Lietošanas instrukcija lv

PDS™ II
(POLIDIOKSANONS)
STERILS SINTĒTISKS ABSORBĒJAMS
ĶIRURĢISKAIS DIEGS

APRAKSTS

Uzsūkšanās ir minimāla līdz aptuveni 90. dienai pēc implantēšanas ... pabeigta laika posmā starp 182. un 238. dienu.

KONTRINDIKĀCIJAS

Šos ķirurģiskos diegus, kas ir absorbējami, nedrīkst lietot gadījumos, ... ilgstoša (ilgāka par sešām nedēļām) audu satuvināšana slodzes apstā... lietot kopā ar protēzēm (piemēram, sirds vārstuļiem vai sintētiskajām ...

BRĪDINĀJUMI/PIESARDZĪBAS PASĀKUMI/MIJIEDARBĪBA

Упатство за употреба mk

Gebruiksaanwijzing nl

Bruksanvisning no

...etreringsytelsen og forårsake nålfraktur. Hvis det holdes for langt bak på enden, kan ...e forårsake bøyning eller knekk. Hvis nåler må omformes, kan de miste styrken og bli ...dre resistente for bøyning og knekk. Brukerne skal utvise forsiktighet ved håndtering ...irurgiske nåler for å unngå uheldige nålstikkskader. Kast brukte nåler i beholderne ...ket "Skarpe gjenstander".
... ikke resteriliseres. Ikke bruk flere ganger. Gjenbruk av denne enheten (eller deler av ...ne enheten) kan føre til produktforringelse og krysskontaminering, som kan føre til ...ksjon eller overføring av blodbårne patogener til pasienter og brukere.

Instrukcja użytkowania pl

PDS™ II
NICI CHIRURGICZNE

Instruções de uso pt

PDS™ II
FIO DE SUTURA

Инструкция по использованию ru

PDS™ II
ШОВНЫЙ МАТЕРИАЛ

Návod na použitie sk

PDS™ II
CHIRURGICKÁ NIŤ

Navodila za uporabo sl

PDS™ II
KIRURŠKA NIT

Uputstvo za upotrebu sr

PDS™ II
KONAC

Bruksanvisning sv

PDS™ II
SUTUR

...blodtillförsel, eftersom bortstötning av suturen och försenad resorption kan förekomma.
Vid hanteringen av detta eller varje annat suturmaterial bör försiktighet iakttas för att undvika skada. Undvik skador som sammanpressning eller veckning orsakade av kirurgiska instrument som tänger eller nålförare.
Fullgod knutsäkerhet kräver kirurgisk standardteknik med kirurgknut och råbandsknop med extra slag beroende på kirurgiska omständigheter samt på kirurgens erfarenhet. Ytterligare slag kan vara lämpliga när man använder sig av en monofil sutur.
Iakttag försiktighet vid hanteringen av kirurgiska nålar för att undvika skada. Fatta nålen inom ett område som är en tredjedel (1/3) till hälften (1/2) av avståndet från infästningsänden till nålspetsen. Att fatta nålen nära spetsen försämrar penetrationen och kan leda till att nålen bryts. Att fatta nålen i övre änden vid infästningspunkten kan leda till att nålen böjs eller bryts. Omformning av nålar kan leda till att de förlorar i styrka och ...

= Varning: Se bruksanvisning
= Tillverkare
REF = Katalognummer
EC REP = Auktoriserad representant i Europeiska gemenskaperna

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Kullanım talimatları tr

PDS™ II
SÜTÜR

使用说明 zh-cn

PDS™ II
缝线

使用說明 zh-tw

PDS™ II
縫合線

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Germany

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PDS™ II

ar خيط جراحي
bg КОНЕЦ
cs ŠICÍ MATERIÁL
da SUTUR
de NAHTMATERIAL
el ΡΑΜΜΑ
en SUTURE
es SUTURA
et ÕMBLUSMATERJAL
fi OMMELAINE
fr FIL DE SUTURE
hr KIRURŠKI KONAC
hu VARRÓANYAG
it SUTURA
ko 봉합사
lt SIŪLAS
lv ĶIRURĢISKAIS DIEGS
mk ХИРУРШКИ КОНЕЦ
nl HECHTMATERIAAL
no SUTUR
pl NICI CHIRURGICZNE
pt FIO DE SUTURA
ru ШОВНЫЙ МАТЕРИАЛ
sk CHIRURGICKÁ NIŤ
sl KIRURŠKA NIT
sr KONAC
sv SUTUR
tr SÜTÜR
zh-cn 缝线
zh-tw 縫合線

08/2019
389806R05
LAB0012226v6

CE 2797

Instructions for use

en

PDS™ II
(POLYDIOXANONE)
STERILE SYNTHETIC, ABSORBABLE
SUTURE

DESCRIPTION
PDS™ II is a sterile synthetic absorbable monofilament suture made from the polyester poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_n$. Polydioxanone polymer has been found to be non-antigenic, non-pyrogenic and elicits only a slight tissue reaction during absorption.

