



URGENT: DEVICE CORRECTION

Zimmer® Trabecular Metal™ Dental Implant, 4.1mmD

Zimmer Dental

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Date

Address

Nature of Correction: Updated Instructions for Use for Select Patients

Subject: Zimmer® Trabecular Metal™ Dental Implant, 4.1mmD

Dear <Customer Name> ,

Zimmer is informing you of a voluntary device correction to the Instructions for Use for the Zimmer Trabecular Metal Dental Implants with a 4.1mm diameter. Our records indicate that your office has received one or more of the Zimmer Trabecular Metal Dental Implants with a 4.1 Diameter. This device correction is being issued by Zimmer Dental as a result of our investigation of a complaint where the apical tip of a 4.1mmD implant separated from the implant assembly during surgery on a patient with a dense (Type D1), thick, inferior border.

This device correction has been reported to the U.S. Food and Drug Administration. Zimmer will provide progress reports on the actions taken as part of this correction to the FDA.

Details of correction:

PRODUCT:

Product Description: Zimmer Trabecular Metal Dental Implant, 4.1mmD

Catalog Numbers: TMT4B10, TMT4B11, TMT4B13, TMM4B10, TMM4B11, TMM4B13

DEVICE CORRECTION:

Precautions have been added to the Instructions for Use indicating additional information regarding the placement of a 4.1mmD Trabecular Metal implant in mandibles with dense (Type D1), thick, inferior border. Refer to attached Technical Bulletin.

ADDED PRECAUTIONS:

When placing the Zimmer® Trabecular Metal™ Dental Implant, 4.1mmD, in mandibles with a dense (Type D1), thick, inferior border where apical implant engagement is expected, follow the dense bone protocol for the 4.1mmD Trabecular Metal Implant with the following exception. After the drill sequence step using the TSV3.8DN or TSV3.8DSN, add an additional drill step utilizing the SV3.8DN or SV3.8DSN drill. If needed, also use the optional TT4.1 Cortical Bone Tap. This correction will provide a wider apical osteotomy to ensure that the apical tip of the implant is not subjected to excessive torque during the final seating process.

CLINICAL IMPLICATIONS (Potential Risks to Health):

- Separation of the implant could cause incomplete seating of the implant and require additional surgical procedures to remove the apical tip from the patient's bone or the need to cover the site and develop an additional osteotomy in an adjacent site.
- Additional time during surgery may be needed to remove the apical tip or release of the patient until the correct trephine bur was received by the office and the remaining piece could be removed resulting in an additional surgery.
- In the case where there is no other sufficient bone available to place a second osteotomy, the tip would need to be removed; however, if the patient has sufficient bone for an alternative osteotomy site, the tip could be grafted over and left to integrate in the bone.

YOUR RESPONSIBILITIES:

Familiarize yourself with the attached Technical Bulletin. Zimmer Dental will follow up to confirm that you received and understand the information.

VIGILANCE REPORTING:

Manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product. Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported to your local Competent Authority.

Zimmer Dental is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation, and we regret any inconvenience this action may cause. Thank you for your assistance. If you have any further questions or concerns please call 1-800-854-7019.

Sincerely,



Regulatory Affairs - Compliance



Technical Bulletin

PRODUCT INFORMATION

To: Zimmer® Trabecular Metal™ Dental Implant 4.1mmD Customers **Date:** March 22, 2012

Subject: Precaution when placing a Zimmer Trabecular Metal Dental Implant 4.1mmD in mandibles with dense (Type D1), thick, inferior border

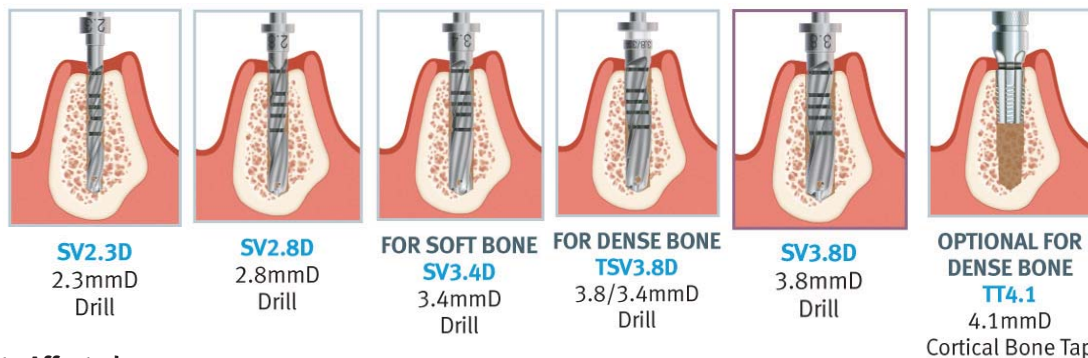
Implant Line: Product Description – Zimmer Trabecular Metal Dental Implant: 4.1mmD Implants
Catalog Number – TMT4B10 TMT4B11 TMT4B13; TMM4B10 TMM4B11 TMM4B13

Zimmer Dental has an additional precaution when placing the 4.1mmD Zimmer Trabecular Metal Dental Implant in mandibles with a dense (Type D1), thick, inferior border where apical implant engagement is expected.

Follow the dense bone protocol for the 4.1mmD Trabecular Metal Dental Implant with the following exception. After the drill sequence step using the TSV3.8DN or TSV3.8DSN, add an additional drill step utilizing the SV3.8DN or SV3.8DSN drill. If needed, also use the optional TT4.1 Cortical Bone Tap. This correction will provide a wider apical osteotomy to ensure that the apical tip of the implant is not subjected to excessive torque during the final seating process.

Modified Instructions For Use:

When placing the 4.1mmD Trabecular Metal Dental Implant in mandibles with a dense (Type D1), thick, inferior border where apical implant engagement is expected, follow the drilling sequence and protocol (with optional tap) as described below.



Products Affected:

Part No.	Description
TMT4B10	IMP TM 4.1MM MTX FULL,10MM
TMT4B11	IMP TM 4.1MM MTX FULL,11.5MM
TMT4B13	IMP TM 4.1MM MTX FULL,13MM
TMM4B10	IMP TM 4.1MM MTX,10MM
TMM4B11	IMP TM 4.1MM MTX,11.5MM
TMM4B13	IMP TM 4.1MM MTX,13MM

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If you have any questions, please contact us:

Technical Service Department (800) 854-7019 or
Customer Service Department (760) 929-4300

