



blatchford

Lister Road
Basingstoke
Hampshire RG22 4AH
United Kingdom

2nd September 2015

Advisory Field Safety Notice

Affected Products:

Part # 539601 – Male Shifting Top Housing
Part # 539602 – Female Shifting Top Housing

These top housings are used on the Endolite Elite Blade and the Endolite Javelin.

Description of problem:

As part of our ongoing post-market product surveillance it was observed that amputees with extreme activity on the old design of top housing after two years of wear are potentially at risk of a critical failure.

It is recommended that part # 539601 and #539602 is replaced for those on spring ratings of category 7 and higher after two years of wear.

We have enhanced the design of our Elite Blade and Javelin for water resistance by enhancing corrosion resistance. The surface now has a satin finish which enables easy identification.

Action to be Taken by Practitioner

- Review any wearers of the 539601 or 539602 Top Housing with a spring set rating of 7 or higher and determine if the age of their Top Housing is greater than 2 years. If so, the Top Housing and screws should be replaced.
(A list of Elite Blades and Javelins that should be assessed is attached).
- Ensure during annual maintenance that the Top Housing and screws are removed and checked for damage and wear. They should be replaced if necessary.
- Ensure the wearer is aware to report any changes in weight, activity and performance (e.g. unusual noises) to their practitioner.

Transmission of this Field Safety Notice:

This notice needs to be communicated to all those that need to be aware within your organisation or to any organisation where the affected devices may have been provided or serviced.

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

Further Information and Support:

Please contact your local Sales Representative for any queries or questions.

Please contact Customer Services on +44 (0) 114 263 7900 for replacement parts.

Julia Pragnell
QA Engineer



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Part # 539601 – Male Shifting Top Housing or Part # 539602 – Female Shifting Top Housing must be checked as described above when used in conjunction with the following spring ratings:

Elite Blade	EB24L7	EB25L7	EB26L7	EB27L7	EB28L7	EB29L7	EB30L7
	EB24L7D	EB25L7D	EB26L7D	EB27L7D	EB28L7D	EB29L7D	EB30L7D
	EB24L8	EB25L8	EB26L8	EB27L8	EB28L8	EB29L8	EB30L8
	EB24L8D	EB25L8D	EB26L8D	EB27L8D	EB28L8D	EB29L8D	EB30L8D
	EB24L9	EB25L9	EB26L9	EB27L9	EB28L9	EB29L9	EB30L9
	EB24L9D	EB25L9D	EB26L9D	EB27L9D	EB28L9D	EB29L9D	EB30L9D
	EB24R7	EB25R7	EB26R7	EB27R7	EB28R7	EB29R7	EB30R7
	EB24R7D	EB25R7D	EB26R7D	EB27R7D	EB28R7D	EB29R7D	EB30R7D
	EB24R8	EB25R8	EB26R8	EB27R8	EB28R8	EB29R8	EB30R8
	EB24R8D	EB25R8D	EB26R8D	EB27R8D	EB28R8D	EB29R8D	EB30R8D
	EB24R9	EB25R9	EB26R9	EB27R9	EB28R9	EB29R9	EB30R9
	EB24R9D	EB25R9D	EB26R9D	EB27R9D	EB28R9D	EB29R9D	EB30R9D

Javelin	JAV22L7	JAV23L7	JAV24L7	JAV25L7	JAV26L7	JAV27L7	JAV28L7	JAV29L7	JAV30L7
	JAV22L7D	JAV23L7D	JAV24L7D	JAV25L7D	JAV26L7D	JAV27L7D	JAV28L7D	JAV29L7D	JAV30L7D
	JAV22L8	JAV23L8	JAV24L8	JAV25L8	JAV26L8	JAV27L8	JAV28L8	JAV29L8	JAV30L8
	JAV22L8D	JAV23L8D	JAV24L8D	JAV25L8D	JAV26L8D	JAV27L8D	JAV28L8D	JAV29L8D	JAV30L8D
	JAV22R7	JAV23R7	JAV24L9	JAV25L9	JAV26L9	JAV27L9	JAV28L9	JAV29L9	JAV30L9
	JAV22R7D	JAV23R7D	JAV24L9D	JAV25L9D	JAV26L9D	JAV27L9D	JAV28L9D	JAV29L9D	JAV30L9D
	JAV22R8	JAV23R8	JAV24R7	JAV25R7	JAV26R7	JAV27R7	JAV28R7	JAV29R7	JAV30R7
	JAV22R8D	JAV23R8D	JAV24R7D	JAV25R7D	JAV26R7D	JAV27R7D	JAV28R7D	JAV29R7D	JAV30R7D
			JAV24R8	JAV25R8	JAV26R8	JAV27R8	JAV28R8	JAV29R8	JAV30R8
			JAV24R8D	JAV25R8D	JAV26R8D	JAV27R8D	JAV28R8D	JAV29R8D	JAV30R8D
			JAV24R9	JAV25R9	JAV26R9	JAV27R9	JAV28R9	JAV29R9D	JAV30R9
			JAV24R9D	JAV25R9D	JAV26R9D	JAV27R9D	JAV28R9D	JAV29L7	JAV30R9D



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