

FieldSafetyNotice			FSN_SMAG_001_01_02	Ver. 1 Rev. 1	
MODULITH SLX-F2					
Ersteller: KlausHugen	Geprüft: ChristinaFan	Genehmigt: RonaldCojocariu	Freigabedatum: 18.02.2016	Seite 1 von 1	

Dear customer,

Storz Medical AG is committed to complete quality and that is why we place great emphasis on highest reliability and safety of our products.

As part of our Medical Device Vigilance System we continuously monitor our products.

In a recent assessment of the MODULITH SLX-F2 , we have identified a potential issue, which can compromise the performance of the device under certain circumstances.

Along with this letter you are receiving the Technical Service Information No. T-252-A, and we would like to inform you about:

- what the problem exactly comprises and under what circumstances it can occur
- what measures you can take to prevent the occurrence of the problem
- what measures are planned by Storz Medical AG to remedy the problem

**The TSI No. T-252-A contains important information to continue to operate your device safely and correctly.**

Please make this TSI available to all other employees, for whom this information is relevant.

It is important that the implications of this notice are understood.

If you need further information or support concerning this issue, please contact:

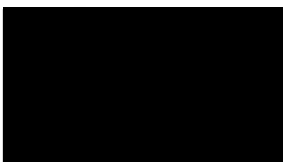
our Storz Medical Hotline

- Phone: 0041 71 677 45 87
- Email: [service@storzmedical.com](mailto:service@storzmedical.com)

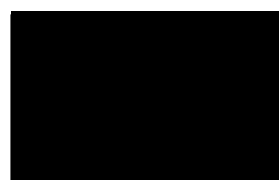
or your local Storz Medical Distributor.

We apologize for any inconvenience and hope that any questions that might arise from your side are adequately answered by this letter.

Yours Sincerely



Dr. Christina Fan  
Medical Device Vigilance Manager  
Storz Medical AG



Dipl. Ing. Klaus Hugen  
Director Quality Management  
Storz Medical AG



Information-No.: T-252-A	Date: 17.02.2016	Page: 1 of 3
Category: Safety	Priority: A	Appendix: None
Product Code: OR/	Affected SN: See page 1	
Modification No: CC16/017		

Product Codes: A=MODULITH® SL10 / SL20; C=MINILITH SL1-0C; D=MODULITH® SLX; F=XR-AX, G=MINILITH SL1-0G, 0L,1L= MODULITH® SLK, M=XR-MX; Q=MODULITH® SLC; R=MODULITH® SLX-F2; AS/BS=MASTERPULS MP50/200; AT/TT/BT=DUOLITH® SD1 (T-Top/Tower/Ultra)

## Table insert does not fit properly

### Affected System / serial numbers:

OR.079, OR.269, OR.110, OR.299

### Purpose:

Field Safety Notice urgently to be forwarded to the customer!

### Problem description

The system includes a table insert from carbon fibre as part of the optional urology kit.

We have observed that - due to the addition of tolerances of the table insert and the table cutout - the table insert can slip out of place.

### Potential risk

During patient treatment the slipping of the insert plate can lead to a sudden downward movement of the patient. This patient movement will be compensated by the patient foil after a few centimeters. Nevertheless, if at this moment an endoscopic instrument is inserted into the patient, serious injury may occur.

### Actions to be taken by the user:

To prevent the risk of injuries, the user must make sure that the lithotripter is no longer operated in combination with the actual carbon fibre insert plate.

A table insert replacement will be provided by STORZ MEDICAL asap.

For all other treatments the system can be used without any restrictions.

### Actions to be taken by SMAG

1. SMAG has informed the operators of the affected units by phone and mail to no longer use the actual carbon fibre table insert.
2. SMAG will supply plywood plates from the SMAG stock as a temporary replacement of the carbon fibre table insert.
3. SMAG will redesign the carbon fibre table insert.
4. As soon as the redesigned table insert is available SMAG service staff will replace the temporary plates by appropriate validated carbon fibre inserts at all affected units

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## Contact details

In case you need further information or support in this matter please contact:

STORZ MEDICAL AG  
Service Department  
Lohstampfstrasse 8  
CH- 8274 Tägerwilen  
Switzerland  
phone: +41 71 677 4587  
fax: +41 71 677 45 09  
email: [service@storzmedical.com](mailto:service@storzmedical.com)

### NOTE

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## TSI - Reporting back

for

## Table insert does not fit properly

Hospital: \_\_\_\_\_

Service engineer: \_\_\_\_\_

+ STORZ MEDICAL engineer number

**OR -**

SERIAL No.

total hour counter  
total OH

total shock counter  
total SW

current shock counter  
coil SW

TSI executed on: \_\_\_\_\_

### Notice

After execution of the activities written in this TSI, please send or fax this form back to:

STORZ MEDICAL AG  
Lohstampfstrasse 8  
CH - 8274 Tägerwilen  
Switzerland  
Fax: 0041 71 677 45 09