Dornier MedTech

Name/Name: Konstantin Fotiadis
Abtlg./Dept. Quality Management
Email: mdro@dornier.com
Datum/Date: Wessling, August 29th 2019

Final Report on Urgent Field Safety Notice (FSN 1821):

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

Dear Ladies and Gentlemen,

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".

While the failures were caused under laboratory-induced stress conditions that have a low probability of occurrence (as defined by the standard ASTM D4169, 3.2.2.1.), Dornier conducted a deep and thorough investigation including state-of the art tests regarding packaging of sterile medical devices.

Below is a summary of the in 2018/2019 conducted tests during the re-evaluation of the sterile packaging for transport and shelf life:

Dornier MedTech

Evaluation of Packaging Properties after Sterilization and Transport			
Test	**Normative Basis/ Procedure**	**Sample Size**	**Status/ Results**
Transport Simulation / Integrity			
Transport Simulation	ASTM D 4169 DC13 /Ass. Lv. II EN ISO 11607-1 (5.5, 8.1, 8.2.1)	30 (3 Lots)	Paconsult Lab: ☒ Passed ☐ Failed
Visual Test	ASTM F1886	30 (3 Lots)	Paconsult Lab: ☒ Passed ☐ Failed
Bubble Test	ASTM F2096 EN ISO 11607-1 (5.5, 8.1, 8.2.1)	30 (3 Lots)	Paconsult Lab: ☒ Passed ☐ Failed
Performance			
Performance Qualification	K2015631 VVP Light Guides for Diode Lasers	30 (3 Lots)	DMTL: ☒ Passed ☐ Failed

DMTL: Dornier MedTech Laser GmbH

Dornier MedTech GmbH www.dornier.com

Argelsrieder Feld 7
Office:
D-82234 Wessling
T01FC6183C
Postfach 1113
D-82231 Wessling
Tel.: +49 (0) 8153 888-0
Fax: +49 (0) 8153 888-665

Sitz der Gesellschaft:
Wessling

Amtsgericht München
HRB 114520
Ust-Id Nr. DE 183642248
Steuer-Nr. 117/115/20580

Vorsitzender des Aufsichtsrats:
Phillip Yeo

Geschäftsführung:
Abel Ang
Prokurist:
Koo Suay Lan
Goh Siew Hoon

Bankverbindung:
Bayerische Landesbank München

Konto: 1211842 BLZ: 700 500 00
SWIFT: BYLA DE MM
IBAN: DE70 7005 0000 0001 2118 42

Singapore Registered
Eintr. Regn No.:

No. 2 Venture Drive
#23- 18 Vision Exchange
Singapore 608526
Tel.: +65 6572-6068
Fax: +65 6572-6093

Dornier MedTech

Evaluation of Packaging Properties **Shelf Life**			
Test	**Normative Basis/ Procedure**	**Sample Size/ condition**	**Status/ Results**
Integrity of the Sterile Barrier			
Seal strength	DIN EN 868-5, ASTM F88/F8BM ISO 11607-1 (5.1.8, 5.1.9)	15 (3 Lots)/ real aged	Inpac Medizintechnik Lab: ☒ Passed ☐ Failed
Dye penetration	ASTM F1929	10 (3 Lots)/ real aged	MDS Lab: ☒ Passed ☐ Failed
Visual Test	ASTM F1886/F1886M ISO 11607-1 & 2 (5.1, 5.4 & 5.4.1.)	Dornier: 34 (3 Lots) GfPs: 38 (4 Lots) / real aged	Dornier/GfPS Lab: ☒ Passed ☐ Failed
Microbial Barrier	DIN 58953-6 & ISO 11607-1 (5.3, 8)	38 (4 Lots) / real aged	GfPS Lab: ☒ Passed ☐ Failed
Performance Qualification	K2015631 VVP Light Guides for Diode Lasers	18 (4 Lots)/ real aged	DMTL: ☒ Passed ☐ Failed

DMTL: Dornier MedTech Laser GmbH

The conclusions reached by our successful testing apply to all Diode and Nd:YAG sterile light guides produced and placed in the market by Dornier MedTech GmbH.

Dornier MedTech

Based on the tests results for the relevant transport and shelf life aspects summarized in this document, we have sufficient evidence from our accredited laboratories and own testing to close the file Field Safety Notice (FSN 1821) from 05.04.2019 for our sterile products.

Please confirm us at your convenience the receipt of this final report and the closing of the file.

For any questions, please do not hesitate to contact us.

Kind regards
Dornier MedTech GmbH

Konstantin Fotiadis
Medical Device Reporting Officer

Dornier MedTech GmbH www.dornier.com

Argelsrieder Feld 7
Office:
D-82234 Wessling
T01FC6183C
Postfach 1113
D-82231 Wessling
Tel.: +49 (0) 8153 888-0
Fax: +49 (0) 8153 888-665

Sitz der Gesellschaft:
Wessling

Amtsgericht München
HRB 114520
Ust-Id Nr. DE 183642248
Steuer-Nr. 117/115/20580

Vorsitzender des Aufsichtsrats:
Phillip Yeo

Geschäftsführung:
Abel Ang
Prokurist:
Koo Suay Lan
Goh Siew Hoon

Bankverbindung:
Bayerische Landesbank München

Konto: 1211842 BLZ: 700 500 00
SWIFT: BYLA DE MM
IBAN: DE70 7005 0000 0001 2118 42

Singapore Registered Eintr. Regn No.:

No. 2 Venture Drive
#23- 18 Vision Exchange
Singapore 608526
Tel.: +65 6572-6068
Fax: +65 6572-6093