

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.

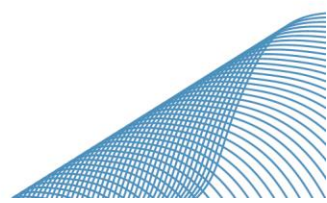
Device types The Invisalign system aligners are Class IIa patient matched medical devices specifically manufactured for a specific patient for the treatment of malocclusion.
GMDN – 44738 – Orthodontic Appliance system, progressive

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	PID	Country	PID	Country
11198037	ES	9815215	ES	10232142	IT
14074000	ES	8302582	FR	12918817	CZ
10296080	ES	13589278	FR	10411525	CZ
14056960	ES	11027198	FR	8489571	CZ
14112972	ES	6837069	FR	13692331	LV
14112972	ES	80007233	FR	13692331	LV
14112972	ES	80013250	FR	13692331	LV
12158920	ES	12768410	FR	14341583	NL
13939130	ES	13912545	IT	13848194	PL
13978033	ES	13912545	IT	14079063	TR
13978033	ES	13912545	IT	14138387	TR
13978033	ES	13912545	IT	13924037	TR
13978033	ES	13912545	IT	13819738	TR
14148718	ES	13912545	IT	14063154	GB
13623645	ES	13912545	IT		

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.



Necessary Steps to be taken Align will contact all doctors involved 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.

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Signed by: xxx

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