Date

URGENT FIELD SAFETY NOTICE: RA2015-068

FSCA Identifier: Product Field Action RA 2015-068

Type of Action: Field Safety Corrective Action

Description: rHead, uHead, Sigmoid Notch, ReMotion, Radio Capitellum

Legal Manufacturer Stryker Trauma AG, Bohnackerweg 1, 2545 Selzach, Switzerland
Note: Products have been distributed and labelled by former manufacturer Small Bone Innovations Inc, 1380 S. Pennsylvania Ave., Morrisville, PA 19057, USA

Catalogue #s: Refer to the attached list on page 5

Lot #s: Refer to the attached list on page 5

Dear Customer,

Please find attached details of a Product Field Action that has been initiated by Stryker Trauma AG, Division Trauma and Extremities concerning the above referenced devices. Concerned products have been distributed and labelled by former manufacturer Small Bone Innovations Inc, 1380 S. Pennsylvania Ave., Morrisville, PA 19057, USA.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. It may be that you no longer have any physical inventory on site.

This action has been taken to ensure that users are aware of important Information concerning the devices listed above. You are required only to read the attached Field Safety Notice and then sign and return the customer response form confirming that you have completed the actions requested by the manufacturer.

Completing the Customer Response Form (see page 8) 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.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is 5th August 2015 and your timely response will enable us to ensure that we meet this target and ensure that non conforming devices are removed from the market as quickly as possible.

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: X

Position:	Regulatory Affairs Specialist
E-mail:	X
Tel:	X
Fax:	X

In line with the recommendations of the MEDDEV Vigilance Guidance document Ref 2.12-1, we can confirm that this FCA (Field Corrective Action) 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 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,

X
Quality Assurance and Regulatory Affairs

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Dear Customer,

Stryker Trauma AG, Division Trauma and Extremities, has initiated a Product Field Action for the devices identified above. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue

Stryker became aware during laboratory testing that there is a potential that the packaging integrity (sterile barrier) of the packaging type KIT I may be compromised by transportation. A compromised sterile barrier could result in the surgeon selecting a back-up device or, if not recognized, an unintended implantation of a potentially non sterile device. The packaging type KIT I consists of a white cardboard box, an outer peel pouch, and an inner peel pouch:

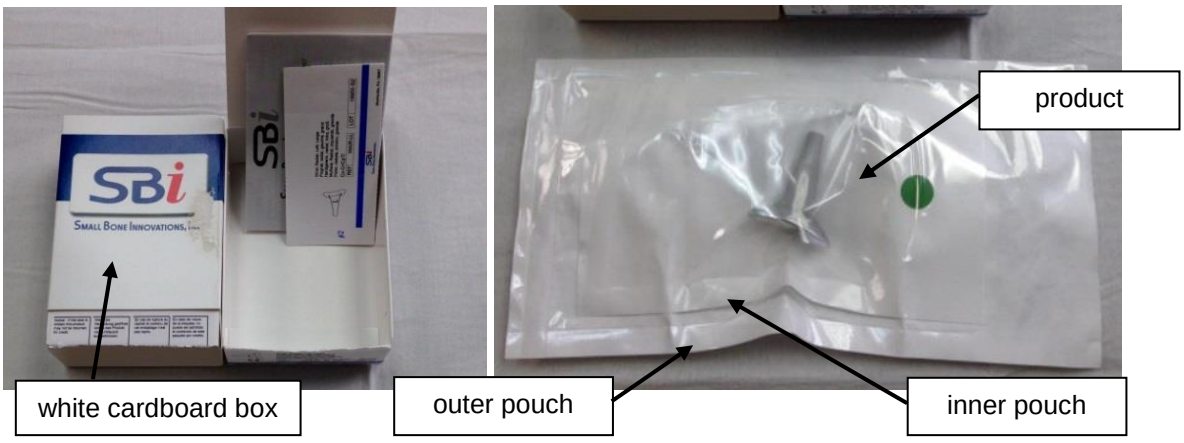

Figure 1: Example of KIT I packaging configuration

Potential Hazards

A compromised sterile barrier could potentially cause:

- Additional time under anesthesia due to prolongation of surgery
- Implantation of potentially non-sterile device

Mitigating Factors
- The initial sterilization of the affected products remains effective.
- As per IFU, 'The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.'
- Packaging evaluations reveal that a contamination due to the described issue is considered to be unlikely. Furthermore, any contaminate to remain viable and cause infection would require a difficult path.
- It is standard practice for surgeons to prescribe antibiotics peri-operatively in order to reduce the risk of potential infection, especially in situations where the injury was caused due to excessive trauma.
- The affected products should not be used for upcoming procedures.

