

URGENT VOLUNTARY PRODUCT RECALL NOTIFICATION – R2015033
VEPTR® Vertical Expandable Prosthetic Titanium Rib Caudal Rib Supports (Rib-to-Rib Construct Only)

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

Synthes GmbH has initiated a voluntary recall of the VEPTR® Vertical Expandable Prosthetic Titanium Rib Caudal Rib Supports, which are used as a part of the VEPTR system to mechanically stabilize and distract the thorax in patients with thoracic insufficiency syndrome. It is important to note that this recall is only for VEPTR Caudal Rib Supports used for rib-to-rib constructs and NOT VEPTR Lumbar Extensions or any VEPTR II™ Titanium Rib Components. Please refer to the attached affected product listing, and be aware that some products in your possession may be affected.

REASON FOR THE RECALL

The last hole on certain VEPTR Caudal Rib Supports, subject to this recall, may be partially formed.

POTENTIAL HAZARD

Fully lengthening the construct to the partially formed last hole may result in mechanical failure of the construct due to extension bar breakage, which could require unplanned surgical intervention to exchange components. In addition to the risks inherent to re-operation, potential effects on the patient could also include pain, loss of deformity correction, and/or soft tissue/visceral injury.

To date we are not aware of any confirmed complaints of extension bar breakage directly related to a partially formed hole on the Caudal Rib Support. However, we have identified 8 complaints reported since VEPTR introduction in 2004 of extension bar breakage potentially occurring when lengthened to the terminal ends of the Caudal Rib Support.

PRODUCTS AFFECTED

This field safety notice involves the following product:

Product Code	Product Description	Affected lots
See Appendix 1	VEPTR Caudal Rib Supports	See Appendix 1

ACTIONS REQUIRED FROM YOU

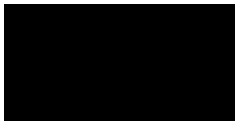
1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected product will not be used.

2. Review, complete, sign and return the attached Customer Acknowledgement Form to your DePuy Synthes sales representative or fax it to 6720 0750 within 5 business days of receipt of this notification.
3. To return affected product in your inventory, contact your DePuy Synthes sales representative or call our customer service. Attach a photocopy of the Customer Acknowledgement Form with the products. Johnson & Johnson Medical Singapore will issue credit for returned products, if applicable.
4. Pass this Field Safety Notice to anyone in your facility that needs to be informed.
5. If any of the affected products have been forwarded to another facility, contact that facility and arrange for the return.
6. Maintain awareness of this notice until all affected products have been returned to Johnson & Johnson Medical Singapore.
7. Keep a copy of this notice.
8. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

We apologize for the inconvenience this product recall may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your DePuy Synthes sales representatives.



Thank you for your cooperation and patience.

Yours sincerely,



Lee Ching Hwee
Senior Regulatory Affairs Executive

Appendix 1
Impacted Device Listing

Product Description	Item Number	Lot Numbers	
<p>Caudal Rib Supports, Neutral, 70 mm radius</p> 	Size 6 497.087	4550443 6005310 4938481 7613026 4947780 4955532 4947788 6011867 4955528 7371262 4955529 7371275 5830333 7424595 5830334 7459468	
	Size 7 497.088	4814417 5770304 4884492 5830335 4938495 6011868 4947969 7371263 4955498 7459469 4955501 7613027	
	Size 8 497.089	4686201 4938766 4814414 4947971 4938497 6011869 4938501	
	Size 9 497.241	4362268 4948022 4617047 4948024 4686202 4969628 4814412 5642583 4885508	
	Size 10 497.242	4686203 4969627 4885509 5759696 4948026 5835992 4948027 6011896	
	Size 11 497.243	4208597 5505857 4686204 5505862 4885510 5816076 4938751 6011855 4947982 6367928 4948033 6882133 4948034 7544008 4969626 9807745	
	<p>Caudal Rib Supports, Right, 70 mm radius</p> 	Size 6 497.093	4362289 5767359 4393923 5770641 4816422 5812094 4935344 6011844 4938512 7371280 4938515 7423480 4938759 7613044 4947977
		Size 7 497.094	4362288 4938758 4816420 4947978 4938517 6024576 4938519 7371281
		Size 8 497.095	4362286 4938523 4816414 4938756 4816415 5811904 4938521 6011884

Caudal Rib Supports,
Right, 70 mm radius
(Cont.)



