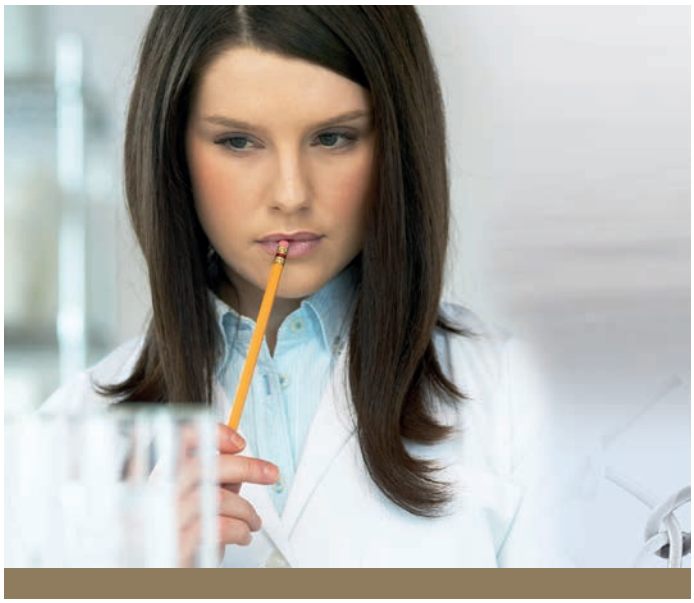
B BRAUN
SHARING EXPERTISE

Abdominal Wall Closure

Monomax®

Clinical Evidence

For Abdominal Wall Closure



The INLINE Meta-Analysis (1)

- 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.

" ... there is a lower chance of developing incisional hernia if the abdominal fascia is closed with a continuous technique using slowly absorbable suture material in comparison with interrupted technique with rapid-absorbable suture material."

The INSECT Study (2)

- 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 Study (3)

- 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."

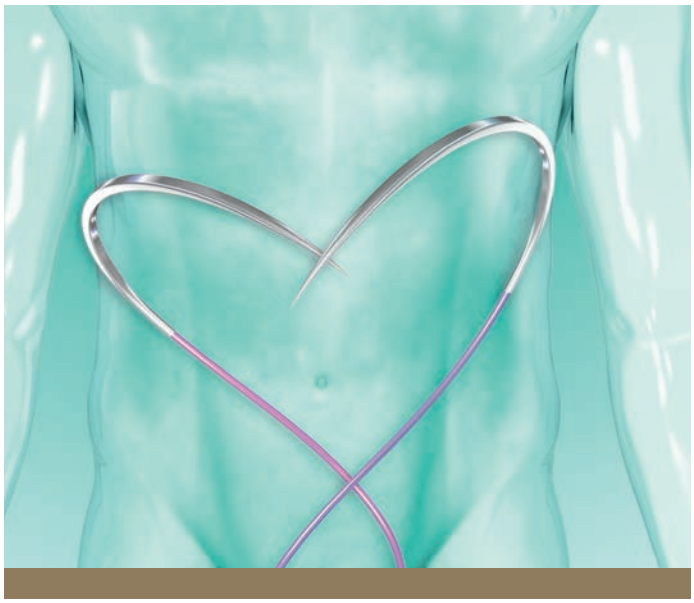
The MULTIMAC Study (4)

- Evaluation of Monomax® suture performance for transverse and midline abdominal wall closure in daily clinical practice even in high risk patients (no BMI limit).
- A multicenter, international, prospective, observational, single-arm study including 200 patients.

" The application of Monomax® is safe and effective, including for the closure of transverse abdominal wounds."

" The low short-term complication rates (burst abdomen and wound infection) observed using Monomax® suture in obese, AAA and diabetic patients in the current study indicate a beneficial clinical outcome also for high-risk patients."

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.

