ZIMMER BIOMET

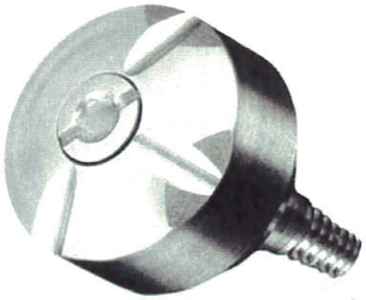
January 10, 2020

To: Clinicians who may be in possession of affected products

Subject: **URGENT MEDICAL DEVICE RECALL**

Zimmer Biomet is conducting a medical device recall for specific catalog numbers and lots of Certain® BellaTek® Encode® Healing Abutments listed in the table below. The resulting impression or scanned data produced from these particular Certain BellaTek Encode Healing Abutment lots will result in an incorrect rotation of approximately 30 degrees and/or margin contour misalignment of the definitive BellaTek abutment.

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



BellaTek Encode Healing Abutment

Table 1

Reference Numbers	Description	Lot Numbers
IEHA343	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 3.4MM(D) X 3.8MM(P) X 3MM(H)	1228842 1230153
IEHA344	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 3.4MM(D) X 3.8MM(P) X 4MM(H)	1228885 1229618 1230155 1230308
IEHA346	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 3.4MM(D) X 3.8MM(P) X 6MM(H)	1228247
IEHA353	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 3.4MM(D) X 5MM(P) X 3MM(H)	1228667
IEHA354	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 3.4MM(D) X 5MM(P) X 4MM(H)	1228687 1229554 1229555

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Reference Numbers	Description	Lot Numbers
IEHA356	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 3.4MM(D) X 5MM(P) X 6MM(H)	1228605
IEHA443	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 4.1MM(P) X 3MM(H)	1227135 1228599
IEHA444	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 4.1MM(P) X 4MM(H)	1228625 1229564
IEHA446	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 4.1MM(P) X 6MM(H)	1228703
IEHA453	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 5MM(P) X 3MM(H)	1228602
IEHA454	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 5MM(P) X 4MM(H)	1227498 1228248 1228639 1228692 1227504 1228863 1229535 1229557 1228807
IEHA456	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 5MM(P) X 6MM(H)	1229560
IEHA463	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 6MM(P) X 3MM(H)	1228840
IEHA464	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 6MM(P) X 4MM(H)	1229063 1229569
IEHA466	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 6MM(P) X 6MM(H)	1228704
IEHA474	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 4.1MM(D) X 7.5MM(P) X 4MM(H)	1228899
IEHA553	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 5MM(D) X 5.6MM(P) X 3MM(H)	1228597 1228828 1230625
IEHA554	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 5MM(D) X 5.6MM(P) X 4MM(H)	1228904 1230638
IEHA563	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 5MM(D) X 6MM(P) X 3MM(H)	1228593 1230791
IEHA564	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 5MM(D) X 6MM(P) X 4MM(H)	1228628 1230644 1232164 1232542 1232758
IEHA566	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 5MM(D) X 6MM(P) X 6MM(H)	1228701 1230640 1232762
IEHA574	CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT 5MM(D) X 7.5MM(P) X 4MM(H)	1229061

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The identified BellaTek Encode Healing Abutments and lot numbers in **Table 1** above 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 May 7, 2019 and December 12, 2019. 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.

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 at the number 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 at the number 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 call BellaTek Customer Service team at the number referenced in Step G below 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 call the BellaTek Customer Service team at 1-888-800-8045 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a prompt to leave a voicemail. Alternatively, your questions may be emailed to: DentalCSDigital@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® 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: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date**____/____/____

