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Important notification

Issued: 18.02.2019

Product: Cannula Needle, 80mm, 18G

Reference: 8001769 **Lot number:** 18.09.19

Manufacturing date: (19 + 20).09.2018

Dear Customer,

In order to avoid misuse of the product as reference to the above we have made the following **Field Safety Notification.** The result of our investigations showed that this incident which was reported is due to a misuse of the cannula needle.

- 1. Indeed, the cannula needle had been bended voluntarily during the surgical intervention. This action should not be done.
- 2. Not to use the cannula needle as to scraping instrument, rather as intended as an irrigation tool.
- 3. The cannula needle should not be in contact with other mechanical surgical instruments.

Therefore we state the following field Safety notification

- Do not use this product for any purpose other than that for which it is intended:
 Irrigation
- Do not bend the cannula.
- Do **not** use the device as a rubbing utensil against tissues or bones
- Make sure other mechanical devices do not come into contact with the cannula
- After use, please check that the olive is still in place on the cannula

Please feel free to contact our quality department for further information, If required on: + 41 21 948 92 74 or by email: quality@applimed.ch or info@applimed.ch.

Please accept our deepest apologies for the inconvenience and thank you for the trust you have placed in us.

The Management