BAAT MEDICAL Products BV
F. Hazemeijerstraat 800
7555 RJ Hengelo
The Netherlands

Field Safety Notice

ArthroSave Knee reviver

CONFIDENTIAL

BAAT Medical Products BV
FSN-Identifier 14018BR180207
Revision 2
16-4-2018

Commercial name of the affected product	ArthroSave Knee reviver
FSCA-identifier	14011BR180322_FSCA_ID238
Type of action	Advise given my manufacturer regarding use of the device

Details on affected devices

REF	Product Name	LOT(s)	Legal Manufacturer
AS1+AS3	Knee reviver left	B9871	BAAT Medical Products BV
AS2+AS4	Knee reviver right	B9893	BAAT Medical Products BV
AS8	half-pin locking-bolt with collet	B9687/ B9359	BAAT Medical Products BV
1401803100	Half pin 200x5mm	000693	MK Medical GmbH

Description of the problem

BAAT has identified that the accessory 'Half pin 200x5mm' (REF 1401803100 LOT: 000693) used in combination with the ArthroSave Knee Reviver (AS1-AS4) has broken on one occasion near the 1st cortex, which has resulted in early termination of the treatment and an un retrieved device fragment (the tip of the broken pin). . Cause of the failure is loosening of the remainder of the pins resulting in overloading of the broken pin. Loosening of pins has been observed in several other patients and is caused by faulty tip geometry.

Furthermore BAAT has identified that the distraction adjustment on the ArthroSave Knee Reviver (AS1-AS4) on several occasions did not maintain its original position during use of the product, which could result in over or under distraction of the knee joint resulting in unknown treatment outcome.

Advise on action to be taken by the user

<u>Device quarantining and return to supplier/manufacturer:</u>

- Half pin 200x5mm (REF 1401803100, LOT 000693) shall not be used in combination with the Arthrosave Knee Reviver, and is to be quarantined and returned to BAAT Medical.

Updated instructions for use of device:

- ArthroSave treatments are to be continued with Stryker bone pins (REF 5018-6-200 Apex Self-drilling Half Pin).
- ArthroSave Knee Reviver distraction adjustment shall be appended with a manual blockade of the adjustment nut by the health care professional using tape (e.g. Leukosilk 1,25cm breed)

Patient follow up:

- Regular monitoring of next 5 patients is to be shared with BAAT. Further patient treatment is to be continued only when next 5 patient treatments have not shown recurrence of pin loosening, pin failure or distraction change within the 6 week treatment period.

Transmission of this Field Safety Notice

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.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person

Name : Martijn Heikens
Organisation : BAAT Medical
Address : F. Hazemeijerstraat 800, 7555 RJ Hengelo
Contact details : 0885656600

The undersign confirms that this notice has been notified the appropriate Regulatory Agencies

Yours sincerely,

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17-04-2018