

URGENT: Field Safety Notice

**HEALAFLOW
A-HEA060**



IMPORTANT PRECAUTION OF USE – ADVICE FROM THE MANUFACTURER

Date: 27.06.2016

Attention: HANDLING OF THE BACKSTOP INSTRUCTIONS

Please read this Field Safety Notice thoroughly to understand the issue and ensure continued safe use of the product.

Details on affected devices:

This notice concerns all HEALAFLOW Products commercialized by Aptissen.

Batches:

-341329

-341331

Description of the problem:

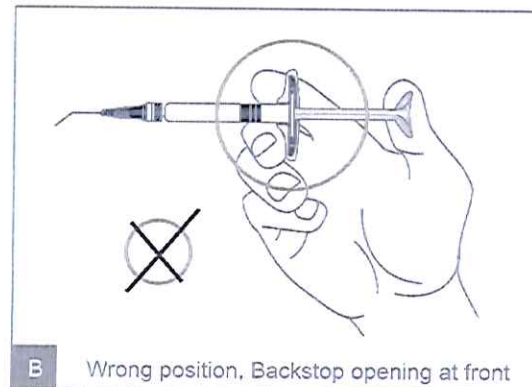
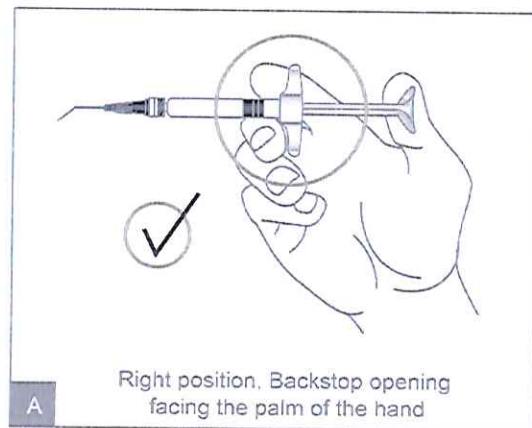
A special attention should be attached to the handling of the syringe backstop before Injection.

If the backstop is handled on the wrong side, there is a risk that it will unclip, under a horizontal pressure during injection, and it can lead to an unexpected movement, which can injure the eye of the patient.

Syringe Orientation: Hold the syringe with the opening of the finger grip (backstop) facing the palm of the hand

Advise on action to be taken by the user:

Please follow this scheme to be sure of the handling position:



Also the 25 G cannula provided with the product should be used.

Transmission of this Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where HEALAFLOW have been transferred.

Please transfer this notice to the physicians that already bought HEALAFLOW products.

Except the diffusion of the handling information, there is no need to return the product, it can be used safely if those precautions are followed.

APTISSEN SA will include this information and scheme in the next Instruction for Use revision.

Thank you for your attention to this matter.

If you have any questions, or in the event of any product complaints or adverse events, please contact us.

The relevant Regulatory Agencies have been made aware of this action.

Contact reference person:

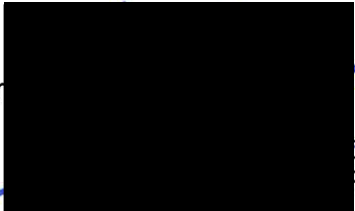
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