



CLOZEX: The Next Generation of Wound Closure

Improves Safety, Speed
and Satisfaction



INTRODUCTION

Globally, more than 350 million surgical incisions are made each year – roughly 37 million in the US.¹ Nearly all these require some form of closure – sutures, staples, adhesive, or tape.² In addition to these surgical wounds, more than 50 million accidental and traumatic injuries produce acute wounds and lacerations in need of cleaning and closure. The aging of the US and other populations continues to drive the demand for surgical services.³

The number of surgeries associated with an inpatient hospital stay is growing. For example, in the US from 2003 to 2012, bariatric procedures increased 11% per year and arthroplasties increased 5% per year.⁴ In 2012, the most common inpatient surgeries were orthopedic procedures – knee arthroplasty, disk surgery, hip replacement, and spinal fusion.⁴

Similarly, the number of ambulatory surgeries is growing. The most common ambulatory surgeries performed in hospitals in 2014 included muscle, tendon, and soft tissue procedures; incision or fusion of joint; cholecystectomy; removal of knee meniscus; and hernia repair.⁵ Along with increasing number of invasive therapeutic procedures, cosmetic surgical procedures increased 100% from 1997 to 2016.⁶

Surgical incisions are closed in hospital operating rooms (OR), emergency departments (ED), ambulatory surgery suites, outpatient clinics, and physicians' offices. Accidental and traumatic injuries may be treated by first responders in the field or in transit to the ED as well as in worksite clinics, urgent care centers, schools, sports arenas, and other public venues.

Closing Wounds...

Surgical wounds are generally closed by primary intention: aligning the two sides of the incision and mechanically securing them together using sutures or staples. Sutures may be permanent or absorbable, natural or synthetic, braided multi-filament or monofilament, barbed, and bioactive – coated or impregnated with antimicrobial or anesthetic agents⁷. Staples are generally metal but also may be absorbable, composed of copolymers.⁸



The overwhelming majority of surgical incisions are closed using these invasive methods, which puncture the skin, produce inflammation, increase the risk of surgical site infections (SSIs), and require follow-up visits for removal.

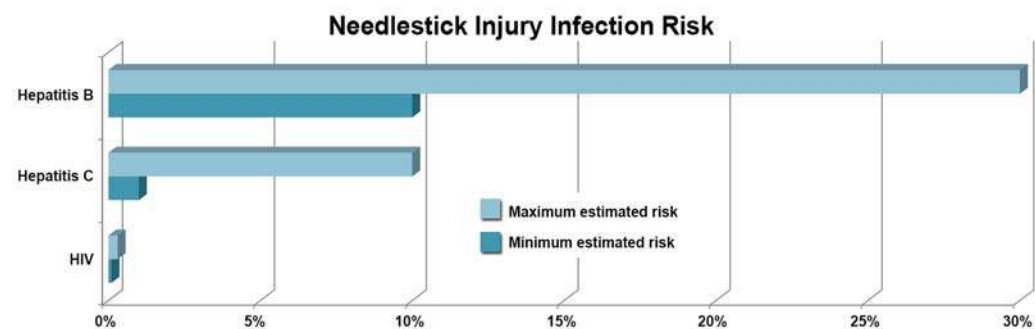
Requires Skill...

Achieving rapid and aesthetic healing of incisions using these sutures and staples is operator-dependent; it requires a surgeon-specific mix of cognitive and technical skills⁹ to swiftly and accurately re-approximate wound margins. For example, to prevent wound breakdown and excessive scarring, tension on the wound edges must be low.

Although stapling is faster than stitching, it often requires two practitioners: one to align the edges of the incision and the other to staple. Staples close incisions more quickly than sutures and their removal takes less time, but patients experience considerably more anxiety and discomfort with staple removal than with suture removal. Like stitching, stapling is highly operator-dependent: it may be technically challenging to approximate wound margins using staples.¹⁰ For example, should one edge be dragged over the other by the staples, a separation of the epithelial surfaces may produce a wider and more unsightly scar.

And Carries Considerable Risk.

