



W&H Dentalwerk, PO Box 1, 5111 Bürmoos, Austria

Your sign:
Your message:
Our sign:
Done By:
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22.12.2017

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.

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.



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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.

We kindly ask you to submit the necessary information on <http://www.wh.com/footcontrol/> or alternatively fill out the attached reply form and send it via e-mail, fax or mail.

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

We deeply regret the inconvenience and thank you for your understanding.

Should you have any questions, please contact the following address:

Contact:

A handwritten signature in blue ink, appearing to read 'H. Eibl'.

Johann Eibl
Vice President R&D



W&H Dentalwerk

Reply form:

W&H Dentalwerk Bürmoos GmbH
Key word "Foot control"
Postfach 1
5111 Bürmoos

E-Mail: footcontrol@wh.com
 Fax: +43 / 6274 / 6236 - 655

In order to be of quick service for you, please fill in the data completely. Should you have more foot controls, we kindly ask you to fill out this form for each foot control separately.



REF-Number*: _____

Serial number*: _____

Name Surname*: _____

Address / Street / State / Zip Code / Country*: _____

eMail*: _____

phone: _____

I confirm that I have taken note of the above mentioned information.

 Signature*