



Erbe Elektromedizin GmbH P. O. Box 14 20 72004 Tuebingen Germany

«Name1»  
 «Name2»  
 «Name3»  
 «Name4»  
 «Strasse»  
 «PLZ» «Ort»  
 «Land»

March 13, 2017

## Recall of ERGO handle with Erbe REF numbers:

- **20195-240 ERGO handle for BiClamp E LAP forceps**  
 Concerned LOT numbers: **OP271317** and **OP272560**
- **20195-245 ERGO handle for bipolar instruments**  
 Concerned LOT number: **OP269409**



Dear Sir or Madam,

Due to a wrong delivery from a supplier, the above mentioned handles have been manufactured with a spring that is not corrosion-resistant. As a consequence, repeated reprocessing of these handles can lead to a functional impairment or failure.

According to our assessment, this does not pose any risk for patients, users or others. However, it may lead to delays during surgical procedures. Corrosion of the spring may impair the movement of the handle; changing and rotating the shaft during the surgical intervention may also be limited. The activation of the electrode's jaws, however, is not affected.

As these products do not uphold the quality standards of Erbe Elektromedizin GmbH, all distributed ERGO handles which are affected will be replaced as a preventive measure.

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Baden-Württembergische Bank  
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 BIC: SOLADEST600

Kreissparkasse Tübingen  
 IBAN: DE54 6415 0020 0000 0001 41  
 BIC: SOLADES1TUB

Postbank Stuttgart  
 IBAN: DE64 6001 0070 0001 4147 01  
 BIC: PBKDEFF



According to our records the following handles have been delivered to you:

REF no.	LOT no.	Delivered with complete instrument REF no.	LOT no.	Invoice No.	Invoice date	Amount

**Please do not use these instruments with immediate effect.**

Please send all affected handles together with the attached form, if possible by March 24, 2017, to the following address:

Erbe Elektromedizin GmbH  
Service  
**ESV-00-101484**  
Waldhoernlestr. 17  
72072 Tuebingen  
Germany

All returned handles will be immediately replaced by new handles. Measures are currently being defined and put in place in order to avoid a recurrence of this kind in the future.

We would like to apologize for the inconvenience caused by this recall and replacement.

If you have any questions or require further information, please contact our Customer Care Hotline by phone at +49 7071 755-123, by telefax at +49 7071 755-5123 or per e-mail at [Support@erbe-med.com](mailto:Support@erbe-med.com). Alternatively, you may also contact your Erbe sales representative.

Thank you for your help in this matter.

Yours faithfully,

Erbe Elektromedizin GmbH

Martin Viesel  
Director Quality Assurance  
Security Officer in accordance with § 30 Medical Products Directive

Encl.