STITCH Study (5)

- Comparison of the large bites suture technique with the small bites technique for fascial closure of midline laparotomy incisions. The primary outcome was the occurrence of incisional hernia.
- Prospective, multicentre, double-blind, randomised controlled trial including 560 patients.
- At 1 year follow-up:

	Small bites	Large bites
Incisional hernia rate	13 %	21 %

Rates of adverse events did not differ significantly between groups.

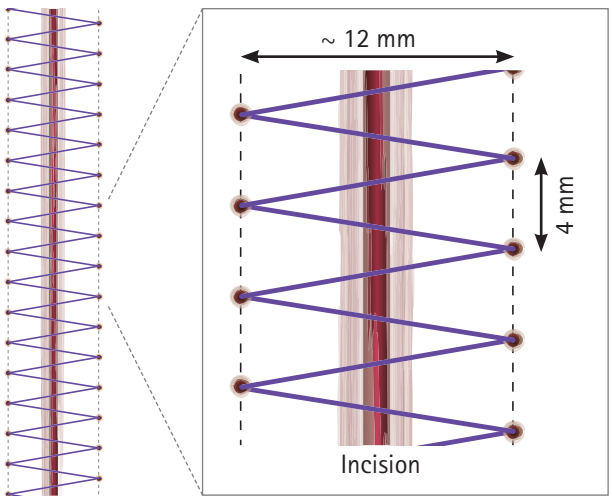
" Our findings show that the small bites suture technique is more effective than the traditional large bites technique for prevention of incisional hernia in midline incisions."

Suggested technique to help reduce trauma of the abdominal wall (6)

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 ≥ 5:1.
- Distance between stitches: 4 - 5 mm.
- Distance to wound edge: 5 - 8 mm.
- Very small tension applied to suture.

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



The Challenge of Abdominal Wall Closure

The Challenge:

- **Incisional hernias:**
  Incisional hernia is a frequent complication after midline incisions of the abdominal wall. Its incidence varies from 9 % to 20 % in different studies (1).
- **Trocar site hernias:**
  Incidence of about 1 % (higher incidence rates when using trocars of ≥10 mm compared with smaller trocars) (7).
- **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 (8).
- **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 (9).

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 (10).

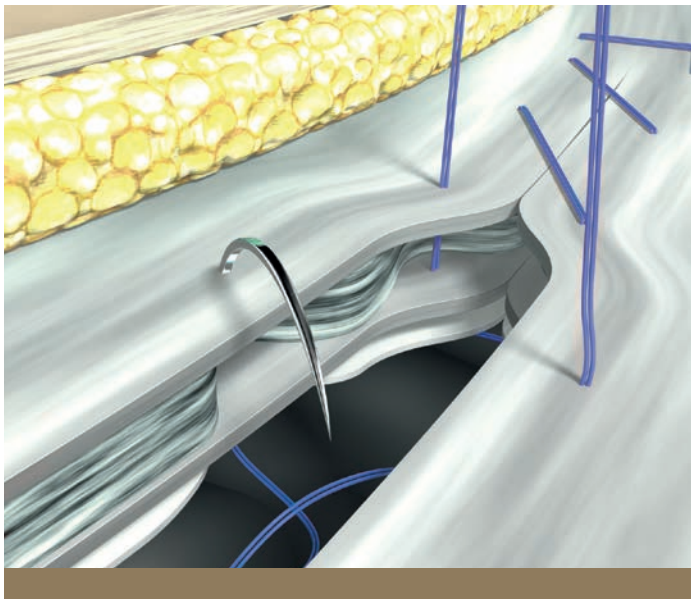
Current literature supports the use of slow absorbable monofilament sutures to close the abdominal wall in elective cases (1) and also of the trocar sites (7).

After having found unexpectedly high rates of incisional hernia in all groups (interrupted VICRYL®, continuous PDS®, continuous MonoPlus®), the INSECT study concluded that new concepts are still needed for abdominal wall closure (2).