Account No. _____ **Facility Name:** _____

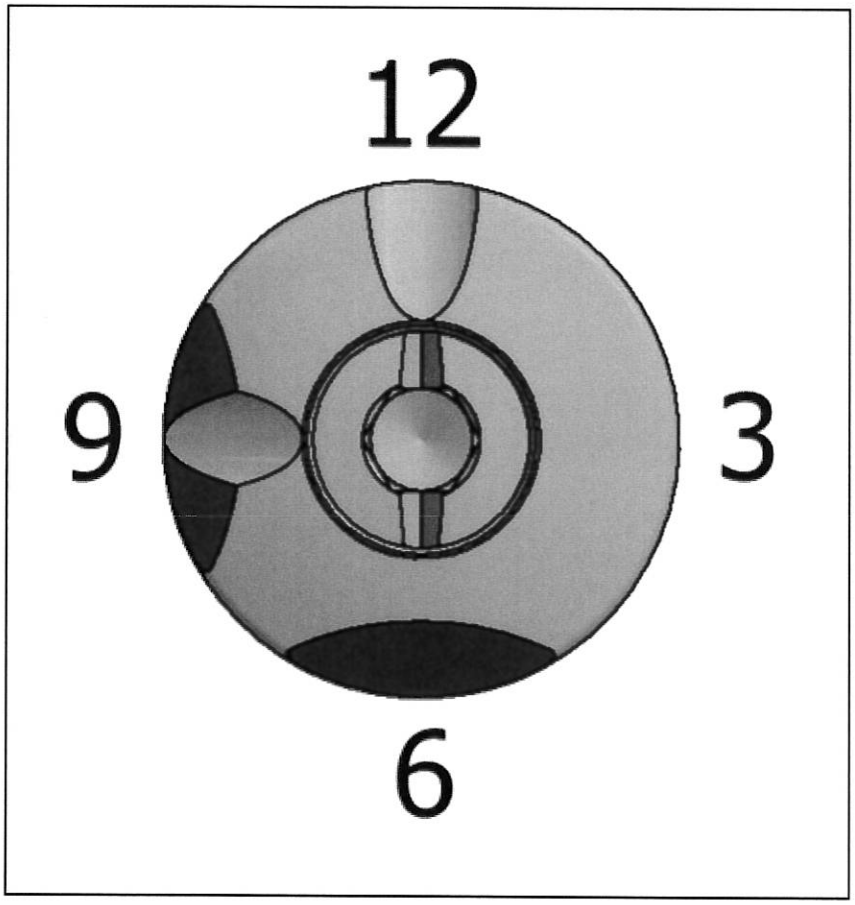
Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

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.

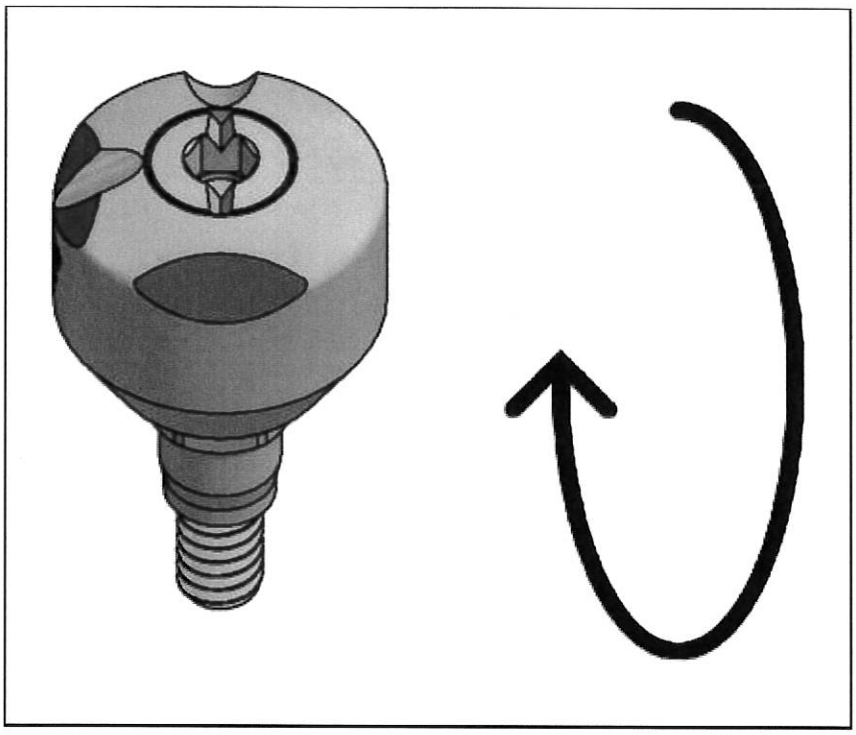
ATTACHMENT 2
Identification of affected Certain® BellaTek® Encode® Healing Abutments

