ALIGN TECHNOLOGY B.V. Herikerbergweg 312, 1101 CT Amsterdam, The Netherlands | aligntech.com

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Date: 09-Aug-2021

FSCA REF: IT2051211 (IGJ)

Field Safety Notice

Invisalign System Aligners

Dear Customer,

The purpose of this notification is to inform you that Align Technology has identified a potential issue with some of our Aligners produced between the 15th of May 2021 and the 28th of July 2021. Even though this issue will most likely not lead to any incidents or serious health threats, Align Technology decided to undertake a voluntary product replacement. This action reflects our commitment to delivering the highest quality products to our doctors and their patients.

Device types

The Invisalign system aligners are Class lla patient matched medical devices specifically manufactured for a specific patient for the treatment of malocclusion.
GMDN – 44738 – Orthodontic Appliance system, progressive

Products involved

Align Technology has identified this issue only concerns the Invisalign Systems aligners with the following PID'S (Patient Identification Numbers) in the EU:

PID	Country
11198037	ES
14074000	ES
10296080	ES
14056960	ES
14112972	ES
14112972	ES
14112972	ES
12158920	ES
13939130	ES
13978033	ES
13978033	ES
13978033	ES
13978033	ES
14148718	ES
13623645	ES

PID	Country
9815215	ES
8302582	FR
13589278	FR
11027198	FR
6837069	FR
80007233	FR
80013250	FR
12768410	FR
13912545	IT
13912545	IT
13912545	IT
13912545	IT
13912545	IT
13912545	IT
13912545	IT

PID	Country
10232142	IT
12918817	CZ
10411525	CZ
8489571	CZ
13692331	LV
13692331	LV
13692331	LV
14341583	NL
13848194	PL
14079063	TR
14138387	TR
13924037	TR
13819738	TR
14063154	GB

Explanation Issue

Due to a software issue in some of the stages the attachment position in the aligner was inadvertently shifted toward the gingiva.

Impact on Patient

For the cases/teeth which there is a deviation of the attachment position that is greater than 1.5mm or less than 1.0, there is no risk and severity would be negligible. For those cases in which the deviation is between 1.0mm-1.5mm, the risk may be marginal if the fit is forced and the patient may suffer some discomfort. The discomfort could arise from the tightness of the fit due to the attachment position shift as well as the impingement of the aligner trim line on the gingiva. To date, no complaints of pain or injury have been reported in association with this issue.

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Necessary Steps to be taken	Align will contact all doctors involded to inform them about this issue and let them know that Align will re-manufacturing all affected orders in full, they should be arriving at their offices within a few days after our call. • If a patient has not yet started the impacted stage, the doctor can provide the re-manufactured aligner to the patient. • If a patient has already successfully completed the affected stages, there is no action required. However, we are manufacturing all of these orders for the doctors' convenience.
Contact Information	**EU Authorized-Representative**: Align Technology B.V. Herikerbergweg 312, 1101CT Amsterdam +31(0)20-5863600 **Legal Manufacturer:** Align Technology Inc. 2820 Orchard Parkway, San Jose, CA 95134 United States

Signed by: xxx

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