Dornier MedTech

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## Update on Urgent Field Safety Notice (FSN):

## Shelf Life Issue of *Dornier Diode Lightguides and Nd:YAG Lightguides*

Dear Valued Customer,

Referring to the Urgent Field Safety Notice "Shelf Life Issue of Dornier Standard Diode and Nd:YAG Lightguides", which was issued on 05.04.2019 - see below the following excerpt from our initial FSN:

"During a routine re-evaluation of the packaging design for the diode fibers conducted to confirm a 5-year shelf life, test results indicated that the current package design, paper/poly pouch, of the products with the article numbers as listed below, showed pin hole package failures. The samples tested were units retrieved from the field during the aforesaid routine re-evaluation. Dornier has not received any customer complaints regarding this issue. Although further testing is underway, **out of an abundance of caution**, Dornier has stopped shipping all fibers that have this package design and has initiated this action. Accordingly, Dornier MedTech is issuing this Field Safety Notice as a precautionary measure to prevent the use of product where the sterility barrier **may** have been compromised".

We now would like to submit an update:

We have conducted a deep and thorough investigation including all required state-of the art tests regarding packaging of sterile medical devices. After the successful conclusion of all the required tests, we have now sufficient evidence from our accredited laboratories to withdraw the quarantine on our sterile products.

### What does the users have to do?

1. Please check the light guides on stock for visual damage and proceed according to the instructions for use and label:

    "Light guides from damaged sterile packing may not be used".

2. After the visual inspection has been performed, the light guides can be used as described in the intended use.

The conclusions reached by our successful state of the art testing apply to all sterile light guides produced and placed in the market by Dornier MedTech GmbH. Therefore, the SBU's (selling business units), are with immediate effect able to place fibers into the market and/or order fibers from the legal manufacturer (factory).

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a. Note 1: until the factory is up and running at full speed all TTTS customers, resp. a medical urgency arises – for Nd:YAG and Diode fibers - will be served with the highest priority
b. Note 2: we will be still supplying alternative fibers from another supplier (if the registration / certificate of exemption is available in the relevant country and/or no need for registration in the relevant countries is required).

We sincerely apologize for all inconvenience this situation has caused to you and we appreciate your understanding and patience, as we have taken all the necessary steps to ensure the patient / customer safety, which is our priority.

For any questions, please do not hesitate to contact your local Regulatory Affairs Associate.

Kind regards
Dornier MedTech GmbH

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