Stryker House, Hambridge Road
Newbury, Berkshire RG14 5AW
t: +44(0)1635 262400 f: +44(0)1635 580300
www.stryker.co.uk

stryker®
UK

URGENT Field Safety Notice: RA 2016-077

Description: Triathlon Modular Handle

Product Code: 6541-4-808

Lot Number: See attached list

Dear Customer,

Stryker Orthopaedics has initiated a recall for the Triathlon Modular Handle. The intent of this letter is to list all known hazards potentially associated with the use of instrument and list the risk mitigation factors.

Issue:

Analysis of two instruments from Finished Goods indicated that the press fit specifications between the dowel pin and the mating hole in the shaft were not being achieved by the supplier, potentially resulting in disassociation from the instrument.

Potential Hazards:

The handle components, including a dowel pin and a locking pin, may potentially disassociate and fall into the wound intraoperatively, necessitating retrieval. As such, the potential hazards may include:

- Complications associated with extended surgery time of less than 15 minutes.
- Complications associated with extended surgery time of 31-60 minutes should an intraoperative x-ray be performed.
- Local inflammatory response.
- Tissue Damage
- Revision surgery to retrieve loose components.
- Inflammatory response.

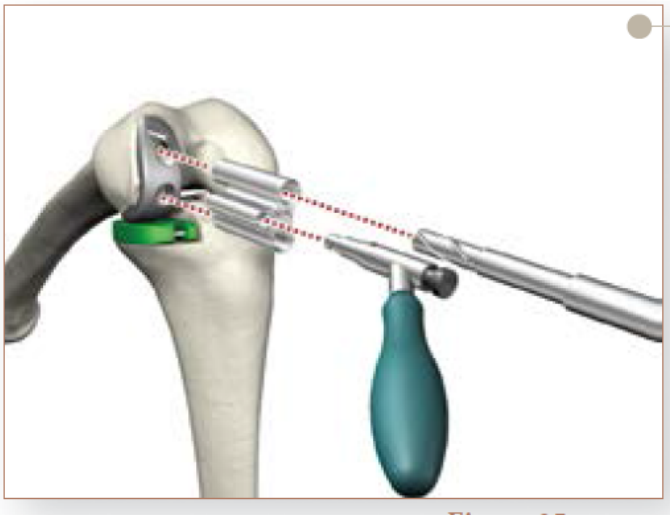
Risk Mitigation:

Inspection of reusable devices as described in Stryker Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices (LSTPI-B, Rev. 2) indicates that "instruments with moving parts should be operated to check correct operation". Additionally, the Instructions for Use (QIN 4382, Rev. D) states that "instruments with articulating surfaces must be tested for movement." Performing these inspections as instructed may result in the device disassociating prior to reaching the operating room, which could mitigate all of the potential hazards.

bsi.
RS11877

If the handle disassociates, the instrument cannot be used, thereby increasing awareness of the disassociation.

Triathlon PKR surgical protocol (TRIPKR-SP-1_10434) is being updated where it is explained about an alternative approach that does not require use of the Triathlon Modular Handle instrument:



- The Femoral Trial Drill Guide is attached to the Modular Handle and assembled into the holes on the articulation surface of the femoral trial. Alternatively, the Femoral Drill guide can be assembled into the holes manually. Using the appropriately sized Peg Drill (Small Drill for sizes 1-2, Large Drill for sizes 3-6), both holes are drilled. The Peg Drill is advanced until the step on the drill makes contact with the front face of the Femoral Trial Drill Guide.

Note: To prevent possible impingement of the drill, fully engage the Peg Drill in the Femoral Trial Drill Guide before beginning to drill for the femoral peg holes.

- The Femoral Trial Drill Guide is removed from the trial and the Peg Trial is pushed into the posterior hole of the Femoral Trial. The knee is taken through a final range of motion to confirm component placement and size.
- The Femoral Trial Peg can be removed with the Modular Handle. Alternatively the Femoral Trial and Femoral Trial Peg can be removed in one step using a towel clamp or osteotome. The Tibial Trial is also removed.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

Actions Required

1. Immediately check your internal inventory to locate subject devices referenced in this notice.

2. Immediately quarantine any subject devices that are located to ensure that they are withdrawn from service.

3. Circulate this Field Safety Notice internally to all interested / affected parties.

4. Maintain awareness of this notice internally until all required actions have been completed within your facility.

5. Inform Stryker if any of the subject devices have been distributed to other organisations.

   a) Please provide contact details so that Stryker can inform the recipients appropriately.
   b) If you are a Distributor, note that you are responsible for notifying your affected customers.