B. Braun goes a step further and designs an innovative solution in Abdominal Wall Health.

Monomax®

For Abdominal Wall Closure



Monomax® is the first and unique extra-long term absorbable monofilament synthetic suture material (11).

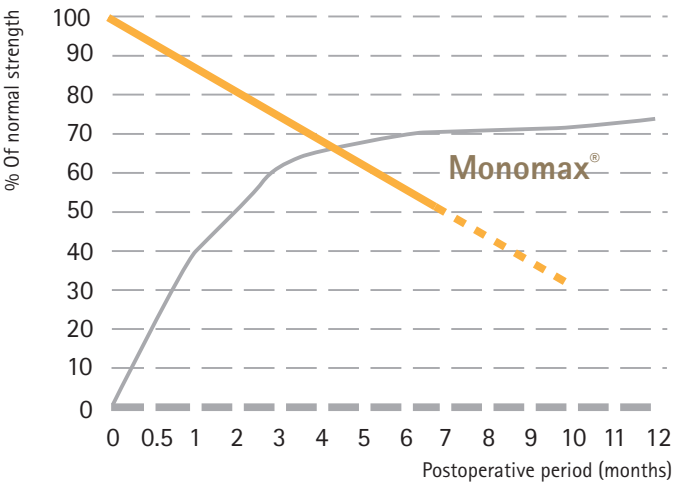


Figure 2:
Abdominal wall strength recovery compared with Monomax® degradation profiles (USP 1 and 0) (9, 12).

Monomax® degradation profile

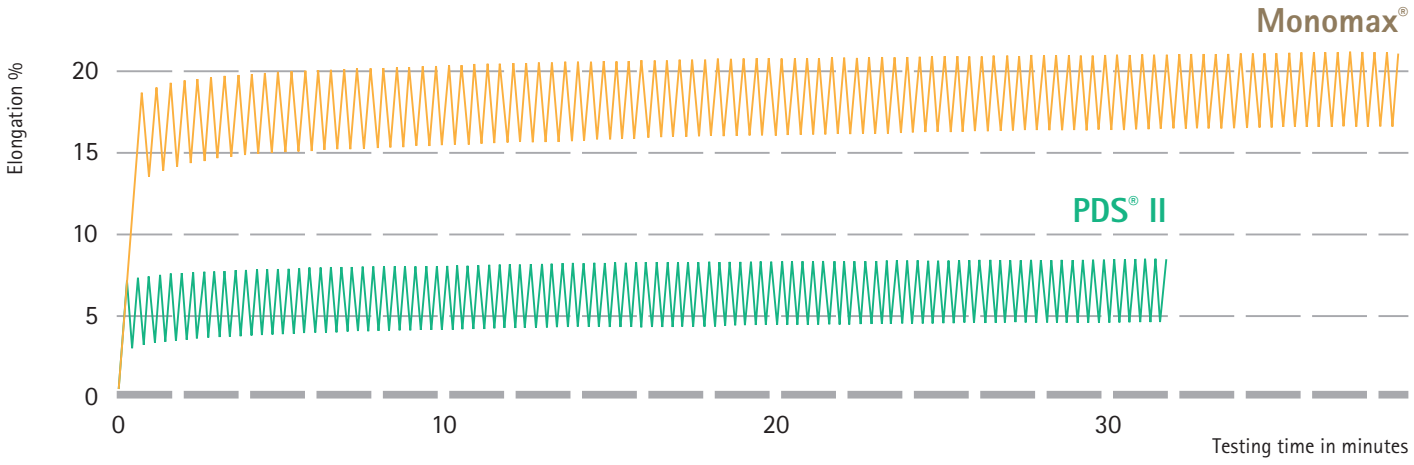
Strength recovery abdominal wall

Maximum Elongation

Monomax® elongates twice as much as polydioxanone sutures (13).

