Plus Sutures

Plus Antibacterial Sutures Evidence Summary

Technical, Clinical, and Economic Data Supporting Plus Sutures

The petri dish image is for illustrative purposes only, zone of inhibition testing results can vary.

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Introduction

Although they are not always the primary focus of surgical procedures, sutures play an integral role in assisting a patient's successful recovery. An ideal suture should cause minimal tissue damage, be resistant to bacterial contamination, and most important, provide adequate tissue support.[1]

Selecting the appropriate suture by considering the specific biological structure, physiological function, and healing profile of the tissue allows the surgical team to address many of the risk factors associated with surgical wound closure. Issues such as wound dehiscence and surgical site infections (SSIs) can compromise the surgical outcome and contribute to morbidity and mortality.[1,2]

Increasingly, hospitals are adopting procedures to help avoid healthcare-acquired conditions such as SSIs, medical errors, and other preventable complications; these efforts help to promote a high quality of care and control medical costs.[2,3] The American College of Healthcare Executives (ACHE) lists patient safety and quality of care among its critical objectives.[4] In addition, the Centers for Medicare & Medicaid Services (CMS) is phasing in more stringent reporting requirements and payment disincentives that place additional importance on preventing negative outcomes.[5]

This Evidence Summary is a compilation of technical information, clinical and economic data, and research published over the last decade that demonstrates the important contribution Plus Antibacterial Sutures can make in addressing a known risk factor for SSIs.

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Executive summary

Section highlights

- SSIs are a serious healthcare problem that increase a patient's risk of morbidity and mortality, and can result in a substantial economic burden[2]
- Plus Antibacterial Sutures are designed to address a known risk factor for SSIs

SSIs—an ongoing problem

SSIs account for an estimated 17% of healthcare-acquired infections.[2]

- SSIs place patients at risk for increased morbidity and mortality. Patients may be subject to longer hospitalizations, may have increased exposure to antibiotics and other medications, and are more likely to experience additional healthcare-associated complications[2,6]

Risks factors for SSIs

Many risk factors contribute to SSIs.

- Because some risk factors (such as patient age, health, and smoking status) cannot be controlled, hospitals have adopted numerous policies to help reduce infection risk throughout the perioperative period[7]
- Steps can be taken to address some risk factors, such as bacterial colonization of the suture
- Coating or impregnating the suture with an antimicrobial agent is an effective way to address a known risk factor for SSI[8-11]

Antibacterial sutures with triclosan

Triclosan is a broad-spectrum antimicrobial agent used extensively for over 40 years.[8]

- The safety profile of triclosan has been established in extensive testing and decades of use[8]

Plus Antibacterial Sutures

Plus Sutures with IRGACARE® MP* (triclosan):

- are the only commercially available sutures with antibacterial protection†
- inhibit bacterial colonization on the suture[9-11]
- have been shown in vitro to inhibit colonization of the suture for 7 days or more[9-11]
- have been extensively evaluated in preclinical and clinical studies
- retain the same handling and performance characteristics as non-antibacterial sutures made from the same materials[12]

*Trademark of BASF SE.

†Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture, MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture, and PDS® Plus Antibacterial (polydioxanone) Suture are active in vitro against *Staphylococcus aureus*, methicillin-resistant *S. aureus* (MRSA), *Staphylococcus epidermis*, and methicillin-resistant *S. epidermis* (MRSE). MONOCRYL Plus Suture and PDS Plus Suture have also demonstrated activity against *Klebsiella pneumoniae* and *Escherichia coli* in vitro.

