

FSN Ref: 2021-01-29-03

FSCA Ref: 2021-01-29-03

Date: 08/26/2021

Urgent Field Safety Notice

EXACTECH GXL LINERS FOR NOVATION, ACUMATCH, AND MCS SYSTEMS

For Attention of:

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Urgent Field Safety Notice

EXACTECH GXL LINERS FOR NOVATION, ACUMATCH, AND MCS SYSTEMS


1. Information on Affected Devices	
1.	<p>1. Device Type(s)</p> <p>EXACTECH GXL LINERS FOR NOVATION, ACUMATCH, AND MCS SYSTEMS</p>
1.	<p>2. Commercial name(s)</p> <p>See Attachment 1</p>
1.	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>See Attachment 1</p>
1.	<p>4. Primary clinical purpose of device(s)</p> <p><u>Novation GXL Liners:</u></p> <p>All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.</p> <ul style="list-style-type: none"> • Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only. • Press-fit femoral stems and acetabular cups are intended for press-fit fixation. • Femoral heads and endoprotheses are intended for use in cemented and press-fit applications. <p><u>Acumatch GXL Liners:</u></p> <p>All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.</p>

	<ul style="list-style-type: none"> • Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only. • Press-fit femoral stems and acetabular cups are intended for press-fit fixation. • Femoral heads and endoprostheses are intended for use in cemented and press-fit applications. <p><u>MCS GXL Liners:</u> The Exactech Porous Coated Total Hip System is indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, congenital hip dysplasia, and post-traumatic degenerative problems of the hip. It is also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present.</p>
1.	5. Device Model/Catalogue/part number(s) See Attachment 1
1.	6. Software version Not Applicable
1.	7. Affected serial or lot number range All Serial Numbers
1.	8. Associated devices Not Applicable

2 Reason for Field Safety Corrective Action (FSCA)	
2	1. Description of the product problem
.	Journal articles have been published which identified a number of revision surgeries due to excessive wear for the related GXL Liners for NOVATION, ACUMATCH, and MCS Systems
2	2. Hazard giving rise to the FSCA
.	A number of variables including user error, implant positioning, patient factors, and implant size selection (fitness for surgery, biomechanics, activity level and local tissue oxidation potential) could have all contributed to the increased trend in complaints. Literature also shows that surgical approach (1) and implant positioning (2) can impact the wear performance of total hip arthroplasty: 1. Watanabe K, Mitsui K, Usuda Y, Nemoto K.; An increase in the risk of excessive femoral anteversion for relatively younger age and types of femoral morphology in total hip arthroplasty with direct anterior approach.; The Journal of Orthopaedic Surgery 2019; 27 (2), 1-6.

	2. Mayeda BF, Haw JG, Battenberg AK, Schmalzried TP.; Femoral-Acetabular Mating: The Effect of Femoral and Combined
2	3. Probability of problem arising
.	Based upon Exactech’s health hazard evaluation, the likelihood of occurrence is very low (0.47%) considering the number of variables that could contribute to excessive wear.
2	4. Predicted risk to patient/users
.	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect).
2	5. Further information to help characterise the problem
.	Reference the Dear Healthcare Professional Letter (DHCP) and the Frequently Asked Questions (FAQ).
2	6. Background on Issue
.	Over the past 9 months Exactech has become aware of the three journal articles that have been published or submitted for publication which identified a number of revisions due to excessive wear for GXL Liners. The total number of cases that were reported in these articles is 19. <ul style="list-style-type: none"> • Early Polyethylene Failure in a Modern Total Hip Prosthesis: A Note of Caution; Thomas, Parvataneni, Vlasak, and Gray; The Journal of Arthroplasty, 35, 2020, 1297-11302 • Early Failure of Modern Moderately Cross-Linked Polyethylene Acetabular Liner; Kahlenberg, Menken, Ranawat, and Rodriguez; Arthroplasty Today, 6, 2020, 224-226 • Unexpected Wear of a Moderately Crosslinked Polyethylene in Total Hip Arthroplasty; Yakkanti, Ocksrider, Patel, Kolevar, Moore, Rimnac, Kraay, Wright, Baral, Robinson; Abstract for AAOS (future publication)
2	7. Other information relevant to FSCA
.	None

