

---

## Field Safety Notice II

**Custom Made Dental Abutment: ATLANTIS Abutment Titanium  
Produced and Shipped between June-01-2015 and June-03-2015**

***Note: This information references only abutments that were placed clinically***

---

Date: 2015-July-03

Dear Madam, Dear Sir,

**The following is to confirm in a written format the information you have received previously by phone or email.**

You have already received the general information about the issue (Field Safety Notice I)

This information is referring to a limited number of abutments (2 in total) that have been placed clinically.

**Please note the following information about the above mentioned products:**

Advice: We were informed that the abutment in discussion was already placed into patient's oral cavity before you received the note to not use it clinically. To ensure a long-term success of the treatment, we recommend a close follow-up. Due to the nature of the flaw, this is particularly indicated in the early period of function. Therefore a subsequent clinical follow-up should be performed within a time frame of 6-12 months after first examination.

- To detect any signs of or even screw loosening clinical inspection is mandatory: Any local clinical signs of inflammation in surrounding tissues, (this can occur without the presence of a faulty abutment) might be a hint of an improper fitting abutment.
- Furthermore probing and mobility testing are recommended to analyze the clinical situation in detail.
- If no symptoms were detected after the above mentioned follow-up period, the restoration can be checked according the dentist's advised routine.
- In case of detecting any symptoms we recommend to replace the prosthetic restoration. Any replacement of abutment and consequently also a new crown will be on the expense of DENTSPLY Implants.
- Although abutments do not show any evidence of mobility or clinical signs of inflammation, the patients need to be briefed about the potential misfit. Besides they need to be informed about the option of removal and replacement with a new abutment and a new crown, the related clinical steps and potentially related risks to do so.

If the dentist in accordance with the patient decides to not exchange an abutment that is currently free of any complications, we recommend instructing the patient to contact the dentist for consultation if any signs of mobility or local inflammation occur.

In case of desire or necessity to replace a prosthetic restoration or if further clarification is needed please contact

### Contact data

Legal Manufacturer:

DENTSPLY Implants Healthcare AB

PO Box 14

SE - 431 21 Mölndal

Contact Person:

**Dr. Ricarda Jansen or Torsten Meyer-Elmenhorst**

Medical Device Safety Officer (MPA EU)/ Sicherheitsbeauftragte für Medizinprodukte (MPG EU)

Phone +49 (0) 621 4302-1370

Fax +49 (0) 621 4302-2370

E-mail: [implants-safetyofficer@dentsply.com](mailto:implants-safetyofficer@dentsply.com)