#### **DYCROM®** EN Monofilament Stainless Steel NON - ABSORBABLE Sutur

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CE Mark Colour Coding Needle Image / I Length (eg. • Round Bo	3/8 = 3/8 Circle needle 35mm) = Stretched length of the needle in mm
<ul> <li>Reverse C</li> <li>Straight C</li> <li>Convention</li> <li>Fineline®</li> </ul>	utting C Blunt nal Cutting M Special Cutting
C € 0297	
C C 0297	CE-Mark and Identification Number of the Notified Body Product conforms to the Essential Requirements of the
	Medical Device Directive 93/42/EEC
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/EP
$\Sigma$	
LOT	Expiry Date (year, month)
STERILE	Refers to the batch number and allows full traceability
STERILE R	Sterile
8	Method of sterilisation R = gamma irradiation Do not reuse
$\overline{\Lambda}$	Caution
REF	Reference number
ECREP	Do not use if package is damaged Authorised EU Representative
	·
	Date of manufacture
	Manufacturer's name and address
\$\$	Recyclable materials
	Do not resterilise
I	Fragile, handle with care
	Consult Instructions For Use
迷	Keep away from sunlight
	Keep dry
S Description	tore below 25°C

### Description

Dycrom® suture is a monofilament non-absorbable implantable surgical suture material made of high-grade surgical stainless steel AISI 316 LVM.

Dycrom<sup>®</sup> sutures are available in different lengths and diameters and are armed with single high-grade stainless steel needles of different types of points, lengths, and curves. Dycrom<sup>®</sup> sutures comply with the requirements of the US Pharmacopeia in terms of sterile, surgical suture materials.

Intended Use - Dycrom<sup>®</sup> sutures are indicated for use in procedures Intended for closing of the sternum, wound closure, cardiothoracic (Sternotomy) and orthopaedic surgery. To be used in procedures requiring a non-absorbable suture.

### Actions

Dycrom<sup>®</sup> sutures trigger a minimal acute inflamed reaction in the tissues. Absorption does not occur.

## Side-effects

The following side-effects can occur with the insertion of Dycrom<sup>®</sup> sutures: wound dehiscence, wound infections, allergic reactions in patients who are sensitive towards or allergic to high-grade steel AISI 316 LVM, slight acute inflamed reactions in the tissues a nd temporary local irritation.

### Indication

Dycrom<sup>®</sup> sutures are intended for the closing of the sternum, using surgical techniques by which means monofilament suture materials made of high-grade stainless steel are inserted. Dycrom<sup>®</sup> sutures are not indicated for use in the heart, the central

circulatory system and central nervous system.

## Contraindications

Dycrom<sup>®</sup> sutures are not approved for use in patients who are sensitive towards or allergic to the metals contained in the high-grade stainless steel AISI 316 LVM (iron, nickel, chromium and manganese, etc.). Dycrom<sup>®</sup> sutures are not indicated for use in the heart, the central circulatory system and central nervous system.

## Application

The needle and thread combination to be used is selected according to the condition of wound, patient, area or application, surgical technique being applied and corresponding with the experience of the surgeon.

# Warnings / Precautions

▲ Since the risk of wound dehiscence is dependent on the area of the body and suture material being inserted, the user should be familiar with surgical methods and techniques (especially with knot

techniques), by which means Dycrom® sutures are used for sealing wounds.

riangle In the event of drainage, or closure of infected or contaminated wounds, then generally acknowledged surgical techniques must be followed.

 $\triangle$  In general, when using Dycrom® sutures, you should ensure that the suture material is not damaged or squashed by surgical instruments such as forceps, needle-holders or tweezers, since this could result in negative changes in the tensile strength of the suture material and in its safety.

△ When using Dycrom<sup>®</sup> sutures, you should ensure that you do not damage either the point or armed end of the needle with surgical instruments like tweezers or needle holders, since otherwise this can cause the needle to bend or break. When separating needle from wire suitable forceps should be used and the separation must occur at a distance of at least 4 to 5cm from the end of the needle shaft. In general, surgical needles should be handled with meticulous care when in use in order to avoid needle-prick injuries to patient and user. Suitable containers must he used for the disposal of needles. containers must be used for the disposal of needles.

Tips on the sterility Dycrom® sutures are packed in units of 1-6 and supplied in a sterile state. If packaging is damaged the suture materials must not be used. With With unopened packs sterility is guaranteed to the expiry date on the pack.

Storage conditions Dycrom<sup>®</sup> sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained

<sup>®</sup> Registered trademark of Dynek Pty Ltd

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