Zip skin closure

Faster closure. Better outcomes.¹,²,⁸

Clinically proven
Over 600,000 cases
21 clinical studies
Over 30 countries
Zip is a non-invasive skin closure device for incisions and lacerations. Unlike sutures and staples, Zip uses an isolation zone and dynamic compression technology to create a puncture-free skin closure. This reduces wound complications, saving you cost and time.

Zip’s benefits aren’t only limited to healthcare providers. The non-invasive closure method also leads to greater patient satisfaction. This means less pain, a greater range of motion during recovery, and reduced scarring.

**How it works**

Zip surgical skin closure it uses a unique, non-invasive, adjustable force distribution technology and hydrocolloid skin adhesive for advanced skin closure and protection. Zip sticks to clean, dry skin adjacent to the incision, and the micro-adjustable zip straps allow the provider to approximate the incision edges for optimal closure.

The device’s isolation zone provides even distribution of forces for superior wound protection. The incision remains isolated by the scaffold-like structure and less closure force is needed to maintain wound integrity.

Zip offers flexibility during motion through dynamic compression. When the incision lengthens during flexion, the Zip accommodates while maintain would integrity due to alternating perforations between the locks on the adhesive strip.

**Key benefits**

**Reduces cost**

in hospital and after discharge

- Patients required no home health nurse visits that were otherwise required for staples
- Reduces wound-related complications and readmissions
- Reduces incision-related clinic events: 60% reduction in incision-related phone calls
- Reduces OR time and improves efficiency: Zip was 4x faster than sutures and saved an average of 7.5 minutes per procedure

**Non-invasive skin closure**

- Fewer wound-related complications
- Less bacteria penetration into the wound
- Absence of abscesses that can occur from absorbable suture material and elimination of tissue punctures that can be pathways for bacteria

**Creates a better experience**

for you and your patients

- Easier, faster, and less painful to apply and remove
- Reduced scarring
- Increased range of motion during recovery

**Improves closure strength and protection**

- 12x greater skin-holding strength vs. sutures
- Greater isolation from tension that promotes keloid and hypertrophic scars
- Higher tissue perfusion to promote healing
**Reduce** hospital and post-discharge clinic costs

Hospital/surgery center

Wound complications occur in 2–5% of all inpatient surgeries, affecting 300,000 patients every year, and the average hospital has about 40–50 wound complications per year costing the average hospital over $1 million in wound-related costs. Zip’s ability to reduce wound complications can save you cost and time, increasing your overall ROI.

---

**$59–$314**
Hospital savings per procedure based on time + materials

**$233**
Hospital savings per procedure based on fewer readmissions*

**Zip <1% of DRG**
Payment based on TKA

*Based on clinical study readmission rates of 1.79% for TKA with staples vs. 0% with Zip (p=0.045) x $13k mean cost of readmission

---

**Post op/clinic**

**Fewer incision-related events**

**$20–$143**
Savings per procedure by eliminating clinic visit to remove device

60%
Reduction in incision-related calls to clinic

75%
Reduction in antibiotics prescribed

45%
Reduction in post-discharge incision-related actual clinic costs

---

**$190 savings per problem patient**

<table>
<thead>
<tr>
<th>Labor cost</th>
<th>Revenue cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>$30</td>
<td>$250</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Zip patient</th>
<th>Staple patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zip patient</td>
<td>Staple patient</td>
</tr>
</tbody>
</table>

In this study, a follow-up clinic visit was calculated as $300, and a new patient visit was calculated as $500 (typical billable values for these visits)
A novel skin closure device for total knee arthroplasty: randomized controlled trial versus staples


Study design:
Prospective randomized, controlled study on patients undergoing same-day bilateral TKA, n=25, skin closure with Zip on one knee, staples on the other. Endpoints: Range of motion, pain, scar assessment by patient, surgeon and panel of three independent plastic surgeons. Follow-up: hospital discharge, 2 wks, 8 wks post-op. ZipLine Medical-sponsored study.

