samyang

(주)비티케이 BTK

Antibacterial Suture (항균 봉합사)

NEOSORB® PLUS + RM REMOVABLE

- 삼양의 국내 최초 항균 봉합사
- 국제표준시험법으로 항균효과 입증
- 세계일류상품 인증 봉합원사 사용

WORLD CLASS PRODUCT OF KOREA 1

세계일류상품

• Product Specification [8]

ISO 13485

Product	Needle					Suture							Packing Unit
	Point Shape		Circle		Length (mm)	Length (cm)	Color	USP Size별 제품코드					
								4-0	3-0	2-0	0	1	
NEOSORB® PLUS	Taper Point		1/2		17mm	70cm	● Violet	NPV411A					36개입/ Box
									NPV310A				
					22mm			NPV413A					
									NPV312A				
					26mm				NPV317A				
										NPV215A			
										NPV216A			
											NPV014A		
			5/8		26mm					NPV21IA			
											NPV01HA		
			1/2		36mm	70cm	● Violet			NPV219A			
											NPV01BA		
							● Undyed				NPU01AA		
					40mm					NPV21GA			
											NPV01FA		
												NPV11DA	
						90cm	● Violet				NPV01EA		
												NPV11CA	
	Reverse Cutting					70cm						NPV14LA	
	Blunt Point				48mm	90cm	● Undyed					NPU12JA	
NEOSORB® PLUS RM (Removable)	Taper Point		1/2		17mm	45cm	● Undyed	NPU491A					96개입/ Box
					22mm			NPV493A					
									NPV392A				
					26mm			NPV498A					
									NPV397A				
							● Violet			NPV295A			
										NPV296A			
					36mm						NPV09AA		
					40mm						NPV09FA		
	Blunt Point				48mm	45cm	● Undyed				NPU09KA		
												NPU19JA	
NEOSORB® PLUS (Without needle)	-		-		-	70cm	● Violet	NPV405					36개입/ Box
	-		-		-				NPV305				
	-		-		-						NPV005		
	-		-		-	45cm		NPV406					

Product	USP Size별 EDI 코드				
	4-0	3-0	2-0	0	1
NEOSORB® PLUS NEOSORB® PLUS RM (Removable)	B0744009	B0743009	B0742009	B0741009	B0731009

Ref 8) 식약처 허가사항 (제허 13-414 호)

SY-MD-NSP-20210SV2

제조원 : (주)삼양홀딩스 대전광역시 대덕구 문평서로 18번길 55
Tel. 82-2-2157-9838 Fax. 82-2-2157-9062 www.samyangbiopharm.com

판매원 : (주)비티케이 경기도 안양시 동안구 시민대로 280, 210호 (관양동 평촌사르망2)
Tel. 031-345-9930 Fax. 031-345-9931 http://btkmedical.com

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(주)비티케이 BTK

• Product Information[1]

제품명	NEOSORB® PLUS	NEOSORB® PLUS RM (Removable)
제품사진		
품목명	의약품함유봉합사*	
봉합사 성분	PGLA+CHA*	
보험 여부	급여	
Color	● Violet, ● Undyed	
작용 원리	이식 2주 후 65% 이상의 강력유지율을 나타내며 이식 후 56-70일에 완전 분해되는 생분해성 봉합사	
제조사	(주) 삼양홀딩스(국내생산)	
판매사	(주) BTK(비티케이)	

NEOSORB® PLUS	Needle	Type	Taper Point, Blunt Point, Reverse Cutting
		Circle	1/2C, 5/8C
		Length	17mm, 22mm, 26mm, 36mm, 40mm, 48mm
	Suture	USP Size	4-0, 3-0, 2-0, 0, 1
		Color	● Violet, ● Undyed
		Length	70cm, 90cm
NEOSORB® PLUS (Without needle)	Needle	Type	Without needle
	Suture	USP Size	4-0, 3-0, 0
		Color	● Violet
		Length	45cm, 70cm
NEOSORB® PLUS RM (Removable)	Needle	Type	Taper Point, Blunt Point
		Circle	1/2C
		Length	17mm, 22mm, 26mm, 36mm, 40mm, 48mm
	Suture	USP Size	4-0, 3-0, 2-0, 0, 1
		Color	● Violet, ● Undyed
		Length	45cm