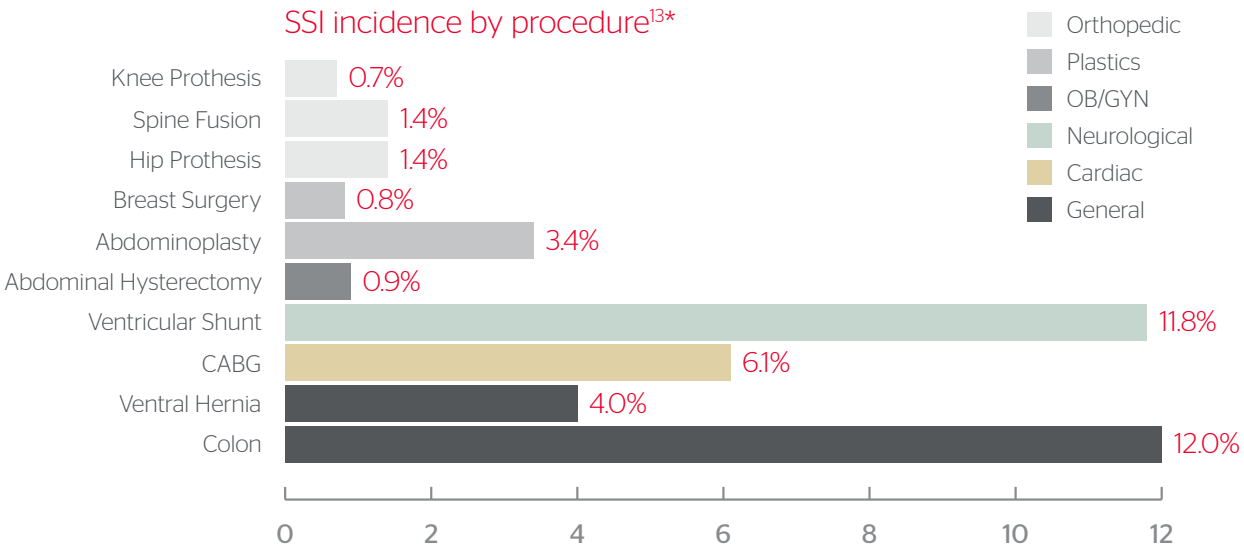
SSIs — an ongoing problem

Section highlights

- Despite preventive measures, SSIs are still a serious concern
- SSIs are a potentially life-threatening surgical complication[6]

Approximately 780,000 SSIs occur annually in the US[6]

SSIs occur in approximately 2.6% of surgical procedures and account for an estimated 17% of all healthcare-acquired infections.[2,6]



Patients with SSIs are:

5X | more likely to be readmitted[6]

Hospitalized for **up to 10** additional days[13]

2X | as likely to die[6]

Patients with SSIs experience:

- Increased use of antibiotics and other medications[14]
- Potential pain management complications[14]
- Other healthcare-associated risks, including pressure ulcers and catheter-related infections[14]
- Increased morbidity and mortality[2]
- Interruption of work and personal life

*An analysis of hospital discharge data from 600 hospitals collected in the Premier Perspective™ Comparative Database (2007–2009), a national administrative discharge database. The analysis included adult inpatient surgical cases in 6 surgical specialties.

Burden of SSIs

Section highlights

- New reimbursement and reporting policies place increasing pressure on hospitals to avoid SSIs[5]
- A single SSI can result in a substantial economic burden by increasing the length and cost of a hospitalization, and by potentially leading to readmission[13]
- An SSI can cost the hospital nearly $39,000[13*]

Patient safety and quality of care—areas of increasing attention—are significantly impacted by SSIs

- A study of 2005 data from the Agency for Healthcare Research and Quality (AHRQ) revealed that SSIs extended length of stay (LOS) by nearly 10 days and substantially increased hospital costs[14]
- Projecting AHRQ data to the total US population suggests nearly 1 million additional inpatient days[14]

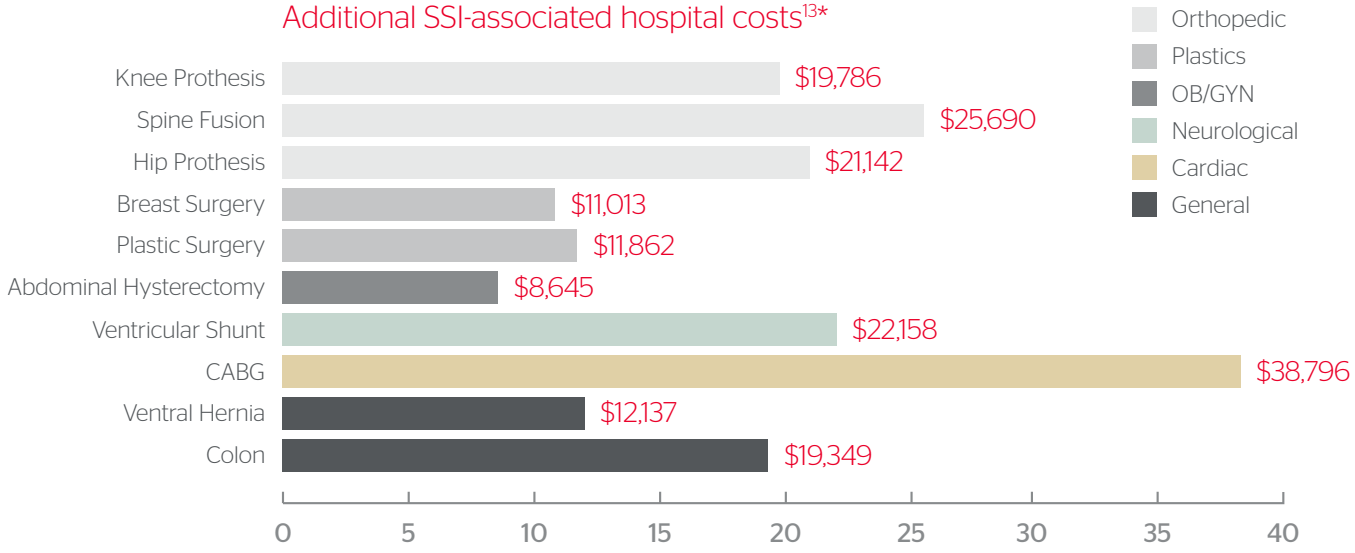
Healthcare reimbursement policies place increasing pressure on hospitals

