

January \*, 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**)



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

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 1227504 1228807	1228248 1228863	1228639 1229535	1228692 1229557
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 1232758	1230644	1232164	1232542
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			



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

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 EMEA CS (insert number) 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 EMEA Customer Service (insert number) 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 Customer Service EMEA (insert number) team for instructions on how to remediate the case. The lab will not be charged twice for the Certain BellaTek Encode Healing 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

[Vigilance.EU@zimmerbiomet.com](mailto:Vigilance.EU@zimmerbiomet.com)

E. Include a copy of **Attachment 1 – Certificate of Acknowledgement** with any product to be returned. Customer service will contact you to organize product pick-up.

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 e-mail to:

[Vigilance.EU@zimmerbiomet.com](mailto:Vigilance.EU@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.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [3iEUComplaints@zimmerbiomet.com](mailto:3iEUComplaints@zimmerbiomet.com).

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

Sincerely,

A large black rectangular box redacting the signature of the undersigned.

# ATTACHMENT 1

## Certificate of Acknowledgement

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product:** Certain® Encode® Healing Abutments  
00415

**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:** \_\_\_\_\_

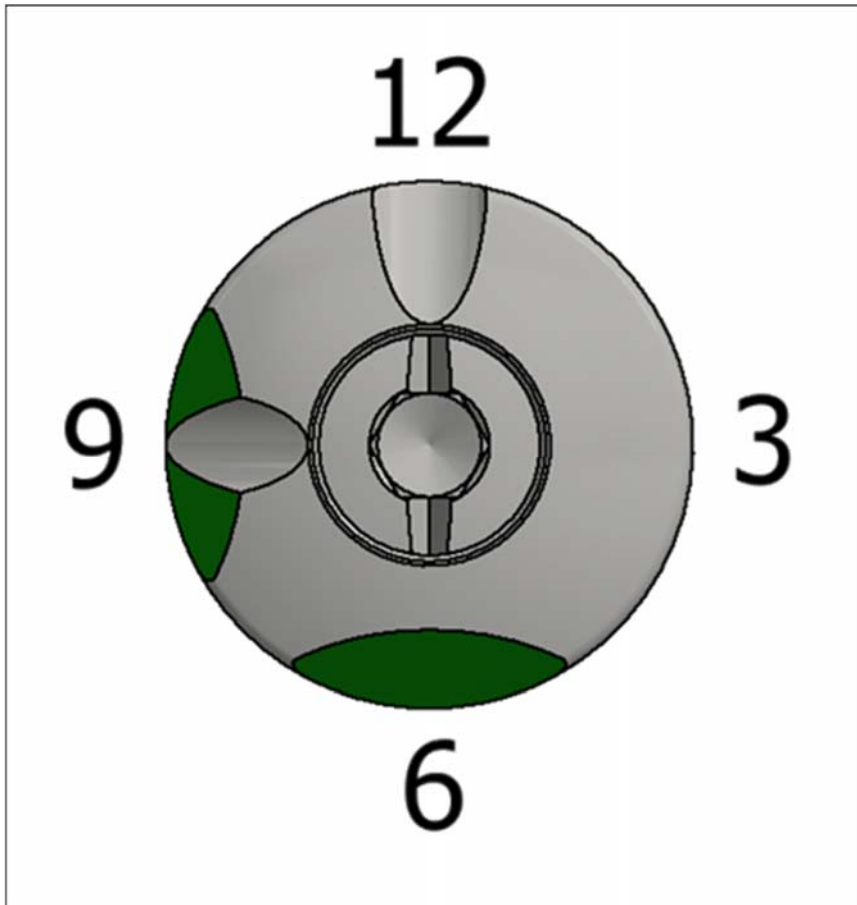
**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **ZIP:** \_\_\_\_\_

**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 [Vigilance.EU@zimmerbiomet.com](mailto:Vigilance.EU@zimmerbiomet.com) or fax to +34 93 193 42 79.

