

K133858



**This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.**

**GENERAL INFORMATION**

**APPLICANT:** Dallen Medical, Inc.  
1046 Calle Recodo, Suite G  
San Clemente, CA 92673  
(949) 218-0030 Phone  
(949) 218-0040 Fax

**CONTACT PERSON:** Al Memmolo  
Chief Operating Officer

**DATE PREPARED:** February 27, 2014

**DEVICE DESCRIPTION:**

**TRADE NAME:** Tensyn™ Band

**MODEL:** 09-0025, 09-0026, 09-0027, 09-0028

**GENERIC/COMMONNAME** Button / Lock / Suture

**CLASSIFICATION NAME:** Washer, Bolt Nut, CFR 888.3030 (code HTN)

**DEVICE CLASSIFICATION:** Class II

**PREDICATE DEVICES:** Tensyn Band (K131850)  
Tightrope Syndesmosis Repair Kit, Titanium, Model Ar-8920Ds; Stainless Steel. Model Ar-8921Ds (K043248)  
ToggleLoc System (K083070)  
Compressyn Band (K130431)

**Product Description:**

The Tensyn™ Band is a knotless system for fixation of syndesmosis disruptions. The Tensyn™ Band is a low profile system comprised of a polymer coated flat polyethylene terephthalate (PET) suture band tensioned and secured between a narrow button and a lock. The Tensyn™ Band is available in titanium and stainless steel.

K133858

**Indications for Use:**

Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures which have been properly stabilized and which allow stable placement of the Tensyn band apart from any other fixation hardware.

**Technical Characteristics:**

The Tensyn™ Band has similar physical and technical characteristics to the predicate devices since all devices achieve fixation through a suture between two metal fasteners.

**Performance Data:**

All necessary testing has been performed with the Tensyn™ Band to assure substantial equivalence to the predicate devices. Testing included rotational loading, cyclic loading, ultimate load, load at 3 mm and shear test. The testing demonstrated that the Tensyn™ Band is substantially equivalent to the predicate devices.

**Basis for Determination of Substantial Equivalence:**

Upon reviewing the technical information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Tensyn™ Band is determined to be substantially equivalent to existing legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 28, 2014

Dallen Medical, Incorporated  
Mr. Al Memmolo  
Chief Operating Officer  
1046 Calle Recodo, Suite G  
San Clemente, California 92673

Re: K133858

Trade/Device Name: Tensyn™ Band  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.  
Regulatory Class: Class II  
Product Code: HTN  
Dated: January 2, 2014  
Received: January 3, 2014

Dear Mr. Memmolo,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Mr. Al Memmolo

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Vincent J. Deylin -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use Statement**

Page 1 of 1

510(k) Number (if known): K133858

Device Name: **Tensyn™ Band**

Indications for Use:

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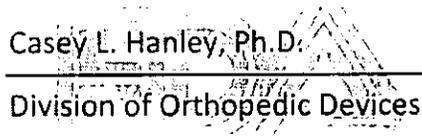
Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Casey L. Hanley, Ph.D.  
\_\_\_\_\_  
Division of Orthopedic Devices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 28, 2014

Dallen Medical, Incorporated  
Mr. Al Memmolo  
Chief Operating Officer  
1046 Calle Recodo, Suite G  
San Clemente, California 92673

Re: K133858

Trade/Device Name: Tensyn™ Band

Regulation Number: 21 CFR 888.3030

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Regulatory Class: Class II

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Page 2 – Mr. Al Memmolo

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Sincerely yours,

Vincent J. Deylin -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Page 3 – Mr. Al Memmolo

**Concurrence & Template History Page**

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

**Full Submission Number:** K133858/S001

For Office of Compliance Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=318](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318)

For Office of Surveillance and Biometrics Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=423](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423)

Digital Signature Concurrence Table	
Reviewer Sign-Off	Daniel Ramsey
Branch Chief Sign-Off	Casey Hanley (2/28/2014)
Division Sign-Off	Vincent J. Devlin 2014.02.28 16:02:48 -05'00'

f/t:DSR:CAK (2/28/14)

Template Name: K1(A) – SE after 1996

**Template History:**

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 <sup>st</sup> page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

**Indications for Use Statement**

Page 1 of 1

510(k) Number (if known): K133858

Device Name: **Tensyn™ Band**

**Indications for Use:**

Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures which have been properly stabilized and which allow stable placement of the Tensyn band apart from any other fixation hardware.

Prescription Use X OR Over-The-Counter-Use \_\_\_\_\_  
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division of Orthopedic Devices

**Section 3**

**510(k) Cover Letter**

December 17, 2013

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

K133858  
FDA CDRH DMC  
DEC 19 2013  
Received

**RE: 510(k) Notification (21 CFR 807(e)), Tensyn™ Band**

Applicant: Dallen Medical, Inc.  
Al Memmolo  
1046 Calle Recodo, Suite G  
San Clemente, CA 92673  
Phone (949) 218-0030  
Fax (949) 218-0040

Dear Sir or Madam:

Pursuant to the provision of Section 510(k) of the Federal Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990, notification is made of the intention of Dallen Medical, Inc. to market and distribute the Tensyn™ Band. Two additional copies of this 510(k) notification are enclosed along with an e-Copy. **The eCopy is an exact duplicate of the paper copy.**

**Administrative Information:**

Common Name: Tensyn™ Band  
Model Number: 09-0025, 09-0026, 09-0027, 09-0028,  
Regulation Name: Washer, Bolt Nut  
Regulation Number: CFR 888.3030  
Regulatory Class: Class II  
Panel: Surgical, Orthopedic and Restorative Devices  
Product Code: HTN  
Previous 510(k): N/A

Dallen Medical regards the information provided in support of this premarket notification to be confidential and proprietary and afforded such protection under 21 CFR 807.95.

Dallen Medical, Inc.  
Tensyn™ Band

Premarket Notification 510(k)

Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

**Section 3**

**510(k) Cover Letter**

**Basis for the Submission:**

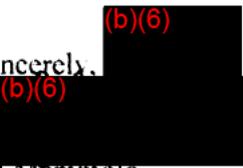
This traditional 510(k) notification is being submitted because the indications for use have been expanded and the device is being manufactured from a different material.

**Design and Use of the Device:**

The design and use of the Tensyn™ Band is presented below in tabular form.

Question	Yes	No
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components from a tissue or biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

If you have questions or additional information is desired to facilitate the evaluation, please feel free to contact me at (949) 218-0030 or via e-mail at [a.memmolo@dallenmedical.com](mailto:a.memmolo@dallenmedical.com).

Sincerely,  
 (b)(6)

Al Memmolo  
 Chief Operating Officer

Enclosures

**TRADITIONAL 510(k) PREMARKET NOTIFICATION**  
**Dallen Medical, Inc.**  
**Tensyn™ Band**

**APPLICANT**

Dallen Medical, Inc.  
1046 Calle Recodo, Suite G  
San Clemente, CA 92673

**OFFICIAL CORRESPONDENT**

Al Memmolo  
Chief Operating Officer

Phone: (949) 218-0030  
Fax: (949) 218-0040  
Email: a.memmolo@dallenmedical.com

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**Section 1**  
**Medical Device User Fee Cover Sheet (Form FDA 3601)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
---	---

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/cover sheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  DALLEN MEDICAL 1046 CALLE RECODO #G SAN CLEMENTE CA 92673 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8711	2. CONTACT NAME Al Memmolo 2.1 E-MAIL ADDRESS a.memmolo@dallenmedical.com 2.2 TELEPHONE NUMBER (include Area code) 949-218-0030 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
--	--

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm>)

Select an application type:

<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party	3.1 Select a center
<input type="checkbox"/> 513(g) Request for Information	<input checked="" type="checkbox"/> CDRH
<input type="checkbox"/> Biologics License Application (BLA)	<input type="checkbox"/> CBER
<input type="checkbox"/> Premarket Approval Application (PMA)	3.2 Select one of the types below
<input type="checkbox"/> Modular PMA	<input checked="" type="checkbox"/> Original Application
<input type="checkbox"/> Product Development Protocol (PDP)	Supplement Types:
<input type="checkbox"/> Premarket Report (PMR)	<input type="checkbox"/> Efficacy (BLA)
<input type="checkbox"/> 30-Day Notice	<input type="checkbox"/> Panel Track (PMA, PMR, PDP)
	<input type="checkbox"/> Real-Time (PMA, PMR, PDP)
	<input type="checkbox"/> 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA      NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD148101

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES       NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 16 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing

Questions? Contact FDA/CDRH/OCE/DSD at CDRH-PERS@FDA.HHS.gov or 301-796-8113

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above (b)(6) it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBM (b)(4) REMARKET APPLICATION

12-17-13

16-Dec-2013

"Close Window" [Print Cover sheet](#)

**Section 2**  
**CDRH Premarket Review Submission Cover Sheet**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				
Date of Submission: <b>December 17, 2013</b>		User Fee Payment ID Number <b>(b)(4)</b>	FDA Submission Document Number (if known)	
SECTION A Type of Submission				
<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Amendment	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption</b> <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<b>Class II Exemption</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> Describe Submission:
SECTION B APPLICANT OR SPONSOR				
Company / Institution Name: <b>Dallen Medical, Inc.</b>		Establishment Registration Number (if known) <b>3009596646</b>		
Division Name (if applicable)		Phone Number (include area code) <b>(949) 218-0030</b>		
Street Address: <b>1046 Calle Recodo, Suite G</b>		FAX Number (include area code): <b>(949) 218-0040</b>		
City: <b>San Clemente</b>	State/Province: <b>CA</b>	ZIP Code <b>92673</b>	Country: <b>USA</b>	
Contact Name: <b>Al Memmolo</b>		Contact E-mail Address: <b>a.memmolo@dallenmedical.com</b>		
Contact Title: <b>Chief Operating Officer</b>				
SECTION C SUBMISSION CORRESPONDENT (IF DIFFERENT FROM ABOVE)				
Company / Institution Name:		Establishment Registration Number (if known)		
Division Name (if applicable)		Phone Number (include area code) ( ) -		
Street Address:		FAX Number (include area code): ( ) -		
City:	State/Province:	ZIP Code	Country:	
Contact Name:		Contact E-mail Address:		
Contact Title:				

<b>SECTION D1 REASON FOR APPLICATION – PMA, PDP, OR HDE</b>		
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request for Remove or Add Manufacturing Site  <input type="checkbox"/> Process Change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below):  <input type="checkbox"/> Response to FDA correspondence:   <input type="checkbox"/> Other Reason (specify):	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)  <input type="checkbox"/> Labeling Change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location Change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager  <input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment  <input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change in Applicant Address
<b>SECTION D2 REASON FOR APPLICATION – IDE</b>		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension Of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access  <input type="checkbox"/> Other Reason (Specify):	<input type="checkbox"/> Change In: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol – Feasibility <input type="checkbox"/> Protocol – Other <input type="checkbox"/> Sponsor  <input type="checkbox"/> Report Submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Response To FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension Of Time To Respond To FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<b>SECTION D3 REASON FOR SUBMISSION – 510(k)</b>		
<input type="checkbox"/> New Device  <input type="checkbox"/> Other Reason (Specify):	<input checked="" type="checkbox"/> Additional Or Expanded Indications	<input type="checkbox"/> Change In Technology

<b>SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS</b>				
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness information:
1 HTN	2	3	4	<input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
5	6	7	8	
Information on devices to which substantial equivalence is claimed ( <i>if known</i> )				
	510(k) Number		Trade or Proprietary or Model Name	Manufacturer
1	K131850	1	Tensyn Band	1 Dallen Medical, Inc.
2	K043248	2	Tightrope Syndesmosis Repair Kit, Titanium, Model Ar-8920Ds; Stainless Steel. Model Ar-8921Ds	2 Arthrex, Inc.
3	K083070	3	ToggleLoc System	3 Biomet, Inc.
4	K130431	4	Compressyn Band	4 Dallen Medical, Inc.
<b>SECTION F PRODUCT INFORMATION – APPLICABLE TO ALL APPLICATIONS</b>				
Common or usual name or classification name:				
Trade or Proprietary or Model Name				Model Number
1	<b>Tensyn Band</b>			1 <b>09-0025, 09-0026, 09-0027, 09-0028</b>
2				2
3				3
4				4
5				5
FDA document numbers of all prior related submissions (regardless of outcome):				
1	K131850	2	3	4
5		6		
7		8	9	10
11		12		
Data Included in Submission: <input type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials				
<b>SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL APPLICATIONS</b>				
Product Code: <b>HTN</b>		C.F.R. Section (if applicable) <b>CFR 888.3030</b>		Device Class:
Classification Panel: <b>Surgical, Orthopedic and Restorative Devices</b>				<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Indications (from labeling): The Tensyn Band is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. Specifically, the Tensyn Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.				
<b>Note:</b> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.				FDA Document Number ( <i>if known</i> )

<b>SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION</b>			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number <b>3009596646</b>	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company/Institution Name: <b>Dallen Medical, Inc.</b>		Establishment Registration Number (if known) <b>3009596646</b>	
Division Name (if applicable):		Phone Number (include area code) <b>(949) 218-0030</b>	
Street Address: <b>1046 Calle Recodo, Suite G</b>		FAX Number (include area code): <b>(949) 218-0040</b>	
City: <b>San Clemente</b>	State/Province: <b>CA</b>	Country: <b>USA</b>	
Contact Name: <b>Al Memmolo</b>			
Contact title: <b>Chief Operating Officer</b>		Contact E-mail Address: <b>a.memmolo@dallenmedical.com</b>	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager /Relabeler
Company / Institution Name:		Establishment Registration Number (if known)	
Division Name (if applicable):		Phone Number (include area code)	
Street Address:		FAX Number (include area code)	
City:	State / Province:	Country:	
Contact Name:			
Contact Title:		Contact E-mail Address:	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name:		Establishment Registration Number:	
Division Name (if applicable):		Phone Number (include area code)	
Street Address:		FAX Number (include area code)	
City:	State / Province:	Country:	
Contact Name:			
Contact Title:		Contact E-mail Address:	

<b>SECTION I UTILIZATION OF STANDARDS</b>					
<b>Note:</b> Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ASTM F 899-02	ASTM	Standard Specification for Stainless Steels for Surgical Instruments	Edition 12B	2012-01-12
2	ISO 10993-1:2009	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	Fourth Edition	2009-10-15
3	ISO 10993-7:2008	ISO	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals	Second Edition	2008-10-15
4	ISO 11135-1:2007	ISO	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	First Edition	2007-05-01
5	ISO 11607-1:2006	ISO	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems	First Edition	2006-04-15
6	ASTM F1108-04:2009	ASTM	Standard Specification For Titanium-6Aluminum-4Vanadium Alloy Castings For Surgical Implants	Fourth Edition	2009-04-01
7	ASTM F67-13:2013	ASTM	Standard Specification for Unalloyed Titanium, for Surgical Implant Applications	Third Edition	2013-06-01
<b>See Section 21: Standards Data Report for 510(k)s, Form FDA 3654.</b>					

**Section 3  
510(k) Cover Letter**

**Section 3**

**510(k) Cover Letter**

December 17, 2013

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**RE: 510(k) Notification (21 CFR 807(e)), Tensyn™ Band**

Applicant: Dallen Medical, Inc.  
Al Memmolo  
1046 Calle Recodo, Suite G  
San Clemente, CA 92673  
Phone (949) 218-0030  
Fax (949) 218-0040

Dear Sir or Madam:

Pursuant to the provision of Section 510(k) of the Federal Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990, notification is made of the intention of Dallen Medical, Inc. to market and distribute the Tensyn™ Band. Two additional copies of this 510(k) notification are enclosed along with an e-Copy. **The eCopy is an exact duplicate of the paper copy.**

**Administrative Information:**

Common Name: Tensyn™ Band  
Model Number: 09-0025, 09-0026, 09-0027, 09-0028,  
Regulation Name: Washer, Bolt Nut  
Regulation Number: CFR 888.3030  
Regulatory Class: Class II  
Panel: Surgical, Orthopedic and Restorative Devices  
Product Code: HTN  
Previous 510(k): N/A

Dallen Medical regards the information provided in support of this premarket notification to be confidential and proprietary and afforded such protection under 21 CFR 807.95.

Dallen Medical, Inc.  
Tensyn™ Band

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIA@FDA.HHS.GOV or 301-796-8118

**Section 3**

**510(k) Cover Letter**

**Basis for the Submission:**

This traditional 510(k) notification is being submitted because the indications for use have been expanded and the device is being manufactured from a different material.

**Design and Use of the Device:**

The design and use of the Tensyn™ Band is presented below in tabular form.

Question	Yes	No
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components from a tissue or biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

If you have questions or additional information is desired to facilitate the evaluation, please feel free to contact me at (949) 218-0030 or via e-mail at a.memmo@a.dallenmedical.com.

(b)(6)  
Sincerely,  
(b)(6)  
Al Memmo  
Chief Operating Officer

Enclosures

**Section 4**  
**Indications for Use Statement**

**Indications for Use Statement**

510(k) Number (if known): \_\_\_\_\_

Device Name: **Tensyn™ Band**

Indications for Use:

The Tensyn™ Band is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. Specifically, the Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Prescription Use  X  OR Over-The-Counter-Use \_\_\_\_\_  
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

**Section 5  
510(k) Summary**



**This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.**

**GENERAL INFORMATION**

**APPLICANT:** Dallen Medical, Inc.  
1046 Calle Recodo, Suite G  
San Clemente, CA 92673  
(949) 218-0030 Phone  
(949) 218-0040 Fax

**CONTACT PERSON:** Al Memmolo  
Chief Operating Officer

**DATE PREPARED:** December 17, 2013

**DEVICE DESCRIPTION:**

**TRADE NAME:** Tensyn™ Band

**MODEL:** 09-0025, 09-0026, 09-0027, 09-0028

**GENERIC/Common Name:** Button / Lock / Suture

**CLASSIFICATION NAME:** Washer, Bolt Nut, CFR 888.3030 (code HTN)

**DEVICE CLASSIFICATION:** Class II

**PREDICATE DEVICES:** Tensyn Band (K131850)  
Tightrope Syndesmosis Repair Kit, Titanium, Model Ar-8920Ds; Stainless Steel. Model Ar-8921Ds (K043248)  
ToggleLoc System (K083070)  
Compressyn Band (K130431)

**Product Description:**

The Tensyn™ Band is a knotless system for fixation of syndesmosis disruptions. The Tensyn™ Band is a low profile system comprised of a polymer coated flat polyethylene terephthalate (PET) suture band tensioned and secured between a narrow button and a lock. The Tensyn™ Band is available in titanium and stainless steel.

**Indications for Use:**

The Tensyn™ Band is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. Specifically, the Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

**Technical Characteristics:**

The Tensyn™ Band has similar physical and technical characteristics to the predicate devices since all devices achieve fixation through a suture between two metal fasteners.

**Performance Data:**

All necessary testing has been performed with the Tensyn™ Band to assure substantial equivalence to the predicate devices. Testing included rotational loading, cyclic loading, ultimate load, load at 3 mm and shear test. The testing demonstrated that the Tensyn™ Band is substantially equivalent to the predicate devices.

**Basis for Determination of Substantial Equivalence:**

Upon reviewing the technical information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Tensyn™ Band is determined to be substantially equivalent to existing legally marketed devices.

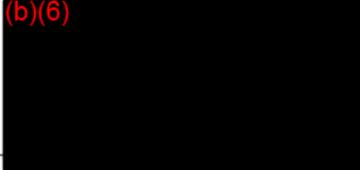
**Section 6**  
**Truthful and Accuracy Statement**

**Section 6**

**Truthful and Accuracy Statement**

**PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT**

Pursuant to 21 CFR 807.87(j) I certify that, in my capacity as Chief Operating Officer of Dallen Medical, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)  


\_\_\_\_\_  
Al Memmolo  
Chief Operating Officer  
Dallen Medical, Inc.

12-17-13  
Date

**Section 7**  
**Class III Summary and Certification**

The Tensyn™ Band is a class II medical device regulated under 21 CFR §888.3030. The Class III Summary and Certification requirement as described in 21 CFR §807.87(j) and §807.94 does not apply to this device and submission.

**Section 8**  
**Financial Certification or Disclosure Statement**

**Section 8**

**Financial Certification or Disclosure Statement**

The requirement for financial certification or disclosure statement as described in 21 CFR §807.87(i) does not apply to this submission.

**Section 9** **Declarations of Conformity and Summary Reports**

---

**Section 9**  
**Declarations of Conformity and Summary Reports**

**Section 9** **Declarations of Conformity and Summary Reports**

This submission is a traditional 510(k) submission. The requirement for a declaration of conformity and a summary report of testing does not apply.

**Section 10**  
**Executive Summary**

## Description of the Device

The Tensyn™ Band is a low profile implant device intended to provide stabilized fixation of tissues to facilitate syndesmosis repair. These tissues include bone and soft tissue to bone. The Tensyn™ Band can provide this stabilized fixation for bone fractures, osteotomies, and arthrodesis, plus soft tissue to bone attachment. It is designed to apply a restorative fixation force across the tissue segments to stabilize them. The Tensyn™ Band's rigidity and compliant nature will provide rigid and consistent fixation during the healing phase.

The Tensyn™ Band is delivered through a pre-drilled hole through the tibia and fibula by means of a pilot needle delivery, exiting the skin opposite the initial insertion site. The flat band is secured to the bone by pulling the metal button through both the tibial and fibula bones and then toggled into position to create tension across the two bone segments. Once the button is secure against the bone the suture attached to the needle can be cut and removed from the operative site. Pulling the flat suture tails against the lock at the initial insertion site will tension the band and bone segments in place. The Tensyn™ Band offers syndesmosis repair with a knotless closure.

The Tensyn™ Band is an assembly of four main components; a suture band, a narrow button, a lock and a straight needle. The woven suture is made from the same polyester (PET) as most sutures. The PET suture is coated with (b)(4). The lock and the narrow button are manufactured from either (b)(4) stainless steel or (b)(4) titanium alloy. The straight needle assembly is composed of a PET suture tether and a guide cap.