Type of Action
Recall of subject devices.

Immediate actions
Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions:

Our records indicate that you have received at least one of the subject devices listed above. We therefore request that you:

1. Please inform users of this Medical Device Field Removal and pass this notice to all those individuals who need to be aware within your organization.
2. Complete and sign the enclosed PFA Acknowledgment Form and return to X by fax (X) or by email (X). A Stryker representative will then be in contact to arrange for product return.
3. Keep a copy of the completed and executed Business Reply Form for your records.
4. Report all adverse events or product quality problems to Stryker.

We sincerely regret any inconvenience that this action may cause you and on behalf of Stryker would like to thank you for your help and support in completing this action in a timely manner.

Should you have any queries on this matter please do not hesitate to contact the undersigned.

Yours faithfully

X
Quality Assurance and Regulatory Affairs

Appendix:
PFA Acknowledgment Form

RA2015-068 Affected Product and Lot Codes

Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
310-0000	Lateral Assembly, Radial Implant, Size 1	22288301, 22890701, 23424401, 23916901, 19058-S2, 19452-S2, 19661-S2, 19662-S2, 19712-S2, 19736-S2, 19841-S2
310-0001	Lateral Assembly, Radial Stem Implant, Size 2	22629201, 22890801, 23424501, 23917001, 19453-S2, 19737-S2, 19765-S2, 19766-S2, 19793-S2
310-0002	Lateral Assembly, Radial Stem Implant, Size 3	22288401, 22629301, 23198901, 23424601, 23917101, 19678-S2, 19767-S2, 19768-S2, 19794-S2, 19842-S2
310-0003	Lateral Assembly, Radial Stem Implant, Size 4	22288501, 23199001, 23424701, 23917201, 19068-S2, 19679-S2, 19713-S2, 19738-S2, 19795-S2, 19843-S2
310-0004	Lat Assembly, Rad Stem Implant,Collar 6mm,Size1	22288601, 23424801, 19057-S2, 19067-S2, 19454-S2, 19739-S2, 19796-S2, 19844-S2
310-0005	Lat Assembly, Rad Stem Implant,Collar 6mm,Size2	23424901, 23917301, 19063-S2, 19124-S2, 19455-S2, 19714-S2, 19740-S2, 19797-S2
310-0006	Lat Assembly, Rad Stem Implant,Collar 6mm,Size3	23199101, 23425001, 19059-S2, 19456-S2, 19680-S2, 19741-S2, 19798-S2, 19845-S2
310-0007	Lat Assembly, Rad Stem Implant,Collar 6mm,Size4	22890901, 23425101, 19060-S2, 19125-S2, 19457-S2
310-0008	Lateral Assembly, Radial Head Implant, Size 2	22288701, 22629401, 22891001, 23199201, 23425201, 23917401
310-0009	Lateral Assembly, Radial Head Implant, Size 3	15886, 22288801, 22629501, 22891101, 23199301, 23425301, 23917501, 23917502
310-0010	Lat Assembly, Rad Stem Head Implant, Size 4	15887, 23199401, 23425401, 23917601, 19458-S2
310-0011	Lateral Assembly, Radial Head Impl Assembly,Size2	16708, 16709, 22629601, 22891201, 23425501
310-0012	Lateral Assembly, Radial Head Impl Assembly,Size3	16710, 16711, 22629701, 22891301, 23425601
310-0013	Lateral Assembly, Radial Head Impl Assembly,Size4	16712, 23425701
310-2010	rHead Stem Implant Plasma Coated, Size 1	22552401, 19693-S2, 19742-S2, 19799-S2
310-2011	rHead Stem Implant Plasma Coated, Size 2	22552501, 19694-S2, 19743-S2
310-2012	rHead Stem Implant Plasma Coated, Size 3	22552601, 19070-S2, 19695-S2, 19744-S2, 19800-S2
310-2013	rHead Stem Implant Plasma Coated, Size 4	22552701, 19696-S2, 19745-S2
310-2014	rHead Stem Implant 6mm Collar,Size 1	22552801, 22552802, 19697-S2, 19698-S2, 19746-S2
310-2015	rHead Stem Implant 6mm Collar,Size 2	22552901, 19699-S2, 19747-S2, 19915-S2
310-2016	rHead Stem Implant 6mm Collar,Size 3	22553001, 19700-S2, 19748-S2
310-2017	rHead Stem Implant 6mm Collar,Size 4	22553101
310-2018	rHead Recon Stem Implant Plasma Coated, Size 1	22553201, 22889801, 19701-S2, 19749-S2, 19801-S2
310-2019	rHead Recon Stem Implant Plasma Coated, Size 2	22553301, 22889901, 19702-S2, 19750-S2, 19916-S2, 19975-S2
310-2020	rHead Recon Stem Implant Plasma Coated, Size 3	22553401, 22890001, 19703-S2, 19751-S2, 19802-S2, 19976-S2
310-2021	rHead Recon Stem Implant Plasma Coated, Size 4	22553501, 22890101, 19076-S2, 19704-S2, 19752-S2, 19917-S2, 19977-S2
310-2022	rHead Recon Stem Implant 6mm Collar,Size 1	22553601, 22890201, 19705-S2, 19753-S2
310-2023	rHead Recon Stem Implant 6mm Collar,Size 2	22553701, 22890301, 19706-S2, 19754-S2

