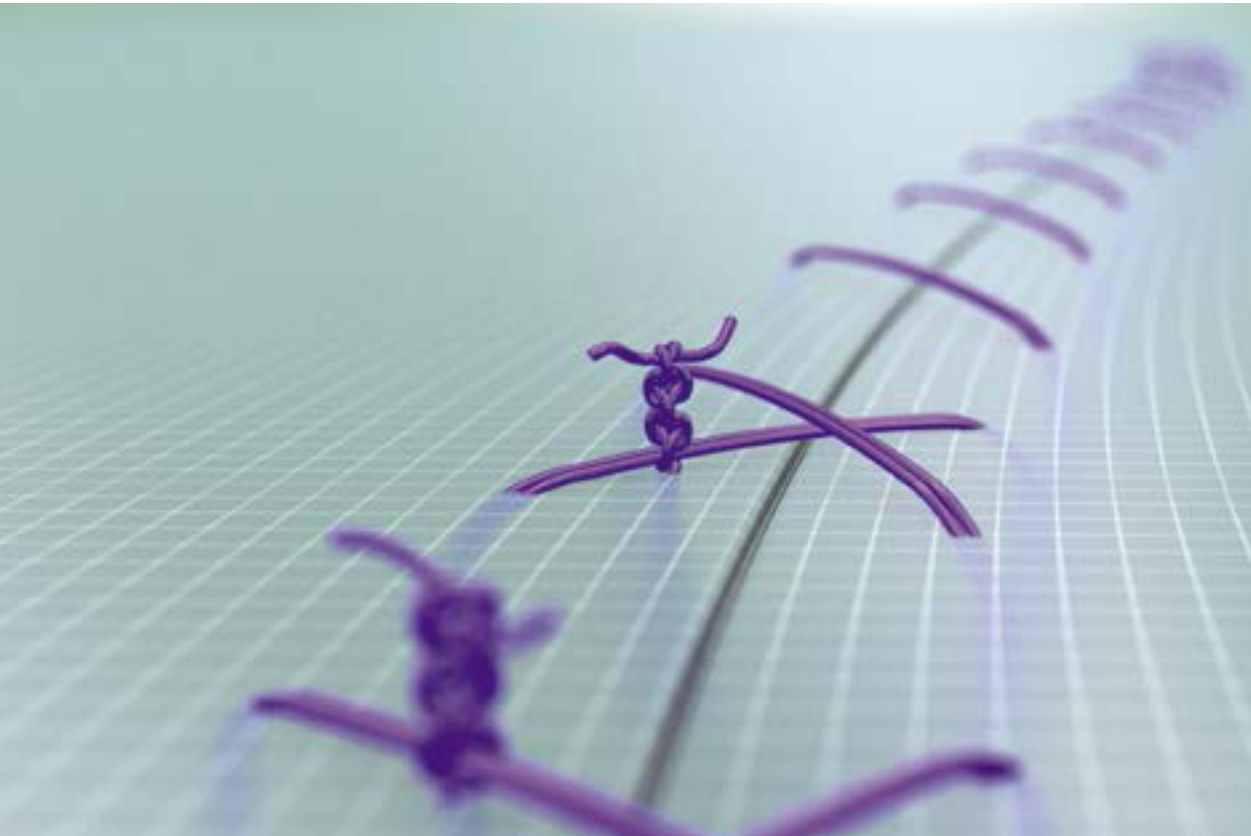




GENERAL OPEN
SURGERY

Monomax[®]

SPECIALLY ENGINEERED FOR ABDOMINAL WALL CLOSURE

Monomax[®]

THE MONOFILAMENT ADVANTAGE



B. BRAUN OFFERS A COMPREHENSIVE SYNTHETIC MONOFILAMENT PORTFOLIO:

- **Monosyn Quick:**
Short term absorbable suture for fast healing tissue.
- **Monosyn:**
Mid term absorbable suture for soft tissue approximation.
- **MonoPlus:**
Long term absorbable suture for slow healing tissue.
- **Monomax:**
Extra long term absorbable suture specially engineered for Abdominal Wall Closure.