**Figure 10-1: Tensyn™ Band**

## Intended Use

The Tensyn™ Band is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. Specifically, the Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as

fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

## Predicate Device

The Tenysn™ Band is substantially equivalent in intended use, principal of operation, and technological characteristics to the predicate devices, Tenysn™ Band, (K131850), Tightrope, Syndesmosis Repair Kit (K043248) and ToggleLoc System (K083070). The subject Tenysn™ Band is identical to the predicate Tenysn™ Band except for the use of titanium as the base material and the use of a polymer (b)(4) coated PET suture. A summary of the substantial equivalence between the Tenysn™ Band and the predicates is summarized below.

**Table 10-1 Device Comparison Table**

<b>Product</b>	<b>Intended Use</b>	<b>Principle of Operation</b>	<b>Overall Technological Characteristics</b>
<b>Dallen Medical Tenysn™ Band</b>	The Tenysn™ Band is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. Specifically, the Tenysn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.	Provide fixation for ankle syndesmosis	A suture tensioned between a narrow button and a lock.
<b>Dallen Medical Tenysn™ Band K131850</b>	The Tenysn™ Band is intended to provide fixation during the healing process following an isolated syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions).	Provide fixation for ankle syndesmosis	A polymer coated suture tensioned between a narrow button and a lock.
<b>Arthrex Tightrope Syndesmosis Repair Kit, K043248</b>	The Tightrope Syndesmosis Repair Kit is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Tightrope is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.	Provide fixation for ankle syndesmosis	A suture tensioned between an oblong button and a round button.
<b>Biomet ToggleLoc System K083070</b>	The ToggleLoc System is intended for soft tissue to bone fixation for the following foot and ankle indications: Medial/lateral repair and reconstruction, Mid- and forefoot repair, Hallux valgus reconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair, Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in	Provide fixation for ankle syndesmosis	A suture tensioned between a tophat button and a toggle button.

**Section 10****Executive Summary**

	connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc with Tophat).		
<b>Dallen Medical Compressyn Band K130431</b>	The Compressyn Band is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.	Provide stabilization of sternal fracture	A polymer coated implant device providing stabilization by tension.

**Performance Testing**

Performance testing was conducted for the Tensyn™ Band to demonstrate the integrity and suitability of the device for its intended use. The results of the testing indicate that the Tensyn™ Band is substantially equivalent to the Tensyn™ Band predicate device and is safe and effective for its intended use.

**Section 11  
Device Description**

**Device Description**

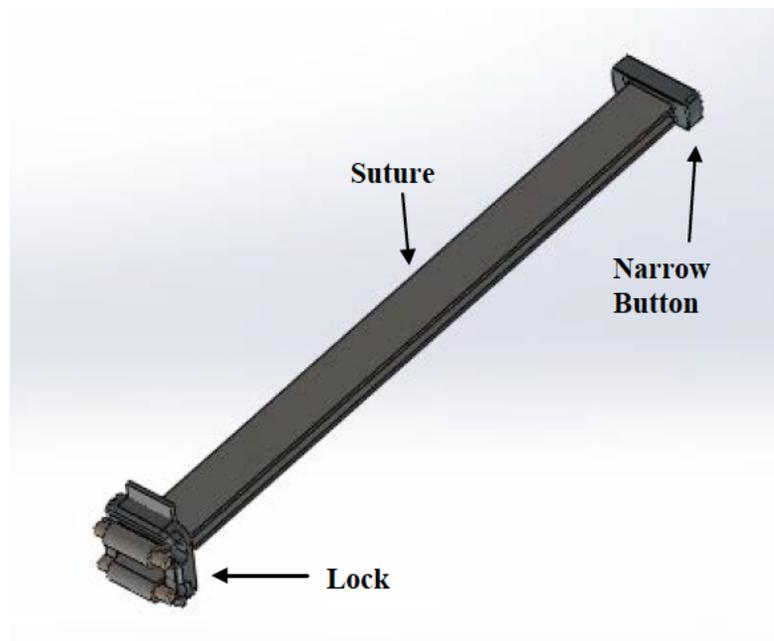
The Tensyn™ Band is a low profile implant device intended to provide stabilized fixation of tissues to facilitate syndesmosis repair. These tissues include bone and soft tissue to bone. The Tensyn™ Band can provide this stabilized fixation for bone fractures, osteotomies, and arthrodesis, plus soft tissue to bone attachment. It is designed to apply a restorative fixation force across the tissue segments to stabilize them. The Tensyn™ Band's rigidity and compliant nature will provide rigid and consistent fixation during the healing phase.

The Tensyn™ Band is delivered through a pre-drilled hole through the tibia and fibula by means of a pilot needle delivery, exiting the skin opposite the initial insertion site. The flat band is secured to the bone by pulling the metal button through both the tibial and fibula bones and then toggled into position to create tension across the two bone segments. Once the button is secure against the bone the suture attached to the needle can be cut and removed from the operative site. Pulling the flat suture tails against the lock at the initial insertion site will tension the band and bone segments in place. The Tensyn™ Band offers syndesmosis repair with a knotless closure.

The Tensyn™ Band kit contains one (1) Tensyn™ Band. The number of Tensyn™ Bands used per procedure will be based on physician discretion.

The Tensyn™ Band is provided sterile and is intended for single use by a licensed medical practitioner.

**Figure 11-1: Tensyn™ Band**



**Device Construction**

The Tensyn™ Band is fabricated from materials commonly used in the medical device industry and manufactured using well-known and established processes.

The Tensyn™ Band is an assembly of four main components; a suture band, a narrow button, a lock and a straight needle. The woven suture is made from the same polyester (PET) as most sutures. The woven PET suture is also provided with a polymer (b)(4) coating. The lock and the narrow button are manufactured from (b)(4) stainless steel and (b)(4) titanium. The straight needle assembly is composed of a PET suture tether and a guide cap.

Suture Band

The woven suture is polyester made from PET (polyethylene terephthalate), the same polyester as most commercially available sutures. The woven PET suture is also provided with a polymer (b)(4) coating. The suture is provided in an overall length of 36 inches. The suture length between the narrow button and the lock in the Tensyn™ Band assembly is nominally set to 3 inches and is adjusted by the physician per the anatomical requirements of the patient.

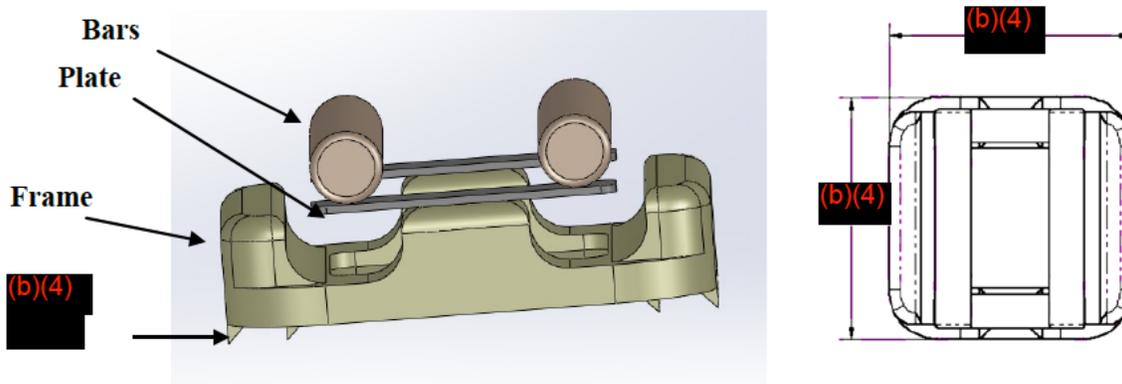
Straight Needle

The needle is made from (b)(4) stainless steel that is used in most surgical needles. The needle is 6 inches in length and has a diameter of (b)(4). A (b)(4) inch polyester (PET) suture is used to attach the needle and narrow button. After placement of the narrow button, the suture and the straight needle are discarded.

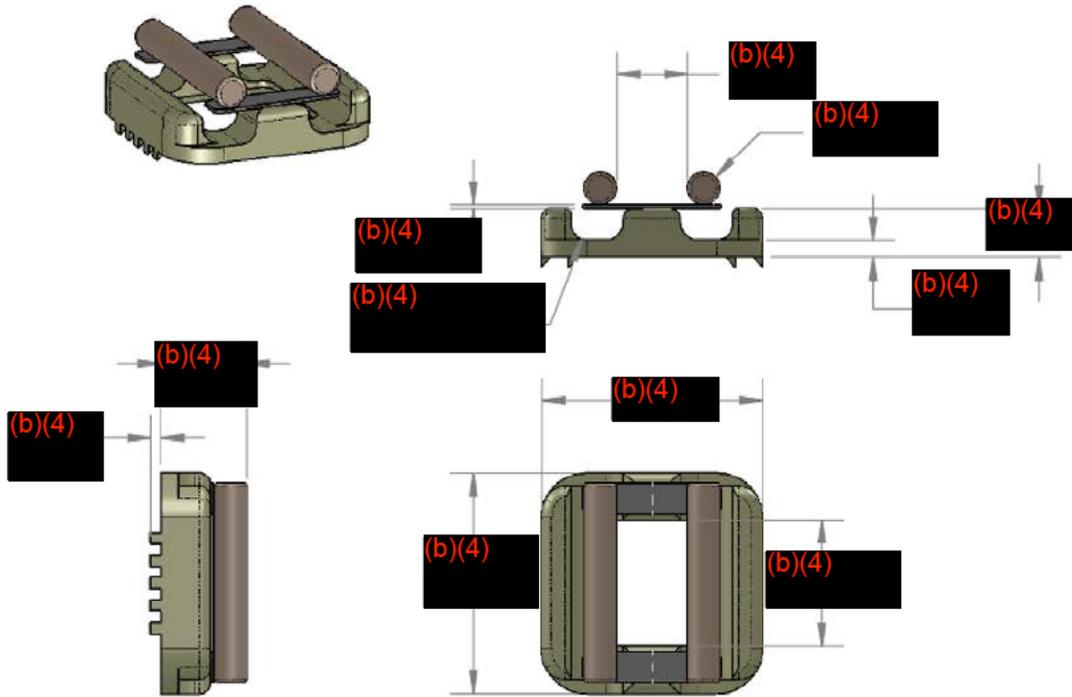
Lock

The lock assembly is composed entirely of (b)(4) stainless steel or titanium. The assembly is two bars on a plate, attached to the frame with (b)(4). For the titanium version the plate is composed of titanium (b)(4) and the rest of the assembly is made from (b)(4). During use when the two ends of the suture are tensioned, the bars are moved into their locking position and an integrated (b)(4). See Figure 11-2 and Figure 11-3 below.

**Figure 11-2: Lock Assembly**



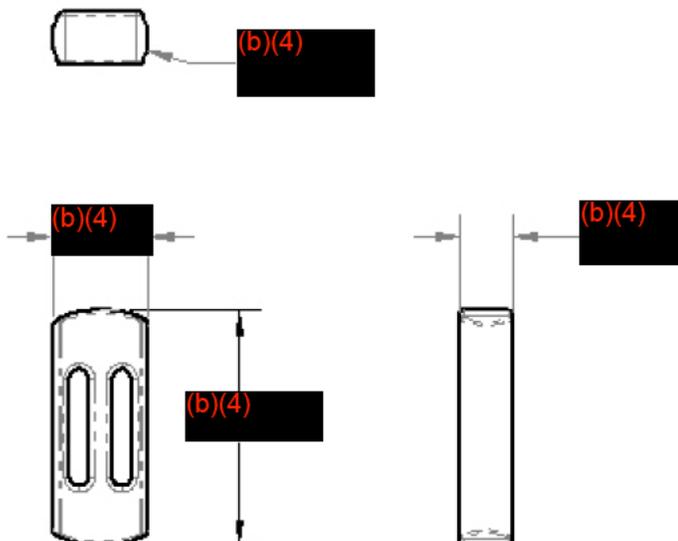
**Figure 11-3: Dimensional Drawing, Lock Assembly**



Narrow Button

The narrow button is manufactured from (b)(4) stainless steel or (b)(4) titanium. The narrow button is supplied pre-threaded with the suture band prior to use. See Figure 11-4 below.

**Figure 11-4: Narrow Button**



*Available Sizes*

The Tensyn™ Band is available in a single size, as previously described.

*Available Models*

The Tensyn™ Band will be available in four models:

09-0025 – Stainless steel with uncoated suture (submitted in K131850 as Model 09-0006)

09-0026 – Stainless steel with polymer coated suture

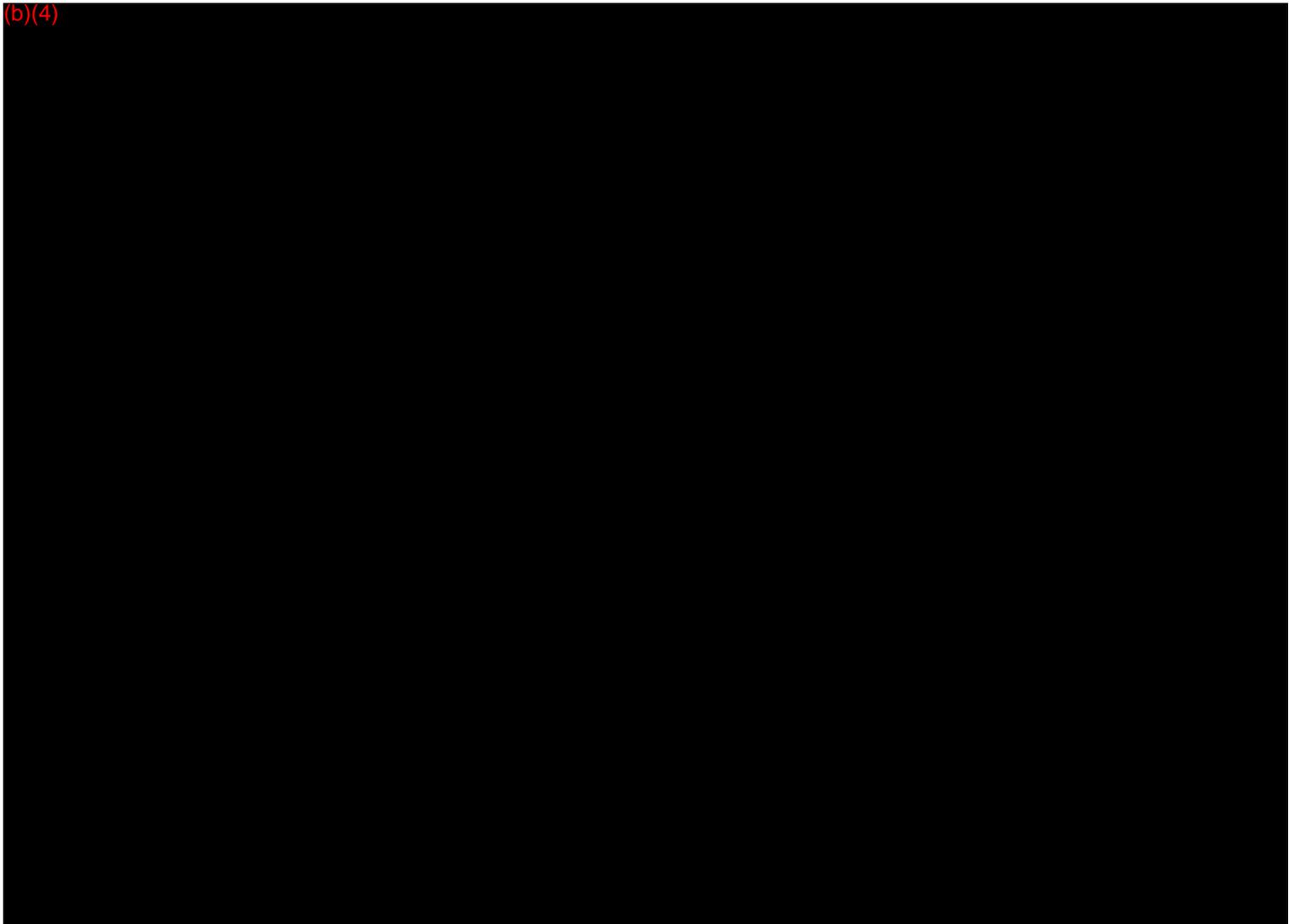
09-0027 – Titanium with uncoated suture

09-0028 – Titanium with polymer coated suture

**Device Operation and Features**

The Tensyn™ Band is delivered using similar techniques to other syndesmosis repair devices. A 3.6 mm hole is pre-drilled through the cortices of the tibia and fibula from the open lateral side. A straight guide needle is passed through the drilled hole in the tibia and fibula and through the skin on the medial side, taking care to register the narrow button into the pre-drilled hole. Tension is applied to pull the narrow button to medial side assuring the narrow button lies flat against the bone. The suture tether and needle are discarded. Pulling the suture band lightly on each end will bring the lateral lock to resting flat on fibula. A final pull with sufficient force will fully engage the lock. The suture ends are then cut.

**Figure 11-5: Technical Drawing**



**Table 11-1: Tensyn™ Band Materials and FDA Recognized Standards**

<i>Material</i>	(b) Stainless Steel	(b)(4) Stainless Steel	(b)(4)	(b)(4)	Polyethylene Terephthalate (PET)	(b)(4)	(b)(4)
<i>Where Used</i>	Straight Needle	Lock Assembly and Narrow Button	Lock Assembly and Narrow Button	Plate on Lock Assembly	Suture Band and SutureTether	Suture Band	Guide Cap
<i>FDA Recognized Standards</i>	ASTM F899-02	ASTM F899-02	ASTM F1108-04	ASTM F67-13	(b)(4)	N/A	N/A

**Section 12**  
**Substantial Equivalence Discussion**

**Substantial Equivalence**

The Tensyn™ Band is substantially equivalent to the predicate Tensyn Band™ (K131850), Arthrex Tightrope Syndesmosis Repair Kit (K043248), Biomet ToggleLoc System (K083070) and the Compressyn™ Band (K130431).

**Indications for Use**

The Tensyn™ Band and the predicates, the Tensyn™ Band (K131850), Arthrex Tightrope Syndesmosis Repair Kit (K043248) and Biomet ToggleLoc System (K083070) share the same general indications. The subject Tensyn™ Band is expanding the indications for use to include use of the device as an adjunct in fracture repair. The Biomet ToggleLoc labeling uses the following statement, “However, the device can be used without trauma hardware in stable fractures as determined appropriate by the surgeon.” The Arthrex Tightrope labeling uses the following statement, “High fibula fractures can be managed by reduction and syndesmosis fixation only using two Tightropes.” Published peer-reviewed literature clearly shows the use of the Arthrex Tightrope adjunct to fracture repair independent of a plate system<sup>1</sup>. A 2008 report of 25 cases describes the use of the Arthrex Tightrope in 24% of the cases outside the lateral plate versus 76% within the plate. The Tightrope was placed adjacent to the plate due to particular fracture patterns<sup>2</sup>. The expanded indication for use statement for the subject Tensyn™ Band has been included in the 510(k) clearances and is still present in the current labeling of the predicate devices (K043248 and K083070). The use of the Tensyn™ Band adjunct to fracture repair is additionally supported by clinical literature. Copies of the predicate device labeling and clinical articles are provided in APPENDIX 1, Predicate Device Labeling and Clinical Literature, of this premarket notification.

<sup>1</sup> Frania SJ, Judge MS, Meszaros A, Canales MB and Masdeh S. *Technique of Syndesmotic Repair: Investigating the Innovative Tightrope™ in Treatment of Syndesmotic Injuries*. Vickers NS (editor), Reconstructive Surgery of the Foot and Leg, Update 2006. Podiatry Institute Publishing Co., Tucker, GA, pp. 37-43.

<sup>2</sup> Cottom JM, Hyer CF, Philbin TM, Berlet GC. Treatment of syndesmotic disruptions with the Arthrex Tightrope: a report of 25 cases. *Foot Ankle Int.* 2008 Aug;29(8):773-80.

**Section 12****Substantial Equivalence Discussion**

The indication statements for the Tensyn™ Band and the predicate devices are illustrated below:

**Table 12-1: Comparison of Indication Statements**

<b>Dallen Medical Tensyn™ Band</b>	<b>Dallen Medical Tensyn™ Band K131850</b>	<b>Arthrex Tightrope Syndesmosis Repair Kit K043248</b>	<b>Biomet ToggleLoc System K083070</b>
<p>The Tensyn™ Band is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. Specifically, the Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.</p>	<p>The Tensyn™ Band is intended to provide fixation during the healing process following an isolated syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions).</p>	<p>The Tightrope is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Tightrope is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.</p>	<p>The ToggleLoc is intended for soft tissue to bone fixation for the following foot and ankle indications: Medial/lateral repair and reconstruction, Mid- and forefoot repair, Hallux valgusreconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair, Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc with Tophat).</p>

### Technological Characteristics

The Tensyn™ Band has identical technological characteristics to the predicate Tensyn™ Band (K131850). The only two differences are material related; 1) the subject device is composed of titanium versus stainless steel for the predicate, and 2) the subject device uses the identical PET suture material which is coated with a polymer (b)(4) versus uncoated for the predicate. The identical polymer coated PET suture was cleared for use in (b) (6) Table 12-2 illustrates the similarities and differences in technological characteristics.

