

«Hospital\_Name»  
«Users\_Name»- «Department»  
«Customer\_Address»  
«Zip\_Code» «City» - «Country\_name»

Reference: 90461367-FA

December xx, 2008

## Field Safety Notice

### Urgent Medical Device Recall

### RF Ablation™ System Foot Switch

Dear «Users\_Name»,

Boston Scientific is initiating a recall of select **RF Ablation™ System Foot Switches** used with the Maestro 3000 Controller and the EPT-1000XP Controller. During the investigation of a returned device related to a customer complaint, we discovered a short in the foot switch connector. If there is a short in the foot switch connector, it is possible that delivery of RF energy can begin without depressing the foot switch. If the ablation catheter has already been placed inside the patient, there is the potential to inadvertently ablate tissue in the heart or the vasculature, which may cause bleeding and possibly perforate the heart tissue, which may lead to tamponade. Although there have been no reported injuries to date, Boston Scientific has received 4 complaints in association with this product issue.

Please note that the Boston Scientific RF Cardiac Ablation Systems may be operated without the use of a foot switch. Please refer to the Operator's Manuals for details.

Our records indicate that your facility received some of the affected product. The **Attachment** provides:

- on page 1: **instructions for determining if you have product affected** by this recall
- on page 2: a **complete list of all recalled products**, including Product Description, Material number, Catalog number and Batch / Serial numbers.

Please note that only the product with Serial Numbers listed in the Attachment are affected. No other Boston Scientific product is involved in this voluntary recall.

You will receive replacement product for all recalled product returned to Boston Scientific.

**INSTRUCTIONS:**

1. **Please immediately discontinue use of the Boston Scientific product listed in Attachment and remove all of the affected units from your inventory** (whether in EP/Cath Lab., Radiology, Fluoroscopy Suite, Interventional Operating Room, Central Supply, Shipping & Receiving and any other relevant location). **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 fax the Verification Form to your local Boston Scientific Customer Service** to the attention of «Customer\_Service\_Fax\_Number» on or before **January XX, 2008.**
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 Customer Service, to arrange return.**
5. Please pass this notice to any health professional of your organization that need 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 take action 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,

Quality Department  
Boston Scientific International S.A.

**Attachments:** - Verification Form  
- Instructions for Determining Affected Product  
- List of Product Subject to Recall

**Urgent Medical Device Recall - RF Ablation™ System Foot Switch  
(90461367-FA)  
ATTACHMENT**

**INSTRUCTIONS FOR DETERMINING AFFECTED PRODUCT**

Below is a photograph depicting the labels for products that are subject to this recall. Foot switches containing labels that are different from the example below are not part of this recall and may continue to be used. If you have difficulty reading the foot switch label, return the foot switch to Boston Scientific.

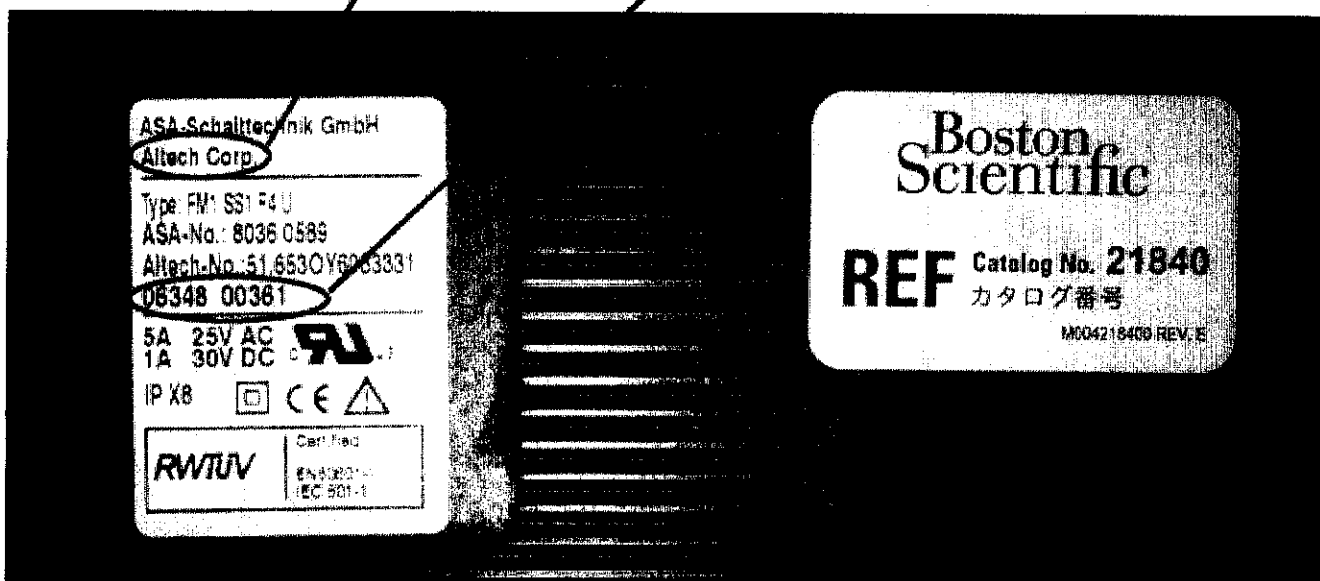
**This label is located on the bottom of the unit.**

Foot switches that contain labels from Altech Corp. shown below are subject to this recall if the first five digits of the serial number are 07064 or lower.

As an example, included in the recall: 06348 00361 (pictured below) would be included in the recall and should be returned.