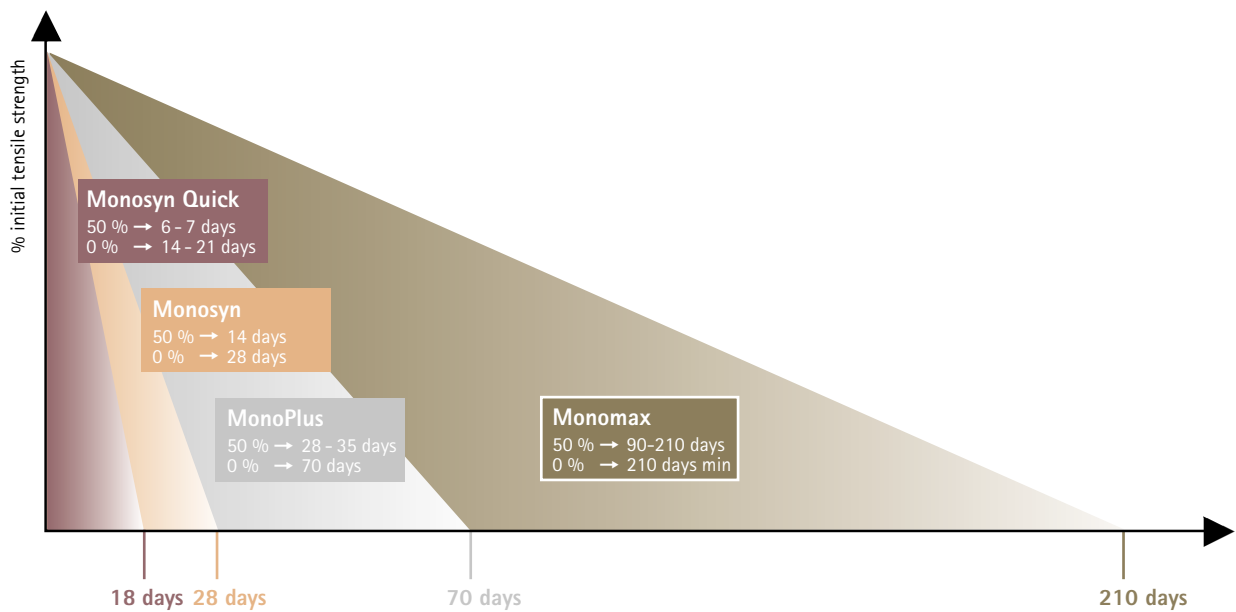
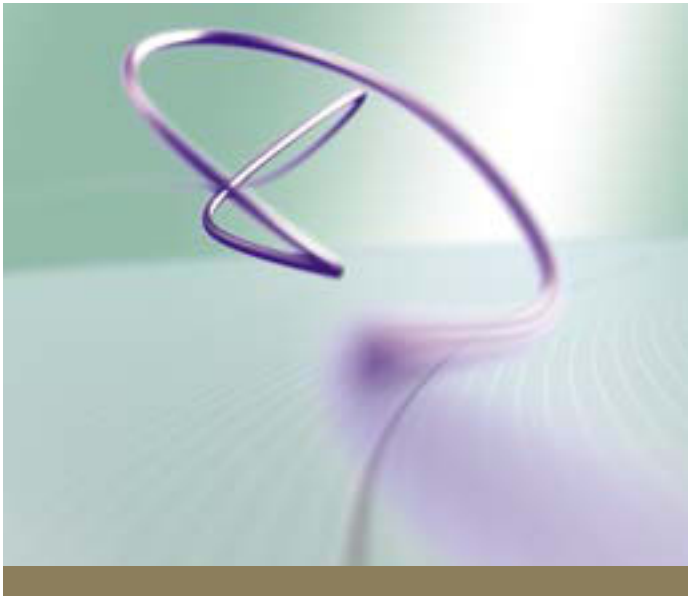


Figure 1: Tensile strength retention of the B. Braun Synthetic Monofilament Sutures



