Clinical Investigation Plan (CIP)

Zip® Surgical Skin Closure Device

ZIPS Study - **Z**ip **I**ncision a**P**proximation vs. **S**taple

A prospective, randomized controlled post-market study to compare the use of the Zip® Surgical Skin Closure Device versus conventional staples for skin closure in subjects having undergone bilateral knee arthroplasty – Protocol No. 006

Sponsor:	ZipLine Medical, Inc. 747 Camden Ave., Suite A, Campbell, CA 95008 Phone: 1-888-326-8999 Fax: 1-888-265-0669 Email (non-study inquiry): customerservice@ziplinemedical.com Web: www.ziplinemedical.com
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Principal Investigator:	Reference Section 7.2
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Date of Issue:	21Apr2015, Version 1.0

This protocol contains confidential information for use by the Investigators and their designated representatives participating in this clinical investigation. It should be held confidential and maintained in a secure location.

1 *ZIPS Study-* Trial Protocol Synopsis

Study Title	**ZIPS Study - Zip Incision aPproximation vs. Staple** A prospective, randomized controlled post-market study to compare the use of the Zip® Surgical Skin Closure Device versus conventional staples for skin closure in subjects having undergone bilateral knee arthroplasty – Protocol No. 006
Overall Objective	The objective of this study is to evaluate the Zip Surgical Skin Closure device versus conventional steel staple placement when utilized for surgical wound closure after bi lateral unicompartmental (UNI) or bi lateral total knee replacement (TKA).
Study Device	ZipLine Medical Inc., Zip Surgical Skin Closure Device
Indication for Use	The Zip Surgical Skin Closure Device is indicated for use during and after skin incision procedures to approximate skin and hold together the skin edges until healing can take place.
Study Design	A prospective, non-blinded, randomized, within patient control study. A total of up to 25 subjects (targeted min. n=22) requiring bilateral knee arthroplasty (unicompartmental or total) will be enrolled. Each subject will serve as their own control, since one knee closure will be with staples, and the other knee closure with Zip device. The order of patients will be randomized to receive Zip device on one knee and steel staples on the opposing knee.
Number of Subjects	A total of up to 25 patients (serving as their own control) will be enrolled. There is anticipated patient fall out (screen failures) post procedure due to surgeon not knowing which procedure is required (total or unicompartmental) until time of surgery.
Number of Sites	≤ 3
Duration of Study	Each enrolled subject will be followed until 6 to 8 weeks post-procedure.
Primary Effectiveness Endpoints	Wound healing as judged by the CVAS (Cosmetic Visual Analogue Scale) wound healing scale – *From photos taken between 6 to 8 weeks post op visit – to be judged by panel of Plastic Surgeon blinded to treatment assignments.*

Secondary Effectiveness Endpoints	• **Surgeon** evaluation including:
	  o Closure Method Satisfaction
	  o Scar Satisfaction
	  o Wound Healing as judged by the surgeon using the WES (Wound Evaluation Scale) at the 6 to 8 week final post op visit.
	• **Physical Therapist**
	  o Range of Motion (ROM) Measurements
	• **Patient** experience including:
	  o Pain (General Post-Operative & Incisional)
	  o Closure Method Comfort
	  o Closure Method Satisfaction
	  o Scar Satisfaction

Primary Safety Endpoint	The incidence and severity of adverse effects associated with Zip device and standard steel staple usage.
Secondary Safety Endpoint	None
Follow-Up Schedule	The study will be considered complete (with regard to the primary endpoint) after 22 subjects have completed the 6 to 8 - week follow up visit.
Inclusion Criteria	1. Patients 18 years of age and older; 2. Patients requiring epidermal closure after bi lateral total or partial (unicompartmental) knee arthroplasty; 3. Patients willing to be evaluated at discharge, 2 weeks, and at the 6 to 8 week post op.
Exclusion Criteria	1. Known bleeding disorder not caused by medication 2. Known personal or family history of keloid formation or scar hypertrophy 3. Known allergy or hypersensitivity to non-latex skin adhesives 4. Atrophic skin deemed clinically prone to blistering 5. Any skin disorder affecting wound healing 6. Any other condition that in the opinion of the investigator would make a particular patient unsuitable for this study

Study Administration		
Manager Clinical Affairs	Christy Cowley 747 Camden Ave., Suite A, Campbell, CA 95008 ccowley@ziplinemedical.com	408-857-2083 (cell)

2 Table of Contents

3 Introduction

3.1 Background and Rationale

Surgical site wound closure plays a vital role in post-operative success. This effect is magnified with commonly performed elective procedures such as knee arthroplasty[1]. Sutures and staples are most commonly used based on surgeon preference and wound location. Staples are frequently used due to their deployment speed advantage over sutures. It has been suggested that the ideal method of wound/incision closure should be fast and non-traumatic, be associated with a low incidence of dehiscence and infection, and should yield acceptable cosmetic results; and while sutures and staples are presently the most common method of surgical closure, they do not demonstrate many of these properties [1,2]. Therefore, developing new methods to reduce overall treatment time while producing comparable or potentially improved cosmetic scar results and maintaining low complication rates has obvious benefits.

ZipLine Medical, Inc. has developed a novel, non-invasive skin closure device called "Zip Surgical Skin Closure" to replace sutures, staples and glue for closure of the skin layer for surgical incisions or laceration repair. The device is FDA Class I, 510(k) Exempt and began commercial use in the USA in April 2013. The device is designed to provide closure speed superior to sutures, while resulting in a suture-like cosmetic outcome. Both pre-clinical feasibility study data and feedback from over 2000 human cases during the device's commercial use in the USA suggest that these design intentions are correct. This study will test these assertions in a controlled clinical setting, with the goal of providing results with statistical significance.

We anticipate this clinical study to be completed within 12 months from site initiation/training to site closure.

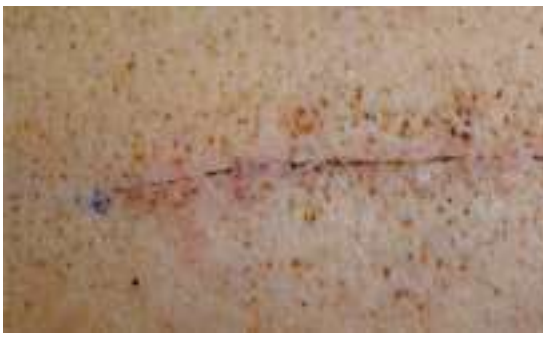
3.2 Summary of Findings from Previous Studies

3.2.1 Pre-clinical Studies

Preclinical feasibility testing of the ZipLine technology using a chronic porcine model was conducted in 2010. Surgical incisions were closed either with the ZipLine technology, or absorbable subcuticular sutures. Devices were removed at two weeks post-operatively, and resulting scars were evaluated at 6-weeks by a blinded panel of four board-certified plastic surgeons. Results revealed excellent cosmesis when compared to subcuticular suture controls.

Below is an example of comparative outcomes at 2 weeks post-op:

ZipLine Closure



Subcuticular Suture Closure

The Cosmetic Visual Analog Scale (CVAS) and ordinal Wound Evaluation Scale (WES) were used to evaluate photographs of each scar from the test subjects. Evaluators were blinded to the type of closure method used for each wound.

Surgical Incision Closure

	Closure Mechanism	Avg WES	Avg CVAS
Subject 1	Controls, n=2	5.25	83.5
	ZipLine 10cm, n=4	5.95	92.75
Subject 2	Controls, n=2	5.90	84.5
	ZipLine 10cm, n=4	5.95	93.0

Skin Excision Closure

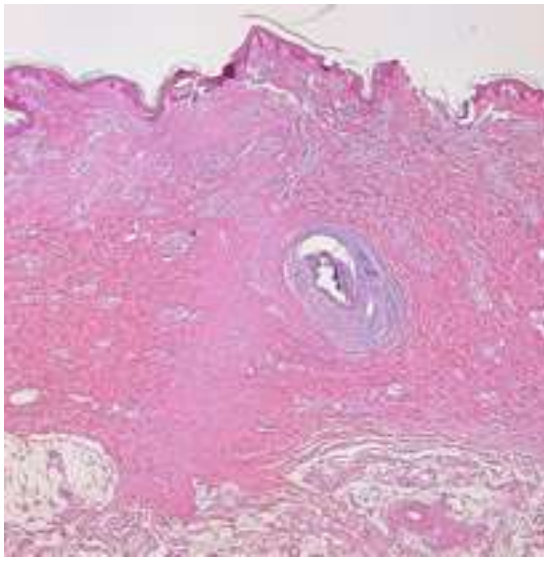
	Closure Mechanism	Avg WES	Avg CVAS
Subject 1	Controls, n=2	5.55	89
	ZipLine excision, n=1	6.00	88
Subject 2	Controls, n=1	5.50	89
	ZipLine excision, n=1	6.00	88

These results suggest that incisions and excisions closed using ZipLine technology can result in at least equivalent cosmesis when compared to suture closure.