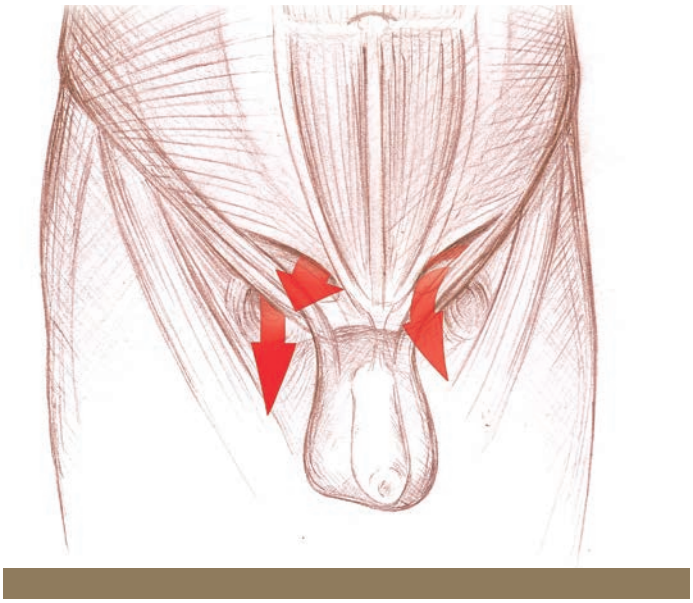
" Monomax® has peak values of elongation more than double the elongation values of PDS® II. According to the basic assumption that a more elongable suture material should have a positive impact on the tissue strangulation, Monomax® can follow peak loads (during coughing, movements, etc.) easier than PDS® II. The latter one is rather rigid already beginning at low forces which might disturb the blood supply to the sutured tissues."

Figure 3:
Elongation of Monomax® and PDS® II after applying pressure peaks (5 - 20 N) vs. time (13).



Monomax®

For 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 (7).

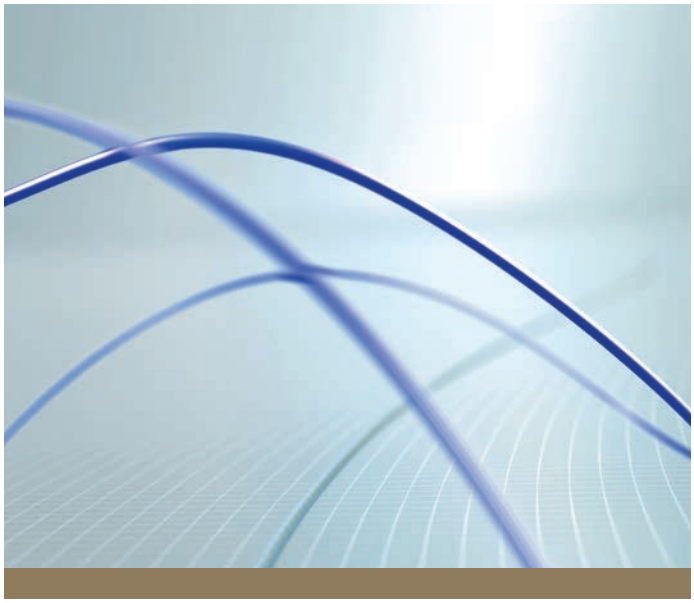
Monomax® possibly reduces the incidence of incisional hernias in comparison to polypropylene sutures (in 2 years follow-up) (14).

The use of Monomax® is adequate for fascia closure in open or in laparoscopic procedures (15, 16).

Monomax® with hook needles for laparoscopic procedures.

