



APPLIMED

SA

Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

Important notification

Issued: 21.02.2019

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.

There are only batch involved because:

- Misuse by the customer.
- The holding of olive was 100% tested before using cannula needles for production.
- Hartmann is the only customer for this product and he distributes Applimed's product (8001769).

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

