



URGENT MEDICAL DEVICE RECALL NOTICE  
October 17, 2014

RE: Titanium Mandible Implants

Dear Valued Customer / Distributor,

This notice is to inform you of an Urgent Medical Device Recall initiated by Biomet Microfixation which involves certain Titanium Mandible Implants that have been consigned and/or invoiced to your account. Biomet Microfixation has initiated this recall following an internal investigation which identified that the Titanium Mandible Implants may exhibit fatigue fracture due to a laser etch that was delivered at a more powerful setting resulting in a wider and deeper etch. The laser is used to etch the part number, lot number, and logo on the implant.

A Health Hazard Evaluation was completed and determined that this constitutes a potentially high risk to the patient. In the event of mandibular component fatigue fracture the patient would experience difficulty with normal jaw function and would require surgical intervention to replace the fractured implant.

This action requires the immediate location and discontinued use of the items identified on page two of this notice, and their immediate return to Biomet Microfixation. Specifically, you are **REQUIRED** to take the following steps:

- Immediately locate and remove from circulation the items invoiced/consigned/loaned to your account as identified on page two of this notice.
- Carefully follow the instructions on the enclosed "Response Form".
- If you have further distributed these items to medical facilities, you **MUST** notify them of this action. This letter **MUST** be given to the person responsible for receiving recall notices. However, you are charged with the location and return of these items.

**To date, Biomet Microfixation has not received any reports of events in which failure of an effected Titanium Mandible Implant has occurred.**

Health care professionals and consumers may report serious adverse events or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone:

Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

Regular Mail: Use postage-paid FDA form 3500 available at [www.fda.gov/Medwatch/getforms.htm](http://www.fda.gov/Medwatch/getforms.htm) and mail to Medwatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

Fax: (800) FDA-0178

Phone: (800) FDA-1088



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Thank you in advance for your assistance and prompt attention to this matter. Biomet Microfixation apologizes for any inconvenience resulting from this field action. Questions related to this notice should be directed to Rachel Osbeck at 1-800-874-7711 or 904-741-4400, extension 9448, Monday through Friday, 8 a.m. to 4 p.m. EST.

Sincerely,

Rachel Osbeck  
Director, Quality Assurance & Regulatory Compliance  
Biomet Microfixation

The following units have been invoiced to your account:

Part Number	Description	Lot



**Response Form**

Attention:	Rachel Osbeck, Director, Quality Assurance & Regulatory Compliance (x 9448)
Fax Number:	904-741-9425
Regulatory Action:	Medical Device Recall; Recall #: 2172
Description:	Titanium Mandible Implants
Lot Number(s):	See Attached

Instructions:

1. If items are being returned, ship the package via priority carrier utilizing FedEx Account # 290613205, and **include a copy of this completed and signed Response Form with your shipment**. The box will be returned to:  
**Recall #: 2172**  
Attn: Danielle Wernikowski  
Biomet Microfixation  
1520 Tradeport Drive  
Jacksonville, FL 32218
2. If no items are available for return, please fax (904-741-9425) or email (danielle.wernikowski@biomet.com)
3. Please email **tracking number and your contact information** to Danielle Wernikowski at danielle.wernikowski@biomet.com

**Please check the appropriate boxes:**

We have the following items referenced in the enclosed letter and are returning them for credit:

Part Number:	Lot Number:	Quantity:

We have physically checked ALL inventory and hospital locations and we do not have the following affected product:

Part Number:	Lot Number:	Quantity:

Company/Distributor Name:	
Contact Name/Title:	
Phone Number:	
Address:	
Contact Signature:	

RE: Titanium Mandible Implants

Dear Surgeon,

This notice is to inform you of an Urgent Medical Device Recall initiated by Biomet Microfixation which involves certain Titanium Mandible Implants that have been implanted at your facility. Biomet Microfixation has initiated this recall following an internal investigation which identified that the Titanium Mandible Implants may exhibit fatigue fracture due to a laser etch that was delivered at a more powerful setting resulting in a wider and deeper etch. The laser is used to etch the part number, lot number, and logo on the implant.

A Health Hazard Evaluation was completed and determined that this constitutes a potentially high risk to the patient. In the event of mandibular component fatigue fracture the patient would experience difficulty with normal jaw function and would require surgical intervention to replace the fractured implant.

If the implant does not fracture following implantation, the risks of a revision surgery may outweigh the benefits of device removal. Provided that the patient remains asymptomatic, and there is no fracture of the condylar neck, removing the implant could result in unnecessary soft tissue and nerve damage. If however, the implant does fracture (Figure 1.), it is likely that jaw function would be negatively impacted, and a device removal would be required. Such risks for a revision surgery would be similar to other revision surgeries where there is a device failure (e.g. screw loosening).

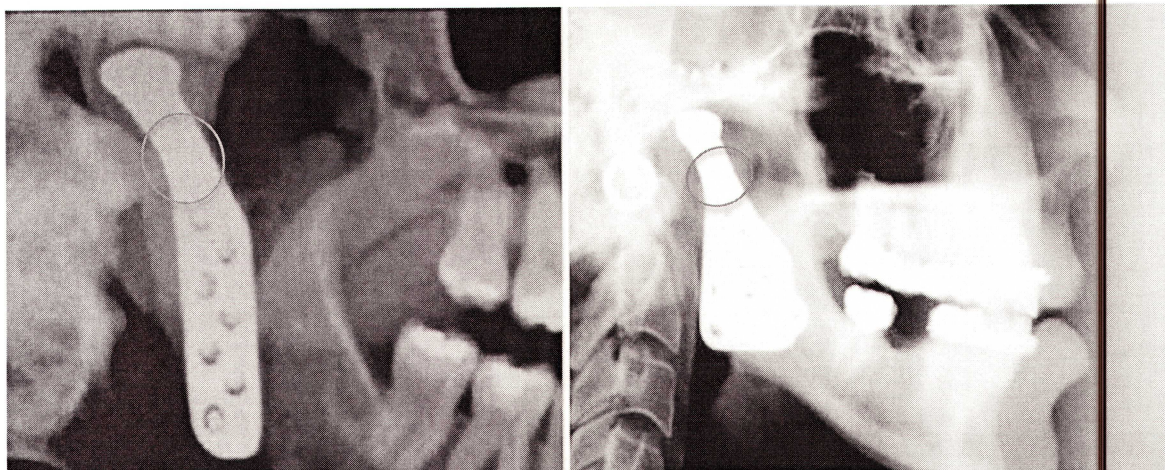


Figure 1: Narrow TI Mandible Implant (left) and Standard TI Mandible Implant (right) red markings indicate location of potential fracture site.

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Director, Quality Assurance & Regulatory Compliance  
Biomet Microfixation