

Field Safety Notice

Field Safety Notice

Medical Devices Vigilance System (MEDDEV 2.12/1 rev. 8)

Commercial name of the affected product: AP Cutting Block Triathlon / Scorpio (part of Patella in Place Knee Balancer Instrumentation abbreviated as PIPB).

FSCA-identifier: PKB02112015

Type of action: Corrective action of AP Cutting Block

Date: 12 November 2015

Attention:

Stryker Amsterdam
Stryker Europe RAQA Director
Herikerbergweg 110
1101 CM Amsterdam
The Netherlands

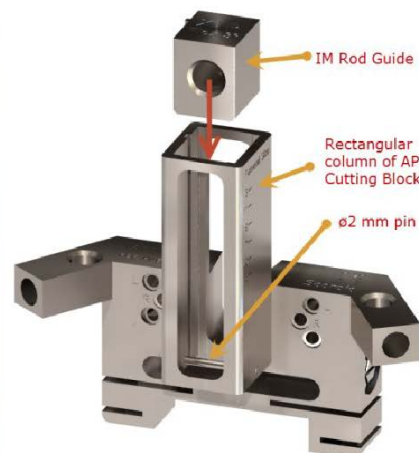
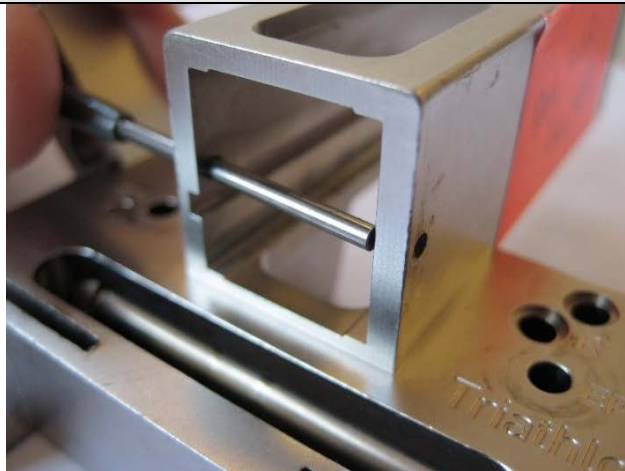
1 Details on affected devices

The devices affected are

47x AP Cutting Block Triathlon – reference number: PKB-1009-25, lotnumber 011101

4x AP Cutting Block Scorpio – reference number: PKB-1008-25, lotnumber 011101

2 Description of the problem



See pictures above. The rectangular column of the AP Cutting Block is a slot in which the IM Rod Guides are placed. This slot is open on the upper side and 'closed' by the ø2 mm pin on the lower side. The only function of the ø2 mm pin is to prevent the IM Rod Guide falling through the slot during assembly and disassembly, it has no function during the surgery itself due to the fact that the IM Rod Guide is positioned above the pin by the IM Rod during surgery. Due to a weld problem, the weld of the ø2 mm pin might break. This could result in withdrawal of the pin during use with a low risk of falling into the patients wound.

3 Advise on action to be taken by the user

There are two possible situations for the items involved and subsequently the following actions should be taken:

- **The AP Cutting Block has the pin still in place. This item is at risk**
 - o Return item as soon as possible to the manufacturer. The weld is replaced by a new weld. Items will be returned within one week.
- **If the AP Cutting Block has no pin in place anymore, the risk is removed:**
 - o Please inform manufacturer. A suitable date will be scheduled with you to replace the AP Cutting Block.

4 Transmission of this Field Safety Notice *(if appropriate)*

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. *(If appropriate)*

5 Contact reference person

Contact:
Project Manager
Spierings Orthopaedics B.V.
Madoerastraat 24
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Tel nr.: +31 (0)243501603
Email:

Date: 16-Nov-2015

Signature

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