Summary results:
- Less Pain: @2wks, significantly better with Zip at discharge (p=0.03) and during device removal at POD 14 (p=0.003).
- Greater Range of Motion: @ 2wks, 72% of patients had greater range of motion on the Zip knee (p=.002), with 44% demonstrating more than 5° difference between the Zip and staple knees.
- Better Scar: @8wks scar (Likert scale, 0 to 10, 0 being best possible outcome and 10 being worst possible outcome) was significantly better with Zip device as rated by the patients (1.3 vs. 2.6,p=0.04), the surgeon (1.9 vs. 3.3, p=0.0006), and three independent plastic surgeons (3.7 vs. 4.8, p <0.001).
- Zip patients had 45% reduction in post-discharge incision-related actual clinic costs
- Zip patients had 60% reduction in incision-related calls to the clinic
- Zip patients had 75% reduction in incision-related antibiotics prescribed
- Zip patients found their scar to be cosmetically more appealing and device removal less painful
- Wound-related readmission and complication rates were lower in the Zip group (p = 0.045)
- Zip group had higher BMI (p = 0.001), incidence of diabetes (p = 0.035) and smoking (p = 0.005).

Non-invasive, zip type skin closure device vs. Conventional staples in total knee arthroplasty: which method holds greater potential for bundled payments?


Study design:
N=130 TKA patients, half staples, half Zip. Patients were followed from surgery to first clinic post-operative visit (day 21-28) for assessment. Investigator-sponsored study.

Summary results:
- Zip patients had 46% reduction in post-discharge incision-related actual clinic costs
- Zip patients had 60% reduction in incision-related calls to the clinic
- Zip patients had 75% reduction in incision-related antibiotics prescribed
- Zip patients found their scar to be cosmetically more appealing and device removal less painful

Using a non-invasive secure skin closure following total knee arthroplasty leads to fewer wound complications and no patient home care visits compared to surgical staples.


Study design:
221 prospective, consecutive subjects undergoing TKA with Zip closure. Results compared to retrospective cohort of 1001 TKA subjects with staple closure from the same surgeon. Total subjects n=1222. Investigator-sponsored study.

Summary results:
- Zip patients removed device at home; staple patients required home health visit for removal
- Wound-related readmission and complication rates were lower in the Zip group (p = 0.045)
- Zip group had higher BMI (p = 0.001), incidence of diabetes (p = 0.035) and smoking (p = 0.005)
Noninvasive device helps with elective, traumatic shoulder incision closure


Study design:
Case series of 360 shoulder arthroplasty, biceps tenodesis, proximal humerus fractures and trauma cases without substantial soft tissue injury at Johns Hopkins University-affiliated hospital. Investigator-sponsored study.

Summary results:
- No wound-related postoperative complications, dehiscence, skin irritation or infection
- Adjustable/reversible feature allows in-situ correction of under-tightening or over-tightening situations
- Zip is device of choice because of ease of use, patient satisfaction, low complication

Do zip-type skin-closing devices show better wound status compared to conventional staple devices in total knee arthroplasty?


Study design:
Randomized, Prospective, Controlled Study, Total Knee Arthroplasty, n=90, staple control.

Summary results:
Pain, cosmesis, complications. Cosmesis was significantly better with the Zip at POD 1, 3, 14 and 90 using VSS score. Zip showed less pain on postoperative 14 day, especially during dressing and removal of device. Investigator-sponsored study.

Noninvasive tissue adhesive for cardiac implantable electronic device pocket closure: the TAPE pilot study


Study design:
Does using the Zip device decrease pocket closure times without increasing the risk of pocket infections? Retrospective cohort study comparing closure times and infection rates between the Zip and standard suture for CIED. n=175 (Zip n=80, suture n=95)

Summary results:
- 26% reduction in pocket closure time. Pocket closure time was significantly shorter for the Zip group (14.9 ± 6.8 vs 20.1 ± 11.09 min, p = 0.0003).
- 22% reduction in procedure time. Procedure time was significantly shorter for the ZIP group (65.02 ± 30.4 vs 83.83 ± 40.3 min, p = 0.0008).
- No complications occurred in the Zip group, while the suture group had 2 complications: 1 wound dehiscence and 1 pocket infection (NSS).
- The Zip device resulted in significantly shorter pocket closure and procedure times without increasing device pocket infections.
**Improvement in S-ICD Incision Closure Time and High Implanter Satisfaction Using a Novel Skin Closure Device.**


**Summary results:**
- Zip was 4x faster than sutures and saved an average of 7.5 minutes per procedure
- Case to case closure time variability with sutures was 8x higher than with Zip
- Physician satisfaction with the Zip was 3.9/4.0 (4.0=best) based on ease of use, speed and quality of closure
- All physicians were “very likely” to use Zip again

**Study design:**
1 Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) implanters at 21 US sites for a total of 39 patients; Zip n=18, Suture n=21. Investigator-sponsored Study.

