

PROMEDICS MEDIZINISCHE SYSTEME
GMBH
Oelser Strasse 9
40231 Düsseldorf
Germany

Attention to RA and Vigilance Manager

ECULLY, 2017, June 12th

Ref : FSN-20170612
ID : PROMEDICS

URGENT – SAFETY CORRECTIVE AND PREVENTIVE ACTION

Devices concerned : **mont blanc MIS**
Posterior fusion minimal invasive spine surgery

REF: **470TSO1**

Description: **MIS Tightening shaft for outer locking screw**
Lot: **215410, 216172, 216173, 217052, 217053**

Action: **Safety notice**

Dear customer,

We inform you that Spineway SA is voluntary launching a field safety corrective and preventive action FSN-20170612 on medical devices listed above in order to prevent any incident or serious injury related to the potential risk we identified.

Details on affected devices :

The MIS Tightening shaft for outer locking screw REF. 470TSO1 is usually placed into the Mont Blanc MIS instrument set ref. C1MIS03.

It is intended to tighten the external part of the dual locking screw in order to perform rod maneuvers.

Description of the issue :

We noticed that the distal part of the instrument ref. 470TSO1 composed with 4 metallic tip ends can be damaged if the surgical technic applied is not compliant with the recommended one when the dual locking screw ref. MIS1DLS is implanted.

The instrument damage is characterized by a or several tip ends breakage occurring during the surgery.

Because of the tiny size of the broken part or particles generated, their recovery can be challenging for the surgeon and could remain in-situ after the locking of the dual set screw.

Patient risk :

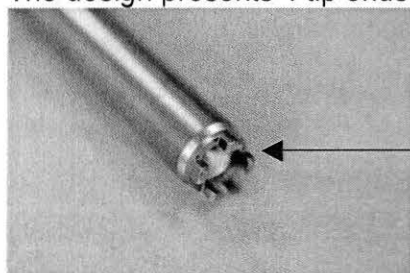
The particles of the instrument could potentially migrate to the dura mera area. Some immunologic reactions could also be observed post operatively due to the raw material.

1. Advices to be followed by user:

We thank you to be prepared to :

1. Identify where the ref. 470TSO1 is located in your premises
2. Inspect carefully the distal part of ref. 470TSO1 you own.

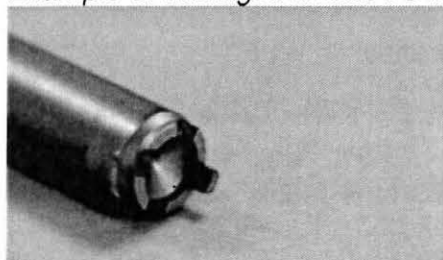
The design presents 4 tip ends as following :



Tip end

3. In case of one missing tip end or at least a part is damaged, we thank you in advance to return back the instrument along with a complaint form in order we can replace it.

Example of damaged device : 3 missing tip ends



In addition, we recommend to check the post-operative X-Rays of patients who have been implanted with one or several dual locking screws ref. MIS1DLS in order to insure you that no external elements remained as described above.

4. Inform Spineway of any event that could be linked with this issue
4. For you future surgeries, we do recommend to follow the current surgical technic as followed :

The Tightening shaft for outer locking screw needs to be inserted through the rod reduction system ref. 482PS1 to be aligned with the dual locking screw.
Also, the torque limiter ref. 490STL1 is mandatory to lock the dual locking screw with a proper strength.

Transmission of this field corrective action

We inform you we have notified the ANSM and others Competent Authorities concerned by this action.

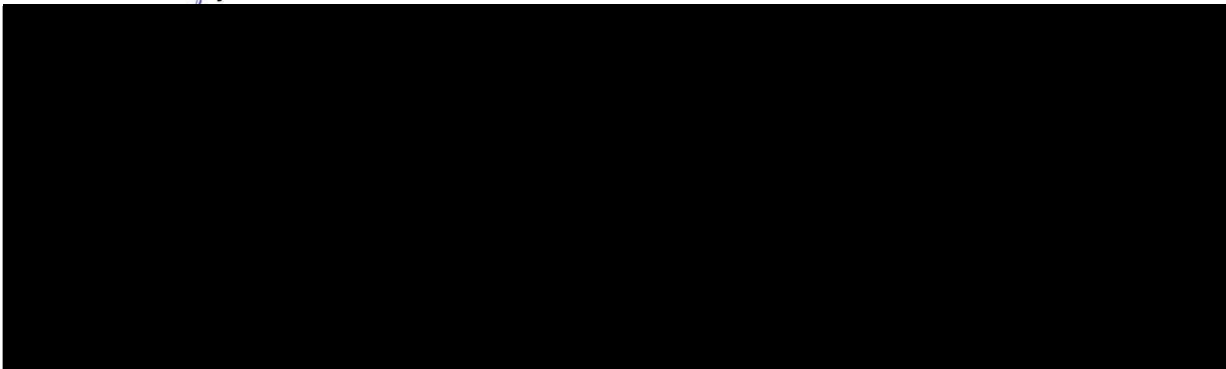
We thank you for your conscientiousness to :

1. Forward without any delay this notification to other organization, service or person where such devices have been delivered in order these actions to be taken during the use of the instrument.
2. **Complete the customer answer follow-up form hereafter and return it back within 7 days as soon as you receive this notification by Fax : +33(0)4 78 38 10 17 or email quality@spineaway.com**

We apologize for the inconvenience and we thank you for your understanding and cooperation.

Our customer service and I are staying at your disposal for any further information you'd need about.

Yours sincerely



CUSTOMER FOLLOW UP FORM
Safety corrective and preventive action

Spineway –Mont Blanc MIS Instrument
Posterior fusion minimal invasive spine surgery

Ref : FSN-20170612
 ID : PROMEDICS

I declare to have:

1. Received and been aware of the safety corrective and preventive action FSN-20170612 launched by Spineway SA the last June 12th
2. Forwarded this information to the all organizations and persons concerned

The stock , all the storage and using places have been inspected and the results are recorded bellow :

We do not have devices concerned

We have devices concerned :

Reference	Description	Lot	Quantity delivered by Spineway	Quantity in your inventory to be fulfilled
470TSO1	Posterior Fusion Minimal Invasive Spine Surgery	216173	1	

If you have delivered a concerned device, please note hereafter the identification of the person and organization you delivered

Name : Adress :

Contact name:		Company Stample:	
Function :			
Date and visa:			
Telephone :		Email :	