- Medicare and many Medicaid programs are no longer reimbursing for the additional costs associated with preventable hospital-acquired infections (HAIs), including SSI associated with bariatric surgery (laparoscopic gastric bypass [or laparoscopic roux-en-Y bypass], laparoscopic adjustable gastric banding, laparoscopic sleeve gastrectomy, and laparoscopic gastroenterostomy), certain orthopedic procedures (including spine, neck, shoulder, and elbow), and CABG surgery (mediastinitis)[15]
- Since January 1, 2012, all hospitals have been required to report SSI rates for colon surgery and abdominal hysterectomy[16]
- Reporting all SSIs at acute care facilities is mandatory in 32 states[5]
  - Failure to report SSI data will lead to a reduction in Medicare reimbursement[5]
  - Additionally, In 2013 the Affordable Care Act implemented nationwide pay for performance and value-based[5] strategies to drive reporting
  - Due to increasing pressure, states are rapidly implementing or expanding effective HAI prevention policies and regulations[5]

*This figure applies specifically to SSIs following coronary artery bypass grafting

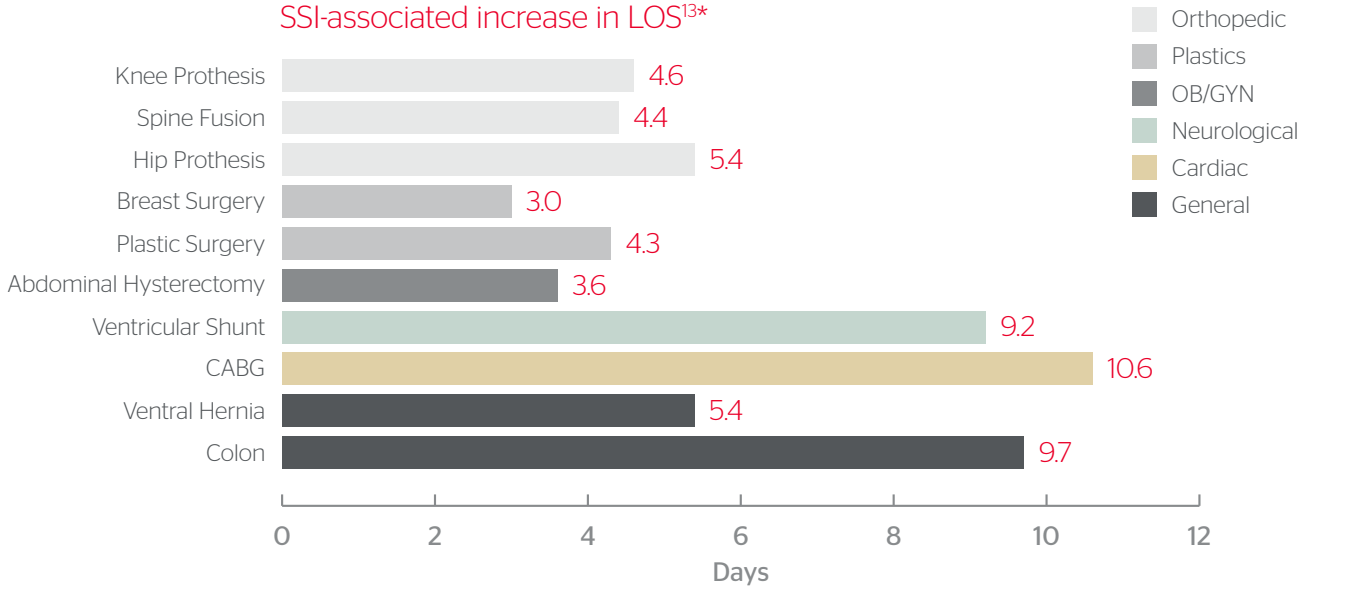
Cost and length of hospitalization

Additional SSI-associated hospital costs[13]*



- SSIs were associated with substantial expenditures in healthcare resources[13]
- An SSI can cost a hospital nearly $39,000[13]

SSI-associated increase in LOS[13]*



- SSIs were associated with increases in LOS of up to 10 days[13]
- Longer hospitalization leads to both increased expenditure and increased risk to the patient[14]

* An analysis of hospital discharge data from 600 hospitals collected in the Premier Perspective™ Comparative Database (2007–2009), a national administrative discharge database. The analysis included adult inpatient surgical cases in 6 surgical specialties.

