

# DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CADDESİ 91A ORTAHİSAR - TRABZON - TÜRKİYE

**CERRAHİ İPLİKLER, GEÇİCİ PACE TELLERİ VE EMİLEBİLİR HEMOSTAT  
TASARIMI, ÜRETİMİ VE SATIŞI**

kapsamında

## EN ISO 13485:2016

Uluslararası Tıbbi Cihazlar Kalite Yönetim Sistemi Standardına uygun bir yönetim sistemi kurmuştur.

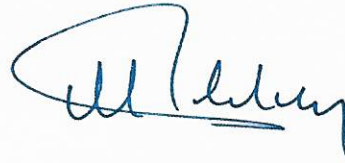
*"Standardın aşağıda verilen maddeleri hariç tutulmuştur"  
"7.5.3" "7.5.4"*

Sertifika No : M 11652  
İlk Belgelendirme Tarihi : 20 Şubat 2019  
Sertifika Tarihi : 05 Ocak 2022  
Son Geçerlilik Tarihi : 04 Ocak 2025

Kiwa Belgelendirme Hizmetleri A.Ş.  
İTOSB 9. Cadde No: 15 Tepeören Tuzla  
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[www.kiwa.com.tr](http://www.kiwa.com.tr)

Sertifikalar periyodik ara denetimlerin başarılı ile tamamlanması kaydıyla geçerlidir. Detaylı bilgi için yukarıdaki numaralara başvurulabilir.



Genel Müdür



# DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CADDESİ 91A ORTAHİSAR - TRABZON - TURKEY

DESIGN, PRODUCTION AND SALES OF SURGICAL SUTURES, TEMPORARY  
PACING WIRES AND ABSORBABLE HEMOSTAT

with a scope of

## EN ISO 13485:2016

Has established a management system in accordance  
with international Medical Devices Quality Management System Standard

*"Following elements of the standard are excluded"*

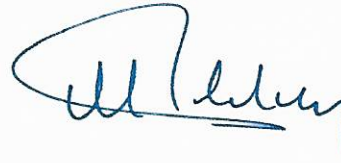
*"7.5.3" "7.5.4"*

Certificate No : M 11652  
Initial Certification Date : 20 February 2019  
Certification Date : 05 January 2022  
Expiration Date : 04 January 2025

Kiwa Belgelendirme Hizmetleri A.Ş.  
ITOSB 9. Cadde No. 15 Tepeören Tuzla  
Istanbul / Turkey

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Certificate is valid till expiration date,  
subject to successful completion of  
periodical surveillance audits.  
Please contact above numbers for  
detailed information.



General Manager



TÜRKAK BDS NO  
YS-6478-8BE3

## AT Sertifikası

### Tam Kalite Güvence Sistemi

### Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3

Sertifika Numarası: 1984-MDD-21-784

Aşağıda bahsi geçen kuruluşun tam kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-II (Bölüm 4 muaf tutularak) gereksinimlerine göre yapıldığını beyan ederiz. Tam kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

**Kuruluş:**

### DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CAD. 91A, ORTAHİSAR, TRABZON - TÜRKİYE

**Ürünler:** PEGELAK, PEGELAK rapid, PEGESORB, PEGESORB rapid, TROFİLEN, DAYLON, İPEK, PROPİLEN, POLİTER, TEKMON, PEDESENTE, TEKTEL, DOPACE, KANSTAT, DAXTON, ONTREX, xnat pedesente, xnat®tekmon

Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Bu sertifika kapsamında olan sınıf III ürünler için ayrıca Tıbbi Cihaz Yönetmeliği Tam Kalite Güvence Sistemi 93/42/AT Ek-II Bölüm 4 sertifikası da zorunludur.