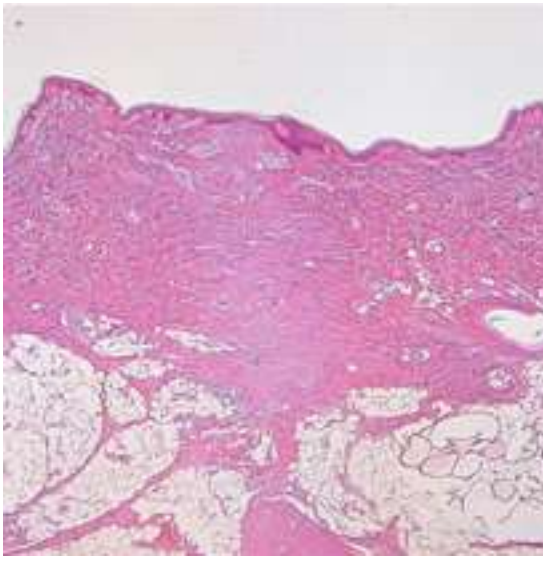
Histology

Histological analysis was performed on sample scars from both test and control groups.

Surgical Incision Closure

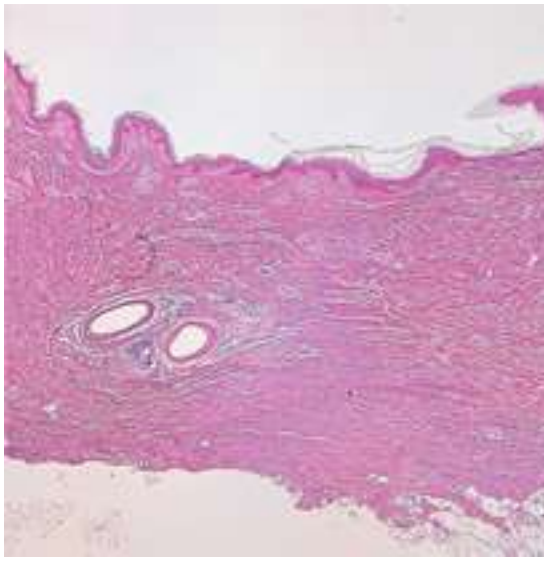


Subcuticular Suture Closure

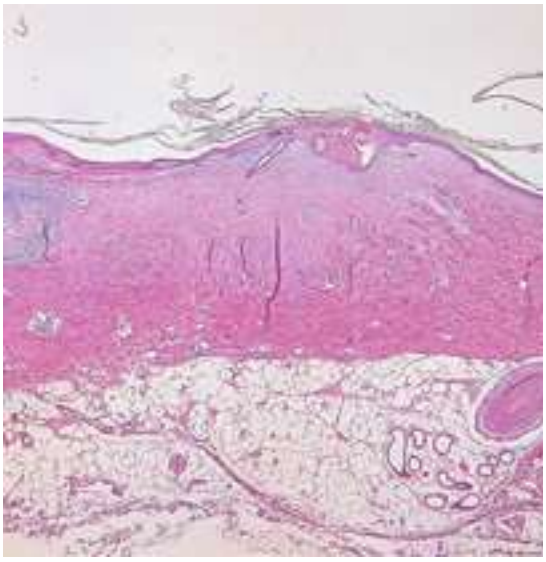


ZipLine Closure

Skin Excision Closure



Subcuticular Suture Closure



ZipLine Closure

H&E staining was performed on representative cross-sections of incisions closed with traditional suture techniques vs. the ZipLine device. The width and depth of the resulting scars as well as the degree of local inflammatory response were evaluated by a pathologist blinded to the closure method. The degrees of scarring and inflammation were deemed to be qualitatively equivalent between the two groups.

This was an internal feasibility study and the results have not been published.

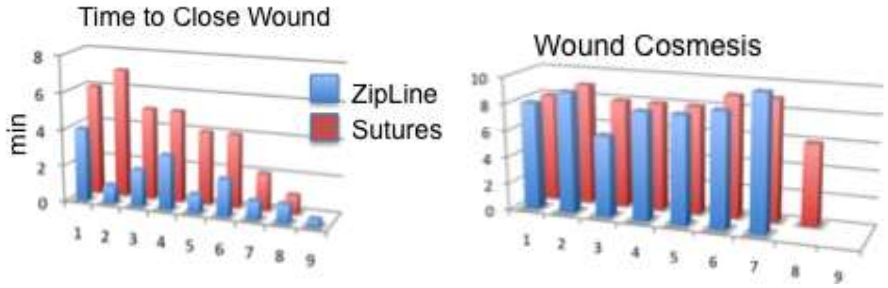
3.2.2 Clinical Studies

Mt. Sinai School of Medicine-

A randomized, controlled, prospective post-market study was recently completed at Mt. Sinai School of Medicine's Division of Mohs, Reconstructive, and Cosmetic Surgery. The study compared suture control to an earlier variant of the Zip Surgical Skin Closure device for skin cancer excision. The manuscript has been completed and submitted to a peer-reviewed journal for publication.

Preliminary clinical study results from this study were presented at the 16th Annual Mount Sinai Winter Symposium on Advances in Medical and Surgical Dermatology which took place Dec. 6-8, 2013 in New York.

Hooman Khorasani, M.D., Chief of the Division of Mohs, Reconstructive, and Cosmetic Surgery at Mount Sinai School of Medicine, and principal investigator for the study presented the preliminary results to an audience of over 400 dermatological surgeons. He is deeply involved in minimal scar wound repair research and has done extensive research in this area of scar-less wound healing. He is currently conducting two clinical trials addressing improved scarring after surgery.



"In the study, the ZipLine device produced similar cosmetic outcomes to a traditional suture closure while significantly reducing the treatment time, which can in turn reduce the overall cost of the procedure. In addition, since with the ZipLine there are no sutures to remove, this limited the need for immediate patient return, which can benefit both the patient and clinic. The patient can instead return later when the wound is more healed," said Dr. Khorasani. The preliminary data suggested a 57% reduction in wound closure procedure time when using the ZipLine device instead of sutures.

UC San Diego CIED (Pacemaker) Study –

A blinded, controlled and randomized study is currently underway at UC San Diego. Most cases have already been completed with promising results. A total of 40 patients underwent pacemaker or defibrillator insertions, and skin closure was randomly assigned to either subcuticular sutures or the Zip Surgical Skin Closure device. Primary endpoints for the study are closure time and cosmesis.

The Zip Surgical Skin Closure Device is an FDA Class I, 510(k) Exempt device, and no clinical studies were required for regulatory clearance. The aforementioned clinical studies are post-market studies aimed at providing statistically significant performance data regarding the Zip device.

3.3 Risks and Benefits

3.3.1 Risks

Complications that may occur include:

- Allergic response
- Infection
- Dehiscence requiring intervention
- Device failure / malfunction
- Edema
- Wound site pain / discomfort
- Excessive scarring including:
    - Step-off
    - Contour irregularities
    - Excessive distortion
    - Poor cosmetic appearance

Previous evaluations have not shown any additional risks in comparison to those associated with existing wound closure methods.

3.3.2 Benefits

The potential benefits of the Zip Surgical Skin Closure device over staples include:

- Improved cosmetic outcome

- Equivalent adverse event (e.g., dehiscence, infection) occurrence
- Greater patient satisfaction
- Reduced risk of surgical site infection due to the ZIP device's non-invasive application
- Reduced number and expertise (MD vs. PA) of resources required for closure

This study is intended to measure the result of some or all of these benefits.

4 Device Description

4.1 Device Overview

ZipLine Medical, Inc. has developed a novel, non-invasive skin closure device called "Zip Surgical Skin Closure" to replace sutures, staples and glue for closure of the skin layer for surgical incisions or laceration repair. The device is designed to provide closure speed superior to sutures, while resulting in a suture-like cosmetic outcome. Both pre-clinical feasibility study data and feedback from over 2000 human cases during the device's commercial use in the USA suggest that these design intentions are correct. This study will test these assertions in a controlled clinical setting, with the goal of providing results with statistical significance.

The Zip device is a single use, sterile medical device.

