

Urgent Information - Field Safety Notice

Corrective action: IonoStar Plus to be returned to manufacturer

The following medical devices are affected:

Ionostar Plus REF 2540, 2543, 2544, 2545, 2546, 2547, 2548, 2549

The following batch numbers may be affected and are being recalled:

Markings on foil pouch:

2337273, 2338414, 2335390, 2339566, 2342041, 2340169, 2343466, 2340387, 2345584

Markings on outer packaging:

2338391, 2338699, 2339674, 2342432, 2342564, 2342696, 2347154, 2344046, 2345701,
2341373, 2342759, 2347596, 2344045, 2346781, 2347058, 2346781, 2347058, 2340289,
2344470, 2346290, 2340290, 2342129, 2342760, 2344016, 2344047, 2345723, 2348446,
2349627, 2351341, 2348682, 2350272, 2351343, 2347789, 2349537, 2345123, 2348503,
2349452, 2351123, 2348681, 2348681, 2349221, 2349453, 2351346, 2350138, 2351233

Description of problem:

Due to an error in the manufacturing process, it is possible that an incorrect plunger has been fitted to some capsules. This plunger does not contain the correct reactive component for IonoStar Plus. When these capsules are activated, curing is significantly delayed and incomplete. Processing according to the instructions for use is not possible.

The reactive component in the incorrect plungers contains small amounts of BHT and methacrylate. These ingredients are not listed in the instructions for use.

Allergic reactions cannot be ruled out in patients with known hypersensitivities to any of these ingredients.

Necessary action to be taken:

Please return the affected products to us. Please ask for any units already sold to be returned to you by the end users and forward those units to us. We will supply replacements for the returned units to you as soon as this is possible.

Our reference number: VNr 227 (Please indicate this number when returning goods to VOCO.)

Please ensure within your organisation that all end users of the above-mentioned products and all other persons requiring this information are made aware of this **urgent field safety notice**.

Please confirm to us that you have received this urgent field safety notice and that you have communicated this urgent safety information to your clients.

Contact:

Should you have further questions, please contact the person responsible for regulatory compliance at VOCO, Mr. Michael Cyll, whose e-mail address is m.cyll@voco.de.

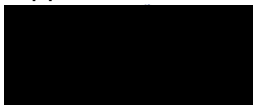
Please keep this information notice in your files at least until the date when the corrective action has been completed. The supervisory authority concerned has received a copy of this urgent field safety notice.

We sincerely regret any inconvenience caused and thank you for your support!!

With best regards,

VOCO GmbH

ppa.



R. Plaumann

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