**Rapor No:** M.6104.01

**Son Geçerlilik Tarihi:** 27 Mayıs 2024



Muhteşem Gökhan Yücel  
Onaylanmış Kuruluş Başkanı

17 Mayıs 2021, İstanbul, Türkiye

**AT Sertifikası Eki:**

**Tam Kalite Güvence Sistemi**

**Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3**

**Sertifika No: 1984-MDD-21-784**

İlgili tıbbi cihazlar;

**Ürün: PEGELAK®**

Poli(glikolid-ko-laktid) Emilebilir, Örgülü Cerrahi İplik

**Tipleri:** İğneli veya iğnesiz, Mor veya boyasız, kaplanmış

**Ürün: PEGELAK® rapid**

Poli(glikolid-ko-laktid) Emilebilir, Örgülü Cerrahi İplik

**Tipleri:** İğneli veya iğnesiz, boyasız, kaplanmış

**Ürün: PEGESORB®**

Poliglikolik Asit Emilebilir, Örgülü Cerrahi İplik

**Tipleri:** İğneli veya iğnesiz, mor veya boyasız, kaplanmış

**Ürün: PEGESORB rapid®**

Poli(glikolid-ko-laktid) Emilebilir, Örgülü Cerrahi İplik

**Tipleri:** İğneli veya iğnesiz, boyasız, kaplanmış

**Ürün: TROFİLEN®**

Poliviniliden florür Emilmeyen, Monofilaman Cerrahi İplik

**Tipleri:** İğneli (tek veya çift) veya iğnesiz

**Ürün: DAYLON®**

Poliamid Emilmeyen, Monofilaman Cerrahi İplik

**Tipleri:** İğneli (Tek veya çift)

**Ürün: İPEK®**

İpek Absorbe Olmayan, Örgülü, Kaplanmış Cerrahi İplik

**Tipleri:** İğneli (tek veya çift) veya iğnesiz



Muhtesem Gökhan Yücel  
Onaylanmış Kuruluş Başkanı

17 Mayıs 2021, İstanbul, Türkiye

**AT Sertifikası Eki:**

**Tam Kalite Güvence Sistemi**

**Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3**

**Sertifika No: 1984-MDD-21-784**

İlgili tıbbi cihazlar;

**Ürün: PROPİLEN®**

Polipropilen Emilmeyen, Monofilaman Cerrahi İplik

**Tipleri:** PTFE Pledget içeren ve içermeyen, İğneli (tek veya çift) veya iğnesiz

**Ürün: POLİTER®**

Poliester Absorbe olmayan, Örgülü, Kaplanmış Cerrahi İplik

**Tipleri:** PTFE Pledget içeren ve içermeyen, İğneli (tek veya çift) veya iğnesiz

**Ürün: TEKMON®**

Poli(glikolid-ko-kaprolakton) Emilebilir, Monofilaman Cerrahi İplik

**Tipleri:** Mor veya boyasız, İğneli (tek veya çift) veya iğnesiz

**Ürün: PEDESENTE®**

Emilebilir, Monofilaman Cerrahi İplik(Polidioksanon)

**Tipleri:** Mor veya boyasız, İğneli (tek veya çift) veya iğnesiz

**Ürün: TEKTEL®**

Cerrahi Paslanmaz Çelik Tel Sütür

**Tipleri:** Sabit veya döner başlıklı iğneli, Doğal-Metallik,Kaplanmamış/izolasyonsuz,

**Ürün: DOPACE®**

Geçici Pace Teli

**Tipleri:** Bükülü 316L paslanmaz çelik, izolasyonlu Çift iğneli, çapalı veya çapasız

**Ürün: KANSTAT®**

Emilebilir Hemostat (Okside Edilmiş Rejenere Selüloz)

**Tipleri:** KANSTAT® Orj

KANSTAT® Fabric

KANSTAT® Felt

KANSTAT® Fibril



Muhteşem Gökhan Yücel  
Onaylanmış Kuruluş Başkanı

17 Mayıs 2021, İstanbul, Türkiye

Kiwa Belgelendirme Hizmetleri A.Ş.

İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye

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**AT Sertifikası Eki:**

**Tam Kalite Güvence Sistemi**

**Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3**

**Sertifika No: 1984-MDD-21-784**

İlgili tıbbi cihazlar;

**Ürün: DAXTON®**

DAXTON® - D PTFE ve DAXTON® - K ePTFE

Emilmeyen, Monofilaman Cerrahi İplik

**Tipleri:** İğneli (tek veya çift) veya iğnesiz,

**Ürün: ONTREX®**

Polietilen Emilmeyen Multifilamen Cerrahi İplik ve Bant

**Tipleri:** İğneli (tek veya çift) veya iğnesiz

**Ürün: xnat®pedesente**

Düğümsüz Doku Kontrol Cihazı, Polidioksanon Emilebilir Monofilamen Çentikli İplik

**Tipleri:** tek yönlü veya çift yönlü, spiral veya spiral olmayan çentik tipli, ucu sabitleme çapalı veya ilmekli, iğneli veya iğnesiz, boyalı veya boyasız

**Ürün: xnat®tekmon**

Düğümsüz Doku Kontrol Cihazı, Poli(glikolid-ko-kaprolakton) Emilebilir

Monofilamen Çentikli İplik

**Tipleri:** tek yönlü veya çift yönlü, spiral veya spiral olmayan çentik tipli, ucu sabitleme çapalı veya ilmekli, iğneli veya iğnesiz, boyalı veya boyasız

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.



Muhteşem Gökhan Yücel  
Onaylanmış Kuruluş Başkanı

17 Mayıs 2021, İstanbul, Türkiye

**EC Certificate**  
**Full Quality Assurance System according to**  
**Medical Devices Directive 93/42/EEC Annex-II Section 3**

**Certificate Number: 1984-MDD-21-784**

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

**Organization:**

**DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.**

RİZE CAD. 91A, ORTAHİSAR, TRABZON - TURKEY

**Products:** PEGELAK, PEGELAK rapid, PEGESORB, PEGESORB rapid, TROFİLEN, DAYLON, İPEK, PROPİLEN, POLİTER, TEKMON, PEDESENTE, TEKTEL, DOPACE, KANSTAT, DAXTON, ONTREX, xnat pedesente, xnat®tekmon

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

**Report Number:** M.6104.01

**Expiry Date:** 27 May 2024



**Muhteşem Gökhan Yücel**  
Head of Notified Body

17 May 2021, Istanbul, Turkey

**Enclosure of the EC Certificate:  
Full Quality Assurance System according to  
Medical Devices Directive 93/42/EEC Annex-II Section 3  
Certificate Number: 1984-MDD-21-784**

Concerned medical devices;

**Product:** PEGELAK®

Poly(glycolide-co-lactide) Absorbable Braided Surgical Suture

**Types:** With or without Needles, Violet or Undyed, Coated

**Product:** PEGELAK®rapid

Poly(glycolide-co-lactide) Absorbable Braided Surgical Suture

**Types:** With or Without Needles, Undyed, Coated

**Product:** PEGESORB®

Polyglycolic Acid Absorbable Braided Surgical Suture

**Types:** With or Without Needles, Violet or Undyed, Coated

**Product:** PEGESORB®rapid

Polyglycolic Acid Absorbable Braided Surgical Suture

**Types:** With or Without Needles, Undyed, Coated

**Product:** DAYLON®

Polyamide Non-Absorbable Monofilament Surgical Suture

**Types:** with single/double needle(s)

**Product:** TROFİLEN®

Polyvinylidene Fluoride Non-Absorbable Monofilament Surgical Suture

**Types:** with single/double or without needle(s)

**Product:** İPEK®

Silk Non-Absorbable Braided Surgical Suture

**Types:** With single/double or without needle(s)

A handwritten signature in black ink, appearing to read "Muhteşem Gökhan Yücel".

