Zip® Surgical Skin Closure

Suture-like outcomes at the speed of staples¹

• Clinically Proven
• Over 500,000 Cases
• 16 Clinical Studies
• Over 30 Countries
NON-INVASIVE WOUND CLOSURE DEVICE

The Zip Surgical Skin Closure is a non-invasive, advanced wound closure device for incisions and lacerations. It not only replaces staples, sutures and glue, but also provides additional benefits for better clinical outcomes and significant episode-of-care cost savings. The Zip is available in 4 lengths, can be applied on a gentle curve, and may be cut or combined as needed.

KEY BENEFITS:

• Reduces Cost in Hospital and After Discharge
  > Eliminates clinic or nurse visit for staple or suture removal 3, 4, 5
  > Reduces wound-related complications and readmissions 3, 4, 5
  > Reduces clinical revenue losses due to problem patients on clinic revenue by 78% and labor by 44% 5, 6
  > Reduces incision-related clinic events: 60% fewer phone calls, fewer ER admissions and fewer antibiotics prescribed 5
  > Reduces OR time and improves efficiency – Zip is 4x faster and 5x more consistent between users 7

• Reduces Invasiveness of Wound Closure
  > Fewer wound-related complications 3, 5
  > Less bacteria penetration into the wound 8
  > Eliminates piercing of healthy, intact skin and does not leave foreign material in the wound
  > Increases staff safety with fewer needle-stick injuries

• Increases Patient Satisfaction
  > Less patient pain 9, 10
  > Superior scar quality 1, 5, 9, 10
  > Greater patient range of motion 9

• Improves Wound Closure Strength and Protection
  > 12x greater skin-holding strength vs. sutures 11
  > Greater isolation from tension that promotes keloid & hypertrophic scars 11, 12
  > Higher tissue perfusion to promote healing and reduce complications 13, 14
  > When used with tissue glue, proven >99% effective through 72 hours in vitro against bacteria associated with Surgical Site Infection (SSI) 15

HOW IT WORKS

The Zip Surgical Skin Closure is not a staple, suture or glue; it uses a unique, non-invasive, adjustable force distribution technology and advanced hydrocolloid skin adhesive for advanced wound closure and protection. The Zip sticks to healthy, intact skin adjacent to the wound, and the micro-adjustable zip straps allow the provider to approximate wound edges for optimal closure. The patented force distribution structure acts as a cage or scaffold to distribute tension and offload external distraction forces, resulting in a lower-tension closure, with greater perfusion for better healing. For knees, the integrated structure uniquely extends with the wound during joint flexion, providing gentle compression to maintain wound integrity during rehab exercises or normal daily movement.

* at provider discretion.
**REDUCE HOSPITAL AND POST-DISCHARGE CLINIC COSTS**

**HOSPITAL / SURGERY CENTER**

<table>
<thead>
<tr>
<th>Method</th>
<th>Staples</th>
<th>Suture</th>
<th>Prineo</th>
<th>ZipLine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mat'l Cost*</td>
<td>$33</td>
<td>$12</td>
<td>$122</td>
<td>$92</td>
</tr>
<tr>
<td>Time (min)</td>
<td>6.9</td>
<td>14.4</td>
<td>18.1**</td>
<td>3.7</td>
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<tr>
<td>Cost of Time</td>
<td>$257</td>
<td>$533</td>
<td>$671</td>
<td>$138</td>
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<tr>
<td>Time+Mat'l</td>
<td>$290</td>
<td>$545</td>
<td>$793</td>
<td>$230</td>
</tr>
<tr>
<td>Cost Savings</td>
<td>$59</td>
<td>$314</td>
<td>$563</td>
<td></td>
</tr>
</tbody>
</table>

* Publicly available/published prices for materials needed to close a 16cm incision
** Prineo case includes subcuticular suture step

**$59 – $563**
Hospital savings per procedure based on time + materials\(^{7,16-21}\)

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

Based on clinical study readmission rates of 1.79% for TKA with staples vs. 0% with Zip (p=0.045)\(^3\) x $13k mean cost of readmission\(^{22}\)

**Zip <1% of DRG**
Payment based on TKA\(^{23}\)

**POST OP / CLINIC**

**$20 – $143**
Savings per procedure by eliminating nurse or clinic visit to remove device\(^{3,5,24}\)

<table>
<thead>
<tr>
<th>Fewer Incision-Related Events(^5)</th>
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</thead>
<tbody>
<tr>
<td><strong>60%</strong></td>
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<tr>
<td>Reduction in incision-related calls to clinic</td>
</tr>
<tr>
<td><strong>75%</strong></td>
</tr>
<tr>
<td>Reduction in antibiotics prescribed</td>
</tr>
<tr>
<td><strong>60%</strong></td>
</tr>
<tr>
<td>Fewer incision-related ER visits</td>
</tr>
<tr>
<td>Reduction in incision-related clinic visits</td>
</tr>
</tbody>
</table>

**$190 Savings per Problem Patient\(^5\)**

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)
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.

