

Urgent Field Safety Notice (FSN)

FSCA Ref# S-PSC 2025-06-30

Date: 2025-07-29

Dear Dental Professional,

We regret to inform you that the below listed products may not work as expected due to a manufacturing issue. This Urgent Field Safety Notice is intended to inform you about the issue and to advise you on how to respond. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Details on Affected Products:

Product name	Used for	Article Number	UDI-DI	Affected Lots (6-pack)
IO FLO-S Kit A04A	Astra TX 20° UniAbutment	68020032	07392532249426	10529852
IO FLO-S Kit A04B	Astra TX 45° UniAbutment	68020033	07392532249433	10544044 10488578
IO FLO-S Kit A04S	EV Multibase Abutment Megagen Multi-unit Abutment (N_type) Biohorizons Multi-unit Abutment	68020034	07392532249440	10515863 10512084 10505543 10556741

Product Description and Primary Clinical Purpose of Product

The Atlantis intraoral feature locating object for suprastructures (IO FLO-S) is intended to support the prosthetic procedure with the aim of restoring chewing function in partial or complete edentulous patients, by enabling digital impression taking on implant or abutment level for all positions in the mouth of the patient **or** on the master model.

Each Atlantis IO FLO-S article number is sold as a kit containing a tray with 6 IO FLO-S for storing the non-sterile IO FLO-S and a Tag (to be placed in the Atlantis FLO-S case) for 1 specific connection.

Description of the Product Problem

Due to a defect in the thread area of an affected IO FLO-S, the device will not be able to be completely engaged and seated with an abutment as intended resulting in an unintended gap between the IO FLO-S and the abutment.

Hazard giving rise to the Field Safety Corrective Action

If an affected IO FLO-S is used, the scan taken using the device will result in an incorrect patient specific dental restoration with fit issues in a clinical situation. The mechanical stability of the abutment / restoration connection will be affected by this fit issue (gap, etc.).

Action to be taken by the Customer:

1. Stop use of the affected lots immediately.
2. If the IO FLO-S has already been used for scanning, please immediately contact the dental laboratory that manufactured the dental restoration and direct the laboratory to contact Dentsply Sirona Atlantis Customer Service, immediately (see contact data below) to verify if the scans are correct.
3. If the IO FLO-S has already been used and a structure has been manufactured and placed into the patient, please immediately contact the patient and verify the correct engagement of the suprastructure, correct fit and torque of the prosthetic screws. Please contact your local Dentsply Sirona Atlantis Customer Service, immediately (see contact data below).
4. Return any affected lots for refund or replacement to the address below by including the completed and signed Answer Letter (see page 3). If unable to identify the affected lots, please return **all products** of the affected types.

Dentsply Sirona Deutschland GmbH

Rückruf

Fabrikstr. 39

64625 Bensheim

5. Please return the completed and signed Answer Letter (page 3 of this document) to the local Dentsply Sirona country organization identified above within one week after receipt of this Urgent Field Safety Notice. Timely completion will allow us to process your replacement product more quickly.

Transmission of this Urgent Field Safety Notice

Please provide this Notice to everyone that needs to be aware of this issue inside or outside of your organization.

Specifically, please provide this Notice to any organization where the potentially affected product(s) have been transferred or used within the workflow to create a patient-specific restoration, or where this issue may have an impact.

Please continue to review and abide by this Notice for an adequate timeframe so all affected products are identified, and appropriate measure are taken.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact data in case of questions:

Atlantis Customer Service

Phone 06251 / 16 16 11

E-Mail CS-Digital@dentsplysirona.com

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

Answer Letter to Urgent Field Safety Notice (FSN)

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IO FLO-S Kit A04A (68020032), Affected Lot #10529852

IO FLO-S Kit A04B (68020033), Affected Lots #10544044, #10488578

IO FLO-S Kit A04S (68020034), Affected Lots #10515863, #10512084, #10505543, #10556741

Customer / User:

Customer ID:

Name:

Street:

Address

Phone:

Email:

or Practice Stamp

We hereby confirm that we have received the Urgent Field Safety Notice (FSN) for above mentioned products 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 or used within the workflow to create the custom-made restoration.

Date:

Signature:

Request for refund OR free replacement of affected IO FLO-S Kit

Product name	Article Number	REFUND Quantity of products to be refunded:	REPLACEMENT Quantity of products to be replaced:
IO FLO-S Kit A04A	68020032		
IO FLO-S Kit A04B	68020033		
IO FLO-S Kit A04S	68020034		

Identified products need to be sent to the address below for refund OR replacement. Please include a copy of this Answer Letter with the return delivery.

**Dentsply Sirona Deutschland GmbH
Rückruf
Fabrikstr. 39
64625 Bensheim
Tel.: 06251 / 16 16 11**