**Section 12****Substantial Equivalence Discussion****Table 12-2: Comparison of Technological Characteristics**

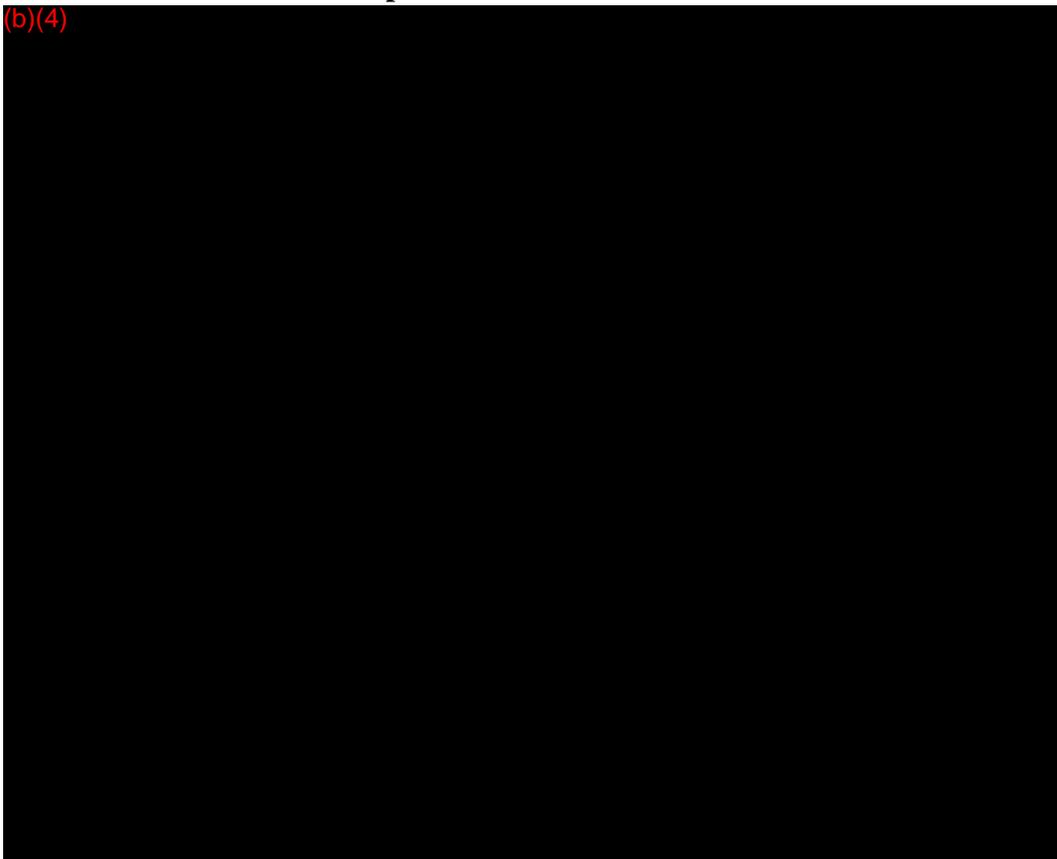
	<b>Dallen Medical Tensyn™ Band</b>	<b>Dallen Medical Tensyn™ Band (K131850)</b>	<b>Dallen Medical Compressyn™ Band (K130431)</b>
<b>Principle of Operation</b>	Fixation through a suture between two metal fasteners	Fixation through a suture between two metal fasteners	Provide stabilization of sternal fracture
<b>Panel</b>	Surgical, Orthopedic and Restorative	Surgical, Orthopedic and Restorative	Surgical, Orthopedic and Restorative
<b>Application Method</b>	Hand tensioning	Hand tensioning	Specialized instrument – Tensioner
<b>Components</b>	Lock, Narrow Button, Suture, Straight Needle, Suture Tether and Guide Cap	Lock, Narrow Button, Suture, Straight Needle, Suture Tether and Guide Cap	Woven Band w/Needle Buckle
<b>Implantable Materials of Construction</b>	Titanium, Polyester (PET)	Stainless Steel, Polyester (PET)	Stainless Steel, PET (b)(4)
<b>Permanent Implant</b>	Yes	Yes	Yes
<b>Suture Material</b>	Polyester woven suture made from polyethylene terephthalate (PET) coated with (b)(4)	Polyester woven suture made from polyethylene terephthalate (PET)	Polyester woven suture made from polyethylene terephthalate (PET) coated with (b)(4)
<b>Nominal Thickness of Polymer Coating</b>	(b)(4)	(b)(4)	(b)(4)
<b>Devices per Procedure</b>	1	1	4-5

**Performance Data**

The performance data submitted in this premarket notification demonstrates equivalence between the Tensyn™ Band and Tensyn™ Band (K131850) predicate. Performance testing of the subject Tensyn™ Band as compared to previously submitted Tensyn™ Band (K131850) testing showed the subject device performed equivalent to the predicate device. Table 12-3 below reports the results of the performance testing that demonstrated substantial equivalence.

**Table 12-3: Mean Comparison of Performance Data**

(b)(4)

**Conclusion**

The Tensyn™ Band and the predicate Tensyn™ Band (K131850), the predicate Arthrex Tightrope Syndesmosis Repair Kit (K043248) and the predicate Biomet ToggleLoc System (K083070) share the same general indications. The expanded Tensyn™ Band indications for use for adjunct fracture repair are supported by the predicate device labeling and clinical literature. The subject Tensyn™ Band and the predicate Tensyn™ Band (K131850) share the same technological characteristics, the only difference between the two devices is the addition of titanium for the base material and the addition of the coating of the PET suture. The performance data for the Tensyn™ Band was substantially equivalent to the predicate Tensyn™ Band (K131850). The Tensyn™ Band is substantially equivalent in terms of intended use, principle of operation, technological characteristics, and performance characteristics to the listed predicates.

**Section 13  
Proposed Labeling**

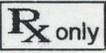
 Dallen Medical, Inc.  
1046 Calle Recodo Suite G  
San Clemente, CA 92673

CONTENTS: 1 EACH

REF	xxxxxx	LOT	xxxxxx
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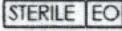
**TENSYN™ BAND**

IMPLANT MATERIAL: TITANIUM, STEEL  
POLYETHYLENE TEREPHTHALATE

STERILE	EO
---------	----

 2013-08
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Symbol	Definition	dallen MEDICAL
	BATCH CODE	
	CAUTION; U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	
	KEEP AWAY FROM SUNLIGHT	
	KEEP DRY	
	DO NOT RE-USE	
	EO STERILIZED	
	CONSULT OPERATING INSTRUCTIONS	
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS	
	MANUFACTURER	
	DATE OF MANUFACTURE	
	CATALOG NUMBER	

## **Tensyn™ Band (Proposed) Instructions for Use**

Model 09-0025, Model 09-0026, Model 09-0027, Model 09-0028

Caution: This device is restricted to use by or on the order of a physician.

### **DESCRIPTION**

The Tensyn™ Band is a low profile implant device intended to provide stabilized fixation of tissues to facilitate syndesmosis repair with a knotless closure. These tissues include bone and soft tissue to bone.

### **INDICATIONS FOR USE**

The Tensyn™ Band is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. Specifically, the Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

### **CONTRAINDICATIONS**

1. Surgical procedures other than those listed in the INDICATIONS section.
2. Patients with known sensitivities or allergies to chromium, nickel, copper, cobalt, iron, and polyester or silicone based plastics.
3. Insufficient quantity or quality of bone.
4. Blood supply limitations and previous infections, which may retard healing.
5. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
6. Foreign body reactions. See Adverse Effects-Allergic Type Reactions.
7. Any active infection or blood supply limitations.
8. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.

### **POSSIBLE ADVERSE EFFECTS**

1. Osteomyelitis surrounding the Tensyn™ Band.
2. Rediastasis resulting from a failure of the implant insertion technique.
3. Infections, both deep and superficial.
4. Foreign body reactions.
5. Nonunion or delayed union, which may lead to breakage of the implant.
6. Loosening or migration of the implant.
7. Pain, discomfort or abnormal sensation due to the presence of the device.
8. Nerve damage to surgical trauma.
9. Necrosis of bone or tissue.
10. Inadequate healing.
11. Intraoperative or postoperative bone fracture and/or postoperative pain.

**WARNINGS (PRECAUTIONS)**

1. Do not re-sterilize this device.
2. All metallic implant devices used for this surgical procedure should be of identical material, including the plates that might be used.
3. Post-operatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The post-operative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
4. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device.
5. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate post-operative management.
6. Detailed instructions on the use and limitations of the device should be given to the patient.
7. This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
8. This device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating or migration in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.
9. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from post-operative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate post-operative management to avoid re-fracture.
10. In handling suture material and lock assembly, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
11. Needles contain sharp points; appropriate needle stick precautions should be taken in the handling and implant of this device.

**STERILIZATION**

The Tensyn™ Band implant is provided EO sterilized. Do not re-sterilize.

**STORAGE AND HANDLING**

Store at room temperature. Avoid storing the Tensyn™ Band at conditions of excessive heat or humidity. Do not use after expiration date on label. All components should be handled carefully to avoid damaging the device.

**PROCEDURE**

Note: Use of a drill guide is optional. If drill guide is used, place the drill guide on the fibula and drill through it to the tibia per the technique described in Step 1.

1. Using a 3.6 mm drill bit (and optional drill guide), advance the drill bit cortices of the tibia and fibula from the open lateral side, angled 30 degrees upwards from the coronal plane and 2 cm above the ankle joint. Care should be taken to avoid the saphenous vein and nerve (anterior to medial malleolus).
2. Remove Tensyn™ Band from packaging and remove the protective cap from the straight guide needle.
3. Pass the straight guide needle through the drilled hole in the tibia and fibula and through the skin on the medial side, taking care to register the narrow button into the pre-drilled hole.
4. Continue to apply tension with the guide needle, suture and narrow button. Pull through to medial side; lightly pull suture (band) from lateral side such that the medial, narrow button lies flat against the bone.
5. Cut and remove suture tether and needle.
6. Grasping each end of the lateral suture (band) pull lightly on each end until lock is resting flat on the fibula. Adjustment or loosening can be achieved by lifting up on lock to loosen and pulling lightly on the suture to retighten.
7. Pulling the suture ends with sufficient force will result in the lock fully engaging. At this point no further adjustment is possible.
8. Cut both suture ends about 4 mm from lock.

**DISPOSAL PROCEDURES**

Upon completion of the procedure, dispose of the other removed components per hospital procedure in accordance with clinical-internal, administrative and/or applicable legal regulations.

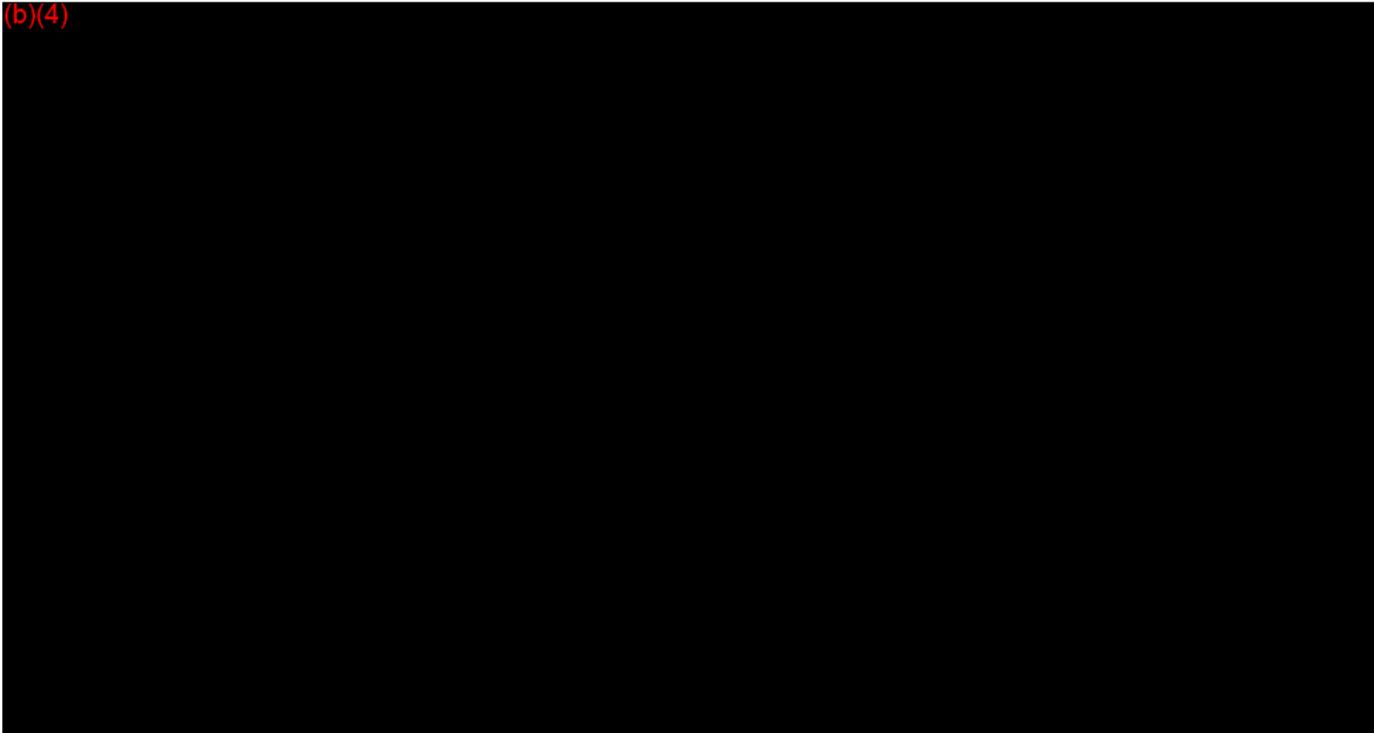
**MANUFACTURED BY:**

Dallen Medical, Inc.  
1046 Calle Recodo, Suite G  
San Clemente, CA 92673  
Phone: (949) 218-0030  
Fax: (949) 218-0040

**Section 14**  
**Sterilization and Shelf Life**

**Sterilization and Shelf Life**

(b)(4)



Pyrogenicity

No claim for nonpyrogenicity is made, therefore no Limulus Amebocyte Lysate (LAL) testing is required to substantiate this claim.

Description of Packaging

The packaging of the device will comply with ISO 11607-1:2006, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems*.

Primary Packaging: One (1) Tensyn™ Band, one (1) drill guide and one (1) drill secured on a high-density polyethylene (HDPE) backer card and sealed inside a 21-inch long x 4-inch wide Tyvek and polyethylene pouch.

Secondary Packaging: One (1) sealed 21 x 4-inch sealed Tyvek and polyethylene pouch is placed inside another sealed tyvek and polyethylene pouch.

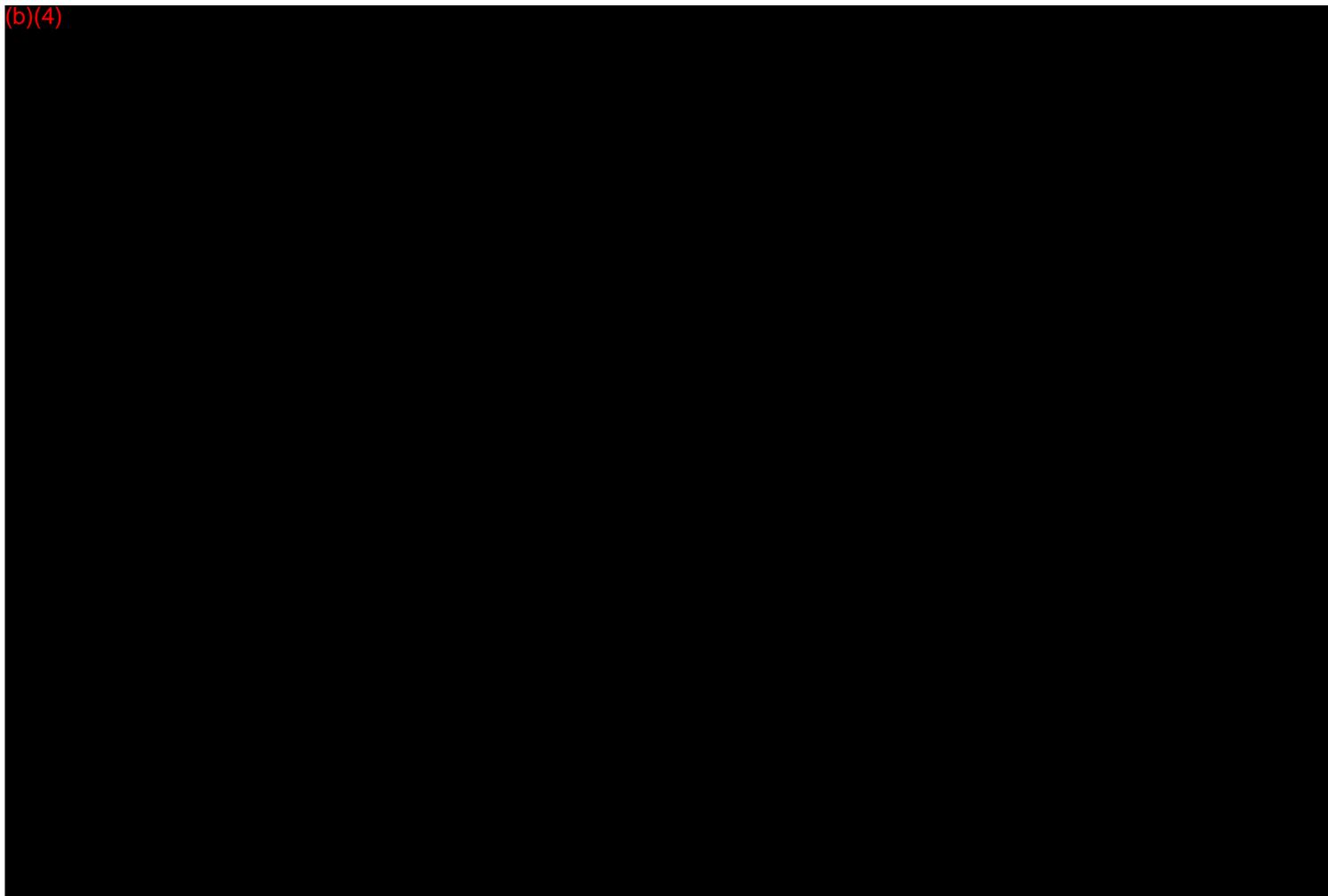
Tertiary Packaging: One (1) 21 x 4-inch sealed Tyvek and polyethylene pouch placed inside a shelf carton along with an IFU.

Quaternary Packaging: Five (5) shelf cartons are placed inside a shipping box.

**Section 14**

**Sterilization and Shelf Life**

(b)(4)



**Section 15**  
**Biocompatibility**

**Biocompatibility-Applied Standard**

ISO 10993-1 was used as a standard for biocompatibility compliance. ISO 10993-1 was used to determine the appropriate categorization of the device based on the nature and duration of contact with the body. The Blue Book Memorandum G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and Table 1 of ISO 10993-1 were used as tools for the initial evaluation of tests for consideration.

**Categorization of the Device**Intended Use

The Tensyn™ Band is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. Specifically, the Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Nature and Duration of Body Contact

The Tensyn™ Band is designed to be used as a permanent implant.

Device Categorization

The ISO 10993-1 device categorization for the Tensyn™ Band is a tissue contacting permanent implant (> 30 days).

**Predicate Identification**

The Tensyn™ Band is composed of stainless steel or titanium in combination with polyester (PET), all commonly used materials for permanently implanted medical devices. The PET suture is provided with a polymer coating of (b)(4). The Tensyn™ Band predicate (K131850) is composed of stainless steel and PET polyester. (b)(4)

The Tightrope (K043248) predicate uses two buttons made from either stainless steel or titanium. The ToggleLoc (K083070) predicate uses buttons that are made from stainless steel and titanium. All three predicate syndesmosis devices are also permanently implanted devices for similar indications for use. (b)(4).

**Conclusion**

The Tensyn™ Band is composed of stainless steel or titanium in combination with a polymer-coated polyester (PET), all commonly used permanently implanted materials in syndesmosis repair. The Tensyn™ Band and predicates are composed of essentially the same materials. Dallen Medical believes that the Tensyn™ Band is biocompatible for its intended use.

**Section 16  
Software**

**Section 16**

**Software**

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This section is not applicable because the device does not contain any software/firmware.

**Section 17** **Electromagnetic Compatibility and Electrical Safety**

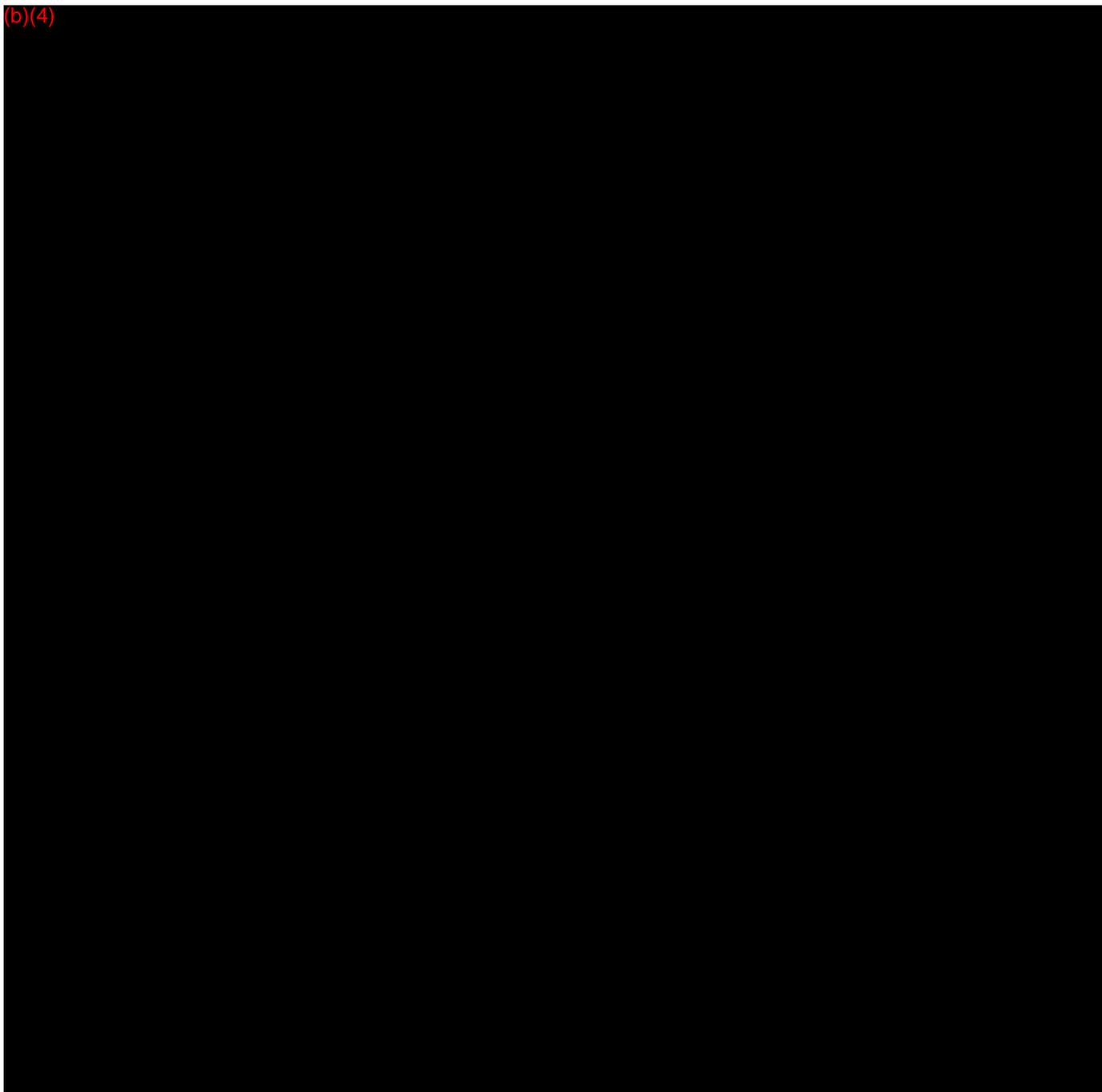
**Section 17**  
**Electromagnetic Compatibility and Electrical Safety**

**Section 17** **Electromagnetic Compatibility and Electrical Safety**

This is a non-electrical device; therefore, this section is not applicable because the device does not require EMC or Electrical Safety Evaluation.