3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

4. General Information	
4.	1. FSN Type New
4.	2. For updated FSN, reference number and date of previous FSN Not Applicable
4.	3. For Updated FSN, key new information as follows: See proposed actions detailed in the Dear Healthcare Professional Letter (DHCP) and Frequently Asked Questions (FAQ).
4.	4. Further advice or information already expected in follow-up FSN? No
4	5. If follow-up FSN expected, what is the further advice expected to relate to: Not Applicable
4	6. Anticipated timescale for follow-up FSN Not Applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Exactech, Inc.
	b. Address 2320 NW 66 th Court, Gainesville, FL 32653
	c. Website address www.exac.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
4.	9. List of attachments/appendices: See Attachment 1
4.	10. Name/Signature Kate Jacobson Director Quality Management Systems & Compliance Signature  <small>Kate Jacobson (Aug 26, 2021 14:24 EDT)</small>

Transmission of this Field Safety Notice	
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)
	Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Distributor/Importer Reply Form

1. Field Safety Notice Information	
Correction Notice Ref. no.:	2021-01-29-03
Correction Notice Date:	26:08:2021
Product/ Device name	EXACTECH GXL LINERS FOR NOVATION, ACUMATCH, AND MCS SYSTEMS
Product Code(s)	See Attachment 1
Batch/Serial Number (s)	All Serial Numbers

2. Distributor/Importer Details	
Company Name	Exactech Italy S.p.A.
Address	via Bonfadina 65 25046 Cazzago San Martino (BS) Italy
Contact Name	Marco Migliori
Title or Function	Country Manager
Telephone number	+39 030 7283433
Email	marco.migliori@exacitalia.com

1. Return acknowledgement to Sender	
Email	recalls@exac.com
Distributor/Importer Helpline	+1 800-392-2832
Postal Address	2320 NW 66th Court, Gainesville, FL 32653 USA
Web Portal	www.exac.com
Deadline for returning the Distributor/Importer reply form*	Within 15 business days of receipt of Field Safety Notice.

2. Distributors/Importers (check all that apply)	
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.
<input type="checkbox"/>	I have identified customers that received or may have received this device.

<input type="checkbox"/>	I have informed the identified customers of this Field Safety Notice and that Exactech is required to follow up with any patients who have had the affected devices implanted.	Date of communication:
Print Name		
Signature		
Date		

It is important that your organization confirms that you have received the Field Safety Notice and takes the actions detailed in this Field Safety Notice.

Your organization's reply is the evidence we need to monitor the progress of the proposed actions.






DRAFT_Exactech Field Safety Notice_EN_IT(2)

Final Audit Report

2021-08-26

Created:	2021-08-26
By:	Damon Speight (damon.speight@exac.com)
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"DRAFT_Exactech Field Safety Notice_EN_IT(2)" History

-  Document created by Damon Speight (damon.speight@exac.com)
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Signature Date: 2021-08-26 - 6:24:55 PM GMT - Time Source: server- IP address: 209.251.142.125
-  Agreement completed.
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Attachment 1: Product Information (EU)**The Brand Name and The Common Name, Classification Name, Or Usual Name Of The Device And The Intended Use Of The Device.**

The GXL Liners for Novation, Acumatch and MCS systems is a finished device provided sterile.

The Brand Name and the Common Name:

***Note, any sales before 2009, were prior to upclass and will not have a CE certificate number**

All serial numbers for the following catalog numbers are potentially within the scope of this correction:

