Radio-Frequency Plasma Surgical Electrodes

User Manual

Version 02

This user manual only applies to the radio-frequency plasma surgical electrodes manufactured by Lysistech GmbH.
The product complies with the following directives:
MDD 93/42/EEC, EN 60601-1: 2006 EN 60601-1-2: 2007.
EN60601-2-2: 2009 A11: 2011, DIN EN ISO 10993-1: 2009/AC: 2010, EN ISO11135-1: 200
Our model numbers are:
LAC301, LAC302, LAC304, LAC305, LAC306T, LAC306R, LAC390, LAC401, LAC401AD, LAC402, LAC404, LAC405M, LAC405E.
AC, BC and MC represent the three different types of connectors.

1. Compatibility

A radio-frequency plasma surgical electrode (referred to as 'electrode' in the following text) should only be used in combination with a radio-frequency generator (referred to as 'controller' in the following text).

The controller's output parameters are as follows:

Output voltage: AC 0 ~ 360 Vrms ± 20%; 100 kHz ± 20 kHz; 1A; type BF device

2. Indication

The electrode should only be used with LYSISTECH or RF-compatible controllers. This applies to the following surgical procedures:

cutting and excision, ablation, coagulation and haemostasis in soft tissue. The application of RF electrodes is generally indicated in various fields – including (but not limited to) ENT, orthopaedics, spine (sports medicine) and urology – in procedures such as tonsillotomy, meniscectomy, lateral release, benign prostatic hyperplasia, nucleoplasty etc.

3. Contraindications

The electrosurgical controller and the corresponding electrodes cannot be used on all patients – this mainly includes patients with cardiac pacemakers or other electronic implants. The electrodes are not to be used for debridement of bone surfaces because it may lead to surgical complications and also cause damage to the electrodes.

4. Components

The electrode comprises a bipolar plasma electrode at the functional end, a shank, a plastic handle and, optionally, an integrated cable (some electrodes have no integrated cable). Models LAC390, LAC405E, LAC401, LAC401AD, LAC402 have additional irrigation modules and/or suction tubes. The nominal voltage of the electrode is 500 V in all models.

5. Safety information

5.1. Please read the user manual and the instructions (provided with the compatible controller) carefully before using the product. The electrode is not designed for standalone application and can therefore be used only as a system together with a compatible controller.

5.2. DO NOT touch the tip of the electrode or discharge it when connected to the power supply. Avoid contact with metallic objects while using or operating the electrode as it may harm the patient or damage the electrode.

5.3. When not in use, the electrode should be placed at a safe distance from the patient.

5.4. For electrodes with suction, it should be ensured that the suction tube is connected at all times. Do not use the electrode without the connected suction tube. Otherwise, it may cause injury to the patient/user or damage the electrode. The suction pump head should not come in contact with the patient as this would result in a serious risk of burning.

5.5. Electrodes with suction have an incorporated suction lumen to evacuate blisters and/or small tissue fragments from the operation site. The suction lumen is not intended for large volumes and/or large operating areas. A separate outflow source should be connected while using the system.

5.6. During a procedure it may not be possible to completely avoid electromagnetic interference. For this reason, this system is not suitable for the treatment of patients with a cardiac pacemaker or other active implants.

5.7. Patients should not be in contact with grounded metallic objects with powerful capacitors (e.g. operating table rails). The use of electronic separators is recommended.
5.8. Skin contact should be avoided. The electrode tip should always be kept at a safe distance from the patient (use a dry gauze in order to protect the patient from direct contact with the electrode).
5.9. It is recommended to use monitoring systems with an integrated overcurrent protection device (to limit the RF current) under all circumstances.
5.10. When used in combination with a plasma surgery system, the electrode should only be applied in the presence of electrically conductive fluids, for instance saline solution (medical grade). DO NOT use any non-conductive media (e.g. distilled water, air, gas, glycine etc.).
5.11. Do not use in the presence of explosive anaesthetic substances, oxidising gases or in the direct vicinity of liquid solvents because electronic surgical devices are a potential source of ignition. Carefully remove all flammable reagents and cleaning agents before the operation. Flammable substances in the patient's body, e.g. in depressions (navel) or cavities (e.g. vaginal area), should be cleaned out before using the system.

