Urgent Field Safety Notice: RA2023-3471895

December 2023

Affected product

Product Family Names: Scorpio, Duracon, PCA, Trident

Identification of the Affected Products: See Part/Lot Number Attachment: PFA RA2023-3471895 starting on page 3

Dear Customer,

Stryker has initiated a voluntary, lot specific recall for the devices listed in the Part/Lot Number Attachment: PFA RA2023-3471895. The intent of this letter is to list all known hazards and harms potentially associated with the below noted issue and list the risk mitigation factors associated with the use of the product.

Issue

The industry guidance for storage duration of Ultra High Molecular Weight Polyethylene (UHMWPE) raw material used in the manufacture of soft implant bearing/articulating material of prosthetic joints is less than 5 years. Product manufactured using UHMWPE raw material over 5 years of age has the potential for elevated levels of oxidation. Oxidation within UHMWPE can have an impact on its material properties.

Stryker has become aware that the devices listed in the Part/Lot Number Attachment: PFA RA2023-3471895 have been manufactured with UHMWPE raw material aged over 5 years.

Potential Hazards

- Excessive Wear Debris
- Material Fragments
- Fractured Device

Potential Harms

- Revision Surgery
- Pain
- Inflammation

Risk Mitigations

Product with a high oxidation index can become discolored. However, not all product with a high oxidation index becomes discolored. In instances where the product is discolored, the issue may be recognized by the user.

Recommendations for patients already implanted with an impacted device

Post-market and National Registry Joint data were evaluated for devices in scope. Stryker identified no trends for the potential hazards. Patients treated with an impacted product identified should continue to be followed per the normal protocol established by his or her surgeon(s). There are no recommended changes to the frequency of the standard follow-up care protocol. Additional or more frequent patient monitoring or follow-up may be required in accordance with clinical judgment.

Actions needed

Our records indicate that you may have received the affected product(s). 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. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.

1. Circulate this Field Safety Notice internally to all interested/affected parties.
2. Maintain awareness of this notice internally until all required actions have been completed within your facility.
3. Discontinue use of the recalled devices identified in the affected product list (see *Table 1)*.
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
    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.
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
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.
    a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt.

Please respond event if you do not have a record of receiving affected inventory. This will enable us to update our records and negate the need to send unnecessary reminder letters.
Your timely response will enable us to update our records and negate the need to send reminder notices.

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: Amandip Auluck
Position: Associate Manager, Post-Market Surveillance
email: amandip.auluck@stryker.com

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.

