE1812X	CHOOSTENT® Esophagus (CCC)	16045035	4	2016-06-09	
133	MECE1812X	CHOOSTENT® Esophagus (CCC)	16045036	4	2016-06-09	
134	MECE1812X	CHOOSTENT® Esophagus (CCC)	16045037	2	2016-06-09	
135	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045023	4	2016-06-09	
136	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045024	4	2016-06-09	
137	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045025	4	2016-06-09	
138	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045026	4	2016-06-09	
139	MECE1808X	CHOOSTENT® Esophagus (CCC)	16045027	4	2016-06-09	
140	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045028	4	2016-06-09	
141	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045029	4	2016-06-09	
142	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045030	4	2016-06-09	
143	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045031	4	2016-06-09	

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
144	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045032	4	2016-06-09	Japan
145	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045033	4	2016-06-09	
146	MECE1810X	CHOOSTENT® Esophagus (CCC)	16045034	1	2016-06-09	
147	MECJ1810X	CHOOSTENT® Esophagus Upper (CCC)	16045038	3	2016-06-09	
148	MECE1808X	CHOOSTENT® Esophagus (CCC)	16055004	4	2016-07-06	
149	MECE1808X	CHOOSTENT® Esophagus (CCC)	16055005	4	2016-07-06	
150	MECE1808X	CHOOSTENT® Esophagus (CCC)	16055006	4	2016-07-06	
151	MECE1808X	CHOOSTENT® Esophagus (CCC)	16055007	4	2016-07-06	
152	MECE1808X	CHOOSTENT® Esophagus (CCC)	16055008	4	2016-07-06	
153	MECE1808X	CHOOSTENT® Esophagus (CCC)	16055009	4	2016-07-06	
154	MECE1810X	CHOOSTENT® Esophagus (CCC)	16055010	4	2016-07-06	
155	MECE1810X	CHOOSTENT® Esophagus (CCC)	16055011	4	2016-07-06	
156	MECE1810X	CHOOSTENT® Esophagus (CCC)	16055012	4	2016-07-06	
157	MECE1810X	CHOOSTENT® Esophagus (CCC)	16055013	4	2016-07-06	
158	MECE1812X	CHOOSTENT® Esophagus (CCC)	16055014	4	2016-07-06	
159	MECE1812X	CHOOSTENT® Esophagus (CCC)	16055015	4	2016-07-06	
160	MECE1812X	CHOOSTENT® Esophagus (CCC)	16055016	4	2016-07-06	
161	MECB1810X	HANAROSTENT® Esophagus (CCC)	16055001	3	2016-07-06	
162	ECP18060-X070	HANAROSTENT® Esophagus Upper (CCC)	16050096	1	2016-05-25	Germany
163	ECP18080-X070	HANAROSTENT® Esophagus Upper (CCC)	16050097	2	2016-05-25	
164	ECP18100-X070	HANAROSTENT® Esophagus Upper (CCC)	16050098	2	2016-05-25	
165	ECP18150-X070	HANAROSTENT® Esophagus Upper (CCC)	16050099	1	2016-05-25	
166	EPB18110-X070	HANAROSTENT® Esophagus (NCN)	16050100	4	2016-05-25	
167	EPB18140-X070	HANAROSTENT® Esophagus (NCN)	16050101	4	2016-05-25	
168	EPB18170-X070	HANAROSTENT® Esophagus (NCN)	16050102	2	2016-05-25	
169	HES-18-080-070	HANAROSTENT® Esophagus (CCC)	16050106	2	2016-05-25	
170	HES-18-110-070	HANAROSTENT® Esophagus (CCC)	16050107	3	2016-05-25	
171	HES-18-170-070	HANAROSTENT® Esophagus (CCC)	16050108	2	2016-05-25	
172	HES-18-180-070	HANAROSTENT® Esophagus (CCC)	16050109	1	2016-05-25	
173	HES-18-080-070	HANAROSTENT® Esophagus (CCC)	16060315	2	2016-06-24	
174	HES-18-110-070	HANAROSTENT® Esophagus (CCC)	16060316	4	2016-06-24	
175	HES-18-110-070	HANAROSTENT® Esophagus (CCC)	16060317	4	2016-06-24	
