Urgent Field Safety Notice (FSN)

Atlantis Abutment, titanium (Biomet 3i Certain connection)
– REF 35502, Case# 17220052, 17224554, 20647414 and 30177022

Lab-Scan Atlantis Abutment, titanium (Biomet 3i Certain connection)
– REF 35502S, Case# 17221267, 17222853 and 20647529

Lab-Scan Atlantis CustomBase, titanium with Core File (Biomet 3i Certain connection)
– REF 35091ST, Case# 20646083

Lab-Scan Atlantis CustomBase, titanium gold-shaded with Core File (Biomet 3i Certain connection)
– REF 35091SG, Case# 25281599

Date: 2020-09-XX

Dear Dental Professional,

We regret to inform you that due to a manufacturing issue the above-mentioned products may not work as expected. This Field Safety Notice is intended to inform you about the issue and to give advice how to act.

Details on affected devices:

Atlantis Abutment, titanium (Biomet 3i Certain connection)
– REF 35502, Case# 17220052, 17224554, 20647414 and 30177022

Lab-Scan Atlantis Abutment, titanium (Biomet 3i Certain connection)
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www.dentsplysirona.com

Background
The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.

Description of the issue
A milling defect caused by a manufacturing issues has been detected. This defect is positioned where the abutment plane connects to the implant. This can cause a small gap between implant and abutment.

Warning
When the Atlantis Abutment is in patient use, with a small gap between the implant-abutment plane, it will be impossible for the patient to clean between the implant and the abutment. The possible consequence of this is that over time microbes aggregated in the gap will cause a soft tissue inflammation (mucositis) that over time, in more severe cases, can lead to periimplantitis. With a gap the mechanical stability of implant/abutment connection may also be affected, especially in long-term use.

Advise on action to be taken by the user:
If the abutment has not yet been installed in the mouth of the patient, please contact Dentsply Sirona Atlantis Customer Service, immediately (see contact information below). Atlantis Customer Service will make sure that the faulty abutment is replaced with a new abutment.
Central Atlantis Customer Service: atlantis.europe@dentsplysirona.com

If the abutment is already installed in the mouth of the patient the abutment must be replaced with a new abutment. Please contact Dentsply Sirona Atlantis Customer Service, immediately (see contact information below). Atlantis Customer Service will make sure that the faulty abutment is replaced with a new abutment.
Central Atlantis Customer Service: atlantis.europe@dentsplysirona.com

Independent from the result of your verification we would ask you to return the completed and signed answer letter (page 3 of this document) by email to:
Central Atlantis Customer Service: atlantis.europe@dentsplysirona.com

Transmission of this Advisory 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 product(s) have been transferred.

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

Contact data in case of questions:

Norbert Bergner
Medical Device Safety Officer (MPA EU)
Sirona Dental Systems
Fabrikstr. 31
D-64625 Bensheim
GERMANY
Phone: +49 6251 16 3775
E-mail: implants-safetyofficer@dentsplysirona.com

We sincerely regret the inconvenience this manufacturing issue may cause for you and your patients.

Answer Letter to Field Safety Notice (FSN)

Atlantis Custom Base/Abutment in titanium/titanium gold-shaded for Biomet 3i Certain connection

Customer / User:

Customer ID: _____

Name: _____

Street: _____

Address _____

Phone: _____

Email: _____

or Practice Stamp

We hereby confirm that we have receive the Field Safety Notice (FSN) for above mentioned product and that we will follow the instruction given by this document.
In addition, we will transfer this information to our organization or to any organization where the potentially affected product(s) have been transferred.

Date: …….. Signature: ……..

This is the response to above mentioned Advisory Notice.
Please send the completed and signed response to
Central Atlantis Customer Service: atlantis.europe@dentsplysirona.com