



## Urgent Medical Device Field Correction- Immediate Action Required

### Rotablator™ Rotational Atherectomy System and Labsystem™ PRO

April 2019

Dear Customer:

Boston Scientific is initiating a field correction for certain Rotablator and Labsystem PRO systems due to a labeling issue. The labels applied locally in China incorrectly list the manufacturing site as Fremont. The manufacturing site for these products is San Jose.

There are no adverse health consequences expected to result from the incorrect labeling.

Refer to Table 1 for affected Material/Lot information. This correction includes only product listed below. A Boston Scientific Certified Field Service Engineer (FSE) will be visiting your facility to replace the label with the correct manufacturing site label. No action is required by your facility prior to the FSE visit.

**Table 1: Affected Product Listing**

Product Description	Material Number (UPN)	Serial/ Batch Number
Rotablator Console Kit assy gen 230V	H802220200381	
Clearsign II Amp 40 Channels	M00420020210	
Clearsign II Amp 80 Channels	M00420020220	
LS9900 WIN 7 SW 2.7A CPU	M00420020340	
Leadwire Ten 36-IN ECG	M0042003380	
Cable ECG Bamp 6 Meters	M00420012420	
Junction Box + Cable Clearsign 6m	M00420012510	
Cable Stimulator Input 6m	M00420012540	

We ask that you please confirm receipt of this notification by completing the enclosed correction form and sending it to our facility.

We are notifying regulatory authorities of this action as required. We regret any inconvenience that this may cause and appreciate your understanding as we take the necessary steps to ensure this is resolved in an expedient and satisfactory matter. We are committed to continuing to offer products that meet the high-quality standards that you expect from Boston Scientific.

Sincerely,

[Redacted Signature]

Field Action Team Lead  
763-494-1133

[Redacted Contact Information]

Encl: Correction Instructions  
Correction Form

## Urgent Recall for Product Correction - Immediate Action Required

The Correction Form enclosed with this Notice must be completed and returned **even if you do not have any affected units.**

1. **Complete and return the Correction Form.**

- Complete the enclosed Correction Form even if you do not have any affected product, following the directions on this page and on the Correction Form.

- Return the Correction Form as described below:

**Email:** **“To be completed by local Team”**

or

**Fax to:** **“Fill in local number”**

**Please email or fax your Correction Form(s) immediately.**