

S-BC/Distributor, Street No., Postcode/Zipcode City, Country

Company Name/Hospital
Dept./Attn.
Street No.
Postcode/Zipcode City
Country

Your Reference:
Your Message from:
Our Reference:
Our Message from:

Name:
Phone:
Telefax:
E-Mail:

Date: 2014-04-xx

Important Safety Information/Urgent Field Safety Notice – CelonProSurge Electrode

Dear Customer,
Dear Health Care Practitioner,

OLYMPUS has become aware of an issue that requires your attention. We provide important information regarding the

CelonProSurge Bipolar Coagulation Electrode.

Users of the bipolar coagulation electrode reported an unusually low radiofrequency energy input and early automatic stop of the ablation procedure.

OLYMPUS could identify the cause of this malfunction/problem. Incorrect assembly of an internal component resulted in insufficient cooling at the bipolar coagulation electrode's tip. Electrodes without sufficient cooling show a decreased capability to transfer radiofrequency energy into the tissue.

The decreased transfer of radiofrequency energy may result in coagulation volumes that are smaller than intended. This could cause an incomplete ablation and may require an additional ablation procedure.

The following measures are necessary and have to be implemented:

- 1. Do not use the bipolar coagulation electrodes of the affected lots** (see table on the next page)!
- 2. Return all bipolar coagulation electrodes of the affected lots to your local vendor/OLYMPUS partner** (including the filled out and signed Reply Form – ref. attachment)! For these electrodes you will get a replacement free of charge.

OLYMPUS could identify the electrode types and production lots that have a significantly increased probability to be affected by the described malfunction:

| Article Name | Article Number (REF) | Lot Number (LOT) |
|-----------------------|----------------------|------------------|
| CelonProSurge 100-T30 | WB990146 | ... |
| CelonProSurge 150-T30 | WB990149 | ... |
| CelonProSurge 150-T40 | WB990150 | ... |
| CelonProSurge 200-T20 | WB990151 | ... |
| CelonProSurge 200-T30 | WB990152 | ... |
| CelonProSurge 200-T40 | WB990153 | ... |
| CelonProSurge 200-T20 | WB990218 | ... |

The affected bipolar coagulation electrodes can be easily identified by their article (REF) and lot (LOT) number, printed on the outer packaging label as well as on the sterile packaging label.

OLYMPUS regrets if the implementation of these measures might cause inconveniences and fully appreciates your prompt cooperation in addressing this situation. In case of any questions, please do not hesitate to contact your local vendor/OLYMPUS partner who will be delighted to support you or make the necessary arrangements.

Please fill out, sign and return the attached Reply Form to your local vendor/OLYMPUS partner, even if you do not own any bipolar coagulation electrodes of the affected lots.

Kind regards,

Name
 Position
 Department
 S-BC/Distributor

Reply Form

S-BC/Distributor
Dept./Attn.
Street No.
Postcode/Zipcode City
Country

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Dear Sir or Madam,

Herewith we confirm the receipt of your Safety Information Letter/Field Safety Notice, dated from 2014-04-xx. We have understood and will follow the recommendations given by the medical device manufacturer.

Name: _____

Hospital: _____

Department: _____

Street No.: _____

Postcode/Zipcode City: _____

Date Signature