THE ADVANTAGES OF USING MONOFILAMENT SUTURES:

- Less infection promoting effect
- Improved wound healing
- Reliable knotting
- Low tissue dragging effect

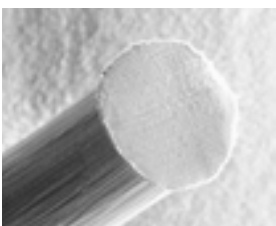
THE ADVANTAGES OF USING MONOFILAMENT SUTURES:

1. Less infection promoting effect^{1,2}



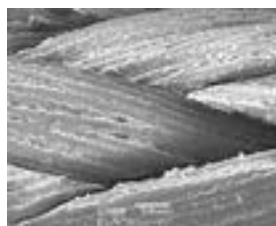
"Monofilament sutures showed a significantly lower level of bacterial infiltration and colonization"²

2. Improved wound healing, due to the smooth passage through the tissue:



Monofilament sutures:

- Smooth surface
- Low tissue drag
- Low tissue damage



Braided sutures:

- High frictional coefficient
- High tissue drag
- Normally coated to reduce tissue drag effect

3. Reliable knotting, due to the longitudinal elasticity of monofilaments^{*3}

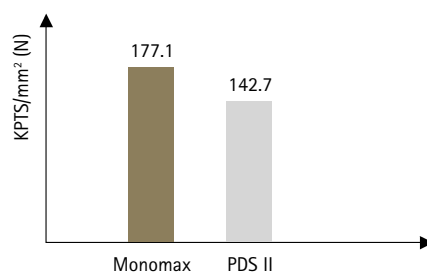


Figure 2:
Comparison of knot pull tensile strength (USP 1).

THE CHALLENGE OF ABDOMINAL WALL CLOSURE

THE CHALLENGE:

■ Incisional hernias:

Incidence of up to 20 % (9 to 20 %) 1 year postoperatively.^{3,4}

■ Trocar site hernias:

Incidence of about 1 % (higher incidence rates when using trocars of ≥ 10 mm compared with smaller trocars).⁵

■ Paediatric trocar site hernias:

Incidence of 5.3 %.⁵

■ High intra-abdominal pressure:

The suture line is frequently exposed to heavy loads, which might cause conventional sutures to cut the tissue and thus trigger hernias.⁶

■ Long healing process:

The abdominal wall fascia requires approximately 2 months to regain 50 % of its original strength and only recovers 70 % of the original strength 1 year postoperatively.⁷

THE NEED

The ideal material should not only have a high tear resistance but also adequate elasticity to absorb and intercept the tension from the fascia dynamics.⁸

Current literature supports the use of slow absorbable monofilament sutures to close the abdominal wall in elective cases⁹ and also of the trocar sites.⁵

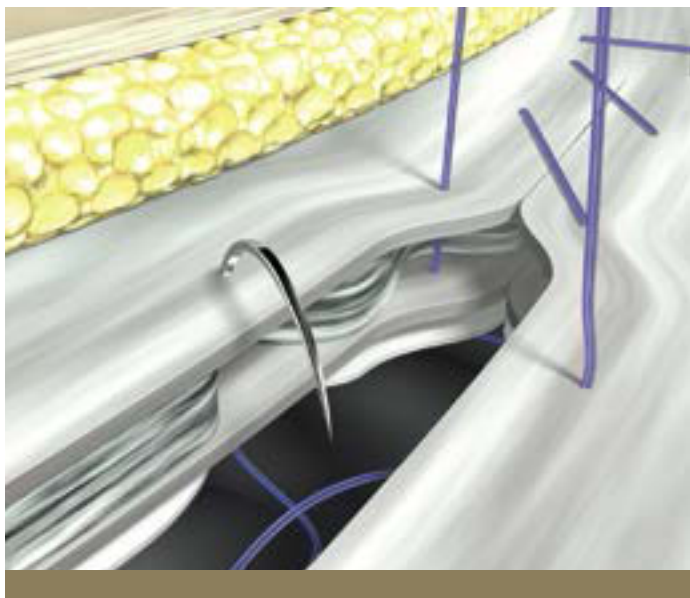
After having found unexpectedly high rates of incisional hernia in all groups, the INSECT study concluded that new concepts are still needed for abdominal wall closure.¹⁰



