HELICA LTC PROBES

Operating Instructions & Service Information





Medical Instruments

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Table of Contents

Table of Contents	2
FOREWORD	3
PRE-USE CHECK	
PLEASE READ CAREFULLY	
PROBE CONTROL	5
LABELS IN USE WITH PROBES & PACKAGING	8
PROBE OUTER BOX INFORMATION	8

FOREWORD

The Helica Probes & TC r2 device are a major development in tissue coagulation and cutting. The concept was developed in the UK and makes possible a wide range of improved surgical techniques in a variety of specialities.

Please consult this manual carefully before use as it gives detailed operating instructions. For further information please consult our Helica TC Operating Instructions.

Brief Description of Equipment

An application probe to supply Helium gas and power to the application point.

The probe consists of a tube carrying the Helium with a supply wire enclosed. The diameter and design of the probe varies, with different lengths of probe, different designs of end and different diameters of tubing for a variety of applications.

Intended Use

The device is a helium gas electrosurgical cutting and coagulator for use in all soft tissue surgery – laparoscopic, endoscopic and open.

Exclusion Criteria

The following are excluded from intended use:

- Patients with advanced endometriosis.
- Patients who are pregnant.

Equipment Application Specification

The device has several medical purposes as a treatment as it is used for helium gas electrosurgical cutting and coagulation for use in all soft tissue surgery – laparoscopic, endoscopic and open.

PRE-USE CHECK

The probe must be directed to an earth or metal object to check the unit is operating. Using the foot switch, the tester holding the probe will charge up and may discharge to metal in a similar way to static charge caused by some carpets or cars.

Test Procedure – An optional test may be performed to confirm the instrument is ready. This should not be conducted near a patient. Direct the end of the probe towards a very wet swab or an insulated metal object and press the footswitch. A clearly observed plasma beam indicates the instrument is ready for use.

After these checks have been carried out the instrument is ready for use, according to the Helica TC operating instructions detailed in the section "OPERATING INSTRUCTIONS – HELICA TC".

Please scan the below QR code for full device IFU:



WARNINGS

PLEASE READ CAREFULLY

WARNING: Probes are supplied sterilised and are one use only. Care must be taken not to touch other parts of the probe when fitting the probe socket and plug to the unit.

WARNING: Check the plasma beam against a wet swab. Do not test near the patient.

<u>WARNING:</u> The probe cable should be positioned so it has no contact with the patient or other leads or cables.

WARNING: Please do not open/close the cutting probes whilst depressing the footswitch.

WARNING: Do not use the probe as a manipulator.

TYPES OF PROBES & USES

Туре	Code	UDI	Description
LTC (Retractable tip)	4001/5301	05060504150026	Laparoscopic coagulating & cutting probe

Please contact the Helica office for other speciality probes.

IMPORTANT: For safe use of the LTC probes

Familiarise yourself with the cutting probe prior to use.

Remember to remove the red plastic protective cover from the cutting tip end. Always start using the low power setting (6 watts) and increase power as required.

Care must be taken when probes are introduced through the cannula. It is recommended to hold the yellow outer sheath so that the cutting tip stays inside the probe. Afterwards, by moving the yellow outer sheath up & down will expose and retract the cutting tip. Care should be taken that this is done under vision. To retract the probe from the cannula, use the blue handle this will keep the cutting tip inside the probe.

Always retract the cutting tip when not in use, especially when inside the peritoneal cavity.

Remember to vent out the gas from the peritoneal cavity and monitor the gas pressure.

Do not use the probes or cutting tips as manipulating tool. – Ensure its highlighted. IMPORTANT: The HF probe is a type BF applied part.

PROBE CONTROL

The Helica TC works by producing an electrical discharge that mixes with helium, resulting in a plasma beam that discharges from the tip of the probe. If the tip becomes clogged with saline, blood or any other material this will affect the operation of the instrument. Bending the tip of the probe can result in the plasma beam not being in the centre of the tubing. Therefore, check the tip prior to use. Any matter which is obstructing the end of the probe will have adverse effects and will not allow the smooth operation of the instrument.