Muhteşem Gökhan Yücel  
Head of Notified Body

17 May 2021, Istanbul, Turkey



**Enclosure of the EC Certificate:**  
**Full Quality Assurance System according to**  
**Medical Devices Directive 93/42/EEC Annex-II Section 3**  
**Certificate Number: 1984-MDD-21-784**

Concerned medical devices;

**Product: PROPİLEN®**

Polypropylene Non-Absorbable Monofilament Surgical Suture

**Types:** With or without needle(s), with or without PTFE Pledgets

**Product: POLİTER®**

Polyester Non-Absorbable Braided Surgical Suture

**Types:** With single/double or without needle(s), with or without PTFE Pledgets

**Product: TEKMON®**

absorbable monofilament surgical suture Poly(glycolide-co-caprolactone)

**Types:** Undyed or violet, with single/double or without needle(s)

**Product: PEDESENTE®**

absorbable monofilament surgical suture (Polydioxanone)

**Types:** Undyed or violet, with single/double or without needle(s)

**Product: TEKTEL®**

Surgical Stainless Steel Wire

**Types:** With fixed or Rotating Needle, Natural-Metallic, Noncoated/Nonsheated

**Product: DOPACE®**

Temporary Pacing Wire

**Types:** Twisted 316L stainless steel, insulated, with double needle, with or without anchor

**Product: KANSTAT®**

Absorbable Hemostat (Oxidized Regenerated Cellulose)

**Types:** KANSTAT® ORJ

KANSTAT® FABRIC

KANSTAT® FELT

KANSTAT® FIBRIL



Muhteşem Gökhan Yücel  
Head of Notified Body

17 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.  
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Turkey  
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Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

**Enclosure of the EC Certificate:  
Full Quality Assurance System according to  
Medical Devices Directive 93/42/EEC Annex-II Section 3  
Certificate Number: 1984-MDD-21-784**

Concerned medical devices;


**Product:** DAXTON®  
DAXTON®- D (PTFE) and DAXTON®- K (ePTFE)  
Non-Absorbable, monofilament surgical suture  
**Types:** with single/double or without needle(s)

**Product:** ONTRES®  
Polyethylene Non-absorbable Multifilament Surgical Suture and Tape  
**Types:** With needles (single or double) or without needles

**Product:** xnat®pedesente  
Knotless Tissue Control Device, Polydioxanone Absorbable Monofilament Barbed Suture  
**Types:** uni-directional or bi-directional, spiral or non-spiral barbed type, with a fixation tab or end-loop design, in a variety of lengths, with or without needles, violet or undyed

**Product:** xnat®tekmon  
Knotless Tissue Control Device, Poly (glycolide-co-caprolactone) Absorbable Monofilament Barbed Suture  
**Types:** uni-directional or bi-directional, spiral or non-spiral barbed type, with a fixation tab or end-loop design, in a variety of lengths, with or without needles, violet or undyed





Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhteşem Gökhan Yücel  
Head of Notified Body

17 May 2021, Istanbul, Turkey

## SPECIFICATIONS & PACKAGE

PRODUCT TYPE	SIZE, cmxcm	REF
<b>Kanstat® ORJ</b> 	1.25 x 5	KL02
	5 x 7.5	KL04
	5 x 35	KL06
	10 x 20	KL08
<b>Kanstat® FABRIC</b> 	2.5 x 2.5	KH02
	2.5 x 7.5	KH03
	5 x 7.5	KH04
	7.5 x 10	KH06
	15 x 22.5	KH08
<b>Kanstat® FELT</b> 	2.5 x 5	KW02
	5 x 10	KW04
	10 x 10	KW07
<b>Kanstat® FIBRIL</b> 	2.5 x 5	KB02
	5 x 10	KB04
	10 x 10	KB07

IKSTB 2/2020



**Doğsan Tıbbi Malzeme Sanayi A.Ş.**  
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Yıldız Caddesi 55, Besiktas 34353 ISTANBUL - TURKEY  
T: +90 (212) 258 00 54 • dogsan@dogsan.com.tr • www.dogsan.com.tr

# KANSTAT®

**OXIDIZED REGENERATED CELLULOSE  
ABSORBABLE HEMOSTAT**







## Kanstat® ORJ

Standard Use



- Good visibility of surgical site due to sheer knit structure
- High flexibility and drapeability
- Kanstat® is bactericidal in vitro against a wide range of microorganisms