* 의약품함유봉합사 : 항균물질인 클로르헥시딘(chlorhexidine)을 함유, PGLA(poly(glycolide-latide))(90/10) copolymer로 제조된 합성 흡수성 봉합사 완제품으로 조직의 봉합, 결찰 및 고정에 사용

* PGLA+CHA : PGLA(poly(glycolide-latide))(90/10) copolymer + 클로르헥시딘(chlorhexidine)

Ref 1) 식약처 허가사항 (제허 13-414 호)

Antibacterial Suture (항균 봉합사)

NEOSORB® PLUS + RM REMOVABLE

"삼양은 20년 기술의 Know-How를 기반으로
국내 최초 항균 봉합사인 NEOSORB® PLUS를 출시 했습니다."

• 삼양은 자체 R&D 기술력으로 봉합사의 품질을 인정 받았습니다.

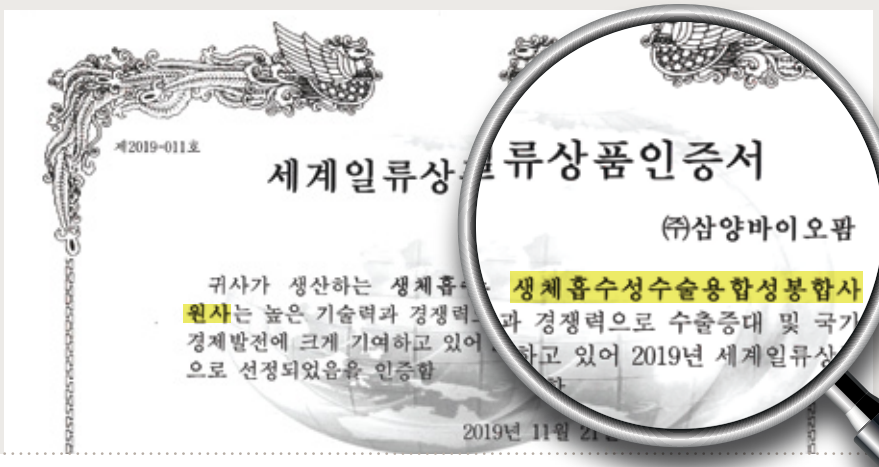
• 삼양은 글로벌 봉합사 생산업체에 흡수성 봉합 원사를 제공하고 있습니다.

글로벌 원사 시장 점유율	1위
지금까지 판매 된 봉합사 길이	지구 36바퀴
전 세계 수출국 수	40개국
전 세계 고객사 수	200사

• NEOSORB® PLUS는 삼양이 획득한 세계일류상품 인증 봉합원사로 만든 제품 입니다.

WORLD CLASS PRODUCT OF KOREA 1
세계일류상품

삼양 봉합원사 11종
세계일류상품 인증

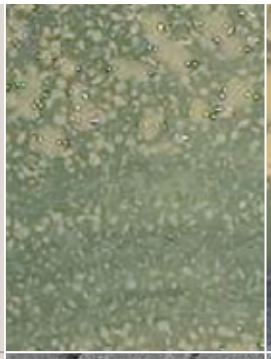
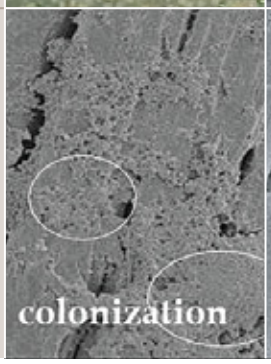
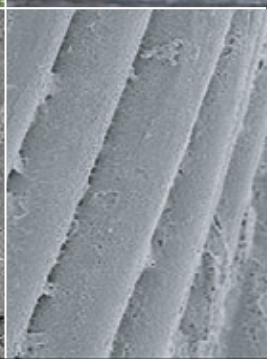


