On Distributor's Letter Head

Urgent Field Safety Notice (Removal)

Cordis PRECISE® PRO RX Nitinol Stent System (Carotid) 16 Cat. Nbrs, 179 lots
See Catalog/Lot listing in Table 1 at end of letter
dd- May 2016

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

The purpose of this communication is to inform you that Cordis is recalling (removing) 179 lots of Cordis PRECISE ® PRO RX Nitinol Stent System (Carotid) ("PRECISE ® PRO Carotid Stent").

OVERVIEW

Based on recent complaints and subsequent investigation, Cordis has determined that products made between April 27, 2015 and November 22, 2015 (lots in Table 1) have been associated with an increased frequency of incidents of deployment difficulty and in some instances outer member shaft separation resulting in inability to deploy the stent or partial stent deployment. Product manufactured after November 22, 2015, including product currently manufactured and supplied are not affected.

There have been no patient injuries reported to us related to this issue. However, considering the products risk analysis the potential impact of inability to deploy the stent or partial stent deployment include an intra-procedural delay while a replacement device is prepared; vessel damage requiring unplanned percutaneous or surgical intervention to prevent permanent injury or impairment; or in most severe cases, transient Ischemic Attack or stroke.

Cordis is voluntarily recalling the listed lots

PRODUCTS AFFECTED

Carotid: Cordis PRECISE ® PRO RX Nitinol Stent System;
-Specific lot numbers per Table 1 of Catalog numbers "PCxxyyXCE".

The following photos are provided to help you identify the affected product. A PRECISE ® PRO carton and carton label is provided as an example.

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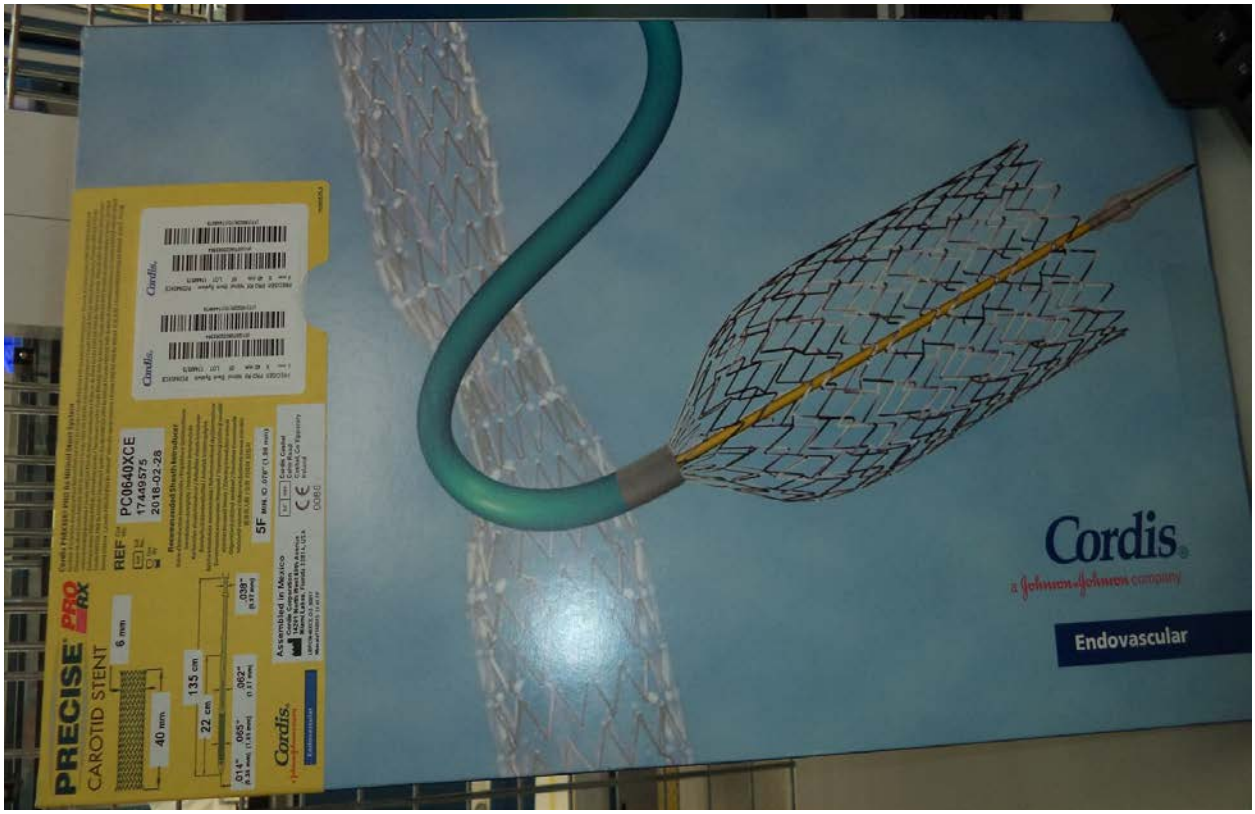
PRECISE ® PRO Carotid Stent Carton



