

**Medical Device Recall**

TGA REF: RC-2015-RN-01207-1

Australia

**To:** Chief Executive Officer – CEO **Date:** 09 December 2015  
**Attention:** The Nurse Unit Manager, Operating Theatres **ARTG No.:** 242297  
**Product:** Titanium Fluted Stem Extender **Catalogue No.:** See Appendix 1



Stryker's Titanium Fluted Stem Extender is used with Stryker's Duracon and Scorpio Total Stabilizer Knee Implant Systems and Modular Rotating Hinge (MRH) Knee Implant Systems.

**Product Issue:**

Stryker Orthopaedics has become aware of the potential for confusion with regards to the intended use for the Titanium Fluted Stem Extender based on the addition of the text "Cemented Use Only" on the product label.

The fixation method of the Titanium Fluted Stem Extenders are not restricted in Australia and can be used for Cemented or Cementless applications, even though the labelling states "Cemented Use Only" for the lots identified in appendix A. As a result, there exists the potential for confusion in the operating theatre, resulting in complications associated with an extended surgery time of less than five minutes.

Our records indicate that you have received the above referenced product. Please assist us in meeting our regulatory obligation by completing the following actions:

**Required Action:**

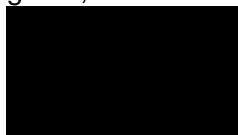
1. Immediately check all stock areas and quarantine any affected item.
2. A Stryker Representative will contact you to arrange for all affected components to be removed from your facility and arrange for a replacement, as required.
3. Once this has been completed, please sign the enclosed "Medical Device Recall Notification Response" form and return to the Stryker Representative or email: [sspra@stryker.com](mailto:sspra@stryker.com)

We are issuing this notice following consultation with the Therapeutic Goods Administration.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Corrective Action may create and appreciate your cooperation with our request.

**Additional Information:** Please contact your local Stryker representative or Kelly Rose (Marketing Manager, Orthopaedics) (+61 2 9467 1052).

Regards,



**Lachlan McKenzie**

Regulatory Affairs Principal,  
Stryker South Pacific

**NSW Office**

8 Herbert Street,  
St Leonards, NSW 2065  
T: (02) 9467 1111  
F: (02) 9467 1110

**Victorian Office**

Unit 3, 23 Bell Street  
Preston, VIC 3072  
T: (03) 9458 7000  
F: (03) 9458 7040

**Queensland Office**

2/14 Hockings Street  
West End, QLD 4101  
T: (07) 3840 5200  
F: (08) 3844 8688

**Western Australian Office**

33 Richardson Street, West  
Perth WA 6005  
T: (08) 9215 3600  
F: (08) 9215 3601

**South Australian Office**

33 Magill Road,  
Stepney, SA 5069  
T: (08) 8130 3000  
F: (08) 8130 3099

## ***Medical Device Recall Notification Response***

We:

\_\_\_\_\_  
(Insert Hospital Name – Please PRINT)

have received notification of the Medical Device Recall for the **Titanium Fluted Stem Extender**, and the required actions have been completed.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Phone No.

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Date

**Please Return by Fax to (02) 9467 1042**  
**or**  
**return a scanned copy via email at [sspra@stryker.com](mailto:sspra@stryker.com)**

\_\_\_\_\_  
Return response to:  
Seamus Orr (RA 2013-080)

Stryker Australia  
8 Herbert Street  
St. Leonards, NSW 2065

1800 803 601 (free-call)  
02 9467 1167 (direct line – Seamus Orr)  
02 9467 1042 (facsimile)

## **Affected Items and Lots**

Item No	Lot
64786600	T3371
64786600	T3363
64786600	T3388
64786600	T3327
64786600	T3401
64786600	T3326
64786600	T3372
64786605	T3366
64786605	T3364
64786605	T3406
64786610	T3367
64786610	T3369
64786610	T3368
64786610	T3415
64786610	T3413
64786610	T3414
64786615	T3376
64786615	T3377
64786615	T3379
64786615	T3307
64786615	T3378
64786615	T3308
64786615	T3301
64786620	T3346
64786620	T3348
64786620	T3303
64786620	T3380
64786620	T3304
64786620	T3305
64786620	T3402
64786620	T3349
64786620	T3347
64786620	T3430
64786625	T3331
64786625	T3251
64786625	T3389
64786625	T3400
64786625	T3399
64786625	T3396
64786625	T3390
64786625	T3398
64786625	T3432

Item No	Lot
64786625	T3445
64786625	T3373
64786625	T3397
64786630	T3386
64786630	T3351
64786630	T3321
64786630	T3417
64786630	T3352
64786630	T3387
64786630	T3416
64786635	T3394
64786635	T3261
64786635	T3420
64786635	T3421
64786635	T3323
64786635	T3333
64786635	T3262
64786640	T3313
64786640	T3314
64786640	T3411
64786640	T3412
64786645	T3258
64786645	T3391
64786645	T3337
64786645	T3338
64786655	T3324
64786655	T3256
64786680	T3294
64786680	T3295
64786680	T3381
64786680	T3393
64786685	T3358
64786685	T3325
64786685	T3403
64786690	T3362
64786690	T3392
64786690	T3306
64786690	T3404
64786695	T3328
64786695	T3410
64786695	T3409
64786695	T3332
64786695	T3282

Item No	Lot
64786705	T3343
64786705	T3292
64786705	T3423
64786705	T3344
64786705	T3342
64786710	T3339
64786710	T3340
64786715	T3226
64786715	T3227
64786715	T3357
64786715	T3427
64786720	T3233
64786730	T3230
64786750	T3234
64786750	T3285