Urgent Field Safety Notice

Implant Driver Profile EV 4.2, Long
REF 25465, Lot# 401290, Manufacturing date: 2017-03-17

Date: 2017-04-11

Dear Dental Professional,

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

We regret to inform you that due to a manufacturing error the above mentioned product is faulty. This product should not be used and be returned to the manufacturer.

Details on affected devices:

Implant driver Profile EV 4.2, Long
REF 25465
Lot# 401290
Manufacturing date: 2017-03-17
www.dentsplysirona.com

Background

Astra Tech Implant System is a dental implant system used to replace missing teeth.

The concerned product Implant driver Profile EV 4.2 long is used to engage and lift an OsseoSpeed Profile EV implant from its packaging into the patient's mouth and to rotate it down in a prepared osteotomy to its designated position. OsseoSpeed Profile EV implants have a sloped marginal portion – a design for sloped bone ridges.
The OsseoSpeed Profile EV implant has a unique interface with one-position only placement of all indexed components and includes an option for index free placement for single and for multiple unit restorations.

The Implant driver Profile EV 4.2 long has a marking consisting of a flat surface with a dimple. This portion of the driver is aimed at the most apical point of the slope to facilitate optimal placement of the implant.

Description of the problem

The identified faulty product has its flat surface with the dimple rotated 180 degrees from its intended position.

When using the faulty product, the lowest portion of the implant will be positioned in the wrong direction related to the jaw bone and instead of being aligned with the lowest portion of the crest it will be submerged below the highest part of the crest, which will not be in contact with the implant. The

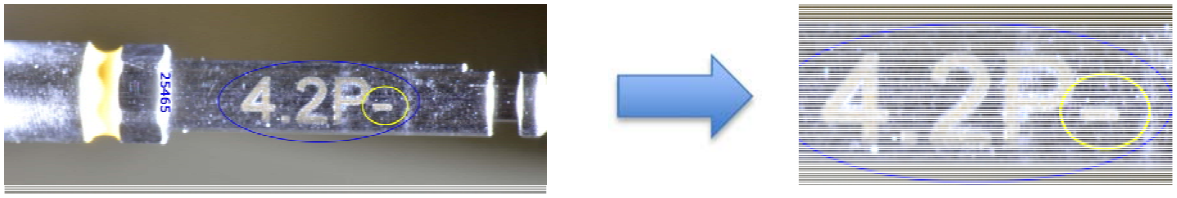
highest portion of the implant will be exposed since the osteotomy will be too shallow to allow this part of the implant to be embedded in bone which may lead to esthetical compromises if not detected and corrected during surgery.

Advise on action to be taken by the user:
This product should not be used and be returned to the manufacturer.

Please return the product(s) without delay to:

DENTSPLY Implants Manufacturing GmbH
Steinzeugstrasse 50
D-68229 Mannheim
GERMANY

Should you have multiple Implant driver Profile EV 4.2 long in your possession, please return only those that have a hyphen (-) on its shaft, see picture, as these drivers are from the concerned faulty items lot.



If you have difficulties to identify the faulty implant drivers please get in contact to your local sales rep to get the products identified and removed.

In case you have already used the Implant driver Profile EV 4.2, Long, REF 25465, Lot# 401290 please verify that the implants were installed as intended by checking the X-Ray taken after the surgery. If there is no post-surgery X-Ray available we would ask you to make an appointment with any patient who was treated using this product and verify that the implant is seated correctly

OsseoSpeed Profile EV implants having the wrong orientation do not have to be removed. However you may need to use non indexed stock abutment(s), or, Atlantis abutment(s) for the forthcoming prosthetic restoration. Please get in contact with your local Dentsply Sirona sales representative if support is needed due to the use of the faulty implant driver.

For upcoming OsseoSpeed Profile EV cases:
For your next OsseoSpeed Profile EV case you may use the

Implant Driver Profile EV 4.2, Short, REF 25464
(if needed together with an Implant Driver Extender EV-GS, REF 26021).

According to our records you have already such an implant driver as well as an extension for it in your possession. If not, these products will be sent to you on request.

Replacement delivery for the faulty 25465 Implant Driver Profile EV 4.2, Long is expected in the beginning of May 2017.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact data in case of questions:

Norbert Bergner
Medical Device Safety Officer (MPA EU)
Sicherheitsbeauftragter für Medizinprodukte (MPG EU)
DENTSPLY lmplants Manufacturing GmbH
Steinzeugstrasse 50
D-68229 Mannheim
GERMANY
Phone: +49 (0) 621 4302-1210
Fax : +49 (0) 621 4302-2210
E-mail: implants-safetyofficer@dentsplysirona.com

We sincerely regret the inconvenience this manufacturing error is causing you and your patients.

Signature