NOUVAG

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Urgent safety information

Information for the market to adapt the intended patient group regarding

Dispenser DP 30 (REF 4180)

03.07.2023

Dear Ladies and Gentlemen,

We, Nouvag AG, hereby inform you of a voluntary Field Safety Notice concerning the following listed products and our records show that you have received one or more items of the affected products.

Sender (Published by):

Nouvag AG St. Gallerstrasse 25, 9403 Goldach, Switzerland PRRC: Christian Micheletti, c.micheletti@nouvag.com Tel. +41 71 846 66 79

Addressee:

This urgent safety information concerns all distributors, users and relevant staff of health care facilities who use and distribute the above-mentioned product.

Identification of the medical devices concerned:

- Dispenser DP 30 (Art.No.4180 / 4180-115ang / 4180-230ang / 4180cov / 4180int / 4180med)

Description of the problem including the identified cause:

1. In the context of the update of the clinical evaluation, an adjustment of the intended use was made due to the lack of evidence of a possible use in underage patients: adjustment of the age of the intended patient.

Specification so far: Use on patients of all ages. New: Use exclusively on adult patients.

Result: Exclusion of patients who have not yet reached the age of majority.

2. In the context of the update of the clinical evaluation, additional specifications were added regarding tumescent anesthesia infiltration parameters.

Specification so far: max. concentration of anesthetic and type of solution to be used. New: added max. recommended flow and max. lidocaine dose, as well as expected flows for different operating settings.

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There is no technical adaptation or malfunction of the product. There are no risks for patients, users or third parties in the further use of the product. There are no risks for underage patients who have already been treated.

What measures are to be taken by the addressee?

- Inform all relevant customers/users about this change. Affected products do not need to be replaced.
- Advise users/customers to contact the manufacturer (See return address or letterhead) if they have any uncertainties, problems or concerns.
- The measures are valid immediately and do not require an implementation period.
- Observe this safety notice until the measure has been completed at your site. Keep a copy of this safety instruction.

Information on vigilance:

The competent national authorities have been informed about this voluntary safety measure.

Please inform Nouvag AG of any adverse event related to the affected products or any item related to the product. Use https://nouvag.com/en/contact-us or your Area Sales Manager to report any incident.

We apologise for any inconvenience this may cause. If you have any further queries, please do not hesitate to contact us.

Contact person (EU):

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DE-AR-000005643

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Goldach, 03.07.2023

Christian Gerlach, CEO
Nouvag AG

Christian Micheletti, PRRC
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