310-2024	rHead Recon Stem Implant 6mm Collar,Size 3	22553801, 22890401, 19075-S2, 19707-S2, 19755-S2
310-2025	rHead Recon Stem Implant 6mm Collar,Size 4	22553901, 22890501, 19071-S2
390-0305	Sigmoid Notch Radial Stem Small	18362, 22834401, 23852901
390-0307	Sigmoid Notch Radial Stem Large	18728, 18815, 18816, 18817, 22834501, 23853001
410-0000	Radio Capitellum Large, Left	18832, 22193201, 22193202, 22193203, 22258301, 22957101, 23853901, 19069-S2, 19077-S2, 19155-S2
410-0001	Radio Capitellum Small, Left	18833, 18834, 22193301, 22193302, 22193303, 22766801, 22956201, 23853101
410-0002	Radio Capitellum Large, Right	18835, 18836, 22193401, 22193402, 22193403, 22766901, 22956301, 23853201, 19074-S2
410-0003	Radio Capitellum Small, Right	18565, 22193501, 22193502, 22193503, 22767001, 22956401, 23853301
410-0100	rHead Standard Extended Stem, 6mm Collar, Size 1	18527, 18724, 19681-S2, 19715-S2
410-0101	rHead Standard Extended Stem, 6mm Collar, Size 2	18528, 18725, 19682-S2, 19756-S2
410-0102	rHead Standard Extended Stem, 6mm Collar, Size 3	18529, 18726, 19663-S2, 19757-S2
410-0103	rHead Standard Extended Stem, 6mm Collar, Size 4	18530, 18727, 19683-S2, 19758-S2
RCN-S1	#1 Bipolar stem implant (Sterile packed)	18566, 18567, 18568, 18697, 18837, 22297901, 22297902, 22848901, 19099-S2, 19101-S2, 19684-S2, 19685-S2, 19716-S2, 19769-S2, 19803-S2, 19846-S2, 19918-S2, 19919-S2, 19982-S2
RCN-S160	rHead Recon Stem Implant non-coated, Size 1	18370, 18371, 18388, 18569, 18698, 18718, 18838, 22614101, 22849001, 23068201, 19102-S2, 19103-S2, 19104-S2, 19717-S2, 19804-S2, 19920-S2
RCN-S2	#2 Bipolar stem implant (Sterile packed)	18295, 18753, 18839, 22098402, 22298001, 22298002, 22614201, 22614202, 22849101, 23068301, 19664-S2, 19718-S2, 19719-S2, 19770-S2, 19771-S2, 19772-S2, 19805-S2, 19847-S2, 19848-S2, 19849-S2, 19850-S2, 19921-S2
RCN-S260	rHead Recon Stem Implant non-coated, Size 2	18372, 18373, 18699, 18719, 18840, 22614301, 22849201, 23068401, 19105-S2, 19106-S2, 19107-S2, 19773-S2, 19851-S2, 19984-S2
RCN-S3	#3 Bipolar stem implant (Sterile packed)	18296, 18754, 22298101, 22298102, 22614401, 22614402, 22849301, 23068501, 23068502, 23479701, 19665-S2, 19720-S2, 19721-S2, 19722-S2, 19774-S2, 19775-S2, 19776-S2, 19806-S2, 19852-S2, 19853-S2, R23479701
RCN-S360	rHead Recon Stem Implant non-coated, Size 3	18570, 18571, 18700, 18701, 18702, 18755, 18841, 18842, 22298301, 22298302, 22849401, 23479801, 19108-S2, 19686-S2, 19723-S2, 19807-S2, 19854-S2, 19986-S2, R23479801
RCN-S4	#4 Bipolar stem implant (Sterile packed)	18885, 18886, 22298201, 22298202, 22614501, 22614502, 22849501, 23068601, 23479901, 19666-S2, 19724-S2, 19725-S2, 19777-S2, 19808-S2, 19855-S2, 19856-S2, 19922-S2, 19988-S2, R23479901
RCN-S460	rHead Recon Stem Implant non-coated, Size 4	18572, 18703, 18704, 18756, 18843, 18844, 22298401, 22614601, 22849601, 19109-S2, 19110-S2
RHA-S1	radial stem implant #1 (Sterile packed)	18374, 18387, 18500, 18574, 18705, 18706, 18845, 18846, 18847, 22613001, 22850001, 23069001, 19111-S2, 19112-S2, 19726-S2, 19778-S2, 19857-S2
RHA-S160	rHead, Radial Implant 6 mm Collar, Size 1	18375, 18386, 18501, 18707, 18708, 18848, 18849, 18850, 18851, 18852, 22613101, 22850101, 23069101, 19113-S2, 19114-S2, 19115-S2, 19779-S2, 19809-S2
RHA-S2	radial stem implant #2 (Sterile packed)	22098802, 22279401, 22279402, 22613201, 22850201, 23069201, 23493402, 19667-S2, 19780-S2, 19781-S2, 19810-S2, 19859-S2, 19860-S2, 19861-S2, 19923-S2, R23493402
RHA-S260	rHead, Radial Implant 6 mm Collar, Size 2	18376, 18384, 18385, 18502, 18575, 18709, 18720, 18853, 18854, 22613301, 22850301, 23069301, 19116-S2, 19117-S2, 19782-S2
RHA-S3	radial stem implant #3 (Sterile packed)	18855, 22098902, 22279501, 22279502, 22613401, 22613402, 22850401, 23069401, 23226201, 23490201, 19687-S2, 19727-S2, 19728-S2, 19729-S2, 19783-S2, 19811-S2, 19812-S2, 19862-S2, 19863-S2, 19924-S2, 19925-S2, R23490201

