

11 September 2013

## URGENT FIELD SAFETY NOTICE

### Reprocessing of unsterile surgical needles and cannulas

#### To Whom It May Concern

Our unsterile surgical needles and cannulas are marked as reusable products. We have nevertheless discovered that our practical guidance for reprocessing these products not complies in relevant steps with standard DIN EN 17664. We have concluded that the latter cannot be safely carried out.

Reusing the instruments may expose the patient being treated to the risk of contamination. Despite this, we consider that the risk of those incidents is low. We have so far not been notified of any such cases.

Please ensure that all users of the above-mentioned products and other individuals needing to be informed become familiar with this urgent security information.

For future practice, our team is currently working to provide you with a reliable instruction for safely reprocessing the instruments. Please make sure that, until then, our above-mentioned instruments will be used as disposable products. They have to be destroyed after use.

The Federal Institute for Drugs and Medical Products (*Bundesinstitut für Arzneimittel und Medizinprodukte*) has been supplied with a copy of this Urgent Field Safety Notice.

It is unfortunate that we must take this corrective action and we apologize for any inconvenience caused. We are however obliged to provide you with products certified to most demanding quality standards. Our instruments have to guarantee utmost safety for their use.

If you have any further questions, you can contact our Quality Manager, Mr Thomas Ott (tel. 0049/6103/983-446) or our Managing Director, Mrs Silja Kluge (tel. 0049/6103/983-426).

Yours Faithfully

Ernst Kratz GmbH



Silja Kluge  
Managing Director