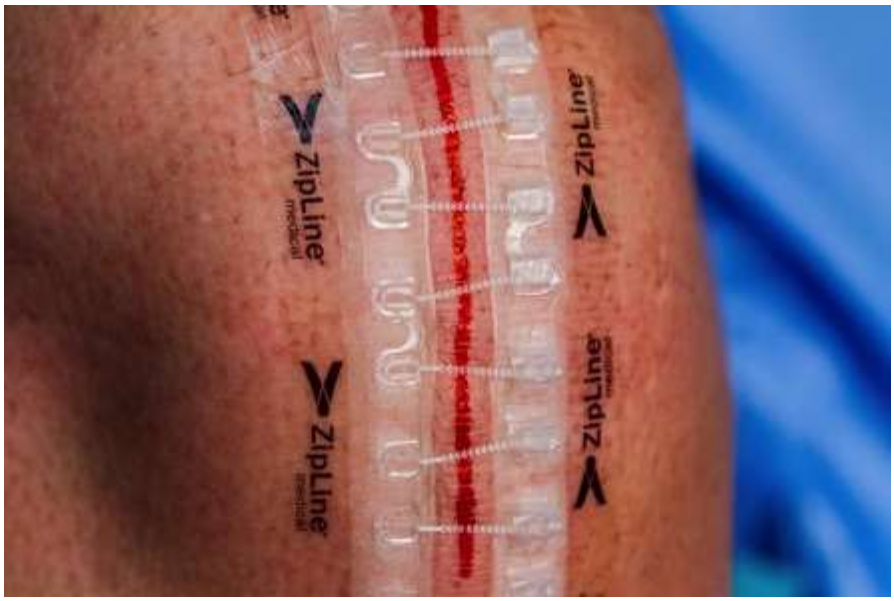


Figure 1. Zip Surgical Skin Closure Device

The Zip Surgical Skin Closure Device is applied to clean, dry skin after deeper tension-relieving (i.e., dermal or subcutaneous) sutures have been applied.

The device adheres to the skin adjacent to an incision by use of pressure-sensitive skin adhesives. A combination of acrylic and hydrocolloid adhesives are used to provide a skin-friendly environment while providing the necessary tack to maintain skin adhesion during the recommended wear time of the device (7-14 days).

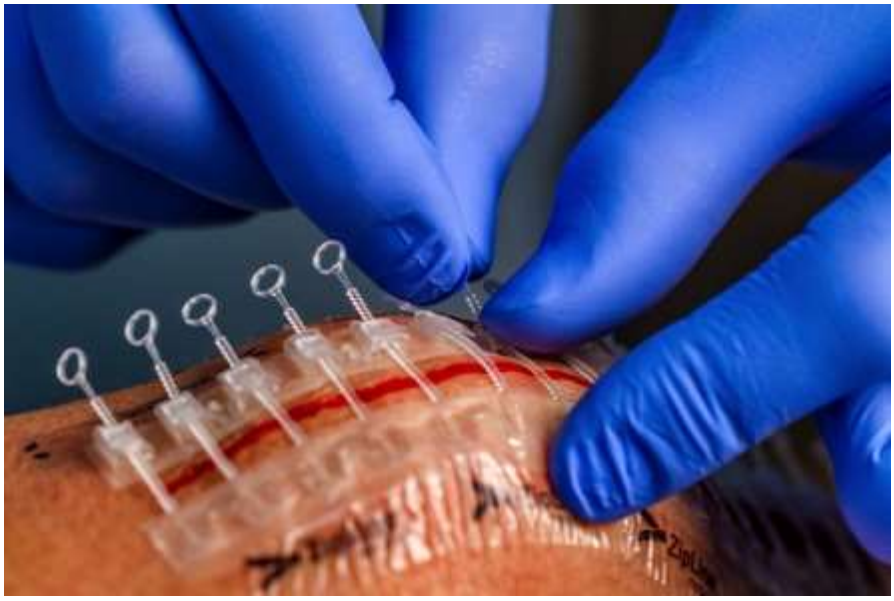


Figure 2. Adjusting Incision Closure Tension

The device remains on the skin for the recommended 7-14 days. During this period, patients may shower (but not soak in a tub or pool) with the device on. The device is removed by lifting the edge of the device and gently peeling along the incision, taking care not to apply stress to the incision. If there is a risk of skin stripping, an adhesive removal agent may be used during removal.

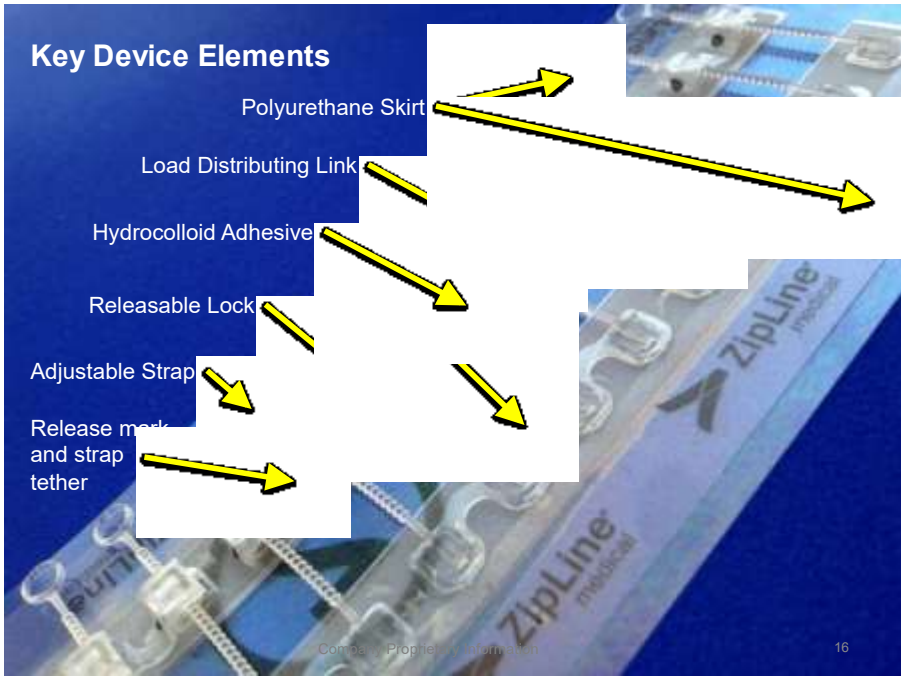


Figure 3. Key Components of the Zip Surgical Skin Closure Device

In addition to the pressure-sensitive adhesives, the device's closure and force distribution components are made up of polyurethane monofilm, polyethylene tape, polyester and nylon.

After application, the surgeon approximates the incision edges and tensions the wound by adjusting the ratcheting straps located along the device. Once the desired tension is achieved, the excess strap ends are trimmed with scissors, and a conventional absorptive dressing may be applied.

4.2 Regulatory Status

The Zip Surgical Skin Closure is a FDA Class I, 510(k) Exempt device.

In 2010, ZipLine Medical, Inc. submitted a "513(g)" request for product classification to the U.S. Food and Drug Administration (FDA). In July 2010, ZipLine Medical received a letter from the FDA indicating that FDA reviewers "*believe the ZipLine 1 System falls within Title 21 of the Code of Federal Regulations (CFR) 880.5240, Medical adhesive tape and adhesive bandage (Product Code- KGX). A Medical adhesive tape and adhesive bandage is a Class I type device, exempt from the premarket notification [510(k)] requirements of the Act, subject to the limitations of the exemption found in 21 CRF 880.9."*

Quality System Regulations: The Zip Surgical Skin Closure Devices have been developed and are manufactured in full compliance with FDA Title 21 CFR Part 820 Quality System Regulations, including design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product, corrective and preventive action, labeling and package control, handling, storage, distribution and installation, record keeping, servicing, and statistical techniques.

Origin of Manufacture: The Zip® brand Surgical Skin Closure Devices are manufactured in the USA.

Company Registration: ZipLine Medical, Inc. is registered with the FDA in compliance with Title 21 Code of Federal Regulations (CFR) Part 807, Subparts A-D.

4.3 Indication For Use

The Zip Surgical Skin Closure Device is indicated for use during and after skin incision procedures to approximate skin and hold together the skin edges until healing can take place.

4.4 Device Labeling

The Zip Surgical Skin Closure Devices are labeled in full compliance with FDA Title 21 CFR Part 820 Quality System Regulations. Each device label includes the *device name, part number, lot number and expiration (use by) date*. The devices are provided sterile, each in a sealed pouch designed for aseptic handoff into a sterile field. The devices are provided in boxes of 10 individually packaged devices, and a copy of the device Instructions For Use (IFU) accompanies each box of 10 devices.