## Kanstat® FABRIC

For Heavier Bleeding



- More dense than Kanstat® ORJ  
Suitable for heavier bleeding with faster hemostasis (incl. emergency and trauma)
- Density suitable for suturing
- No fabric memory effects

## Kanstat® FIBRIL

Improved Conformability



- Easy peels off in any thickness and quantity required
- High flexibility and conformability to surgical site (e.g. irregular shape of wound and hard to reach areas)
- Can be shaped or molded to various shapes for optimal adherence or used in multiple sites

## Kanstat® FELT

Maximized effect & superior handling (both open and laparoscopic surgery)



- Non-Woven structure increases surface contact to bleeding site
- More advanced conformability & superior handling
- Easy to deploy and manipulate in laparoscopic surgery

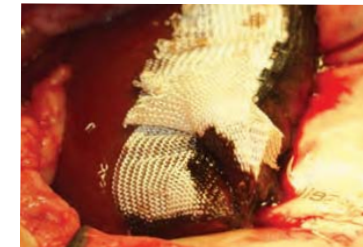
## EFFICACY TEST

hemostatic effect is proved in vivo

Proved to be effective achieving hemostasis after liver resection in porcine model



Spleen resection surgery



In porcine hepatic model

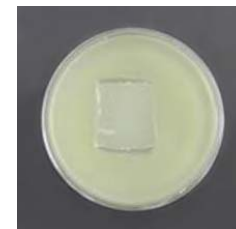


Liver resection surgery

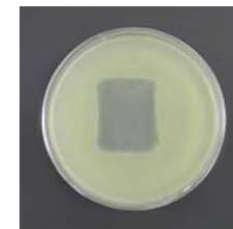
Kanstat® ORJ

## ANTIBACTERIAL EFFECT

helps to minimize risk of infection



Attached sample



After removal of the sample

Kanstat® has antibacterial activity in vitro against a broad spectrum of microorganisms including antibiotic resistant bacteria, such as methicillin resistant *Staphylococcus aureus* and methicillin resistant *Staphylococcus epidermidis*

- › Conforms to the requirements of USP United States Pharmacopeia "Oxidized Regenerated Cellulose (ORC)" standard
- › ORC Absorbable Hemostat has been long and widely used in a variety of surgeries
- › Plant derivative product with minimal tissue reaction
- › Does not contain human or animal originated tissue
- › Has antibacterial effect



**DOĞSAN**

# **SURGICAL SUTURES**

**Product Guide**



Surgical Sutures

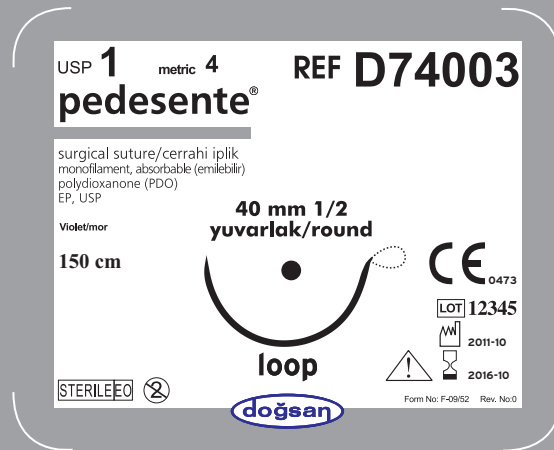




# Absorbable Sutures






# pedesente®









- Description:** Absorbable, synthetic, monofilament suture for long term wound support, ideal for slow healing wounds
- Characteristics:** Easy passage through tissue/smoothness of a monofilament  
High initial strength  
Slow decrease in tensile strength  
Minimal tissue reaction  
Ideal for long term support
- Long term wound support ( ~ 60 days)
- Tensile strength:** ~ 75 % after 2 weeks  
~ 60 % after 4 weeks  
~ 0 % after 10 weeks
- Absorption:** Essentially complete in 180-210 days
- Material :** polydioxanone, PDO 100%
- Structure:** Monofilament
- Colour :** Violet
- Sterilization:** EO
- Packaging:** Available in USP 7/0 (metric 0.5) through USP 2 (metric 5) in boxes of 12 (one dozen) aluminium pouches.






