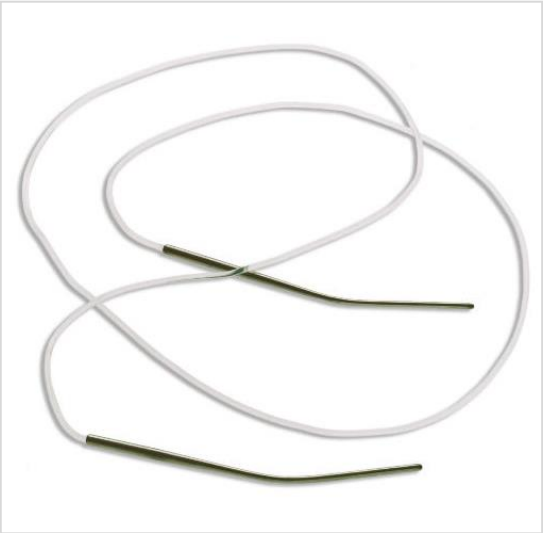
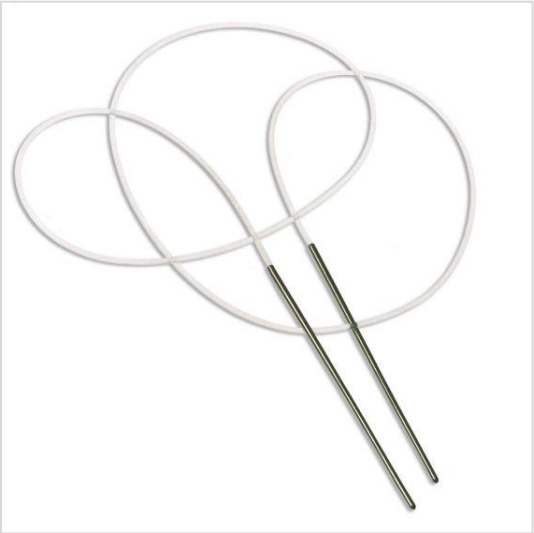
DCR Bodkins Specification Sheet





Product Overview

- Bodkin length 45 mm with 20 gauge, silicon rod length 400 mm
- Available in straight or angled format
- Supplied sterile, single use only, three per box, declared 5 year shelf life

Product	Code
DCR Bodkin Straight	51-922
DCR Bodkin Angled	51-923

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Material Specification

Product Component	Specification
Needle	304V Austenitic Stainless Steel
Silicone Tubing	100% medical grade silicone
Pouch	Tyvek/Film
Outer Box/Carton Packaging	500 Micron White Boxboard

Intended Use

DCR Bodkins are intended for probing and /or silicone intubation during a dacryocystorhinostomy (DCR) procedure. Dacryocystorhinostomy (DCR) surgery is a procedure that aims to eliminate fluid and mucus retention within the lacrimal sac, and to increase tear drainage for relief of epiphora (water running down the face). A DCR procedure involves removal of bone adjacent to the nasolacrimal sac and incorporating the lacrimal sac with the lateral nasal mucosa in order to bypass the nasolacrimal duct obstruction. This allows tears to drain directly into the nasal cavity from the canaliculi via a new low-resistance pathway.

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

DCR Bodkins are disposable surgically invasive surgical instruments intended for short-term use. The Classification therefore is IIa according to rule 7 of Annex IX of the Medical Devices Directive 93/42/EEC.

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