4.5 Commercial Status and Clinical Experience

The Zip device has been commercially available since April 2013, with over 2000 clinical cases conducted in the USA, and approximately 60% of these cases being orthopedic procedures. Feedback from these cases includes the following:

- Orthopedic surgeons generally close in several layers, including a deep dermal layer.
- Devices are typically removed at 10-14 days.
- Orthopedic surgeons have indicated that they are impressed with the ease of application at the end of a case; in some cases surgeons delegated skin closure with the Zip to an assistant, such as a Physician's Assistant in the sterile field. They also felt that the outcomes were excellent at the time of removal.
- Orthopedic surgeons liked the ability to cut the device to match the incision size and to combine devices for longer incisions.

5 Study Objective

The primary objective of this post-market study is to evaluate scar appearance / cosmesis associated with the use of the Zip Surgical Skin Closure versus conventional staples when utilized for surgical wound closure after bilateral knee arthroplasty (unicompartmental or total). For safety analysis, the rate of adverse events up to 8 weeks post-surgery will be compared between the ZipLine Surgical Skin Closure and standard staples.

5.1 Sample Size

A total of up to 25 subjects (targeted min. n=22) requiring bilateral knee arthroplasty (unicompartmental or total) will be enrolled. There is anticipated patient fall out (screen failures) post procedure due to surgeon not knowing exactly which procedure is required (total or unicompartmental) until time of surgery. Subjects who are initially enrolled in the study and surgery results in a total knee on one side and a unicompartmental on the other side will be exited from the study and not included in the final analysis. Each subject will serve as their own control since one knee closure will be with staples, and the other knee closure with Zip device. The order of patients will be randomized to receive Zip device on one knee and steel staples on the opposing knee.

5.2 Investigational Sites

NAME	ADDRESS	CONACT INFORMATION
SITE 1	Shelbourne Knee Center 1815 N. Capital Ave., Suite 600 Indianapolis, IN 46202 317 924 8636 (office phone) 317 921 0230 (office fax)	Rodney Benner, MD Principal Investigator 317 924 8636 RBenner@fixknee.com Tinker Gray, MA, ELS Research Director/Medical Writer tgray@fixknee.com 317 924 8655 Heather Freeman, PT, DHS Research Coordinator hfreeman@fixknee.com 317 624 8417 Heather Garrison hgarrison@fixknee.com 317 924 8676 Diane Davidson ddavidson@fixknee.com 317 924 8670

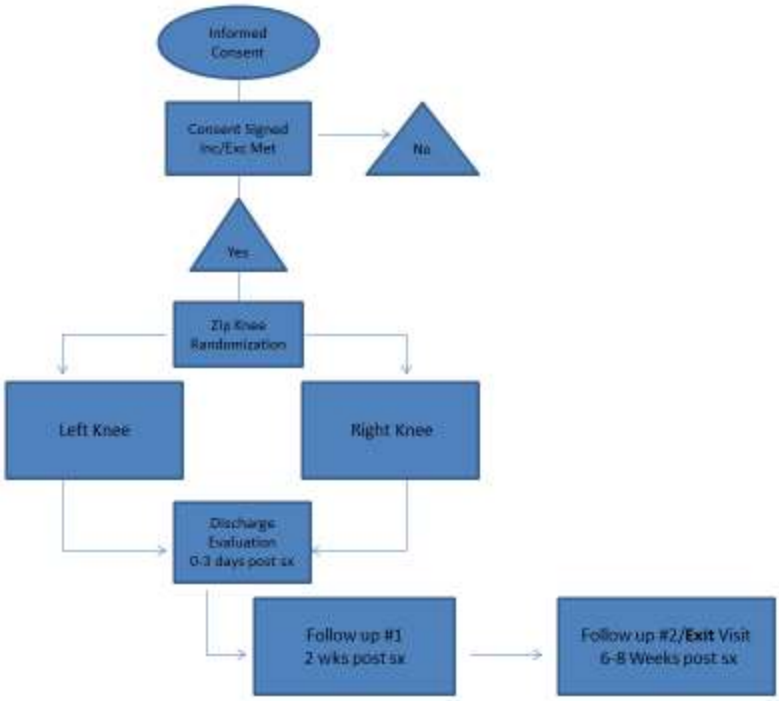


Figure 4. Schematic of Study Design

6 Study Population

6.1 Selection Criteria

The following pages outline the specific inclusion and exclusion criteria for the study. Before the study inclusion, a subject must meet all of the inclusion and exclusion criteria.

6.1.1 Inclusion Criteria

All subjects are required to meet the following inclusion criteria in order to be considered eligible for participation in this study:

Inclusion Criteria	1. Patients 18 years of age and older; 2. Patients requiring epidermal closure after bi lateral total or partial (unicompartmental) knee arthroplasty; 3. Patients willing to be evaluated at discharge, 2 weeks and 6 or 8 -weeks post op.

6.1.2 Exclusion Criteria

Subjects will be excluded from participating in this study if they meet any of the following exclusion criteria prior to initiation of the Zip Surgical Skin Closure Device.

Exclusion Criteria	1. Known bleeding disorders not caused by medication; 2. Known personal or family history of keloid formation or scar hypertrophy; 3. Known allergy or hypersensitivity to non-latex skin adhesives; 4. Atrophic skin deemed clinically prone to blistering; 5. Any skin disorder affecting wound healing; 6. Any other condition that in the opinion of the investigator would make a particular subject unsuitable for this study.

6.2 Withdrawal of Subjects

Subjects may withdraw from the study at any time, with or without reason and without prejudice to further treatment. In all cases of withdrawal, the reason(s) for withdrawal (if given) will be recorded upon study termination.

In addition, the investigator may withdraw the subject due to any of the following situations:

- adverse event;
- any other reason determined by the investigator to be in the best interest of the subject.

Subjects withdrawn due to an adverse event should be followed until the event has been resolved or is stable, if at all possible.

7 Written Informed Consent

Written Informed Consent must be obtained for all subjects who are potential study candidates before any study-specific tests or procedures are performed.

The medical records of patients who are scheduled in clinic may be screened to prior to consent to assess eligibility for the study. Patients who meet general entry criteria will be asked to sign the study-specific, Institutional Review Board (IRB)-approved Informed Consent form before any study-specific tests or procedures are performed.

If the patient fails to meet study eligibility criteria or the patient's eligibility changes prior to randomization, the patient will be considered a screen failure and their participation will not count toward enrollment for the study. A Screening/Enrollment Log will be maintained to document select information about candidates who fail to meet the entry criteria.

8 Study Procedures and Enrollment

8.1 Duration of Subject Participation

Subjects enrolled in the study will participate until the Zip device and staples are removed from the subject and then continue participation until the final follow-up point (between 6 and 8 weeks post op).

8.2 Enrollment

Subjects that meet the inclusion/exclusion criteria will be invited to participate in the study and sign the Institutional Review Board (IRB) or Ethics Committee (EC) approved informed consent form. All subjects must provide written informed consent before undergoing any study related activity.

Subjects that meet all the eligibility criteria will be enrolled in the study and will serve as their own control. Subjects will be randomized in a 1:1 ratio to receive both the Zip device treatment and the staples on each knee.

8.3 Visit Schedule

The following table outlines the required study assessments.

Table 1. Study Event Schedule

	Before Procedure	Uni/TKA Procedure- Zip device or staple control Placement	Discharge 0-3 days Post Procedure	14 days (+/-1 week) post Procedure	6-8 weeks** (+/-4 days) post Procedure
Study Initiation:	X				
Informed Consent	X				
Demographics/ Medical History	X				
Clinical Status evaluation/site evaluation prior to wound closure device placement	X				
Inclusion / Exclusion Criteria Assessment	X				
Left/Right Knee Randomization to Zip device or staples	X				

Photographs Taken			X*	X	X
Adverse Events/Complications		X	X	X	X
Physician Evaluations (Satisfaction)			X		X
Physical Therapist Evaluations (ROM)	X			X	X
Patient Evaluations(Pain, Comfort, Satisfaction)	X		X	X	X
Cosmetic outcome (CVAS, WES)				X	X
Study Exit Form -CRF					X
*Optional **Final visit will take place between week 6 and week 8 post surgery depending on surgeons standard visit schedule.					

8.4 Study Procedures

8.4.1 Pre-Procedure

Prior to the subject's scheduled procedure, obtain informed consent, a medical history, pain assessment, ROM and record the subject's demographic (age, race, sex and date of birth) and baseline information (height, weight). Patient's medical records may be screened prior to obtaining consent to assess eligibility for the study.

(Please reference Figure 4 – Schematic of Study Design)

8.4.2 Randomization – Wound Closure Device Placement

All subjects will be screened for inclusion/exclusion criteria by study site personnel.

Once the screening and consent process is completed, subjects will be randomized to receive the Zip device (Treatment Group) on either the right or left knee by opening one of the sealed envelopes containing a randomization card. The subject will receive the staples (Control Group) on the opposing knee. The subject is considered enrolled into the study upon randomization and the subject disposition will be accounted for in study reports.

