

Crawford-type Intubation Set Specification Sheet



Product Overview

- Complete set for Dacryocystorhinostomy, supplied with retrieval device included
- Probe length 150mm, silicone tube length 320mm, Retrieval device 105mm length
- 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	52-208



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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 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 multilingual 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

Canaliculus Intubation sets are disposable medical devices which are invasive in a body orifice (non-surgically) and intended for long term use. The Classification therefore is IIb according to rule 5 of Annex IX of the Medical Devices Directive 93/42/EEC.