Impact of readmission

SSI-related readmission adds substantial cost[13]*

	Rate of SSI-related Readmissions		Additional Mean Hospital Stay (Days)		Additional Mean Cost of SSI-related Readmission	
	0-30 Days Postsurgery	31-90 Days Postsurgery	0-30 Days Postsurgery	31-90 Days Postsurgery	0-30 Days Postsurgery	31-90 Days Postsurgery
Overall Population	0.5%	0.1%	4.2	10.3	$6,839	$21,666
Medicare Population	0.6%	0.2%	5.4	12.6	$8,584	$26,812
Colon Surgery	1.5%	0.5%	4.4	14.4	$7,269	$29,378
CABG	0.9%	0.2%	5.6	17.0	$9,094	$44,266
Abdominal Hysterectomy	0.9%	0.1%	3.4	6.2	$5,013	$11,510
Ventricular Shunt	0.3%	0.2%	2.8	7.8	$5,807	$15,808

- Medicare patients are at a higher risk for SSI-related readmissions[13]
- Risk of SSI-related readmissions is greater with certain surgeries[13]

Recent Centers for Disease Control and Prevention (CDC) estimates place annual excess healthcare expenditures due to SSIs at $3.5 to $10 billion[2]

* An analysis of hospital discharge data from 600 hospitals collected in the Premier Perspective™ Comparative Database (2007–2009), a national administrative discharge database. The analysis included adult inpatient surgical cases in 6 surgical specialties.

Risk factors for SSIs

Section highlights

- SSIs are contributed to by a number of risk factors[7]
- Precautions are being taken to address many risk factors[7]
- Bacterial colonization of the suture is a risk factor that can be addressed[17]*

SSIs are contributed to by a number of risk factors

- Endogenous bacteria[7]
- Exogenous bacteria from[7]
  - Surgical personnel
  - Surgical tools
  - OR environments
- Operating time[7]
- Bacterial colonization of the suture and other implanted devices[7, 17]

- Patient comorbidities[7]
  - Age
  - Diabetes
  - Smoking
  - Obesity
  - Altered immune response
- Prior contamination of the wound[7]

Precautions are already in place to control the risk of bacterial contamination throughout the perioperative period

- Scrubbing
- Gowning
- Skin antisepsis
- Controlling OR environment
- Sterilizing instruments
- Using minimally invasive surgical techniques
- Use of antibacterial-treated devices

However, steps can be taken to address risks such as bacterial colonization of the suture[17]

Wound closure provides an opportunity to address a risk factor for SSIs

* Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture, MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture, and PDS® Plus Antibacterial (polydioxanone) Suture are active in vitro against *Staphylococcus aureus*, methicillin-resistant *S. aureus* (MRSA), *Staphylococcus epidermis*, and methicillin-resistant *S. epidermis* (MRSE). MONOCRYL Plus Suture and PDS Plus Suture have also demonstrated activity against *Klebsiella pneumoniae* and *Escherichia coli* in vitro.

Rationale for antibacterial sutures

Section highlights

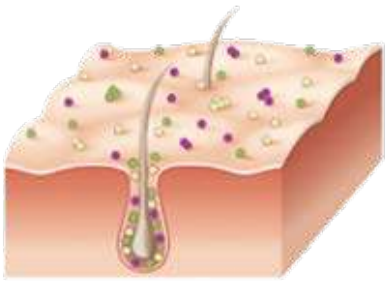
- Percutaneous sutures can provide a route for bacteria to pass from the skin's surface into the wound[7]
- The suture, like any medical device, may act as a nidus of infection[17]
- The presence of suture material reduces the minimum infective dose of bacteria 1,000-fold[7]
- Antibacterial sutures address these risk factors and inhibit bacterial colonization on the suture[9-11]

The suture as a route of infection

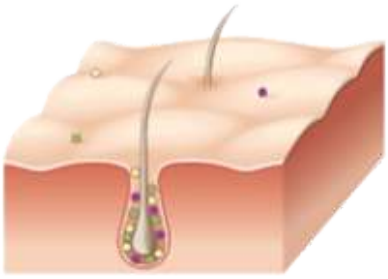
Passage of the needle and suture through tissue creates a conduit that may allow bacteria to invade the wound from the patient's own skin.[7]