6. Complete the attached customer response form and return to Nina Goddard by fax (01635 262 464) or by e-mail (nina.goddard@stryker.com). Once a completed form has been received, a Stryker Representative will contact you to organise the collection and replacement of any affected devices located on site.

   a) Please complete this form even if you do not have any products to return. This will preclude the need for Stryker to send any reminder notice.

7. Please inform Stryker of any adverse events concerning the use of the subject devices.

8. Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

We request that you respond to this notice within 7 calendar days from the date of receipt.

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours faithfully,

Nina Goddard
Quality Assurance and Regulatory Affairs

RA 2016-077: Affected lot codes

SB1K14	SB2V87J	SB3L20K	SB4L05A	SB5L40TD
SB1K14A	SB2V87JX1	SB3L45	SB4N17	SB5L40X
SB1K14A1	SB2V87K	SB3L45A	SB4N17E	SB6A22
SB1K14P	SB2V87X	SB3L45A1	SB4N17M	SB6A22A
SB1K15	SB2V87X1	SB3L45A2	SB4N17M1	SB6A22D
SB1K15A	SB2W23	SB3L45D	SB4N18	SB6M83
SB1K15A1	SB2W23G	SB3L45DX1	SB4N18A	SB6M83A
SB1K15A2	SB2W23X	SB3L45L	SB4N18A1	SB6M83D
SB1M25	SB2W23X1	SB3L45T	SB4N18D	SB6M83H
SB1M25A	SB3A20	SB3M17	SB4N18M	SB6M83J
SB1M25A1	SB3A20A	SB3M17A	SB4N18T	SB6M83T
SB1M25A2	SB3A21	SB3M17K	SB4S01	SB6M83TD
SB1M25A2X1	SB3A21D	SB3M17M	SB4S01D	SB6N01
SB1N02	SB3A21M	SB3M18	SB4S01J	SB6N01A
SB1N02A	SB3A21X	SB3M18A	SB4V07	SB6N01AT
SB1N02A1	SB3A22	SB3M18AX1	SB4V07L	SB6N01H
SB1N02A2	SB3A22A1	SB3M18D	SB4V07M	SB6N01K
SB1N02A3	SB3A22X1	SB3M18M	SB4V07MM	SB6N01L
SB1N02X1	SB3A55	SB3M18R	SB5A02	SB6N01T
SB1T05	SB3A55A	SB3M19	SB5A02A	SB6N01TE
SB1T05A	SB3A55A2	SB3M19A	SB5A02A1	SB6N02
SB1T05A1	SB3A55AX1	SB3M19A1	SB5A55	SB6N02D
SB1T05AX1	SB3A55M	SB3M19S	SB5A55A	SB6N02H
SB1T05AX2	SB3A55X1	SB3M19T	SB5A55D	SB6N02L
SB1T05K	SB3H25	SB3M19W	SB5A55M	SB6N02N
SB1V01	SB3H25D	SB3N46	SB5A55X	SB6N02P
SB1V01K	SB3H25G	SB3N46D	SB5C45	SB7A26
SB1V01L	SB3H25X1	SB3N46P	SB5C45A	SB7A26Y
SB1V01X1	SB3H26	SB3N46X1	SB5C45D	SB7A27
SB1V01X2	SB3H26D	SB4C12	SB5C45M	SB7A27A
SB1V01X3	SB3H26DX1	SB4C12X1	SB5C45P	SB7A27E
SB1W14	SB3H26X2	SB4C37	SB5C45T	SB7A27M
SB1W14K	SB3K09	SB4C37X1	SB5C45V	SB7A27T
SB1W14X1	SB3K09X1	SB4C38	SB5C45W	SB7A28
SB2T19	SB3K10	SB4C38A	SB5L06	SB7A28E
SB2T19A	SB3K10L	SB4C38D	SB5L06A	SB7A28EE
SB2T19D	SB3K10M	SB4E18	SB5L06T	SB7A29
SB2T19DX1	SB3K10MX1	SB4E181	SB5L40	SB7A29A
SB2T19DX2	SB3K10X1	SB4E181X1	SB5L40A	SB7A29M
SB2T19J	SB3L19	SB4E18A	SB5L40D	SB7A29N
SB2T19K	SB3L19D	SB4E18D	SB5L40F	SB7A29R
SB2T19KX1	SB3L19K	SB4E18T	SB5L40J	SB7N23
SB2T19KX2	SB3L19L	SB4H79	SB5L40JR	SB7N23A
SB2T19X3	SB3L19P	SB4H79A	SB5L40L	SB7N23M
SB2V87	SB3L19P1	SB4H79M	SB5L40M	SB7N23P
SB2V87A	SB3L20	SB4L05	SB5L40T	SB7N23T