• SY BI(Business Intelligence) 자료, 언론 보도자료

• NEOSORB® PLUS는 국제표준시험법 (ISO20645)을 이용해 항균효과를 입증 하였습니다.[2]

총 6종의 대표적 박테리아에 대해 Agar Diffusion 및 SEM Test를 이용하여 항균력 테스트를 완료 하였습니다.

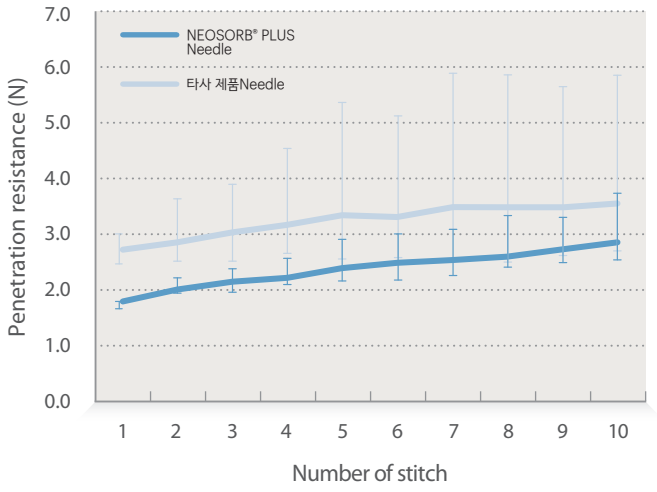
박테리아	시험기관	항균력 평가
S. aureus (*Staphylococcus aureus*)	Samyang R&D Center [3]	Good effect
S. epidermidis (*Staphylococcal epidermidis*)		Good effect
MRSE (Methicillin-Resistant *Staphylococcal epidermidis*)		Good effect
E. coli (*Escherichia coli*)		Good effect
MRSA (Methicllin-Resistant *Staphylococcus aureus*)	LSAG *[4] (독일)	Good effect
Klebsiella sp.		Good effect

구 분	일반 봉합사	NEOSORB® PLUS
Agar Diffusion Test [3,4]		
SEM *[5] evaluation		

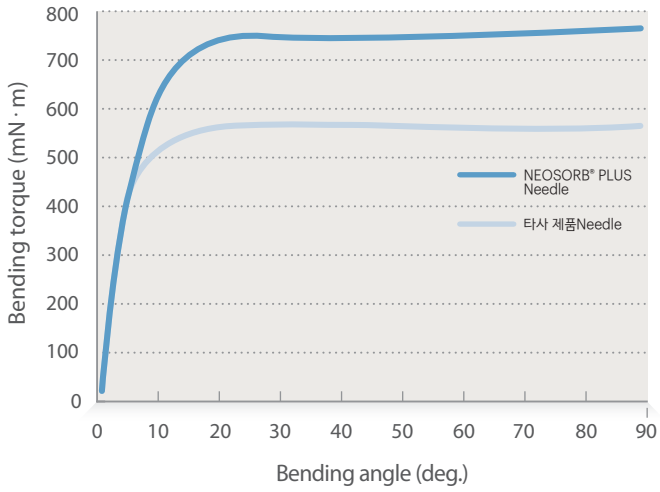
• NEOSORB® PLUS는 우수한 품질의 Needle을 사용한 제품 입니다.[6]

NEOSORB® PLUS의 Needle은 Penetration Test 및 Bending Test에서 우수한 실험 결과를 나타냈습니다.