PRECISE ® PRO Carotid Carton Label

Usage of the Device:
The PRECISE ® PRO RX Nitinol Stent System is indicated for use in patients with stenotic lesions of the carotid artery(ies).

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DESCRIPTION OF THE PROBLEM

What is the summary of the issue?

Based on complaints, Cordis has detected an increased frequency of users reporting difficulty with stent deployment and/or separation of the bond between sections of the device outer member. We have isolated the issue to product made between April 27, 2015 and November 22, 2015 and are recalling lots of affected product. Product manufactured after November 22, 2015, including product currently manufactured and supplied are not affected.

What are the potential health consequences if the product being recalled were used?

During use, the operator may experience stent deployment difficulties when operating the affected product including inability to deploy the stent, and/or partial stent deployment.

The most reported deployment difficulty experienced by users is the inability to deploy the stent resulting in an intra-procedural delay for the patient while a replacement device is prepped. However, partial stent deployment may result in vessel damage (carotid dissection or perforation, vessel spasm,) requiring unplanned percutaneous or surgical intervention to prevent permanent injury or impairment. In most severe cases, partial stent deployment may potentially result in Transient Ischemic Attack or stroke.

Lab personnel are highly trained in identifying and mitigating hazards associated with these medical devices. To date, no patient injuries have been reported from any of the deployment difficulties experienced by the users.

Is there any concern with the product already used successfully in procedures?
No. The recall is for deployment issues and does not affect PRECISE® PRO stents successfully deployed.

What other actions is Cordis taking?
Cordis has an active investigation underway. We have determined that the scope of the problem is limited to the lots listed in the letter that were manufactured between April 27, 2015 and November 22, 2015. Cordis has not identified any other lots that may be affected. In keeping with our commitment to provide customers with quality products, Cordis has voluntarily decided to recall the affected lots listed in this letter.

ACTION REQUIRED FROM YOU

You are receiving this letter because our records indicate that products from the affected lots were shipped to you. Please ensure the product lots listed in Table 1 are returned immediately to Cordis, and are not used in the patient.

1. Immediately check your inventory to confirm whether you have any units from affected lots in your possession. Identify and set aside any units from the affected lots in a manner that ensures the affected product will not be used. Check all storage and usage locations.

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2. Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form.

3. Return all affected product per the attached instruction, or contact your local sales representative to facilitate return of the affected product. Your sales representative will inform you of the product replacement or credit options.

4. Share this letter with others in your facility who need to be made aware of this recall. Contact any other facilities that have been provided with units of affected lots. Maintain awareness of this notice until all affected product has been returned to Cordis.

5. Keep a copy of this notice with any affected product until returned.

For questions related to this Field Safety Notice and the Acknowledgement Form please contact your local Cordis sales representative.

The applicable regulatory bodies are being notified that Cordis is voluntarily taking this action.

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.

Thank you for your cooperation and patience.

Yours sincerely,

NAME

DESIGNATION

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Table 1 -
Cordis PRECISE® PRO RX Nitinol Stent System (Carotid) 16 Cat. Nbrs, 179 lots

Catalog No.	Lot No.
PC0540XCE	17358952
PC0620XCE	17268216
PC0620XCE	17364506
PC0620XCE	17386229
PC0630XCE	17255096
PC0630XCE	17259976
PC0630XCE	17265885
PC0630XCE	17269316
PC0630XCE	17276753
PC0630XCE	17282137
PC0630XCE	17306047
PC0630XCE	17313247
PC0630XCE	17322267
PC0630XCE	17339528
PC0630XCE	17356084
PC0630XCE	17358953
PC0630XCE	17364566
PC0630XCE	17376720
PC0640XCE	17256212
PC0640XCE	17291874
PC0640XCE	17306043
PC0640XCE	17323766
PC0640XCE	17331382
PC0640XCE	17337067
PC0640XCE	17339529
PC0640XCE	17344454
PC0640XCE	17349016
PC0640XCE	17366680
PC0640XCE	17381649
PC0720XCE	17371406
PC0730XCE	17249851
PC0730XCE	17255097
PC0730XCE	17264996
PC0730XCE	17276755
PC0730XCE	17287133
PC0730XCE	17290642
PC0730XCE	17290951
PC0730XCE	17294355
PC0730XCE	17300216
PC0730XCE	17306045
PC0730XCE	17308315
PC0730XCE	17320013
PC0730XCE	17320014
PC0730XCE	17322269
PC0730XCE	17328143