Size 9	497.244	4362267	4947989
		4617048	4969625
		4885511	5767354
		4938753	5770536
		4947983	6005308
4947984	6011856		
Size 10	497.245	4362266	4947993
		4885512	4969624
		4938754	5682975
		4938755	5770675
		4947991	6011857
Size 11	497.246	4208598	5812078
		4938757	5812079
		4938760	6011877
		4938761	6087168
		4938765	6367930
		4947999	7599075
		4948002	7613037
		4948004	9807752
		5770692	

Caudal Rib Supports, Left
70 mm radius



Size 6	497.098	4362283	4947925
		4562149	4955412
		4617874	4955413
		4816115	6005302
		4816117	6011850
4884494	7371288		
4938540	7844724		
4947924			
Size 7	497.099	4362282	6011872
		4685618	7371266
		4698047	7423469
		4816113	7544000
		4938543	7613030
		4938549	7775437
4947926			
Size 8	497.100	4362281	4938560
		4393924	4947927
		4685619	4947928
		4816110	6011873
4938503			
Size 9	497.247	4362265	4948009
		4816096	4969623
		4938669	5835993
		4938768	5891761
		4948006	6005313
Size 10	497.248	4362264	5649087
		4816094	5744115
		4885514	5816079
		4938672	5835994
		4948013	5861990
		4969622	6011913
Size 11	497.249	4208599	4969621
		4617050	5767416
		4695408	5770683
		4816091	6005309
		4816092	6011858
		4885515	6052891
		4938674	6916285
		4948016	7404349
		4948018	7544315
4948021			

Caudal Rib Supports, Neutral, 220 mm radius					
   	Size 9	497.225	4362280 4393905 4550457 4568693 4617037 4686343 4686346 4694014 4694234 4755789 4755791 4755793 4821421 4882741 4882742 4882743 4882744 4947893	4947894 4947895 4947896 4947897 4947898 4947899 4947900 4969661 4969663 5816072 5857598 5883097 5883098 6031197 6031198 6079441 6087165	
	Size 10	497.226	4362279 4393906 4550458 4568694 4617038 4686347 4686349 4686351 4694235 4709517 4755785 4755786 4755787 4821415 4882745 4882747 4882748 4938735 4947901	4947902 4947903 4947905 4947910 4969659 4969660 5642635 5702649 5744112 5744238 5883100 5883101 6011907 6024580 6087170 6087171 6087172 6087173	
	Size 11	497.227	4362278 4393910 4550459 4617039 4686353 4694236 4709518 4755783 4755784 4821410 4882750 4882751 4882752 4882753 4938737 4947911	4947912 4947913 4969658 5668754 5697400 5770445 5857607 5872385 5883103 5883105 6021058 6024577 6031199 6031200 6063205	
	Size 12	497.228	4362277 4550460 4568695 4617040 4686356 4694237 4755478 4755479 4755480 4821407 4882754 4882755 4882756 4882757	4947914 4947915 4947916 4947917 4947918 5426428 5770298 5839271 5857616 5883106 5883107 6016089 6031201 6031202	

Caudal Rib Supports, Neutral, 220 mm radius, (Cont.)			4568700 4617041 4686359 4694021 4694238 4755472 4755474 4755476 4821404 4882758 4882759 4882760	4882761 4947919 4947920 4947921 4969657 5839270 5872094 5872378 6024578 6031203 6031204	
	Caudal Rib Supports, Right, 220 mm radius	Size 9	497.229	4362275 4550461 4686290 4938738 4947987	4947988 4947990 6011885 6031206
	Size 10	497.231	4362275 4550461 4686290 4820557	4820559 6011885 6031206	
	Size 11	497.232	4362274 4686291 4697978 4755469 4885458 4938739 4947992	4947994 4947996 5407126 6030989 6030990 6031207 6052890	
	Size 12	497.233	4362273 4697984 4755468 4885459 4938740 4947997	4947998 4948000 4948001 6011847 6031208	
	Size 13	497.234	4686293 4820546 4885461 4938741	4948003 4948005 6011853	
	Caudal Rib Supports, Left, 220 mm radius	Size 9	497.235	4362271 4686363 4755466 4755467 4885471 4948007 4948008 4948010 4948012	4969634 5365436 5668735 5668742 5680726 5872325 6009825 6016101 6031209
	Size 10	497.236	4362270 4393912 4686365 4695024 4820936 4885476 4938742	4938744 4948014 5407131 5407133 6011874 6031031 6031210	
	Size 11	497.237	4686366 4695025 4755464 4820933 4820934 4885480	4938746 4948015 5407129 5407130 6031211	
	Size 12	497.238	4362269 4686367 4695026 4755462 4820931	4820932 4938747 4948017 6011854	
	Size 13	497.239	4686368 4820929 4948019	4948020 6011876 6024579	