

TROKAMED GmbH · Kleine Breite 17 · 78187 Geisingen

#### To whom it may concern

YYYY-MM-DD

# Important customer information Maintenance on the moresolution control unit – Article No [BfArM FSN Ref. No.]

Dear Sir or Madam,

As you have purchased a control unit for the morcellator system moresolution with article number Article No. from Customer, today we would like to inform you that under irregular circumstances (such as a misinterpretation of possible moisture in the handle) a functional error with the number #1101 may occur and will be shown on the display of the moresolution control unit.

This error means that the device cannot be activated via the morcellator handle anymore being no longer ready for operation at this moment.

### For your information:

If this error message occurs during the operation, you can continue safely by using the foot switch Article No. for the activation of the device.

Below you can find a description of how to set up the system in this case:

## Description of the procedure A:

- 1. Switch off the control unit
- 2. Wait until the display switches off
- 3. Unplug the control cable of the Grip Module from the control unit and do not plug it back in.
- 4. Switch on the unit with no control cable plugged in
- 5. As soon as the unit is ready for use, plug in the Foot Switch.
- 6. Select the Foot Switch.
- 7. Display shows: "Foot switch OK".
- 8. Continue the operation with the Foot Switch.

#### Alternative procedure B:

Continue the operation with a replacement unit.



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We were able to locate the source of the potential error code, which can be corrected by a maintenance work that would be carried out by TROKAMED GmbH, who is the legal manufacturer of the device.

We would like to inform you that with this action the probability of the error message #1101 is reduced to such an extent that the general functionality of the morcellator is guaranteed. The application of a Morcellator control unit/device with software version 2.1f and older should not be used with the 5-times-use handle.

As manufacturer of medical products, it is important to us, that patients and users can rely on a smooth and safe process of device handling.

Therefore, to avoid long waiting periods for maintenance work and to prevent possible distortion during surgery, we offer to service the unit directly up front, or in the <a href="Customer">Customer</a> repairs shop town or we exchange your device against an exchange unit, free of charge.

Please contact your Customer sales representative to arrange an appointment for the maintenance.

With best regards TROKAMED GmbH

General Manager