ZIMMER BIOMET

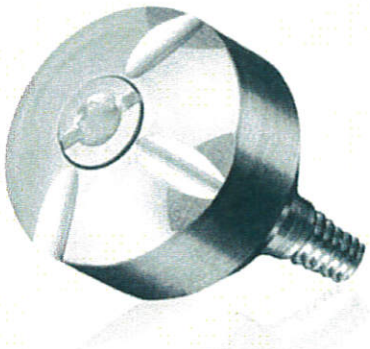
May 11, 2020

To: Clinicians who may be in possession of affected products

Subject: **URGENT MEDICAL DEVICE RECALL**

On January 13, 2020, you received a communication from Zimmer Biomet Dental regarding a product recall with specific lots of BellaTek® Encode® Healing Abutments for the Certain® Internal Connection. The identified BellaTek Encode Healing Abutments were incorrectly manufactured wherein the orientation flat on the Encode Healing Abutment's occlusal surface is misaligned by 30°. As part of further investigation an additional two lots with the same manufacturing condition were recently identified. Therefore, we are expanding the initial recall on the Certain BellaTek Encode Healing abutments to include the two additional lot numbers listed in the table below.

Affected Product: Certain® BellaTek® Encode® Healing Abutments (**Image 1**)



BellaTek Encode Healing Abutment

Table 1

Reference Numbers	Description	Lot Numbers
IEHA554	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 5MM(D) X 5.6MM(P) X 4MM(H)	1228905
IEHA564	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 5MM(D) X 6MM(P) X 4MM(H)	1229062

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The identified BellaTek Encode Healing Abutments and lot numbers in **Table 1** were incorrectly manufactured wherein the orientation flat on the Encode Healing Abutment's occlusal surface is misaligned by 30°. The orientation flat incorrectly aligns with a point of the abutment's external hex feature as illustrated in **Attachment 2**. The orientation flat should be aligned with a flat of the abutment's external hex feature. Because of this misalignment, the resulting definitive abutment will be rotated by 30°.

The affected products were sold between July 3, 2019 and April 20, 2020. Our records indicate that you have received one or more of the affected products.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Delay in completion of treatment	*Delay in completion of treatment*
Describe long-range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*None*

Zimmer Biomet will be providing replacement Certain® BellaTek Encode Healing Abutments at no charge. Please contact Customer Service at DentalCS@ZimmerBiomet.com to set up shipment of your replacement BellaTek Encode Healing Abutment(s).

Clinician Responsibilities:

Surgical Clinicians

A. Review this notification for awareness of the contents.

1. **Step 1**: Quarantine any unused affected products in your inventory for return to Zimmer Biomet Dental.
2. **Step 2**: Identify any patients **currently in your care** who have received an affected Certain Encode Healing Abutment with the lot numbers in **Table 1.**
    a) For those patients for whom you have verified the lot number, please contact Zimmer Biomet Dental via email as provided in Step G below for an immediate replacement Certain BellaTek Encode Healing Abutment. Please replace the affected Certain BellaTek Encode Healing Abutment

with a new Certain BellaTek Encode Healing Abutment during the patient's next visit, and prior to surgical release.

b) If the lot number of the Certain BellaTek Encode Healing Abutment is unknown, inspect for the product condition using **Attachment 2.**

a. If the referenced product condition is present, please contact Zimmer Biomet per the instructions in Step 2a above. The affected healing abutment must be returned to Zimmer Biomet Dental.

b. If the referenced condition is not present, reinsert the original healing abutment and release the patient.

3. **Step 3**: For patients **no longer in your care** (e.g., those already surgically released to a collaborating restorative/ prescribing clinician to undergo impressioning/scanning), please notify the clinician(s) currently treating the affected patients (the "**restorative clinicians**") by providing them with a copy of this communication. **Each restorative clinician should review and complete the Restorative Clinician instructions below as applicable and ZBD will work directly with them on replacements**.
4. Complete steps C through F below.

