



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 374572 Dynek Pty Ltd - Monovek® - Suture, polydioxanone

ARTG entry for	Medical Device Included Class III
Sponsor	Dynek Pty Ltd
Postal Address	PO Box 2346, PORT ADELAIDE, SA, 5015 Australia
ARTG Start Date	13/09/2021
Product Category	Medical Device Class III
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
 - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Dynek Pty Ltd	9 Circuit Drive HENDON, SA, 5014 Australia

Products

1 . Monovek® - Suture, polydioxanone

Product Type	Single Device Product	Effective Date	13/09/2021
GMDN	16584 Suture, polydioxanone		
Functional Description	Suture, absorbable, synthetic, monofilament, absorption by hydrolysis providing consistent absorption irrespective of patient health		
Intended Purpose	Surgical procedures for tying off, ligation and/or tissue approximation, including ophthalmic surgery.		
Variant information	Suture, colour Violet Suture, needle, physical attributes Needle Curvature: 3/8 Circle Suture, needle, physical attributes Needle Curvature: 1/2 Circle Suture, needle, physical attributes Needle Curvature: 4/5 Circle Suture, needle, physical attributes Needle Profile: Reverse Cutting Suture, needle, physical attributes Needle Profile: Round Bodied Taper Suture, needle, physical attributes Needle Profile: Round Bodied Blunt Point Suture, needle, physical attributes Needle Profile: Reverse Premium Cutting Point Suture, needle, physical attributes Needle: Round Bodied - Blunt Taper Point - Heavy Suture, needle, physical attributes Needle Profile: Round Bodied - Blunt Taper Point Suture, needle, physical attributes Needle Profile: Conventional Cutting Suture, needle, physical attributes Needle Profile: Fish hook round bodied taper Suture, needle, physical attributes Needle Profile: Conventional Cutting - Heavy Suture, needle, physical attributes Needle Curvature: 5/8 Circle Suture, needle, physical attributes Needle		

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Therapeutic Goods Administration

Curvature: N/A (Straight)
Suture, needle, physical attributes Needle length:
10mm - 260mm
Suture, needle, physical attributes No Needle
(precut length)
Suture, needle, physical attributes Needle Profile:
Diamond Point
Suture, needle, physical attributes Needle: Round
Bodied Cutting Tip (A-cute®) - Heavy
Suture, needle, physical attributes Needle Profile:
Round Bodied Cutting Tip (A-cute®)
Suture, needle, physical attributes Needle Profile:
Fineline® Cutting
Suture, needle, physical attributes Needle Profile:
Round Bodied Taper - Heavy
Suture, needle, physical attributes Needle Profile:
Straight Cutting
Suture, needle, physical attributes Needle Profile:
Reverse Cutting - Heavy
Suture, needle, physical attributes Needle Profile:
Special Cutting
Diameter (mm) 0.050 - 0.610
Length (cm) 30 - 150
Suture, needle, physical attributes Needle Profile:
Straight Round Bodied Taper

Specific Conditions

No Specific Conditions included on Record

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