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…

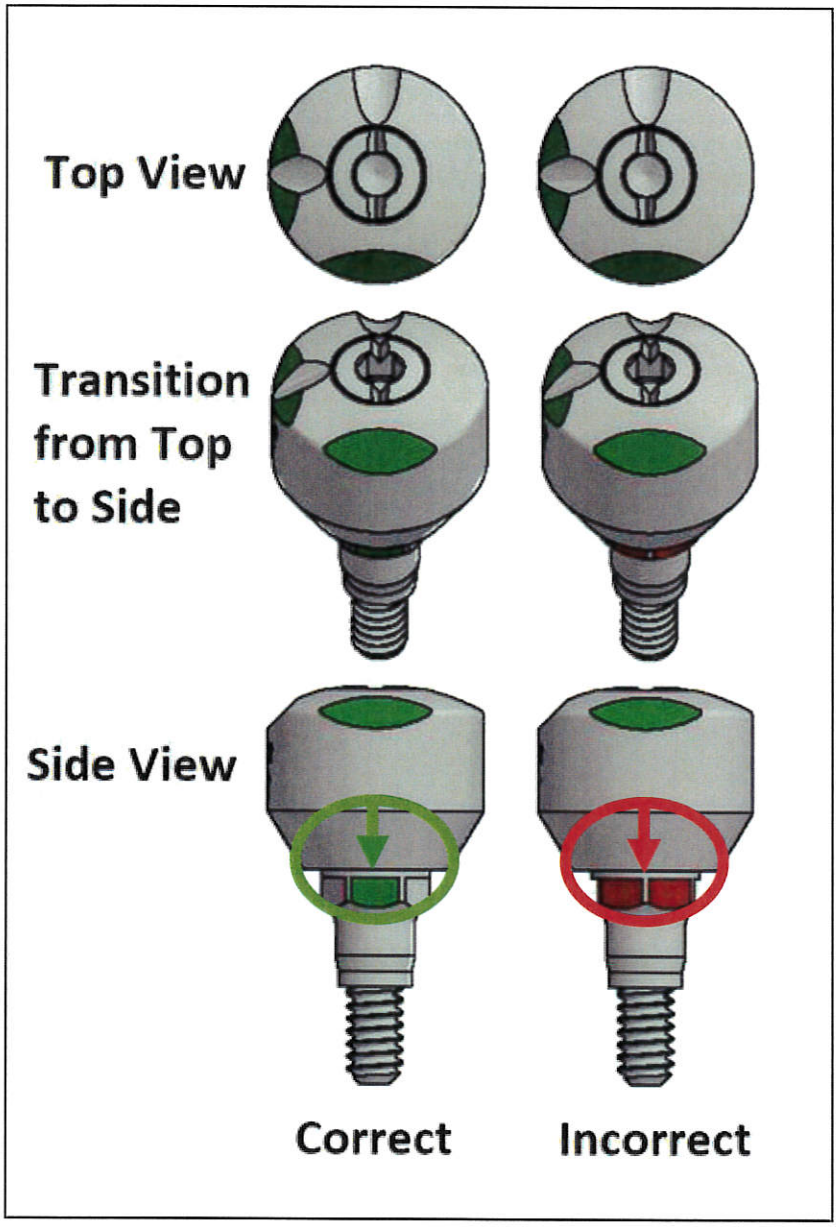
2. Rotate the Encode Healing Abutment such that the base comes towards you and the top of rotates away from you, as shown below.



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.