Preparation of the skin surface with surgical scrubs and antiseptics can address only superficial bacteria, not the bacteria hiding in deeper skin layers, hair follicles, or other skin appendages.[17]

In addition, the surgical incision creates a breach in the epidermis that can become contaminated from a failed wound closure or other complications. The deployment of an antibacterial-coated material in the surgical wound may be effective in arresting bacterial growth.[17]



Before
antiseptic application



Immediately following
antiseptic application

"Although the role of suture material as a nidus for wound infection has been the subject of speculation for more than 30 years, our findings suggest that as a biomedical device, surgical sutures exhibit an affinity for microbial adherence and colonization similar to that of other synthetic implantable devices."

Edmiston CE, Seabrook GR, Goheen MP, et al. Bacterial adherence to surgical sutures: Can antibacterial coated sutures reduce the risk of microbial contamination? *J Am Coll Surg.* 2006;203:481-489.[17]

The suture as site of infection

Generally, large numbers of bacteria are required for infection to occur.[7] In a typical patient, the infective dose is >100,000 microorganisms per gram of tissue, although this number is dependent on the bacterial species and may be lower if the patient's immune system is depressed due to medication or disease.[7]

Sutures—like all implanted material—can substantially lower the infective threshold.[7] Studies have shown that the presence of a suture can decrease the dose of bacteria on the suture necessary to cause an SSI to just 100 staphylococci per gram of tissue.[7]

When implanted in the body, the inert surface of any foreign implant is coated with tissue proteins almost immediately upon placement.[17] These proteins, including fibrinogen, fibronectin, collagen, and other substrates, function as adhesives for microbial attachment.[17] Numerous types of bacteria can form a biofilm—an extracellular matrix—that promotes rapid bacterial multiplication and protects the colony from both host defenses and antibiotic therapy.[18] Reoperation to remove the implant is sometimes necessary to eradicate biofilm infection.[18]

Typical bacterial concentration required for SSI to develop:

>100,000

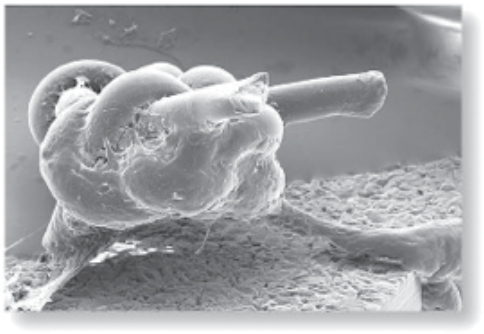
per gram of tissue[7]

Staphylococci concentration required on suture for SSI to develop:

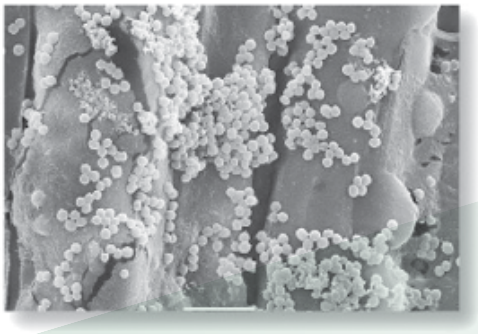
100

per gram of tissue[7]

Biofilm formation increases the difficulty of treating an infection, even in the presence of antibiotics.[18]



Colonization of suture knot



Colonization of braided suture

Coating or impregnating the suture with an antimicrobial agent that inhibits colonization of the suture is a way to address a known risk factor for SSIs.[9-11]

Triclosan is a safe, effective component of antibacterial sutures

Section highlights

- Triclosan is a safe and effective antimicrobial agent[8-11]
- Triclosan-coated sutures inhibit bacterial colonization of the suture[9-11]
- Exposure to triclosan from a suture is minimal[8]

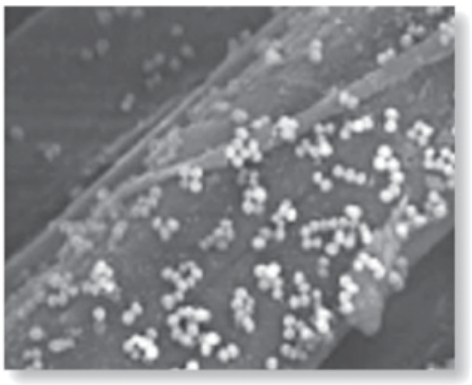
Triclosan is a broad-spectrum antimicrobial agent used extensively in personal care products for over 40 years[8]

