

URGENT: DEVICE CORRECTION



Zimmer Dental

1900 Aston Avenue
Carlsbad, CA 92008
760.929.4300
www.zimmerdental.com
January xx, 2016

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To: Health Care Professionals

Affected Product:

Catalog #	Description	Implant Diameter	Length	Platform Diameter	Lot #
TMM4B10	IMPLANT, TM, MTX®	4.1 mm	10 mm	3.5 mm	63192993
					63216163
TMM4B11	IMPLANT, TM, MTX®	4.1 mm	11.5 mm	3.5 mm	63192991
					63207953
TMM4B13	IMPLANT, TM, MTX®	4.1 mm	13 mm	3.5 mm	63203121
					63207952
					63216164
TMMB10	IMPLANT, TM, MTX®	3.7 mm	10 mm	3.5 mm	63193919
					63212189
TMMB11	IMPLANT, TM, MTX®	3.7 mm	11.5 mm	3.5 mm	63212190
TMMB13	IMPLANT, TM, MTX®	3.7 mm	13 mm	3.5 mm	63216838
TMT4B10	IMPLANT, TM, MTX® FULL	4.1 mm	10 mm	3.5 mm	63187148
					63192992
					63212188
					63216161
TMT4B11	IMPLANT, TM, MTX® FULL	4.1 mm	11.5 mm	3.5 mm	63192990
					63203112
					63236810
TMT4B13	IMPLANT, TM, MTX® FULL	4.1 mm	13 mm	3.5 mm	63203119
					63207951
					63232552
TMTB10	IMPLANT, TM, MTX® FULL	3.7 mm	10 mm	3.5 mm	63193918
					63223934
TMTB11	IMPLANT, TM, MTX® FULL	3.7 mm	11.5 mm	3.5 mm	63193920
					63244217
TMTB13	IMPLANT, TM, MTX® FULL	3.7 mm	13 mm	3.5 mm	63193921
					63236806
TMTB16	IMPLANT, TM, MTX® FULL	3.7 mm	16 mm	3.5 mm	63192173

Dear Health Care Professional:

Zimmer Dental is conducting a voluntary device correction of the above products. Our records indicate that your office previously received a shipment of the affected lot(s) between September-December



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Zimmer® Trabecular Metal™ Dental Implant, 4.1mmD & 3.7mmD

2015.

Through investigation, Zimmer Dental determined that information specific to the 3.7mmD and 4.1mmD Trabecular Metal implants was omitted from the latest revision of the applicable IFU in the Indications, Contraindications, and Precautions sections.

You are receiving the enclosed Technical Bulletin with a complete summary of omitted information to correct the issue.

Risks:

- If the clinician attempts to place a 3.7mmD implant in the molar region or in the pre-molar region without splinting, the implant could loosen or fracture, leading to subsequent surgeries.
- If the clinician attempts to place a 4.1mmD implant in the molar region without splinting, or does not follow the proper drilling procedure, the osteotomy could be under-prepared the implant could loosen or fracture, leading to subsequent surgeries.

Responsibilities:

1. Please review this notice and check your inventory for the affected units.
2. If you wish to keep the product, please familiarize yourself with the Technical Bulletin information.
- 3. If you wish to return the affected product, please call Zimmer Dental Customer Service at 1-800-854-7019 to obtain a Return Authorization Number and to setup a FedEx pick-up to return the products.**
4. Complete Attachment 1, the Business Reply Form.

Please maintain a copy of this notice and a signed copy of Attachment 1 for your records to assist in any future regulatory agencies audits of this field action.

Other Information

This voluntary notification will be reported to the U.S. Food and Drug Administration.

Zimmer Dental takes quality very seriously, and we work diligently to ensure that we are improving lives by developing and delivering high quality, safe and effective products. We apologize for any inconvenience this may have caused and appreciate your continued business. For assistance or any other questions that you may have, please contact Zimmer Dental Customer Service at 1-800-854-7019. Customer Service is available 7:00am to 5:00pm (Pacific), Monday through Friday.



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Zimmer® Trabecular Metal™ Dental Implant, 4.1mmD & 3.7mmD



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Zimmer® Trabecular Metal™ Dental Implant, 4.1mmD & 3.7mmD

ATTACHMENT 1
BUSINESS REPLY FORM

Instructions:

1. If you have product to return, please **call Zimmer Dental Customer Service at 1-800-854-7019** to obtain a Return Authorization (RA) number and to set up a FedEx pick-up to return products.
2. Please ensure that the shipping container lists the RA number for quick processing.
3. Complete the form below and email a copy to corporatequality.postmarket@zimmer.com or fax to (574)372-4265.

Please Return Affected Product to:

Zimmer Dental
Attention: Complaints & Returns
6221 El Camino Real
Carlsbad, CA 92009

Completion of this Reply Form confirms that I have read the above Notice regarding 3.7mmD and 4.1mmD *Trabecular Metal* implants.

NAME OF DISTRIBUTOR/SALES ASSOCIATE COMPLETING THIS FORM:

Printed Name: _____ Signature: _____

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

Please complete and fax or email within five (5) business days to:

Fax – 574-372-4265

Email – corporatequality.postmarket@zimmer.com