NYLENE®

EN

Monofilament Nylon
NON – ABSORBABLE Suture

Classification IIb

Colour Coding — Suture pack - Green, Thread – Dark Blue
Needle Image / Length — 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in mm

- Round Bodied Taper
- Conventional Cutting
- Reverse Cutting
- Blunt
- Straight Cutting
- Special Point
- A-Cute® (RB Cutting Tip)
- Lancet-Spatula (side cutting)
- Fineline® (to be used with Gilles needle holder)
- Premium Cutting Point (PCP)

CV300 — Unique Stainless Steel Material (high bending resistance, yet flexible when bent)
Met — Refers to the thread diameter in 1/10mm. The number above Met (eg. 2/0) explains the thread size in USP / BP.

Expiry Date (year, month)
LOT — Refers to the batch number and allows full traceability.
STERILE R — Sterile
Method of sterilisation
R = gamma irradiation
Do not reuse
See instructions for use / Warnings

Description - Nylene® suture is a monofilament of polyamide nylon 6. The suture is untreated and supplied as either clear (undyed) or dark blue (coloured with FD & C Blue # 2). The material is non-absorbable.

Actions - As with other synthetic sutures, Nylene® may cause minimal tissue reaction.

Indications - Nylene® suture should only be used in surgical procedures requiring a non-absorbable suture or ligature.

Contraindications - None

⚠ **Warnings -** Nylene® sutures are supplied sterile and are single use only devices. Nylene® sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened.**

⚠ Nylene® sutures are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non-absorbable sutures before employing Nylene®.

⚠ All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instruction for use, remains that of the user.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to grasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Nylene® sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 6/0 to 2 (Metric 0.7. to 5). Other sizes may be available upon request.

Storage - Nylene® sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained.

® Registered trademark of Dynek Pty Ltd

DYSILK®

EN

Braided Treated Silk
NON – ABSORBABLE Suture

Classification IIb

Colour Coding — Suture pack - Light Blue, Thread - Black
Needle Image / Length — 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in mm

- Round Bodied Taper
- Conventional Cutting
- Reverse Cutting
- Blunt
- Straight Cutting
- Special Point
- A-Cute® (RB Cutting Tip)
- Lancet-Spatula (side cutting)
- Fineline® (to be used with Gilles needle holder)
- Premium Cutting Point (PCP)

CV300 — Unique Stainless Steel Material (high bending resistance, yet flexible when bent)
Met — Refers to the thread diameter in 1/10mm. The number above Met (eg. 2/0) explains the thread size in USP / BP.

Expiry Date (year, month)
LOT — Refers to the batch number and allows full traceability.
STERILE — Sterile
STERILE R — Method of sterilisation
R = gamma irradiation
Do not reuse
See instructions for use / Warnings

Description - Dysilk® suture is a braided multifilament of silk filaments. Dysilk® suture is supplied as either black (coloured with Logwood Extract or white (undyed). Dysilk® suture is supplied wax treated. Dysilk® suture is non-absorbable.

Actions - Dysilk® may cause minimal tissue reaction.

Indications - Dysilk® sutures should only be used in surgical procedures requiring a non-absorbable suture or ligature.

Contraindications - None

⚠ **Warnings -** Dysilk® sutures are supplied sterile and are single use only devices. Dysilk® sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened.**

⚠ Dysilk® sutures are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non-absorbable sutures before employing Dysilk®.

⚠ All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instruction for use, remains that of the user.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to grasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Dysilk® (black or white/ undyed) sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 7/0 to 5 (Metric 0.5. to 7). Other sizes may be available upon request.

Storage - Dysilk® sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained.