European Country	Catalog Number	Product Description	CE Number	Year First Sold	GTIN
France	130-28-51	Novation GXL Liner, Neutral, 28mm ID, Group 1 Cups	*Not Applicable	2008	10885862022066
	130-28-52	Novation GXL Liner, Neutral, 28mm ID, Group 2 Cups	CE 549082	2009	10885862022073
	132-28-51	Novation GXL Liner, Lipped, 28mm ID, Group 1 Cups	CE 549082	2009	10885862023155
	132-28-52	Novation GXL Liner, Lipped, 28mm ID, Group 2 Cups	CE 549082	2009	10885862023162
	132-32-52	Novation GXL Liner, Lipped, 31mm ID, Group 2 Cups	CE 549082	2009	10885862023315
	132-32-53	Novation GXL Liner, Lipped, 32mm ID, Group 3 Cups	CE 549082	2009	10885862023322
	132-32-54	Novation GXL Liner, Lipped, 32mm ID, Group 4 Cups	CE 549082	2009	10885862023339
	132-36-53	Novation GXL Liner, Lipped, 36mm ID, Group 3 Cups	CE 549082	2009	10885862023421
Germany	130-32-51	Novation GXL Liner, Neutral, 32mm ID, Group 1 Cups	CE 549082	2011	10885862207074
	130-32-52	Novation GXL Liner, Neutral, 32mm ID, Group 2 Cups	CE 549082	2010	10885862022165
	130-32-53	Novation GXL Liner, Neutral, 32mm ID, Group 3 Cups	CE 549082	2010	10885862022172
	130-32-54	Novation GXL Liner, Neutral, 32mm ID, Group 4 Cups	CE 549082	2014	10885862022189
	130-32-55	Novation GXL Liner, Neutral, 32mm ID, Group 5 Cups	CE 549082	2015	10885862022196
	130-36-52	Novation GXL Liner, Neutral, 36mm ID, Group 2 Cups	CE 549082	2016	10885862207081
	130-36-53	Novation GXL Liner, Neutral, 36mm ID, Group 3 Cups	CE 549082	2011	10885862022233
	130-36-54	Novation GXL Liner, Neutral, 36mm ID, Group 4 Cups	CE 549082	2011	10885862022240
	130-36-55	Novation GXL Liner, Neutral, 36mm ID, Group 5 Cups	CE 549082	2011	10885862022257
	132-32-51	Novation GXL Liner, Lipped, 32mm ID, Group 1 Cups	CE 549082	2011	10885862207029
	132-36-52	Novation GXL Liner, Lipped, 36mm ID, Group 2 Cups	CE 549082	2011	10885862207036
	136-32-51	Novation GXL Liner, +5mm Lateralized, 32mm, G1 - 48/50mm Cups	CE 549082	2010	10885862024275
	136-32-52	Novation GXL Liner, +5mm Lateralized, 32mm, G2 - 52/54mm Cups	CE 549082	2011	10885862024282
	136-32-53	Novation GXL Liner, +5mm Lateralized, 32mm ID, Group 3 Cups	CE 549082	2014	10885862024299
	136-32-54	Novation GXL Liner, +5mm Lateralized, 32mm ID, Group 4 Cups	CE 549082	2015	10885862024305
	136-32-55	Novation GXL Liner, +5mm Lateralized, 32mm ID, Group 5 Cups	CE 549082	2015	10885862024312
	136-36-52	Novation GXL Liner, +5mm Lateralized, 36mm, G2 - 52/54mm Cups	CE 549082	2011	10885862024329

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European Country	Catalog Number	Product Description	CE Number	Year First Sold	GTIN
	136-36-53	Novation GXL Liner, +5mm Lateralized, 36mm, G3-56/58mm Cups	CE 549082	2011	10885862024336
	136-36-54	Novation GXL Liner, +5mm Lateralized, 36mm, G4-60/62mm Cups	CE 549082	2011	10885862024343
	136-36-55	Novation GXL Liner, +5mm Lateralized, 36mm, G5-64/66/68mm Cups	CE 549082	2012	10885862024350
	138-32-51	Novation GXL Liner, 10 Deg Face, 32mm ID, Group 1 Cup	CE 549082	2012	10885862024732
	138-36-52	Novation GXL Liner, 10 Deg Face, 32mm ID, Group 2 Cup	CE 549082	2011	10885862024749
	138-36-53	Novation GXL Liner, 10 Deg Face, 32mm ID, Group 3 Cup	CE 549082	2011	10885862024756
	138-36-54	Novation GXL Liner, 10 Deg Face, 32mm ID, Group 4 Cup	CE 549082	2012	10885862024763
	138-36-55	Novation GXL Liner, 10 Deg Face, 32mm ID, Group 5 Cup	CE 549082	2014	10885862024770
Greece	132-28-24	Acumatch GXL 15 Degree Liner, 28mm Size D	*Not Applicable	2008	10885862023063
	132-28-25	Acumatch GXL 15 Degree Liner, 28mm Size E	*Not Applicable	2008	10885862023070
	132-32-55	Novation GXL Liner, Lipped, 32mm ID, Group 5 Cups	*Not Applicable	2008	10885862023346
Italy	132-36-54	Novation GXL Liner, Lipped, 36mm ID, Group 4 Cups	CE 549082	2012	10885862023438
Portugal	130-40-53	Novation GXL Liner, Neutral, 40mm ID, Group 3 Cups	CE 549082	2016	10885862207098
	130-40-54	Novation GXL Liner, Neutral, 40mm ID, Group 4 Cups	CE 549082	2015	10885862207104
	132-40-53	Novation GXL Liner, Lipped, 40mm ID, Group 3 Cups	CE 549082	2017	10885862207043
	132-40-54	Novation GXL Liner, Lipped, 40mm ID, Group 4 Cups	CE 549082	2016	10885862207050
Spain	130-40-55	Novation GXL Liner, Neutral, 40mm ID, Group 5 Cups	CE 549082	2011	10885862207111
	132-22-70	Novation GXL Liner, G00, 22mm ID	CE 549082	2010	10885862022967
	132-40-55	Novation GXL Liner, Lipped, 40mm ID, Group 5 Cups	CE 549082	2010	10885862207067