Penetration Test



Bending Test



* SEM : Scanning Electron Microscopy(SEM) evaluation
* LSAG : Labor L+S AG

Ref 2) 식약처 허가사항 (제허 13-414 호)
Ref 3) Antibacterial Evaluation of NEOSORB® PLUS Using Agar diffusion plate method (SY Document No. R-O-R-41 Rev.1, No. R-O-R-51 Rev.0)
Ref 4) Determination of antibacterial activity according to ISO 20645 (MRSA : Test Report NO. 11801859-11801869, *Klebsiella sp.* : Test Report NO. 09420441-09420451)
Ref 5) Bacterial Adherence Evaluation of NEOSORB® PLUS Using SEM (SY Document No. R-O-R-42)
Ref 6) SY Comparative Test Report

• NEOSORB® PLUS의 임상 결과는 국제 학술지에 등재 되었습니다.[7]

Tae *et al. BMC Surgery* (2018) 18:45
https://doi.org/10.1186/s12893-018-0377-4

BMC Surgery

RESEARCH ARTICLE Open Access

Comparison of intraoperative handling and wound healing between (NEOSORB® plus) and coated polyglactin 910 suture (NEOSORB®): a prospective, single-blind, randomized controlled trial

Bum Sik Tae[1†], Ju Hyun Park[2†], Jung Kwon Kim[3], Ja Hyeon Ku[4], Cheol Kwak[4], Hyeon Hoe Kim[4] and Chang Wook Jeong[4*]

Abstract

Background: Coated polyglactin 910 suture with chlorhexidine (NEOSORB®Plus) has recently been developed to imbue the parent suture with antibacterial activity against organisms that commonly cause surgical site infections (SSI). This prospective, single-blinded, randomized trial, was performed to compare the intraoperative handling and wound healing characteristics of NEOSORB® Plus with those of the traditional polyglactin 910 suture (NEOSORB®) in urologic surgery patients.

Methods: Patients (aged 19 to 80 years, n =100) were randomized in a 1:1 ratio for treatment with either NEOSORB® Plus or NEOSORB®, and stratified into an open surgery or a minimally invasive surgery group. The primary endpoint was the assessment of overall intraoperative handling of the sutures. Secondary endpoints included specific intraoperative handling measures and wound healing characteristics. Wound healing was assessed at one and 11 days after surgery. Cumulative skin infection, seroma, and suture sinus events within 30 day safter surgery were also evaluated.

Results: A total of 96 patients were included, with 47 patients in the NEOSORB® Plus group and 49 patients in the NEOSORB® group. Scores for intraoperative handling were favorable and were not significantly different between the two suture groups. Wound healing characteristics were also comparable. Thein cidence of adverse events was 13.6%, although none were deemed attributable to the suture, and no difference was observed between the two groups.

Conclusions: NEOSORB® Plus is not inferior to traditional sutures in terms of intraoperative handling and wound healing, potentially making NEOSORB® Plus a beneficial alternative for patients at increased risk of SSI.

Trialregistration: ClinicalTrials.gov:NCT02431039. Trial registration date 14 August 2015.

Keywords: Surgical site infection, Intraoperative handling, Chlorhexidine acetate, Polyglactin 910 suture

• 시험대상
- 19세~80세 100명
- Open surgery 및 MIS(Minimally Invasive Surgery) 그룹에서 1:1 무작위 배정

• 시험제품
- NEOSORB® PLUS 와 NEOSORB®

• 시험방법
- 수술 중 전반적인 봉합사의 Handling에 대한 평가
- 특정 수술 중 Handling measures와 Wound healing characteristics에 대한 평가

• 시험결과
- NEOSORB® PLUS는 수술 중 Handling과 Wound healing 측면에서 Traditional suture에 비해 열등 하지 않았으며,
잠재적으로 SSI (Surgical Site Infections) 위험이 높은 환자에게 NEOSORB® PLUS 제품이 적절한 대안 임을 확인 하였습니다.

Ref 7) Tae et al. *BMC Surgery* (2018) 18:45