needle information	needle diameter	colour	suture length	0.5	0.7	1	1.5	2
				7/0	6/0	5/0	4/0	3/0

8 mm									
3/8 round bodied, double		220 μ	violet	75 cm	D0812				
		330 μ	violet	45 cm		D1812			
				75 cm		D1912			
3/8 round bodied		330 μ	violet	60 cm		D1872			
3/8 KD, double		330 μ	violet	30 cm		D181			

9 mm									
3/8 round bodied, double		200 μ	violet	75 cm	D0912				

10 mm									
3/8 cutting		330 μ	violet	45 cm		D103			
3/8 cutting, double		330 μ	violet	45 cm		D1032			

13 mm									
3/8 round bodied, double		220 μ	violet	45 cm	D0312				
		330 μ	violet	75 cm		D1312	D2312		
3/8 PL		380 μ	violet	45 cm		D139	D239		

16 mm									
1/2 round bodied			violet	75 cm			D2160	D3160	D4160
1/2 round bodied			violet	75 cm			D2161	D3161	
1/2 round bodied, double			violet	90 cm			D21602	D31602	
3/8 cutting			violet	75 cm			D2165	D3165	D4165
3/8 PL			violet	45 cm			D2169	D3169	

**propilen®**

polypropylene

**trofilen®**

polyvinylidene fluoride

**daylon®**

polyamide

**politer®**

polyester

**silk**

silk

**tektel®**

stainless steel wire

# Non-Absorbable Sutures





# propilen®

USP 7/0<sup>metric</sup> 0.5 REF P0814  
**propilen®**

surgical suture/cerrahi iplik  
monofilament, non-absorbable,  
polypropylene  
EP, USP

mavi/blue

60 cm

8 mm 3/8  
yuvarlak-round  
siyah-black



çift-double  
220 µ

CE<sup>0473</sup>

LOT 12345

2011-10

2016-10

TSEK  
STERILE



Form No: F-0935 Rev. No:2



**Description:** Non-Absorbable, monofilament suture, made of specially extruded condensed polypropylene, very smooth and ideal for cardio vascular surgery

**Characteristics:** Ideal suture for cardio vascular surgery  
Very smooth flow through the tissue  
Very high tensile strength  
High softness and flexibility  
Minimum tissue reaction, ideal for infected tissues  
Good knot security

**Tensile strength:** Permanent -Very high tensile strength

**Material :** polypropylene







**Structure:** Monofilament



**Colour :** Blue/Undyed (clear)







**Sterilization:** EO

**Packaging:** Available in USP 10/0 (metric 0.2) through USP 2 (metric 5) in boxes of 12 (one dozen) pouches.

needle information	colour	suture length	1	1.5	2	3	3.5
			5/0	4/0	3/0	2/0	0

20 mm								
1/2 round bodied		blue	75 cm	P2200	P3200	P4200	P5200	
1/2 round bodied, double		blue	90 cm	P22002	P32002	P42002		
	 black	blue	90 cm		P32004			
1/2 KD, double		blue	90 cm	P22072	P32072			
3/8 cutting		blue	45 cm	P2205	P3205	P4205		
3/8 cutting		blue	45 cm	P2203	P3203	P4203		
		blue	75 cm	P2213	P3213	P4213		

22 mm								
1/2 round bodied		blue	90 cm	P22202	P32202			
1/2 cutting		blue	45 cm			P4224		

25 mm								
1/2 round bodied		blue	75 cm		P3250	P4250	P5250	P6250
		undyed	75 cm			X4250		
1/2 round bodied, double		blue	90 cm		P32502	P42502	P52502	
	 black	blue	90 cm		P32504	P42504		
3/8 PL		blue	45 cm	P2259	P3259	P4259		
1/2 KD, double		blue	90 cm		P32572	P42572	P52572	
3/8 cutting		blue	45 cm		P3255	P4255	P5255	
		blue	75 cm		P3245			