Monomax®

Product Features



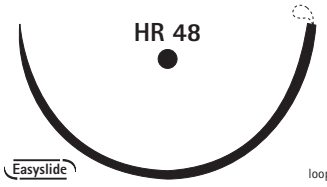
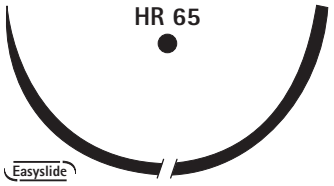
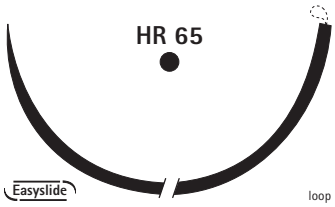
Structure	Monofilament
Chemical composition	Poly-4-hydroxybutyrate
Color	Violet
Size	USP 1 (metric 4), USP 0 (metric 3.5), USP 2/0 (metric 3)
Tensile strength retention	50 % tensile strength retention at 90 - 210 days
Mass absorption	Essentially completed between 13 months and more than 36 months (17)
Indication	General soft tissue approximation when extended wound support is needed (more than 3 months) in abdominal fascial closure
Sterilization	Ethylene oxide (EO)

Monomax®

Needle-Thread Combination Easyslide

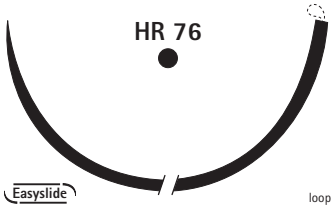
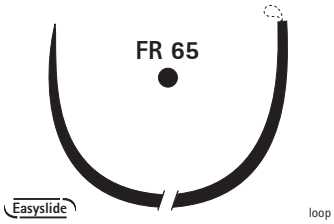
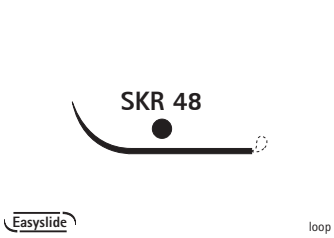
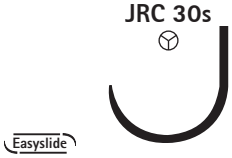
Needle length mm	Thread length cm color	USP (metric) 4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)	4 (6)
1/2 circle round bodied needle									
HR 20 Easyslide	90 violet			B0041037					
HR 22 Easyslide	70 violet			B0041415	B0041416				
HR 22s Easyslide	70 violet				B0041033				
HR 26 Easyslide	70 90 150 violet			B0041249 B0041258 B0041444	B0041250 B0041441				
HR 26s Easyslide	70 150 violet				B0041002 B0041442				
HR 30 Easyslide	70 90 150 violet			B0041267 B0041278 B0041453	 B0041455	B0041269 B0041280			
HR 37 Easyslide	70 90 150 violet			B0041015 B0041044	 B0041024	 B0041025			
HR 37 Easyslide loop	 150 violet				 B0041038				
HR 37s Easyslide	70 90 150 violet			B0041034 B0041042	B0041035 B0041046 B0041043	B0041036 B0041047			
HR 40 Easyslide	 70 90 violet			B0041057	 B0041066	 B0041067			
HR 40s Easyslide	 70 90 violet			B0041086	 B0041087 B0041097	 B0041088 B0041098			

C Box of 36 units	B Box of 24 units	G Box of 12 units	M Box of 6 units

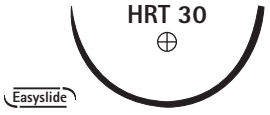
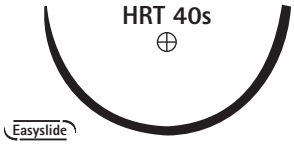
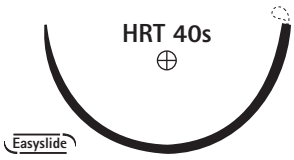
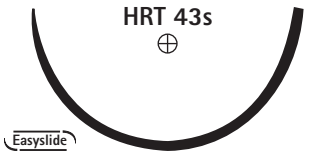
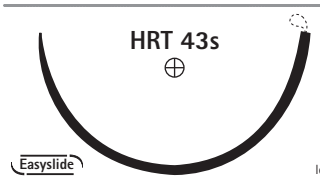
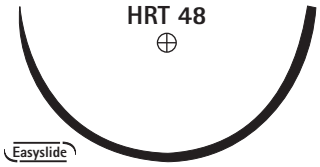
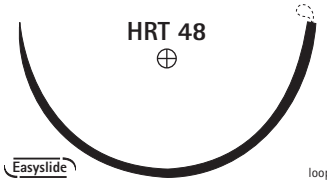
Needle length mm	Thread length cm color	USP (metric) 4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)	4 (6)
1/2 circle round bodied needle									
	150 violet				B0041076	B0041077			
	70 violet				B0041298				
	150 violet					B0041307			
	90 violet				B0041107	B0041108			
	70 90 violet			B0041128	B0041137	B0041138			
	150 violet			B0041117	B0041118	B0041119			
	90 violet					B0041003			
	150 violet				B0041147	B0041148			