B. BRAUN GOES A STEP FURTHER AND DESIGNS AN INNOVATIVE SOLUTION IN ABDOMINAL WALL HEALTH.

Monomax[®]

SPECIALLY ENGINEERED FOR ABDOMINAL WALL CLOSURE



EXCELLENT FUNCTIONALITY

Monomax provides 2 times more support to the abdominal wall than polydioxanone sutures, as it maintains 50 % of its original tensile strength for more than 3 months and keeps on supporting the abdominal wall physically for up to 6 months.¹¹

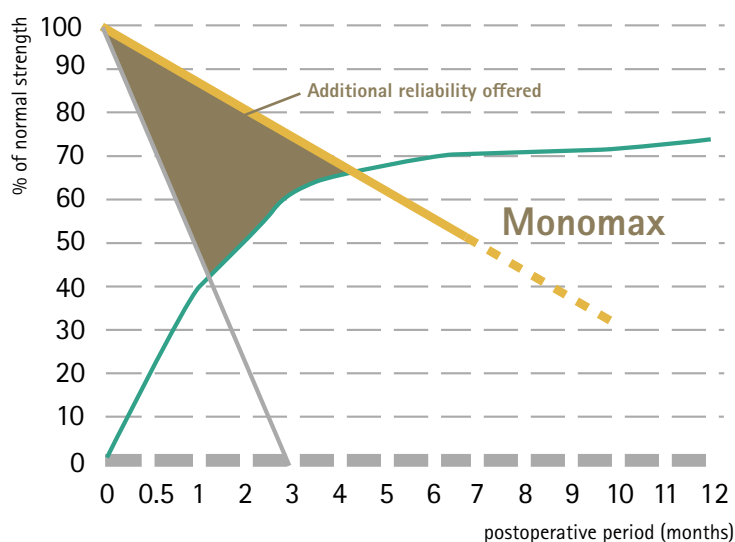


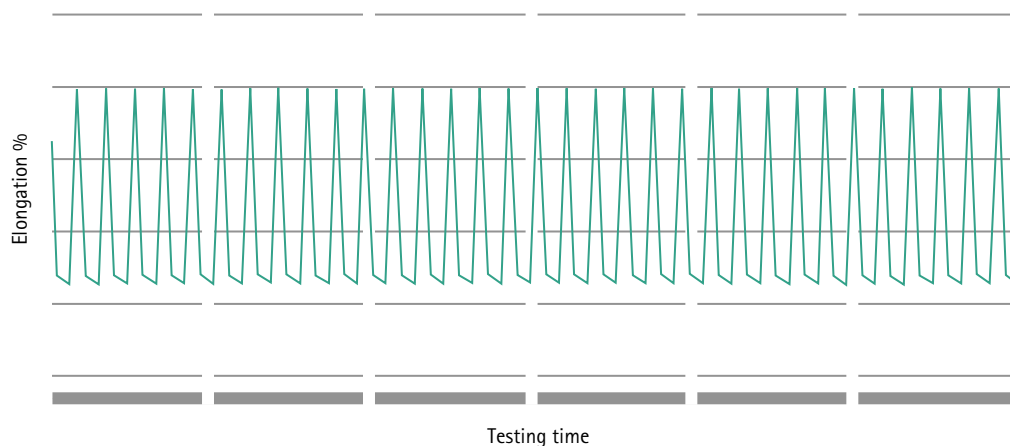
Figure 3:
Abdominal wall strength recovery compared with Monomax and polydioxanone suture degradation profiles (USP 1 and 0).

- Strength recovery abdominal wall
- Monomax degradation profile
- Polydioxanone degradation profile

Figure 4:
Elongation of Monomax after applying pressure peaks (5-20 N) vs. time. The thread shows no deformation.