---

**Cardiac device implant skin closure with a novel adjustable, coaptive tape-based device**


**Summary results:**
- Zip demonstrated 64% reduction in mean closure time per cm of incision length (18.0 ± 2.0 sec/cm for Zip vs. 50.1 ± 6 sec/cm for suture, p<0.001)
- Zip closure demonstrated less patient-patient variance in closure time (Zip std. err. 2.08 vs. sutures std. err. 6.72 p<0.001)

**Study design:**
Pacemaker and ICD implant. Prospective, randomized, controlled study, n=40, suture control. ZipLine-sponsored study. Investigators declared no conflict of interest.

---

**New skin closure system facilitates wound healing after cardiovascular implantable electronic device surgery**


**Summary results:**
- Case 1: Subcutaneous-implantable cardioverter defibrillator (S-ICD) generator swap; Zip removed at POD14; excellent results at 6mo follow up
- Case 2: “Zip Rescue”: Obese diabetic on hemodialysis with incomplete wound healing from traditional method for skin closure at three weeks after ICD implant: sutured wound dehisced and Zip device was placed as a “rescue”; Zip was removed 14 days later without further complications.

**Study design:**
Two case series of ICD and S-ICD closure using Zip device. The author found the Zip to be particularly useful when wound healing is difficult with traditional methods and in patients at high risk for surgical site infections (SSIs). Investigator-sponsored study.
Randomized study of a new non-invasive skin closure device for use after congenital heart operations.

Study design:
Randomized, prospective, controlled study. n=214, suture control; patients undergoing cardiac operations (sternotomy). Patient Age (months)- Primary group: 18.6 ± 36.8 months old for Zip, 16.8 ± 25.3 months old for suture arms; Reoperation group: 30.5 ± 45.9 months old for Zip, 21.6 ± 19.8 months old for suture arms. Investigator-sponsored study.

Summary results:
- Zip 3.3x faster than sutures (113.0 ± 9.1 sec for Zip vs 375.9 ± 60.2 sec for sutures, p < 0.001)
- Variance in Zip closure time was considerably smaller compared to the suture time variance
- Cosmetic appearance was significantly better in the Zip group
- Fewer wound infections occurred in the Zip group (non-statistically significant result)
- Zip patients showed less pain during removal vs. stitches, (7.1% vs 52.5%, p < 0.001)
- Procedure time reduced by 59% with children and 62% with adults. Average total treatment time in the pediatric and adult cohorts using the Zip was reduced by 59%(p=0.004) and 62%(p=0.010), respectively, when compared to sutures
- 69% less patient pain. All patients reported 69 percent less pain during closure (mean VAS 12.8 and 40.9, respectively), 31 percent less pain during closure removal, and 54 percent less pain when assessing overall scar pain (mean VAS 9.7 and 20.8, respectively) with the Zip versus sutures
- 66% less patient anxiety. Patients treated with the Zip reported 66% less fear or anxiety during wound closure compared to sutures (mean VAS 11.8 and 34.6, respectively)
- Eliminated additional clinic visit. The majority of patients receiving the Zip removed the device at home while the suture cohort required an additional visit to a local primary care provider for suture removal.

Non-invasive Zip wound closure for lacerations in the adult and pediatric A & E

Study design:
13 pediatric and 13 adult patients presenting to the emergency department with a laceration were randomized to receive Zip or nylon sutures. Primary outcome was total procedure time, with patient pain as a secondary outcome, both measured using the Visual Analog Scale. Patient satisfaction, pain and adverse events were recorded via phone interview 10 and 30 days post-treatment.