Monomax®

Needle-Thread Combination Easyslide

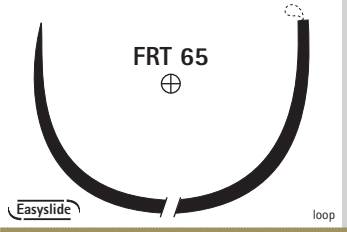
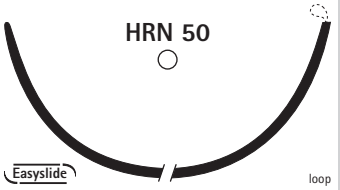
Needle length mm	Thread length cm color	USP (metric) 4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)	4 (6)
1/2 circle round bodied needle									
	150 violet					B0041157			
5/8 circle round bodied needle									
	70 violet			B0041887	B0041888	B0041889			
	70 90 violet					B0041571 B0041573			
	150 violet					B0041001			
Ski needle round bodied needle									
	70 violet					B0041004			
Hook round bodied needle with short cutting point									
	70 violet					B0041560			
1/2 circle round bodied needle with trocar point									
	70 150 violet			B0041175 B0041463	B0041176				

C Box of 36 units	**B** Box of 24 units	**G** Box of 12 units	**M** Box of 6 units

Needle length mm	Thread length cm color	USP (metric) 4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)	4 (6)
1/2 circle round bodied needle with trocar point									
	150 violet			B0041472					
	70 90 violet				B0041352	B0041344			
	90 violet					B0041194			
	150 violet				B0041184	B0041185			
	90 violet					B0041212			
	150 violet					B0041203			
	90 violet				B0041240	B0041241			
	120 150 violet				B0041221	B0041310 B0041222			

Monomax®

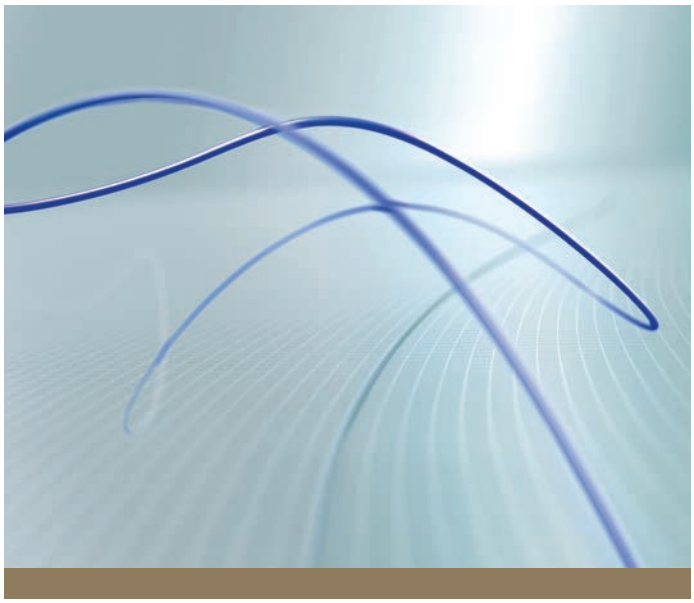
Needle-Thread Combination Easyslide

Needle length mm	Thread length cm color	USP (metric) 4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)	4 (6)
5/8 circle round bodied needle with trocar point									
	150 violet				B0041005	B0041006			
1/2 circle round bodied needle with blunt point									
	150 violet					B0041166			