Please watch out for the risk of fire from flammable gases. Certain materials like cotton, wool and (oxygenated) gauze could cause fire, triggered by the sparks (discharge) from the electrodes, even if the system is being operated properly. Please keep the fire protection measures in mind at all times. Sparking and heating in connection with electrosurgical procedures can be a potential source of ignition.

6. Safety instructions
6.1. Before using the product for the first time, it should be ensured that all package inserts, including warnings, precautionary measures, operating instructions and user manuals have been properly read and understood.
6.2. The electrode is supplied in sterilised packaging and is meant for one-time use only. DO NOT clean, sterilise or use the electrode again. This could lead to damages or malfunctions in the electrode and also cause injuries and/or the transmission of infectious diseases in patients. After use with medical particles, discard in the appropriate waste disposal.
6.3. Check the date of expiry of the sterile electrode before use. If the package is damaged, the electrode should not be re-sterilised and/or used.
6.4. As far as possible, ECG electrodes should be kept away from surgical electrodes when RF surgical systems and physiological monitoring equipment are being used on the patient at the same time. The use of needle electrodes for ECG is not recommended.
6.5. The tip of the electrode must NOT come in contact with the tissue that will not be treated, as this could lead to accidental injury to the patient. The electrode should only be applied for surgery on the target tissue. Unnecessary damage may be caused if the electrode comes in contact with tissue that is not being treated. The electrode control should be activated only when the electrode is in direct vicinity of (or in contact with) the target tissue. Otherwise, it may cause injury.
6.6. This electrode is not suitable for RF cardiac ablation.
6.7. The controller and the electrodes should be stored in a weather-proof environment, far away from high temperatures, moisture and UV rays.
6.8. The electrode is not suitable for use as a lever or for mechanical application on bones. It should not be used as a lever to extend surgical access to the target tissue. These measures may damage the electrode or loosen the electrode components, as well as damaging the controller and/or breaking the spacer.
6.9. Examine the patient for predisposing health problems that may be aggravated by the surgical procedure.
6.10. Safe and effective RF surgery depends not only on the product design but also, to a great extent, on factors that are subject to the skill of the user/surgeon.
6.11. DO NOT use preheated electrodes as this could cause thermal damage to the tissue not being treated.
6.12. If the electrodes with suction are used for arthroscopic procedures, care should be taken to ensure that the tip of the electrode is completely covered with the irrigation solution (during application).
6.13. If electrodes with both irrigation and suction are being used, then sufficient flow and circulation of saline solution should be ensured in order to prevent unnecessary heating of the irrigation liquid (which may cause thermal tissue damage).
6.14. Never place the surgical electrode near patients or other cables.
6.15. As with of other electrosurgical devices, electrodes and cables could be a potential conduit for RF current. The cable should be positioned in such a way that it is not in contact with patients or other individuals. It may cause malfunctions in other electrical devices if they are kept near the system.

7. Operating instructions
7.1. Always select an appropriate electrode model. Check the package contents and the electrode before application. If the contents of the package appear damaged in any way, the electrode cannot be used.
7.2. Appropriate surgical expertise and experience is required for using the electrode. Preoperative and operative procedures, including proper

patient selection, knowledge of surgical techniques, as well as proper device selection are important prerequisites for using this system.

7.3. Patients should be made fully aware of the possible risks and complications related to the surgical procedure (and the use of the device). The electrode user should have complete and thorough knowledge of RF surgery. Preoperative preparation should always be done in accordance with the rules and regulations for electrosurgery.

7.4. For electrodes with suction, the suction cavity (suction lumen) should be connected to the appropriate pumping system, the flow regulator should be activated and the negative pressure should be set between a minimum of 200 mmHg (26.6 kPa) to a maximum of 400 mmHg (53.2 kPa). Failure to observe these instructions may lead to device defects. Not attaching the suction tube and/or improper suction may lead to burns on the patient or the user.

