



Canaliculus Intubation Set Specification Sheet



Product Overview

- Complete set for silicone intubation procedures
- Probe length 185mm, silicone tube length 300mm
- No olive tip
- Supplied sterile, single use only, one per box, declared 5 year shelf life
- Manufactured in the UK

Product

Code

Canaliculus Intubation Set

51-920

Material Specification

Product Component

Specification

Probe shank	T302 S26 Austenitic Stainless Steel
Silicone Tubing	100% medical grade silicone. Meets USP Class VI, suitable for long term implantation.
Pouch	Tyvek/Film
Outer Box/Carton Packaging	500 Micron White Boxboard



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Intended Use

Crawford Intubation and Canaliculus Intubation Sets are intended for silicone intubation procedures. The device provides a means of restoring the patency of the lacrimal system.

Instructions for Use

The instructions for use and suggested surgical technique are supplied in the form of a multi-lingual leaflet with instructions given in diagram form where appropriate. The international symbols used on the packaging are explained in each language. A leaflet is supplied with each product.

Sterilisation

Products are sterilised by Gamma irradiation from a Cobalt 60 source in accordance with a validated 25 kGy cycle. Sterilisation is carried out in accordance with the requirements of ISO 11137-1 (current) and 11137-2 (current) and the 25 kGy dose is substantiated by VD₂₅ Method Max testing.

Conformity to the European Directives

Canaliculus Intubation sets are disposable medical devices which are surgically invasive in a body orifice and Intended for long term use. The Classification therefore is IIb according to rule 8 of Annex IX of the Medical Devices Directive 93/42/EEC.