SB7N23X	SBYC02K	SBZA02H	SBZL16H	
SB8H28	SBYC03A	SBZA02J	SBZL16P	
SB8H28E	SBYC03C	SBZC12	SBZT03	
SB8H28EE	SBYC03D	SBZC12A	SBZT03A	
SB8H28T	SBYC03F	SBZC12AA	SBZT03A1	
SB8S43	SBYC03G	SBZC12C	SBZT03C	
SB8S43A	SBYC05C	SBZC12D	SBZT03D	
SB8S43E	SBYC05D	SBZC12E	SBZT03E	
SB8S43L	SBYC05E	SBZC12F	SBZT03F	
SB8S43P	SBYC05F	SBZC12G	SBZT03W	
SB8S43X	SBYC05G	SBZK09A	SBZT46	
SB8T21	SBYC05H	SBZK09C	SBZT46A	
SB8T21A	SBYC05JA	SBZK09D	SBZT46A1	
SB8T21J	SBYC05K	SBZK09E	SBZT46A2	
SB8T21M	SBYC05L	SBZK09F	SBZT46C	
SB8T21T	SBYE02	SBZK09G	SBZT46D	
SB8V41	SBYE02A	SBZK09H	SBZT46E	
SB8V41A	SBYE02D	SBZL07	SBZT46F	
SB8V41J	SBYE02E	SBZL07A	SBZT46H	
SB8V41K	SBYE02F	SBZL07AA	SBZT46J	
SB8V41L	SBYE02G	SBZL07AC	SBZT46JK	
SB9C23	SBYE02H	SBZL07AD	SBZT46K	
SB9C23A	SBYK05	SBZL07C	SBZT46KX1	
SB9C23D	SBYK05C	SBZL07D	SBZT46P	
SB9C23E	SBYK05D	SBZL07E	SBZT46W	
SB9C23L	SBYK05E	SBZL07F	SBZT46X	
SB9C23M	SBYK05F	SBZL07G	SI4371801	
SB9E55	SBYK05G	SBZL07H	SI4371801A	
SB9E55A	SBYK05H	SBZL07J	SI4371801D	
SB9E55D	SBYK05J	SBZL07K	SI4371801H	
SB9E55K	SBYT01	SBZL07L	SI4371801JK	
SB9E55T	SBYT01A	SBZL07M	SI4429101	
SBYC01	SBYT01C	SBZL07N	SI4429101A	
SBYC01D	SBYT01CA	SBZL07P	SI4429101D	
SBYC01F	SBYT01CC	SBZL07P1	SI4429101E	
SBYC01K	SBYT01D	SBZL07S	SI4507701	
SBYC01L	SBYT01E	SBZL07T	SI4507701A	
SBYC01M	SBYT01F	SBZL07V	SI4507701D	
SBYC01N	SBYT01G	SBZL07W		
SBYC01P	SBYT01H	SBZL07X		
SBYC02A	SBYT01J	SBZL07Y		
SBYC02C	SBYT01K	SBZL16		
SBYC02D	SBZA02	SBZL16A		
SBYC02E	SBZA02A	SBZL16C		
SBYC02F	SBZA02C	SBZL16D		
SBYC02G	SBZA02D	SBZL16E		
SBYC02H	SBZA02E	SBZL16F		
SBYC02J	SBZA02G	SBZL16G		

RA 2016-077: PFA Acknowledgement Form

Description: Triathlon Modular Handle

Product Code: 6541-4-808

Lot Number: See attached list

I acknowledge receipt of the Field Safety Notice for RA 2016-077 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*	

We have located the following devices:			
Product Description	**Product Reference**	**Lot Number**	**Qty**

We have further distributed subject devices to the following organisations:	
Facility Name	
Facility Address	

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO NINA.GODDARD@STRYKER.COM.