Restorative Clinicians:

B. Review this notification for awareness of the contents.

1. **Step 1**: Quarantine any unused affected products in your inventory for return to Zimmer Biomet Dental.
2. **Step 2**: Identify any patients **currently in your care** who have received an affected Certain Encode Healing Abutment with the lot numbers in **Table 1.**

a) If the lot number of the Certain BellaTek Encode Healing Abutment is known:

a. If the patient has **not yet undergone scanning/impressioning**, the affected Certain BellaTek Encode Healing Abutment should be replaced with a new Certain BellaTek Encode Healing Abutment prior to scanning/impressioning. Please contact Zimmer Biomet Dental via email as provided in Step G below for an immediate replacement Certain BellaTek Encode Healing Abutment.

b. If the case has already been started and the **scan/impression has been sent to a lab**, please ask the lab to contact the Customer Service team at DentalCS@zimmerbiomet.com for instructions on how to remediate the case. The lab will not be charged twice for the BellaTek abutment.

b) If the lot number of the Certain BellaTek Encode Healing Abutment is unknown, inspect for the product condition using **Attachment 2.**

a. If the referenced product condition is present, please follow the instructions in Step 2a above. The affected healing abutment must be returned to Zimmer Biomet Dental per the below instructions.

b. If the referenced condition is not present, reinsert the original healing abutment and release the patient.

3. Complete steps D through F below.

C. (Surgical clinicians) Provide the name and contact information of all restorative clinician(s) in **Attachment 1**– Certificate of Acknowledgement. This will allow Zimmer Biomet to follow up with the restorative clinician(s) if necessary.

D. Complete **Attachment 1** – Certificate of Acknowledgement and email to CorporateQuality.PostMarket@zimmerbiomet.com

E. Include a copy of **Attachment 1 – Certificate of Acknowledgement** with any product to be returned. Using the return shipping label (to be provided on request by Zimmer Biomet), please return affected product to:

Field Action
PM Regulatory Compliance
Zimmer Biomet
4555 Riverside Dr.
Palm Beach Gardens, FL 33410 US

F. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your facility's documentation.

G. If you have further questions or concerns after reviewing this notice, please send an email to the Customer Service team at: DentalCS@zimmerbiomet.com.

Other Information

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing DomesticComplaints@zimmerbiomet.com.

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Thank you for your assistance. We regret any inconvenience caused by this product removal.

Sincerely,

Kevin W. Escapule, Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Certain® BellaTek® Encode® Healing Abutments

Field Action Reference: ZFA 2019-00415

Do you have affected product in your facility?

☐ **Yes**, we currently have one or more affected items in our facility.

_____ Quantity Returning

☐ **No**, we currently have no affected items in our facility.

If one or more patients have been transferred or released to a Referring Clinician (as defined above), please provide the following information (attach additional sheets as necessary):

Referring Clinician Name: _____ Phone Number: _____ Facility Address (including city, state, zip code): _____ _____	Referring Clinician Name: _____ Phone Number: _____ Facility Address (including city, state, zip code): _____ _____
Referring Clinician Name: _____ Phone Number: _____ Facility Address (including city, state, zip code): _____ _____	Referring Clinician Name: _____ Phone Number: _____ Facility Address (including city, state, zip code): _____ _____

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice, and that I will return any additional affected product subsequently recovered from patients currently in my care.

Printed Name: Beth Mohr **Signature:** Beth E. Mohr

Title: Surgical Implant Coordinator **Telephone:** (563) 557-1440 **Date** ___/___/___

Account No. 131532 **Facility Name:** Great River Oral + Maxillofacial Surgery, P.C.