- Triclosan is effective against the most common pathogens associated with SSIs, including[9-11]:
  - *Staphylococcus aureus (S. aureus)*
  - Methicillin-resistant *S. aureus* (MRSA)
  - *Staphylococcus epidermidis (S. epidermidis)*
  - Methicillin-resistant *S. epidermidis* (MRSE)
  - *Escherichia coli (E. coli)*
  - *Klebsiella pneumoniae (K. pneumoniae)*
- The development of resistance to triclosan has not been observed[17]

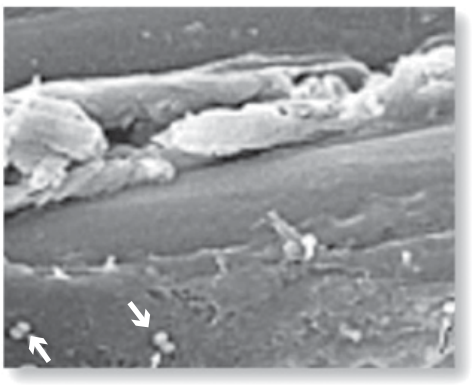
In vivo studies have demonstrated that triclosan-treated sutures inhibit bacterial colonization of the suture after direct challenge with bacteria[9-11]

Fewer bacteria adhere to triclosan-treated polyglactin 910 suture[17]

Scanning electron micrographs of non-triclosan-treated sutures and triclosan-treated polyglactin 910 suture exposed briefly to 100,000 bacteria:



MRSA adhere to **non-triclosan-treated suture** (magnification 5,400x)[17]



Few MRSA (arrows) adhere to **triclosan-treated suture** (magnification 5,260x)[17]

Triclosan has a well-established safety profile[8]

Safety profile established in extensive testing and decades of use

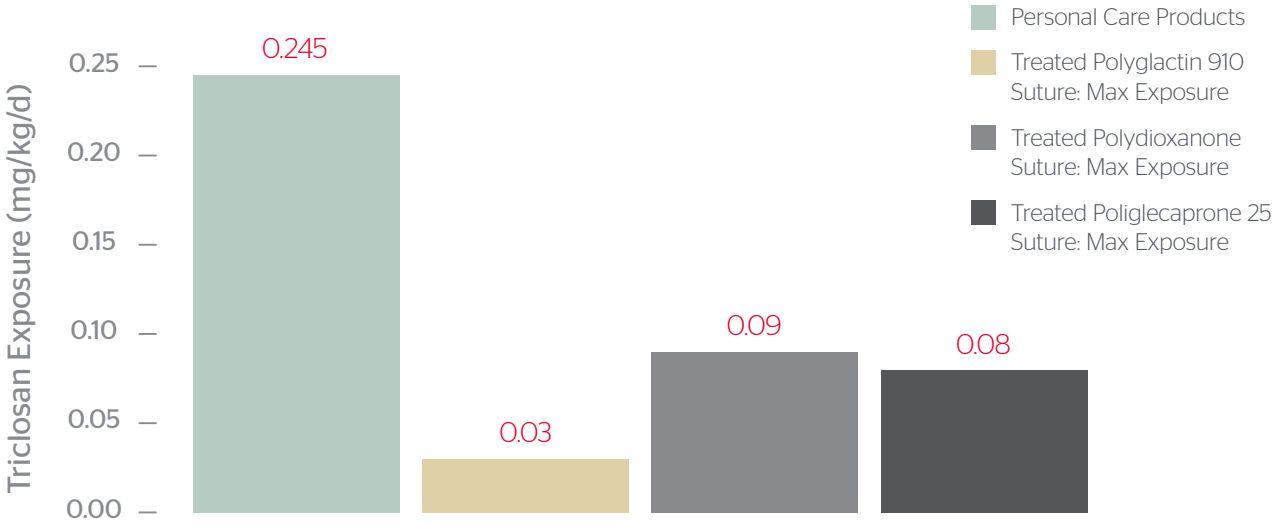
- Toxicity studies of triclosan have found no evidence of[8]*:
  - Chronic toxicity
  - Carcinogenicity
  - Reproductive toxicity
  - Immunotoxicity
  - Cytotoxicity
  - Intracutaneous reactivity
  - Material-mediated pyrogenicity
- Does not accumulate in plasma—triclosan and its metabolites are eliminated in urine and feces[8]

Exposure to triclosan from suture is minimal[8]

Less than typical daily exposure from personal care products[19-22]:

- Oral and topical exposure to triclosan through personal care products is .245 mg/kg/day[19]
- Maximal exposure from triclosan-treated sutures
  - Polyglactin 910 antibacterial suture: 0.03 mg/kg[20]
  - Polydioxanone antibacterial suture: 0.09 mg/kg[21]
  - Poliglecaprone 25 antibacterial suture: 0.08 mg/kg[22]

Estimated Adult Internal Exposure to Triclosan from Consumer Products vs Triclosan-treated Sutures[19-22]



- Exposure to triclosan from repeated use of common consumer products grows over time, while exposure from an implanted triclosan-treated suture diminishes over time[8]

*In animal studies.