Catalog No.	Lot No.
PC0730XCE	17333402
PC0730XCE	17347011
PC0730XCE	17349809
PC0730XCE	17354591
PC0730XCE	17361604
PC0730XCE	17366681
PC0730XCE	17370804
PC0730XCE	17387884
PC0730XCE	17392575
PC0740XCE	17250950
PC0740XCE	17256216
PC0740XCE	17264997
PC0740XCE	17269317
PC0740XCE	17270629
PC0740XCE	17272814
PC0740XCE	17282142
PC0740XCE	17286331
PC0740XCE	17290952
PC0740XCE	17291875
PC0740XCE	17299028
PC0740XCE	17306046
PC0740XCE	17306578
PC0740XCE	17308317
PC0740XCE	17321488
PC0740XCE	17325374
PC0740XCE	17332270
PC0740XCE	17335083
PC0740XCE	17340804
PC0740XCE	17340806
PC0740XCE	17347025
PC0740XCE	17351476
PC0740XCE	17354592
PC0740XCE	17358954
PC0740XCE	17364568
PC0740XCE	17371408
PC0740XCE	17375321
PC0740XCE	17378614
PC0740XCE	17381651
PC0740XCE	17386231
PC0820XCE	17300218
PC0820XCE	17344456
PC0830XCE	17255098
PC0830XCE	17259048
PC0830XCE	17265887
PC0830XCE	17270631

Catalog No.	Lot No.
PC0830XCE	17276756
PC0830XCE	17276780
PC0830XCE	17280876
PC0830XCE	17287134
PC0830XCE	17290953
PC0830XCE	17300219
PC0830XCE	17335803
PC0830XCE	17349017
PC0830XCE	17360671
PC0830XCE	17370805
PC0830XCE	17374436
PC0830XCE	17378615
PC0830XCE	17382574
PC0830XCE	17387885
PC0830XCE	17394537
PC0840XCE	17247326
PC0840XCE	17251836
PC0840XCE	17253600
PC0840XCE	17256218
PC0840XCE	17259053
PC0840XCE	17259978
PC0840XCE	17265888
PC0840XCE	17265889
PC0840XCE	17269318
PC0840XCE	17272816
PC0840XCE	17279782
PC0840XCE	17279783
PC0840XCE	17282143
PC0840XCE	17283331
PC0840XCE	17286332
PC0840XCE	17287347
PC0840XCE	17291877
PC0840XCE	17295227
PC0840XCE	17296213
PC0840XCE	17299029
PC0840XCE	17306049
PC0840XCE	17309348
PC0840XCE	17321490
PC0840XCE	17322271
PC0840XCE	17323769
PC0840XCE	17328146
PC0840XCE	17328367
PC0840XCE	17335804
PC0840XCE	17335805
PC0840XCE	17339530

Catalog No.	Lot No.
PC0840XCE	17346760
PC0840XCE	17346761
PC0840XCE	17349812
PC0840XCE	17351477
PC0840XCE	17356087
PC0840XCE	17364508
PC0840XCE	17369478
PC0840XCE	17374437
PC0840XCE	17376722
PC0840XCE	17378616
PC0840XCE	17379884
PC0840XCE	17382575
PC0840XCE	17383951
PC0840XCE	17383952
PC0840XCE	17392576
PC0920XCE	17274487
PC0930XCE	17259055
PC0930XCE	17307876
PC0930XCE	17314384
PC0930XCE	17332271
PC0940XCE	17249852
PC0940XCE	17274484
PC0940XCE	17286333
PC0940XCE	17307878
PC0940XCE	17313249
PC0940XCE	17319033
PC0940XCE	17319034
PC0940XCE	17325376
PC0940XCE	17329302
PC0940XCE	17331384
PC0940XCE	17344457
PC0940XCE	17349813
PC0940XCE	17379885
PC0940XCE	17382576
PC1020XCE	17393272
PC1030XCE	17268218
PC1030XCE	17274486
PC1030XCE	17388952
PC1040XCE	17260990
PC1040XCE	17283333
PC1040XCE	17287136
PC1040XCE	17290954
PC1040XCE	17316970
PC1040XCE	17374438