

CORONET

Artificial Anterior Chamber Specification Sheet



Product Overview

The CORONET® Artificial Anterior Chamber provides a versatile one size fits all solution for a variety of donor tissue preparation methods.

- Supplied with two tissue retaining heads (small 14.5mm-16.0mm, large 16.0mm-18.00mm)
- Single chamber design can be adapted to fit graft tissue between 14.5mm and 18.0mm
- Provides improved approximation between the donor button and patient cornea
- Designed to allow required intraocular pressure to be recreated
- Constructed to provide a leak free chamber
- Graticule cross hairs for improved precision
- Suitable for use with both manual trephines and femto-second lasers
- Weighted and broad base gives a stable platform
- Supplied sterile, single use only, one per box, declared 5 year shelf life
- Manufactured in the UK

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Product	Pack Size	Code
Artificial Anterior Chamber- One size fits all	1 per box with x2 tissue retaining heads	51-935

Material Specification

Product Component	Specification
Chamber Body	ABS
Compression Ring	ABS
Tissue Retaining Heads	MAKROLON Polycarbonate
Blister Packaging	0.7mm PETG Blister/ TYVEK Lid (122mm x 188mm)
Outer Box/Carton	500 Micron Printed White Boxboard

Intended Use

The CORONET® Artificial Anterior Chamber allows the donor cornea to be secured accurately and for the tissue to be supported on a reservoir of balanced salt solution or viscoelastic, the pressure of which can be varied according to the requirements of the procedure. The donor button can then be cut through the epithelial surface and the incision directly mirrors the cut on the recipient cornea. The chamber may also be used to hold the donor cornea for lamellar 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 Ethylene Oxide (EO) according to a validated cycle and the requirements of BS EN ISO 11135-1 (current).

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Conformity to the European Directives

The CORONET® Artificial Anterior Chamber is non-invasive to the body intended for transient use for storing corneal tissue but supplied sterile for single use only and is therefore classified as a Class IIa Sterile device (Rule 2, Annex IX 93/42/EEC Medical Devices Directive).