**Altech Corp.**

**Serial Number**



Note: We have included a listing of the UPN/Models/serial numbers of the affected foot switches as further information to assist you. If your serial number appears on the listing, it is included in the recall.

Please contact your Sales Representative with any questions regarding the recall.

## LISTING OF PRODUCTS SUBJECT TO RECALL

UPN	Catalog #	Product Description
<b>M004218400</b>	<b>21840</b>	<b>RF Ablation™ System Foot Switch</b>

Batch / Serial Numbers								
0430200001	0530100046	0610000091	0620200136	0626500181	0629900226	0629900271	0629900316	0634800361
0430200002	0530100047	0610000092	0620200137	0626500182	0629900227	0629900272	0629900317	0634800362
0430200003	0530100048	0610000093	0620200138	0626500183	0629900228	0629900273	0629900318	0634800363
0430200004	0530100049	0610000094	0620200139	0626500184	0629900229	0629900274	0629900319	0634800364
0430200005	0530100050	0610000095	0620200140	0626500185	0629900230	0629900275	0629900320	0634800365
0530100006	0530100051	0610000096	0620200141	0626500186	0629900231	0629900276	0629900321	0634800366
0530100007	0530100052	0610000097	0620200142	0626500187	0629900232	0629900277	0629900322	0634800367
0530100008	0530100053	0610000098	0620200143	0626500188	0629900233	0629900278	0629900323	0634800368
0530100009	0530100054	0610000099	0620200144	0626500189	0629900234	0629900279	0629900324	0634800369
0530100010	0530100055	0610000100	0620200145	0626500190	0629900235	0629900280	0629900325	0634800370
0530100011	0606100056	0610000101	0620200146	0626500191	0629900236	0629900281	0629900326	0634800371
0530100012	0606100057	0610000102	0620200147	0626500192	0629900237	0629900282	0629900327	0634800372
0530100013	0606100058	0610000103	0620200148	0626500193	0629900238	0629900283	0629900328	0634800373
0530100014	0606100059	0610000104	0620200149	0626500194	0629900239	0629900284	0629900329	0634800374
0530100015	0606100060	0610000105	0620200150	0626500195	0629900240	0629900285	0629900330	0634800375
0530100016	0606100061	0620200106	0620200151	0626500196	0629900241	0629900286	0629900331	0634800376
0530100017	0606100062	0620200107	0620200152	0626500197	0629900242	0629900287	0629900332	0634800377
0530100018	0606100063	0620200108	0620200153	0626500198	0629900243	0629900288	0629900333	0634800378
0530100019	0606100064	0620200109	0620200154	0626500199	0629900244	0629900289	0629900334	0634800379
0530100020	0606100065	0620200110	0620200155	0626500200	0629900245	0629900290	0629900335	0634800380
0530100021	0606100066	0620200111	0623700156	0626500201	0629900246	0629900291	0629900336	0634800381
0530100022	0606100067	0620200112	0623700157	0626500202	0629900247	0629900292	0629900337	0634800382
0530100023	0606100068	0620200113	0623700158	0626500203	0629900248	0629900293	0629900338	0634800383
0530100024	0606100069	0620200114	0623700159	0626500204	0629900249	0629900294	0629900339	0634800384
0530100025	0606100070	0620200115	0623700160	0626500205	0629900250	0629900295	0629900340	0634800385
0530100026	0606100071	0620200116	0623700161	0629900206	0629900251	0629900296	0629900341	0634800386
0530100027	0606100072	0620200117	0623700162	0629900207	0629900252	0629900297	0629900342	0634800387
0530100028	0606100073	0620200118	0623700163	0629900208	0629900253	0629900298	0629900343	0634800388
0530100029	0606100074	0620200119	0623700164	0629900209	0629900254	0629900299	0629900344	0634800389
0530100030	0606100075	0620200120	0623700165	0629900210	0629900255	0629900300	0629900345	0634800390
0530100031	0606100076	0620200121	0623700166	0629900211	0629900256	0629900301	0629900346	0634800391
0530100032	0606100077	0620200122	0623700167	0629900212	0629900257	0629900302	0629900347	0634800392
0530100033	0606100078	0620200123	0623700168	0629900213	0629900258	0629900303	0629900348	0634800393
0530100034	0606100079	0620200124	0623700169	0629900214	0629900259	0629900304	0629900349	0634800394
0530100035	0606100080	0620200125	0623700170	0629900215	0629900260	0629900305	0629900350	0634800395
0530100036	0610000081	0620200126	0623700171	0629900216	0629900261	0629900306	0629900351	0634800396
0530100037	0610000082	0620200127	0623700172	0629900217	0629900262	0629900307	0629900352	0634800397
0530100038	0610000083	0620200128	0623700173	0629900218	0629900263	0629900308	0629900353	0634800398
0530100039	0610000084	0620200129	0623700174	0629900219	0629900264	0629900309	0629900354	0634800399
0530100040	0610000085	0620200130	0623700175	0629900220	0629900265	0629900310	0629900355	0634800400
0530100041	0610000086	0620200131	0623700176	0629900221	0629900266	0629900311	0634800356	0634800401
0530100042	0610000087	0620200132	0623700177	0629900222	0629900267	0629900312	0634800357	0634800402
0530100043	0610000088	0620200133	0623700178	0629900223	0629900268	0629900313	0634800358	0634800403
0530100044	0610000089	0620200134	0623700179	0629900224	0629900269	0629900314	0634800359	0634800404
0530100045	0610000090	0620200135	0623700180	0629900225	0629900270	0629900315	0634800360	0634800405