® Registered trademark of Dynek Pty Ltd

DYLOC®

EN

Monofilament Polyether
NON-ABSORBABLE Suture

Classification IIb

Colour Coding — Suture pack - Teal, Thread - Light Blue
Needle Image / Length — 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in mm

- Round Bodied Taper (RBT)
- Blunt
- Reverse Cutting
- Straight cutting
- Conventional Cutting
- Lancet-Spatula (side cutting)
- A-Cute® (RB Cutting Tip)
- Special Point
- Fineline® (to be used with Gilles needle holder)
- Premium Reverse Cutting Point (PCP)

CV300 — Unique Stainless Steel Material (high bending resistance, yet flexible when bent)
Met — Refers to the thread diameter in 1/10mm. The number above Met (eg. 2/0) explains the thread size in USP / BP.

Expiry Date (year, month)
LOT — Refers to the batch number and allows full traceability.
STERILE — Sterile
Method of sterilisation
R = gamma irradiation
Do not reuse
See instructions for use / Warnings

Description - Dyloc® suture is a monofilament of a thermoplastic polyether-ester elastomer. The suture is untreated and supplied as light blue using an FDA approved colouring agent. The material is non-absorbable.

Actions - As with other synthetic sutures, Dyloc® may cause minimal tissue reaction.

Indications - Dyloc® suture should only be used in surgical procedures requiring a non-absorbable suture.

Contraindications - None

⚠ **Warnings -** Dyloc® sutures are supplied sterile and are single use only devices. Dyloc® sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened**.

⚠ Dyloc® suture are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non-absorbable sutures before employing Dyloc®.

⚠ All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instruction for use, remains that of the user.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to grasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

As Dyloc® suture has elastic properties, care should be taken when using it as a subcuticular stitch. Dyloc® suture should not be pulled tightly or over stretched as it may recoil when being removed.

To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Dyloc® sutures are supplied in various sizes and lengths with pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 6/0 to 2 (Metric 0.7. to 5). Other sizes may be available upon request.

Storage - Dyloc® sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained.

® Registered trademark of Dynek Pty Ltd

RADENE®

EN

Monofilament Polyvinylidene Fluoride (PVDF)
NON-ABSORBABLE Suture

Classification III

Colour Coding — Suture pack - Rust, Thread - Yellow

Needle Image / Length — 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in mm

- Round Bodied Taper
- Conventional Cutting
- Reverse Cutting
- Blunt
- Straight Cutting
- Special Point
- A-Cute® (RB Cutting)
- Lancet-Spatula (side cutting)
- Fineline® (to be used with Gilles needle holder)
- Premium Cutting Point (PCP)

CV300 — Unique Stainless Steel Material (high bending resistance, yet flexible when bent)

Met — Refers to the thread diameter in 1/10mm. The number above Met (eg. 2/0) explains the thread size in USP / BP.

Expiry Date (year, month)

LOT — Refers to the batch number and allows full traceability.

STERILE — Sterile

STERILE R — Method of sterilisation R = gamma irradiation

Do not reuse

See instructions for use / Warnings

Description - Radene® suture is a monofilament of polyvinylidene fluoride. The suture is untreated and supplied as a yellow colour using an FDA approved colouring agent. The material is non-absorbable.

Actions - Although physiologically inert, as with other synthetic sutures, Radene® may cause minimal tissue reaction.

Indications - Radene® sutures should only be used in surgical procedures requiring a non-absorbable suture or ligature.

Contraindications - None

⚠**Warnings -** Radene® sutures are supplied sterile and are single use only devices. Radene® sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened.**

⚠Radene® sutures are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non-absorbable sutures before employing Radene®.

⚠All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instruction for use, remains that of the user.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to grasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Radene® sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 11/0 to 5 (Metric 0.1 to 7). Other sizes may be available upon request. All Radene® sutures are sterilised by gamma irradiation.

25° **Storage -** Radene® sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained.

® Registered trademark of Dynek Pty Ltd

VILENE®

EN

Monofilament Polyvinylidene Fluoride (PVDF)
NON-ABSORBABLE Suture

Classification III

Colour Coding — Suture pack - Blue Bright, Thread - Blue

Needle Image / Length — 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in mm

- Round Bodied Taper
- Conventional Cutting
- Reverse Cutting
- Blunt
- Straight Cutting
- Special Point
- A-Cute® (RB Cutting Tip)
- Lancet-Spatula (side cutting)
- Fineline® (to be used with Gilles needle holder)
- Premium Cutting Point (PCP)

CV300 — Unique Stainless Steel Material (high bending resistance, yet flexible when bent)

Met — Refers to the thread diameter in 1/10mm. The number above Met (eg. 2/0) explains the thread size in USP / BP.