176	HES-18-110-070	HANAROSTENT® Esophagus (CCC)	16060318	4	2016-06-24	
177	HES-18-140-070	HANAROSTENT® Esophagus (CCC)	16060319	4	2016-06-24	
178	HES-18-140-070	HANAROSTENT® Esophagus (CCC)	16060320	4	2016-06-24	
179	ECP18100-X070	HANAROSTENT® Esophagus Upper (CCC)	16060304	2	2016-06-24	
180	ECP18150-X070	HANAROSTENT® Esophagus Upper (CCC)	16060305	2	2016-06-24	

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
181	ECP18170-X070	HANAROSTENT® Esophagus Upper (CCC)	16060306	2	2016-06-24	Germany
182	EPB18080-X070	HANAROSTENT® Esophagus (NCN)	16060307	2	2016-06-24	
183	EPB18110-X070	HANAROSTENT® Esophagus (NCN)	16060308	4	2016-06-24	
184	EPB18170-X070	HANAROSTENT® Esophagus (NCN)	16060309	1	2016-06-24	
185	ECP18100-X070	HANAROSTENT® Esophagus Upper (CCC)	16060878	2	2016-07-15	
186	EPB18110-X070	HANAROSTENT® Esophagus (NCN)	16060879	1	2016-07-15	
187	HES-18-080-070	HANAROSTENT® Esophagus (CCC)	16060885	4	2016-07-15	
188	HES-18-110-070	HANAROSTENT® Esophagus (CCC)	16060886	1	2016-07-15	
189	HES-18-170-070	HANAROSTENT® Esophagus (CCC)	16060887	1	2016-07-15	
190	ECP18100-X070	HANAROSTENT® Esophagus Upper (CCC)	16070311	2	2016-07-22	
191	HES-18-110-070	HANAROSTENT® Esophagus (CCC)	16070315	2	2016-07-22	
192	HES-18-140-070	HANAROSTENT® Esophagus (CCC)	16070316	4	2016-07-22	
193	HES-18-170-070	HANAROSTENT® Esophagus (CCC)	16070317	2	2016-07-22	
194	ECP18100-X070	HANAROSTENT® Esophagus Upper (CCC)	16070730	2	2016-08-12	
195	ECP18150-X070	HANAROSTENT® Esophagus Upper (CCC)	16070731	3	2016-08-12	
196	ECP18170-X070	HANAROSTENT® Esophagus Upper (CCC)	16070732	2	2016-08-12	
197	EPB18110-X070	HANAROSTENT® Esophagus (NCN)	16070733	3	2016-08-12	
198	EPB18140-X070	HANAROSTENT® Esophagus (NCN)	16070734	1	2016-08-12	
199	HES-18-060-070	HANAROSTENT® Esophagus (CCC)	16070737	1	2016-08-12	
200	HES-18-080-070	HANAROSTENT® Esophagus (CCC)	16070738	2	2016-08-12	
201	HES-18-110-070	HANAROSTENT® Esophagus (CCC)	16070739	3	2016-08-12	
202	NES-18-060-070	CHOOSTENT® Esophagus (CCC)	16050382	2	2016-05-30	China
203	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16050383	4	2016-05-30	
204	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16050384	4	2016-05-30	
205	NES-18-140-070	CHOOSTENT® Esophagus (CCC)	16050385	2	2016-05-30	
206	NES-20-140-070	CHOOSTENT® Esophagus (CCC)	16050392	2	2016-05-30	
207	NES-20-100-070	CHOOSTENT® Esophagus (CCC)	16050394	4	2016-05-30	
208	NES-20-080-070	CHOOSTENT® Esophagus (CCC)	16050386	4	2016-05-30	
209	NES-20-080-070	CHOOSTENT® Esophagus (CCC)	16050387	4	2016-05-30	
210	NES-20-100-070	CHOOSTENT® Esophagus (CCC)	16050388	4	2016-05-30	
211	NES-20-100-070	CHOOSTENT® Esophagus (CCC)	16050389	4	2016-05-30	
212	NES-20-120-070	CHOOSTENT® Esophagus (CCC)	16050390	4	2016-05-30	
213	NES-20-120-070	CHOOSTENT® Esophagus (CCC)	16050391	4	2016-05-30	
214	NES-18-060-070	CHOOSTENT® Esophagus (CCC)	16060572	2	2016-06-30	
215	NES-18-080-070	CHOOSTENT® Esophagus (CCC)	16060573	4	2016-06-30	
216	NES-18-080-070	CHOOSTENT® Esophagus (CCC)	16060574	2	2016-06-30	
217	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16060575	4	2016-06-30	

