

Field Safety Notice

Device: Trinity Acetabular Shell

Part Numbers: See table below

Lot Numbers: See table below

Action: Voluntary device withdrawal

Date: February 3, 2016

Dear Customer,

The purpose of this letter is to advise you that Corin Limited is voluntarily recalling specific lot numbers of the Trinity Acetabular Shell identified in the table below.

Intended Use:

The Trinity Acetabular System is intended for use in total hip arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip joint articulation where there is evidence of sufficient sound bone to seat and support the components.

Reason for the Voluntary Recall:

Corin Limited has identified the potential for abrasion of the sterile barrier pouches of the new packaging system, which was introduced in November 2015. This issue is related only to the Trinity Acetabular Shell devices.

There have been no product complaints reported from the field with this issue. If this failure were to occur it could potentially render the product non-sterile.

Risk to Health:

The implantation of an unsterile device into a patient could lead to infection. Detection in some situations may be difficult, therefore Corin is recalling all identified product with the new packaging system for the Trinity Acetabular Shell.

Please check your records from November 2015 for patients who have undergone surgery and may have received one of these devices. The affected part numbers and lot codes are provided in the table below.

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Corin Ltd | The Corinium Centre | Cirencester | Gloucestershire | GL7 1YJ

Main: +44 (0)1285 659 866 **Fax:** +44 (0)1285 658 960 **Email:** info@coringroup.com

Registered office: The Corinium Centre, Cirencester, Gloucestershire, GL7 1YJ. Company number: 1910453. Registered in England

Actions to be taken by the Customer:

All recalled product should be returned to Corin Limited, including product which have been consigned to hospitals.

Please complete and sign the attached customer response form indicating product disposition and quantities to be returned.

Please complete the form even if you have no affected product to return. Return the form by email to the address quoted on it.

Product and Distribution Information:

Product and Distribution Information Table					
Part Number	Lot Code	Description	Manufacturing Date (MM/DD/YYYY)	Expire Date (MM/DD/YYYY)	Quantity
1025.50	321154	ALPHA KONISPHAR SCREW CUP 50mm	23-Nov-2015	21-Nov-2020	6
320.02.348	323741	NON OCCLUDED TPS SHELL Ø48mm TAPER SZ2	14-Jan-2016	12-Jan-2021	1
321.01.344	320023	CLUSTER SHELL Ø44mm TAPER SIZE 1	14-Dec-2015	12-Dec-2020	6
321.02.048	322986	NO HOLE SHELL Ø48mm TAPER - SIZE 2	30-Nov-2015	28-Nov-2020	28
321.02.048	323743	NO HOLE SHELL Ø48mm TAPER - SIZE 2	06-Jan-2016	04-Jan-2021	11
321.02.050	320026	NO HOLE SHELL Ø50mm TAPER - SIZE 2	23-Nov-2015	21-Nov-2020	27
321.02.050	322977	NO HOLE SHELL Ø50mm TAPER - SIZE 2	02-Dec-2015	30-Nov-2020	14
321.02.050	323744	NO HOLE SHELL Ø50mm TAPER - SIZE 2	06-Jan-2016	04-Jan-2021	1
321.02.346	320018	CLUSTER SHELL Ø46mm TAPER SIZE 2	23-Nov-2015	21-Nov-2020	8
321.02.348	321691	CLUSTER SHELL Ø48mm TAPER SIZE 2	01-Dec-2015	29-Nov-2020	27
321.02.348	322402	CLUSTER SHELL Ø48mm TAPER SIZE 2	26-Nov-2015	24-Nov-2020	27
321.02.348	322981	CLUSTER SHELL Ø48mm TAPER SIZE 2	09-Dec-2015	07-Dec-2020	2
321.02.348	322982	CLUSTER SHELL Ø48mm TAPER SIZE 2	07-Dec-2015	05-Dec-2020	14
321.02.348	323745	CLUSTER SHELL Ø48mm TAPER SIZE 2	11-Jan-2016	09-Jan-2021	21
321.02.348	323746	CLUSTER SHELL Ø48mm TAPER SIZE 2	08-Jan-2016	06-Jan-2021	9
321.02.348	324298	CLUSTER SHELL Ø48mm TAPER SIZE 2	19-Jan-2016	17-Jan-2021	5
321.02.350	321954	CLUSTER SHELL Ø50mm TAPER SIZE 2	23-Nov-2015	21-Nov-2020	19
321.02.350	322753	CLUSTER SHELL Ø50mm TAPER SIZE 2	25-Nov-2015	23-Nov-2020	18
321.02.350	322980	CLUSTER SHELL Ø50mm TAPER SIZE 2	09-Dec-2015	07-Dec-2020	5
321.03.052	322396	NO HOLE SHELL Ø52mm TAPER - SIZE 3	23-Nov-2015	21-Nov-2020	27
321.03.052	322971	NO HOLE SHELL Ø52mm TAPER - SIZE 3	03-Dec-2015	01-Dec-2020	2
321.03.054	322403	NO HOLE SHELL Ø54mm TAPER - SIZE 3	26-Nov-2015	24-Nov-2020	13
321.03.054	322984	NO HOLE SHELL Ø54mm TAPER - SIZE 3	18-Dec-2015	16-Dec-2020	18
321.03.054	322985	NO HOLE SHELL Ø54mm TAPER - SIZE 3	02-Dec-2015	30-Nov-2020	25
321.03.054	323750	NO HOLE SHELL Ø54mm TAPER - SIZE 3	07-Jan-2016	05-Jan-2021	2
321.03.350	321688	CLUSTER SHELL Ø50mm TAPER SIZE 3	24-Nov-2015	22-Nov-2020	27
321.03.350	321689	CLUSTER SHELL Ø50mm TAPER SIZE 3	25-Nov-2015	23-Nov-2020	24

