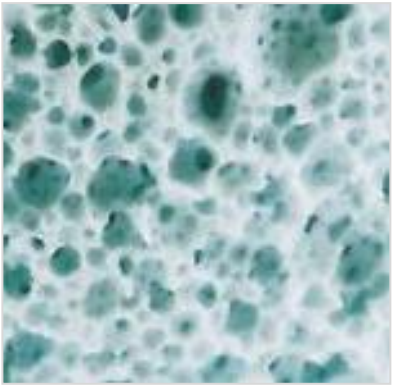
CORONET

Hydroxyapatite Orbital Implants Specification Sheet



Product Overview

All CORONET® Hydroxyapatite Orbital Implants have a 100% interconnected micro pore structure, which provides an ideal surface area for absorption of biomolecules, essential for cellular attachment and infiltration.

- Ultra-high porosity (80%>)
- Constructed with 100% medical grade synthetic Hydroxyapatite (HA)
- Recommended for PEG procedures for oculoplastic prosthesis.
- Supplied sterile, single use only, one per pack, 5 year declared shelf life

Orbital Implant Options

Size (mm)	**54-300** 100% medical grade synthetic hydroxyapatite (HA)
14.00	54-300-14.00
16.00	54-300-16.00
17.00	54-300-17.00
18.00	54-300-18.00
19.00	54-300-19.00
20.00	54-300-20.00
21.00	54-300-21.00
22.00	54-300-22.00

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Material Specification

Product Component	Specification
Implant	100% medical grade synthetic hydroxyapatite (HA)
Pouch	Inner Pouch, Outer Pouch - poly/tyvek peel pouch
Shelf Carton	500 micron Printed White Boxboard

Intended Use

The Orbital Implant is intended for use as a primary orbital implant at the time of enucleation or evisceration procedures, or as a secondary/exchange implant for later socket reconstructive surgery. It is not intended for any other purpose.

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

The devices have been classified as Class III, in accordance with Annex IX of the 93/42/EEC Medical Devices Directive., as they are manufactured utilising animal tissues or derivative which are rendered non-viable during the process – i.e. one of the minor (but crucial) transient processing aids is derived from an animal substance (Rule 17).

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