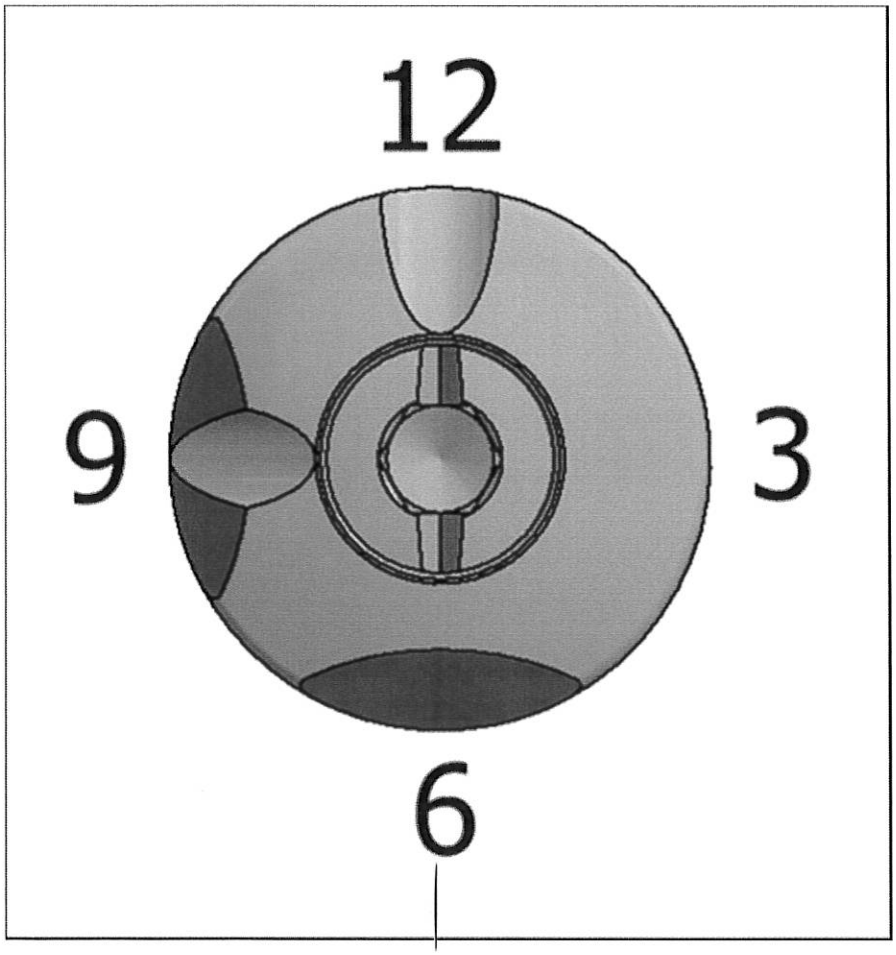
Facility Address: 100 Bryant Street

City: Dubuque **State:** IA **ZIP:** 52003

Note: This form must be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-373-3589.

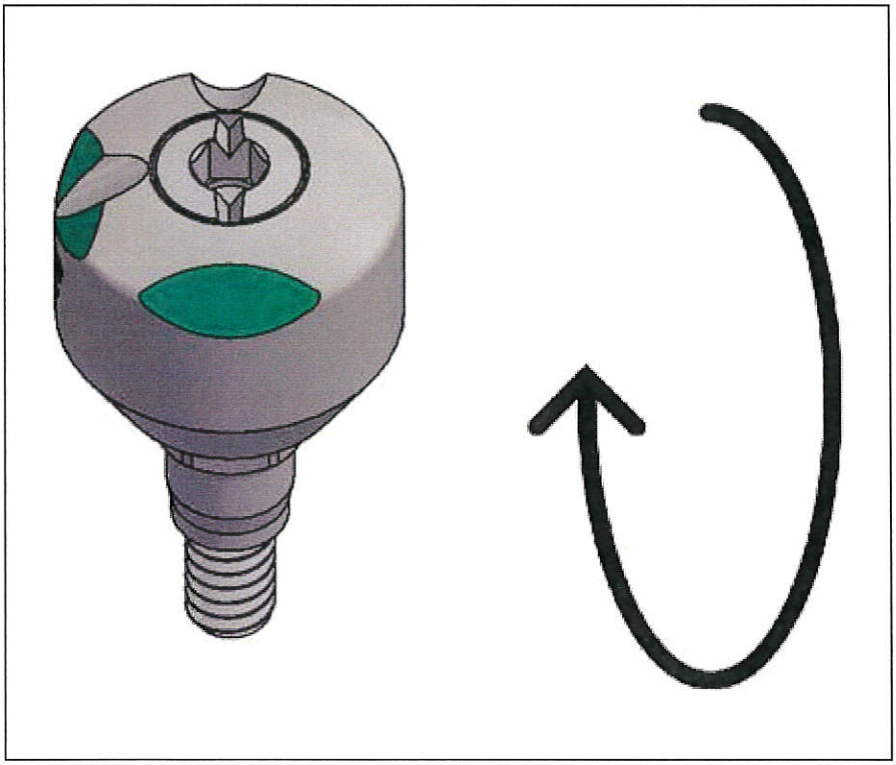
ATTACHMENT 2
Identification of affected Certain® BellaTek® Encode® Healing Abutments

1. From a top-down view, orient the two large Encode flats (shown in green) at 6 o'clock and 9 o'clock. Additional smaller flats/grooves may also be present at other locations.



