

Month, Day, Year

URGENT FIELD SAFETY NOTICE: RA Ref # 1638238

FSCA Identifier: Product Field Action RA Ref # 1638239

Type of Action: Field Safety Corrective Action

Description: rHead Radial Head and Uni-Elbow

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

Product name: See Attachment

Catalogue #: See Attachment

Lot #s: All lots

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.

A Stryker rHead Radial Head and Uni-Elbow System will be available upon request as part of our loaner set programs for revision surgeries, if the appropriate criteria exist, procedure failure is NOT related to the implant, and the implant is not to be available for an initial or primary procedure.

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.

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 to 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. Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.
6. 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.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

If returning the product would adversely impact your ability to provide necessary medical care to patients, you can consider re-sterilizing the product per Sterilization instructions contained in the Instruction for Use.

We request that you respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is ----- 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:

Position:

Email

Telephone

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.

Yours Sincerely,

RA Ref # 1638238 Affected Product and Lot Codes

Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
3100000	Lateral Assembly, Radial Implant, Size 1	all
3100001	Lateral Assembly, Radial Stem Implant, Size 2	all
3100002	Lateral Assembly, Radial Stem Implant, Size 3	all
3100003	Lateral Assembly, Radial Stem Implant, Size 4	all
3100004	Lat Assembly, Rad Stem Implant,Collar 6mm,Size1	all
3100005	Lat Assembly, Rad Stem Implant,Collar 6mm,Size2	all
3100006	Lat Assembly, Rad Stem Implant,Collar 6mm,Size3	all
3100007	Lat Assembly, Rad Stem Implant,Collar 6mm,Size4	all
3100008	Lateral Assembly, Radial Head Implant, Size 2	all
3100009	Lateral Assembly, Radial Head Implant, Size 3	all
3100010	Lat Assembly, Rad Stem Head Implant, Size 4	all
3100011	Lateral Assembly, Radial Head Impl Assembly,Size2	all
3100012	Lateral Assembly, Radial Head Impl Assembly,Size3	all
3100013	Lateral Assembly, Radial Head Impl Assembly,Size4	all
3102010	rHead Stem Implant Plasma Coated, Size 1	all
3102011	rHead Stem Implant Plasma Coated, Size 2	all
3102012	rHead Stem Implant Plasma Coated, Size 3	all
3102013	rHead Stem Implant Plasma Coated, Size 4	all
3102014	rHead Stem Implant 6mm Collar,Size 1	all
3102015	rHead Stem Implant 6mm Collar,Size 2	all
3102016	rHead Stem Implant 6mm Collar,Size 3	all
3102017	rHead Stem Implant 6mm Collar,Size 4	all
3102018	rHead Recon Stem Implant Plasma Coated, Size 1	all
3102019	rHead Recon Stem Implant Plasma Coated, Size 2	all
3102020	rHead Recon Stem Implant Plasma Coated, Size 3	all
3102021	rHead Recon Stem Implant Plasma Coated, Size 4	all
3102022	rHead Recon Stem Implant 6mm Collar,Size 1	all
3102023	rHead Recon Stem Implant 6mm Collar,Size 2	all
3102024	rHead Recon Stem Implant 6mm Collar,Size 3	all
3102025	rHead Recon Stem Implant 6mm Collar,Size 4	all
4100000	Radio Capitellum Large, Left	all
4100001	Radio Capitellum Small, Left	all
4100002	Radio Capitellum Large, Right	all
4100003	Radio Capitellum Small, Right	all
4100004	Radial Head Assy Size #2, Rad	all
4100005	Radial Head Assy Size #3, Rad	all
4100006	Radial Head Assy Size #4, Rad	all
4100007	Radio Capitellum, Recon Head, Size #2	all
4100008	Radio Capitellum, Recon Head, Size #3	all
4100009	Radio Capitellum, Recon Head, Size #4	all
4100100	rHead Standard Extended Stem, 6mm Collar, Size 1	all
4100101	rHead Standard Extended Stem, 6mm Collar, Size 2	all
4100102	rHead Standard Extended Stem, 6mm Collar, Size 3	all
4100103	rHead Standard Extended Stem, 6mm Collar, Size 4	all