MAXIMUM ELASTICITY

Monomax provides excellent wound compatibility to acute or constant intra-abdominal pressure conditions, facilitating a native vascularization. Compared to polydioxanone sutures, Monomax is 2 times more elastic and 3 times more pliable.*



CLINICAL EVIDENCE



THE INLINE META-ANALYSIS⁹

- Evaluation of the optimal suture technique and material for abdominal fascia closure after elective midline laparotomy.
- 5 systematic reviews and 14 trials including 7711 patients were analysed.

"...lower chance of developing an incisional hernia if the abdominal fascia is closed with a continuous technique using slowly absorbable suture material."

THE INSECT STUDY¹⁰

- Comparison of the interrupted technique using a rapidly absorbable braided suture with the continuous technique using different slowly absorbable monofilament sutures, focusing on the incidence of incisional hernia rate 1 year postoperatively.
- Multicenter randomized controlled trial with 3 parallel groups including 625 patients.

"The incidence of incisional hernias and the frequency of wound infection was higher than expected in all groups. New concepts need to be developed and studied to substantially reduce the frequency of incisional hernias."

THE ISSAAC STUDY¹²

- Assessment of the safety and efficacy of the new ultra-long-term absorbable, elastic monofilament suture material Monomax for abdominal wall closure.
- Historically controlled, single-arm, multicentre prospective study with 150 patients. The control group consisted of 141 patients from the INSECT study receiving a continuous slowly absorbable polydioxanone suture (PDO).

- Primary endpoint: Burst abdomen and/or wound infection rate until day of discharge:

ISSAAC (Monomax group)	INSECT (PDO group)
7.3 %	11.3 %

- Secondary endpoint: Incidence of incisional hernias 12 months postoperatively.

ISSAAC (Monomax group)	INSECT (PDO group)
14.0 %	21.3 %

"... Monomax is safe and efficient for abdominal wall closure."

NEW TRENDS IN ABDOMINAL WALL CLOSURE



THE "SMALL BITES" TECHNIQUE

In addition to the suture material, the technique plays an important role in the reduction of postoperative complications.

Millbourn et al.¹³ showed that the incisional hernia and wound infection rates were significantly reduced using the "small bites" technique in comparison to the "large bites" technique:

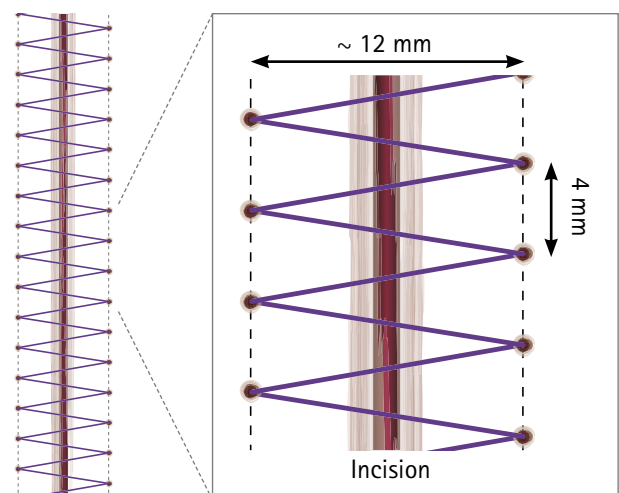
	Small bites	Large bites
Wound infection rate	5.2 %	10.2 %
Incisional hernia rate	5.6 %	18 %