**Section 18**  
**Performance Testing – Bench**

**Bench Testing**



**Section 19**  
**Performance Testing - Animal**

**Section 19**

**Performance Testing - Animal**

This section does not apply because no animal studies were conducted for this device.

**Section 20**  
**Performance Testing - Clinical**

**Section 20**

**Performance Testing - Clinical**

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This section does not apply because no clinical studies were conducted for this device.

**Section 21**  
**Standards Data Report for 510(k)s, Form FDA 3654**

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F1108-04:2009 Standard specification for titanium-6aluminum-4vanadium alloy castings for surgical implants

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 8-189

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F1108-04:2009 Standard specification for titanium-6aluminum-4vanadium alloy castings for surgical implants		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER N/A	SECTION TITLE N/A	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
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DESCRIPTION		
JUSTIFICATION		
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TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<b>Paperwork Reduction Act Statement</b>		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="margin-left: 40px;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="margin-left: 40px;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F67-13:2013 Standard specification for unalloyed titanium for surgical implant applications

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 8-129

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....         
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....         
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....      

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....         
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F67-13:2013 Standard specification for unalloyed titanium for surgical implant applications		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER N/A	SECTION TITLE N/A	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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 (To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F 899-02 Standard specification for stainless steels for surgical instruments

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

FDA Recognition number <sup>3</sup> ..... # N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes     No  
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes     No

Does this standard include acceptance criteria? .....  Yes     No  
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes     No  
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....  Yes     No  
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes     No

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....  Yes     No  
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes     No  
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....  Yes     No  
 If yes, was the guidance document followed in preparation of this 510k? .....  Yes     No

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ASTM F 899-02 Standard specification for stainless steels for surgical instruments

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009 Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 2-179

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

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If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-1:2009 Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-7:2008 Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-335

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-7:2008 Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11135-1:2007 Sterilization of health care products--Ethylene oxide--Part 1: Requirements for development, validation and....

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-331

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
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Were there any exclusions from the standard? .....       
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Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11135-1:2007 Sterilization of health care products--Ethylene oxide--Part 1: Requirements for development, validation and...

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*  
N/A

DESCRIPTION  
N/A

JUSTIFICATION  
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11607-1:2006 Packaging for terminally sterilized medical devices--Part 1: Requirements for materials, sterile barrier systems...

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-355

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11607-1:2006 Packaging for terminally sterilized medical devices--Part 1: Requirements for materials, sterile barrier systems...

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*  
N/A

DESCRIPTION  
N/A

JUSTIFICATION  
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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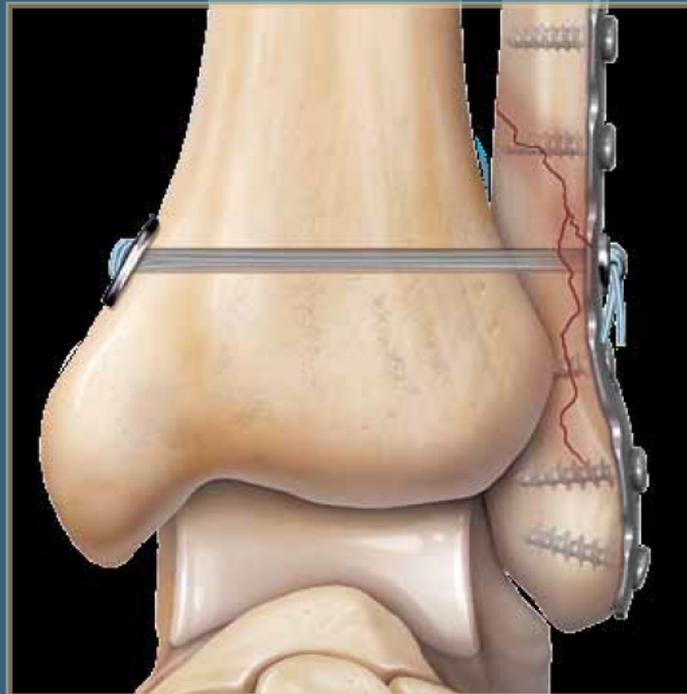
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Rockville, MD 20850

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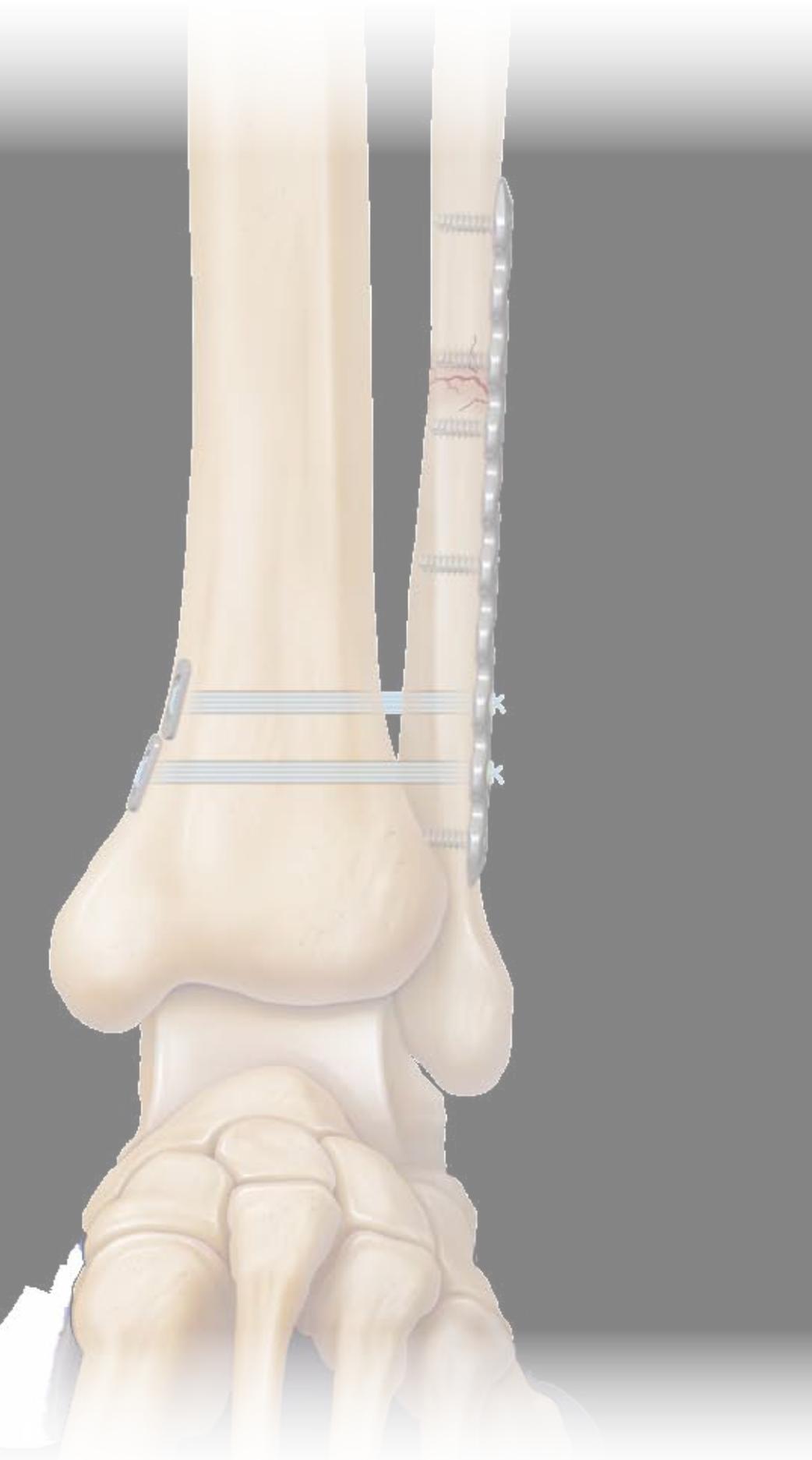
**Appendix 1**  
**Predicate Device Labeling and Clinical Literature**



TightRope® Syndesmosis Fixation  
Surgical Technique



# TightRope Syndesmosis Fixation



## Arthrex TightRope & Fracture Fixation

The Syndesmosis TightRope provides fixation of syndesmosis disruptions with or without associated ankle fractures. The TightRope is comprised of a #5 FiberWire® loop, which when tensioned and secured between metallic buttons and placed against the tibia and fibula, provides physiologic stabilization of the ankle mortise. Biomechanical testing and clinical trials have shown equivalent strength and improved patient outcome with the TightRope technique. The TightRope obviates the need for a second procedure for removal, therefore late diastasis cannot occur. Cyclic loading does not promote device failure. The "snowshoe" hold on cortical bone makes the TightRope suitable in osteoporotic bone where polymer or metallic screws cut out.

With over 50,000 syndesmotic ruptures annually and over 70,000 TightRopes implanted worldwide to date, Arthrex is positioned to continue to dominate syndesmotic repairs with the new Knotless TightRope. The TightRope has quickly become the implant of choice for syndesmotic repairs to prevent second surgeries and may help to promote quicker return to activity. The Knotless TightRope will now give the surgeon an option when limited soft tissue coverage is a concern.

The modular, low profile Ankle Fracture Management System consists of stainless steel specialty plates in unique configurations and locking screws designed for most types of ankle fractures. Plates feature nested holes for a flush TightRope profile without increasing implant prominence.

Fractures in the lower two-thirds of the fibula should be rigidly and anatomicly fixed to ensure correct fibular length and rotation. High fibula fractures (Maisonneuve injury) can be managed by reduction and syndesmosis fixation only, using two TightRopes.

### Advantages:

- No need for routine removal
- Eliminates broken screw complications
- Achieves strong, anatomic and flexible fixation
- Simplifies lateral insertion technique
- Facilitates double TightRope technique for Maisonneuve fracture
- Weight-bearing may be commenced earlier than with screw fixation
- No second procedure needed for removal of broken metal screws
- Biomechanical testing and clinical results have shown equivalent strength and improved patient outcomes\*

### Indications

The TightRope is intended to provide syndesmosis fixation during the healing process following a syndesmotic trauma, usually seen with Weber B and C ankle fractures.

### Syndesmosis Reduction

The syndesmosis should be normally reduced prior to fixation and confirmed using fluoroscopy. Internal rotation in moderate ankle plantar flexion is the usual method of reduction. Dorsiflexion of the ankle to reduce is not recommended as it may cause malreduction and compromise the end result. Overtightening of the syndesmosis will not occur using the TightRope.

For more information go to:  
<http://tightrope.arthrex.com>

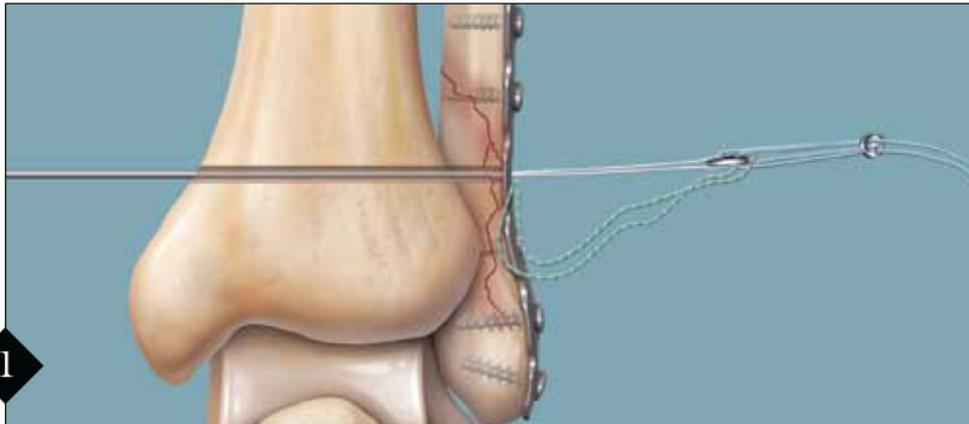
\*Data on file



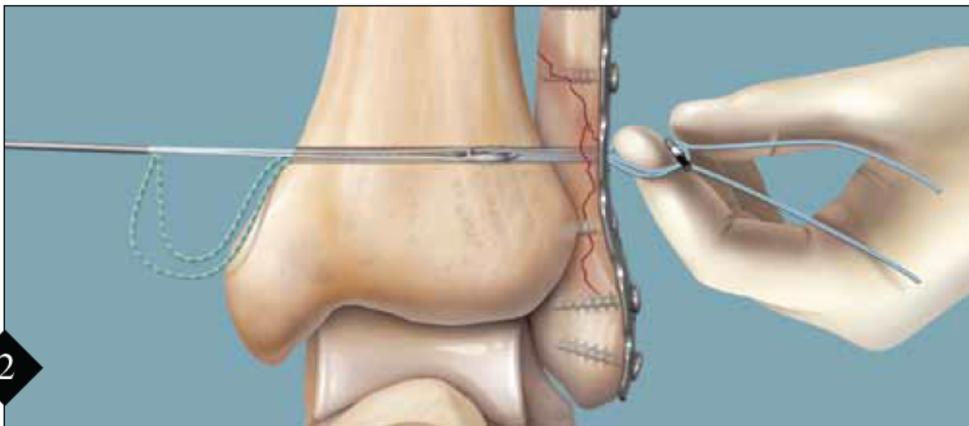


## TightRope Syndesmosis Fixation

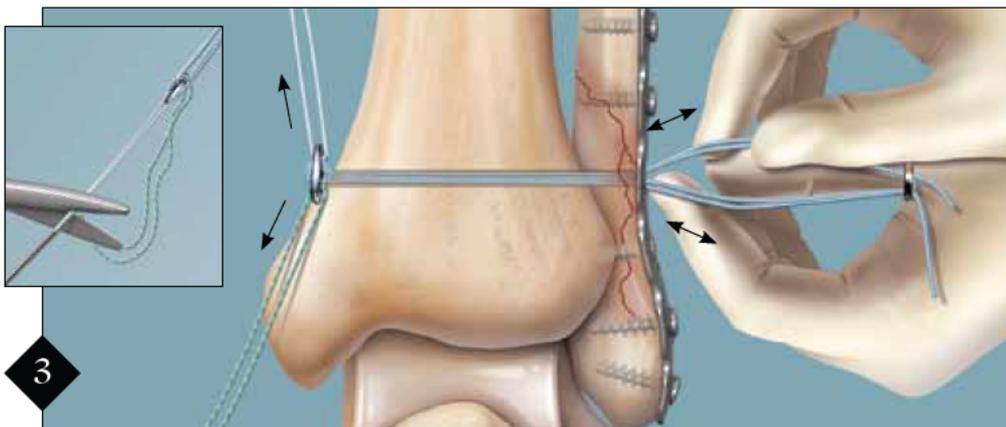
*TightRope Plus Syndesmosis Implant is used in the illustrations depicted in this surgical technique.*



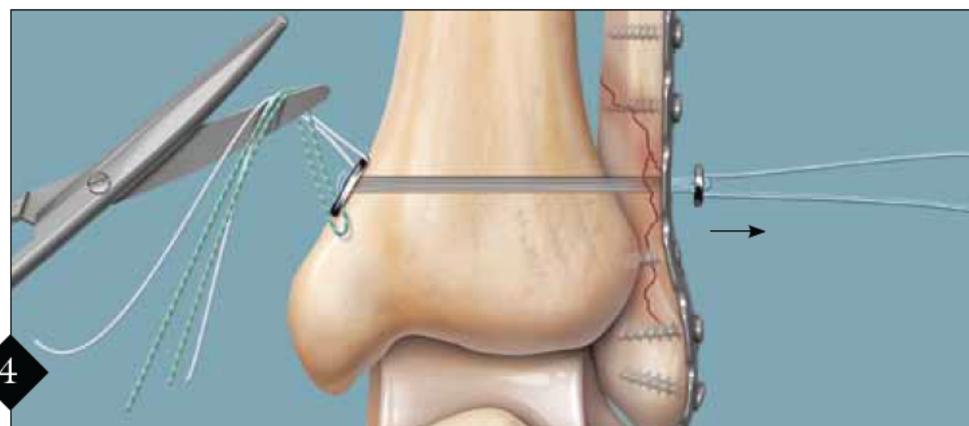
Drill all four cortices, 1.5 cm above the ankle joint, in the transmalleolar plane (30° anterior to the coronal plane), using the 3.5 mm Drill Bit. The needle and pull-through sutures are passed along the drill hole and out the intact medial skin.



The white 2-0 FiberWire pull-through suture advances the leading Oblong Button, until it just exits the medial tibial cortex. (Note: The green/white 2-0 FiberWire suture has been added to help facilitate placement of the medial button during step 3. Do not tension the green/white suture while passing the button from the fibula through the tibia.) It should remain slack as it passes through the drill hole.

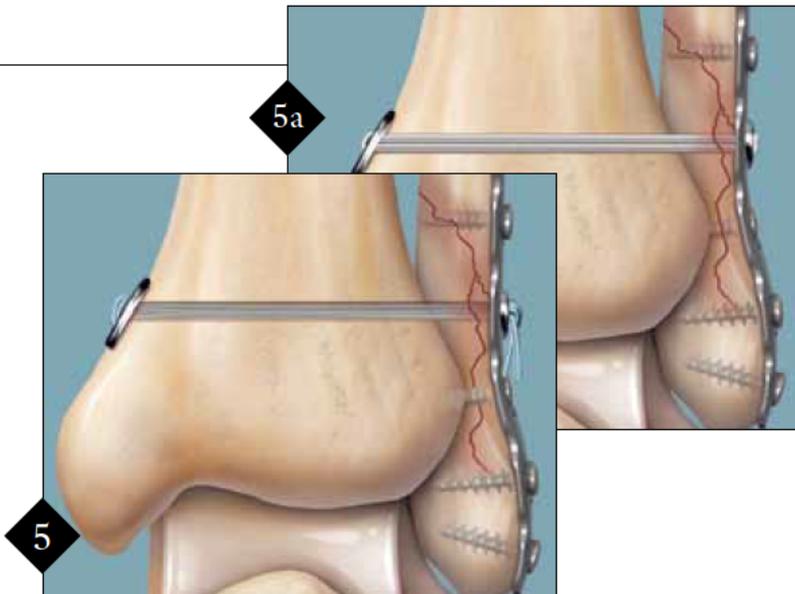


Cut the green/white and white pull-through sutures where they connect to the needle after passage through the medial skin. Slight upward tension should be placed on the white pull-through suture, while placing downward tension on the green/white suture. The button should seat easily along the medial cortex. Confirm placement using C-arm. (Note: Toggling the two pairs of #5 FiberWire on the lateral side will also aid in seating the medial button.)



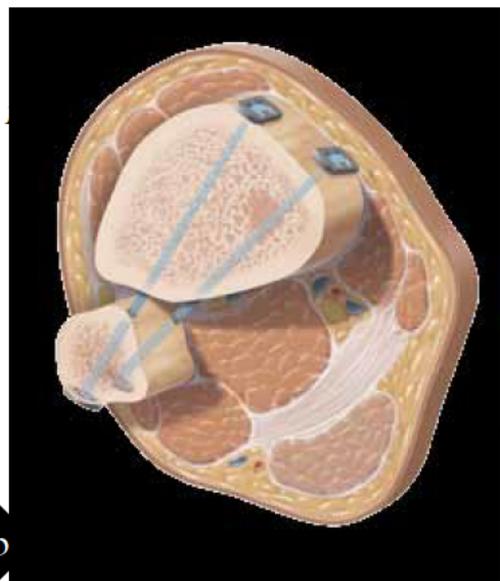
The white and green/white pull-through sutures are cut and removed. The trailing lateral button is tightened down on the lateral side by pulling on the free ends of the syndesmosis suture with the syndesmosis reduced (internal rotation and moderate ankle plantar flexion).

**Surgical Technique**

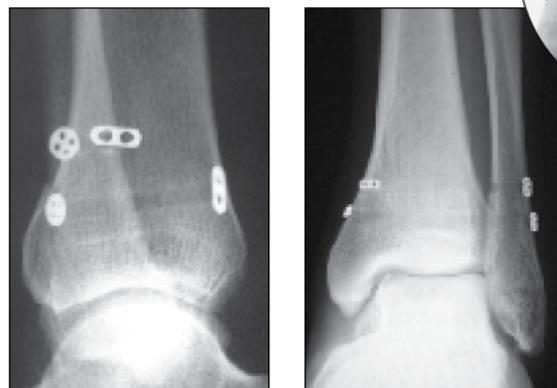


*Step 5:* The construct is secured with three half-hitches. The suture ends are cut at least 2 cm long to allow the knot and suture to lay down, reducing knot prominence.