Summary results:
- Procedure time reduced by 59% with children and 62% with adults.
- Average total treatment time in the pediatric and adult cohorts using the Zip was reduced by 59%(p=0.004) and 62%(p=0.010), respectively, when compared to sutures.
- 69% less patient pain. All patients reported 69 percent less pain during closure (mean VAS 12.8 and 40.9, respectively), 31 percent less pain during closure removal, and 54 percent less pain when assessing overall scar pain (mean VAS 9.7 and 20.8, respectively) with the Zip versus sutures.
- 66% less patient anxiety. Patients treated with the Zip reported 66% less fear or anxiety during wound closure compared to sutures (mean VAS 11.8 and 34.6, respectively).
- Eliminated additional clinic visit. The majority of patients receiving the Zip removed the device at home while the suture cohort required an additional visit to a local primary care provider for suture removal.
Reconstructive/plastic surgery

Use of a novel non-invasive skin closure for prevention of wound dehiscence in trunk based surgery


Summary results:
- Case series, n=8, use of Zip device in abdominoplasty, panniculectomy and breast reconstruction
- When sutures or staples are used, trunk-based surgical procedures are at high risk of complications (up to 33%)
- The study recorded factors affecting wound healing, including BMI, smoking, steroid use, use of liposuction and history of bariatric surgery
- All patients had excellent results, no wound-related complications with Zip device. Ongoing studies are planned

Control of the skin edge tension after resection: a new adjustable, adhesive medical device.


Summary results:
Uncontrolled case series of 21 patients received Zip after undergoing scar resection, cancer, flap, burn sequela, pressure sore or re-closure of previous postoperative dehiscence. Zip devices were placed operatively with an average wear time of 42 days and with an average of 3 device changes. Scars were evaluated by independent evaluators; results were considered positive if scars remained linear without secondary enlargement after 6 months. Serial use of the Zip for an average of 6 consecutive weeks appears to limit postoperative mechanical tension and minimize scars, even in areas in tension and after keloid excision. Investigator-sponsored study.

Infection prevention and wound healing

In-Vivo Efficacy Study Showing Comparative Advantage of Bacterial Infection Prevention with Zip-Type Skin Closure Device Vs. Subcuticular Sutures


Study design:
Controlled, prospective quantitative in-vivo animal study assessing environmental bacteria penetration with the Zip compared to subcuticular suture. n=16. Two dorsal incisions were made on each subject, one closed with Zip and the other with running subcuticular sutures. Closed incisions were exposed to common bacteria (S. aureus) and then exposed to controlled distraction forces to simulate normal patient movement during recovery. Subjects were observed daily and euthanized on POD7. Incisional skin was excised, H&E stained and evaluated for inflammation and the presence of bacterial infection. A portion of each incision was cultured and colony-forming unit was quantified and compared

Summary results:
- 100x less bacteria in Zip incisions. Mean bacteria in Zip incisions was 10^-3 CFU/10 uL, while the mean bacteria count in the sutured samples was 10^-5 CFU/10 uL
- Significantly less inflammation in Zip incisions. Inflammation measured by histology analysis: Zip incisions rated minimal to slight; sutured incisions rated moderate to severe. This suggests that formation of scar tissue may be less with the Zip. Sutured incisions had large abscesses with suture material inside them as well as purulent exudate containing pus, neutrophils, debris and large numbers of bacteria
- The data indicate less bacteria in the wound site and a possible lower rate of infection in surgical incisions closed with the Zip compared to subcuticular sutures
Mechanics of Wound Closure: Emerging Tape-Based Wound Closure Technology vs. Traditional Methods


Study design:
In-vivo animal study measuring the effect of Zip force distribution and isolation mechanism on minimizing distraction forces on an incision. Incisions were closed with subcuticular sutures, staples or Zip. Two experiments were performed: 1) skin on either side of the closed incision was stretched to strains of 5% and 10% and tissue strain was analyzed using Digital Image Correlation (DIC), and 2) distraction force was applied and measured until incision edges acutely separated by 1mm. ZipLine-sponsored study.

Summary results:
• The Zip showed greater and more uniform isolation from shear compared to staples and sutures
• Staples demonstrated significant non-uniform shear strains which can lead to scarring
• Shear was lower with sutures vs. staples but higher vs. Zip. In 40% of the sites, sutures were unable to hold the wound intact during the experiment, leading to dehiscence
• The holding strength difference between the Zip and staples was not statistically significant (p > 0.05); staples and Zip had a significantly higher holding strength with respect to sutures (p < 0.01); however, while the pull force required to separate the stapled wound was relatively high, staples were observed to pinch healthy skin around the staples, causing inflammatory reaction
• 12x greater skin-holding strength vs. sutures

Experience with the use of “supplementary kit for infection prevention” in joint replacement surgery in Military Hospital Central

Insuasty M, Arbelaez W, Avendario E, Guzman Melo L. “Experience with the use of “supplementary kit for infection prevention” in joint replacement surgery in Military Hospital Central.” Poster session presented at 12th Annual ELCCR – Latin American Meeting of Hip and Knee Surgeons, August 3-6, 2016, Cartagena, Colombia. (translated from Spanish)

Study design:
Observational, descriptive, retrospective study of case series, primary replacement of the hip or knee using a group of products for prevention of infection. 22 patients. Investigator sponsored study.