Hot blood entering the end of the tube will congeal and solidify after use. This has to be removed for the probe to operate normally. If saline is up the tube the Helium gas will blow this away and the probe will then operate correctly. To check if an operation is correct the plasma beam should be inspected. If this working correctly the instrument will operate when moved closely to the tissue which requires treatment. The probe should be held at 90 degrees to the tissue. This may not always be possible, but the nearer to 90 degrees the better. An angle less than 45 degrees may affect the performance but laparoscopically a more acute angle is sometimes unavoidable. Starting the probe further away and moving closer will help.

After developing a feel for the instrument, the surgeon will be able to adjust his techniques so that difficult areas can be treated. The depth of penetration is controlled by the power on the control panel at the front of the instrument. This is also controlled by the distance of the probe from the tissue and the length of time that the plasma beam is directed to a particular area.

The Helica TC, unlike the argon gas coagulator, operates at a lower power and gas flow, the recommended starting parameter for power for the Helica TC is 6 watts then increase the power until the desired effect is achieved. The starting probe - to - tissue gap is 5mm. The gas flow is automatically determined by the probe diameter. Laparoscopically use the lowest power necessary for the desired effect. Avoid 33w power and long duration applications of the Helica TC to tissue sensitive to depth of penetration such as vessels covered by thin membranes. Unwanted tissue damage may result.

Contraindications

The extensive use of the Helica TC on the digestive tract (for example the stomach and intestines) is contraindicated and may lead to post-operative complications such as tissue rupture. The Helica TC probes are a Class IIa transient device and should be used for less than one hour during surgery.

EXPLANATION OF SYMBOLS

^	Type BF applied part complying with IEC 60601-1
	Consult instructions for use
<u> </u>	Caution
LOT	Batch code
REF	Catalogue number
2	Do not reuse

	Manufacturer
	Date of manufacture
	Use by date
STERRIZE	Do not resterilise
	Do not use if packaging is damaged
**	Keep dry

C € 1639	Notified Body
STERILE	Sterilised using Ethylene oxide
-11	Variability in steps
	Variability
Ċ	Off (only for part of the equipment)
堂	Neutral Plate Grounding Symbol
	Risk of Overbalance
90kPa 108.5kPa	Storage Pressure Range
I	Packaging Fragile

SN	Serial Number
	Non ionising radiation
	Off (power disconnection from the mains)
	On (power connection to the mains)
•	On (only for part of the equipment)
	Warning
EC REP	European Representative
3°	Storage Temperature Range
25%	Storage Humidity Range

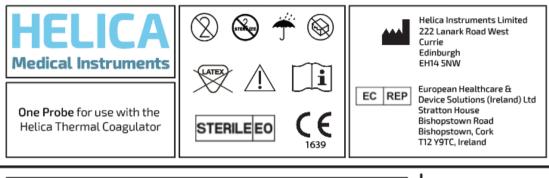
LABELS IN USE WITH PROBES & PACKAGING

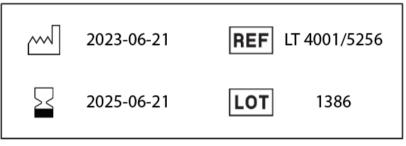
Example of front label of probe packaging

Laparoscopic Probe for Coagulation

Use with the Helica Thermal Coagulator

HL001h







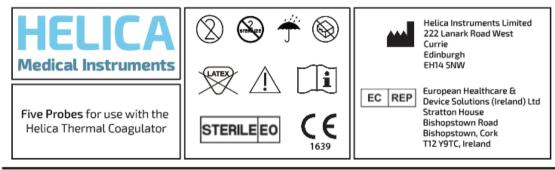
PROBE OUTER BOX INFORMATION

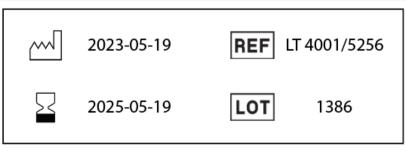
Example of the outer probe box

Laparoscopic Probe for Coagulation

Use with the Helica Thermal Coagulator

PK001f







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