*Option 5a:* Using the new *Knotless TightRope* allows for knot prominence reduction



A second TightRope should be used to treat Maisonneuve injuries, or if further syndesmosis stability is required. The second TightRope should be placed 1 cm above the first, with slight axial divergence to increase rotational stability. (see illustration (b) and x-ray (a))



Repair is complete using one TightRope.

**Postoperative Management**

Following wound closure, immobilize the ankle in the neutral position in a below-knee cast, nonweight-bearing for the first two weeks. Depending on fracture fixation stability and satisfactory wound healing, partial weight-bearing (50% body weight) may be permitted in a cast or walker boot, until six weeks postoperatively. Full weight-bearing can be allowed out of the cast at six weeks.

**Implant Removal**

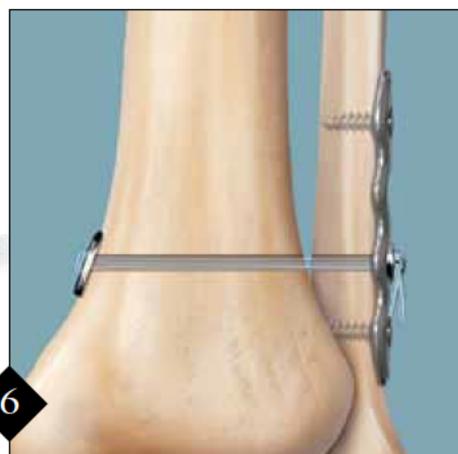
Routine removal of the TightRope is not required. If, for any reason it needs removal, small incisions over both buttons and cutting the suture make removal of the buttons and suture easy.

**TightRope Syndesmosis Buttress Plate Implant**

The TightRope Syndesmosis Buttress Plate (SBT Implant) features a four-hole, contoured, titanium plate, to be used as a "buttress" for ankle syndesmosis repairs with or without ankle fracture. The plate has two inner holes that custom fit the Round Button of the TightRope and two outer holes that accept two 3.5 mm x 14 mm nonlocking screws. The implant comes with everything required to complete the syndesmosis fixation.



6



The 3.5 mm screws are placed in the proximal and distal holes of the Buttress Plate. A TightRope is then placed in either the third hole (6), or both central holes (inset), if desired.

**Ordering Information**

***TightRope Plus Syndesmosis Repair Implants, can***

- TightRope Syndesmosis Repair Implant, cannulated, titanium, sterile, SU
- TightRope Syndesmosis Repair Implant, cannulated, stainless steel, sterile, SU

***TightRope Plus Syndesmosis Implants incl***

- Drill Bit, 3.5 mm
- Drill Guide, disposable
- Oblong Button, 3.5 mm x 10 mm (medial)
- Round Button, 6.5 mm (lateral side placem)
- #5 FiberWire Suture (blue)
- 2-0 FiberWire (white)
- 2-0 FiberWire (green/white) (TightRope)
- Guidewire, 1.6 mm (with pull-through suture and green/white)

***Knotless TightRope Syndesmosis Repair Kits:***

- Knotless TightRope Syndesmosis Repair Kit, cannulated, titanium, sterile AR-8926T
- Knotless TightRope Syndesmosis Repair Kit, cannulated, stainless steel, sterile AR-8926SS

***Knotless TightRope Syndesmosis Kits include:***

- Drill Bit, 3.7 mm
- Drill Guide, disposable
- Oblong Button, 3.5 mm x 13 mm (medial side placement)
- Round Button, 6.5 mm (lateral side placement)
- #5 UHMWPE (white)
- 2-0 FiberWire (white)
- 2-0 FiberWire (green/white)
- Guidewire, 1.6 mm (with pull-through suture, white and green/white)

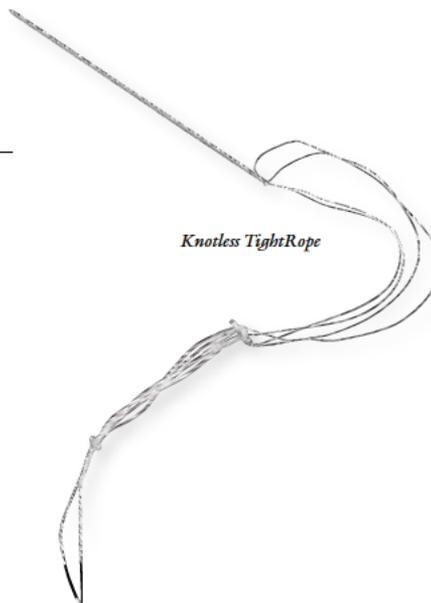
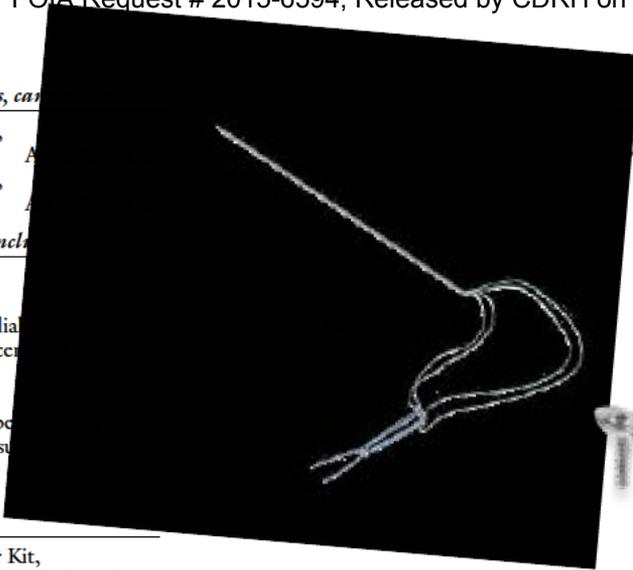
***Syndesmosis Buttress Plate Implant (AR-8947DS) includes:***

- SBT Plate, 43 mm length
- TightRope, titanium
- LPS Screw, 3.5 mm x 14 mm, qty. 2
- Guidewire, 2.4 mm
- Drill Bit, 3.5 mm
- Screwdriver, T15

***Ankle Fracture Management System (AR-8943S)***

***Ankle Fracture Screw Set (AR- 8943C-31)***

For information on the full list of materials, see our *Ankle Fracture Management System Brochure, LB0439*



***Ankle Fracture Plates:***

***Locking Distal Fibula Plate***

- Right 4HAR-8943BR-04
- Right 5HAR-8943BR-05
- Right 6HAR-8943BR-06
- Right 8HAR-8943BR-08
- Left 4H AR-8943BL-04
- Left 5H AR-8943BL-05
- Left 6H AR-8943BL-06
- Left 8H AR-8943BL-08



***Implants:***

***2.7 mm Low Profile Screw Locking***

- 10 mm AR-8827L-10
- 12 mm AR-8827L-12
- 14 mm AR-8827L-14
- 16 mm AR-8827L-16
- 18 mm AR-8827L-18
- 20 mm AR-8827L-20
- 22 mm AR-8827L-22
- 24 mm AR-8827L-24
- 26 mm AR-8827L-26

***3.5 mm Low Profile Screw Locking***

- 10 mm AR-8835L-10
- 12 mm AR-8835L-12
- 14 mm AR-8835L-14
- 16 mm AR-8835L-16
- 18 mm AR-8835L-18
- 20 mm AR-8835L-20
- 22 mm AR-8835L-22
- 24 mm AR-8835L-24
- 26 mm AR-8835L-26
- 28 mm AR-8835L-28
- 30 mm AR-8835L-30
- 32 mm AR-8835L-32
- 34 mm AR-8835L-34
- 36 mm AR-8835L-36
- 38 mm AR-8835L-38
- 40 mm AR-8835L-40
- 45 mm AR-8835L-45
- 50 mm AR-8835L-50



*Ankle Fracture Screw Set, AR-8943C-31*

**Locking Straight Plate**

- 4H AR-8943C-04
- 6H AR-8943C-06
- 7H AR-8943C-07
- 8H AR-8943C-08
- 10H AR-8943C-10
- 12H AR-8943C-12

**Locking Deltoid Avulsion Plate**

- 3H AR-8943H-03
- 5H AR-8943H-05
- 7H AR-8943H-07

**Locking Third Tubular Plate**

- 4H AR-8943T-04
- 5H AR-8943T-05
- 6H AR-8943T-06
- 7H AR-8943T-07
- 8H AR-8943T-08
- 10H AR-8943T-10
- 12H AR-8943T-12

**Locking Third Tubular Hook Plate**

- 3H AR-8943TH-03
- 5H AR-8943TH-05
- 7H AR-8943TH-07



**3 mm Low Profile Screw  
Nonlocking-Cancellous**

- 10 mm AR-8830-10
- 12 mm AR-8830-12
- 14 mm AR-8830-14
- 16 mm AR-8830-16
- 18 mm AR-8830-18
- 20 mm AR-8830-20
- 22 mm AR-8830-22
- 24 mm AR-8830-24
- 26 mm AR-8830-26
- 28 mm AR-8830-28
- 30 mm AR-8830-30

**4 mm Low Profile Screw  
Nonlocking-Cancellous**

- 10 mm AR-8840-10
- 12 mm AR-8840-12
- 14 mm AR-8840-14
- 16 mm AR-8840-16
- 18 mm AR-8840-18
- 20 mm AR-8840-20
- 22 mm AR-8840-22
- 24 mm AR-8840-24
- 26 mm AR-8840-26
- 28 mm AR-8840-28
- 30 mm AR-8840-30
- 32 mm AR-8840-32
- 34 mm AR-8840-34
- 36 mm AR-8840-36
- 38 mm AR-8840-38
- 40 mm AR-8840-40
- 42 mm AR-8840-42
- 44 mm AR-8840-44
- 45 mm AR-8840-45
- 46 mm AR-8840-46
- 48 mm AR-8840-48
- 50 mm AR-8840-50
- 55 mm AR-8840-55
- 60 mm AR-8840-60

**4 mm Low Profile Screw  
Short Thread**

- 30 mm AR-8840P-30
- 32 mm AR-8840P-32
- 34 mm AR-8840P-34
- 36 mm AR-8840P-36
- 38 mm AR-8840P-38
- 40 mm AR-8840P-40
- 42 mm AR-8840P-42
- 44 mm AR-8840P-44
- 46 mm AR-8840P-46
- 48 mm AR-8840P-48
- 50 mm AR-8840P-50
- 55 mm AR-8840P-55
- 60 mm AR-8840P-60

**4 mm Low Profile Screw  
Short Thread-Cannulated**

- 30 mm AR-8840C-30
- 32 mm AR-8840C-32
- 34 mm AR-8840C-34
- 35 mm AR-8840C-35
- 36 mm AR-8840C-36
- 38 mm AR-8840C-38
- 40 mm AR-8840C-40
- 42 mm AR-8840C-42
- 44 mm AR-8840C-44
- 45 mm AR-8840C-45
- 46 mm AR-8840C-46
- 48 mm AR-8840C-48
- 50 mm AR-8840C-50
- 55 mm AR-8840C-55
- 60 mm AR-8840C-60

**3.5 mm Low Profile Screw  
Nonlocking-Cortical**

- 10 mm AR-8835-10
- 12 mm AR-8835-12
- 14 mm AR-8835-14
- 16 mm AR-8835-16
- 18 mm AR-8835-18
- 20 mm AR-8835-20
- 22 mm AR-8835-22
- 24 mm AR-8835-24
- 26 mm AR-8835-26
- 28 mm AR-8835-28
- 30 mm AR-8835-30
- 32 mm AR-8835-32
- 34 mm AR-8835-34
- 35 mm AR-8835-35
- 36 mm AR-8835-36
- 38 mm AR-8835-38
- 40 mm AR-8835-40
- 42 mm AR-8835-42
- 44 mm AR-8835-44
- 45 mm AR-8835-45
- 46 mm AR-8835-46
- 48 mm AR-8835-48
- 50 mm AR-8835-50
- 55 mm AR-8835-55
- 60 mm AR-8835-60

**4 mm Low Profile Screw  
Long Thread**

- 30 mm AR-8840PL-30
- 32 mm AR-8840PL-32
- 34 mm AR-8840PL-34
- 36 mm AR-8840PL-36
- 38 mm AR-8840PL-38
- 40 mm AR-8840PL-40
- 42 mm AR-8840PL-42
- 44 mm AR-8840PL-44
- 46 mm AR-8840PL-46
- 48 mm AR-8840PL-48
- 50 mm AR-8840PL-50
- 55 mm AR-8840PL-55
- 60 mm AR-8840PL-60

**4 mm Low Profile Screw  
Long Thread-Cannulated**

- 30 mm AR-8840CL-30
- 32 mm AR-8840CL-32
- 34 mm AR-8840CL-34
- 35 mm AR-8840CL-35
- 36 mm AR-8840CL-36
- 38 mm AR-8840CL-38
- 40 mm AR-8840CL-40
- 42 mm AR-8840CL-42
- 44 mm AR-8840CL-44
- 45 mm AR-8840CL-45
- 46 mm AR-8840CL-46
- 48 mm AR-8840CL-48
- 50 mm AR-8840CL-50
- 55 mm AR-8840CL-55
- 60 mm AR-8840CL-60



*Developed in conjunction with Brian Thornes, M.D., Dublin, Ireland*

*This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's Directions For Use.*



U.S. PATENT NO. 6,716,234 and PATENT PENDING

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# ZIPTIGHT™

FIXATION SYSTEM

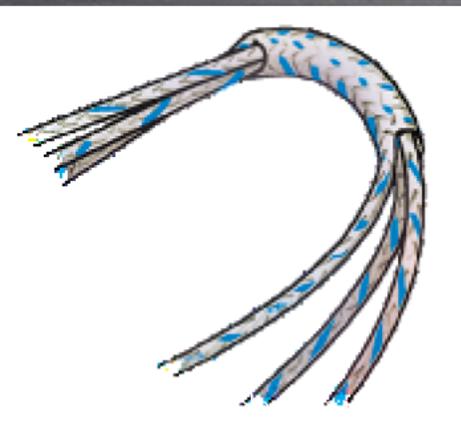
Featuring... *ZipLoop*™  
TECHNOLOGY



## Ankle Syndesmosis

Surgical Protocol by  
Timothy Charlton, M.D.

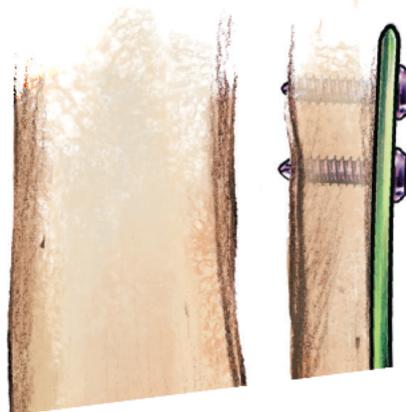
**BIOMET**®  
SPORTS MEDICINE



weave in which a single strand of braided polyethylene is woven through itself twice in opposite directions. This construct allows Biomet Sports Medicine to produce innovative products that can vary in length and compression/tension addressing the individual needs of each patient. Products utilizing ZipLoop™ Technology are resistant to slippage without tying knots.<sup>1</sup> Procedure-specific animations, surgical protocols and surgery videos are available at [www.ziploop.net](http://www.ziploop.net).

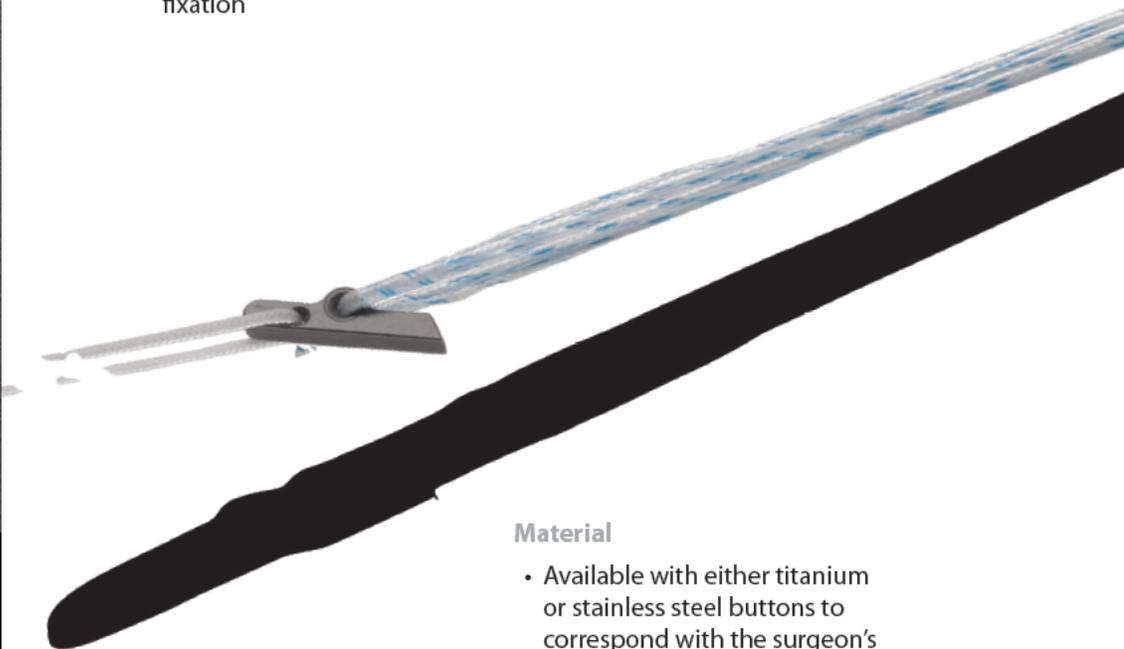


[www.ziploop.net](http://www.ziploop.net)



**Medial Fixation**

- Smaller version of the ToggleLoc™ Fixation Device for medial side fixation



**Material**

- Available with either titanium or stainless steel buttons to correspond with the surgeon's preferred plating system

1. Data on file at Biomet Sports Medicine. Bench test results are not necessarily indicative of clinical performance.

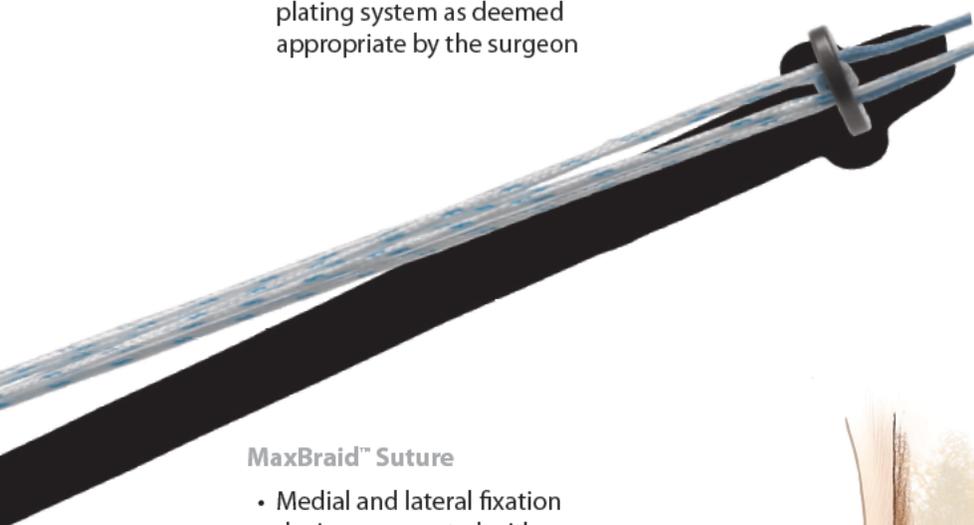
This brochure is presented to demonstrate the surgical technique and postoperative protocol utilized by Timothy Charlton, M.D. Biomet Sports Medicine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each patient. For more information, please contact Biomet Sports Medicine at 1-800-796-8118.

