

Bulletin No.: 2013-015/2-O
Date: June 6th, 2013
To: All Sales International / All Partners & Distributors
From: Patrick Schill, Product Manager OPERON[®]
Contact for inquiries: Patrick.Schill@BERCHTOLD.biz

OPERON[®] Safety Advice of March 11th, 2013

- Hand Pendants for D 760, D 820 and D 850

Valued Partners,

With the letter dated March 11th, 2013 we informed you that BERCHTOLD has become aware of unintended movements occurring at customer sites in the USA.

We have performed intense investigation and test and would like to update you today on the findings and measures.

Description of the potential problem and identified Root Cause:

The identified root cause has been the applied cleaning process for hand pendants allowing fluids to get into the hand pendant. Unintended table movements have been reported at sites where pendants have been submerged in aggressive disinfection fluids.

To our findings those hand pendants have not been disinfected according to the instructions clearly given in the BERCHTOLD's User Manuals.

Mandatory Actions:

Care and Clean the BERCHTOLD OPERON[®] Hand Pendant according to the User Manual / Safety Advice of March 11th, 2013:

- Do not immerse in fluids
- Do not use prohibited fluids to clean/disinfect the hand pendant
- Use only a damp cloth and wipe. Never spray the hand pendant with cleaning/disinfection solution, only spray the cloth
- Do not use a damaged hand control (e.g. housing broken, clip detached/broken, cable pulled out)
- When the hand pendant is not in use, always attach it to the side rails on the respective table section or the head module side rails

Please ensure that your Customers and staff responsible for that matter are aware of this mandatory treatment of the hand pendant.

OPERON® Hand Pendant Design

Intensive tests have shown that the BERCHTOLD Hand Pendant works well if treated according to the User's Manual.

Therefore BERCHTOLD is not obliged to carry out a wholesale replacement of existing table hand control pendants. This is contrary to the information provided in our earlier safety vigilance document of March 2013.

We would like to thank you for your patience and your support during this time period and excuse the inconveniences occurred for you.

Transmission of this information:

Please assure that all people within your organization and users being affected by aforementioned notice are notified by this information.

If you have submitted information to customers and/or third parties, please forward a copy of this information to his/her attention.

Competent Authorities of the specific countries will be notified by a separate note.

Supply of OPERON® Operating Tables:

BERCHTOLD is further glad to announce that the supply of OPERON® Operating Tables D 760, D 820 and D 850 will be up and running within a short time frame; latest by end of month.

Tables shipped without a hand pendant will receive a hand pendant automatically within the next weeks. Please get in touch for specific shipping dates with your Customer Service Contact once you didn't receive an expected shipment date by May 31st.

Thank you for your attention.

Best Regards,



Hubert Heubuch
Marketing Director International

Best regards,



Patrick Schill
Product Manager OPERON®
Surgical Table Systems