[XX] January [XX] 2019 [Reference: QIL-151P-01]

[URGENT: FIELD SAFETY NOTICE / FIELD SAFETY CORRECTIVE ACTION]
[URGENT: RECALL - MEDICAL DEVICE CORRECTIVE ACTION]

Attention: Operating Room Manager

Regarding: CelonProSurge Bipolar Applicators - change of contraindications

Model Number	Model Description	Lot Number(s)
[to be populated]	[to be populated]	[to be populated]
[to be populated]	[to be populated]	[to be populated]
[to be populated]	[to be populated]	[to be populated]

[Dear Customer,/:]
[Dear Healthcare Provider,/:]
[Dear Healthcare Practitioner,/:]

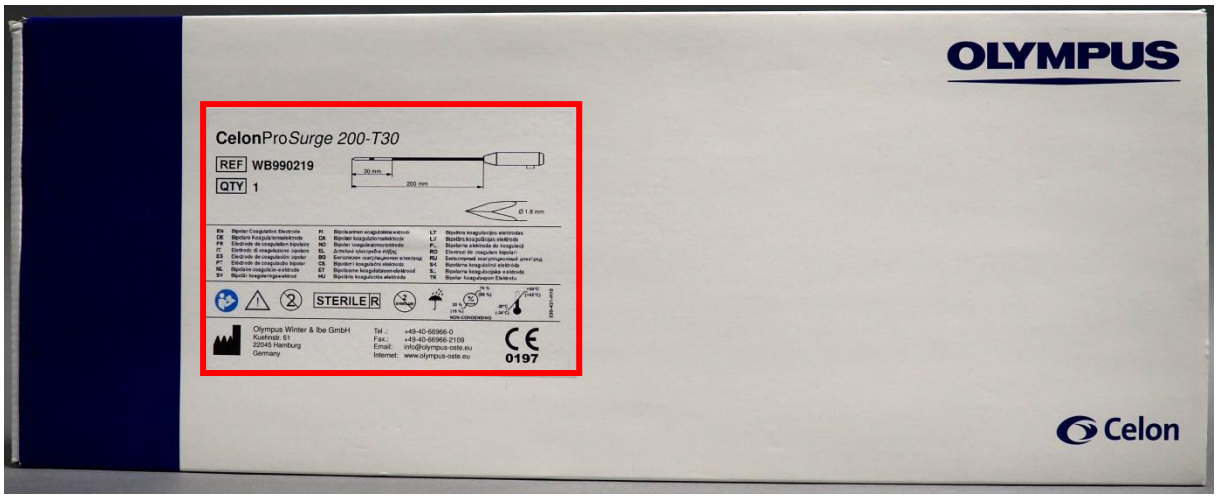
OLYMPUS is implementing a [Field Safety Corrective Action (FSCA) / medical device corrective action] for the bipolar applicators referenced above. Bipolar applicators are intended to be used for ablation and coagulation of soft tissue, including thermal inactivation and volume reduction of locally defined tissue areas, e.g. tumors, in combination with a compatible radiofrequency ablation (RFA) control unit and a compatible pump. This method of treatment is also called bipolar radiofrequency-induced thermotherapy (RFITT).

OLYMPUS has initiated this [FSCA / medical device corrective action] after receiving a complaint where a patient had sustained damage to the spinal cord after a RFA of spinal metastases with the referenced bipolar applicators. Treating tissue areas close to important nerves, vessels and organs can lead to damage to these structures. Potential complications associated with the use of bipolar applicators include, but are not limited to bleeding, infections, edema, thermal injury to neighboring tissue/structure and nerve injury. Nerve injury, including thermal injury, can lead to neuritis, paresis and paralysis.

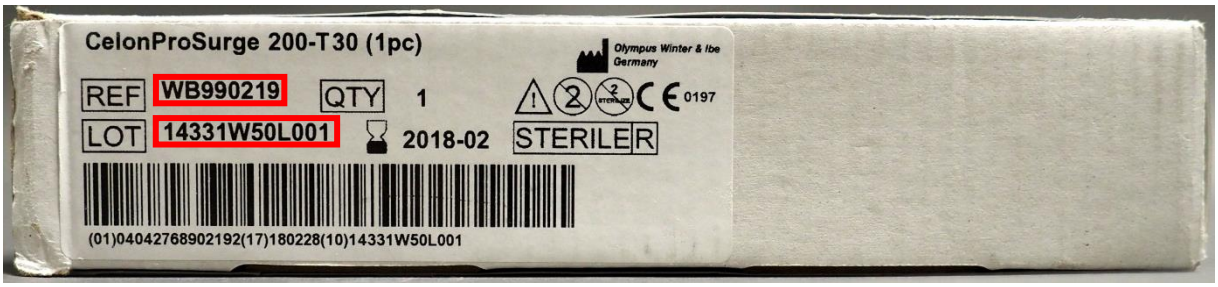
In an effort to prevent recurrence of such an [incident/adverse event], OLYMPUS is changing the contraindications for the referenced bipolar applicators. **With immediate effect, their application in close proximity to the heart, the central circulatory system, the central nervous system and the spine is contraindicated.**