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
218	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16060576	4	2016-06-30	Germany
219	NES-18-140-070	CHOOSTENT® Esophagus (CCC)	16060577	2	2016-06-30	
220	NES-20-080-070	CHOOSTENT® Esophagus (CCC)	16060578	4	2016-06-30	
221	NES-20-080-070	CHOOSTENT® Esophagus (CCC)	16060579	4	2016-06-30	
222	NES-20-100-070	CHOOSTENT® Esophagus (CCC)	16060580	4	2016-06-30	
223	NES-20-100-070	CHOOSTENT® Esophagus (CCC)	16060581	4	2016-06-30	
224	NES-20-120-070	CHOOSTENT® Esophagus (CCC)	16060582	4	2016-06-30	
225	NES-20-100-070	CHOOSTENT® Esophagus (CCC)	16060583	4	2016-06-30	
226	NES-20-140-070	CHOOSTENT® Esophagus (CCC)	16060584	2	2016-06-30	
227	NES-18-140-070	CHOOSTENT® Esophagus (CCC)	16050010	1	2016-06-03	
228	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16050585	1	2016-06-14	
229	NES-18-140-070	CHOOSTENT® Esophagus (CCC)	16050010	1	2016-06-14	
230	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16050585	1	2016-06-21	
231	NES-18-080-070	CHOOSTENT® Esophagus (CCC)	16050583	1	2016-06-27	
232	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16050605	1	2016-06-27	
233	NES-20-180-070	CHOOSTENT® Esophagus (CCC)	16060499	1	2016-06-27	
234	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16050585	1	2016-06-28	
235	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16050605	1	2016-06-30	
236	NES-18-060-070	CHOOSTENT® Esophagus (CCC)	16050463	1	2016-07-04	
237	NES-18-080-070	CHOOSTENT® Esophagus (CCC)	16050583	1	2016-07-04	
238	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16050827	1	2016-07-06	
239	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16050658	1	2016-07-06	
240	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16060526	1	2016-07-06	
241	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16060792	1	2016-07-11	
242	NES-18-080-070	CHOOSTENT® Esophagus (CCC)	16050927	1	2016-07-13	
243	NES-18-120-070	CHOOSTENT® Esophagus (CCC)	16060938	1	2016-07-25	
244	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16050827	1	2016-07-27	
245	NES-18-080-070	CHOOSTENT® Esophagus (CCC)	16060069	1	2016-07-28	
246	NES-18-140-070	CHOOSTENT® Esophagus (CCC)	16060070	1	2016-07-28	
247	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16050926	1	2016-08-02	
248	NES-18-080-070	CHOOSTENT® Esophagus (CCC)	16060515	1	2016-08-08	
249	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16051005	1	2016-08-08	
250	NES-18-100-070	CHOOSTENT® Esophagus (CCC)	16051005	1	2016-08-10	
251	NES-18-080-070	CHOOSTENT® Esophagus (CCC)	16060724	1	2016-08-11	
252	NES-20-140-070	CHOOSTENT® Esophagus (CCC)	16050200	4	2016-05-23	India
253	NES-20-140-070	CHOOSTENT® Esophagus (CCC)	16050201	4	2016-05-23	
254	NES-20-140-070	CHOOSTENT® Esophagus (CCC)	16050202	2	2016-05-23	

No.	REF. No.	Device Description	Lot. #	Qty's	Released Date	Remark
255	EPE18110-X070	CHOOSTENT® Esophagus (NCN)	16050203	4	2016-05-23	India
256	EPE18110-X070	CHOOSTENT® Esophagus (NCN)	16050204	4	2016-05-23	
257	EPE18110-X070	CHOOSTENT® Esophagus (NCN)	16050205	2	2016-05-23	
258	EPE20140-X070	CHOOSTENT® Esophagus (NCN)	16050210	4	2016-05-23	