7.5. Instructions for the surgical procedure: Position the functional end of the electrode at the operation site, switch on the compatible controller and tap on the foot switch to activate the device. For detailed protocols on soft tissue ablation, coagulation and haemostasis, please refer to the user manual for RF-compatible or plasma surgery controller. The user should have complete and thorough knowledge of the system's operation described here.

7.6. The electrode tip should be checked at regular intervals in order to ensure that the functional end is intact and the electrode is functioning as intended. In case the electrode is not intact, it should not be used any further and the operation site should be carefully examined. Excessive usage beyond the specified value (maximum 5 min.) could lower the device's operating life or cause damage to the electrode and/or the controller.

7.7. Appropriate inflow and outflow of conductive fluids (e.g. medical-grade saline solution) should be ensured during the procedure in order to prevent possible burns to the patient.

7.8. After the procedure is complete, the electrode should be removed, the controller should be switched off and the electrode disconnected from the controller. The subsequent disposal of the medical material should proceed in accordance with the requirements of applicable regulations.

7.9. Electrosurgical interventions may cause damage to the surrounding tissue. Therefore, the instructions for use should be followed precisely.

7.10. Electrodes are not intended for longer ablation procedures (max. 5 min.). The wear and tear of electrodes caused by ordinary use may not always be the same as the wear and tear due to other factors. Factors that exacerbate wear and tear of the electrode include, among other things: ablation performance – high power setting, longer usage on bone surface and low suction and fluid management. The electrodes should be intermittently checked to ensure that the electrode is intact and fully functional. The recommended default setting should provide the desired surgical results.

7.11. A considerably reduced ablation rate could be an indication that the electrode is not functioning optimally. If the problem persists, the electrode should be replaced.

7.12. Ablation rate and ablation depth on the tissue are determined by the specified value, the pressure on the tissue, electrode integrity and the speed at which the electrode is moved on the target tissue.

7.13. While using electrodes LAC390, LAC404, LAC405E and LAC405M for an arthroscopic procedure, the electrode should not exceed a cumulative ablation period of **5 minutes** (specified value in setting mode 7). Excessive usage and/or usage beyond the specified value poses the risk of reduced operating life of the electrode. Changing the specified setting mode may cause burns. Excessive wear and tear or damaging of the electrode due to forceful use on extremely thick or bony surfaces could lead to reduced electrode performance and injuries to the patient. If damage to the electrode is detected, its use should be ceased immediately and the cavities in the operation area should be carefully examined.

8. Sterilisation with ethylene oxide
9. Shelf life two years from the date of manufacture. DO NOT use after the expiration date.
10. Type BF: classified by shock resistance (to current)
11. Intermittent charging and continuous working mode: classified by operation mode
12. Transport and storage

Temperature range: -40 °C ~ +70 °C Relative humidity: 10% ~ 100% Atmospheric pressure: 500 hPa ~ 1060 hPa

13. Working conditions

Temperature range: 10 °C ~ 40 °C Relative humidity: 30% ~ 75% Atmospheric pressure: 700 hPa ~ 1060 hPa

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14. Refer to the following table for the legend:

	Manufacturer
	Authorised representation in the European Union
	Date of expiry of the medical device
	Date of manufacture of the medical device
	Batch code of the manufacturer for identification of the batch or LOT
	Medical device is sterilised with ethylene oxide
	Indicates that the medical device is for one-time use only or that it is intended for use on one patient during a single procedure.
	Do not use if the package is damaged
	Type BF
	Non-ionising radiation
	The product must not be disposed of with household waste; it should be sent to the appropriate facility for further processing and recycling.
	Refer to the user manual.
	Refer to the package inserts, usage instructions and/or user manual.
	CE marking and identification number of the Notified Body. The product compliant with the basic requirements of the Medical Devices Directive 93/42/EEC.