SUGGESTED TECHNIQUE TO HELP REDUCE TRAUMA OF THE ABDOMINAL WALL

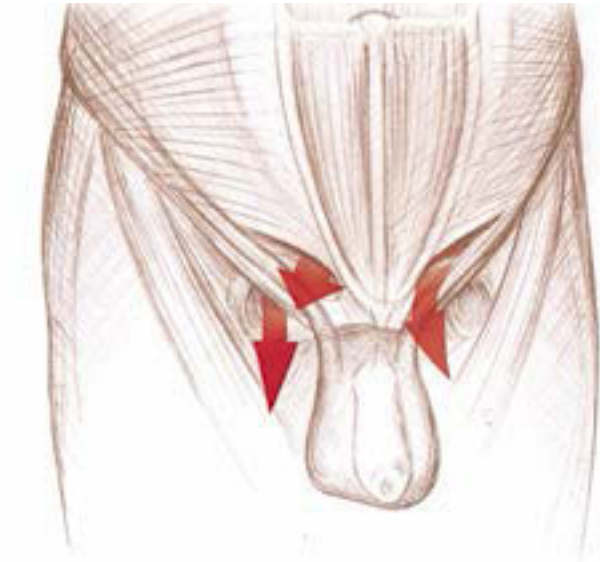
By reducing stitch spacing and achieving moderate thread strain.

- Extra-long term monofilament
- USP 0 or 2/0, single thread, 150 cm
- Small needle (HR26 or HR30)
- Continuous suturing
- Only aponeurosis grasping
- Thread length: Incision length ratio $\geq 5:1$
- Distance between stitches: 4–5 mm
- Distance to wound edge: 5–8 mm
- Very small tension applied to suture

Figure 4:
"Small bites" technique scheme. Scale 3:1.



NEW TRENDS IN ABDOMINAL WALL CLOSURE



Monomax FOR SINGLE INCISION LAPAROSCOPY AND
CLASSICAL MINIMAL INVASIVE SURGERY:

Literature reports the need to use a slowly-absorbable or
even non-absorbable suture to prevent trocar site hernias.⁵

The use of Monomax for fascia closure in open or in laparoscopic
procedures may help to reduce hernias (also those of trocar sites),
as it provides extra support to the abdominal wall during the
wound healing process.



NEW!

RANGE UPDATE:

Monomax is now available in USP 3/0!

For more detailed information on the suture range
and the needle type, please check the Monomax
needle-thread combinations in the end of catalogue.

Monomax[®]

PRODUCT FEATURES



Structure	Monofilament
Chemical composition	Poly-4-hydroxybutyrate
Colour	Violet
Size	USP 1 (metric 4), USP 0 (metric 3.5), USP 2/0 (metric 3) and USP 3/0 (metric 2.5)
Tensile strength retention	50% tensile strength retention at 90-210 days
Mass absorption	Essentially completed between 13 months and more than 36 months*
Indication	General soft tissue approximation, especially when the use of an absorbable monofilament suture with an extended wound support up to 15 weeks is indicated. i.e. abdominal wall closure
Sterilization	Ethylene oxide (EO)



Round bodied needle



Needle length mm	Thread length cm colour	USP (metric)							
		5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
1/2 circle round bodied needle									
	70 Violet			B0041982	B0041425				
	70 Violet			B0041061					
	70 Violet			B0041053	B0041415	B0041416			
	70 Violet			B0041010					
	70 90 150 Violet			B0041092	B0041249 B0041258 B0041444	B0041250			
	70 150 Violet			B0041112		B0041442			
	70 90 150 Violet			B0041153	B0041267 B0041278 B0041453		B0041269 B0041280		

Round bodied needle

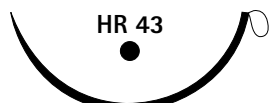


Needle	Thread	USP (metric)							
length mm	length cm colour	5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
1/2 circle round bodied needle									
 HR 37	70 90 Violet				B0041015	B0041024	B0041025		
 HR 37	150 Violet					B0041038			
 HR 37s	70 90 150 Violet			B0041348	B0041034	B0041035 B0041046 B0041043	B0041036 B0041047		
 HR 40	70 90 Violet				B0041057	B0041066	B0041067		
 HR 40s	70 90 Violet				B0041086	B0041087 B0041097	B0041088 B0041098	B0041180	
 HR 40s	150 Violet					B0041076	B0041077		
 HR 43	70 Violet					B0041298			

