Crawford Type Intubation Set Specification Sheet

Product Overview

- Complete set for Dacryocystorhinostomy, supplied with retrieval device included
- Retrieval device also available separately (51-917) as box of 5
- Probe length 150mm, silicone tube length 320mm, Retrieval device 105mm length
- Olive Tip
- Supplied sterile, single use only, one per box, declared 5 year shelf life
- Manufactured in the UK

Product	Code
Crawford-type Intubation with Retrieval Device	51-918
Retrieval Device	51-917

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Material Specification

Product Component	Specification
Probe teardrop	Solder 96.2% Sn / 3.8% Ag Eutecrod 157
Probe shank	304V Austenitic Stainless Steel
Silicone Tubing	100% medical grade silicone. Meets USP Class VI, suitable for long term implantation.
Retrieval device shank	316 (AISI) Stainless Steel
Retrieval device handle	Polypropylene
Pouch	Tyvek/Film
Outer Box/Carton Packaging	500 Micron White Boxboard

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 VD_{25} Method Max testing.

Conformity to the European Directives

Crawford Type 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.

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