

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,

A handwritten signature in blue ink, appearing to read "ngoddard".

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
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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: <i>(please delete if not applicable)</i>			
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