



**Urgent Medical Device Recall – Immediate Action Required
Swiss LithoClast® Pneumatic Probes**

September 17, 2009

Dear Risk/Materials/Office Manager:

Boston Scientific Corporation is conducting a Medical Device Recall of the Swiss LithoClast® Pneumatic Probes. The label states "Compatible with 330mm Ultrasound Probes," whereas the label should state "Compatible with 403mm Ultrasound Probes". If the wrong combination set were to be utilized, the probes would not be flush and both lithotripters would not work simultaneously. Energy would be delivered solely through the protruding pneumatic probe in direct contact with calculi; ultrasonic lithotripsy could not be performed.

The most likely clinical consequence is a delay to the procedure.

Further distribution or use of any remaining product affected by this Recall should cease immediately. If you are a distributor, please note that the recall depth is to the hospital level and the recall notification should be forwarded to your customers.

Below is a list of affected product, including Product Description, Material/UPN/Catalog Number and Lot/Batch Number.

Product Description	Material/UPN/Catalog Number	Lot/Batch Number
Swiss LithoClast® Pneumatic Probes – 1.0mm x 570mm Disposable	M0068407330	12723202, 12745667, 12767883, 12777930, 12782625, 12808559, 12813607, 12850772, 12861508

All affected Regulatory authorities will be notified of this Recall.

Enclosed (on the Reply Verification Tracking Form) is a copy of our records showing the lot/batch number(s) that were shipped from our distribution center and addressed to your facility. Although we believe our records to be accurate, we include this information solely to facilitate your inventory review and can neither state with certainty the location of product after it leaves our facility, nor guarantee the accuracy or completeness of this information.

The Reply Verification Tracking Form enclosed with this letter must **be completed and returned** in all cases even if you do not have any of the units remaining from the Recall lot(s). Please complete and return the Reply Verification Tracking Form within two weeks from the date of this notification.

Please read carefully through the Recall instructions below. Your local Sales Representative can answer any questions that you may have regarding this Recall.

1. **Immediately discontinue use of and segregate Recall product.**
 - Immediately remove the affected lot of Recall product from your inventory (whether in Labs, Central Supply, Shipping and Receiving or any other location).
 - Segregate this product in a secure location for return to Boston Scientific.
2. **Complete and return the Reply Verification Tracking Form.**
 - Complete the enclosed Reply Verification Tracking Form (even if you do not have any product to return), following the directions on this page and the Reply Verification Tracking Form.
 - Fax the Reply Verification Tracking Form to:

Megan Wijas
508-683-5578

If affected product is located in your institution, please call **Customer Service at 1-866-868-4004** between 8:30 a.m. and 6:00 p.m. (Eastern Standard Time) to obtain a **Returns Authorization (RGA) number**. Customer Service will arrange for a replacement.



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3. Package/ship the Recall product.

- Package any product that is being returned in an appropriate shipping box.
- Affix shipping label to the outside of the shipping box.
- Write the RGA number in large print on the outside of the box, either on or very near to the shipping label.
- Feel free to use our Federal Express Number (2932-6666-2) to return this package via second day delivery.
- Seal the box and return to:

Boston Scientific Corporation
Distribution Center
Attn: QA Returns
500 Commander Shea Blvd
Quincy, MA 02171

Please fax Reply Verification Tracking Form immediately upon completion of the above process to Megan Wijas at 508-683-5578.

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. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

Megan Wijas
Field Action Team
508-683-4427(p)
508-683-5578(f)