8.4.3 Procedure

For consented subjects that meet the eligibility criteria, record the relevant data regarding their procedure. Record the following procedure information:

- Treatment and control sides
- Length of incisions
- Note: Subjects who require a total knee on one side and a unicompartmental on the other side will not be included in the final analysis and should be exited from the study.

8.4.4 Wound Closure Procedure / Protocol

The Zip device placement will be carried out following a standard protocol as described in the Instructions for Use (IFU)

8.4.5 Data to be collected at time of procedure and/or prior to discharge:

- Closure Method Satisfaction (Surgeon Rating)

- Pain (Subject Rating) - A 11 point Numerical Rating Scale rating pain from *No Pain (0)* to *Worst Pain Imaginable (10)* will be used to measure general pre and post-operative pain and specific incisional pain.
- Any complications/adverse events
- High resolution digital photographs of any preexisting scar or unusual skin appearance at the incision site and immediately after incision closure (optional)

8.4.6 Data to be collected at follow up visits

While performing the **2 week f**ollow up visit, record the following information:

- Cosmetic Outcome (Surgeon Rating)
    - Wound Evaluation Scale (WES) – The surgeon will conduct a follow up evaluation of the wound using the WES assessment. The WES evaluates six clinical variables including incision edges, contour irregularity, width, edge inversion, inflammation and overall cosmesis.
- Any complications/adverse events
- Range of Motion Measurements
- High definition photos will be taken of the incision/scar areas.
- Closure Method Comfort (Subject Rating)
    - A 5 point Likert Scale ranging from *Very Comfortable* to *Very Uncomfortable*
- Pain (Subject Rating)
    - A 11 point Numerical Rating Scale rating pain from *No Pain (0)* to *Worst Pain Imaginable (10)* will be used to measure general post- operative pain and specific incisional pain

While performing the **final** follow up visit (between week 6 and week 8), record the following information:

- Range of Motion Measurements (Physical Therapist Ratings)
- Pain (Subject Rating)
    - A 11 point Numerical Rating Scale rating pain from *No Pain (0)* to *Worst Pain Imaginable (10)* will be used to measure general post- operative pain and specific incisional pain
- Cosmetic Outcome (Subject & Surgeon Ratings)
    - Scar Satisfaction - A 5 point Likert Scale ranging from *Very Satisfied* to *Very Dissatisfied*
    - Scar Assessment - A 10 point Visual Analog Scale rating scar cosmesis from *0=Best Expected Scar* to *10=Worst Scar*
    - Wound Evaluation Scale (WES) – The surgeon will conduct a follow up evaluation of the wound using the WES assessment. The WES evaluates six clinical variables including incision edges, contour irregularity, width, edge inversion, inflammation and overall cosmesis.
    - Cosmetic Visual Analogue Scale (CVAS) – High definition photos will be taken of the incision/scar area at the final follow-up visit. Photos will be collected and evaluated using a VAS Scar Score by an objective independent panel (not affiliated with the study site) of up to 5 plastic surgeons.

8.5 Follow-up

The subject should be queried before discharge regarding any discomfort experienced after Zip device and staple use. After removal of both the Zip device and staples the status of the wounds should be assessed. Any Adverse Events should be noted. These data will be captured on the Case Report Forms. High resolution digital photographs should be taken after closure device removal (day 14) and at final 6 or 8 week follow-up visit. A user survey will be provided and will be required to be filled out as part of the follow-up.

Scar / cosmetic appearance will be evaluated on a visual analogue scales (CVAS). Physician and patient satisfaction with the closure techniques and the scar appearances will be evaluated.

8.6 Study Exit

Once the subject has completed the final follow-up visit or has withdrawn early, they should be exited from the study. The date of exit and subject status should be recorded on the Case Report Form.

9 Statistical Considerations

9.1 Analysis Populations and Data Handling Conventions

9.1.1 Effectiveness Intent-to-Treat (ITT) Population

All subjects will be included in effectiveness ITT analyses according to the randomized order of patients for treatment assignments, including the dermal closure procedure, regardless of protocol deviations.

9.1.2 Effectiveness Per Protocol Population

The effectiveness per protocol population includes all subjects completing Zip Surgical Skin Closure and standard dermal closure (Staple) treatments per protocol. The analysis will be performed according to the actual treatments received, including the dermal closure procedure.

9.1.3 Safety

All subjects who receive any portion of the Zip Surgical Skin Closure treatment or control (staple) treatment will be included in safety analysis and analyzed by actual treatment received.

9.1.4 Missing Data

Missing or loss data will not be included in the analysis.

9.2 Statistical Analysis Plan

9.2.1 General Summary

CVAS summary statistical results will include, averages standard deviation, range, and Coefficient of Variation (CVs) will be reported for both the control and treatment. Results will include significance testing (t test) with calculated p value(s). Graphic representation of data with distribution analysis of CVAS results will also be presented and summarize. All variables of interest including subject demographics, baseline characteristics, effectiveness and safety endpoints will be summarized.

9.2.2 Effectiveness

11.2.2.1. Primary Effectiveness Analyses

There is one primary endpoint for the study, i.e. Cosmetic Visual Analogue Scale (CVAS) for incision appearance at the final (6 to 8 week) follow-up evaluation for gathering CVAS scores. The purpose is to reveal superior cosmesis results of Zip device in comparison to standard staple closure. The sample size determined, per Section 7, for this study is up to 25 patients.

<u>CVAS</u>

The hypothesis for cosmesis is that use of the Zip Surgical Skin Closure device will result in CVAS results that are significantly superior to standard staples administered. A 1-sided paired “t” test will be performed to reject the H_0 with >95% confidence. Alpha Error for the 1-sided test = 0.025.

The assumption (hypothesis) for CVAS is:

H_0: Zipline CVAS scores will not be superior to CVAS scores for staples.

H_A: Zipline CVAS scores will be superior to CVAS scores for staples.

Since CVAS scores are measured on a 0 – 10 Likert scale for quality of closure, a distribution analysis will also be performed with summary statistics to show that the incisions closed with the Zip devices result in a cosmetically superior scar as compared to the incisions closed with staples.

11.2.2.2 Secondary "Effectiveness" Endpoints Analyses

Secondary effectiveness endpoints include surgeon and patient closure method satisfaction, scar appearance satisfaction and patient pain and comfort surveys. All results will be summarized by treatment.

9.2.3 Safety

Cumulative adverse events from time of closure to final visit (6 to 8 weeks post op) will be collected, analyzed and summarized by closure treatment. Separate tables will be constructed for (a) all reported adverse events, (b) adverse events reported as closure device related, and/or (d) serious adverse events.

The primary safety analysis will be the overall comparison between Zip and staple adverse events.

9.3 Sample Size Justification

Since this is a Bilateral Study, with CVAS scores (Scores: 0 – 10), a paired "t" significant test is the most appropriate test as there is only one variable changing with the patients, i.e., type of closure device. A paired "t" test has more statistical power as well, and is more appropriate since the results will be comparing the treatment and control in a paired fashion.

The targeted minimum sample size of n=22 subjects (paired observations) was determined assuming an average difference (Δ) > 1.0, an hypothesized standard deviation of ~1.5, with the Power of Test set at 90%. Alpha Error for the test of differences = 0.025.

10 Data Management – Data Collection and Processing

Conventional paper-based CRFs will be used. Investigators are responsible for the accurate completion and timely submission of the data collected during the study. All data from the study will be entered into CRFs. Any data issues are to be promptly addressed with the investigator by the sponsor or designee. Investigator and staff training will take place prior to subject enrollment to ensure that complete, accurate and timely data are submitted, that protocol requirements are followed and that complications, adverse events and adverse device effects are correctly reported and investigated, as appropriate. Investigators are to maintain all source documents as required by the protocol, including laboratory results, supporting medical records, and signed Informed Consent forms. The source documents will be used during the regular monitoring visits to verify information from the database against data contained on the completed CRFs.

The Principal Investigator must maintain detailed records on all subjects who sign the Informed Consent and begin the pre-procedure evaluation. Data for enrolled subjects will be entered into CRFs provided by the Sponsor. All data should be entered completely, promptly and legibly. For source documents, corrections should be made in a manner that does not obscure or eliminate the original error, by striking through the original data with one line, and initialing and dating the change, along with the reason for the change (if not obvious).

Study Exit CRFs are completed for all enrolled subjects, regardless if they did or did not complete the study (e.g., subject discontinuation, study termination).