<u>Action steps to be taken by the end user:</u>
Our records indicate that your facility has purchased one or more of the affected bipolar applicators with the lot numbers listed above. **OLYMPUS requires you to take the following actions:**

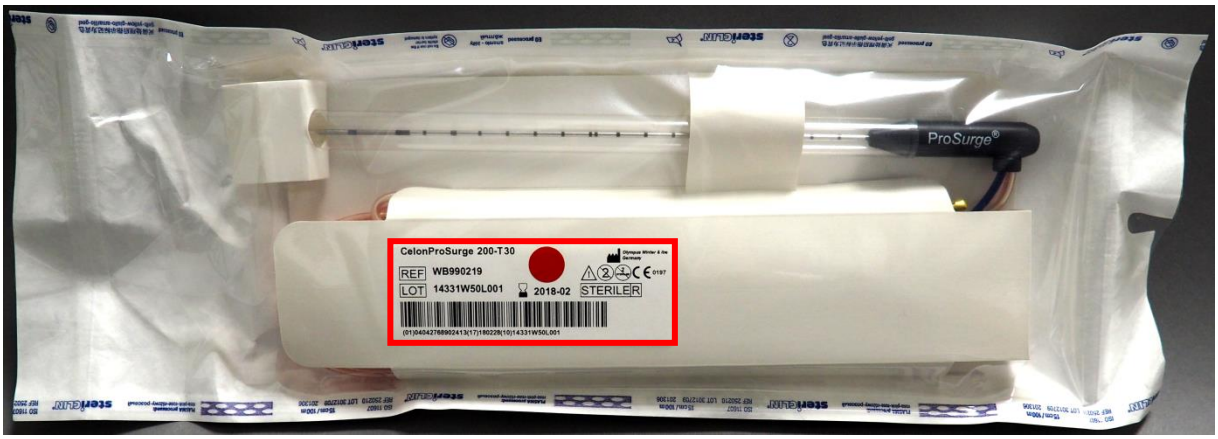
1. Inspect your inventory for the referenced bipolar applicators and identify any of the specified model and lot numbers identified above. The model and lot number can be found on the packaging labels as illustrated in the following pictures:



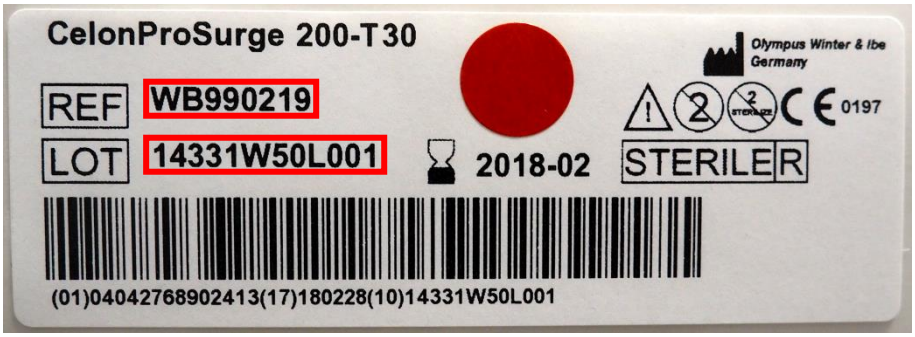
Picture 1: outer packaging of the bipolar applicators (top view)



Picture 2: model (REF) and lot (LOT) number on the outer packaging label (side view)



Picture 3: blister packaging of the bipolar applicators



Picture 4: model (REF) and lot (LOT) number on the blister packaging label

2. Please confirm on the enclosed reply form that you have received this [Field Safety Notice (FSN) / medical device corrective action notice] and **that you have informed your staff about the changed contraindications.**

3. Fax or e-mail the completed reply form to [Department] at [telefax number] or [e-mail address], including the amount of updated Instructions for Use (IfU) you require. You will then be supplied with the necessary number of updated IfUs, if applicable.

4. Upon receipt, replace the original IfUs you initially received with your bipolar applicators with the updated version provided. **Make sure to remove all outdated IfUs from circulation and to inform all relevant staff about the changed contraindications.**

The [local / national Competent Authority] is aware of this action.

OLYMPUS regrets any inconvenience this action may have caused and fully appreciates your prompt cooperation. If you have any questions or concerns, please do not hesitate to contact me directly at [telephone number] or at [e-mail address].

Sincerely,

[Name]
[Position]
[Department]
[S-BC / Distributor]