Suturing poses risks not only to patients but also to surgeons, who sustain about one-quarter of the more than 600,000 to 800,000 needlestick injuries in the US each year.^{11 12} Sutures account for 19% of all needlestick injuries and cost an estimated \$3,043 per incident annually. The costs include laboratory fees for testing workers, counseling, and post-exposure follow-up.^{13 14} With needlestick injuries, transmission of pathogens is anticipated in 10–30% of clinicians when patients are infected with hepatitis B, 1–10% with hepatitis C, and 0.1–0.3% with HIV.¹⁵ Typically, general surgeons suffer 0.8 injuries per 100 hours of operating time, or 210 injuries during their careers, resulting in a 7% lifetime risk of contracting hepatitis C and a 0.2% lifetime risk of HIV infection.¹⁶



Tapes and tissue adhesives utilize glue in liquid form and eliminate the risk of needlestick injury. They may provide barriers to infection, are generally quicker to apply than sutures and staples, and do not require removal as do most staples and sutures. Adhesives are pricy – as much as four times the cost of sutures,⁸ and are not appropriate for incisions under tension and achieve better results for wounds with low stress and tension. They also may be unable to maintain adequate tensile strength throughout wound healing. Incisions closed with adhesives open more frequently than those closed with sutures.^{17 18}

SURGICAL SITE INFECTIONS

The Most Common Preventable Healthcare-Associated Infections

Sutures and staples puncture the skin, compromising its integrity as a protective barrier and increasing the risk of surgical site infections (SSIs). When a needle passes through skin on either side of the wound, it carries epidermal cells and microorganisms along the incision and deep into the wound. *Staphylococcus aureus*, anaerobic enterobacteria, and coagulase negative

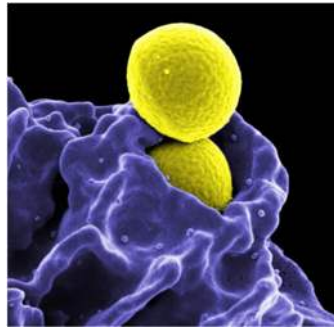
staphylococci are the most commonly implicated pathogens. However, the number of SSIs with resistant bacterial strains is increasing.¹⁹

High Clinical and Economic Costs

Older patients with thin, fragile, and friable skin as well as those with comorbid conditions such as diabetes, obesity, immunological disorders, and tobacco use are at increased risk for SSIs.¹ Patients with SSIs are twice as likely to die, account for more than one-third of hospital-acquired infections, increase hospital stays from 4 to 10 days,²⁰ and are five times as likely to be readmitted.²¹ In the US, the more than 780,000 SSIs each year generate nearly 4 million excess hospital days and an estimated \$3 to 10 billion in hospital costs.^{21 22}

Methicillin-Resistant, *Staphylococcus aureus* (MRSA) bacteria.

National Institute of Allergy and Infectious Diseases



The direct costs of SSIs vary based on the location and type of infection but average \$25,072²³ and may exceed \$90,000 per infection when they involve knee or hip replacement.²⁴ Costs may be considerably higher for infections with antimicrobial resistant pathogens.²⁵ Along with direct healthcare costs – antibiotic treatment, wound care, prolonged hospitalization, and outpatient follow-up – SSIs compromise patient productivity,²⁶ may cause significant physical discomfort and emotional distress, and increase the risk of death.

Sutures have long been implicated in the development of SSIs. Sutures increase the frequency of SSIs and reduce the number of organisms required to produce a postoperative SSI.²⁷ Various bacteria, including biofilm bacteria often associated with implants,²⁸ may contaminate suture material. Braided sutures are more susceptible to microbial colonization than nylon sutures.²⁶

Similarly, randomized controlled trials (RCTs) of metal staples consistently find that though they are quicker and easier to use than sutures, they are associated with the same or greater risk for SSIs.^{29 30 31}

Preventing SSIs

The 2017 Centers for Disease Control and Prevention (CDC) guideline for preventing SSIs includes instructing patients to bathe using soap or an antiseptic agent the night before the procedure, administering preoperative antimicrobials when indicated, and skin preparation using an alcohol-based agent in the OR.³² In addition to these guidelines, the novel technologies described below aim to prevent SSIs.