4100300	rHead Recon Extended Stem Size 1	all
4100301	rHead Recon Extended Stem Size 2	all
4100302	rHead Recon Extended Stem Size 3	all
4100303	rHead Recon Extended Stem Size 4	all
4103050	Radio CapitellumTemplate Small, Assembly	all
4103070	Radio CapitellumTemplate Large, Assembly	all
RCNH2	#2 Bipolar radial head Implant (Sterile packed)	all
RCNH3	#3 Bipolar radial head Implant (Sterile packed)	all
RCNH4	#4 Bipolar radial head Implant (Sterile packed)	all
RCNS1	#1 Bipolar stem implant (Sterile packed)	all
RCNS160	rHead Recon Stem Implant non-coated, Size 1	all
RCNS2	#2 Bipolar stem implant (Sterile packed)	all
RCNS260	rHead Recon Stem Implant non-coated, Size 2	all
RCNS3	#3 Bipolar stem implant (Sterile packed)	all
RCNS360	rHead Recon Stem Implant non-coated, Size 3	all
RCNS4	#4 Bipolar stem implant (Sterile packed)	all
RCNS460	rHead Recon Stem Implant non-coated, Size 4	all
RHAH2	radial head implant #2 (Sterile packed)	all
RHAH3	radial head implant #3 (Sterile packed)	all
RHAH4	radial head implant #4 (Sterile packed)	all
RHAS1	radial stem implant #1 (Sterile packed)	all
RHAS160	rHead, Radial Implant 6 mm Collar, Size 1	all
RHAS2	radial stem implant #2 (Sterile packed)	all
RHAS260	rHead, Radial Implant 6 mm Collar, Size 2	all
RHAS3	radial stem implant #3 (Sterile packed)	all
RHAS360	rHead, Radial Implant 6 mm Collar, Size 3	all
RHAS4	radial stem implant #4 (Sterile packed)	all
RHAS460	rHead, Radial Implant 6 mm Collar, Size 4	all
1000044	rHead Extended Stem Instrument Set	all
170929	rHead Resection Guide 6M M Spacer	all
170946	rHead, Head Trial Size 2	all
170947	rHead, Head Trial Size 3	all
170948	rHead, Head Trial Size 4	all
170949	rHead, Head Trial Size 2	all
170950	rHead, Head Trial Size 3	all
170951	rHead, Head Trial Size 4	all
170952	Broach Assembly Proximal Radial, Size 2	all
170953	Broach Assembly Proximal Radial, Size 3	all
170954	Broach Assembly Proximal Radial, Size 4	all
170956	rHead Impactor Assy	all
170966	RHead Instrument Tray Assembly	all
170967	rHead, Resection Guide	all
170972	rHead, Stem Trial Standard Collar, Size 1	all
170974	rHead Broach Assy Size 1	all
170992	rHead Recon Assembly Tool	all
171649	rHead, Stem Trial Extended Collar, Size 1	all
171650	rHead, Stem Trial Extended Collar, Size 2	all
171651	rHead, Stem Trial Extended Collar, Size 3	all

171652	rHead, Stem Trial Extended Collar, Size 4	all
3120406	Lateral Assembly RADIAL STEM TRIAL,Size 1	all
3120407	Lat Assembly Radial Stem Trial,Collar 6mm, Size 1	all
3120506	Lateral Assembly Radial Stem Trial Size 2	all
3120507	Lat Assembly Radial Stem Trial,Collar 6mm, Size 2	all
3120511	Lateral Assembly Radial Head Trial Size 2	all
3120606	Lateral Assembly Radial Stem Trial Size 3	all
3120607	Lat Assembly Radial Stem Trial,Collar 6mm, Size 3	all
3120611	Lateral Assembly Radial Head Trial Size 3	all
3120706	Lateral Assembly Radial Stem Trial Size 4	all
3120707	Lat Assembly Radial Stem Trial,Collar 6mm, Size 4	all
3120711	Lateral Assembly Radial Head Trial Size 4	all
3120800	rHead Lateral Assembly Tool	all
3120805	Impactor, Stem rHead Lateral	all
3130100	rHead Extended Stem Trial 6mm, Size 1	all
3130101	rHead Extended Stem Trial 6mm, Size 2	all
3130102	rHead Extended Stem Trial 6mm, Size 3	all
3130103	rHead Extended Stem Trial 6mm, Size 4	all
3140101	rHead Extended Stem Broach, Size 1	all
3140102	rHead Extended Stem Broach, Size 2	all
3140103	rHead Extended Stem Broach, Size 3	all
3140104	rHead Extended Stem Broach, Size 4	all
4103010	Radio Capitellum Trial Handle Assembly	all
4103155	Radio Capitellum Trial Small, Left	all
4103175	Radio Capitellum Trial Large, Left	all
4103255	Radio Capitellum Trial Small, Right	all
4103275	Radio Capitellum Trial Large, Right	all
4104150	Radio Capitellum Broach Small, Left	all
4104170	Radio Capitellum Broach Large, Left	all
4104250	Radio Capitellum Broach Small, Right	all
4104270	Radio Capitellum Broach Large, Right	all
4105000	Radio Capitellum Impactor, Assembly	all
4105030	Radio Capitellum Resection Guide, Small	all
4105035	Radio Capitellum Resection Guide, Large	all
4105040	RadioCapitellumResection Guide Handle Assembly	all
4105045	Radio Capitellum Axis Locator Clamp, L-Bar	all
4105050	Radio Capitellum Axis Locator ClampSlotposBolt	all
4105055	Radio Capitellum Axis Locator Clamp Loc Cup	all
4105060	Radio Capitellum Axis Locator Clamp CupposBolt	all
4105065	Radio Capitellum Axis Locator Clamp Upper Arm	all
4105070	Radio Capitellum Axis Locator Clamp DrillGuide	all
4511045	K-wire, Single point, St St, 150mm, .045"	all
6000020	Radio Capitellum Insrtrument Tray	all
6000100	rHead Extended Stem Instrument Tray Lid	all
6030050	Uni ElbowRadioCapitellum Insrtrument Set	all
6030100	rHead Extended Stem Instrument Tray Base	all
9230100	rHead Extended Stem Awl	all
9270100	rHead Extended Stem Res. Guide Flange, 6mm	all

RCKR	rHead Combination Instrument Set	all
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FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

FSCA Identifier: Product Field Action RA Ref # 1638238

Type of Action: Field Safety Corrective Action

Description: rHead Radial Head and Uni-Elbow System

Legal Manufacturer Stryker GmbH, Bohnackerweg 1
2545 Selzach, Switzerland

Product name: See Attachment

Catalogue #: See Attachment

Lot #s: All lots

I acknowledge receipt of the Field Safety Notice for RA Ref # 1638238 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	Qty Quarantined
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				
Form completed by:				

Contact Name _____ **Contact Facility** _____
Contact address _____ **Contact Position** _____
 _____ **Contact Tel No** _____
 _____ **Contact Fax No** _____
 _____ **Contact e-mail** _____

**PLEASE COMPLETE AND FAX THIS FORM TO X
OR EMAIL TO X.**