

Company
 Name Surname
 Sample Street 1
 1234 Sample City
 Country

March 27, 2019

URGENT FIELD SAFETY NOTICE
PFA 1906

Dear Nobel Biocare Partner,

Nobel Biocare internally identified a packaging issue affecting the single-patient use drills for NobelReplace (Tapered Drills, Dense Bone Drills, Screw Taps), Guided Start Drills/Counterbores and Guided Counterbores for NobelReplace, Implant Retrieval Instruments and Abutment Screw Retrieval Instruments listed in Annex 1. These devices are intended to prepare for implant placement or to remove an implant/abutment screw.

This Field Safety Notice is intended to inform you about the problem, the actions that should be taken and the actions planned by Nobel Biocare to correct the problem.

Affected devices	The complete list of affected devices including article number and device description is attached to this letter (Annex 1).
Problem / hazard description	Due to a problem in the packaging sealing process at the supplier of the affected devices, it cannot be guaranteed that the sterilized medical devices in scope of this field action remain sterile during their shelf-life.
Actions to be taken by customers	<ol style="list-style-type: none"> 1. Identify affected devices as detailed in Annex 1. 2. Do not use affected devices. 3. Send back the Customer Reply Form (attached to this letter) and the affected devices.
Actions planned by Nobel Biocare	<p>Nobel Biocare reviewed the packaging sealing process at the supplier site, has taken corrective actions and will initiate preventive actions to ensure a high level of safety and quality of the devices.</p> <p>Nobel Biocare will replace affected devices free of charge.</p>
Transmission of this Field Safety Notice	This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Our records show that you received some of the medical devices in scope of this Field Action. We therefore kindly ask you to follow instructions provided in this Field Safety Notice and return the attached Customer Reply Form to Nobel Biocare before **[date]**, by email to XXXXXXXXX@nobelbiocare.com.

Nobel Biocare confirms that this information has been notified to the appropriate regulatory agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you require any further information or support, please contact your customer service representative [at xxxx \(phone number\)](#). We are sorry for the inconvenience and we thank you for your understanding.

Best regards,

Daniel Verstappen, Vice President QA/RA/DA

Annex 1 – List of affected medical devices

The following devices are in scope of this Field Action. Additionally, devices in scope were included in belowmentioned kits.

Article no.	Article description	Batch	Kit no.	Kit description	Batch		
32737	Guided Start Drill/Counterbore NobRpl NP	73425	37470	Implant Retrieval Kit	857578		
37045	Drill Tapered NP 3.5x8 mm Single-Pat	73466			857597		
37049	Dense Bone Drill 6.0 6x16 mm Single-Pat	73502			857610		
37052	Screw Tap Tapered WP Single-Pat	73499			857615		
37075	Drill Tapered NP 3.5x10 mm Single-Pat	73415			857653		
		73537			857656		
37076	Drill Tapered NP 3.5x11.5 mm Single-Pat	73446			857677		
		73280			857694		
37080	Drill Tapered RP 4.3x10 mm Single-Pat	73433			857708		
		73495			857711		
37081	Drill Tapered RP 4.3x11.5 mm Single-Pat	73474			857717		
		73369			857729		
37082	Drill Tapered RP 4.3x13 mm Single-Pat	73274			857732		
37085	Drill Tapered WP 5x10 mm Single-Pat	73287			818647		
		73428			818682		
37086	Drill Tapered WP 5x11.5 mm Single-Pat	73451			818712		
37089	Drill Tapered 6.0 6x8 mm Single-Pat	73575			818747		
37095	Dense Bone Drill NP 3.5x16 mm Single-Pat	73574			818811		
37098	Dense Bone Drill WP 5x13 mm Single-Pat	73591			37481	Abutment Screw Retrieval Kit	818683
37471	Impl Retr Instr Hex & Tri-Ch NP/RP 22mm	73421					818727
		73491					
		73600					
		73296					
		73315					
		73595					
37472	Impl Retr Instr Hex & Tri-Ch NP/RP 31mm	73303					
37473	Impl Retr Instr CC 3.0 31mm	73306					
37474	Impl Retr Instr CC NP & Ext Hex WP 22mm	73614					
		73256					
37475	Impl Retr Instr CC RP & Tri-Ch WP 22mm	73601					
		73298					
37476	Impl Retr Instr Tri-Channel 6.0 22mm	73313					
37503	Abutment Screw Retr Instrument 3.0/NP	73585					
		73430					
37504	Abutment Screw Retr Instrument RP/WP/6.0	73562					

Field Safety Notice Customer Reply Form

PFA 1906

Name
Customer no.

Please complete and return this Customer Reply Form before **[date]**, via email to XXXXXXXX@nobelbiocare.com

Receipt of Field Safety Notice																													
<input type="checkbox"/> I confirm receipt of the Field Safety Notice and that I read and understood its content.																													
<input type="checkbox"/> I confirm receipt of the Field Safety Notice and that I read and understood its content. However, I have additional questions and wish to be contacted.																													
Customer actions																													
<input type="checkbox"/> I have affected device(s) in my inventory and will send them back as requested. <i>Please enter number of devices to be returned:</i>																													
<table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <thead> <tr style="background-color: #cccccc;"> <th style="padding: 5px;">Article Number</th> <th style="padding: 5px;">Batch Number</th> <th style="padding: 5px;">Quantity</th> </tr> </thead> <tbody> <tr><td style="height: 20px;"> </td><td> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td><td> </td></tr> </tbody> </table>	Article Number	Batch Number	Quantity																										
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<input type="checkbox"/> I no longer have the affected device(s) in my inventory.																													
Customer information																													
<div style="border-bottom: 1px solid black; margin-bottom: 10px; width: 30%;"></div> <p><i>(Name and phone number)</i></p> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%; border-bottom: 1px solid black;"></div> <div style="width: 45%; border-bottom: 1px solid black;"></div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> Signature Date </div>																													