Plus Antibacterial Sutures with IRGACARE® MP* (triclosan)–the only commercially available sutures with antibacterial protection

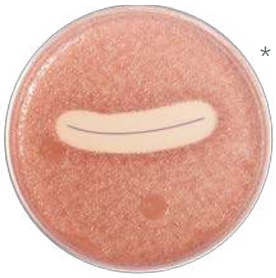
Section highlights

- Plus Sutures are proven in vitro to inhibit bacterial colonization of the suture[9-11]
- Plus Sutures provide the same handling and performance as non-antibacterial sutures[12]
- There is a broad range of Plus Sutures for use in various procedures

Plus Sutures inhibit bacterial colonization on the suture[9-11]

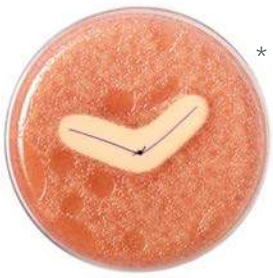
- Plus Sutures utilize the purest form of triclosan (IRGACARE® MP*)[8]
- Plus Sutures retain the same familiar flexibility, tying characteristics, and absorption profiles as the untreated suture materials[12]
- Triclosan on the suture does not cause tissue reaction or impair healing response compared to a non-coated suture[8]

Proven in vitro to inhibit bacterial colonization of the suture for 7 days or more[9-11]



MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture
11 days for *S. aureus*[10]

*The petri dish image is for illustrative purposes only, zone of inhibition testing results can vary.



Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture
>7 days for *S. aureus*[9]

*The petri dish image is for illustrative purposes only, zone of inhibition testing results can vary.

PDS® Plus Antibacterial (polydioxanone) Suture
23 days for S aureus
17 days for *E. coli*[11]

*The petri dish image is for illustrative purposes only, zone of inhibition testing results can vary.

*Trademark of BASF SE.

Product profiles

MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture[23]	Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture[24]	PDS® Plus Antibacterial (polydioxanone) Suture[25]	
Construction			
Monofilament	Braided	Monofilament	
Indication			
MONOCRYL Plus Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery, or ophthalmic surgery.	Coated VICRYL Plus Sutures are indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular, and neurological tissues.	PDS Plus Sutures are indicated for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery (other than contact with cornea and sclera). PDS Plus Sutures are not indicated in adult cardiovascular tissue, microsurgery, and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.	
Breaking Strength Retention			
Undyed 50%-60% at 7 days Dyed 60%-70% at 7 days	75% at 14 days	4-0 and smaller	3-0 and larger
Undyed 20%-30% at 14 days Dyed 30%-40% at 14 days	50% at 21 days	60% at 14 days	80% at 14 days
0% at 28 days	25% at 28 days	40% at 28 days	70% at 28 days
		35% at 42 days	60% at 42 days
Completely Absorbed			
91–119 days	56–70 days	182–238 days	
Spectrum of Activity*			
S. aureus	*S. aureus*	*S. aureus*	
S. epidermidis	*S. epidermidis*	*S. epidermidis*	
MRSA	MRSA	MRSA	
MRSE	MRSE	MRSE	
E. coli		*E. coli*	
K. pneumoniae		*K. pneumoniae*	
Duration of Antibacterial Activity			
11 days for *S. aureus*[10]	>7 days for *S. aureus*[9]	23 days for *S. aureus*	
		17 days for *E. coli*[11]	

*The monofilament sutures are impregnated with a higher concentration of triclosan, while braided sutures are coated.