Expiry Date (year, month)

LOT — Refers to the batch number and allows full traceability.

STERILE — Sterile

STERILE R — Method of sterilisation R = gamma irradiation

Do not reuse

See instructions for use / Warnings

Description – Vilene® suture is a monofilament of polyvinylidene fluoride. The suture is untreated and supplied as deep blue using an FDA approved colouring agent. The material is non-absorbable.

Actions - Although physiologically inert, as with other synthetic sutures, Vilene® may cause minimal tissue reaction.

Indications - Vilene® suture should only be used in surgical procedures requiring a non-absorbable suture or ligature.

Contraindications - None

⚠**Warnings -** Vilene® sutures are supplied sterile and are single use only devices. Vilene® sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened.**

⚠Vilene® sutures are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non-absorbable sutures before employing Vilene®.

⚠All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instruction for use, remains that of the user.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to grasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Vilene® sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 11/0 to 5 (Metric 0.1 to 7). Other sizes may be available upon request. All Vilene® sutures are sterilised by gamma irradiation.

25° **Storage -** Vilene® sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained.

® Registered trademark of Dynek Pty Ltd

DYFLEX® - POLYFLEX® - TEFLEX®

Braided Siliconised Polyester
NON-ABSORBABLE Sutures

EN

Classification IIb

Colour Coding — **Dyflex®** Pack - Orange, Thread - Green
Polyflex® Pack - Orange, Thread - Black
Teflex® Pack - Orange, Thread - White

Needle Image / Length — 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in mm

- Round Bodied Taper
- Conventional Cutting
- Reverse Cutting
- Blunt
- Straight Cutting
- Special Point
- A-Cute® (RB Cutting Tip)
- Lancet-Spatula (side cutting)
- Fineline® (to be used with Gilles needle holder)
- Premium Cutting Point (PCP)

CV300 — Unique Stainless Steel Material (high bending resistance, yet flexible when bent)

Met — Refers to the thread diameter in 1/10mm. The number above Met (eg. 2/0) explains the thread size in USP / BP.

Expiry Date (year, month)

LOT — Refers to the batch number and allows full traceability.

STERILE 3 — Sterile
Method of sterilisation R = gamma irradiation

Do not reuse

See instructions for use / Warnings

Description – Dyflex®, Polyflex® and Teflex® sutures are braided multifilaments of polyester. All sutures are supplied siliconised. Dyflex® suture is green (coloured with D & C Green # 6), Polyflex® is black (coloured with Renol Black) and Teflex® is white (undyed).

Actions - As with other synthetic sutures, Dyflex®, Polyflex® and Teflex® may cause minimal tissue reaction.

Indications - Dyflex®, Polyflex® and Teflex® sutures should only be used in surgical procedures requiring a non-absorbable suture or ligature.

Contraindications - None

⚠**Warnings -** Dyflex®, Polyflex® and Teflex® sutures are supplied sterile and are single use only devices. Dyflex®, Polyflex® and Teflex® sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened.**

⚠Dyflex®, Polyflex® and Teflex® suture are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non absorbable sutures before employing Dyflex®, Polyflex® and Teflex®.

⚠All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instruction for use, remains that of the user.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to rasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Dyflex®, Polyflex® and Teflex® sutures are supplied in various sizes and lengths, with or without preattached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 6/0 to 5 (Metric 0.7. to 7). Other sizes may be available upon request.

25° **Storage -** Dyflex®, Polyflex® and Teflex® sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained.

® Registered trademark of Dynek Pty Ltd.