B Box of 24 units

Round bodied needle



Needle length mm	Thread length cm colour	USP (metric)							
		5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
1/2 circle round bodied needle									
 HR 43	150 Violet						B0041307		
 HR 43s	90 Violet					B0041107	B0041108		
 HR 48	70 90 Violet				B0041128	B0041137	B0041138	B0041198	
 HR 48	150 200 Violet				B0041117	B0041118	B0041119 B0041325		
 HR 65	150 Violet					B0041147	B0041148		
 HR 76	150 Violet						B0041157		

B Box of 24 units

Round bodied needle with trocar point



Needle	Thread	USP (metric)							
length mm	length cm colour	5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
1/2 circle round bodied needle with trocar point									
 HRT 26 ⊕	70 150 Violet				B0041175 B0041463	B0041176			
 HRT 30 ⊕	150 Violet				B0041472				
 HRT 40 ⊕	70 90 Violet					B0041343 B0041352	B0041344		
 HRT 40s ⊕	90 Violet						B0041194		
 HRT 40s ⊕	150 Violet					B0041184	B0041185		
 HRT 43 ⊕	70 90 Violet					B0041369 B0041378			
 HRT 43s ⊕	90 Violet						B0041212	B0041302	

B Box of 24 units

Round bodied needle with trocar point



Needle	Thread	USP (metric)							
length mm	length cm colour	5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
1/2 circle round bodied needle with trocar point									
	150 Violet						B0041203		
	70 90 Violet					B0041240	B0041396 B0041241		
	120 150 180 200 Violet					B0041221 B0041433	B0041310 B0041222 B0041434 B0041231	B0041457	
5/8 circle round bodied needle with trocar point									
	150 Violet					B0041005	B0041006		

Round bodied needle with blunt point

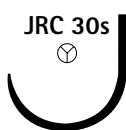


Needle length mm	Thread length cm colour	USP (metric)							
		5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
1/2 circle round bodied needle with blunt point									
 HRN 45	90 Violet							B0041235	
 HRN 50	150 Violet						B0041166		

Monomax[®]
NEEDLE-THREAD COMBINATION

Hook round bodied needle with short cutting point



Needle	Thread	USP (metric)							
		5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
length mm	length cm colour								
Hook round bodied needle with short cutting point									
JRC 30s 	70 Violet						B0041560		

Round bodied needle



Needle length mm	Thread length cm colour	USP (metric)							
		5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
5/8 circle round bodied needle									
	70 Violet				B0041887	B0041888	B0041889		
	70 90 Violet						B0041571 B0041573		
	150 Violet						B0041001		

B Box of 24 units

Reverse cutting needle



Needle length mm	Thread length cm colour	USP (metric)							
		5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
1/2 circle reverse cutting needle									
	90 Violet							B0041365	
	70 Violet							B0041374	
3/8 circle reverse cutting needle									
	45 Violet			B0041845					
	45 Violet			B0041855					
3/8 circle reverse cutting needle with precision point									
	45 Violet			B0041863					
	45 Violet			B0041879					



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- 10 Seiler CM, Bruckner I, Diener MK, Pappan A, Golcher H, Seidlmayer C, et al. Interrupted or continuous slowly absorbable sutures for closure of primary elective midline abdominal incisions: a multicenter randomized trial (INSECT: ISRCIN24023541). *Ann Surg.* 2009 Apr;249(4):576-82.
- 11 Monomax Instructions for Use.
- 12 Albertsmeier M, Seiler CM, Fischer L, Baumann P, Hüsing J, Seidlmayer C, et al. Evaluation of the safety and efficacy of Monomax suture material for abdominal wall closure after primary midline laparotomy – a controlled prospective multicentre trial: ISSAAC. *Langenbecks Arch Surg.* 2012 Mar;397(3):363-71.
- 13 Millbourn D, Cengiz Y, Israelsson LA. Effect of stitch length on wound complications after closure of midline incisions: a randomized controlled trial. *Arch Surg.* 2009 Nov;144(11):1056-9.

* Data on file: Test number PTR/22/0907/MAU according to standard EP SOP/02/FF/013.en.5 (KPTS) and to standard USP SOP/02/FF/014.en.3 (LPTS).

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