ArcRoyal Ltd

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10-200759 Rev00

Sterilisation Instruction Package Insert

These instructions are provided as a guide to procedure pack producers, who must sterile the following non-sterile Medical Devices from O&M Halyard, prior to release to the end user:

AR-LHCBNS	ArcRoyal Light Handle Cover non sterile
AR-26001NS	ArcRoyal Skin Marker Standard Tip non sterile
AR-26002NS	ArcRoyal Skin Marker Fine Tip non sterile
AR-32200NS	ArcRoyal Electrosurgical Tip Cleaner non sterile

The Ethylene Oxide (EO) sterilisation parameter ranges summarised below represent those tested and validated by ArcRoyal for EO sterilisation of their Medical Devices. This EO sterilisation cycle has been validated using the Half Cycle Approach described in Annex B of BS EN ISO 11135:2014+A1:2019 Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices.
The parameters required for sterilisation may vary depending on cycle design, load configuration, and packaging system. The validated sterilisation cycle supports ArcRoyal Medical Devices that:

1) Exhibit case densities less than or equal to 141.5kg/m^3
2) Are packaged in Form-Fill-Seal or Clear Header Bag sterile barrier systems
3) Are processed in 16 and 32 Euro Pallet load configurations

ArcRoyal recommends that procedure pack producers select and validate their sterile barrier system and packing design in accordance with the requirements of BS EN ISO 11607-1:2020+A1:2023 Packaging for terminally sterilized medical devices — Requirements for materials, sterile barrier systems and packaging systems and BS EN ISO 11607-2:2020+A1:2023 Packaging for terminally sterilized medical devices — Validation requirements for forming, sealing and assembly processes.

ArcRoyal recommends that procedure pack producers select and validate their load configuration, microbiological and Physical Performance Qualification in accordance with BS EN ISO 11135:2014+A1:2019 Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices. It is the responsibility of the procedure pack producer to ensure sterility assurance of all components within the pack.

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ArcRoyal Medical Devices are qualified for 1 EO sterilisation cycle only. ArcRoyal medical devices are intended for single use following sterilisation and should not be sterilised by any other method.

Sterilisation Compatibility
Method: 100% Ethylene Oxide
Reference table

Parameter	**Tolerance**
Preconditioning Temperature	40-56°C
Preconditioning Humidity	45 – 75%
Preconditioning Time	12-96 hours
Chamber Temperature	40-56°C
Chamber Vacuum Depth	45-55mbarA
Gas Dwell Pressure Range	965-999mbarA
Gas Dwell Time	3hrs 50min – 5hrs
Aeration Temperature	42-56°C
Aeration Time	12-96 hours
Ethylene Oxide Residuals	Must meet limits specified in ISO10993-7:2008+A1:2022

CH REP	Best Care Consulting GmbH Kehlhofrain 12a CH-6043 Adligenswil Switzerland ar@ch-rep.com
UK RP	RLD Quality Limited, Centenary House, Peninsula Park, Rydon Lane, Exeter, Ex2 7XE, United Kingdom