PLAIN SURGICAL CATGUT

Surgical Catgut
ABSORBABLE Suture
EN
Classification III
NB 0805

Colour Coding Suture pack - Yellow, Thread - Buff
Needle Image / Length 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in mm

- Round Bodied Taper
- Conventional Cutting
- Reverse Cutting
- Blunt
- Straight Cutting
- Special Point
- A-Cute® (RB Cutting Tip)
- Lancet-Spatula (side cutting)
- Fineline® Cutting
- Premium Cutting Point (PCP)

CV300 Unique Stainless Steel Material (high bending resistance, yet flexible when bent)

Met Refers to the thread diameter in 1/10mm. The number above Met (eg. 2/0) explains the thread size in USP

Expiry Date (year, month)

LOT Refers to the batch number and allows full traceability.

STERILE Sterile

STERILE R Sterile (Gamma)

Do not reuse

See instructions for use / Warnings

Description - Plain Surgical catgut sutures are manufactured from the intestinal serosa. The suture is supplied as a spun fiber that has been centreless ground and polished. Plain catgut is supplied untreated. Surgical catgut sutures are absorbable. Plain catgut is intended to be absorbed within 7 to 10 days. All catgut sutures are supplied in a solution of isopropanol / demineralised water. The catgut is only sourced from BSE Negligible Risk countries.

Actions - Plain Surgical Catgut sutures may cause tissue reaction.

Indications - Plain Surgical Catgut sutures should only be used in surgical procedures requiring an absorbable suture or ligature.

Contraindications - None

Warnings - Plain Surgical Catgut sutures are supplied sterile and are single use only devices. Plain Surgical Catgut sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened.**
Do not open the pack prematurely or do not leave the pack opened for a prolonged period of time, as the alcohol solution will evaporate.

Plain Surgical Catgut sutures are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving absorbable sutures before employing Plain Surgical Catgut.

All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instructions for use, remains that of the user.

WE DO NOT RECOMMEND THAT THIS SUTURE IS DIPPED, SOAKED OR RUN THROUGH ANY SOLUTIONS. Once it is removed from the packet, it should be used or discarded.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to grasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

For Plain Surgical Catgut sutures supplied with attached needles, to prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Plain Surgical Catgut sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 6/0 to 3 (Metric 1 to 7). Other sizes may be available upon request.

Storage – Plain Surgical Sutures should be stored at temperatures below 25 degrees Celsius at 50% relative humidity and away from direct heat and moisture to ensure that packaging integrity is maintained.

CHROMIC SURGICAL CATGUT

Surgical Catgut
ABSORBABLE Suture
EN
Classification III

Colour Coding Suture pack - Brown, Thread - Brown
Needle Image / Length 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in mm

- Round Bodied Taper
- Conventional Cutting
- Reverse Cutting
- Blunt
- Straight Cutting
- Special Point
- A-Cute® (RB Cutting Tip)
- Lancet-Spatula (side cutting)
- Fineline® Cutting
- Premium Cutting Point (PCP)

CV300 Unique Stainless Steel Material (high bending resistance, yet flexible when bent)

Met Refers to the thread diameter in 1/10mm. The number above Met (eg. 2/0) explains the thread size in USP.

Expiry Date (year, month)

LOT Refers to the batch number and allows full traceability

STERILE Sterile

STERILE R Sterile (Gamma)

Do not reuse

See instructions for use / Warnings

Description - Chromic Surgical Catgut sutures are manufactured from the intestinal serosa. The suture is supplied as a spun fiber that has been centreless ground and polished. Chromic Surgical Catgut is supplied chromicised (0.15 – 0.30%). Surgical catgut sutures are absorbable. Chromic Catgut is intended to be absorbed within 20 to 40 days. All catgut sutures are supplied in a solution of isopropanol / demineralised water. The catgut is only sourced from BSE Negligible Risk countries.

Actions - Chromic Surgical Catgut sutures may cause tissue reaction.

Indications - Chromic Surgical Catgut sutures should only be used in surgical procedures requiring an absorbable suture or ligature.

Contraindications - None

Warnings - Chromic Surgical Catgut sutures are supplied sterile and are single use only devices. Chromic Surgical Catgut sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened.**
Do not open the pack prematurely or do not leave the pack opened for a prolonged period of time, as the alcohol solution will evaporate.