RHA-S360	rHead, Radial Implant 6 mm Collar, Size 3	18377, 18383, 18503, 18710, 18711, 18856, 18857, 18858, 18859, 22613501, 22850501, 19118-S2, 19119-S2, 19730-S2, 19813-S2
RHA-S4	radial stem implant #4 (Sterile packed)	18378, 22279601, 22613601, 22613602, 22850601, 23069501, 23226301, 23491501, 19668-S2, 19784-S2, 19814-S2, 19864-S2, 19926-S2, 19927-S2, R23491501
RHA-S460	rHead, Radial Implant 6 mm Collar, Size 4	18379, 18382, 18504, 18576, 18712, 18713, 18860, 18861, 18862, 22613701, 22850701, 19120-S2, 19121-S2
UHA-S1	Ulnar Stem Implant # 1 Sterile packed	17584, 17585, 22217301, 22217302, 23470801, 19066-S2, 19417-S2, 19418-S2, 19731-S2, 19732-S2, 19785-S2, 19815-S2, 19865-S2, R23470801
UHA-S120	Recon Ulnar Stem Implant #1, 20mm extension	16725, 16726, 18577, 18757, 18758, 18759, 18867, 23124001, 19056-S2, 19786-S2, 19816-S2, 19928-S2, 19929-S2
UHA-S2	Ulnar Stem Implant # 2 Sterile packed	16714, 16715, 18760, 22760101, 22760102, 23124101, 23124102, 23470901, 19669-S2, 19817-S2, 19866-S2, R23470901
UHA-S220	Recon Ulnar Stem Implant #2, 20mm extension	16720, 16721, 18415, 18761, 18762, 18763, 18764, 18765, 18868, 23124201, 19122-S2, 19787-S2, 19818-S2, 19930-S2, 19931-S2, 19932-S2
UHA-S3	Ulnar Stem Implant # 3 Sterile packed	16716, 16717, 22760201, 22760202, 22760203, 23124301, 23124302, 19788-S2, 19789-S2, 19819-S2, 19820-S2, 19821-S2, 19867-S2, 19868-S2
UHA-S320	Recon Ulnar Stem Implant #3, 20mm extension	16722, 16723, 18869, 19065-S2, 19157-S2, 19733-S2, 19790-S2, 19933-S2
UHA-S4	Ulnar Stem Implant # 4 Sterile packed	16718, 16719, 18766, 18865, 18866, 19156-S2, 19670-S2, 19671-S2, 19672-S2, 19734-S2, 19822-S2, 19869-S2
UHA-S420	Recon Ulnar Stem Implant #4, 20mm extension	16724, 18578, 18767, 18768, 18870, 18871, 22760301, 19072-S2, 19100-S2, 19158-S2, 19791-S2, 19823-S2, 19934-S2, 19935-S2
WA/C-L	Wrist Carpal Implant Large	23689901, 23946601, 23946602, 23946603, 24056601, 19064-S2
WA/C-M	Wrist Carpal Implant Medium	22296901, 22296902, 22595501, 22595502, 22758401, 22758402, 23041201, 23216201, 23689801, 23689802, 23689803, 23946801, 23946802, 23946803, 24056701, 24056702, 24056703