PDS™ II sutures are dyed by adding D & C Violet No.2 (Colour Index number 60725) during polymerisation. Sutures are also available in the undyed form.

PDS™ II is available in a range of gauge sizes and lengths, attached to stainless steel needles of varying types and sizes. The needles may be attached permanently or as CONTROL RELEASE™ which enables the needles to be pulled off instead of being cut off. Full details of the product range are contained in the catalogue.

PDS™ II complies with all the requirements of the European Pharmacopoeia for Sterile Synthetic Absorbable Monofilament Sutures and the requirements of the United States Pharmacopoeia for Absorbable Surgical Sutures except for a slight oversize in diameter.

INDICATIONS
PDS™ II sutures are intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue, in microsurgery and in ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

APPLICATION
Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

PERFORMANCE
PDS™ II suture elicits a minimal initial inflammatory reaction in tissues and is eventually replaced with an in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of PDS™ II sutures occurs by means of hydrolysis, where the polymer degrades to the monomeric acid 2-hydroxyethoxyacetic acid which is subsequently absorbed and eliminated by the body. Absorption begins as loss of tensile strength followed by a loss of mass. Implantation studies in rats show the following profile:

DAYS IMPLANTATION	APPROXIMATE % ORIGINAL STRENGTH REMAINING M 1.5 (4-0) AND SMALLER	APPROXIMATE % ORIGINAL STRENGTH REMAINING M 2.0 (3-0) AND LARGER
14 days	60%	80%
28 days	40%	70%
42 days	35%	60%

Absorption is minimal until about the 90th post implantation day and is essentially complete between 182 and 238 days.

CONTRAINDICATIONS
These sutures, being absorbable, should not be used where prolonged (beyond six weeks) approximation of tissues under stress is required or in conjunction with prosthetic devices, for example, heart valves or synthetic grafts.

WARNINGS/PRECAUTIONS/INTERACTIONS
The safety and effectiveness of PDS™ II sutures have not been established in contact with the central nervous system, in adult cardiac tissue or in large vessels.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing PDS™ II suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Surgeons should consider the in vivo performance (under PERFORMANCE section) when selecting a suture. This suture may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

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 PDS™ II may act transiently as a foreign body.

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

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 distension, or which may require additional support.

Conjunctival, cuticular and vaginal epithelium sutures which remain in place longer than 10 days may cause localised irritation and should be snipped off or removed. Subcuticular sutures should be placed as deeply as possible to minimise the erythema and induration normally associated with the absorption process.

Under some circumstances, notably orthopaedic procedures, immobilisation of joints 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.

In handling this or any other suture material, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting any monofilament suture.

Care should be taken to avoid damage when handling surgical needles. 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. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in 'Sharps' containers.

Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of bloodborne pathogens to patients and users.

ADVERSE REACTIONS
Adverse reactions associated with this device include: transient local irritation at the wound site, transient inflammatory foreign body response and erythema and induration during absorption with subcuticular sutures. Like all foreign bodies PDS™ II may potentiate an existing infection.

STERILITY
PDS™ II sutures are sterilized by ethylene oxide gas.

Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

STORAGE
No special storage conditions required. Do not use after expiry date.

SYMBOLS USED ON LABELLING

= Do not reuse
= Number of units
= Use by – year and month
STERILE EO = Sterile unless package is damaged or opened. Method of sterilization: Ethylene Oxide
CE 2797 = CE-mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC
LOT = Batch number
= Caution: See instructions for use
= Manufacturer
REF = Catalogue Number
EC REP = Authorised Representative in the European Community

