**URGENT**
**PRODUCT RECALL**

June 28, 2016

**FSCA identifier**: Product Field Action RA2016-077

**Type of Action**: Field Safety Corrective Action: **Return to Supplier**

**Description:** Triathlon Modular Handle

**Catalog #:** 6541-4-808

**License #:** DE0017074

**Lot Code:** See attached list

**Product owner:** Howmedica Osteonics Corp., 325 Corporate Drive, Mahwah, NJ 07430, USA

**License holder:** Stryker Singapore Pte Ltd, 108 Pasir Panjang Road #03-04 Golden Agri Plaza Singapore 118535

Dear Hospital Representative,

Stryker Orthopaedics has initiated a voluntary 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.

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

Actions Needed

1. Please inform users of this Urgent Product Recall and forward this notice to all those individuals who need to be aware within your organization.
2. Complete and sign the enclosed Business Reply Form and ASEAN.PMS@stryker.com or hand to your Stryker sales representative**.**

*Please contact your Stryker sales representative for an updated Triathlon PKR surgical protocol (TRIPKR-SP-1_10434) for information about an alternative approach that does not require use of the Triathlon Modular Handle instrument.*

Reporting of Adverse Events

Please report any adverse events or product quality problems associated with this device to Stryker. Healthcare Professionals may also report any suspected adverse events associated with these devices to the Vigilance Branch, Health Products Regulation Group, HAS at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online.

It is our responsibility to ensure that customers who may have received this affected instrument also receive this important communication. **Please assist us in meeting our regulatory obligation by faxing back the attached Business Reply Form within 5 days.**

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact the signatory below.

Sincerely,

Sara Jato
QA Specialist
Stryker ASEAN
sara.jato@stryker.com
ASEAN.PMS@stryker.com
Tel. +84 (0)8 3827 5399 Ext.12

Affected lots

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| SB1K14 | SB2V87A | SB3L19P1 | SB4H79A | SB5L40JR | SB7N23 | SBYC02A | SBYT01F |
| SB1K14A | SB2V87J | SB3L20 | SB4H79M | SB5L40L | SB7N23A | SBYC02C | SBYT01G |
| SB1K14A1 | SB2V87JX1 | SB3L20K | SB4L05 | SB5L40M | SB7N23M | SBYC02D | SBYT01H |
| SB1K14P | SB2V87K | SB3L45 | SB4L05A | SB5L40T | SB7N23P | SBYC02E | SBYT01J |
| SB1K15 | SB2V87X | SB3L45A | SB4N17 | SB5L40TD | SB7N23T | SBYC02F | SBYT01K |
| SB1K15A | SB2V87X1 | SB3L45A1 | SB4N17E | SB5L40X | SB7N23X | SBYC02G | SBZA02 |
| SB1K15A1 | SB2W23 | SB3L45A2 | SB4N17M | SB6A22 | SB8H28 | SBYC02H | SBZA02A |
| SB1K15A2 | SB2W23G | SB3L45D | SB4N17M1 | SB6A22A | SB8H28E | SBYC02J | SBZA02C |
| SB1M25 | SB2W23X | SB3L45DX1 | SB4N18 | SB6A22D | SB8H28EE | SBYC02K | SBZA02D |
| SB1M25A | SB2W23X1 | SB3L45L | SB4N18A | SB6M83 | SB8H28T | SBYC03A | SBZA02E |
| SB1M25A1 | SB3A20 | SB3L45T | SB4N18A1 | SB6M83A | SB8S43 | SBYC03C | SBZA02G |
| SB1M25A2 | SB3A20A | SB3M17 | SB4N18D | SB6M83D | SB8S43A | SBYC03D | SBZA02H |
| SB1M25A2X1 | SB3A21 | SB3M17A | SB4N18M | SB6M83H | SB8S43E | SBYC03F | SBZA02J |
| SB1N02 | SB3A21D | SB3M17K | SB4N18T | SB6M83J | SB8S43L | SBYC03G | SBZC12 |
| SB1N02A | SB3A21M | SB3M17M | SB4S01 | SB6M83T | SB8S43P | SBYC05C | SBZC12A |
| SB1N02A1 | SB3A21X | SB3M18 | SB4S01D | SB6M83TD | SB8S43X | SBYC05D | SBZC12AA |
| SB1N02A2 | SB3A22 | SB3M18A | SB4S01J | SB6N01 | SB8T21 | SBYC05E | SBZC12C |
| SB1N02A3 | SB3A22A1 | SB3M18AX1 | SB4V07 | SB6N01A | SB8T21A | SBYC05F | SBZC12D |
| SB1N02X1 | SB3A22X1 | SB3M18D | SB4V07L | SB6N01AT | SB8T21J | SBYC05G | SBZC12E |
| SB1T05 | SB3A55 | SB3M18M | SB4V07M | SB6N01H | SB8T21M | SBYC05H | SBZC12F |
| SB1T05A | SB3A55A | SB3M18R | SB4V07MM | SB6N01K | SB8T21T | SBYC05JA | SBZC12G |
| SB1T05A1 | SB3A55A2 | SB3M19 | SB5A02 | SB6N01L | SB8V41 | SBYC05K | SBZK09A |
| SB1T05AX1 | SB3A55AX1 | SB3M19A | SB5A02A | SB6N01T | SB8V41A | SBYC05L | SBZK09C |
| SB1T05AX2 | SB3A55M | SB3M19A1 | SB5A02A1 | SB6N01TE | SB8V41J | SBYE02 | SBZK09D |
| SB1T05K | SB3A55X1 | SB3M19S | SB5A55 | SB6N02 | SB8V41K | SBYE02A | SBZK09E |
| SB1V01 | SB3H25 | SB3M19T | SB5A55A | SB6N02D | SB8V41L | SBYE02D | SBZK09F |
| SB1V01K | SB3H25D | SB3M19W | SB5A55D | SB6N02H | SB9C23 | SBYE02E | SBZK09G |
| SB1V01L | SB3H25G | SB3N46 | SB5A55M | SB6N02L | SB9C23A | SBYE02F | SBZK09H |
| SB1V01X1 | SB3H25X1 | SB3N46D | SB5A55X | SB6N02N | SB9C23D | SBYE02G | SBZL07 |
| SB1V01X2 | SB3H26 | SB3N46P | SB5C45 | SB6N02P | SB9C23E | SBYE02H | SBZL07A |
| SB1V01X3 | SB3H26D | SB3N46X1 | SB5C45A | SB7A26 | SB9C23L | SBYK05 | SBZL07AA |
| SB1W14 | SB3H26DX1 | SB4C12 | SB5C45D | SB7A26Y | SB9C23M | SBYK05C | SBZL07AC |
| SB1W14K | SB3H26X2 | SB4C12X1 | SB5C45M | SB7A27 | SB9E55 | SBYK05D | SBZL07AD |
| SB1W14X1 | SB3K09 | SB4C37 | SB5C45P | SB7A27A | SB9E55A | SBYK05E | SBZL07C |
| SB2T19 | SB3K09X1 | SB4C37X1 | SB5C45T | SB7A27E | SB9E55D | SBYK05F | SBZL07D |
| SB2T19A | SB3K10 | SB4C38 | SB5C45V | SB7A27M | SB9E55K | SBYK05G | SBZL07E |
| SB2T19D | SB3K10L | SB4C38A | SB5C45W | SB7A27T | SB9E55T | SBYK05H | SBZL07F |
| SB2T19DX1 | SB3K10M | SB4C38D | SB5L06 | SB7A28 | SBYC01 | SBYK05J | SBZL07G |
| SB2T19DX2 | SB3K10MX1 | SB4E18 | SB5L06A | SB7A28E | SBYC01D | SBYT01 | SBZL07H |
| SB2T19J | SB3K10X1 | SB4E181 | SB5L06T | SB7A28EE | SBYC01F | SBYT01A | SBZL07J |
| SB2T19K | SB3L19 | SB4E181X1 | SB5L40 | SB7A29 | SBYC01K | SBYT01C | SBZL07K |
| SB2T19KX1 | SB3L19D | SB4E18A | SB5L40A | SB7A29A | SBYC01L | SBYT01CA | SBZL07L |
| SB2T19KX2 | SB3L19K | SB4E18D | SB5L40D | SB7A29M | SBYC01M | SBYT01CC | SBZL07M |
| SB2T19X3 | SB3L19L | SB4E18T | SB5L40F | SB7A29N | SBYC01N | SBYT01D | SBZL07N |
| SB2V87 | SB3L19P | SB4H79 | SB5L40J | SB7A29R | SBYC01P | SBYT01E | SBZL07P |

