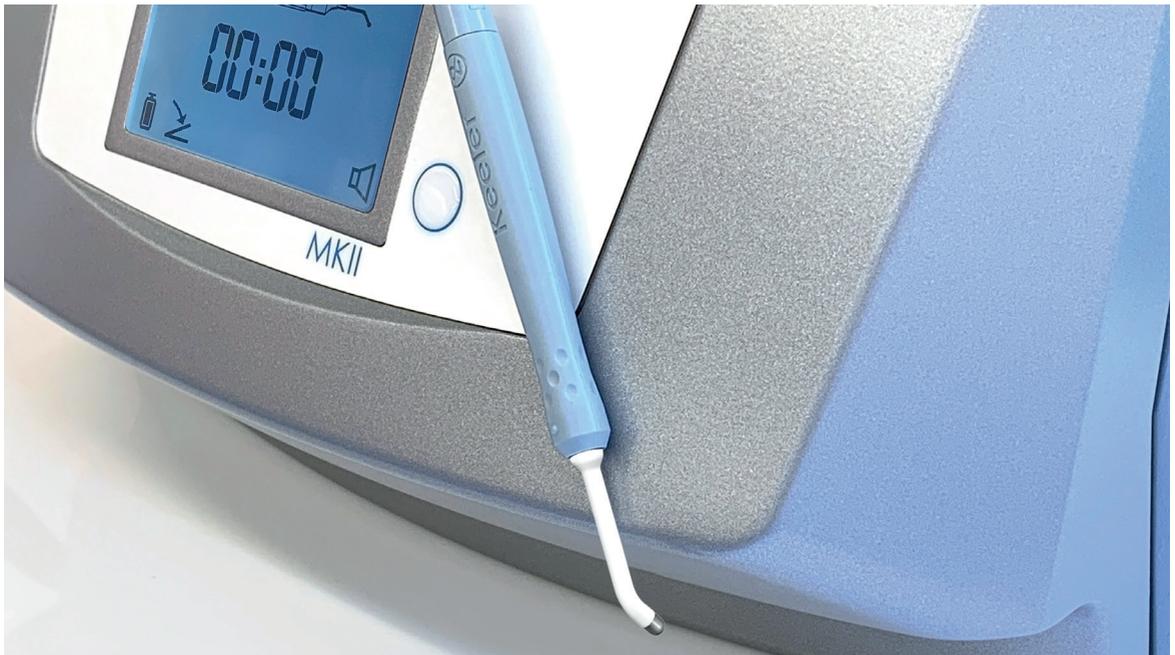


Single Use Cryo Probe

Instructions for use



Keeler



Single Use Cryo Probe

REF 2509-P-8033

Instructions for use Issue C – valid from 01/04/2020

For use only with the Keeler Disposable Probe Adapter (2508-P-8026) and Cryomatic Console (2509-P-1000 or 2509-P-1000-JPN), or the Cryomatic MKII Console (2509-P-1010).

1 Description

The Keeler Single Use Cryo Probe comprises a stainless steel stem with a plastic handle, connected to a long flexible plastic hose, comprising a high pressure tube within an outer protective tube, both of which are terminated within a plastic connector designed for insertion into the Keeler Cryomatic (with Disposable Probe Adaptor) and Keeler Cryomatic MKII.

Intended Use

Keeler Single Use Cryo Probes are for use in ophthalmic surgery such as cryopexy for retinal tears, or detachment of the retina, and works by welding the tissues back together using the ice ball formed at the tip of the probe which results from the release of gas (N₂O or CO₂) at high pressure.

2 Symbols



Mandatory action sign



Keep dry



Caution



*Catalogue Number/
Part Number*



*Refer to instruction
manual*



*Batch Code/LOT Number/
Batch Number*



*Consult Instructions
for Use*



*Sterilised using
ethylene oxide*



Manufacturer

3 Warnings and Precautions



USA federal law restricts this device to sale by order of a physician



Do not use this device if the packaging is in any way broken or damaged



Only use a Keeler Disposable Probe Adapter (2508-P-8026) or the Cryomatic MKII Console (2509-P-1010)



Do not repair and use a damaged product



This device should be used by trained staff, experienced in the use of ophthalmic surgical equipment



Do not use if the hose is twisted or kinked



Test the Single Use Cryo Probe before use



Both Single Use Cryo Probe and Disposable Probe Adapter instructions are to be strictly followed to avoid any usage errors



Do not use probes which are leaking



Do not obstruct the vent holes on the Single Use probe (located on the tube)



This is a sterile device for single use on one patient only. For one use only. Re-use of a single device may result in cross-contamination and infection



Do not attempt to eject the probe while the footswitch is depressed



Do not put this device in any sterilising/decontaminating solution



After use treat as contaminated waste



Do not use after the validity date indicated after the symbol on the label



Do not re-sterilise



Fragile. Avoid knocks and handle with care



When the tip is not in view, use the orientation pip on the handle to identify the tip position

4 Attention Important Safety Information



Test the probe operation prior to use.

Connect the Cryo Probe and depress the foot pedal for 20-30 seconds. The probe should freeze within 5 seconds of pressing the pedal and defrost within 5 seconds of releasing it.



If the above test fails, or you notice a leak, or other malfunction, turn off the gas supply and follow precisely, the instruction on how to disconnect the Single Use Cryo Probe/ console, as described in the relevant instruction for use. Return the faulty Single Use Cryo Probe to Keeler for analysis and exchange.

Take a new Single Use Cryo Probe and refer to the user instructions detailed above.



If the probe tip fails to defrost within 5 seconds of the footswitch being released, immediately switch off the console, and apply sterile water to the tip contact area. This will defrost the tip within a few seconds. Return the faulty Single Use Cryo Probe to Keeler for analysis and exchange.

