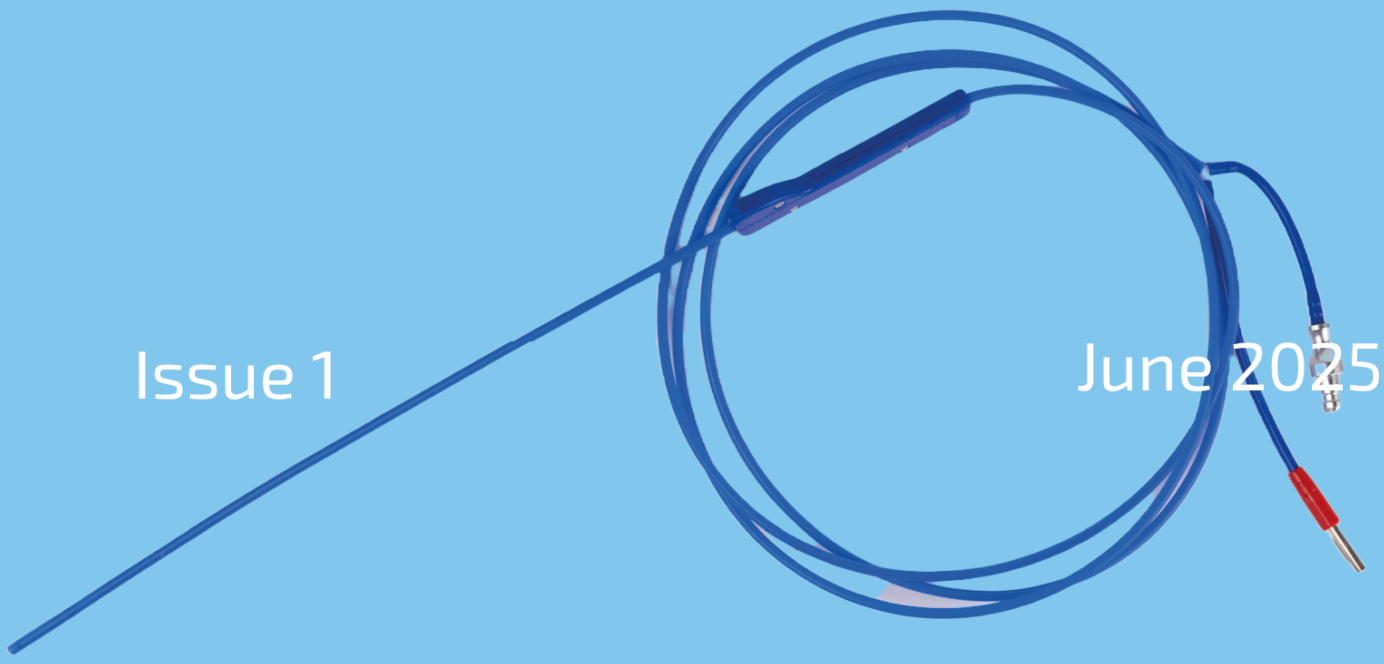
HELICA LT PROBES

Operating Instructions & Service Information



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HELICA
Medical Instruments

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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.

WARNING: 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

Type	Code	UDI	Description
LT	4001/5256	05060504150019	Laparoscopic coagulating probe

Please contact the Helica office for other speciality probes.

IMPORTANT: For safe use of the LT probes
Familiarise yourself with the coagulating probe prior to use.
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.

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.

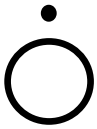
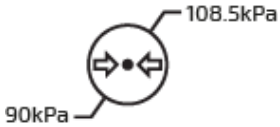
Contraindications

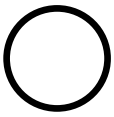
The extensive use of the Helica TC on the digestive tract (for example the stomach and intestines) is contraindicated and may lead to post-operative complications such as tissue rupture. The Helica TC probes are a Class IIa transient device and should be used for less than one hour during surgery.

