

**Urgent Field Safety Notice**  
**Full Contour Zirconia Implant Crown**

For Attention of\*: Bernard Tornare

Contact details of local representative (name, e-mail, telephone, address etc.)*
Jacques Albrecht, <a href="mailto:jacques.albrecht@nobelbiocare.com">jacques.albrecht@nobelbiocare.com</a> , +41 79 814 73 00, Balz-Zimmermann-Strasse 7, 8302 Kloten, Switzerland

**Urgent Field Safety Notice (FSN)**  
**Full Contour Zirconia Implant Crown**  
**Incomplete sintering cycle**

<b>1. Information on Affected Devices*</b>	
1.	1. Device Type(s)* Dental Abutment
1.	2. Commercial name(s) Full Contour Zirconia Implant Crown
1.	3. Unique Device Identifier(s) (UDI-DI) 173940107, GBGD350_0010.C3B
1.	4. Primary clinical purpose of device(s)* Dental Prosthetic
1.	5. Device Model/Catalogue/part number(s)* 77352
1.	6. Software version N/A
1.	7. Affected serial or lot number range N/A
1.	8. Associated devices N/A

<b>2. Reason for Field Safety Corrective Action (FSCA)*</b>	
2.	1. Description of the product problem* The device was not manufacturing according to specifications through an incomplete sintering cycle. The device has conforming dimensions, but may have unexpected material performance.
2.	2. Hazard giving rise to the FSCA* Due to the incomplete sintering cycle, the device may have unknown characteristics and could result in mechanical failure.
2.	3. Probability of problem arising It is estimated with a >20% risk of failure during the lifetime of the device.
2.	4. Predicted risk to patient/users Swallowing or inhaling fractures from the failure.
2.	5. Further information to help characterise the problem N/A
2.	6. Background on Issue Manufacturing error not captured during quality control resulted in releasing of the device to the market.
2.	7. Other information relevant to FSCA N/A

3. Type of Action to mitigate the risk*			
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input checked="" type="checkbox"/> Identify Device    <input checked="" type="checkbox"/> Quarantine Device    <input checked="" type="checkbox"/> Return Device    <input checked="" type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other                      <input type="checkbox"/> None </p> <p>Customer</p> <p>We kindly ask you to follow the instructions below:</p> <ol style="list-style-type: none"> <li>1. Inspect your stock and quarantine affected devices.</li> <li>2. Complete attached Customer Reply Form, even if you do not have any affected stock, and return it to Nobel Biocare, via email to <a href="mailto:order.switzerland@nobelbiocare.com">order.switzerland@nobelbiocare.com</a> or mail to Nobel Biocare Services AG, Balz-Zimmermann-Strasse 7, 8302 Kloten, Switzerland, within 5 days of receipt of this notice.</li> <li>3. Return all affected devices on hand to Nobel Biocare using the shipping label attached to this notice.</li> <li>4. Ensure relevant staff members are informed of this FSCA. If you have supplied or transferred any potentially affected product to another facility or organization, let that facility know of the FSCA by providing a copy of this notice.</li> </ol>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">2. By when should the action be completed?</td> <td>Within 5 days of receipt of this notice</td> </tr> </table>	2. By when should the action be completed?	Within 5 days of receipt of this notice
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3.	<p>3. Particular considerations for:                      Implantable device</p> <p>Is follow-up of patients or review of patients' previous results recommended? Yes</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td style="text-align: center;">Yes</td> </tr> </table>	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
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<b>3.</b>	<p><b>5. Action Being Taken by the Manufacturer</b></p> <p> <input checked="" type="checkbox"/> Product Removal                      <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Software upgrade                      <input type="checkbox"/> IFU or labelling change  <input checked="" type="checkbox"/> Other    <input type="checkbox"/> None </p> <p>New device has been delivered with ID 173940107</p>		
3	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">6. By when should the action be completed?</td> <td>Withing 5 days of release of this notice</td> </tr> </table>	6. By when should the action be completed?	Withing 5 days of release of this notice
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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?		

No	Not appended to this FSN
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4. General Information*	
4.	1. FSN Type* New
4.	2. For updated FSN, reference number and date of previous FSN N/A
4.	3. For Updated FSN, key new information as follows: N/A
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: N/A
4	6. Anticipated timescale for follow-up FSN N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name NobelProcera LLC
	b. Address 800 Corporate Drive, Mahwah, NJ, 07430
	c. Website address www.nobelbiocare.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	9. List of attachments/appendices: 1- Customer Reply Form
4.	10. Name/Signature Jon Chambless
	

Transmission of this Field Safety Notice
<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

## Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PFA2112
FSN Date*	7 <sup>th</sup> of July 2021
Product/ Device name*	NPr FCZ Imp Crwn ASC CC RP CAD 1-25° s3
Product Code(s)	77352
Batch/Serial Number (s)	173940107

2. Customer Details	
Account Number	386047
Healthcare Organisation Name*	Bernard Tornare
Organisation Address*	Bernard Tornare / av. du Crochetan 2 / 1870 Monthey
Department/Unit	N/A
Shipping address if different to above	N/A
Contact Name*	Bernard Tornare
Title or Function	N/A
Telephone number*	+41 024 472 26 66
Email*	Bernard.tornare@martronic.ch

3. Customer action undertaken on behalf of Healthcare Organisation (Tick all that apply)			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Comments:	
<input type="checkbox"/>	I performed all actions requested by the FSN.	Comments:	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Comments:	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:      Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:      Date Returned(DD/MM/YY):
		N/A	Comments:
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:      Date Destroyed (DD/MM/YY):
		Qty	Lot/Serial Number:      Date Destroyed (DD/MM/YY):
		N/A	Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Comments:	
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.	Comments:	
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Enter contact details if different from above and brief description of query:	
Print Name*			

Signature*	
Date*	

<b>4. Return acknowledgement to sender</b>	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.