11 Monitoring Procedures

11.1 Monitoring

Monitoring visits to the clinical sites will be made periodically during the study, to ensure that all aspects of the current, approved protocol/amendment(s) are followed. Original source documents will be reviewed for verification of data in the case report forms. The Investigator/institution guarantees direct access to original source documents by ZipLine Medical Inc. personnel and their designees.

It is important that the Investigator and relevant study personnel are available during the monitoring visits and that sufficient time is devoted to the process.

Phone contacts and site visits will be conducted to ensure that the protocol is being followed and that any protocol deviations are properly documented. Clinical monitoring will include a verification that Informed Consent was properly obtained for all enrolled study participants, a review of clinical records for accuracy and completeness, resolution of missing or inconsistent results and a review of source documents. The clinical monitor will verify that the Case Report Forms (CRFs) are in agreement with the source documentation and other records. The investigator will make available to the clinical monitor for review all Informed Consent documents, access to completed CRFs, source documentation, original laboratory data and other relevant records for all enrolled subjects at the site. It is important that the investigator and other relevant site personnel are available for consultation with the clinical monitors during the monitoring visits and that sufficient time is devoted at the site to the monitoring process.

Additionally, telephone and/or e-mail contact will be conducted on a regular basis with the investigator and the site staff to ensure that the protocol is being followed and to address any issues that may occur during the course of the study.

If a deficiency is noted during an on-site visit (or at any other time during the course of the study), the clinical monitor is required to discuss the situation with the investigator and the Sponsor (if required) to secure compliance. Any protocol deviations will be reported to the IRB within the required timelines.

12 Quality Control and Quality Assurance

12.1 Site Training

To ensure accurate, complete, and reliable data, the Sponsor or its representatives will provide instructional material to the study sites, as appropriate;

- Instruct the Investigators and study personnel on the protocol, the completion of the CRFs, and study procedures
- Communicate regularly with site personnel via mail, email, telephone, and/or fax
- Make periodic visits to the study site.

During those visits, the Sponsor or its representatives will monitor the subject data recorded in the paper CRFs against source documents at the study site.

12.2 Audits and Inspections

The Principal Investigator for the site will also allow representatives of the governing IRB to inspect all study records, CRFs, and corresponding portions of the subject's office and/or hospital medical records at regular intervals throughout the study. These inspections are for the purpose of verifying adherence to the protocol, and completeness and exactness of the data being transcribed onto the CRF.

The Principal Investigator for the site will inform the Sponsor or the Sponsor's designee in advance if they are to be audited or inspected by any regulatory agencies. The Sponsor or the Sponsor's designee will also inform the site if they are made aware of a pending audit or inspection by a regulatory agency.

13 Adverse Events

13.1 General

All adverse events (AE) and serious adverse events (SAE) will be monitored from the time of treatment through 3 months.

An AE is defined as any undesirable clinical occurrence in a subject whether or not it is considered to be device related. In addition, the definition of AE applies to any event with an onset post study procedure or to any underlying diseases, present at baseline, that exacerbate in severity post study procedure. Therefore, an underlying disease that was present at the time of enrollment is not reported as an AE, but any increase in the severity of the underlying disease is to be reported as an AE. This definition includes events occurring during the follow-up period.

All reported AEs must be recorded. A description of the event, including the start date, resolution date, action taken, and the outcome should be provided, along with the Investigator's assessment of the relationship between the AE, the study treatment and the study procedure.

The following definitions for rating severity of adverse events will be used:

Mild	Awareness of signs or symptoms, but easily tolerated; are of minor irritant type; causing no loss of time from normal activities; symptoms would not require medication or a medical evaluation; signs or symptoms are transient.
Moderate	Interferes with the subject's usual activity and/or requires symptomatic treatment.
Severe	Symptom(s) causing severe discomfort and significant impact of the subject's usual activity and requires treatment.

The following definitions will be used to rate the relationship of the adverse event to the study treatment and the study procedure.

Not Related	• not associated with device application • due to an underlying or concurrent illness or effect of another device or drug
Possible	• temporal sequence between device application and event is such that the relationship is not unlikely or subject's condition or concomitant therapy could have caused the adverse event
Probable	• temporal sequence is relevant **or** • event abates upon device removal
Definitely Related	• temporal sequence is relevant **and** • event abates upon device removal **or**

- reappearance of the event on repeat device re-application

A serious adverse event (SAE) is defined as an event which leads to:

- Death due to any cause
- Life-threatening condition
- Results in persistent or significant disability/incapacity
- Requires in-patient hospitalization or prolonged hospitalization
- Necessitates an intervention to prevent a permanent impairment of a body function or permanent damage to a body structure

All SAE's will be reported.

Device-Related Adverse Event*:* an adverse event is considered to be device-related when, in the judgment of the Investigator, the clinical event has a reasonable time sequence associated with use of the device and is unlikely to be attributed to concurrent disease or other procedures or medications. It is reasonable to believe that the device directly caused or contributed to the adverse event.

Procedure-Related Adverse Event*:* an adverse event is considered to be procedure-related when, in the judgment of the Investigator; it is reasonable to believe that the event is associated with the assigned study procedure and is not specific to the device used. Other products, surgical techniques, or medications required specifically for the procedure are likely to have contributed to the occurrence of the event.

Concomitant Medication-Related Adverse Event: an adverse event is considered to be concomitant medication related when, in the judgment of the Investigator, it is reasonable to believe that the event is associated with concomitant medications used in conjunction with the device and is not otherwise specific to the device (e.g. bleeding associated with anticoagulation medication).

Pre-Existing Condition-Related Adverse Event: an adverse event is considered to be related to a pre-existing condition when, in the judgment of the Investigator, it is reasonable to believe that the event is associated with the subject's pre-existing condition and is not specific to the device or procedure. Pre-existing conditions that are aggravated or become more severe during or after the procedure should be evaluated on a case-by-case basis to determine if the event may be more appropriately classified as device-related or procedure-related.

ZipLine Medical Inc. Inc., or its designee, in cooperation with the Investigator, will assess all adverse events considered to be device-related for potential reportability to the FDA and other regulatory authorities as an Unanticipated Adverse Device Effect (UADE).

The Investigator should follow all unresolved serious adverse events until the events are resolved, the subject is lost to follow-up, the subject has withdrawn consent, or the adverse event is otherwise explained.

13.2 Reporting of Serious and Non-Serious Adverse Events

13.2.1 General Reporting Requirements (Serious & Non-Serious Adverse Events)

All serious and potentially device related and/or procedure-related adverse events must be recorded on the Adverse Event CRF by the Investigator (or designee). The report should include: severity, duration, action taken, treatment outcome and relationship of the adverse experience to the study device, procedure, concomitant medications, pre-existing condition, etc. (i.e., unrelated, related or relationship unknown).

In the case of serious adverse events, procedure and/or device observations and malfunctions, medical record documentation (e.g. procedure notes, operative notes, discharge summary, relevant progress notes, imaging or lab studies) must be provided to ZipLine Medical Inc. or its designee.

The following criteria must also be adhered to by the Investigator in the case of serious adverse events:

- The Adverse Event CRF must be signed by the Investigator or Co-Investigator.
- It is the responsibility of the Investigator to inform their IRB/EC of serious adverse events as required by their IRB/EC procedures and in conformance with FDA and local regulatory requirements.

All serious adverse events must be reported by the Investigator (or designee) to the sponsor, within 48 hours of learning of the adverse event via CRF. The ZipLine Medical Inc. contact information for questions is:

Sponsor:

ZipLine Medical, Inc.

747 Camden Ave., Suite A,

Campbell, CA 95008

Contact:

Christy Cowley

Manager, Clinical Affairs

Mobile: 408-857-2083

13.3 Device Failures and Malfunctions

All reported device observations, malfunctions or failures of the Zip device, ZipLine Medical Inc., are required to be documented in the CRF. In the event of a suspected observation or device problem, ZipLine Medical, Inc. Customer Service shall be notified and the Zip device shall be returned to the Sponsor for analysis. If the device has been in contact with the subject or may have been in contact with the subject's bodily fluids, proper biohazard controls and labeling shall be used when handling and transporting the device. Device failures and malfunctions should also be documented in the subject's medical record.

NOTE: Device failures or malfunctions are NOT to be reported as adverse events. However, if there is an adverse event that results from a device failure or malfunction, that specific event would be recorded in the usual way.

14 Ethical Considerations

14.1 Trial Conduct

The study will be performed in accordance with US FDA Good Clinical Practice (GCP) guidelines.

14.2 Institutional Review Board

A copy of the protocol, proposed Informed Consent form, other written subject information and any proposed advertising material must be submitted to the IRB/IEC for written approval. A copy of the written IRB/IEC approval of the protocol and Informed Consent form must be received by ZipLine Medical Inc. before recruitment of subjects into the study may begin.

