



## PRODUCT NOTIFICATION

January 15, 2009

### ATTENTION REHAB DEPARTMENT: VARILITE® Back Support Notification

Dear VARILITE Dealer,

You may have purchased a VARILITE back support in the past.

The purpose of this letter is to inform you of reports of breakage of a fastener used on our Evolution Back™ systems and eBack™ systems. The part involved is the screw used to attach the pin to the pin bar. We have received a few reports of the heads of these zinc plated carbon steel screws popping off, which detaches the pin from the pin bar. The number of reported screw heads that have popped off represents less than 0.2% of the systems shipped. No injuries have been reported.

This photo shows a typical screw with head popped off. The screw involved is carbon steel, zinc plated to provide corrosion resistance. Forensic analysis using electron scanning microscopy indicates that the cause of the breakage is hydrogen embrittlement, which occurs as the carbon steel screws are plated.



Although the final step of the plating process heat treats the screws to drive hydrogen out of the steel and eliminate embrittlement, the heat treating process cannot be relied upon with 100% confidence. Embrittlement cannot be determined through inspection.

Although the probability is remote that your product contains an affected screw, to enhance and ensure the reliability of your system, we have switched to a stainless steel screw. Stainless steel eliminates the chance of embrittlement while retaining corrosion resistance.

The likelihood that the back system you purchased has an affected screw is very low. However, if you wish to replace the pin bar screws on your system, a VARILITE team member will provide stainless steel screws at no charge.



NEW Stainless Steel Screw

Please contact VARILITE customer service at 800.827.4548 for assistance.

Sincerely,

Randall Willett  
Vice President of Medical  
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