Antibiotic Prophylaxis

In an effort to prevent or minimize bacterial colonization on sutures, both monofilament and braided absorbable sutures have been coated or impregnated with broad-spectrum antibiotics. Although some studies report that triclosan-coated sutures decrease the rate of SSIs,³³ others found inconsistent³⁴ or no effect on SSI rates.³⁵ It appears that the effect of triclosan coating depends on the type of suture used and type of surgical procedure. For example, triclosan-coated braided sutures seem to be more effective than coated monofilament, possibly because braided suture has greater surface area, permitting higher concentrations of triclosan.³⁶

There is however, some concern that widespread use of antibiotics may lead to diminished activity against microbial pathogens or decreased therapeutic efficacy of antimicrobial agents. There is also the risk of SSI with a strain such as *Pseudomonas aeruginosa* that is resistant to triclosan.³⁷

Eliminating a Source of Infection

Another technology aims to prevent SSIs by eliminating the sources of infection – sutures, staples, and skin punctured by these invasive wound closure methods – altogether. Coaptive film, a new classification of primary wound closure devices, is an adhesive tape that has been shown to be a safe alternative to invasive skin closure devices. Wound closure tapes and tissue adhesives reduce the risk for SSIs.³⁸

Studies comparing coaptive film to sutures find that it reduces the inflammatory response – edema (swelling) and erythema (redness) – associated with invasive wound closure.^{39 40} An animal study looked at whether *Staphylococcus aureus* could penetrate wounds closed with sutures and those closed with coaptive film. Bacteria were recovered from nearly all the sutured wounds but were not recovered from any wounds closed with coaptive film – they had been effectively sealed against bacterial penetration.⁴¹

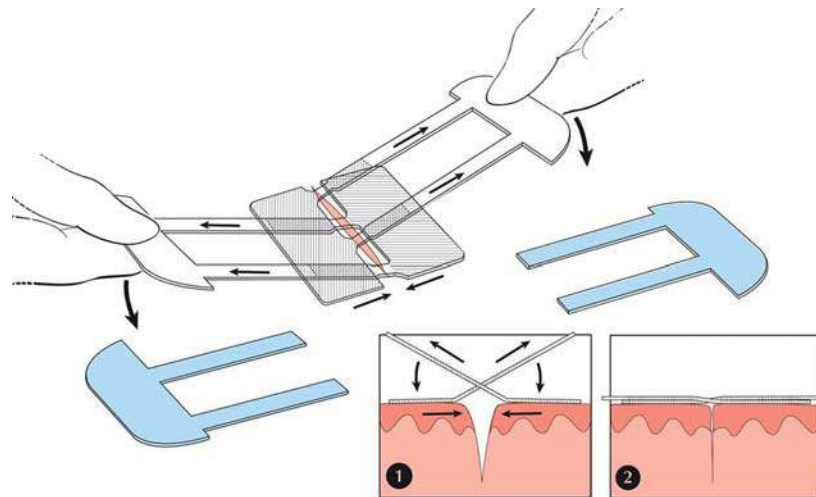
CLOZEX WOUND CLOSURES

A Next Generation Wound Closure Technology

Clozex wound closures are made of breathable polyurethane and polymeric films coated with non-latex, hypoallergenic, pressure sensitive skin adhesives. They may be used to close any clean wound, including most lacerations and surgical incisions, or as an adjunct to, or reinforcement for, suture closures.

FDA approved as a Class I medical device, Clozex is clinically proven and patent protected. Clozex has produced excellent results in more than 10,000 surgical procedures including multiple orthopedic applications – joint replacement, wound closure following fracture fixation, and pediatric spinal and limb surgery. Clozex also has demonstrated effectiveness in cardiothoracic surgical procedures, plastic surgery, and dermatological procedures as well as abdominal surgeries such as hernia repair and bariatric procedures.

Clozex's unique, interlaced design makes it easy to align and secure wound edges quickly, non-invasively and without any additional anesthetic.



Noninvasive Wound Closure is Efficient and Reduces SSI Risk

Clozex offers the opportunity to reduce the risk of infection and provides efficient, precise needle-free wound closure for surgical incisions, excisions, and lacerations. Its transparent

