المركز الوطني لبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

# Safety Communication

## URGENT Field Safety Notice about Orthopedic implant rHead Radial Head and Uni-Elbow Manufactured by Stryker

| | |
|---|---|
| **Device/ Product Name:** | rHead Radial Head and Uni-Elbow |
| **Lot numbers/Serials:** | All lots of the Stryker rHead Radial Head and Uni-Elbow are affected. (see the attached FSN below) |
| **Manufacturer:** | Stryker GmbH |
| **Problem:** | Saudi FDA would like to bring your attention that **Stryker GmbH** issued a Field Safety Notice dated November 2017 informing clinicians of the **recall** of the **rHead Radial Head and Uni-Elbow prosthesis**.<br>The manufacturer identifies the possibility of post-operative implant loosening (septic and aseptic), instability (moderate/severe), stress fracture (bone), cyst formation (bone resorption), stiffness, pain, impingement, heterotopic ossification with these devices.<br><br>This Safety Communication is being issued to ensure that all hospitals are aware of the issue and that adequate action is taken to mitigate potential risk to patients. |
| **Recommendation/Actions:** | • Identify and quarantine all affected devices.<br>• Identify and advise all patients implanted with affected devices to contact their orthopedic surgeon if they develop symptoms such as pain, loss of function or instability.<br>• Follow actions recommended in the manufacturer's Field Safety Notice (below) |

| | | |
|---|---|---|
| **Devices/Products photo:** |  **rHead Radial Head**  **Uni-Elbow** | |
| **Authorized Representative Details** | **Company name:** | **Zimmo Trading Establishment.** |
| | **Contact Person:** | **Rami kabar** |
| | **Phone:** | **(011) 4020325** |
| | **Email:** | regulatory@zimmo.net<br>rami.kabar@zimmo.net |

Healthcare Professionals should **report** any adverse events suspected to be associated with affected Product above to:

**National Center for Medical Devices Reporting**.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team

November 2017

# URGENT Field Safety Notice: RA1638238

**FSCA Identifier:** Product Field Action RA1638238

**Type of Action:** Field Safety Corrective Action

**Description:** rHead Radial Head and Uni-Elbow

**Product Code:** See attached

**Serial/Lot Numbers:** See attached

**Legal Manufacturer:** Stryker GmbH, Bohnackerweg 1, 2545 Selzach, Switzerland

Dear Customer,

Stryker GmbH - Division Trauma & Extremities is initiating a voluntary product removal of the Stryker **rHead Radial Head and Uni-Elbow System**. The system is intended for replacement of the proximal end of the radius.
This includes replacement of the radial head for degenerative or post-traumatic disabilities, presenting pain, crepitation and decreased motion at the radio humeral and/or proximal radio ulnar joint with joint destruction or subluxation visible on x-ray and resistance to conservative treatment.

**Reason for Removal:**
The result of a review of the currently available data of the Stryker rHead Radial Head and Uni-Elbow system was found to be inconclusive to continue supporting the performance of the device. Consequently, we have decided to remove the product from the global markets.

Health care professionals that have patients using the Stryker rHead Radial Head / Uni-Elbow Prosthesis System should continue to follow up those patients in accordance with the routine standard of care.

rHead Radial Head and Uni-Elbow implants will no longer be sold. A Stryker rHead Radial Head and Uni-Elbow System will be available upon request as part of our loaner set programs for revision surgeries.

**Potential Hazards**
Potential Hazards Post-operatively, the following may occur; Implant loosening (septic and aseptic), Instability (mod-severe), Stress fracture (bone), Cyst formation (bone resorption), Stiffness, Pain, Impingement, Heterotopic ossification.

**Immediate Actions**

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

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.

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

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

4. 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.

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

6. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within 07 calendar days from the date of receipt. The target date for completion of this action is 30 November 2017 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
Fax: 01635 262 464
E-mail: nina.goddard@stryker.com

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 caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