EXPLANATION OF SYMBOLS

	Type BF applied part complying with IEC 60601-1
	Consult instructions for use
	Caution
	Batch code
	Catalogue number
	Do not reuse
	Notified Body
	Sterilised using Ethylene oxide

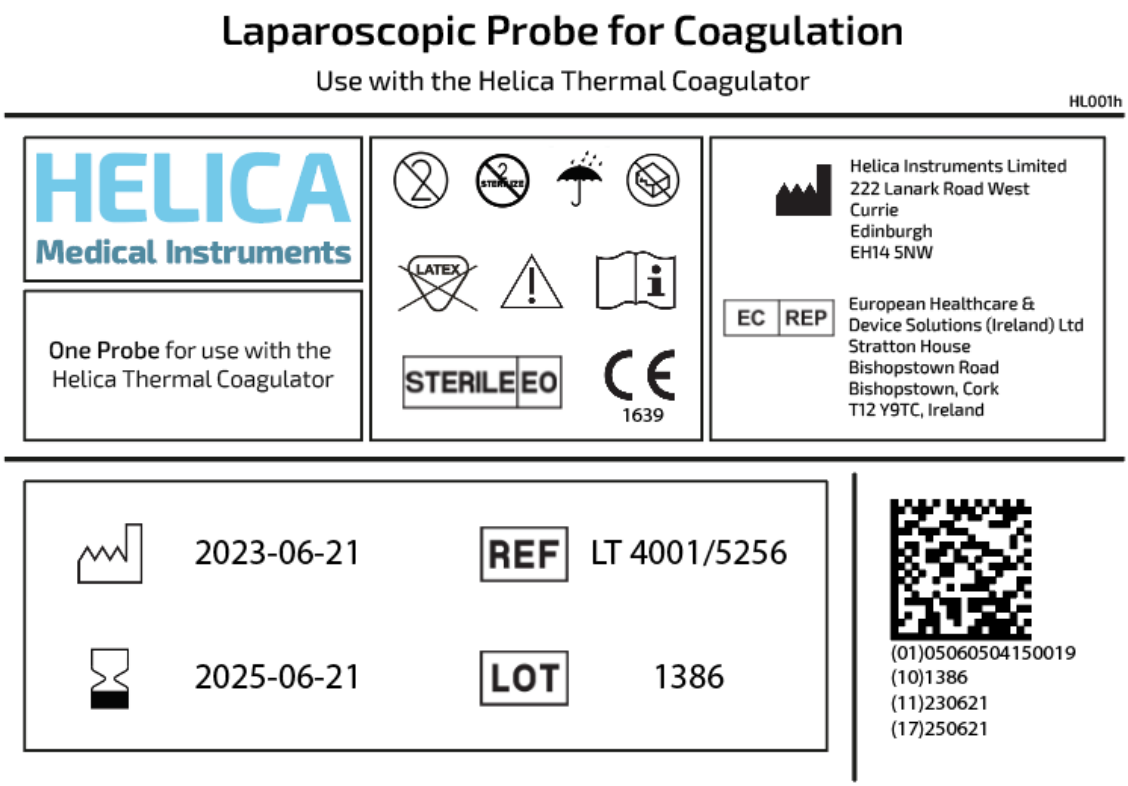
	Manufacturer
	Date of manufacture
	Use by date
	Do not resterilise
	Do not use if packaging is damaged
	Keep dry
	Serial Number
	Non ionising radiation

	Variability in steps
	Variability
	Off (only for part of the equipment)
	Neutral Plate Grounding Symbol
	Risk of Overbalance
	Storage Pressure Range
	Packaging Fragile

	Off (power disconnection from the mains)
	On (power connection to the mains)
	On (only for part of the equipment)
	Warning
	European Representative
	Storage Temperature Range
	Storage Humidity Range

LABELS IN USE WITH PROBES & PACKAGING

Example of front label of probe packaging



PROBE OUTER BOX INFORMATION

Example of the outer probe box