WA/C-S	Wrist Carpal Implant Small	22297001, 22297002, 22431101, 22595601, 22595602, 22758501, 22758502, 23041301, 23689701, 23689702, 23689703, 23946701, 23946702, 23946703, 24056801, 24056802, 24056803
WA/R-LL	Wrist Left Radial Implant, Large	18872, 23946901, 23946902, 23946903, 24056901, 19061-S2, 19605-S2, 19828-S2, 19829-S2, 19955-S2, R19605-S2, R19828-S2, R19829-S2
WA/R-LM	Wrist Left Radial Implant, Medium	22595701, 22758601, 22758602, 23041401, 23690401, 23690402, 23690403, 24057001, 19062-S2, R23690401, R23690402, R23690403
WA/R-LS	Wrist Left Radial Implant, Small	22758701, 22758702, 23041501, 23216301, 23690501, 23690502, 24057101, 24057102, R23690501, R23690502
WA/R-LXS	Distal Radial Comp X-Small, Left, Sterile	18794, 18873, 22758801, 22758802, 23041601
WA/R-RL	Wrist Right Radial Implant, Large	18795, 23690001, 23690002, 23690003, 24057201, R23690001, R23690002, R23690003
WA/R-RM	Wrist Right Radial Implant Medium	15892, 22297101, 22595801, 22758901, 22758902, 23041701, 23261401, 23690101, 23690102, 23690103, 23947101, 23947102, 24057301, R23690101, R23690102
WA/R-RS	Wrist Right Radial Implant Small	22297201, 22595901, 22595902, 22759001, 22759002, 23041801, 23261501, 23690201, 23690202, 23690203, 23947001, 23947002, 23947003, 23947004, 24057401, 19073-S2, R23690201, R23690202
WA/R-RXS	Distal Radial Comp X-Small, Right, Sterile	18796, 18874, 22596001, 22759101, 22759102, 23041901, 23690301, 23690302, 23690303, 23947201, 24057501, R23690301, R23690302, R23690303

RA2015-068: PFA ACKNOWLEDGMENT FORM

FSCA Identifier: Product Field Action RA 2015-068

Type of Action: Field Safety Corrective Action

Description: rHead, uHead, Sigmoid Notch, ReMotion, Radio Capitellum

Legal Manufacturer Stryker Trauma AG, Bohnackerweg 1, 2545 Selzach, Switzerland
Note: Products have been distributed and labelled by former manufacturer Small Bone Innovations Inc, 1380 S. Pennsylvania Ave., Morrisville, PA 19057, USA

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I acknowledge receipt of the Field Safety Notice for RA2015-068 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**	**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.