# ZIPTIGHT™

FIXATION SYSTEM

## Lateral Fixation

- Round top hat button for lateral fixation
- Can be used directly on the lateral cortex of the fibula or in conjunction with a plating system as deemed appropriate by the surgeon

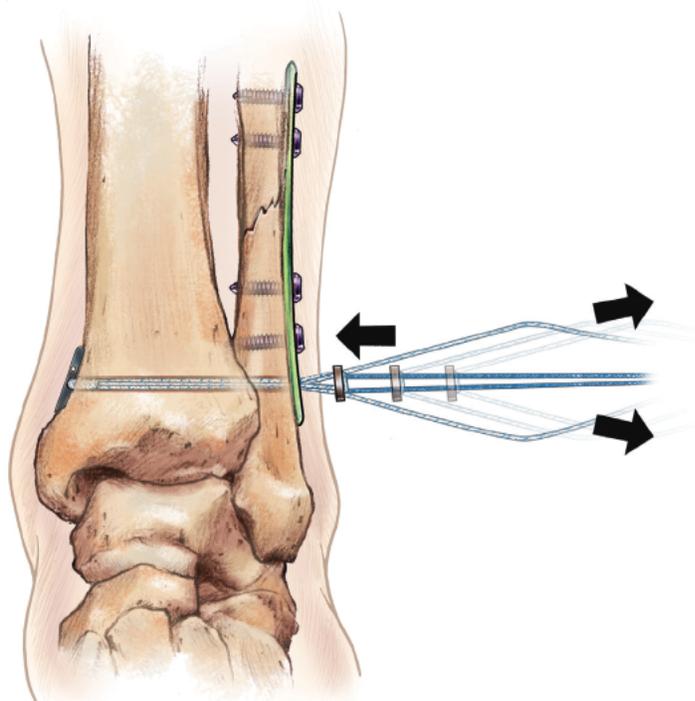


## MaxBraid™ Suture

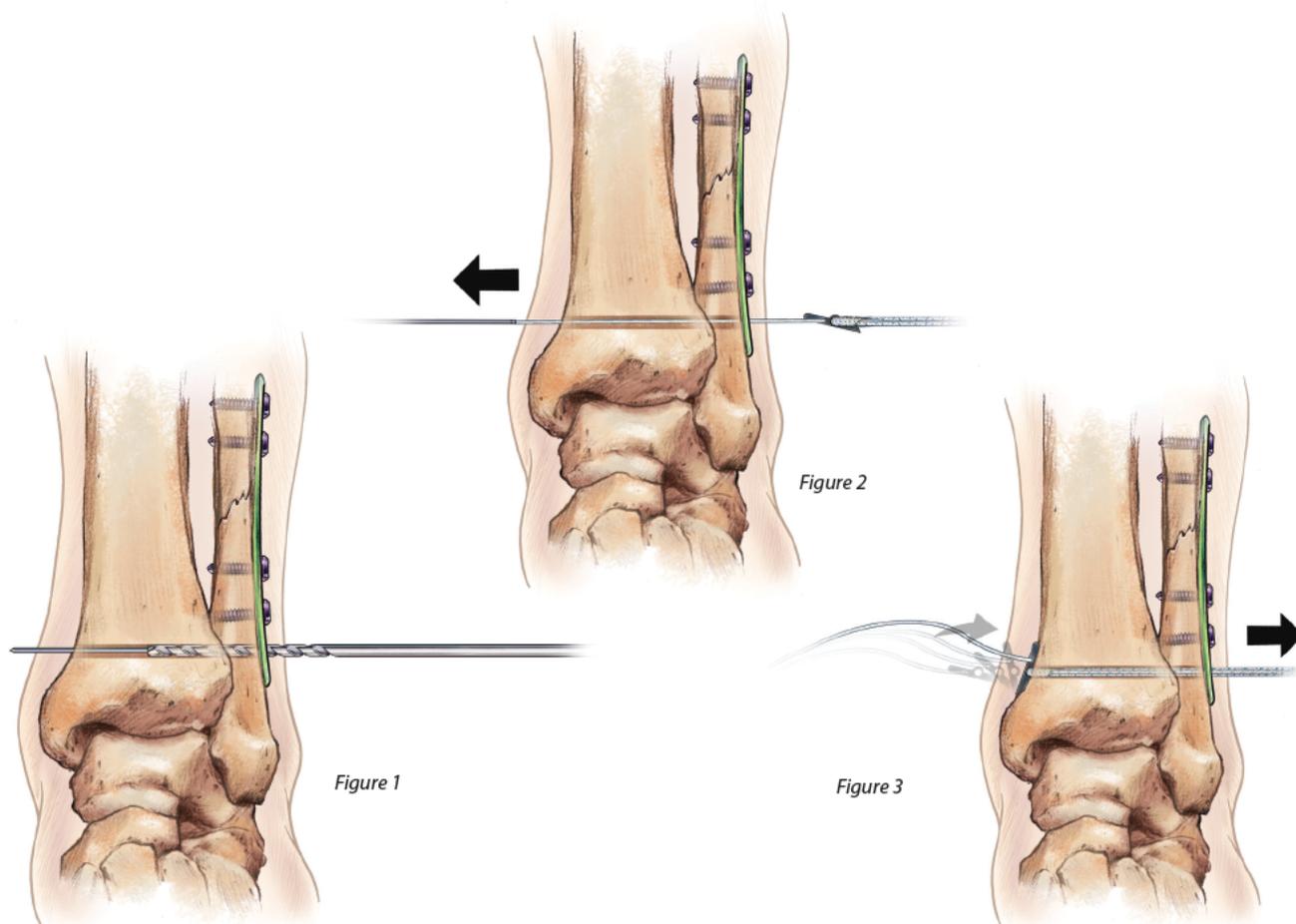
- Medial and lateral fixation devices connected with MaxBraid™ Suture

## Features

- Low profile, knotless suture fixation system featuring ZipLoop™ Technology
- Fixation alternative to rigid stainless steel screws for repairing ankle syndesmosis joint disruptions
- Available with either titanium or stainless steel buttons to correspond with the surgeon's preferred plating system
- Allows for micromotion during healing which more closely mimics the patient's true joint mechanics



## Surgical Technique



### Indications

The ZipTight™ Fixation System for Ankle Syndesmosis is indicated to repair ankle syndesmosis disruptions and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures.

**Note: This surgical technique shows the ZipTight™ Fixation Device used in conjunction with trauma hardware. However, the device can also be used without trauma hardware in length stable fractures as determined appropriate by the surgeon.**

### Reduce Fracture

Reduce fracture to obtain correct length, rotation, and alignment. Reduce the syndesmosis joint as required to achieve anatomical correction, utilizing bone clamp(s). As determined appropriate by the surgeon, place the surgeon preferred trauma hardware plate and screws, in balanced fixation, on to fibula leaving an additional one or two screw holes empty, where ZipTight™ Fixation Device may be placed to repair the ankle syndesmosis disruption.

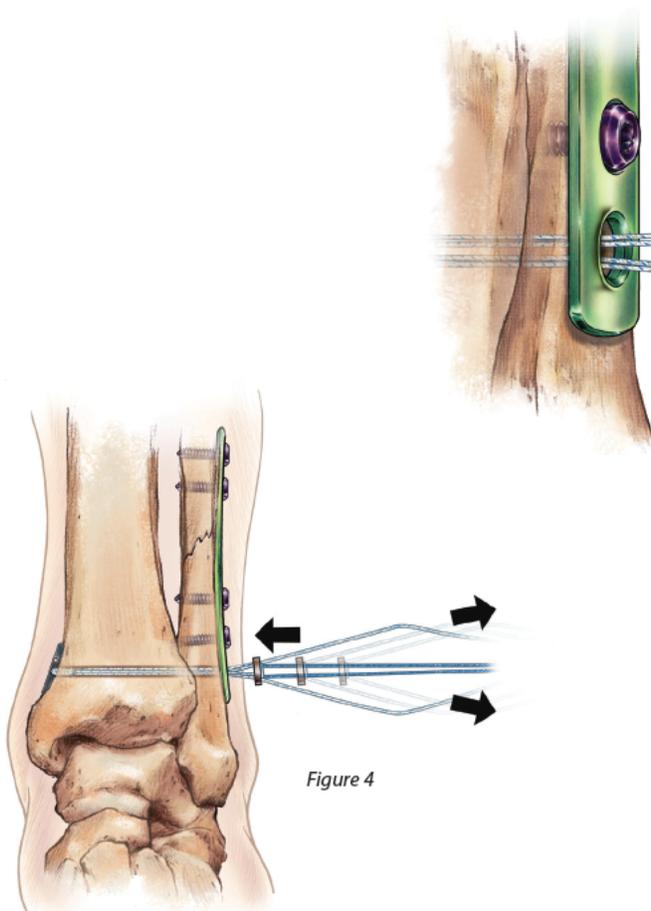
### Drill Through Fibula and Tibia

Using either a solid or cannulated 3.2mm drill, create a drill pathway at or slightly above the incisura of the tibia at the distal tib-fib joint. Penetrate both tibial cortices with the 3.2mm drill (Figure 1).

### Pass the ZipTight™ Fixation Device

After the bone tunnels have been prepared, pass the ZipTight™ Fixation Device pull strands through the tunnels from lateral to medial using the guide pin (Figure 2).

Carefully continue pulling the ZipTight™ Fixation Device pull strand (white MaxBraid™ suture) until the ToggleLoc™ button exits the bone tunnel on the medial side of the tibia. Keeping the device taught from both ends keeps the ToggleLoc™ button angled so that it will easily flip on the medial cortex. As the button exits out of the medial tibial cortex, directing the hand inferiorly may aid in flipping the ToggleLoc™ button. Under fluoroscopic imaging, once the button appears to be out of the medial tibial cortex, pull the device back in the lateral direction so that the ToggleLoc™ button will flip and rest closely against the medial cortex of the tibia (Figure 3).



### Zip the Top Hat Button Into Place

Pull on the blue/white 'zip' strands (blue/white MaxBraid™ suture) while maintaining tension on the solid blue back-tension strand (blue polyester suture). The solid blue back-tension strand provides slight counterforce to help keep the ZipLoop™ sutures organized (Figure 4).

Continuing to pull the blue/white 'zip' strands will bring the round top hat button down against the plate (or lateral fibular cortex if no plate is used) to its final deployed position on the lateral side of the fibula (Figure 5).

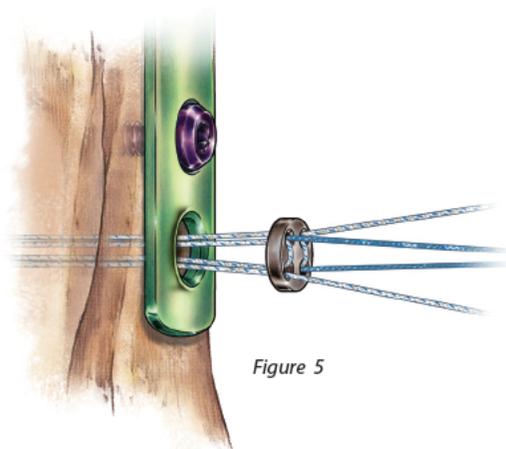


Figure 5

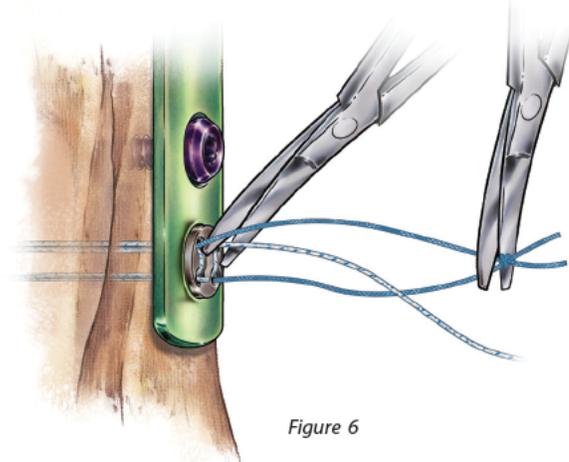


Figure 6

### Final Tensioning

After the round top hat button is seated, the solid blue back-tension strand can be released and the surgeon can provide final tensioning by pulling on each leg of the blue/white 'zip' strand to equalize tension of the legs of the ZipLoop™ strand. A ZipLoop™ puller can be used to assist in final tensioning of the fixation device.

The strands and guide pin can be removed on the medial side. The solid blue 'back-tension' strand can be cut and removed and the 'zip' strands can be carefully cut down near the round top hat button with scissors, the Super MaxCutter™ Suture Cutter or the Disposable Cutter may be used (Figure 6). **Note: No knots need to be tied because the construct utilizes ZipLoop™ Technology.**

## Surgical Technique (continued)

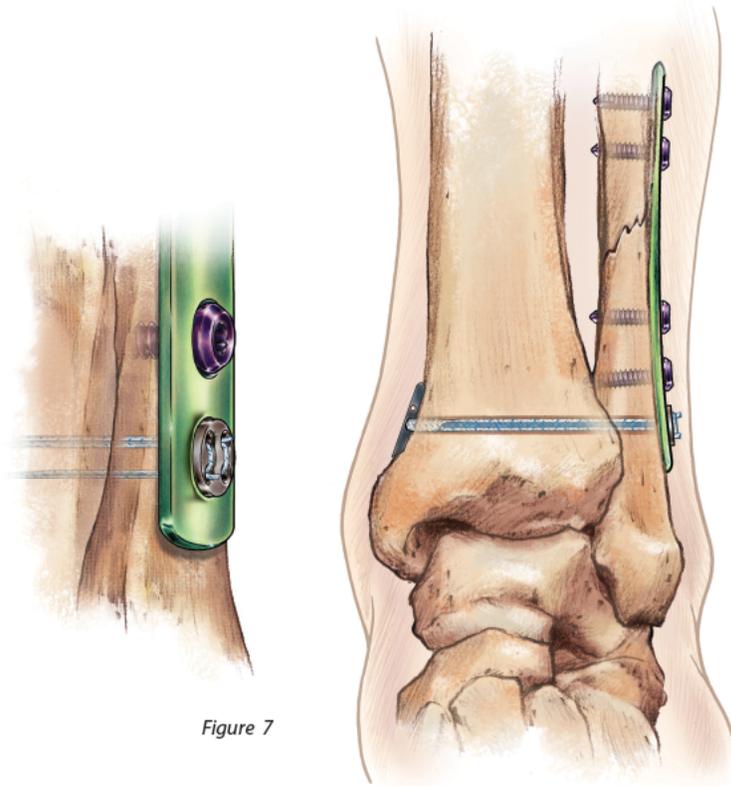


Figure 7

### Postoperative Protocol

Fixation is complete (Figure 7). The patient is placed in a post-operative splint, non-weightbearing until suture removal. Non-weight bearing is maintained for a minimum of four weeks or until sufficient callus ensures length stability of the fibula. A compliant patient can be allowed to do gentle range of motion non-weightbearing at four weeks. In the presence of sufficient fibula healing, protected weightbearing can be started on week six. Advancement to full weightbearing is progressed as clinically indicated.

### Removal

The need for removal will be determined by the surgeon. If removal is desired, a small incision over the ToggleLoc™ button on the medial tibia is made to expose the button. Similarly, a small incision is made over the round top hat button on the lateral fibula. Using a blade or cautery, cut both legs of the ZipLoop™ suture at the round top hat button. The round top hat button can be removed. The ToggleLoc™ button and suture can then be removed from the medial side of the tibia.

# Package Insert

**Biomet Sports Medicine**

56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581 USA



01-50-1186  
Date: 03/09

**Biomet Sports Medicine ToggleLoc™ System**  
**ATTENTION OPERATING SURGEON**

**DESCRIPTION**

The ToggleLoc™ System is a non-resorbable system intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue fixation, due to injury or degenerative disease.

**MATERIALS**

Titanium Alloy  
Ultra-High Molecular Weight Polyethylene (UHMWPE)  
Polypropylene  
Nylon  
Polyester  
Stainless Steel

**INDICATIONS FOR USE**

The ToggleLoc™ System devices are intended for soft tissue to bone fixation for the following indications:

**Shoulder**

Bankart lesion repair  
SLAP lesion repairs  
Acromio-clavicular repair  
Capsular shift/capsulolabral reconstruction  
Deltoid repair  
Rotator cuff tear repair  
Biceps Tenodesis

**Foot and Ankle**

Medial/lateral repair and reconstruction  
Mid- and forefoot repair  
Hallux valgus reconstruction  
Metatarsal ligament/tendon repair or reconstruction  
Achilles tendon repair

Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc™ with Tophat)

**Elbow**

Ulnar or radial collateral ligament reconstruction  
Lateral epicondylitis repair  
Biceps tendon reattachment

**Knee**

ACL/PCL repair / reconstruction  
ACL/PCL patellar bone-tendon-bone grafts  
Double-Tunnel ACL reconstruction  
Extracapsular repair: MCL, LCL, and posterior oblique ligament  
Illiotal band tenodesis  
Patellar tendon repair  
VMO advancement  
Joint capsule closure

**Hand and Wrist**

Collateral ligament repair  
Scapholunate ligament reconstruction  
Tendon transfers in phalanx  
Volar plate reconstruction

**Hip**

Acetabular labral repair

**CONTRAINDICATIONS**

1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

**WARNINGS**

The ToggleLoc™ System devices provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load

bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

Patient selection factors to be considered include: 1) need for soft tissue to bone fixation, 2) ability and willingness of the patient to follow postoperative care instructions until healing is complete, and 3) a good nutritional state of the patient

1. Correct selection of the implant is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, neither the device nor grafts, when used, are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. The implants can loosen or be damaged and the graft can fail when subjected to increased loading associated with nonunion or delayed union. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
3. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
4. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.
5. Care is to be taken to ensure adequate soft tissue fixation at the time of surgery. Failure to achieve adequate fixation or improper positioning or placement of the device can contribute to a subsequent undesirable result.
6. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
7. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
8. DO NOT USE if there is a loss of sterility of the device.
9. Discard and DO NOT USE opened or damaged devices, and use only devices that are package in unopened or undamaged containers.
10. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients effected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.

**PRECAUTIONS**

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat with implants that have been, even momentarily, placed in a

different patient.

Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet Sports Medicine recommends that all instruments be regularly inspected for wear and disfigurement.

If device contains MaxBraid™ suture, refer to manufacturer package insert for further information.

**POSSIBLE ADVERSE EFFECTS**

1. Nonunion or delayed union, which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone or tissue.
8. Inadequate healing.
9. Intraoperative or postoperative bone fracture and/or postoperative pain.

**STERILITY**

The ToggleLoc™ System devices are supplied sterile and are sterilized by exposure to Ethylene Oxide Gas (ETO) if device contains MaxBraid™ PE suture. Do not resterilize. Do not use any component from an opened or damaged package. Do not use past expiration date.

**Caution:** Federal law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw IN 46581 USA, Fax: 574-372-3968.

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Catalogue Number

Lot Number

Flammable

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## Ordering Information

ZipTight™ Fixation Device for Ankle Syndesmosis with ZipLoop™ Technology	
904759	Titanium
909856	Stainless Steel

ZipTight™ Fixation Device for Ankle Syndesmosis with ZipLoop™ Technology Disposable Kits	
909853	Titanium
909857	Stainless Steel
Sterile Kit Includes: Implant, 0.062" (1.57mm) x 6" needle crimped onto passing suture, two 0.062" (1.57mm) x 9" K-wires, one 3.2mm x 7.5" cannulated drill bit, and one 3.2mm x 5" solid drill bit	

### K-wire

951549	.045 (1.1mm) x 9" — Pkg. 2 (Non-Sterile)
945019	.045 (1.1mm) x 9" — Partially Threaded (Sterile)

### Cannulated Drill Bit

948086	3.7mm x 5" (Non-Sterile)
948084	3.2mm x 5" (Non-Sterile)

### Solid Drill Bit

904301	3.2mm x 5" (Non-Sterile)
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### Guide Pin

909634	$\frac{3}{32}$ " x 16" (Non-Sterile)
909540	$\frac{3}{32}$ " (Sterile)

### ZipLoop™ Puller

904776

### Super MaxCutter™ Suture Cutter

900342

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## CHAPTER 9

# TECHNIQUE OF SYNDESMOTIC REPAIR: Investigating the Innovative Tightrope™ in Treatment of Syndesmotic Injuries

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## INTRODUCTION

Fractures of the adult ankle with disruption of the tibiofibular syndesmosis call for sufficient stabilization of the ankle mortise to ensure proper healing of the syndesmotic ligaments. Several internal fixation techniques for stabilization of the syndesmosis have been employed in the past, including 3.5 mm, 4.5 mm, and 5.0 mm metallic and bioabsorbable screws, 1.5 mm and 1.6 mm Kirschner wire fixation, and staple fixation.

As technology advances and we increase our knowledge of the factors involved in the repair of syndesmotic injuries, an innovative syndesmotic repair device has recently been introduced. The TightRope™ (#AR-8920DS, AR-8921DS, Arthrex, Naples, FL) is well suited for syndesmotic injuries of the ankle, because it opposes diastasis while allowing for favorable micromotion. The TightRope™ offers a novel solution to many of the dilemmas encountered with traditional methods of syndesmotic repair. The device is constructed as to not require removal, it is resilient allowing ample ligament healing, and it is less invasive than traditional syndesmotic screw insertion. The TightRope™ displays promise in the field of foot and ankle surgery. With this in mind, we critically look at this emerging tool and introduce the technique of insertion.

## RECENT DEVELOPMENTS

In 1995, Mulligan and Hopkinson noted that two syndesmotic screws purchasing 3 cortices provided more stability than a single screw.<sup>1</sup> Moreover, if the screws engage only 3 cortices, the normal external rotation of the fibula, during dorsiflexion, was preserved and the likelihood of screw failure would consequently decrease. Thompson and associates found no biomechanical advantage of 4.5 mm metallic screws over 3.5 mm metallic screws in 2000.<sup>2</sup>

In 2001, Thordarson reported no statistical difference in range of motion or subjective complaints when he compared 4.5 mm polylactic acid bioabsorbable syndesmotic screw fixation with 4.5 mm stainless steel screw fixation in patients with pronation-external rotation Stage IV injuries.<sup>3</sup> The clear benefit of the bioabsorbable screw was that it obviated the need for screw removal. Hovis, in 2002, treated 33 consecutive patients with a fibular fracture and syndesmotic disruption with traditional plate and screw fixation and a 4.5 bioabsorbable screw purchasing four cortices across the syndesmosis.<sup>4</sup> He concluded that bioabsorbable, transyndesmotic screw fixation was a successful method of treating syndesmotic injuries encountered in ankle fractures.

In 2004, a biomechanical, cadaveric study by Cox and associates revealed that 5.0 mm bioabsorbable screws were biomechanically equivalent to 5.0 mm stainless steel screw for repair of syndesmosis disruption.<sup>5</sup> A randomized, prospective, blinded study by Kaukonen in 2005 showed that polylevulactic acid screws worked as well, or slightly better than, metallic screws for syndesmosis fixation in patients with ankle fractures with associated syndesmotic disruption.<sup>6</sup> In the same year, Hoiness and Stromsoe stated that syndesmosis fixation with 2 tricortical screws was safe overall and improved earlier return to activity when compared to metallic screw fixation. At 1 year followup, there was no noteworthy difference between the bioabsorbable screw and metallic screw groups in functional score, pain, and ankle joint dorsiflexion.