Take a new Single Use Cryo Probe and refer to the user instructions detailed above.



Please ensure that the probe is decontaminated prior to return and is accompanied by a decontamination certificate indicating that it is safe to handle. It is vital that the LOT number of the probe is recorded on the accompanying documentation – this will enable us to identify potential problems with specific batches and take appropriate action.

5 Method of use with Keeler Disposable Probe Adapter

1. Insert the Adapter for the Single Use Cryo Probe into the standard probe socket of the Cryo Unit. Leave or hold the hinged safety clip facing upwards.
2. Insert the Single Use Cryo Probe connector into the Adapter. Push it firmly all the way in until you hear the click of the sprung safety lock.
3. Lower the security clip to ensure that it secures the tubing at the end of the connector.
4. If running software version vG or earlier the Keeler Cryomatic will automatically purge for 90 seconds.



5. If running software version vH or later the Keeler Cryomatic will display the 'Run' symbol.  Press the Run button to proceed.
6. Commence operation of Cryo Unit according to manufacturer's instructions.
7. Test Single Use Cryo Probe before applying to the eye.
8. At the end of the operation, carefully follow shut down procedure of the Cryo Unit. Vent the gas by purging according to the equipment instructions.
9. To remove the Single Use Cryo Probe, first press the sprung safety lock, then lift the hinged safety clip and remove the used probe assembly. Please ensure it is disposed of safely and is not re-used.
10. Use the enclosed peel-off labels to identify the product used on patient/facility records.

6 Method of use with Keeler Cryomatic MKII Console

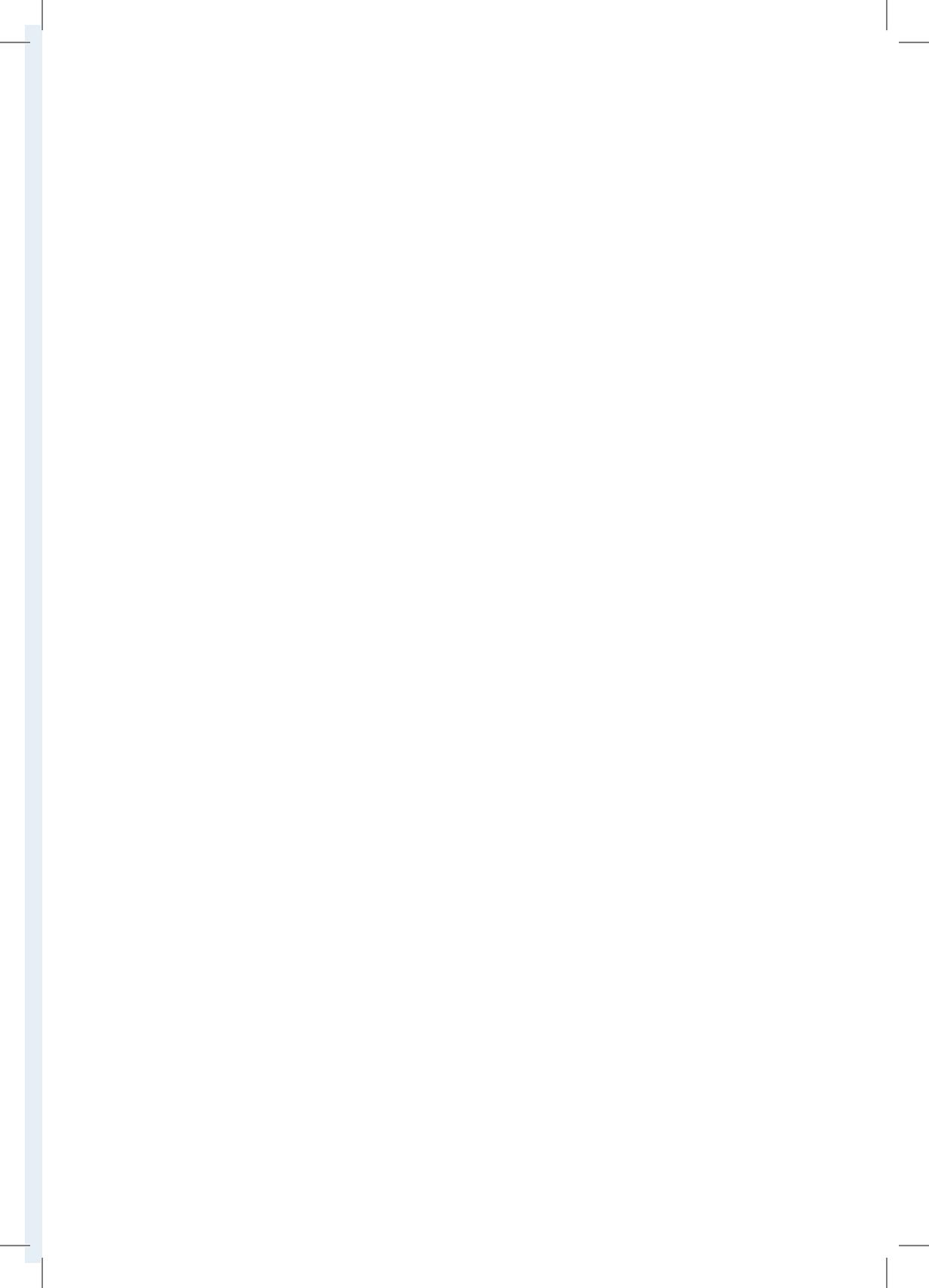


Refer to the Keeler Cryomatic MKII Cryosurgical System user instructions.



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