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FSN REF:01-2019/67847 **FSCA REF:** CMD-67847

Date: 30-Oct-2019

Urgent Field Safety Notice
The Invisalign System Aligners

For attention of:

Dr. Name	Country	Treatment plan
Bogey-Cendron, Juliette	France	Lite
Mora, Marta	Hungary	Comprehensive
Pisoni, Andrea	Italy	Comprehensive
Bakker, Marieke	Netherlands	Comprehensive
Lachmansingh, Monique	Netherlands	Lite
Sieger, Agnieszka	Poland	Full
Rodriguez Rubio Labadia, Maria	Spain	Comprehensive
Qiijada De Aristegui, Enrique	Spain	Comprehensive
Torres, Leticia	Spain	Comprehensive
Roldan Gutierrez, Alicia	Spain	Comprehensive
Garcia Pinto, Rocio	Spain	Comprehensive
Stucki, Nils	Switzerland	Comprehensive
Heekeren, Daniel	Switzerland	Comprehensive
Sabouni, Waddah	United Arab Emirates	Comprehensive
Zai, Shabnam	United Kingdom	Comprehensive
Higgins, Kevin	United Kingdom	Comprehensive
Dattani, Rachna	United Kingdom	Comprehensive
Counihan, Neil	United Kingdom	Comprehensive
Gegau, Romina	United Kingdom	Express
Kothand, Krish	United Kingdom	Comprehensive

Contact details EU Authorized-Representative:
Align Technology B.V.
Arlandaweg 161,1043HS Amsterdam
+31(0)20-5863600

Legal Manufacturer:
Align Technology Inc.
2820 Orchard Parkway, San Jose, CA 95134
United States

Device types:
The Invisalign system aligners are Class I custom-made medical devices specifically manufactured for a specific patient for the treatment of malocclusion.
GMDN – 44738 – Orthodontic Appliance system, progressive

Commercial name:
The Invisalign system aligners

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Primary clinical purpose of the device:

The Invisalign system consists of a series of doctor-prescribed, patient-specific, custom-made, clear plastic removable orthodontic appliances (aligners) that gently move the patient's teeth in small increments from their original state to a more optimal, treated state. Each aligner covers the teeth and the gingival tissue between the teeth. The aligners are trimmed near the gum line between the teeth and the gingival tissue so that the edge of each appliance will be minimally visible. Each plastic aligner surrounds the teeth captured by the prescribing dentist in their impression/intraoral scan, and the aligners may also touch the gingival tissue near the teeth of the patient. The aligner series is intended to replace conventional fixed orthodontic bracket and wire technology for many orthodontic cases.

Purpose of this letter

As a result of the software release on June 1, 2019, in some instances, customers were able to modify and re-approve a number of previously approved versions of the ClinCheck treatment plans. This created a discrepancy between the ClinCheck file version used to manufacture and ship the aligners vs. the original ClinCheck files that had been approved by doctors. In some cases, it also created discrepancies in labeling. In addition, some of the treatment information available on IDS doctor portal and on the aligner bag labels per approved treatment plan did not match the actual geometry of the fabricated aligners.

Device Model/Catalogue/Part-numbers

This concerns aligners of the following treatment plans:

Treatment Plans	Description
Comprehensive	Offers an unlimited number of aligner stages for both the upper and lower dental arches.
Lite	Offers a maximum of 14 aligner stages for both the upper and lower dental arches.
Express	Offers a maximum of 7 aligner stages for both the upper and lower dental arches

Align Technology has identified that the situation only concerns the aligners of the following patients (Patient Identification Numbers provided below):
9009594, 8983724, 9053659, 8919931, 9052735, 9127636, 9135979, 9067723, 9046642, 8899066, 8896260, 8966790, 8989023, 6796976, 7983129, 9066460, 9037201, 9090999, 9103977 and 9140938.

Hazard-giving rise to the FSCA

A risk assessment was performed and there are no major risks that could result in any serious incidents to the patients.
There are minor transient risks, related to the following:

- Differences in approach between the plan that was approved and the one used to fabricate the shipped aligners, which could result in unplanned tooth movements.
- Differences in staging of overcorrection/passive aligners; if the aligner has more movement than what is indicated on the bag label as per approved treatment plan, there is a potential for more tooth movement vs. intended movement.
- If the approved order has more or fewer stages than what was fabricated, this may result in less cumulative movement in the aligners that where shipped.

Although the risk analysis predicts a minor risk to the patient, we as Align Technology recommend doctors involved to check the current aligners received and order warranty aligners when needed.

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Adverse events/ Incidents:

Align Technology has not received any information regarding injuries, public health threats and/or deaths related to the associated custom-made aligners.

Immediate actions taken:

Based on the outcome of the risk analysis of the delivered aligners, we divided them in two groups—A and B—which require slightly different approaches.

A. doctors can keep the aligners if the plan meets their specifications and any labeling differences are minor - or the doctor orders warranty aligners

B. doctors are advised to stop using current set of aligners and make a new scan/impression, so we can offer a new treatment plan and we need to produce new aligners according to the new treatment plan. (Warranty)

20 potentially impacted cases have been manufactured and shipped to doctors' offices; all patients involved are identified as follows:

Group A	**Group B**	
Patient ID	**Patient ID**	
9053659	9909594	8896260
9135979	8983724	8966790
9046642	8919931	8989023
7983129	9052735	6796976
9066460	9127636	9090999
9037201	9067723	9103977
	8899066	9140938

Is customer reply required:

Align Technology has contacted all the doctors involved by phone, notified and explained them the situation and informed them about the action to be taken.

Further advice or information already expected in follow-up FSN

Not applicable.

Transmission of this Field Safety Notice

Please report all device-related incidents to the manufacturer, distributor or local representative as this provides important feedback.

Align Technology B.V. as European Representative has informed the Competent (Regulatory) Authority about this Field safety corrective action. Reference number IT 2026499.

Signed by:

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Sr. Director Regulatory and Governmental Affairs & Quality Assurance EMEA
Align Technology B.V.
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The Netherlands