

Field Safety Notice

FSN_final_2020_01_frost-sens

FSCA reference Vk_20191217_01

Addition to the Product Data Sheets of frost sensitive products

January 13th 2020

Dear Distributor

Our records indicate that your facility has received one of the following products during last year:

| Product Name | Product number |
|-------------------------------------|-----------------------|
| deconex [®] 23 NEUTRAZYM-x | 501820.00 |
| deconex [®] 36 INTENSIV-x | 520000.00 |
| deconex [®] 41 STS | 503800.00 |
| deconex [®] 41 STS ALKA | 517800.00 |
| deconex [®] FOAM ACTIVE | 525100.00 |
| deconex [®] I-ZYME | 526900.00 |
| deconex [®] PROZYME ALKA | 523800.00 |
| deconex [®] PROZYME ALKA-x | 525000.00 |

We kindly ask you to review the following communication

Background and Reason for the Field safety Notice

Up to now, a customer letter concerning the handling of frost-sensitive medical cleaners during transport has been issued and sent to our distributors and customers outside Switzerland.

During the cold season, transport of frost-sensitive products can only be guaranteed, if certain conditions are met: Transport in a temperature controlled lorry / sea container, or temporary use of protection hoods for short transport routes.

Furthermore, the save transport of temperature sensitive medical devices from the manufacturer to direct customers within Switzerland can be guaranteed at any times.

The decision was taken to integrate a respective statement directly into the Product Data Sheet (Instruction for Use) in order to guarantee that the symbol for "frost sensitivity" on the label will be explained directly in the product information.

This information to be amended in the Product Data Sheets led to a Field Safety Corrective Action (FSCA) number: Vk_20191217_01 (assigned by the National Competent Authority).

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Actions to be taken by the distributor

Please follow the requirements concerning the transport of our frost sensitive products characterized and explained in the sentence below and make sure that everyone involved in transporting these products will receive and understand this information.

PLEASE CONFIRM THAT YOU HAVE RECEIVED AND UNDERSTOOD THIS FSN BY REPLYING TO THE SAME EMAIL ADDRESS THAT SENT YOU THIS NOTICE.

Action to be taken by the manufacturer

Correction of the affected Product Data Sheet by amending the following sentence explaining the frost sensitivity of the relative product(s):

"This medical device is frost-sensitive. Avoid whenever possible transportation of this product during the cold periods. If transport during such periods is inevitable, this product must be shipped using temperature controlled lorry / sea container above 5° C, or use protection hoods for short-time transports not longer than 10 hours with transport temperatures not falling below minus 5° C."

We make every effort to integrate this sentence into the product data sheets for each supported language as fast as possible.

We will send you the new versions of the Product Data Sheet as soon as they are available in your language.

Please do not hesitate to contact us if you have any further questions.

Thank you for comprehension and best regards