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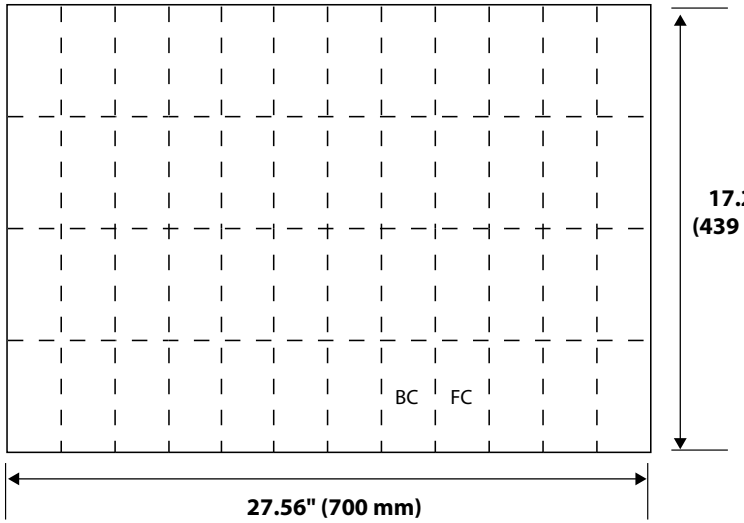
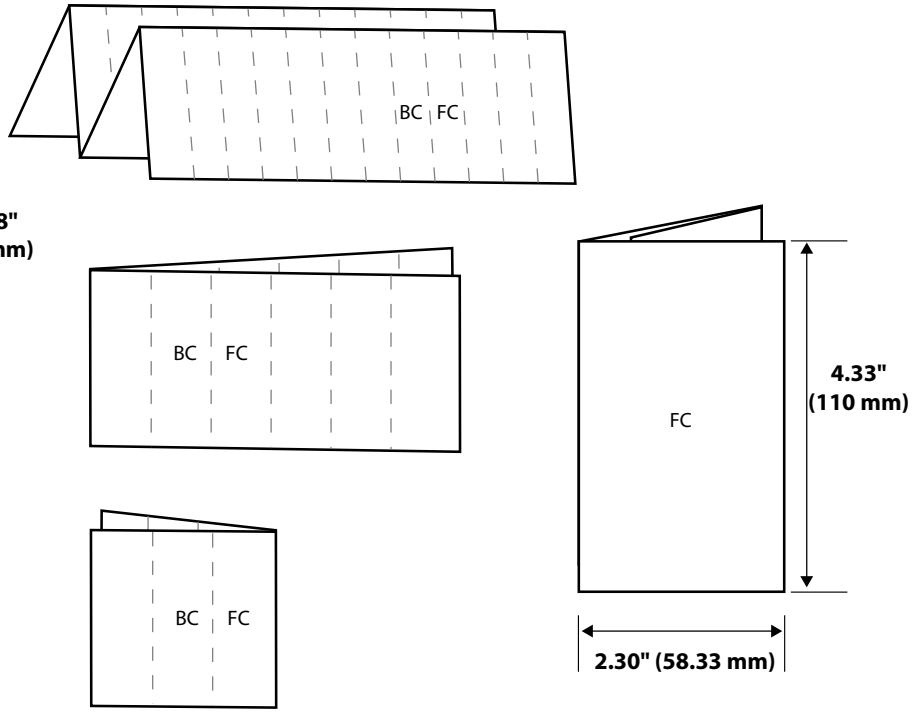
IFU PRINTING SPECIFICATION SHEET

PAGE LAYOUT



Flat Size

FOLD PATTERN



Folded Size

TITLE	DESCRIPTION	LAB NUMBER	SPECIAL INSTRUCTIONS/COMMENTS	BINDING	COLORS
PDS™ II	**Map IFU**	**LAB0012226v6**	**n/a**	**n/a**	**Black**

FLAT SIZE	FOLDED SIZE	RMC NUMBER	PAGE COUNT	LANGUAGES	SELF COVER	PLUS COVER	SEALING METHOD	WAFER SEAL
27.56" x 17.28" 700 mm x 439 mm	**2.30" x 4.33" 58.33 mm x 110 mm**	**389806R05**	**2**	**ar, bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, it, ko, lt, lv, mk, nl, no, pl, pt, ru, sk, sl, sr, sv, tr, zh-cn, zh-tw**	[X]	[ ]		[X]

BLEED SIZE .5" (12.7 mm)	.125" (3.175 mm)	NONE	BLEED ALL SIDES	BLEED TOP	BLEED RIGHT	BLEED LEFT	BLEED BOTTOM
[ ]	[ ]	[X]	[ ]	[ ]	[ ]	[ ]	[ ]

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STOCK
Opakal white CF, 50 g/m²

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