Carli AV, Spiro S, Barlow BT, Haas SB. "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." Knee. 2017 Oct;24(5):1221-1226.

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.

- 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)

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

Emerson, Roger. "Non-invasive, zip type skin closure device vs. conventional staples in total knee arthroplasty: Which method holds greater potential for bundled payments?" Scientific presentation given at The Knee Society 2017 Meeting; Sep 15, 2017; Naples, FL.

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.

- Zip patients had 45% reduction in post-discharge incision-related actual clinic costs
- Zip patients had 60% reduction in incision-related clinic visits
- 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

A Novel Skin Closure Device for [Bilateral] Total Knee Arthroplasty: Randomized Controlled Trial vs. Staples


Randomized, controlled, prospective, n=25, simultaneous bilateral TKA, Zip on one knee vs. staples on the other. Follow-up at discharge, 2 and 8 weeks post-op. ZipLine-sponsored study. Investigators declared no conflict of interest.

- 72% of patients had greater range of motion on Zip knee (p = .002), with 44% demonstrating >5° difference between the Zip and stapled knees
- Less pain on the Zip-closed knee vs. staples at discharge (p = 0.03), at 2-week follow-up (p = 0.03) and during device (Zip and staple) removal (p = 0.003)
- Both physicians and patients rated scar quality better on the Zip-closed knee
- 92% of patients indicated preference for the Zip in their next surgery

Noninvasive device helps with elective, traumatic shoulder incision closure


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.

- 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 rate, cosmesis of closure, speed of application and time savings during follow-up clinic visits
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.

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. 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.

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


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

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

Insuasty M, Arbelaez W, Avendaño F, 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)

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.

• Satisfaction with surgical wound was better than expected in 19 patients and worse in 3 patients
• No infections, hematomas, or other complications
• Use of the Zip demonstrated reduced wound complications and excellent satisfaction

Noninvasive Tissue Adhesive for Cardiac Implantable Electrical Device Pocket Closure: The TAPE Study


Retrospective study on pacemaker patients at University of Missouri. n=175 subjects, Zip (n=80) and Suture (n=95). Metrics: infection rates, total procedure and pocket closure time. Investigator-sponsored study.

• Pocket closure time was significantly shorter for the Zip group (14.9 ± 6.8 min) vs. the suture group (20.1 ± 11.1 min, p=0.0003)
• Procedure time was significantly shorter for the Zip group (65 ± 30.4min) vs. the suture group (83.8 ± 40.3 min, p=0.0008)
• Zip saved on average 19 minutes on nominal 84 minute procedure, or 22% procedure time reduction
• No infections or dehiscence in Zip group; Suture group had one dehiscence and one pocket infection, both leading to device extractions (NSS)
Improvement in S-ICD Incision Closure Time and High Implanter Satisfaction Using a Novel Skin Closure Device.


21 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.

• 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

Cardiac Device Implant Skin Closure with a Novel Adjustable, Coaptive Tape-Based Device


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

• 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)

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


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.

• 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 with excellent results

Randomized Study of a New Noninvasive Skin Closure Device for Use After Congenital Heart Operations.


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 ± 2.5 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.

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


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.

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


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

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


Mechanics of Wound Closure: Emerging Tape-Based Wound Closure Technology vs. Traditional Methods


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.

• 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

2 Compared to standard of care closure such as staples or sutures.

3 Carli AV, Spiro S, Barlow BT, Haas SB. Using a non-invasive secure skin closure following total knee arthroplasty leads to fewer wound complications and no patient home visits compared to surgical staples. Knee. 2017 Oct;24(5):1221-1226.

4 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.

5 Emerson, Roger. “Non-invasive, zip type skin closure device vs. conventional staples in total knee arthroplasty: Which method holds greater potential for bundled payments?” Scientific presentation given at The Knee Society 2017 Meeting; Sep 15, 2017; Naples, FL.

6 Data on file.

7 Goldman DS, Hammill E, Aasbo J, Sterne E, Reddy S. Improvement in S-ICD Incision Closure Time and High Implanter Satisfaction Using a Novel Skin Closure Device. Scientific presentation given at Asia-Pacific Heart Rhythm Society 2017 Meeting; Sep 16, 2017; Yokohama, Japan. Closure rate consistency is based on comparison of interquartile ranges (IQR).


13 Davis A, Vaughn M, Piraino J. “Effect of Surgical Incision Closure Device on Skin Perfusion Following Total Ankle Arthroplasty.” PostersessionpresentedatAmericanCollegeofFootandAnkleSurgeons;Feb27-Mar1;LasVegas,NV.


17 8-20 DERMABOND™ PRINEO™ Skin Closure System 22 cm Instructions for Use. Ethicon, Inc.PM72472B Dermabond 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: 32.87 cm mean incision length, 2.56 min mean application time (excluding dry time). Added to this are 5 minutes dry time, yielding 68 sec/cm total application time, suture + Prineo.


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