259	EPE20140-X070	CHOOSTENT® Esophagus (NCN)	16050211	2	2016-05-23	
260	NES-20-110-070	CHOOSTENT® Esophagus (CCC)	16060977	4	2016-05-23	
261	NES-20-110-070	CHOOSTENT® Esophagus (CCC)	16060978	1	2016-05-23	
262	NES-20-140-070	CHOOSTENT® Esophagus (CCC)	16060979	4	2016-05-23	
263	NES-20-140-070	CHOOSTENT® Esophagus (CCC)	16060980	1	2016-05-23	
264	EPE18110-X070	CHOOSTENT® Esophagus (NCN)	16060984	3	2016-05-23	
265	ECD-20-080-070	HANAROSTENT® Esophagus Skidproof (CCC)	16050785	1	2016-06-03	Lithuania
266	ECD-20-100-070	HANAROSTENT® Esophagus Skidproof (CCC)	16050786	4	2016-06-03	
267	ECD-20-100-070	HANAROSTENT® Esophagus Skidproof (CCC)	16050787	4	2016-06-03	
268	ECD-20-120-070	HANAROSTENT® Esophagus Skidproof (CCC)	16050788	2	2016-06-03	
269	HES-18-080-070	HANAROSTENT® Esophagus (CCC)	16050790	1	2016-06-03	
270	HES-18-110-070	HANAROSTENT® Esophagus (CCC)	16050791	2	2016-06-03	
271	HES-18-080-070	HANAROSTENT® Esophagus (CCC)	16070138	1	2016-07-19	
272	NTS-12-030-090	HANAROSTENT® TracheaBronchium (CCC)	16050374	1	2016-05-27	Canada
273	NTS-16-080-090	HANAROSTENT® TracheaBronchium (CCC)	16050936	1	2016-06-13	
274	NTS-10-040-090	HANAROSTENT® TracheaBronchium (CCC)	16060160	1	2016-06-17	
275	NESC-18-120-070	CHOOSTENT® Esophagus Upper (CCC)	16060021	2	2016-06-17	
276	HES-18-080-070	HANAROSTENT® Esophagus (CCC)	16060025	2	2016-06-17	
277	EPE18140-X070	CHOOSTENT® Esophagus (NCN)	16060783	1	2016-06-30	
278	NES-18-170-070	CHOOSTENT® Esophagus (CCC)	16060922	1	2016-07-11	
279	HES-18-080-070	HANAROSTENT® Esophagus (CCC)	16060923	1	2016-07-11	
280	NES-20-110-070	CHOOSTENT® Esophagus (CCC)	16070967	1	2016-08-12	
281	NTS-10-030-090	HANAROSTENT® TracheaBronchium (CCC)	16070211	2	2016-07-20	
282	NTS-12-030-090	HANAROSTENT® TracheaBronchium (CCC)	16070212	2	2016-07-20	Russia
283	HES-18-100-070	HANAROSTENT® Esophagus (CCC)	16070370	3	2016-07-27	
284	HES-18-120-070	HANAROSTENT® Esophagus (CCC)	16070371	2	2016-07-27	
285	HES-18-140-070	HANAROSTENT® Esophagus (CCC)	16070372	2	2016-07-27	
286	HES-18-160-070	HANAROSTENT® Esophagus (CCC)	16070373	1	2016-07-27	
287	NTS-16-060-050	HANAROSTENT® TracheaBronchium (CCC)	16060906	1	2016-07-07	Brazil
288	NESC-18-080-070	CHOOSTENT® Esophagus Upper (CCC)	16070023	4	2016-07-18	
289	NESC-18-080-070	CHOOSTENT® Esophagus Upper (CCC)	16070024	1	2016-07-18	
290	NESC-18-100-070	CHOOSTENT® Esophagus Upper (CCC)	16070025	1	2016-07-18	
291	NESC-18-120-070	CHOOSTENT® Esophagus Upper (CCC)	16070026	2	2016-07-18	

No.	REF. No.	Device Description	Lot. #	Qty's	Realesed Date	Remark
292	EPB18140-X070	HANAROSTENT® Esophagus (NCN)	16050888	3	2016-06-14	Turkey
293	HES-18-060-070	HANAROSTENT® Esophagus (CCC)	16050904	3	2016-06-14	
294	HES-18-050-070	HANAROSTENT® Esophagus (CCC)	16050905	1	2016-06-14	
295	ECD-20-080-070	HANAROSTENT® Esophagus Skidproof(CCC)	16070789	4	2016-08-11	Saudi Arabia
296	NESA-18-110-070	CHOOSTENT® Esophagus Asymmetric (CCC)	16060090	1	2016-06-20	Bangladesh
297	EPB18140-X070	HANAROSTENT® Esophagus (NCN)	16060092	2	2016-06-20	
298	EPB18110-X070	HANAROSTENT® Esophagus (NCN)	16060709	1	2016-07-27	Lebanon
299	ECP18120-X070	HANAROSTENT® Esophagus Upper (CCC)	16050755	1	2016-06-03	Chile