Summary results:
• Use of the Zip demonstrated reduced wound complications and excellent satisfaction
Effect of Surgical Incision Closure Device on Skin Perfusion Following Total Ankle Arthroplasty

Davis A, Vaughn M, Piraino J. "Effect of Surgical Incision Closure Device on Skin Perfusion Following Total Ankle Arthroplasty." Poster session presented at American College of Foot and Ankle Surgeons; Feb 27-Mar 1; Las Vegas, NV.

Study design: 9 patients underwent total ankle arthroplasty, 5 were closed with Zip, 4 with staples. Laser assisted indocyanine green angiography (LA-ICGA) was used to measure tissue perfusion pre- and post-operatively.

Summary results:
- Zip demonstrated statistically significant higher tissue perfusion than staples (decrease from baseline: Zip -21.6 ± 4.1% vs. staples -39.3 ± 4.3%, p<0.001). Investigator-sponsored study.

Chronic wounds/limb salvage

A randomized, controlled, prospective clinical study comparing a novel skin closure device to conventional suturing


Summary results:
- Surgeons rated an average 4.6/5 ease of application and 4.1/5 ease of removal (5=best)
- POD10 surgeon-reported Wound Evaluation Scale (WES) score of 5.4/6 (6=best)
- Patient-reported postoperative pain 1.5/10 (10=worst) and pain during device removal 0.9/10
- Patient-rated overall satisfaction avg. 3.4/4 and comfort avg. 3.6/4 (4=best)
- Cosmetic outcomes at 2-3 months post-op visit average VAS score was 83.5/100 (100=best)

Dermatology

A Novel Noninvasive Wound Closure Device as the Final Layer in Skin Closure.


Study design: Randomized, controlled prospective study comparing Zip to sutures in melanoma excisions; n=20, patients with basal cell carcinoma, squamous cell carcinoma or dysplastic nevi of the trunk (n=14) or extremities (n=6); This study was conducted using an early version of the Zip device (Zip 3).

Summary results:
- The Zip was twice as fast as suture closure (p=0.001). ZipLine-sponsored study. Investigators declared no conflict of interest.
Orthopaedic Instruments

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Stryker or its affiliated entities own, use, or have applied for the following trademarks or service marks: Stryker and Zip. All other trademarks are trademarks of their respective owners or holders. The absence of a product, feature, or logo from this list does not constitute a waiver of Stryker’s trademark or service name, or logo from this list. All other intellectual property rights concerning that product, feature, or logo are the property of their respective owners or holders. The absence of a product, feature, or logo does not constitute a waiver of Stryker’s trademark or service name, or logo from this list. All other trademarks are the property of their respective owners or holders. The absence of a product, feature, or logo from this list does not constitute a waiver of Stryker’s trademark or service name, or logo from this list.

For more information or to place an order, please contact your Stryker Orthopaedic Instruments sales representative or call 800 253 3210.

Stryker
1941 Stryker Way
Portage, MI 49002 USA

t: 269 323 7700 f: 800 999 3811
toll free: 800 253 3210
stryker.com/surgical

3. Davis A, Vaughn M, Piraino J. “Effect of Surgical Incision Closure Device on Skin Perfusion Following Total Ankle Arthroplasty.” Poster session presented atAmerican College of Foot and Ankle Surgeons; Feb 27.
13. DERMABOND™ PRINEO™ Skin Closure System 22 cm Instructions for Use. Ethicon, Inc.PM724728 Dermanbond Prineo 22 CM Non-CE IFU CLR222US. Assumes application of subcuticular suture skin closure prior to Prineo application. Prineo baseline application time is based on Blondeel, et.al. Evaluation of a New Skin Closure Device in Surgical Incisions Associated With Breast Procedures. Annals of Plastic Surgery, Vol 73, No 6, Dec 2014. Data used: 32.87cm mean incision length,2.56min mean application time (excluding dry time). Added to this are 5 minutes dry time, yielding 68 sec/cm total application time, suture + Prineo.

Literature Number: D0000057253 Rev AA
Copyright © 2020 Stryker