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**To the ATTENTION of:
Operating Room Manager**

29 July 2015

URGENT VOLUNTARY PRODUCT RECALL NOTIFICATION—R2015033

**VEPTR® Vertical Expandable Prosthetic Titanium Rib
Caudal Rib Supports (Rib-to-Rib Construct Only)**

Part Description / Part Number

Part Number	Part Description	Lot numbers
See Attached List	VEPTR Caudal Rib Supports	See Attached List

Dear Sir/Madam,

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.

**The enclosed letter has been communicated to appropriate
Health Care Professionals at your facility. Please keep a copy of this letter.**

Customer immediate actions:

1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form to your local DePuy Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.
7. Keep a copy of this notice.

The applicable regulatory agencies are being notified.

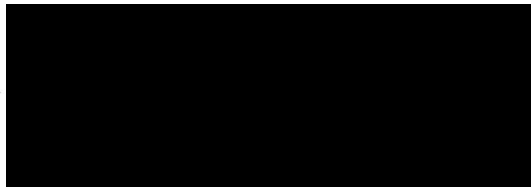
We apologise for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Synthes GmbH



Field Action Manager



Senior Quality Manager, Product Safety and Performance

Cc:

URGENT VOLUNTARY PRODUCT RECALL NOTIFICATION--R2015033

**VEPTR® Vertical Expandable Prosthetic Titanium Rib
Caudal Rib Supports (Rib-to-Rib Construct Only)**

Verification Section

Part Number	GTIN Number	Part Description	Lot numbers
See Attached List	See Attached List	VEPTR Caudal Rib Supports	See Attached List

- We have located the identified product in stock; returned quantity is documented below. We have retained a copy of this letter for our records.

- We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity) and/or COMMENTS:

Hospital name: _____

Name/Title (please print) _____


Phone Number: _____



Signature and Date: _____

URGENT VOLUNTARY PRODUCT RECALL NOTIFICATION

**VEPTR® Vertical Expandable Prosthetic Titanium Rib
Caudal Rib Supports (Rib-to-Rib Construct Only)**

Impacted Device Listing

Product Description	Item Number	Lot Numbers			
Caudal Rib Supports, Neutral, 70 mm radius 	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
	Size 11 497.243	4208597 5505857 4686204 5505862 4885510 5816076 4938751 6011855 4947982 6367928 4948033 6882133 4948034 7544008 4969626 9807745			
		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 4617048 4885511 4938753 4947983 4947984	4947989 4969625 5767354 5770536 6005308 6011856
	Size 10	497.245	4362266 4885512 4938754 4938755 4947991	4947993 4969624 5682975 5770675 6011857
	Size 11	497.246	4208598 4938757 4938760 4938761 4938765 4947999 4948002 4948004 5770692	5812078 5812079 6011877 6087168 6367930 7599075 7613037 9807752
Caudal Rib Supports, Left, 70 mm radius 	Size 6	497.098	4362283 4562149 4617874 4816115 4816117 4884494 4938540 4947924	4947925 4955412 4955413 6005302 6011850 7371288 7844724
	Size 7	497.099	4362282 4685618 4698047 4816113 4938543 4938549 4947926	6011872 7371266 7423469 7544000 7613030 7775437
	Size 8	497.100	4362281 4393924 4685619 4816110 4938503	4938560 4947927 4947928 6011873
	Size 9	497.247	4362265 4816096 4938669 4938768 4948006	4948009 4969623 5835993 5891761 6005313
	Size 10	497.248	4362264 4816094 4885514 4938672 4948013 4969622	5649087 5744115 5816079 5835994 5861990 6011913
	Size 11	497.249	4208599 4617050 4695408 4816091 4816092 4885515 4938674 4948016 4948018 4948021	4969621 5767416 5770683 6005309 6011858 6052891 6916285 7404349 7544315

Caudal Rib Supports,
Neutral, 220 mm radius



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

Caudal Rib Supports, Neutral, 220 mm radius (Cont.)	Size 13	497.229	4568700	4882761	
			4617041	4947919	
Caudal Rib Supports, Right, 220 mm radius	Size 9	497.230	4686359	4947920	
			4694021	4947921	
	Size 10	497.231	4694238	4969657	
			4755472	5839270	
	Size 11	497.232	4755474	5872094	
			4755476	5872378	
	Size 12	497.233	4821404	6024578	
			4882758	6031203	
	Size 13	497.234	4882759	6031204	
			4882760		
	Caudal Rib Supports, Left, 220 mm radius	Size 9	497.235	4362275	4947988
				4550461	4947990
		Size 10	497.236	4686290	6011885
				4938738	6031206
		Size 11	497.237	4947987	
				4362275	4820559
Size 12		497.238	4550461	6011885	
			4686290	6031206	
Size 13		497.239	4820557		
			4362274	4947994	
Size 9		497.235	4686291	4947996	
			4697978	5407126	
Size 10		497.236	4755469	6030989	
			4885458	6030990	
Size 11		497.237	4938739	6031207	
			4947992	6052890	
Size 12	497.238	4362273	4947998		
		4697984	4948000		
Size 13	497.239	4755468	4948001		
		4885459	6011847		
Caudal Rib Supports, Left, 220 mm radius	Size 9	497.235	4938740	6031208	
			4947997		
	Size 10	497.236	4686293	4948003	
			4820546	4948005	
	Size 11	497.237	4885461	6011853	
			4938741		
	Size 12	497.238	4362271	4969634	
			4686363	5365436	
	Size 13	497.239	4755466	5668735	
			4755467	5668742	
	Size 9	497.235	4885471	5680726	
			4948007	5872325	
	Size 10	497.236	4948008	6009825	
			4948010	6016101	
	Size 11	497.237	4948012	6031209	
			4362270	4938744	
Size 12	497.238	4393912	4948014		
		4686365	5407131		
Size 13	497.239	4695024	5407133		
		4820936	6011874		
Size 9	497.235	4885476	6031031		
		4938742	6031210		
Size 10	497.236	4686366	4938746		
		4695025	4948015		
Size 11	497.237	4755464	5407129		
		4820933	5407130		
Size 12	497.238	4820934	6031211		
		4885480			
Size 13	497.239	4362269	4820932		
		4686367	4938747		
Size 9	497.235	4695026	4948017		
		4755462	6011854		
Size 10	497.236	4820931			
		4686368	4948020		
Size 11	497.237	4820929	6011876		
		4948019	6024579		