



21/12/17

Subject: Field Safety Notice! Foot control S-N1/S-N2

Dear Madam/ dear Sir

We hereby inform you that within the framework of our continuous product observation of the market, we have noticed a potential malfunction of individual foot controls of the type S-N1/S-N2.

So far, no incident has been reported. The health and safety of patients are our highest priority. Thus, we consider it our task to inform all users who use the potentially affected products.

Affected foot controls:

"REF" foot control	Serial number "SN"	
	from	to (including)
05046200	22400	23429
05046200	E02201	E02485
05046211	E01011	E01033
05046210	E01035	E01071
06202400	24315	34040
06202400	E01358	E01658
30285000	01001	02318
30285001		

The affected foot controls were delivered either with surgical units (W&H Implantmed and W&H Elcomed produced between March 2016 and September 2017) or separately. Surgical units with the following serial numbers contain potentially affected foot controls:

Please see attached affected surgical unit list.

In case the error occurs, the foot control might not switch back to zero position when the pedal is released. Consequently, the motor keeps rotating. If this happens during automatic thread cutting or automatic screwing-in of implants, it can, in the worst case, lead to a serious injury of the patient.

Due to this potential malfunction, the affected products (foot control) must not be used for thread cutting and screwing in of implants for the time being. These operations have to be conducted manually.

As a trading partner of medical products and sales partner of W&H Dentalwerk Bürmoos GmbH you are obligated to forward the attached information to the affected users in order to exclude any residual risk.



Attached you find the information for the user including a reply form. We kindly ask you to translate the document to your national language if necessary and add the respective local contact address for the end users. The content of the information to the end user must NOT be altered.

The reply of the user will go directly to W&H Dentalwerk Bürmoos GmbH. The following possibilities are available:

- Online link
- Fax
- E-mail
- By mail

After the feedback has been checked, we will inform the user whether the reported foot control is affected or can be used without any problems. If the foot control is affected, the user will be contacted by the W&H organization and informed about further actions.

We deeply regret the inconveniences for you and your customers and thank you for your support.

Should you have any questions, please contact:

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Best regards,

Martin Rolfe
Area Manager – Asia Pacific

cc Chairman Medical Board and Relevant Head of Departments