Sincerely,

Nina Goddard
Regulatory Affairs and Quality Assurance

Part/Lot Number Attachment: PFA RA2023-3471895					
Part Number	**Product Description**	**Lot Numbers**			**GTIN**
3044-0026	SCORPIO RECESSED PATELLA	PVDY TEN1 AMN1	V644 MHHE 4T1K	V355 55LK JR6R	07613327033779
3044-0028	SCORPIO RECESSED PATELLA	A59N	EP7J	X79L	07613327033793
3044-0030	SCORPIO RECESSED PATELLA	PD99	6AHH	RY3J	07613327033809
3044-0032	SCORPIO RECESSED PATELLA	6LR4	R14V	N882	07613327033823
3052-0515	SERIES II TIBIAL BEAR INSERT	WK4PX0			07613327034042
3052-0524	SERIES II TIBIAL BEAR INSERT	K349TP			07613327034073
72-4-0321	SCORPIO TS TIB INSERT	TA21X9			07613327034349
72-4-0510	SCORPIO TS TIB INSERT	H43RDK WR1RE3	768NEY 4J13P1		07613327034363
72-4-7512	SCORPIO TS TIB INSERT	5M6LM1			07613327034790
72-4-7514	SCORPIO TS TIB INSERT	482LM8	HH43K7		07613327034820
72-4-7516	SCORPIO TS TIB INSERT	TN1746	KK82WY		07613327034806
72-4-7518	SCORPIO TS TIB INSERT	9P8360	AK8393		07613327034813
72-4-7521	SCORPIO TS TIB INSERT	VA0X4T			07613327034837
72-4-7524	SCORPIO TS TIB INSERT	V68WW1	93400601		07613327034844
72-15-0324	Scorpio-Flex Ttl Kn P-S Tib Brg Insrt Asy	53867101			07613154020133
72-16-0908	Scorpio-Flex Ttl Kn CR Tib Brg Insrt Asy	42968601			07613154020638
72-16-0910	Scorpio-Flex Ttl Kn CR Tib Brg Insrt Asy	43103101			07613154020645
73-0110	SCORPIO TOTAL KNEE MEDIALIZED DOME PATELLA-SZ #11	79E0 274P	WEKJ LH82	33ND	07613327050288
73-0510	SCORPIO TOTAL KNEE MEDIALIZED DOME PATELLA-SZ #5	57A2 3WP6	E10K X49N	WJ3L 38TY	07613327050301
73-0710	SCORPIO TOTAL KNEE MEDIALIZED DOME PATELLA-SZ #7	RLAR 2P84 EW6V 90AV 4JHN 65A3 22MP NNE7	Y373 58LA VXAL 4201 A2AN 5YP8 X0P9 9A8T	6LN7 WEL3 NDK3 25WJ T2JW YVWT 7DR0 DMVL	07613327050295
73-0910	SCORPIO TOTAL KNEE MEDIALIZED DOME PATELLA-SZ #9	X1WP 6KE9 DL4V HHPW 1NL2 4JHW	0TNX WN5E 2EM2 96N0 HW7E T9NM	J72T M73H HM8H MEM7 M8HN WL3Y	07613327050332
73-2110	SCORPIO TOTAL KNEE CONCENTRIC DOME PATELLA-SZ #11	LT28	4TXX		07613327033816
73-2710	SCORPIO TOTAL KNEE CONCENTRIC DOME PATELLA-SZ #7	V25H MD9E	5MYL H9T8	845P	07613327033847

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Part Number	**Product Description**	**Lot Numbers**			**GTIN**
73-2910	SCORPIO TOTAL KNEE CONCENTRIC DOME PATELLA-SZ #9	A02W NPPV	75TX 6RLN		07613327033854
73-3110	SCORPIO U-DOME PATELLA	XEA7 8P83 690Y MRM3 67D4	4902 YNP7 3AYN AYHM W3MD	76KN K4P9 792H 43T8 MW40	07613327033861
73-3308	SCORPIO U-DOME PATELLA	2H58 2J0W	8H52 64MJ	X0H9 70E9	07613327033878
73-3508	SCORPIO U-DOME PATELLA	EPXH DYAE XVK2 PVP9 LJ0K 12R3	N8P6 T355 8HDN A3EV 5LKW R04Y RKT1	D06K 01JR 3PA4 0AYL W424 53T1 Y7X2	07613327033885
73-3708	SCORPIO U-DOME PATELLA	RDWN 4W3T V768 VJ05 TWT6 ADK0 855 D6D9	TXL1 53RN KR24 M3T4 VE90 EKK2 36L1 NH6E	8PWK R9A4 NWXA D47L 5JVL D16P E2LP 927H JR5N	07613327033892
73-3710	SCORPIO U-DOME PATELLA	RNT5 3YNP PEA1 NNA5	5A2R 98AH T1JH 8D72	E0VH 3PA0 05L4 R608	07613327033908
73-3910	SCORPIO U-DOME PATELLA	73JP V17W N2MY PK0D D3M3	LEAY 4NTR R5WA JN8M 084W K6YE	84A4 XREK YNM1 LY5M M1AT 4873	07613327033915
82-2-0908	Scorpio NRG Tibial Brg Insert Assy	42874701 42912101	42995601		04546540400734
82-2-0910	Scorpio NRG Tibial Brg Insert Assy	42912201	42961901		04546540400741
620-00-28J	HOWMEDICA OSTEONICS TRIDENT 0 deg POLY INSERT	38059601			Inactive
620-00-32J	HOWMEDICA OSTEONICS TRIDENT 0 deg POLY INSERT	29518001			Inactive
6302-6-107	P7 28MM 10 DEGREE +4MM INSERT	61311701	62122001		07613153076155

