



Jan. 27, 2017

**OFFICIAL PRODUCT RECALL**

Dear Sir or Madam,

With this letter, we inform you that we unfortunately have to initiate a recall of our product, and **immediately stop of using the involved Lot numbers.**

The affected devices, is sold in extremely low numbers. Unfortunately, SP Medical A/S have not provided their Notified Body with a change notification when a minor design modification was implemented.

Enclosed you will find a list of all the involved Item numbers and Lots. This action includes all these devices and Lots.

Please check your stock and quarantine all remaining available devices.

Please do also inform your customer and make their attention on the **immediately stop of using the involved Lot numbers.**

Please return these to:

SP Medical A/S  
Møllevej 1  
4653 Karise,  
Denmark  
Att. Corporate Quality Manager  
Karen-Marie Dahlmoes

Best Regards  
Corporate Quality Manager, SP Medical A/S  
Karen-Marie Dahlmoes


Managing Director  
Kenny Rosendahl, SP Medical A/S

**SP Medical A/S**


Møllevej 1  
DK-4653 Karise

Tel. + 45 5676 6000  
Fax + 45 5676 6001

List over all sterile Accoat guide wires (with long flexible tip) delivered from SP Medical A/S in own CE-mark

Product REF:	LOT no.
J3-T100-C-035-150	27672
H-X-X-J3-T120-C-032-400	27669
H-X-X-S-T120-C-035-150	#18937
H-X-X-S-T120-C-035-150	26603
	27765
H-X-X-J3-T120-C-035-150	#18938
	27766
H-J3-T100-C-035-150	27574
H-X-X-S-T120-C-035-180	#18739
	#19103
	21447
	23577
H-X-J1.5-T120-C-035-180	21319
H-X-X-J3-T130-C-035-180	#18312
	#19479
	23578
	26605
	27733
	29478
H-X-X-J3-T120-C-035-180	21448
H-X-X-S-T120-C-035-260	#18740
	21449
	23579
	26606
H-X-X-J3-T120-C-035-260	#18813
	21450
	22266
	23014
	23831
	24364
	28206
	29149
H-X-X-J3-T120-C-035-260	23580
	26607
	27432
	27731
H-X-X-J3-T120-C-035-400	27518
	26741
	20865
H-X-X-S-T120-C-038-150	21231
	21446
SP Medical A/S Autor: 	
Date: 2017.01.27	

List over all sterile Bentson guide wires delivered from SP Medical A/S in own CE-mark

Product REF:	LOT no.
B-S-C-035-150-01	#16057
	#19325
	#18387
	#19487
	23260
	25737
	23429
	26176
B-S-C-035-180-01	#16058
	#17526
B-S-C-035-260-01	23451
	24279
	25146
B-S-C-035-300-01	#20371
	21236
	21504
B-J3-C-035-150-01	23450
	26177
SP Medical A/S Autor: 	
Date: 2017.01.27	