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Urgent Field Safety Notice

Notification of a contraindication

regarding

Reaxon® Direct, Reaxon® Nerve Guide

5th March 2019

Sender:
Mrs Dr. Christina Ackva
Medovent GmbH
Friedrich-Koenig-Straße 3
55129 Mainz

Attention:
Surgeons

Details on affected devices:
Nerve tube (nerve guidance and protection conduit) used to reconstruct and bridge peripheral nerve defects:

- Reaxon® Direct (RD121, RD130, RD140, RD150, RD160)
- Reaxon® Nerve Guide (RG321, RG330, RG340, RG350, RG360)

Description of the problem:
Based on the analysis of singular cases, it has been shown that the implantation at leaky sutured, poorly healing and superficially located wounds can lead to extrusion or part extrusion of dehydrated nerve tubes at the site of the wound crust. The unfavourable wound situation and localisation may lead to dehydration and hardening of the nerve tube which has led to explantation of the product in the documented cases. In case of precarious wound conditions, wound healing disorders, low perfusion conditions and superficially located implants, there is an increased risk for the nerve tube to get dehydrated and hard due to poor soft tissue coverage. The risk applies in particular to implantations carried out on fingers. The Reaxon® products are composed of a chitosan hydrogel which requires a moist environment for the maintenance of its flexibility. The described wound conditions and/or localisations apparently do not guarantee a sufficient protection from dehydration. For these reasons, the following contraindication for the implantation of Reaxon® was specified:

"*In case of compromised or incomplete soft surface coverage of Reaxon® there is an increased risk for the implant to be dehydrated and cause pain and foreign body sensation. Furthermore, there is the possibility that Reaxon® pushes through the skin. Reaxon® should therefore not be*

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used in wound conditions in which low perfusion may occur and wound healing complications are to be expected. Reaxon® should not be used within finger replantations."

Overall, seven such cases have been reported to the manufacturer. Additionally, the manufacturer is aware of three cases with similar complications in which Reaxon® was not used in accordance with its intended purpose (off label use). Considering the new contraindication, the benefit-risk profile of Reaxon® can be principally continued to be evaluated as positive.

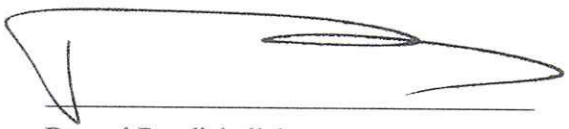
Advise on action to be taken by the user:
The above defined contraindication will be implicated in the instructions for use of Reaxon®. Furthermore, all customers will be informed in a separate letter. Since there is not a product defect, products containing the old instructions for use still in circulation can be used further on. However, the measure itself must be taken into account with immediate effect.

Transmission of this Field Safety Notice:
Please ensure in your organisation that all users of the above mentioned products and other persons to be informed are aware of this **Field Safety Notice**. If you have provided the products to third parties, please forward a copy of this information, or contact the person listed below. Please keep this information at least until the procedure has been completed.

Contact reference person:
Dr. med. Leonardo Ebeling
Dr. Ebeling & Assoc. GmbH
Isestraße 5
20144 Hamburg
Phone: +49 (0)40/548007-0
Fax: +49 (0)40/548007-290

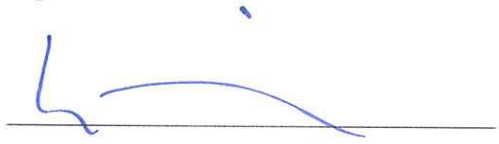
The undersigned confirm that the appropriate Regulatory Agency has been notified of this notice.

Signature



Dougal Bendjaballah,
Managing Director medovent GmbH

Signature



Dr. med. Leonardo Ebeling,
Responsible Person for Medical Device Vigilance (RPMDV)