Part/Lot Number Attachment: PFA RA2023-3471895			
Part Number	**Product Description**	**Lot Numbers**	**GTIN**
6302-6-307	P7 32MM 1O DEGREE +4MM INSERT	62112001 62120801	07613153076407
6637-0-028	LEFT SMALL-PCA MOD.REV.DUR.REV.INSERT	42771401	04546540305831
6637-0-228	LEFT LARGE-PCA MOD.REV.DUR.REV.INSERT	54537601	04546540306012
6637-0-231	LEFT LARGE-PCA MOD.REV.DUR.REV.INSERT	42787901	04546540306029
6637-0-328	LEFT X-LARGE-PCA MOD.REV.DUR.REV.INSERT	42579701	04546540306104
6637-0-631	LEFT SMALL-PCA MOD.REV.DUR.REV.INSERT	36272501 42380501 42771601	04546540306203
6637-0-831	RGT.LARGE-PCA MOD.REV.-DUR.REV.INSERT	47475901	04546540306388
6637-0-928	RGT.LARGE-PCA MOD.REV.-DUR.REV.INSERT	41875401	04546540306463
6637-0-931	RGT.LARGE-PCA MOD.REV.-DUR.REV.INSERT	57403601	04546540306470
6637-4-031	PRIMARY REV.TIB.INSERT-DURACON	36273601 36609701	04546540306920
6637-4-231	"LARGE PRIMARY REV.TIB.INSERT-DURACON	33164901	04546540307101
6642-1-709	DURATION A-P LIPPED TIB.INSERT-DURAC	52098201 56002801 50677001 54184201 56662001	04546540318145
6642-1-911	DURATION A-P LIPPED TIB.INSERT-DURAC	56000801 57491601	04546540318299
6642-2-200	DURATION PLASTIC PATELLA-DURACON	383541	04546540318398
6728-2-609	DUR PCA MTK REV INS LFT	50884601	04546540322876
6728-2-611	DUR PCA MTK REV INS LFT	52814401	04546540322883
6728-2-709	DUR PCA MTK REV INS RT	51828501	04546540322944
6728-2-711	DUR PCA MTK REV INS RT	52177701	04546540322951
6742-1-411	PS LIPPED TIBIAL INSERT ASSY DURACON	584223	04546540324108
6742-1-413	PS LIPPED TIBIAL INSERT ASSY DURACON	559469 584958 561926	04546540324115
6742-1-416	PS LIPPED TIBIAL INSERT ASSY DURACON	571630 584840 582549	04546540324122
7291-0324	TIBIAL BEARING INSERT SERIES P-S I ASSY	59065701	04546540117144

Business Reply Form - response required

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Identification of the Affected Products:	See Part/Lot Number Attachment: PFA RA2023-3471895 starting on page 3

I have received the **Urgent Field Safety Notice** letter from Stryker dated December 2023, stating that the company has initiated a voluntary recall on the above referenced affected products.

Please complete the form even if you do not have inventory. This will preclude us from following up.

Customer information

Hospital name: _____

Name of person completing this form: _____ Title: _____

Direct phone number: _____ Email _____

Address: _____ City: _____

Postal code: _____ Country:_____

If affected inventory, please provide the information below. Attach additional sheet if needed.

Product code	Lot number	Qty quarantined	Qty destroyed	Qty returned

We have not located any of these devices in our inventory *(please add check mark to box)*: ☐

If you have **further distributed** subject devices, please provide information below:

Facility Name	Facility Address	Contact person	Product code	Lot number	Qty

I have read and understand the instructions provided and acknowledge receipt of the subjected Field Safety Notice. I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.

Name (print): _____ Signature: _____ Date: _____

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL nby_qara@stryker.com