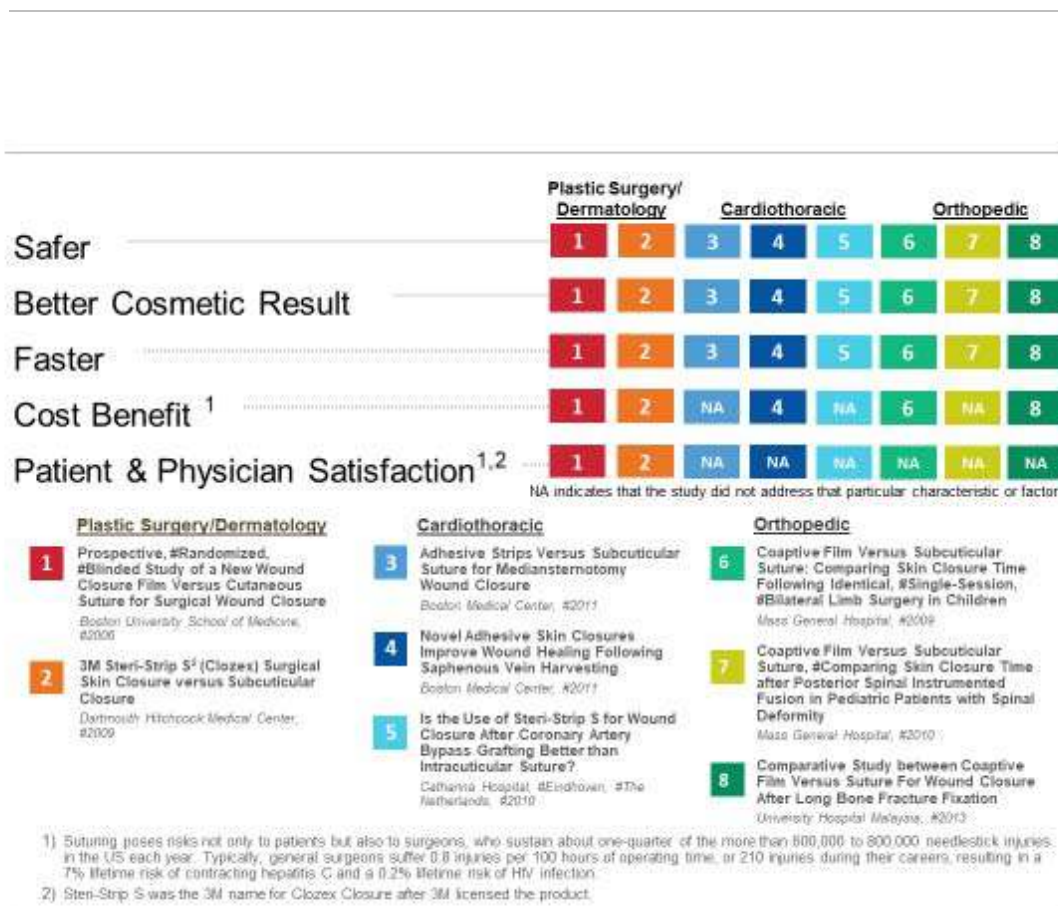
design offers improved visibility, control, safety, and speed of wound closure. It is simple to remove and replace. Its ease of use enables practitioners to quickly and effectively close wounds, freeing surgeons to devote their time, skill and energy to other high-value procedures. With less time spent closing wounds, surgeons, physicians and staff can improve efficiency in the operating and procedure room and feel confident in their wound closure.

High Levels of Physician and Patient Satisfaction

Patients and physicians appreciate the ease, comfort, and convenience of Clozex application and that there is no need for a follow-up visit to remove it as is required for other wound closure devices. They're also pleased with the cosmetic results, which are comparable to those achieved by plastic surgeons. Hospitals and health systems value the improved clinical outcomes and clinician safety as well as reduced OR and ED costs.

Evidence of Safety, Efficacy, and Cost-Effectiveness

The results of eight rigorous clinical studies demonstrate the safety, effectiveness, and cost benefits generated by using ClozeX® for a range of indications.



For example, an RCT comparing Clozex to suture in children undergoing bilateral soft tissue releases concluded that the absence of complications, comparable cosmetic results and time saved, distinguish Clozex as “an attractive and cost-effective option for skin closure after

pediatric surgery.⁴² Another RCT comparing Clozex to subcuticular suture for children undergoing posterior spinal fusion reported significant time savings and comparable complications and cosmetic results.⁴³ A comparison of coaptive film to sutures for wound closure after long bone fracture fixation credited Clozex as not only saving time and money but also producing more aesthetically pleasing results.⁴⁴

Clozex also compared favorably to an absorbable subcuticular suture in an RCT comparing mediasternotomy wound closure; it was faster to apply and produced less initial edema and erythema than sutures.³⁹ Another study found that Clozex skin closure following saphenous vein harvesting was significantly faster, produced significantly less inflammation and significantly improved cosmetic results.⁴⁰ Investigators comparing Clozex to intracuticular suture after coronary artery bypass grafting (CABG) describe Clozex as a “safe, fast alternative for wound closure of the sternotomy incision and graft harvesting site,” and as comparable or slightly better in terms of cosmesis.⁴⁵

A study in which half of a wound was closed with monofilament suture and the other half with Clozex found application of Clozex faster, with no difference in complication rates. Patients and physicians were more satisfied with the Clozex portions of the wounds than the sutured portions.⁴⁶ In a study comparing suture and Clozex for breast reduction or abdominal procedures, physicians reported faster wound closure and increased efficiency without compromising quality as assessed by patient comfort and 6-month postoperative scar quality.⁴⁷

Considerable Cost Savings

Clozex can deliver substantial cost savings. For example, consider the costs associated with closing a 6-7-inch Caesarian section incision using sutures versus Clozex. The savings are attributable to reduced operating room time and the fact that most sutures require a follow-up visit for removal while Clozex does not. Clozex also eliminates the potential costs associated with needlestick injury and may reduce the likelihood of SSIs.

