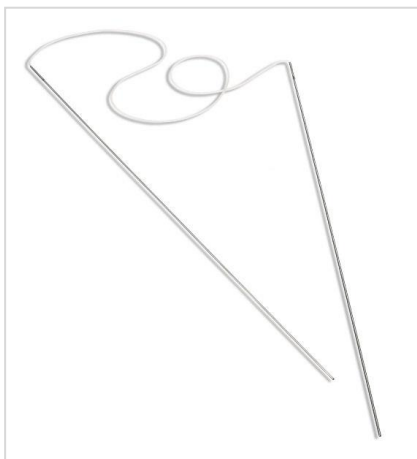


Canaliculus Intubation Set Specification Sheet



Product Overview

- Complete set for silicone intubation procedures
- Probe length 114mm, silicone tube length 300mm
- 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

Canaliculus Intubation Set Specification Sheet

Intended Use

Crawford Intubation and Canaliculus Intubation Sets are intended for silicone intubation procedures.

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.