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321.03.350	322049	CLUSTER SHELL Ø50mm TAPER SIZE 3	23-Nov-2015	21-Nov-2020	20
321.03.350	322050	CLUSTER SHELL Ø50mm TAPER SIZE 3	23-Nov-2015	21-Nov-2020	27
321.03.350	322749	CLUSTER SHELL Ø50mm TAPER SIZE 3	24-Nov-2015	22-Nov-2020	27
321.03.350	322967	CLUSTER SHELL Ø50mm TAPER SIZE 3	10-Dec-2015	08-Dec-2020	19
321.03.350	322968	CLUSTER SHELL Ø50mm TAPER SIZE 3	09-Dec-2015	07-Dec-2020	22
321.03.350	323473	CLUSTER SHELL Ø50mm TAPER SIZE 3	14-Jan-2016	12-Jan-2021	2
321.03.350	323474	CLUSTER SHELL Ø50mm TAPER SIZE 3	18-Dec-2015	16-Dec-2020	22
321.03.350	323475	CLUSTER SHELL Ø50mm TAPER SIZE 3	14-Jan-2016	12-Jan-2021	18
321.04.354	321359	CLUSTER SHELL Ø54mm TAPER SIZE 4	23-Nov-2015	21-Nov-2020	13
321.04.354	322969	CLUSTER SHELL Ø54mm TAPER SIZE 4	14-Jan-2016	12-Jan-2021	4
321.04.354	322990	CLUSTER SHELL Ø54mm TAPER SIZE 4	10-Dec-2015	08-Dec-2020	13
321.04.354	324349	CLUSTER SHELL Ø54mm TAPER SIZE 4	18-Jan-2016	16-Jan-2021	6
321.04.354	324622	CLUSTER SHELL Ø54mm TAPER SIZE 4	21-Jan-2016	19-Jan-2021	6
321.04.354	320021	CLUSTER SHELL Ø54mm TAPER SIZE 4	17-Nov-2015	15-Nov-2020	24
321.04.354	320022	CLUSTER SHELL Ø54mm TAPER SIZE 4	17-Nov-2015	15-Nov-2020	25

Type of Action by the Company:

Corin is replacing the new packaging with its previous packaging to immediately address this issue. Corin will implement corrective actions to address the issue in the long-term.

OTHER INFORMATION:

Product related questions should be addressed to your Corin representative. All other questions on this issue please contact the Compliance Director at +44 (0)1285 649190, Monday through Friday, 8:30AM to 5:00PM, UK Time.

Authorized by:

Name: (Print) Lucinda Gerber

Signature:

Title: Global Regulatory Affairs Manager

Adverse reactions or quality problems experienced with the use of this product may be reported to the local regulatory authority through their Adverse Event Reporting program.

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Customer Response Form

Regulatory Action:	Voluntary Recall
Description:	Trinity Acetabular Shell
Part Numbers:	See FSN
Lot Numbers:	See FSN

Please tick appropriate section:

We have physically checked all inventory and hospital locations, and we do not have the affected product. ☐

We have some of the items referenced in the enclosed February 3, 2016 field safety notice. We wish to return the items listed for replacement. ☐

Product Code	Lot code	Quantity

(Please add separate page if necessary).

Please sign and return this form to acknowledge receipt of the Field Safety Notice below.

Distributor / Hospital Name and Address:	
Contact Name:	
Contact Title:	
Contact Signature:	
Contact Phone No:	
Date:	

We would appreciate it if you return this form as soon as possible to:
Lucinda.gerber@coringroup.com