The Sponsor must submit and, where necessary, obtain approval from the IRB, for all subsequent significant protocol amendments and significant changes to the Informed Consent form. The Investigator should notify the IRB of deviations from the protocol or SAEs and UADEs occurring at the site and other SAE/UADE reports received from ZipLine Medical Inc. in accordance with local procedures.

The Investigator will be responsible for obtaining annual IRB approval and renewal throughout the duration of the study. Copies of the Investigator's reports and the IRB continuance of approval must be sent to ZipLine Medical Inc.

14.3 Informed Consent Form

The written Informed Consent documents should be prepared in the language(s) of the potential patient population.

The reviewing IRB and the sponsor must first approve the Informed Consent forms that are used. The Informed Consent forms that are used should be in accordance with the current guidelines as outlined by the Good Clinical Practices (GCP) guidelines.

Prior to participation in the clinical study, each subject must give written Informed Consent after the context of the study has been fully explained to the subject in language that is easily understood by the subject. The subject must also be given the opportunity to ask questions and have those questions answered to their satisfaction.

14.4 Amending the Protocol

An Investigator may not make protocol changes without prior approval by ZipLine Medical Inc. All significant protocol changes that may affect the following must be submitted and approved by the Sponsor before initiating the change:

- validity of the data or information resulting from the completion of the approved protocol;
- relationship of the likely subject risk to benefit relied upon to approve the protocol;
- scientific soundness of the investigational plan, or;
- rights, safety, or welfare of the human subjects involved in the investigation.

The change must be approved by ZipLine Medical Inc and submitted and subsequently approved by the site IRB. The investigative sites must send ZipLine Medical Inc. a copy of the IRB approval letter for the protocol amendment.

ZipLine Medical Inc. may make certain administrative changes to the protocol without prior approval of the IRB. ZipLine Medical Inc. will notify the investigative site and the IRB of such changes to ensure the study continues to be conducted consistently.

14.5 Emergency Actions

ZipLine Medical Inc. accepts the right of the Investigator to deviate from the protocol in an emergency when necessary to safeguard the life or the physical wellbeing of a study subject. The Investigator must give notice of any emergency deviations and justification for the deviation to ZipLine Medical Inc. and the IRB as quickly as possible after the episode, in any event no later than 24 hours after the emergency to ZipLine Medical Inc. and 10 days to the IRB.

14.6 Protocol Deviations

A protocol deviation is defined as an event where the Clinical Investigator or site personnel did not conduct the study according to the protocol.

Investigators shall be required to obtain prior approval from ZipLine Medical Inc. clinical study management and IRB before initiating deviations from the protocol, except where necessary to protect the life or physical wellbeing of a subject in an emergency. Such approval shall be documented in writing and maintained in clinical study management and Investigator files. Prior approval is generally not expected in situations where unforeseen circumstances are beyond the Investigator's control, (e.g. subject was not available for scheduled follow-up office visit, blood sample lost by laboratory, etc.); however, the event is still considered a deviation and will be reported via the appropriate CRF.

Deviations must be reported to ZipLine Medical Inc. regardless of whether medically justifiable, pre-approved by ZipLine Medical Inc. or taken to protect the subject in an emergency. Subject specific deviations will be reported on the Protocol Deviation case report form. Investigators will also adhere to

procedures for reporting study deviations to their IRB in accordance with their specific IRB reporting policies and procedures.

Regulations require that Investigators maintain accurate, complete and current records, including documents showing the dates of and reasons for each deviation from the protocol.

14.7 Coverage of Expenses

The treated subjects will not be reimbursed or compensated for participating in the study.

14.8 Confidentiality

Confidentiality of subjects will be maintained throughout the study. A unique identification code will be assigned to each subject participating in this study. Any data that may be published in abstracts, scientific journals, or presented at medical meetings will reference a unique subject code and will not reveal the subject's identity. The Sponsor and their designee will make every reasonable effort to protect the confidentiality of the subjects participating in the study.

15 Study Administration

ZipLine Medical Inc., Inc will make necessary efforts to ensure that this study is conducted in compliance with GCPs and all applicable regulatory requirements.

15.1 Pre-Study Documentation Requirements

Prior to enrolling subjects into the study, the following documents must be provided to ZipLine Medical Inc.:

- Signed and dated Investigator Agreement
- A copy of the written IRB/IEC approval of the protocol
- A copy of the written IRB/IEC approval of the Informed Consent Form
- A copy of the curriculum vitae of the Principal Investigator and Co-Principal Investigator (if applicable)

15.2 Source Documentation

The Principal Investigator must maintain detailed source documents on all study subjects who are enrolled in the study or who undergo screening. Source documents include subject medical records, hospital charts, clinic charts, Investigator's subject study files, as well as the results of diagnostic tests (e.g., laboratory tests).

The following minimum information should be recorded in the subject's medical records:

- The date the subject entered the study and the subject number
- The study protocol number and the name of the Sponsor
- The date that informed consent was obtained
- Evidence that the subject meets study eligibility requirements (e.g., medical history, study procedures and/or evaluations)
- The dates of all study related subject visits
- Evidence that required procedures and/or evaluations were completed
- Documentation of specific device used, if any
- Occurrence and status of any Adverse Events

- The date the subject exited the study, and a notation as to whether the subject completed the study or was discontinued, including the reason for discontinuation.

15.3 Record Retention

The Investigator will maintain all essential study documents and source documentation, in original format, that support the data collected on the study subjects in compliance with the ICH/GCP guidelines. Documents must be retained for at least 2 years after the last approval of marketing application or until at least 2 years have elapsed since the formal discontinuation of the clinical investigation of the product. These documents will be retained for a longer period of time by agreement with ZipLine Medical Inc. or in compliance with other regulatory requirements. When these documents no longer need to be maintained, it is the responsibility of ZipLine Medical Inc. to inform the Investigator. The Investigator will take measures to ensure that these essential documents are not accidentally damaged or destroyed. If for any reason the Investigator withdraws responsibility for maintaining these essential documents, custody must be transferred to an individual who will assume responsibility. ZipLine Medical Inc. must receive written notification of this custodial change.

15.4 Criteria for Terminating Study

ZipLine Medical Inc. reserves the right to terminate the study but intends only to exercise this right for valid scientific or administrative reasons and reasons related to protection of ZipLines. Investigators and associated IRB will be notified in writing in the event of termination.

Possible reasons for study termination include:

- The discovery of an unexpected, significant, or unacceptable risk to the ZipLines enrolled in the study;
- A decision on the part of ZipLine Medical Inc. to suspend or discontinue use of the device.

15.5 Criteria for Suspending/Terminating a Study Center

ZipLine Medical Inc. reserves the right to stop the enrollment of ZipLines at a study center at any time after the study initiation visit if no ZipLines have been enrolled or if the center has multiple or severe protocol violations without justification or fails to follow remedial actions.

Possible reasons for suspending/terminating a study center include:

- Repeated failure to complete case report forms prior to scheduled monitoring visits;
- Failure to obtain written Informed Consent;
- Failure to report CEC Events/SAE/UADE to ZipLine Medical Inc. within 48 hours of knowledge.

15.6 Investigator Responsibilities

- Agree to sign and adhere to the Investigator Agreement;
- Agree to participate in Investigator meetings as scheduled by ZipLine Medical Inc.;
- Be willing to provide required assessments for analysis;
- Be willing to perform and be capable of performing treatment procedures as outlined in this protocol;
- Comply with all required elements of this protocol (e.g., perform testing and follow-up as specified, especially during personnel transitions) and supply material suitable for quantitative analysis;
- Agree to obtain written Informed Consent before any study specific procedures are performed in accordance with GCP.

16 Publication Policy

The existence of this clinical study is confidential, and it should not be discussed with persons outside of the study. Additionally, the information in this document and regarding this study contains trade secrets and commercially sensitive information that is confidential and may not be disclosed unless such disclosure is required by regional or national law or regulations. Subject to the foregoing, this information may be disclosed only to those persons involved in the study who have a need to know, but all such persons must be instructed not to further disseminate this information to others. These restrictions of disclosure will apply equally to all future information provided that is indicated as confidential.

The data generated by this clinical study are the property of the Sponsor, ZipLine Medical Inc., and should not be disclosed without their prior written permission. These data may be used by the Sponsor now and in the future for presentation or publication at Sponsor's discretion or for submission to governmental regulatory agencies. The Principal Investigators may publish or present the study results with prior consent of the Sponsor, but will not disclose confidential information. Prior to submission by a Principal Investigator for publication or presentation, the Sponsor will be provided with the opportunity to review the submission for confidential information and accuracy.

