Nouvag AG | St.Gallerstrasse 25 | CH–9403 Goldach
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Urgent safety information

Information for the market to adapt the intended patient group regarding

Dispenser DP 30 (REF 4180)

17.08.2023

SwissMedic REF: *Vk_20230731_10*

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: Klaus Hunziker, prrc-ag@nouvag.com Tel. +41 71 846 66 67

Addressee:

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

Medical devices concerned:

- Dispenser DP 30 (Art.No.4180 / 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.

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):

Nouvag Dental- und Medizintechnik GmbH (EC REP) DE-AR-000005643	Schulthaissstrasse 15, 78462 Konstanz - Germany Phone. +49 (0)7531 1290-0 Info-de@nouvag.com Responsible person (Art. 15, 2017/745 (EU)): Sandra Conzelmann s.conzelmann.prrc@nouvag.com +49 17622527012
Contact person (CH): **NOUVAG AG** CHRN-MF-20000098	St. Gallerstrasse 25, CH-9403 Goldach Phone: 71 846 66 00 info@nouvag.com Contact person: Klaus Hunziker k.hunziker@nouvag.com 071 846 66 67

Goldach, 17.08.2023

Christian Gerlach, CEO
Nouvag AG

Klaus Hunziker, PRRC Nouvag AG

NOUVAG

Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	Manufacturer ref. #: CAPA-2023-0009 SWISSMEDIC ref #: Vk_20230731_10
FSN Date*	03.07.2023
Product/ Device name*	Dispenser DP30
Product Code(s)	4180 / 4180-230ang / 4180cov / 4180int / 4180med
Batch/Serial Number (s)	All sold before 30.06.2023

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		

☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	vigilance@nouvag.com
Customer Helpline	+41 71 846 66 59
Postal Address	St Gallerstrasse 25, CH-9403 Goldach
Web Portal	www.nouvag.com
Fax	
Deadline for returning the customer reply form*	30.09.2023

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.