# RA 1638238 Affected Product and Lot Codes

| Product code | Description |
|---|---|
| 3100000 | Lateral Assembly, Radial Implant, Size 1 |
| 3100001 | Lateral Assembly, Radial Stem Implant, Size 2 |
| 3100002 | Lateral Assembly, Radial Stem Implant, Size 3 |
| 3100003 | Lateral Assembly, Radial Stem Implant, Size 4 |
| 3100004 | Lat Assembly, Rad Stem Implant,Collar 6mm,Size1 |
| 3100005 | Lat Assembly, Rad Stem Implant,Collar 6mm,Size2 |
| 3100006 | Lat Assembly, Rad Stem Implant,Collar 6mm,Size3 |
| 3100007 | Lat Assembly, Rad Stem Implant,Collar 6mm,Size4 |
| 3100008 | Lateral Assembly, Radial Head Implant, Size 2 |
| 3100009 | Lateral Assembly, Radial Head Implant, Size 3 |
| 3100010 | Lat Assembly, Rad Stem Head Implant, Size 4 |
| 3100011 | Lateral Assembly, Radial Head Impl Assembly,Size2 |
| 3100012 | Lateral Assembly, Radial Head Impl Assembly,Size3 |
| 3100013 | Lateral Assembly, Radial Head Impl Assembly,Size4 |
| 3102010 | rHead Stem Implant Plasma Coated, Size 1 |
| 3102011 | rHead Stem Implant Plasma Coated, Size 2 |
| 3102012 | rHead Stem Implant Plasma Coated, Size 3 |
| 3102013 | rHead Stem Implant Plasma Coated, Size 4 |
| 3102014 | rHead Stem Implant 6mm Collar,Size 1 |
| 3102015 | rHead Stem Implant 6mm Collar,Size 2 |
| 3102016 | rHead Stem Implant 6mm Collar,Size 3 |
| 3102017 | rHead Stem Implant 6mm Collar,Size 4 |
| 3102018 | rHead Recon Stem Implant Plasma Coated, Size 1 |
| 3102019 | rHead Recon Stem Implant Plasma Coated, Size 2 |
| 3102020 | rHead Recon Stem Implant Plasma Coated, Size 3 |
| 3102021 | rHead Recon Stem Implant Plasma Coated, Size 4 |
| 3102022 | rHead Recon Stem Implant 6mm Collar,Size 1 |
| 3102023 | rHead Recon Stem Implant 6mm Collar,Size 2 |
| 3102024 | rHead Recon Stem Implant 6mm Collar,Size 3 |
| 3102025 | rHead Recon Stem Implant 6mm Collar,Size 4 |
| 4100000 | Radio Capitellum Large, Left |
| 4100001 | Radio Capitellum Small, Left |
| 4100002 | Radio Capitellum Large, Right |
| 4100003 | Radio Capitellum Small, Right |
| 4100004 | Radial Head Assy Size #2, Rad |
| 4100005 | Radial Head Assy Size #3, Rad |
| 4100006 | Radial Head Assy Size #4, Rad |
| 4100007 | Radio Capitellum, Recon Head, Size #2 |
| 4100008 | Radio Capitellum, Recon Head, Size #3 |
| 4100009 | Radio Capitellum, Recon Head, Size #4 |

| | |
|---|---|
| 4100100 | rHead Standard Extended Stem, 6mm Collar, Size 1 |
| 4100101 | rHead Standard Extended Stem, 6mm Collar, Size 2 |
| 4100102 | rHead Standard Extended Stem, 6mm Collar, Size 3 |
| 4100103 | rHead Standard Extended Stem, 6mm Collar, Size 4 |
| 4100300 | rHead Recon Extended Stem Size 1 |
| 4100301 | rHead Recon Extended Stem Size 2 |
| 4100302 | rHead Recon Extended Stem Size 3 |
| 4100303 | rHead Recon Extended Stem Size 4 |
| RCNH2 | #2 Bipolar radial head Implant (Sterile packed) |
| RCNH3 | #3 Bipolar radial head Implant (Sterile packed) |
| RCNH4 | #4 Bipolar radial head Implant (Sterile packed) |
| RCNS1 | #1 Bipolar stem implant (Sterile packed) |
| RCNS160 | rHead Recon Stem Implant non-coated, Size 1 |
| RCNS2 | #2 Bipolar stem implant (Sterile packed) |
| RCNS260 | rHead Recon Stem Implant non-coated, Size 2 |
| RCNS3 | #3 Bipolar stem implant (Sterile packed) |
| RCNS360 | rHead Recon Stem Implant non-coated, Size 3 |
| RCNS4 | #4 Bipolar stem implant (Sterile packed) |
| RCNS460 | rHead Recon Stem Implant non-coated, Size 4 |
| RHAH2 | radial head implant #2 (Sterile packed) |
| RHAH3 | radial head implant #3 (Sterile packed) |
| RHAH4 | radial head implant #4 (Sterile packed) |
| RHAS1 | radial stem implant #1 (Sterile packed) |
| RHAS160 | rHead, Radial Implant 6 mm Collar, Size 1 |
| RHAS2 | radial stem implant #2 (Sterile packed) |
| RHAS260 | rHead, Radial Implant 6 mm Collar, Size 2 |
| RHAS3 | radial stem implant #3 (Sterile packed) |
| RHAS360 | rHead, Radial Implant 6 mm Collar, Size 3 |
| RHAS4 | radial stem implant #4 (Sterile packed) |
| RHAS460 | rHead, Radial Implant 6 mm Collar, Size 4 |

# RA1638238: PFA Acknowledgement Form

**FSCA Identifier:** Product Field Action RA1638238

**Type of Action:** Field Safety Corrective Action

**Description:** rHead Radial Head and Uni-Elbow

**Product Code:** See attached

**Serial/Lot Numbers:** See attached

**Legal Manufacturer:** Stryker GmbH, Bohnackerweg 1, 2545 Selzach, Switzerland

I acknowledge receipt of the Field Safety Notice for RA1638238 and can confirm that:

| We have not located any of these devices in our inventory:<br>*(please delete if not applicable)* | | | |
|---|---|---|---|
| We have located the following devices: | | | |
| Product Description | Product Reference | Lot Number | Qty to return |
| | | | |
| | | | |
| | | | |
| | | | |
| 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