## 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.

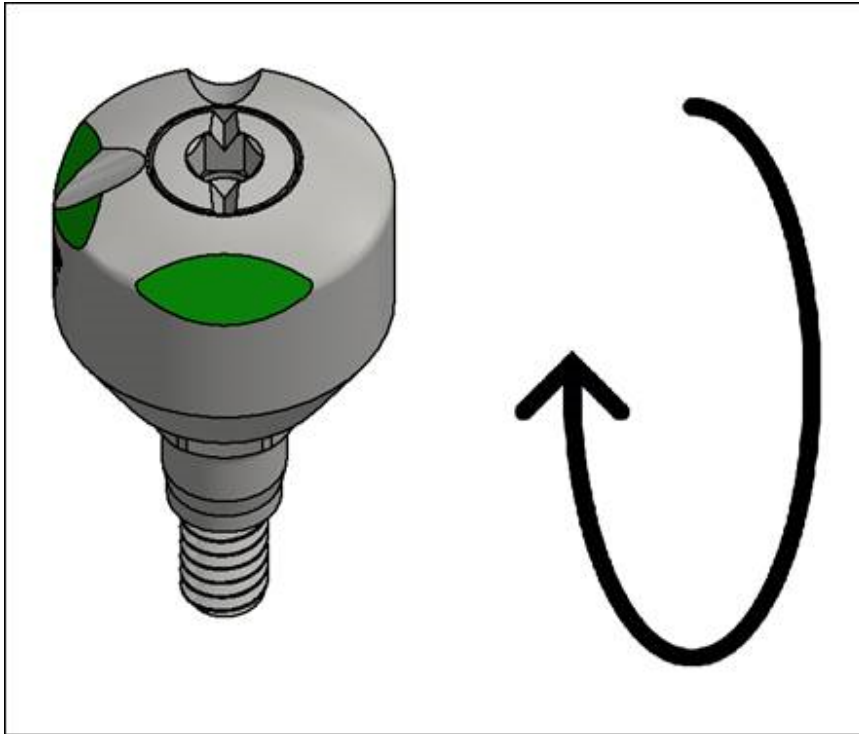




## ATTACHMENT 2

### Identification of affected Certain® BellaTek® Encode® Healing Abutments continued...

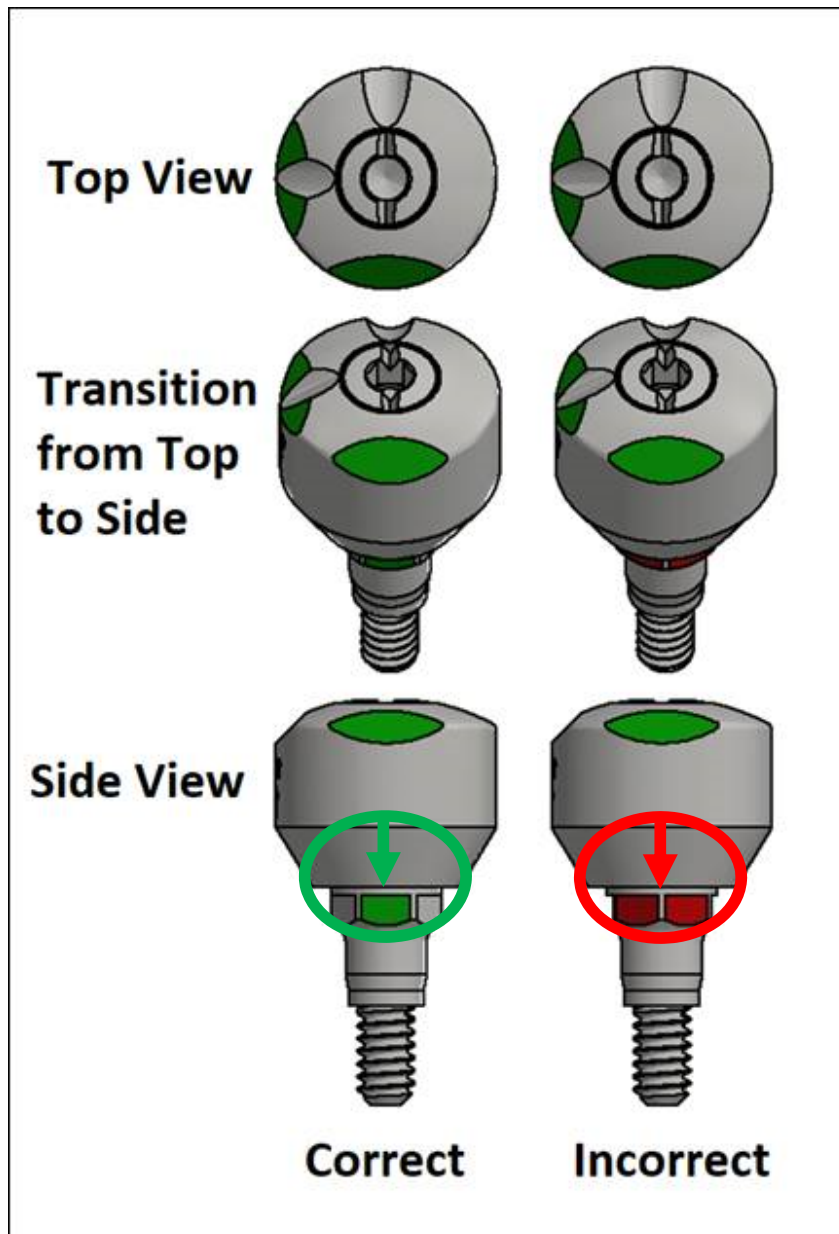
2. Rotate the Encode Healing Abutment such that the base comes towards you and the top of rotates away from you, as shown below.



## ATTACHMENT 2

### Identification of affected Certain® BellaTek® Encode® Healing Abutments continued...

- 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).



- 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.