C Box of 36 units	**B** Box of 24 units	**G** Box of 12 units	**M** Box of 6 units

Monomax®

References



(1) Diener MK, Voss S, Jensen K, Buchler MW, Seiler CM. Elective midline laparotomy closure: The INLINE systematic review and meta analysis. Ann Surg. 2010 May;251(5):843-56.

(2) Seiler CM, Bruckner I, Diener MK, Papyan 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:I SRCIN24023541). Ann Surg. 2009 Apr;249(4):576-82.

(3) Albertsmeier M, Seiler CM, Fischer L, Baumann P, Husing J, Seidlmayer C, et al. Evaluation of he 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.

(4) Baumann P, Savulescu F, Ferko A, Neoral C, Wente MN. Evaluation of a Monofile, Ultra-Long Absorbable Suture with High Elasticity for Abdominal Wall Closure Under Daily Clinical Routine MULTIMAC a Prospective Observational Study. Journal of Surgery. 2019;7(1):1-7.

(5) Deerenberg EB, Harlaar JJ, Steyerberg EW, Lont HE, van Doorn HC, Heisterkamp J, et al. Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet. 2015 Sep;386(10000):1254-60.

(6) Israelsson LA and Milbourn D. Closing midline abdominal incisions. Langenbecks Arch Surg. 2012;397:1201-07.

(7) Helgstrand F, Rosenberg J, Bisgaard T. Trocar site hernia after laparoscopic surgery: a qualitative systematic review. Hernia. 2011 Apr;15(2):113-21.

(8) Hoer J, Stumpf M, Rosch R, Klinge U, Schumpelick V. Prevention of incisional hernia. Chirurg. 2002 Sep;73(9):881-7.

(9) Rath AM, Chevrel JP. The healing of laparotomies: review of the literature. Hernia. 1998 Sep;2:145-9.

(10) van´t Riet M, Steyerberg EW, Nellensteyn J, Bonjer HJ, Jeekel J. Meta-analysis of technqiues for closure of midline abdominal incisions. Br J Surg. 2002; 89(11):1350-6.

(11) Covered by patent EP 1638615 B1 (Polyhydroxyalkanoate medical textiles and fibers).

(12) Instructions for use of Monomax.

(13) Data on file RDR/DID/MON/MAU/13118.

(14) Uske K, Rao SK, Venkateshwar P. RANDOMISED CONTROLLED TRIAL ON COMPARISON OF ABSORBABLE EXTRA LONG TERM (POLY HYDROXY BUTYRATE) SUTURE VS NON ABSORBABLE (POLYPROPYLENE) SUTURE FOR ABDOMINAL WALL CLOSURE. International Journal of Current Research. 2017;9(11):60651-9.

(15) Fink C, Baumann P, Wente MN, Knebel P, Bruckner T, Ulrich A, et al. Incisional hernia rate 3 years after midline laparotomy. Br J Surg. 2014;101(2):51-4.

(16) Fortelny RH, Andrade D, Schirren M, Baumann P, Riedl S, Reisensohn, et al. Effects of the short stitch technique for midline abdominal closure on incisional hernia (ESTOIH): randomized clinical trial. Br J Surg. 2022 Aug 16;109(9):839-45.

(17) In vivo test lab no. 3450.

Notes

B. Braun Surgical, S.A. | Carretera de Terrassa, 121 | 08191 Rubí | Spain
Phone +34 93 586 6200 | www.bbraun.com

AESCULAP® – a B. Braun brand

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | www.aesculap.com

B17502 0325/PDF/11