

Urgent FIELD SAFETY NOTICE (Removal)

Cordis ExoSeal™ Vascular Closure Device (VCD)

Catalog Numbers: EX500CE, EX600CE and EX700CE

All lot numbers* from 15466779 to 15682751

*See FSN List at end of letter

October 29, 2012

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis is recalling (removing) a specific lot range of Cordis ExoSeal™ VCD product.

Overview:	Cordis has identified a potential issue where the affected lots of Cordis ExoSeal™ VCD have been sterilized using a process that did not achieve the sterility assurance level that is required by the standards for this class of product.
Details on Affected Devices, to assist in identification of the specific lots involved:	<p>This letter applies to:</p> <ul style="list-style-type: none"> • All lots distributed prior to this letter. • 179 lots distributed worldwide excluding the USA. Expiration dates range from 2013-07 through 2014-07. For ease of reference, please see attached table for a cross-reference listing of the affected lots in ascending lot order. <p>This letter does NOT apply to:</p> <ul style="list-style-type: none"> • Lot numbers above 15682751 <p>Product Usage: The Cordis ExoSeal™ VCD is indicated for femoral artery puncture site closure, reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional procedures.</p>
Actions requested on your part:	<ul style="list-style-type: none"> • Read the “Description of the problem” section. • Immediately identify and set aside all product listed below in a manner that ensures the affected product will not be used. • Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form. • Either return any affected product per the attached instruction, or contact your local sales representative to facilitate return of the affected product. Credit will be provided. • Pass on this notice to anyone in your facility that needs to be informed. • If any product listed below has been forwarded to another facility, contact that facility to arrange return. • Maintain awareness of this notice until all product listed below has been returned to Cordis. • Maintain a copy of this notice with the affected product.
Description of the problem:	Cordis recently determined that distributed units of Cordis ExoSeal™ VCD were sterilized using a process that did not achieve the sterility assurance level that is required by the standards for this class of product. The discrepancy was detected as part of routine quality control testing. To date, no complaints have been reported that are connected to this issue. This recall is not being undertaken on the basis of adverse medical events.

	<p>In order to assess the risk to the patient, the assurance of sterility was determined for the various components of the device. For the shaft and handle of the Cordis ExoSeal™ VCD, the assurance of sterility is equivalent to that of other elements used during the procedure and that routinely come in contact with the Cordis ExoSeal™ VCD device before it is used in the patient such as: drapes, gowns and back table covers. For the plug, the assurance of sterility is higher, but in some instances slightly lower than the standard required for products that come in contact with compromised tissue. Based on this information, there is no significant increased risk of infection to the patient from exposure to the affected product. Therefore, there is no concern for patients who have already been treated with the device and no additional patient follow-up is required.</p> <p>In keeping with our commitment to provide customers with quality products, Cordis has voluntarily decided to recall the product.</p> <p>Cordis is performing a root cause investigation and will resume product distribution once corrective actions have been implemented.</p>
--	--

Why you are being contacted:	You are receiving this letter because our records indicate that you have received one or more of the affected listed lots.
-------------------------------------	--

Available Assistance:	In addition to your local sales representative, you may contact the local Johnson & Johnson sales office to answer any questions you may have.
------------------------------	--

Additional Information:	<p>The applicable regulatory agencies are being notified. Cordis is voluntarily taking this action.</p> <p>We apologize for any inconvenience this communication may cause. We know that you place high value in our products and we appreciate your cooperation in this matter. Cordis is committed to maintaining your confidence in the safety and quality of the products that Cordis supplies.</p>
--------------------------------	---

Respectfully yours,



Jacqueline Maestri
 WW Vice President, Quality & Regulatory Compliance
 Cardiovascular Care Franchise, Johnson & Johnson

**Urgent FIELD SAFETY NOTICE (Removal)
 Cordis ExoSeal™ Vascular Closure Device (VCD)**

Catalog Numbers: EX500CE, EX600CE, and EX700CE; Lot numbers from 15466779 to 15682751

Table: Cross-reference listing of the 179 affected lots in ascending lot number

Catalog EX500CE	Catalog EX500CE (Cont'd)	Catalog EX600CE	Catalog EX600CE (Cont'd)	Catalog EX600CE (Cont'd)	Catalog EX600CE (Cont'd)	Catalog EX700CE
15466779	15569406	15467626	15539565	15575583	15637962	15467124
15469983	15569407	15467861	15539566	15580194	15639944	15471273
15478506	15576206	15468013	15541580	15580599	15647066	15478419
15481340	15578708	15468871	15543305	15581349	15647067	15482153
15485490	15584506	15472061	15543307	15582045	15647723	15485492
15489969	15588633	15472616	15544327	15588062	15652020	15490396
15494491	15595281	15472617	15544328	15588632	15652671	15501848
15494932	15602200	15474379	15547113	15592712	15657400	15531039
15497634	15603279	15474380	15547805	15595282	15658650	15541022
15499329	15606708	15475055	15548546	15595956	15659246	15547106
15501954	15610800	15480142	15551823	15596792	15659248	15557285
15505185	15614677	15480143	15552612	15598492	15662283	15562227
15513579	15616905	15482863	15553251	15600599	15667772	15567379
15514114	15619677	15483374	15553773	15605531	15667773	15576899
15514115	15623498	15486823	15555391	15605684	15675289	15584049
15516389	15627317	15491197	15555392	15609336		15590615
15516390	15630172	15491198	15556533	15612656		15590616
15518231	15638714	15494934	15558503	15612660		15592690
15521139	15642155	15495792	15558504	15618362		15593458
15531037	15648661	15499330	15560489	15619062		15628084
15538395	15652019	15503013	15560800	15623500		15632185
15538843	15657867	15506925	15565557	15624009		15653231
15541579	15657868	15512716	15566100	15628928		15658649
15545069	15664081	15513559	15570054	15629419		15664082
15547112	15669289	15517368	15570835	15633143		15670769
15562229	15673039	15517369	15570836	15633621		15682751
15564885		15535553	15571625	15634339		
15564886		15535621	15574900	15637263		