

FSN REF:
Date: 06-dec-2022

FSCA REF: IT 2072323

Field Safety Notice Invisalign system of clear aligners

To whom it may concern,

The purpose of this notification is to inform you that Align Technology has identified a potential issue with a very small number of our Invisalign System aligners, produced between 12-nov-2022 and 02-dec-2022 that may have been shipped to your practice last week.

A technical issue related to selected cases with the Invisalign system was identified that was affected by the new Treatment Planning History feature within ClinCheck® software. There may have potential clinical impact, resulting in unnecessary/unprescribed treatment.

One of more of your order(s) have been impacted, and we deeply apologize for any inconvenience this has caused to you and to your patient(s).

In next few days, we will repost your last approved ClinCheck plan for the impacted case (PID) and kindly ask that you review and approve it. After you approve the reposted ClinCheck plan for the impacted order[s], we will re-manufacture this order[s] and expedite shipment to your practice.

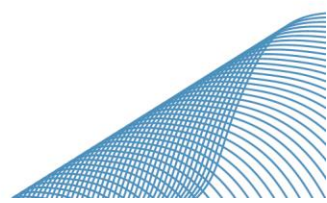
As an immediate action to prevent further issues, we have disabled the ClinCheck feature capability from the Treatment Plan History. Doctors can continue to view their treatment plan history in ClinCheck software.

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 as a precaution. This action reflects our commitment to delivering the highest quality products to our doctors and their patients.

Types of devices 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 Align Technology has identified this issue only concerns the Invisalign system of clear aligners concerned the following PID'S (Patient Identification Numbers) in EMEA region:

PID	Country	PID	Country	PID	Country
15463223	Bahrain	18650640	Italy	18594400	Sweden
18878883	Belgium	9362589	Italy	8809932	Switzerland
18636207	Croatia	18875444	Italy	15725112	Turkey
18582335	Cyprus	9685581	Italy	18660968	Turkey
18749982	Finland	18490064	Italy	18728204	United Arab Emirates
16148219	France	16937272	Kuwait	18612626	United Kingdom
18413074	France	18864567	Morocco	18662118	United Kingdom
18737011	France	18716776	Qatar	18664505	United Kingdom
16480565	France	15217540	Romania	18747012	United Kingdom
18859162	France	18717579	Saudi Arabia	18629083	United Kingdom



PID	Country
13804319	France
13465291	Germany
18661431	Germany
18606528	Germany
18848269	Germany
15214053	Germany
18834034	Germany
12540502	Germany
9738589	Germany
15711426	Germany
18427453	Germany
18700213	Israel
18760570	Israel
12947806	Italy
18664581	Italy
18742606	Italy
16672682	Italy
18636384	Italy
18582561	Italy

PID	Country
18106843	Slovenia
18679394	Spain
10732482	Spain
18749348	Spain
15613029	Spain
16325708	Spain
18805638	Spain
12594214	Spain
13209972	Spain
18540580	Spain
18805778	Spain
15964279	Spain
18344308	Spain
18625483	Spain
18784616	Spain
18832989	Spain
18633376	Spain
18832842	Spain

PID	Country
18725669	United Kingdom
18585732	United Kingdom
18758776	United Kingdom
15343394	United Kingdom
13737836	United Kingdom
18749383	United Kingdom
14989508	United Kingdom
16281543	United Kingdom
18607917	United Kingdom
15078410	United Kingdom
18835486	United Kingdom
15247284	United Kingdom
10112618	United Kingdom
18834982	United Kingdom
18820930	United Kingdom
13611698	United Kingdom
16740882	United Kingdom
16860860	United Kingdom

Problem explanation:

A technical issue related to selected cases with the Invisalign system was identified that was affected by the new Treatment Planning History feature within ClinCheck® software. As a result, certain Invisalign® aligner orders contained:

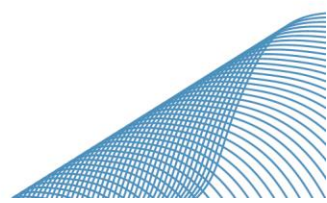
- An incorrect treatment plan overview (PDF file printed or online) was included with the Invisalign case. Aligner bags/labels may also be incorrect and wrongly indicate treatment features, such as Interproximal reduction (IPR) and/or extraction.
- In some cases, the number of aligners in the Invisalign case received may differ from your approved treatment plan.

Impact on patients:

- We are not aware of any patients who have been impacted at this time. We have launched the outreach to the doctors immediately, starting Dec. 5 morning EMEA time.

Necessary steps to be taken:

Align is asking doctors to dispose of the aforementioned Invisalign case(s), including the aligners and packaging, and treatment PDF form-printed or online. Please request that your patients discard the impacted aligners, if they have already been provided to them. The impacted product can be discarded as per the Doctor Instructions for Use or Patient Use and Care Instructions.



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