| | | | | | | |
|---|---|---|---|---|---|---|
| SBZL07P1 | SBZL16A | SBZT03 | SBZT46 | SBZT46H | SI4371801 | SI4429101E |
| SBZL07S | SBZL16C | SBZT03A | SBZT46A | SBZT46J | SI4371801A | SI4507701 |
| SBZL07T | SBZL16D | SBZT03A1 | SBZT46A1 | SBZT46JK | SI4371801D | SI4507701A |
| SBZL07V | SBZL16E | SBZT03C | SBZT46A2 | SBZT46K | SI4371801H | SI4507701D |
| SBZL07W | SBZL16F | SBZT03D | SBZT46C | SBZT46KX1 | SI4371801JK | |
| SBZL07X | SBZL16G | SBZT03E | SBZT46D | SBZT46P | SI4429101 | |
| SBZL07Y | SBZL16H | SBZT03F | SBZT46E | SBZT46W | SI4429101A | |
| SBZL16 | SBZL16P | SBZT03W | SBZT46F | SBZT46X | SI4429101D | |

**STRYKER ORTHOPAEDICS**
**URGENT MEDICAL DEVICE RECALL**
**NOTIFICATION BUSINESS REPLY FORM**

June 28, 2016

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**Product owner:** Howmedica Osteonics Corp., 325 Corporate Drive, Mahwah, NJ 07430, USA

**License holder:** Stryker Singapore Pte Ltd, 108 Pasir Panjang Road #03-04 Golden Agri Plaza Singapore 118535

I have received the product recall letter from Stryker Orthopaedics dated June 28, 2016 stating that the company has initiated a voluntary lot-specific recall of the above referenced instrument.

_____ _____
Hospital Name Date

_____ _____
Hospital Representative (Name and signature) Hospital stamp

**PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT VIA EMAIL (ASEAN.PMS@stryker.com) OR HAND TO YOUR STRYKER SALES REPRESENTATIVE**