Published evidence – clinical studies

Plus Antibacterial Sutures have been studied in 27 clinical trials including over 10,000 patients

- 25 studies performed independently of Ethicon
- 18 randomized controlled trials (RCTs)

Prospectively planned meta-analyses of RCTs were performed on the use of sutures containing triclosan to lower surgical site infection rates. Examples of such meta-analyses include:

- Wang ZX, Jiang CP, Cao Y, Ding YT. Systematic review and meta-analysis of triclosan-coated sutures for prevention of surgical site infections. *Br J Surgery*. 2013;100(4):465-473
- Edmiston CE, Daoud FC, Leaper D. Is there an evidence-based argument for embracing an antimicrobial (triclosan)-coated suture technology to reduce the risk for surgical-site infections? A meta-analysis. *Surgery*. 2013;154:89-100
- Daoud FC. Systematic Literature Review Update of the PROUD Trial: Potential Usefulness of a Collaborative Database. Letter to Surg Infect (Larchmt) 2014;15:857858.
- Edmiston CE, Daoud FC, Leaper D. Is there an evidence-based argument for embracing an antimicrobial (triclosan)-coated suture technology to reduce the risk for surgical-site infections?: A meta-analysis. Surgery 2013;154:89100.
- Guo J, Pan LH, Li YX, et al. Eicacy of triclosan-coated sutures for reducing risk of surgical site infection in adults: a meta-analysis of randomized clinical trials. J Surg Res 2016; 201:105117.
- Sajid MS, Craciunas L, Sains P, et al. Use of antibacterial sutures for skin closure in controlling surgical site infections: a systematic review of published randomized, controlled trials. Gastroenterol Rep 2013;1:4250.
- Sandini M, Mattavelli I, Nespoli L, Uggeri F, Gianotti L. Systematic review and meta-analysis of sutures coated with triclosan for the prevention of surgical site infection after elective colorectal surgery according to the PRISMA statement. Medicine. 2016;95:35(e4057).
- Wang ZX, Jiang CP, Cao Y, et al. Systematic review and meta-analysis of triclosan-coated sutures for the prevention of surgical-site infection. Brit J Surg 2013;100:465473.
- Wu X, Kubilay NZ, Ren J, et al. Antimicrobial-coated sutures to decrease surgical site infections: a systematic review and meta-analysis. Eur J Clin Microbiol Infect Dis. 2016. DOI: 10.1007/s100960162765-y.
- de Jonge SW, Atema JJ, Solomkin JS, Boermeester MA. Meta-analysis and trial sequential analysis of triclosan-coated sutures for the prevention of surgical site infection. Brit J Surg. 2017;ePub-DOI: 10.1002/bjs.10445.

For more detailed information on clinical studies of Plus Sutures, please contact Ethicon Medical Affairs

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

Published evidence

Author/Year	Outcomes/Conclusions
Studies Evaluating Antibacterial Activity	
Ming 2008	• Polydioxanone sutures treated with triclosan showed in vitro inhibition against *S. aureus*, methicillin-resistant *S. aureus* (MRSA), *S. epidermidis*, methicillin-resistant *S. epidermidis* (MRSE), *E. coli*, and *K. pneumoniae* • In vivo, polydioxanone sutures treated with triclosan inhibited the growth of *S. aureus* and *E. coli*
Gomez-Alonso 2007	• Triclosan-coated sutures prevent bacterial colonization on the suture • Triclosan-coated sutures modulate the inflammatory response, allowing tissue to heal, even in infected fields
Ming 2007	• Compared with untreated sutures, poliglecaprone 25 sutures treated with triclosan inhibited colonization of the suture by bacteria after direct in vivo challenge with *S. aureus* and *E. coli*
Ming 2007	• Compared with untreated sutures, poliglecaprone 25 sutures treated with triclosan provided antibacterial efficacy sufficient to inhibit or reduce in vitro colonization of the suture by gram-positive (*S. aureus*, MRSA, *S. epidermidis*, MRSE) and gram-negative (*K. pneumoniae* and *E. coli)* strains of bacteria
Storch 2004	• Triclosan-coated polyglactin 910 sutures inhibit bacterial colonization of the suture after a direct in vivo challenge by *S. aureus* in a guinea pig model
Rothenburger 2002	• The antimicrobial effect of triclosan-coated polyglactin 910 sutures is sufficient to prevent in vitro colonization by both wild-type *S. aureus* and MRSA and MRSE • The in vitro antimicrobial effect of triclosan-coated polyglactin 910 sutures is enduring and not lost with multiple passes through tissue
Studies Evaluating Safety and Handling	
Ford 2005*	• Handling of Coated VICRYL Plus Suture was equivalent to that of regular Coated VICRYL Suture in pediatric patients (n=150)
Barbolt 2002	• There is extensive toxicology data supporting the safety of triclosan • Biocompatibility studies demonstrate the safety of triclosan-coated sutures for clinical use
Storch 2002	• Triclosan-coated sutures do not impede wound healing
Storch 2002	• The addition of triclosan to a suture does not affect the physical handling properties and performance of the suture

*Study sponsored by Ethicon.

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