Chromic Surgical Catgut sutures are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving absorbable sutures before employing Chromic Surgical Catgut.

All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instructions for use, remains that of the user.

WE DO NOT RECOMMEND THAT THIS SUTURE IS DIPPED, SOAKED OR RUN THROUGH ANY SOLUTIONS. Once it is removed from the packet, it should be used or discarded.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to grasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Chromic Surgical Catgut sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 6/0 to 3 (Metric 1 to 7). Other sizes may be available upon request.

Storage - Chromic Surgical Catgut sutures should be stored at temperatures below 25 degrees Celsius at 50% relative humidity and away from direct heat and moisture to ensure that packaging integrity is maintained.

Dynek Pty Ltd

EN

Instructions for Use
Absorbable Synthetic Suture
BIOVEK®
Braided Polyglycolic Acid (PGA) Suture

Classification: Class III
Colour Coding Suture pack - Violet, Thread – Violet, or Clear
Needle Image / Length 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (e.g. 35mm) = Stretched length of the needle (mm)
Length Thread length (cm)

EXPLANATION OF SYMBOLS ON THE PACKAGE

- Round Bodied Taper
- Conventional Cutting
- Reverse Cutting
- Blunt
- Straight Cutting
- Special Point
- A-Cute® (RB Cutting Tip)
- Lancet-Spatula (side cutting)
- Fineline® (to be used with Gilles needle holder)
- Premium Cutting Point (PCP)

CV300 Unique Stainless Steel Material (high bending resistance, yet flexible when bent)

USP Refers to thread diameter (e.g. 2-0) in the United States Pharmacopeia

Met Refers to the thread diameter in 1/10mm.

Expiry date: year/ month

LOT Lot number

See Instructions for Use / Warnings

Do not re-sterilise, do not re-use

STERILE Sterile.

STERILE EO Sterilisation method: ethylene oxide.

Keep away from sunlight

Do not use if primary package is damaged.

Store at not more than 25°C,

Protect from moisture

Date of manufacture

Manufacturer's name and address

EC REP Authorised Representative's name and address

DESCRIPTION

BIOVEK® suture is a synthetic absorbable suture based on Polyglycolic acid. The specification of **BIOVEK®** suture is USP size 8-0 ~ 3 (EP Metric 0.4 ~ 6).

BIOVEK® sutures coated with polycaprolactone and calcium stearate have been found to be inert, non-antigenic and non-pyrogenic. **BIOVEK®** sutures are available dyed (violet) and undyed.

BIOVEK® sutures comply with the requirements of USP and EP.

a) Raw material
Name Polyglycolic acid
Formula of Polyglycolic acid $(C_2H_2O_2)_n$
$(-O\text{-}CH_2\text{-}CO\text{-}O\text{-}CH_2\text{-}CO\text{-})_n$

b) Dyestuff
Name D&C Violet No.2
Chemical Name 1-Hydroxy-4-(*p*-tolylamino)-anthraquinone
Formula $C_{21}H_{15}NO_3$

c) Coating Material
Name Polycaprolactone + Calcium Stearate
Formula $(C_6H_{10}O_2)_n + C_{36}H_{70}O_4Ca$
$[(CH_2)_5\text{-}CO\text{-}O]_n + [CH_3\text{-}(CH_2)_{16}\text{-}CO\text{-}O]_2Ca$
Content of coating material 3~12wt% (depending on suture size)

INTENDED USE

BIOVEK® suture is indicated for use in general soft tissue approximation including ophthalmic surgery. **BIOVEK®** suture is not indicated for cardiovascular and neurological tissue approximation.

ACTIONS

BIOVEK® suture elicits a minimal tissue reaction and ingrowth of fibrous connective tissue.
Absorption of bioabsorbable sutures occurs by hydrolysis, beginning with loss of tensile strength followed by loss of mass. Absorption test in rats show that **BIOVEK®** suture retains approximately 70% of the original tensile strength after 2 weeks post-implantation and retains approximately 35% after 3 weeks. Absorption of **BIOVEK®** suture is essentially complete between 60 to 90 days.

