

23.03.2017 Ha/ko

Important Message regarding Operational Safety
Extension of safety instructions in the instructions for use

Dear Sirs,

Due to the fact that several lithotomy baskets were torn off during the lithotripsy process, we would like to inform you today that we have enhanced the safety instructions in the operating manual accordingly. This affects the lithotomy basket series „Easy-Catch“.

Why did we extend the safety information in the operating instructions?

The above-mentioned lithotomy basket was used for lithotripsy and was combined with instruments (lithotripter spring and/or handle) of other external manufacturers.

Possible risks

The combination of the lithotomy baskets with different lithotripsy springs and handles increases the risk of uncontrolled tearing off and other damages to the lithotomy baskets, in particular when crushing hard bile stones.

Limitation of risks

Design changes to the lithotomy baskets in order to prevent that the user combines the above lithotomy baskets with lithotripsy springs and handles of external manufacturers, unfortunately, are not possible. Therefore, we have adapted the notes in the operating manual.

Note: By means of these lithotomy baskets a lithotripsy can be carried out, too. For instructions regarding this purpose, please consult the instructions for use “lithotripter set“.

In combination with the above-mentioned lithotomy baskets, only use original accessories of MTW Endoskopie, when carrying out a lithotripsy. Otherwise, the patient and/or the user could be injured, and/or the different instruments or the endoscope could be damaged.

Remedies for troubleshooting - instructions

With revision date 22.02.2017, the above-mentioned enhanced note is contained in the updated instructions for use for the affected lithotomy baskets. Since this revision date the

operating manuals are delivered with the extended note, together with the lithotomy baskets.

Please ensure that the users in your establishment are informed about this enhanced note in the current instructions for use.

Therefore, please check your stock for any remaining lithotomy baskets of this series. If necessary, please exchange the corresponding operating manuals.

Attached to this letter you will find a copy of the new instructions for use.

If you need any more copies, please ask for them by e-mail at:

r.koch@mtw-endoskopie.com

Many thanks for your kind support. The signatory confirms that this notification about the remedies for risk minimization has been submitted to the responsible supervisory authority.

For further information, please do not hesitate to contact us.

With best regards,

MTW-Endoskopie

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