PRIMARY COSTS	SUTURES	CLOZEX	SAVINGS
Closure Materials¹	\$29	\$38	(\$9)
Operating Room Time²	\$1,129	\$564	\$565
Suture Removal³	\$155	\$0	\$155
Needlestick Injury⁴	\$3	\$0	\$3
Surgical Site Infections⁵	\$250	\$0	\$250
Total	\$1,566	\$602	\$964

¹ Average of \$29 based on a range of packs of Monocryl sutures (synthetic, absorbable from Ethicon) and Prolene, excluding cost of anesthetic. Antimicrobial sutures would be higher cost. Assumes one pack of Clozex 30 - 60 mm at \$38 per pack.

² Cost of operating room time estimated at \$2,250 for 30 minutes.⁴²

³ Based on assumption that 75% of procedures will require follow-up.

⁴ Sutures account for 24% of all needlestick accidents and cost an estimated \$3,043 per victim annually.^{13 14}

⁵ The cost of surgical site infections is estimated at \$25,072 (range of \$13,780-40,236) /patient. Orthopedic infections cost as much as \$90,000 /patient. Based on a 2007 study adjusted to 2017 dollars via CPI of 1.5%. Assumption that SSI's occur in 2% of surgeries of which 50% are suture related. It is important to note the surgeons report less than 10% of the needlestick injuries that occur as they don't want to be precluded from working.²³

SUMMARY

Clozex is Setting a New Standard for Efficient, Safe Wound Closure

Clozex offers noninvasive wound closure that is safe and easy to use. Unlike suturing and stapling, it is not operator-dependent – in 3 steps it quickly closes wounds, producing consistently good results. Because it does not puncture the skin it reduces the risk of SSIs and eliminates the risk of needlestick injuries.

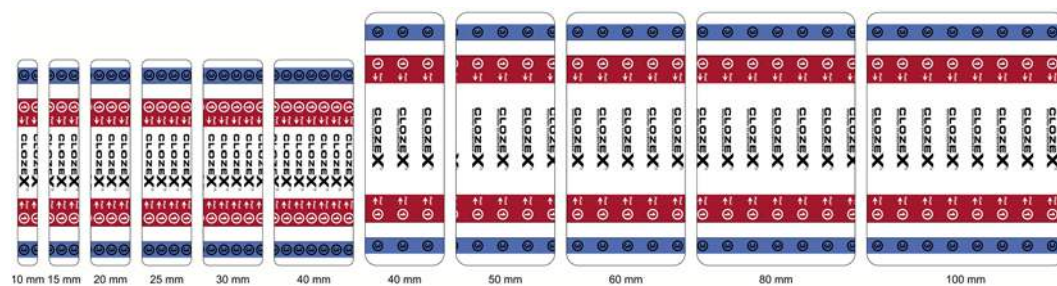
Clozex is applied as quickly as staples but requires just one clinician instead of two. It closes wounds comfortably and conveniently, is easy to remove and replace, and does not require a follow-up visit for removal. Physicians and patients appreciate the cosmetic results, which are comparable to plastic surgeons' suturing.

Clozex is cost-effective – it reduces OR time and the risk for SSIs and diminishes the need for anesthesia in the ED and follow-up visits. It's easily applied by mid-level practitioners and other non-surgical clinicians. Interest in, and demand for Clozex is growing in response to increasing numbers of joint replacements, bariatric surgeries, laparoscopic procedures and cosmetic surgeries. It is the choice of physicians and patients seeking safer, better, faster wound closure.

PRODUCT PORTFOLIO

Clozex is available in 11 product sizes and provided in 20 specialized kits for general healthcare, plastic surgery, obstetrics/gynecology, and orthopedics.

Clozex technology is protected by 6 US and 12 international patents.



Clozex is a registered trademark of Clozex Medical Inc.

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