CONTRAINDICATIONS

BIOVEK® suture is contraindicated where extended approximation of tissue under stress is required.

WARNING
Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.
If there is any breakage in the minimum (primary) package of the product, do not use it.
Do not re-sterilize.

PRECAUTIONS
Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds. **BIOVEK®** suture requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experiences of the surgeon. Skin sutures which remain in place longer than 7 days may cause localized irritation and should be snipped off or removed.

ADVERSE REACTIONS
Reported adverse reactions include inflammatory tissue reaction, localized irritation and wound separation.

STORAGE
Store packed product at below 25°C. Avoid moisture and direct heat. Do not use after expiry date!

HOW SUPPLIED
Coated **BIOVEK®** suture is available sterile, as braided dyed (violet) and undyed strands in sizes 8-0 through 3 (metric sizes 0.4 through 6) in a variety of lengths with or without needles. **BIOVEK®** suture is available in one or three dozen boxes.

Dynek Pty Ltd
Instructions for Use
Absorbable Synthetic Suture
MONOVEK®
Polydioxanone (PDO) Monofilament Suture

EN

EXPLANATION OF SYMBOLS ON THE PACKAGE

Colour Coding	Suture pack – Grey Thread – Violet, or beige (undyed)
Class III	Classification according to Medical Device Directive 93/42/EEC Annex IX Rule 8
Needle Image & Length (mm)	1/2 = 1/2 Circle needle 3/8 = 3/8 Circle needle
Length (cm)	Thread length in cm
● Round Bodied Taper	▲ Conventional Cutting
▼ Reverse Cutting	Blunt
▼ Straight Cutting	Special Point
A-Cute (RBT Cutting Tip)	Lancet-Spatula (side cutting)
Premium Cutting Point (PCP)	
Fineline (used with Gilles needle holder)	

CV300 Unique Stainless Steel Material (high bending resistance, yet flexible when bent)
USP thread diameter (e.g. 2-0) according to US Pharmacopeia
Metric x10 thread diameter (mm) according to European Pharmacopoeia

CE 0297	CE-Mark and Identification Number of the Notified Body. Product conforms to the Essential Requirements of the Medical Device Directive 93/42/EEC
LOT	Lot number
	Expiry Date: year / month
STERILE	Sterile
STERILE EO	Sterilized using ethylene oxide
	Do not re-use
	Caution
REF	Reference number
	Do not use if package is damaged.
EC REP	Authorised EU Representative
	Date of manufacture
	Manufacturer's name and address
	Recyclable materials
25°	To ensure that the integrity of the packet is maintained the product should be stored at temperatures below 25°C, away from direct heat and moisture
	Do not resterilize
	Fragile, handle with care
	Consult Instructions For Use

DESCRIPTION
MONOVEK® is a synthetic absorbable monofilament suture composed of poly(*p*-dioxanone) (abbreviated as PDO) and is available dyed. When dyed, colour additives such as D&C Violet No. 2 are used.
MONOVEK® meets all the requirements of the European Pharmacopoeia (EP) for sterile synthetic absorbable monofilament sutures.

Raw material
Name: Poly(*p*-dioxanone)
Formula: $(-O-CH_2-CH_2-O-CH_2-C-)_n$

Dyestuff
Name: D&C Violet No. 2
Chemical name:1-hydroxy-4-(*p*-tolylamino)-anthraquinone
Formula: $C_{21}H_{15}NO_3$

INDICATIONS
MONOVEK® is indicated for use in general soft tissue approximation, including use in ophthalmology. **MONOVEK®** is not indicated for cardiovascular and neurological tissue approximation or microsurgery.

ACTIONS
MONOVEK® elicits a minimal tissue reaction and ingrowth of fibrous connective tissue. Absorption of bioabsorbable sutures occurs by hydrolysis, beginning with loss of tensile strength followed by loss of mass. Absorption tests in rats show that **MONOVEK®** retains approximately 75% of the original tensile strength at 2 weeks post-implantation, retains approximately 65% at 4 weeks, and retains approximately 50% at 7 weeks. Absorption of **MONOVEK®** is essentially complete after 6 months.