## ARTHREX TIGHTROPE™ SYNDESMOSIS FIXATION DEVICE

The TightRope™ is indicated for the treatment of syndesmotic disruption without associated ankle fractures as well as Weber B and Weber C fractures with syndesmotic disruption. For fractures located in the distal half of the

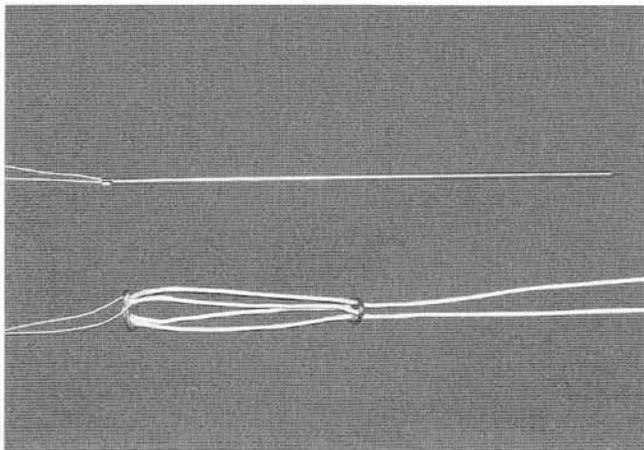


Figure 1. Shown is the TightRope™ with the 1.6 mm Guidewire with 2-0 FiberWire pull-through suture (white), the 3.5 mm and 6.5 mm buttons with #5 FiberWire Suture (blue) looped twice through the holes and buttons.

fibula, it is recommended to restore the length and rotation of the fibula and employ one TightRope™ device 1.5 cm above the mortise ankle. For high Weber C fractures located in the proximal half of the fibula, 2 TightRope™ devices should be utilized in an axially divergent pattern. In patients who are overweight and in those with comminuation, it is suggested 2 TightRope™ devices be used. The device is comprised of #5 Fiber-Wire and uses tension across metal anchors against the medial cortex of the tibia and the lateral cortex of the fibula to stabilize the mortise ankle, thus holding the talus within the malleolar fork. The design of the device allows for simple insertional technique.

TightRope™ Syndesmosis Repair Kit (Figure 1) consists of 3.5 mm Drill Bit, 3.5 mm medial button (Titanium or Stainless Steel), 6.5 mm lateral button (Titanium or Stainless Steel), #5 FiberWire Suture (blue), 2-0 FiberWire pullthrough suture (white), 1.6 mm Guidewire.

## TECHNIQUE (FIGURE 2)

The fibula is maintained within the tibial sulcus utilizing the Large Periarticular Reduction Forceps (#389.228, Synthes, Paoli, PA.) (Figure 3) or the Collinear Reduction Clamp Set (#690.498, Sythes). Utilizing intraoperative flourescopy the 3.5 mm Drill Bit is used to drill across the fibula and tibia (lateral to medial) positioned 1-2 centimeters above and parallel to the ankle joint. The drill hole can be created through a fibular plate or directly through the fibula (Figure 4A-B). Utmost care must be taken to identify and avoid harm to the saphenous nerve and artery located medially. If two TightRopes are being utilized divergent positioning is suggested (Figure 5).

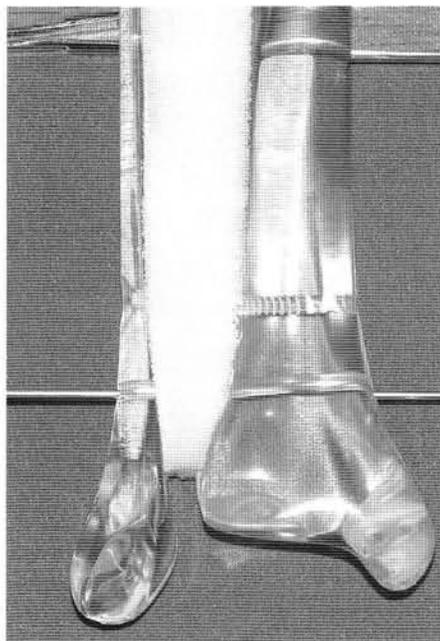


Figure 2A-E. The Guidewire and "pull-through" suture are passed along the drill hole from lateral to medial. The medial button is pulled through the drill hole via "pull-through suture." The medial button exits the drill hole and an upward tension is placed on the "pull-through" suture. It then engages the medial tibial cortex. Pulling on the syndesmosis suture tightens the lateral button on the fibula and secures the distal ankle syndesmosis. Note reduction of the diastasis.

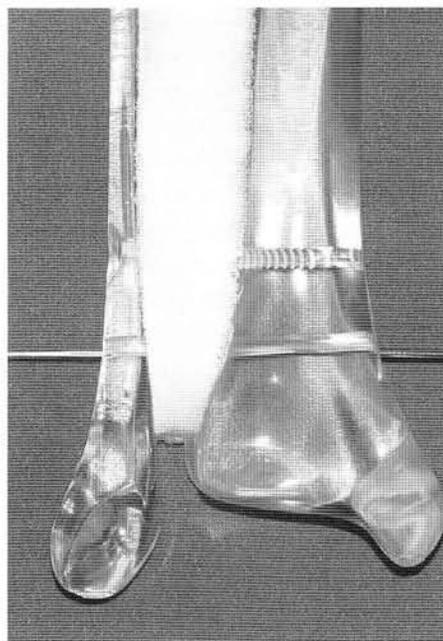


Figure 2B.

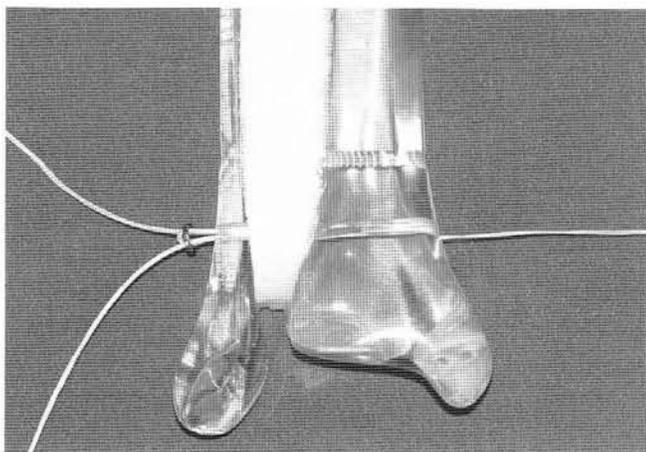


Figure 2C.

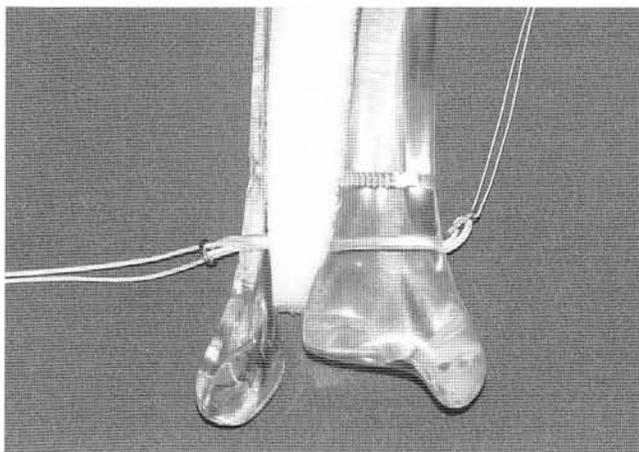


Figure 2D.

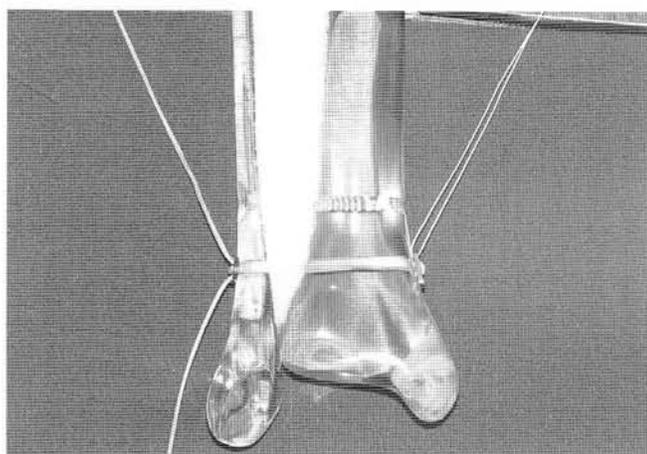


Figure 2E.

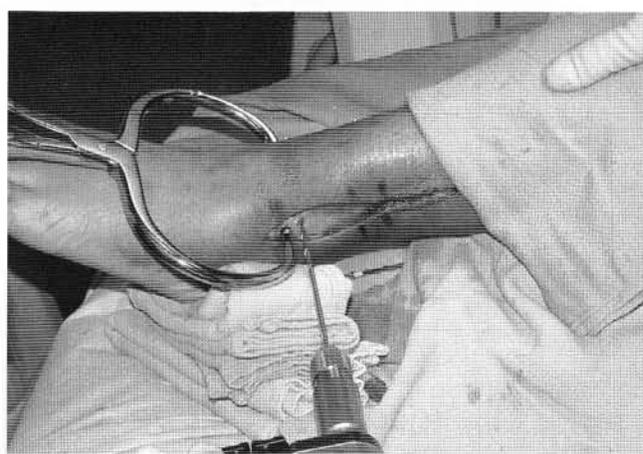


Figure 3. Employment of the Large Periarticular Reduction Forceps in maintaining the fibula's position within the tibial sulcus while drilling the guide hole with the 3.5 mm Drill Bit.

The 1.6 mm Guidewire along with the #5 FiberWire suture, 2-0 FiberWire pull through suture, and 3.5 mm medial button are passed through the drill hole until the medial button and "pull through" suture are retrieved on the medial side. The Guidewire and pull through suture will exit the skin through a small medial puncture. A medial incision is not required; however, it improves visualization of the Guidewire and medial button when proper position is questionable. This medial incision can be circumvented when the surgeon gains confidence in the technique of insertion.

Once the medial button has passed through the medial tibial cortex proximal tension can be placed on the medial "pull-through" suture, thereby "tipping" the medial button into proper position against the tibial

cortex. The color coding of the suture helps facilitate which suture to utilize for pull-through. In addition, palpation of medial skin can facilitate securing of the medial anchor. Insertion of the device is complete when the position of the medial button is confirmed under fluoroscopy, it must sit flush with the cortex. Once proper placement of the medial button has been achieved, the Guidewire and the pull-through suture can be cut and passed from the operative site. The lateral button is tightened down by applying a traction force on the free ends of the #5 Fiberwire and tied by hand utilizing a square reef knot with an extra half-hitch. The ends of the #5 Fiberwire are cut leaving 1 cm tails to permit the knot and free ends to lay flat. If two TightRope™ devices are used, the authors suggest gathering the tails of the #5 FiberWire



Figure 4A. Postoperative radiograph of Weber C fracture after osteosynthesis and TightRope™ fixation 6 months postoperatively. Note the placement of the device outside of the plate.



Figure 4B. Postoperative radiograph of Weber C fracture after osteosynthesis and TightRope™ fixation 2 months postoperatively. Note the placement of the device within the plate.

with 3-0 Vicryl suture (Figure 8). It should be noted that the knot and lateral button are less prominent than a 4.5 mm screw head.

Stability of the syndesmosis should be tested under fluoroscopy with a forced lateral dislocation of the fibula with a bone hook and by external rotation of the foot on the leg. Intra-operative radiographs are helpful and recommended to ensure proper insertion of the device and stability of the syndesmosis. While there is a low learning curve associated with the TightRope™ precise technique is still a requirement.

### DEVICE REMOVAL

There are scenarios necessitating device removal. They include, but are not limited to, infection, failure, and pain. In these cases, fluoroscopic guidance is utilized to identify the buttons and incisions are created over the medial and lateral buttons. The device is then removed by elevating the buttons off the cortical surfaces with an elevator or curette. The authors have had limited experience with removal; however, the only apparent complicating factors are the fibrous ingrowth into the suture and around the buttons, but this is likely to cause minimal difficulty.



Figure 5. Repair of Weber C fracture with two TightRope™ devices. Two devices are suggested in patients with syndesmotic injuries associated with fractures of the proximal half of the fibula, fibula fractures that demonstrate comminution, and in overweight patients.

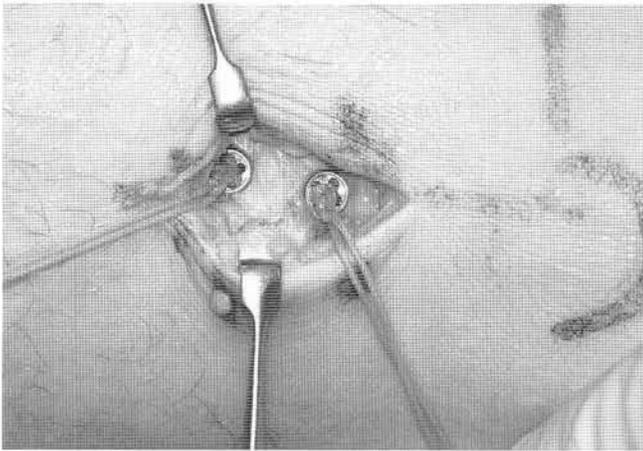


Figure 6A. An intraoperative photograph of the fibula with two TightRope™ devices in place.

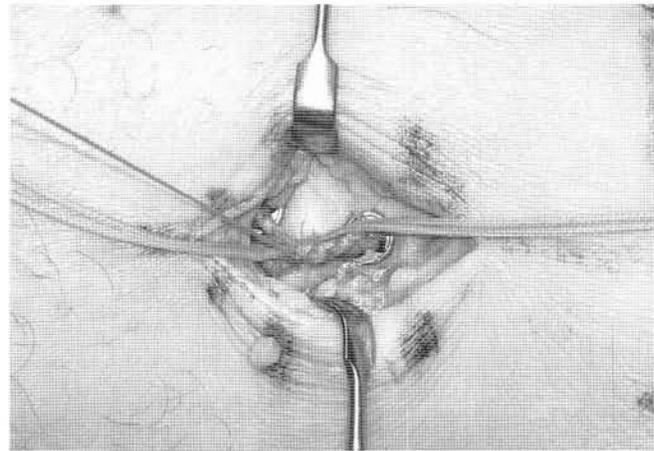


Figure 6B. The technique of gathering the tails of the #5 FiberWire® with 3-0 Vicryl suture.

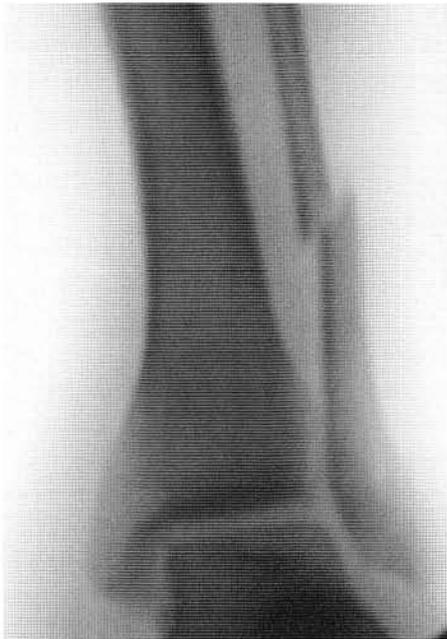


Figure 7A. A Fluoroscopic image of a Weber C fracture.

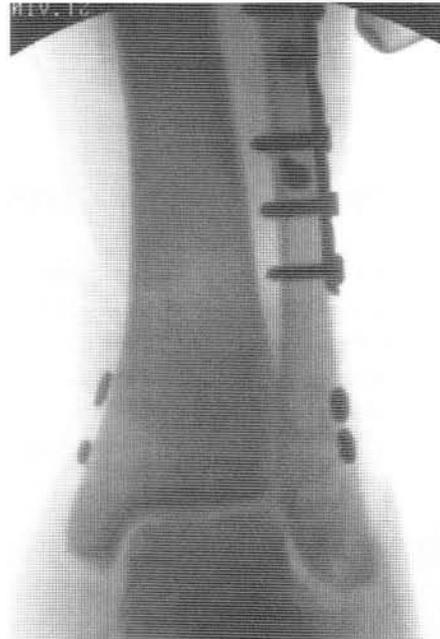


Figure 7B. Postoperative fluoroscopic image following ORIF and insertion of two TightRope™ devices.



Figure 8. Postoperative radiograph of complete repair of a syndesmotic injury associated with a high Weber C fracture.

## POSTOPERATIVE MANAGEMENT

The postoperative course for syndesmotic repair with the TightRope™ includes application of a short-leg cast for 6 weeks, with the first 2 weeks nonweightbearing and the final 4 weeks practicing partial or 50% weightbearing. Following short-leg cast removal at the 6 week mark, full weight bearing can begin in a removable fracture boot or ankle support brace.

## ASSESSING THE POTENTIAL BENEFITS OF THE TIGHTROPE™

Thornes 2-phase cadaveric study compared suture-endobutton flexible fixation and 4.5 mm syndesmotic screw fixation purchasing four cortices.<sup>8</sup> In the first phase of the study, the cadaveric lower extremity specimens, with intact syndesmotic structures, were placed in a jig and an external torque force was applied and measurements of the diastasis were recorded. In the second phase, the performance of suture-endobutton was compared to that of the 4.5 mm screw. There was no difference between rate of failure between the 2 devices in a prospective clinical study by Seitz and associates.<sup>9</sup> The mean American Orthopaedic Foot and Ankle Society ankle scores were significantly better in patients who had suture-button fixation than in a comparative group of 16 patients who



Figure 9. Shown is a fluoroscopic image displaying a unique use of the TightRope™ along the medial cuneiform and second metatarsal in a Lisfranc joint dislocation.

had syndesmotic screw fixation at 3 months and at 12 months postoperatively. Patients receiving the suture-button fixation returned to work approximately 2 months faster than those with screw fixation. No patients who had suture-buttons required a second surgery for device removal.

Seitz and associates performed biomechanical tests on paired cadaver ankles that demonstrated a suture tensile strength of 60 lbs as well as consistent suture-button strength of 49 pounds.<sup>10</sup> Whereas tricortical screw fixation was found to have a 82 pounds higher average pull-out strength; however, screw fixation demonstrated a wide variability depending on bone quality.

In a randomized biomechanical and cadaveric study conducted by Miller, two strands of Number 5 suture were passed through holes through the fibula and tibia and tied.<sup>11</sup> Correspondingly, a 3.5 mm tricortical screw was placed on the opposite cadaveric lower extremity. The ankles were tested to failure. This process was repeated at 2 cm and 5 cm above the tibial plafond. Maximum load and displacement at failure of the suture construct at 2 cm and at 5 cm were compared with the tricortical screw at identical positions on a cadaveric specimen, and no significant difference in strength or displacement was found at either height above the tibial plafond or with either device.

The TightRope™ presents several advantages, over both metal and bioabsorbable screws, in the event of postoperative complications. The TightRope™ does not require removal, while screw removal is recommended from 8 weeks postoperatively to 4 months postoperatively. Weightbearing can begin earlier as loading does not

contribute to failure of the TightRope.<sup>™</sup> The debate still exists as whether weightbearing should be permitted prior to transyndesmotic screw removal for fear of screw failure and backing out. The TightRope<sup>™</sup> flexibility allows normal physiologic motion, resists diastasis, and avoids the possibility of screw failure, and demonstrates potential to be employed in tarsometatarsal joint dislocations (Figure 9).

Most syndesmotic repair techniques require partial device removal before weight bearing can be initiated. Once early fracture healing has been obtained, weight bearing can begin (average 6 weeks). If infection of hardware is encountered, the TightRope<sup>™</sup> is easily removed as opposed to the awkward and arduous process for bioabsorbable screw removal. It is unlikely that the TightRope<sup>™</sup> will loosen, whereas both metal and bioabsorbable screws can loosen and become prominent. While patients undergoing transyndesmotic screw placement should be warned of the probability of screw failure, patients may still view this complication as a surgical error. The TightRope<sup>™</sup> circumvents this drawback. Despite an uneventful postoperative course, late diastasis is possible following screw removal. Conversely, since the TightRope<sup>™</sup> does not require removal, the probability of late diastasis is doubtful. The TightRope<sup>™</sup> can be used in patients with osteopenic bone, while the function of both bioabsorbable and metallic screws is dependent on bone. The cost of the TightRope<sup>™</sup> is considerably greater than traditional methods of fixation, however the surgeon and hospital staff must recognize that the TightRope<sup>™</sup> does not require the fee of surgery for removal the screw. Specifically, an entire instrument set does not need to be prepared and opened for the removal of the TightRope.<sup>™</sup>

## CONCLUSION

Further clinical studies are still needed and no doubt will be forthcoming in the near future. The technique of insertion of the TightRope<sup>™</sup> is relatively simple, but the surgeon must be familiar with the instrumentation and technique to ensure proper application and avoidance of surgical mishap. From our clinical perspective, we have observed enhanced efficiency within the operating room and positive results. While further clinical studies and bench testing are needed to justify the cost of this device, the TightRope<sup>™</sup> shows great promise based on our experiences, and it is our goal to increase the awareness of this device to enhance healing in patients with syndesmotic injuries.