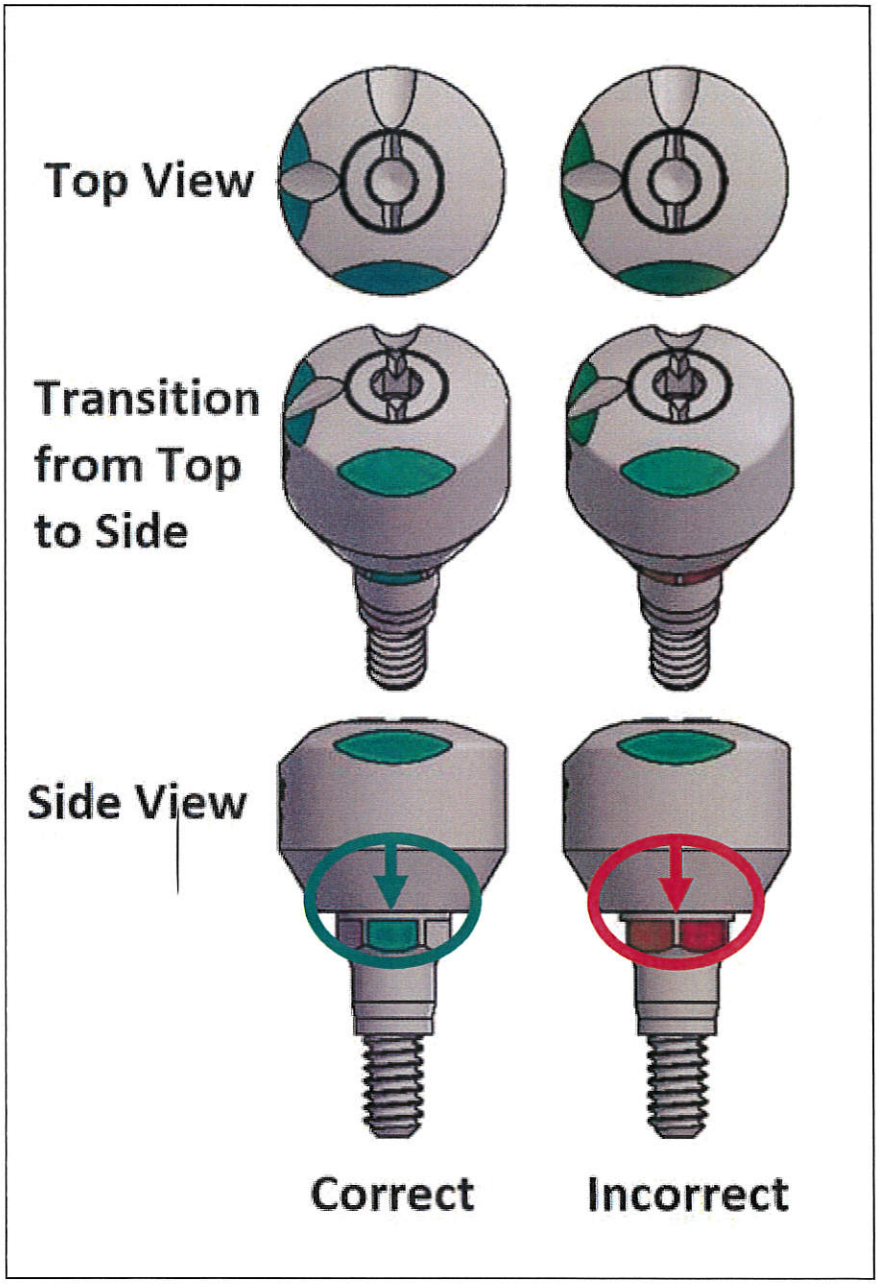
ATTACHMENT 2
Identification of affected Certain® BellaTek® Encode® Healing Abutments *(continued)*

2. Rotate the Encode Healing Abutment such that the base comes toward you and the top rotates away from you, as shown below.



ATTACHMENT 2
Identification of affected Certain® BellaTek® Encode® Healing Abutments *(continued)*

3. Determine if the 6 o'clock flat on the occlusal surface of the Encode Healing Abutment is aligned to a hex flat (green) or a point between hex flats (red).



4. Encode healing abutments with the orientation flat aligned with a point between the hex flats are incorrect and should be returned to Zimmer Biomet Dental per the above instructions.