CONTRA-INDICATIONS
MONOVEK® is contra-indicated where extended approximation of tissue under stress is required and is not to be used in suturing of synthetic implants (i.e. synthetic grafts).

WARNINGS
Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.
If there is any damage to the primary package of the product, do not use it.
Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.
Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing **MONOVEK®** sutures for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) when selecting a suture.
The use of **MONOVEK®** sutures may not be advised in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.
As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.
As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.
As an absorbable suture, **MONOVEK®** sutures may act transiently as a foreign body.
Do not re-sterilize.

PRECAUTIONS
Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds. **MONOVEK®** requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Skin sutures which remain in place longer than 7 days may cause localized irritation and should be snipped off or removed.
Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated.
Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.
Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.
When working with **MONOVEK®** sutures and other suture material, care should be taken avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders, to the strand except when grasping the free end of the suture during an instrument tie.
To avoid damaging needle points and swage areas, grasp the needle in an area one – third (1/3) to one – half (1/2) of the distance from the attachment end to the point. Do not use needle holders or forceps to grasp the attaching part between the needle and the suture and do not use the deformed needle or broken needle. In the case of needle body broken, the residual part should be retrieved.
Waste disposal of **MONOVEK®** sutures should be in accordance with the sanitary management regulations of medicinal institutions.

ADVERSE REACTIONS
Reported adverse reactions include inflammatory tissue reaction, localized irritation and wound separation.
Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site.
Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result on the transmission of blood-borne pathogens.

DOSAGE AND ADMINISTRATION
Use as required.

STORAGE
Store packed product below 25°C in clean and well ventilated room with relative humidity not greater than 80%. Avoid moisture and heat. Do not use after expiry date!

HOW SUPPLIED
MONOVEK® is available sterile, as monofilament dyed (violet) and undyed (clear) strands in sizes USP 7-0 to USP 2 (metric sizes 0.5 to 5) in a variety of lengths with or without needles. **MONOVEK®** is available in one or three dozen boxes.

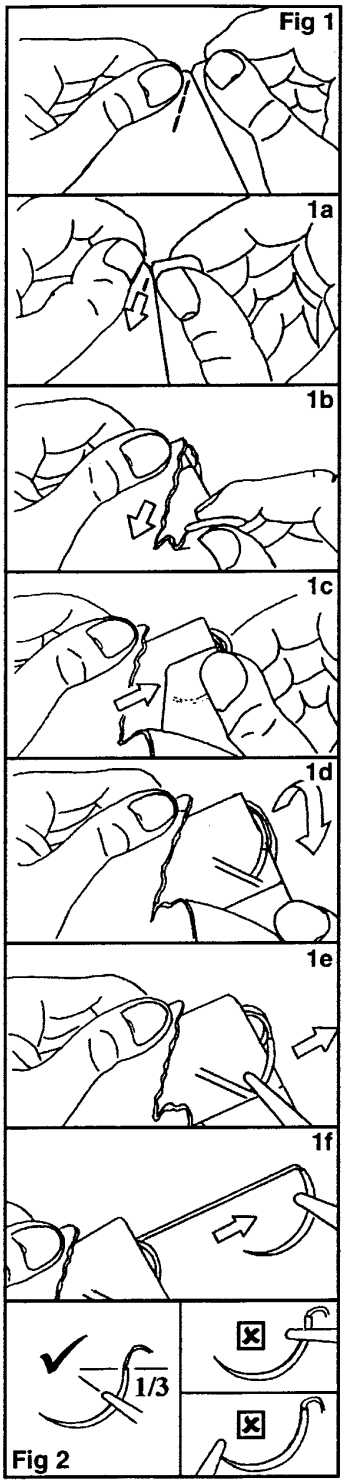
Fig 1
1a
1b
1c
1d
1e
1f
1/3
Fig 2