To:

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Datum/date : Wessling, 05.04.2019

Urgent Field Safety Notice (FSN):

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

Dear Valued Customer,

The purpose of this letter is to advise you that Dornier MedTech, the manufacturer of the Dornier Diode and Nd:YAG Laser Fibers, is voluntarily issuing a Medical Device Recall regarding the laser fibers listed in the table below. Distribution records indicate that you have received one or more of these products that are the subject of this action.

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.

The Dornier Diode Laser Fibers are intended to be used as an accessory for Dornier Medilas D Family of Lasers, as well as the Nd:YAG Family of General Surgical Lasers.

The table below lists the affected products:

Article No	Name
K1008084	LL-E D01-6100-BF-0 10ST BAREFIBER
K1009920	LL-E D01-6180-D-0 10ST DUESE 1.8MM
K1009922	LL-E D01-6100-B-0 10ST BAREFIBER SPUEL
K1009924	LL-E D01-6210-D-0 10ST DUESE 2.1MM
K2010292	LL-E D01-4070-BF-1 10ST BAREFIBER HCL
K2010710	LL-E D01-4070-BF-0 10ST BAREFIBER HCP
K2011577	LL-E S01-4070-BF-0 10ST BAREFIBER HCP
K2011580	LL-E S01-6100-BF-0 10ST BAREFIBER
K2011594	LL-E S01-6180-D-0 10ST DUESE 1.8MM
K2011596	LL-E S01-6210-D-0 10ST DUESE 2.1MM

Article No	Name
K2012393	LL-E D01-6080-BF-0 10ST BAREFIBER
K2012867	LL-E S00-4079-BF-0 10ST BAREFIBER
K2012870	LL-E S00-6109-BF-0 10ST BAREFIBER
K2013073	LL-E S02-6080-BF-1 10ST BAREFIBER
K1001291	LL-EINM ND E-6210-D 10ST DUESE 2.1MM
K1001292	LL-EINM ND E-6180-D 10ST DUESE 1.8MM
K1001295	LL-EINM ND E-6100-B 10ST BAREFIB SPUEL
K1001296	LL-EINM ND E-4070-B 10ST BAREFIB SPUEL
K1010498	LL-EINM ND E-4070-BF 10ST BAREFIBER
K1001293	LL-EINM ND E-6220-G 10ST GEWINDE 2.2MM

K2011822	LL-E D00-4079-BF-0 10ST BAREFIBER
K2011824	LL-E D00-6109-BF-0 10ST BAREFIBER
K2012146	LL-E S02-6100-BF-0 10ST BAREFIBER

K1001294	LL-EINM ND E-6180-G 10ST GEWINDE 1.8MM
K1010500	LL-EINM ND E-6100-BF 10ST BAREFIBER

Pin hole package failures may lead to fibers being unsterile. Given a contaminated laser fiber was used during a clinical procedure, the health consequences mainly consist of microbial contamination of the surgical site that could lead to surgical site infection. Such events could be result in patient pain and the potential for increased length of hospital stay. Such infection could be treated (e.g., antibiotics). Long-term manifestations, although rare, could include osteomyelitis, soft tissue abscess, and sepsis with worst case being septic shock if not treated. Dornier MedTech is not aware of any clinical incidents related to this packaging issue and no customer complaints have been reported.

What does the user have to do?

1. Identify if you have above listed products in stock (article no., lot, quantity).

2. If you have above listed products in stock, please immediately quarantine all inventory of Dornier Diode and Nd:YAG laser fibers and do not use these products until further notice to avoid any health risks to the patient.

3. We are currently analyzing the situation and will inform you what to do with your quarantined stock of lightguides once that determination has been made.

4. If you seek a replacement for your fibers, please check the box on the feedback sheet and send us your affected product. Dornier MedTech will then contact you regarding suitable replacements.

5. We further on request you to please fill in the attached form immediately and send it back within 7 calendar days by FAX or e-Mail, to below mentioned contact.

Thank you for your support. Please contact your local sales contact if you have any questions regarding this FSN, any of our products, or would like assistance with the action:

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Tel.: +49 8153 888-548
Mail: obuchma@dornier.com

We regret any inconvenience that this action may cause, but we appreciate your understanding as we take steps to ensure patient and customer satisfaction.

Kind regards
Dornier MedTech GmbH

Tom Peters
Medical Device Reporting Officer

Dornier MedTech GmbH

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