17 Bibliography

1. Newman JT, et al. Modality of Wound Closure After Total Knee Replacement: Are Staples as Safe as Sutures? A Retrospective Study of 181 Patients. Patient Safety in Surgery. 2011; 5:26.

2. Smith TO, et. al. Sutures vs. Staples for Skin Closure in Orthopaedic Surgery: Meta Analysis. BMJ 2010;340;c1199.

18 Appendices

18.1 Sample Informed Consent Form

[INSERT SAMPLE INFORMED CONSENT FORM HERE]

18.2 Instructions for Use (IFU)

The following is an example of a Zip Surgical Skin Closure Instructions For Use document:

DRESSING

Device may be covered with an absorbent or protective dressing if desired. Do not place dressing adhesive or tape in direct contact with the device.

INSTRUCTIONS FOR CARE

As necessary the wound area may be rinsed and dried carefully. Patient should not swim, soak the device in a bath, allow direct, constant shower water pressure on the device or unnecessarily rub, flex or continuously lay on the closure device as this may weaken the adhesives or otherwise damage the device. If a dressing is not used, patients should avoid clothing edges catching or pulling on device. Provide patient or caregiver with the appropriate after procedure care instructions.

DEVICE REMOVAL

The device may remain on the patient for up to 14 days. Care should be used to not disrupt the incision during removal. To remove device, begin at one end of the incision and gently peel device along the length of the incision. Do not use excessive force or pull in a direction that is away from the incision. To aid in the removal of the device, medical adhesive remover may be used. Continuously wipe a soaked cotton ball or swab along the lifted edge of the device as it is gently pulled along the incision. Adhesive residue may be removed with soap and water.

Explanation of Symbols Used

Rx Only	Federal law (USA) restricts this device to sale by or on order of a physician
	See Instructions for Use
STERILE R	Sterilized Using Irradiation
	Latex Free
	Single Use Only
	Do not use if package is damaged or open
	Keep away from sunlight and heat
	Keep dry
	Expiration Date
EC REP	EU Authorized Representative
REF	Catalog Number
LOT	Lot Number
	Legal Manufacturer

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The Hauge, The Netherlands
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LA0013 Rev. C

ZipLine® Zip™16 Surgical Skin Closure Device
INSTRUCTIONS FOR USE

Description

The Zip™ 16 Surgical Skin Closure Device is a single-use non-invasive skin closure device that may be used to close up to 16cm of incision length. Multiple devices may be applied end-to-end as needed for longer incisions, and the device may be cut for shorter incisions. The device is applied to clean, dry skin prior to skin closure. The device remains on the skin during wound healing. The device is removed by lifting one edge and peeling the device from the skin. The device is made of polymeric materials, utilizes a non-latex, pressure sensitive skin adhesive. The device contents are provided sterile in an intact and unopened package.

Caution

Federal (USA) law restricts this device to use by or on the order of a physician.

Intended Use

The Zip™ 16 Surgical Skin Closure Device is indicated for use during and after skin incision procedures to approximate skin and hold together the skin edges until healing can take place.

Contraindications

1. Do not use where adhesion cannot be obtained. Potential causes of inadequate adhesion are presence of exudate, skin oils, moisture or hair.
2. Do not use on infected wounds.
3. Do not use in high tension wounds which cannot be easily approximated with fingers or forceps.

Warnings

1. The development of postoperative edema may cause skin shearing, skin blistering or loss of adhesion to occur.
2. Application of any surgical tape or adhesive skin closure may result in skin stripping upon removal.
3. As with all adhesive products applied to the skin, a small percentage of individuals may experience allergic reaction and/or hypopigmentation or hyperpigmentation following removal.
4. The effect of petroleum-based ointments when used in conjunction with this device is unknown.
5. Do not use if device becomes damaged during the procedure. Risk of device failure if device is damaged.
6. Single use device. Do not reuse. Risk of device failure or infection if reused.

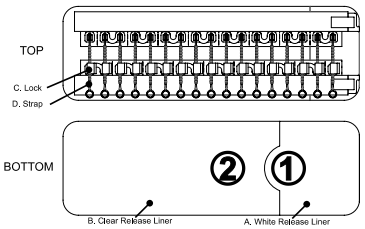
Precautions

1. Skin should be clean, dry and free of exudate, skin oils, excess prep residue or hair for adequate adhesion.
2. If applied to regions such as joints where the skin surrounding the incision is substantially strained, carefully monitor wound closure integrity as mobility is increased.
3. In areas of high body contour, the ability of the device to conform and adhere to the application site should be assessed carefully prior to application.

Precautions, continued

4. Do not swim, soak the device in a bath, or allow direct, constant, shower water pressure on the device to avoid adhesive failure.
5. Do not unnecessarily rub, flex or continuously lay on the closure device as this may weaken the adhesives or otherwise damage the device.
6. If dressings are not used, avoid clothing edges catching or pulling on device.

Device Components



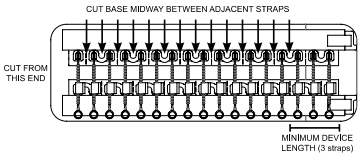
Directions for Use

PREPARATION OF PATIENT AND DEVICE

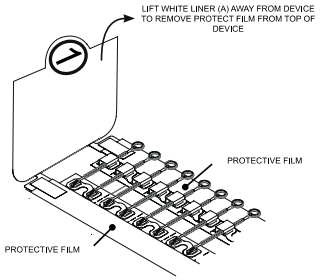
1. Remove excess hair where the device will be applied. Prepare skin per facility protocol and ensure that antimicrobial prep solution is completely dry. Remove any excess prep residue for best adhesion.
2. Inspect the product and packaging prior to use. Do not use if the sterile barrier is opened or damaged, or if the product is damaged.
3. Open the device pouch using sterile technique and remove the components from the tray.
4. PERFORM SURGICAL PROCEDURE AND APPLY SUPPORTING SUTURES: Upon closure, apply any subcutaneous and/or deep, tension-reducing sutures normally used for the procedure as appropriate. For best results, the distance between adjacent incision edges should be 5mm or less.
5. If a surgical incise barrier is used, remove the barrier film from the peri-incisional skin to expose an area of skin slightly larger than the device cover.
6. Ensure that skin is clean and completely dry for adequate device adhesion.

APPLY DEVICE AND CLOSE INCISION

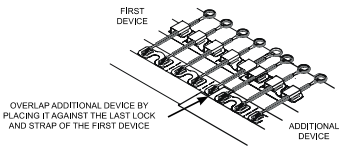
7. OPTIONAL: CUT DEVICE FOR SHORTER INCISION
   If needed, the device may be reduced in length in 1cm increments. Use scissors to cut midway between adjacent straps, so that the resulting segment intended for use contains the White Release Liner (A). The minimum device length is three (3) straps.



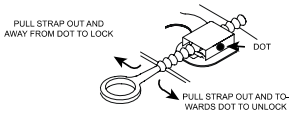
8. Lift the White Release Liner (A) at the tab marked with (1) to expose the skin adhesive. The liner will lift free from the adhesive but will remain attached to the top of the device. Use the White Release Liner (A) as a handle to help position the device on the incision.
9. Place device on skin, centered on the incision. Press firmly where the exposed adhesive contacts skin.
10. Lift the distal end of the device and slowly pull the folded tab on the Clear Release Liner (B) marked with (2) with one hand while pressing the device down onto the skin with the other hand. Press firmly over entire device.
11. Lift White Release Liner (A) from top of device to remove the two strips of clear protective film on the outer edges of the device. Once the protective film is removed, press firmly over the entire device.



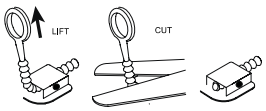
12. OPTIONAL: USING ADDITIONAL DEVICES FOR INCISIONS LONGER THAN 16cm
    If needed, multiple devices may be applied in series as needed for longer incisions. Follow step 11 prior to placing an additional device. Apply all devices, including removing clear protective film on the outer edges of each device, before closing incision. When placing an additional device, overlap the devices by placing the adhesive strip of the additional device directly against the last lock and strap of the first device. Press firmly and continue to apply the remainder of the additional device.



13. CLOSE WOUND: Close the wound by gently squeezing the device sides together and pulling on each Strap (D) until the desired incision edge approximation and closure tension are achieved. To release a Strap (D), pull slightly on the Strap (D) and slide it out the side of the Lock (C) in the direction of the black dot located on one side of the lock. To re-engage, press the strap into the side of the lock in the direction away from the dot until it clicks, and tension as needed.



14. TRIM STRAPS: Lift each strap vertically (away from the skin). Lay the blade of surgical scissors flat against the top of the each lock (similar to cutting excess suture), and trim the straps. It is important to trim the straps as short as possible.



15. Clean the device of any residue and dry thoroughly.