

## **BLATCHFORD PRODUCTS LTD**

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18<sup>th</sup> April 2011

### **Urgent Field Safety Notice**

**Endolite 30mm Pyramid Clamp Adaptors: Part Number 409054 & (P)409028.**

**Details of affected devices:**

**Endolite 30mm Pyramid Clamp Adaptors- Part Number 409054 & (P)409028  
Batch Numbered within this range:**

**P265 to P365 – Manufactured October to December 2007**

**Q001 to Q365 – Manufactured January to December 2008**

**R001 to R365 – Manufactured January to December 2009**

**S001 to S365 – Manufactured January to December 2010**

**T001 to T048 – Manufactured January to February 2011**

**Adaptor 409054 is also contained within the following kits:**

739069, 739045, 739068                    Trans Tibial Pyramid Kits  
739058, 739059                    Trans Tibial Pyramid Kits (2 off per kit)

**Description of problem:**

**A small number of failures (0.85%) have been reported where components have cracked unexpectedly, both at the fitting stage and after a period of use. Similar failures could result in the limb wearer falling and injuring themselves.**

**Analysis of the field failures that have been received and subsequent in-house testing show that the risk of failure is increased if:**

- **The product has been immersed in water / liquids during use which can cause stress corrosion**
- **The product has been over torqued during assembly**

**Action Plan required:**

**Blatchford Products Ltd recommends the 409054 Adaptor is replaced with the new AK30M1 Titanium Adaptor on receipt of this notice.**

- **Where the component is changed in accordance with the above recommendation, Blatchford Products Ltd will give a full refund for every returned 409054 Adaptor.**
- **Please contact our Customer Services Department informing them of the claim and requesting a returns RMA number.**
- **Please return the old Adaptor in the normal manner and the refund will be then be given.**



**endolite**

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Registered in England No. 4395856                    VAT Registration No. 787 4522 87

**Transmission of this Field Safety Notice:**

**This notice needs to be passed on to all those that need to be aware within your organisation or to any organisation where the affected devices have been transferred.**

**Blatchford Products Ltd confirms that the appropriate regulatory authority has been notified of this FSN.**

**Please contact Blatchford Customer Services for your RMA number on: +44(0)1142637900, or by your normal method of communication.**

**Please contact your local Sales Representative in the UK for any queries or questions, or the area Sales Manager covering your country.**