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**Treatment of Syndesmotic Disruptions with the Arthrex Tightrope™: A Report of 25 Cases**

James M. Cottom, Christopher F. Hyer, Terrence M. Philbin and Gregory C. Berlet

*Foot Ankle Int* 2008 29: 773

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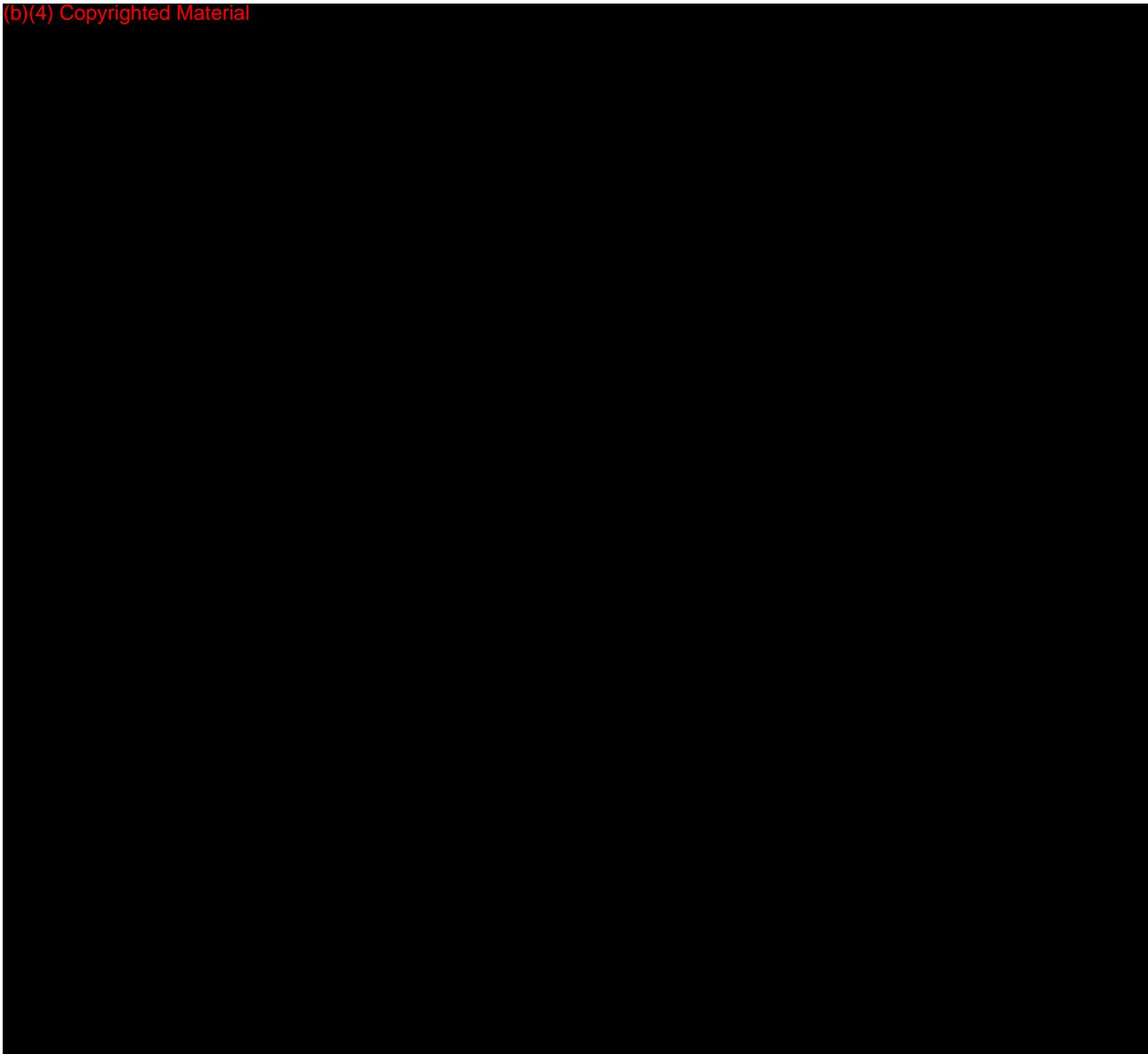
[What is This?](#)

FOOT & ANKLE INTERNATIONAL  
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DOI: 10.3113/FAI.2008.0773

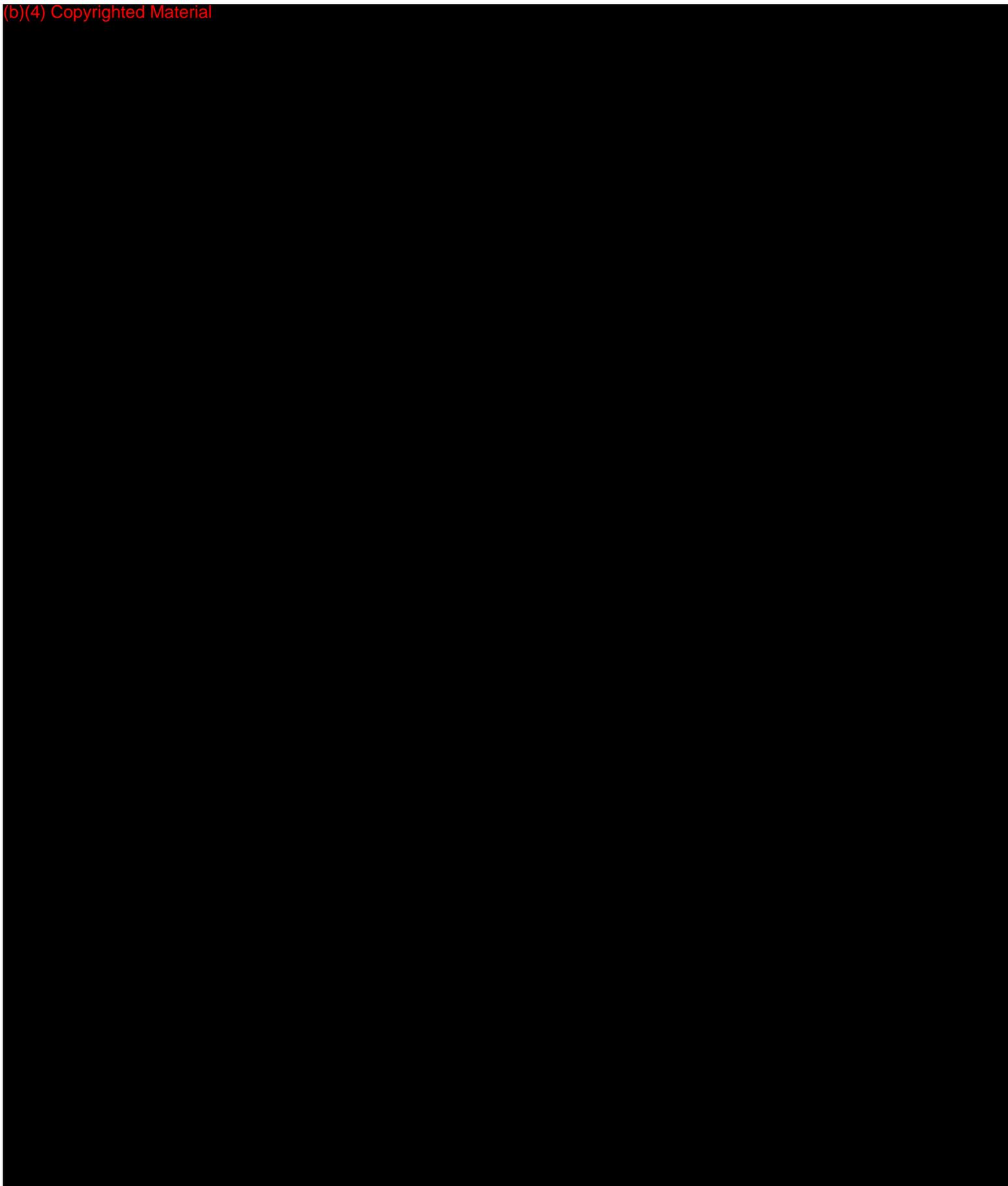
## Treatment of Syndesmotic Disruptions with the Arthrex Tightrope™: A Report of 25 Cases

James M. Cottom, DPM, AACFAS; Christopher F. Hyer, DPM, FACFAS; Terrence M. Philbin, DO; Gregory C. Berlet, MD  
*Columbus, OH*

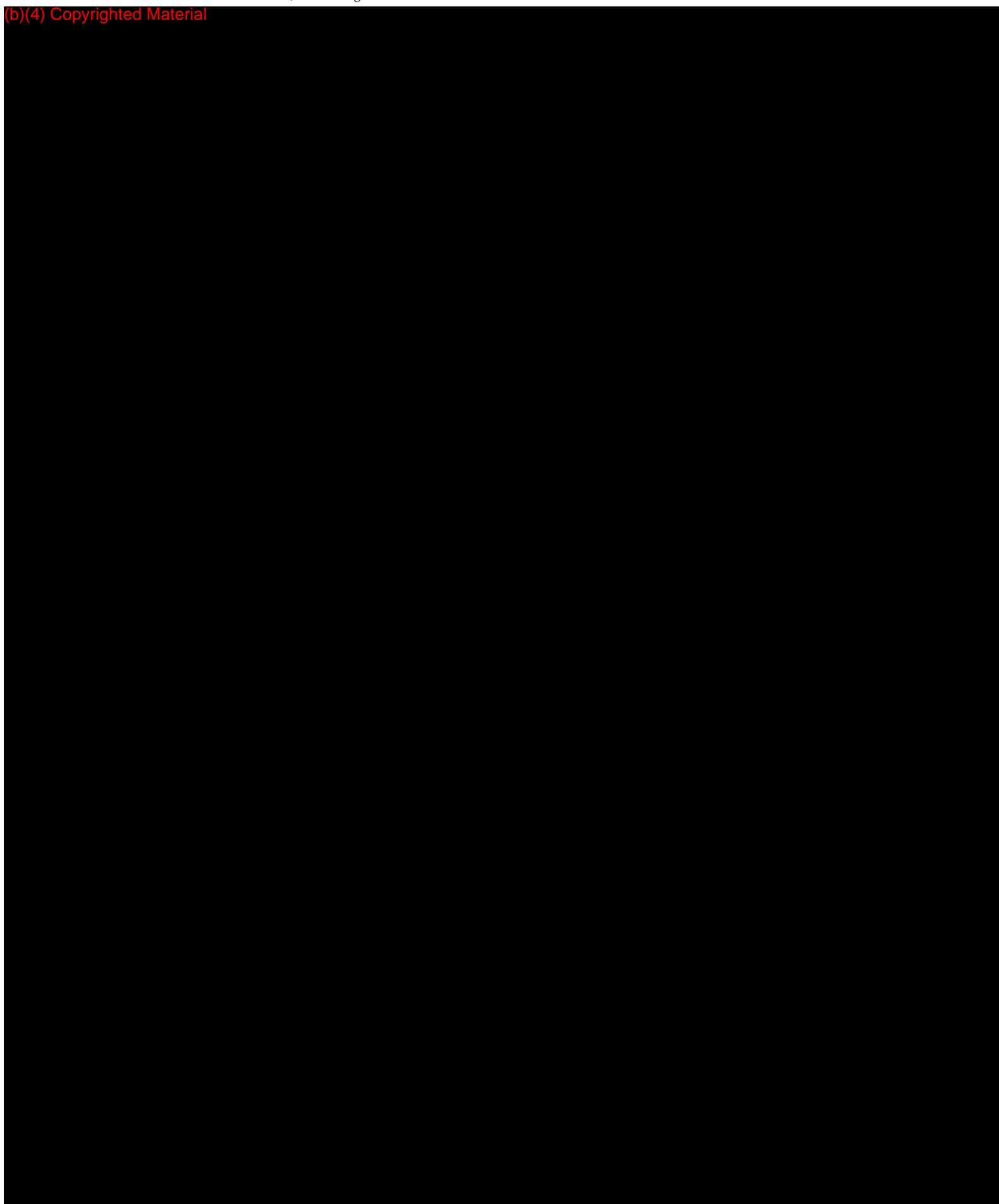
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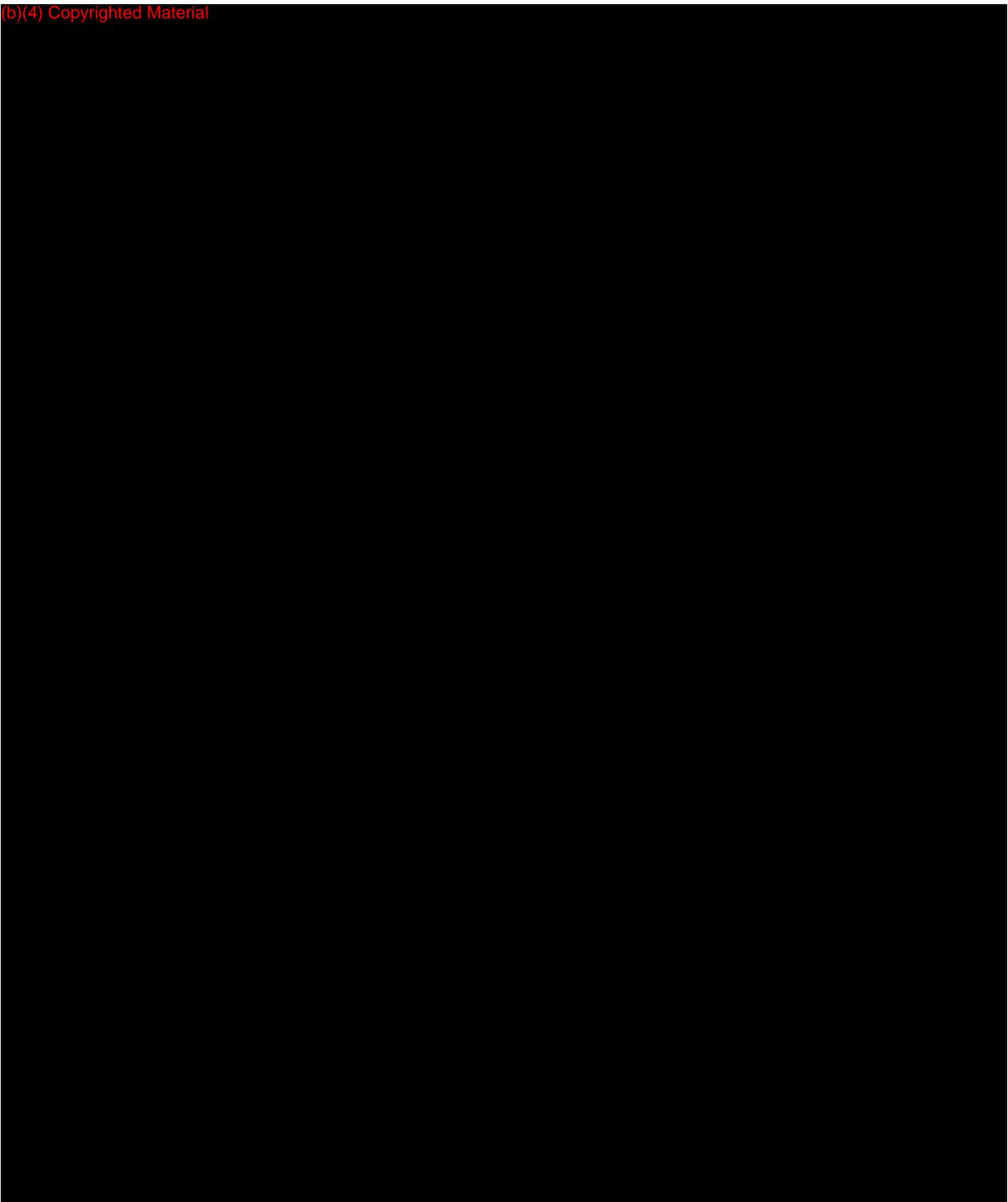
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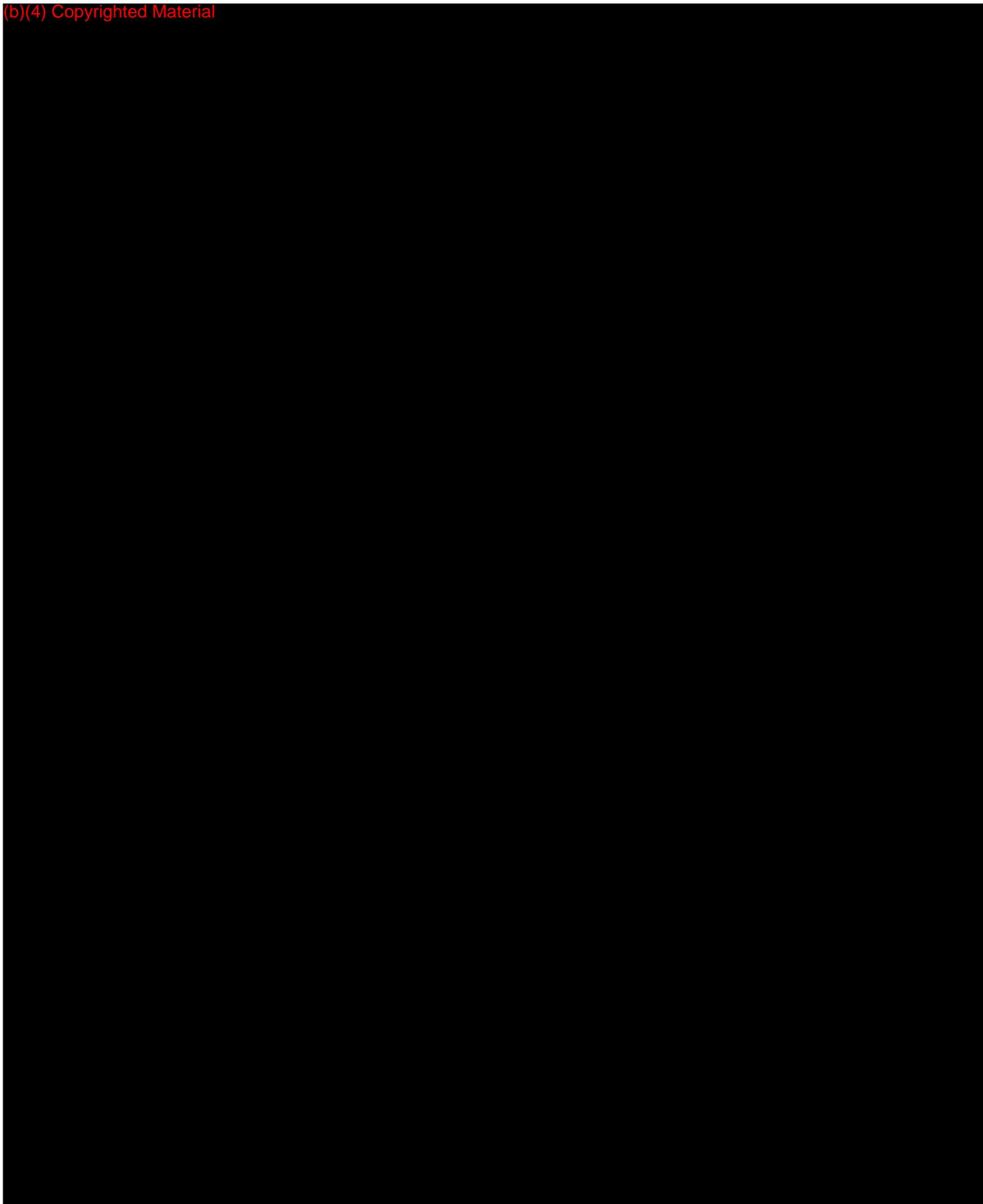
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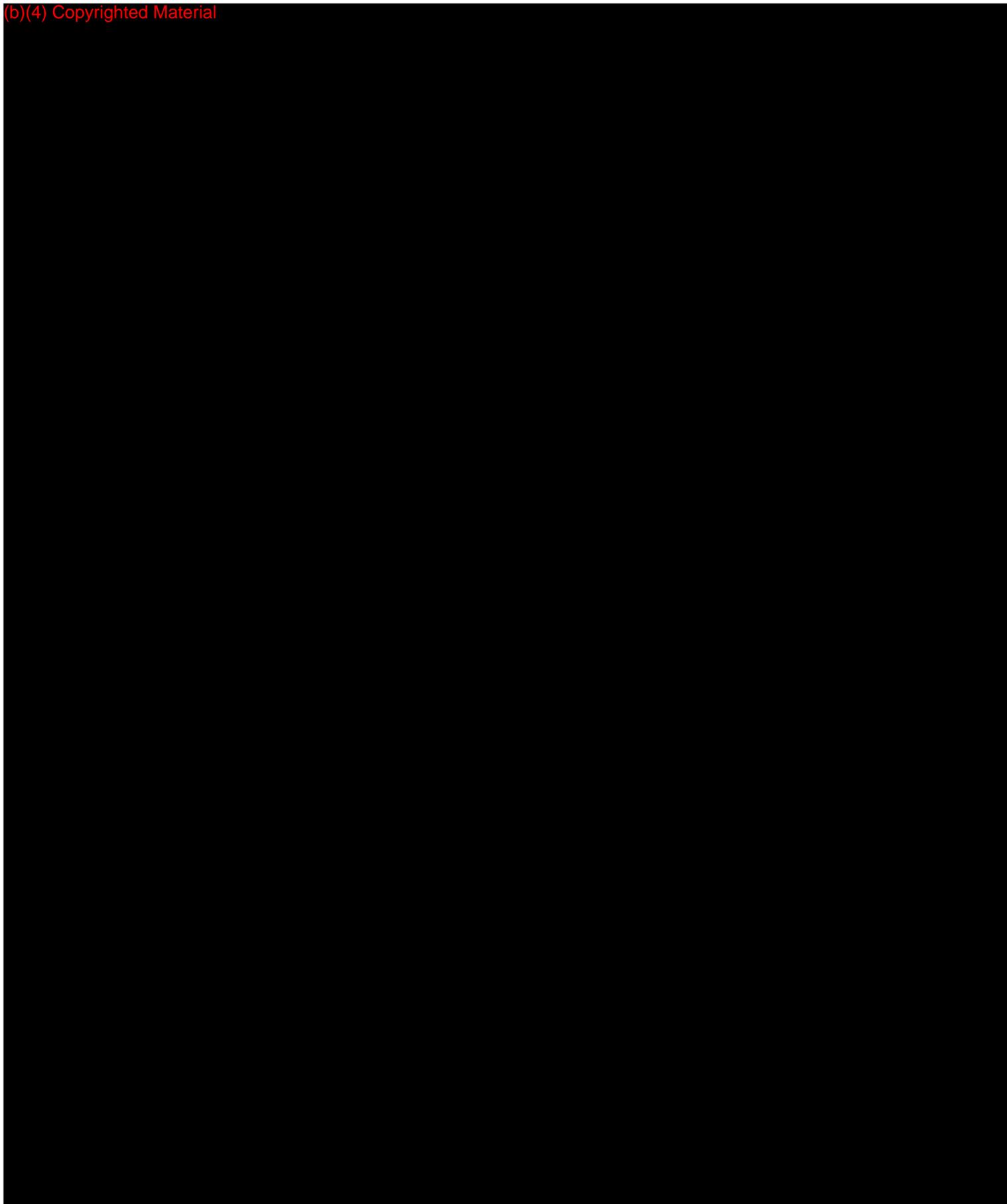
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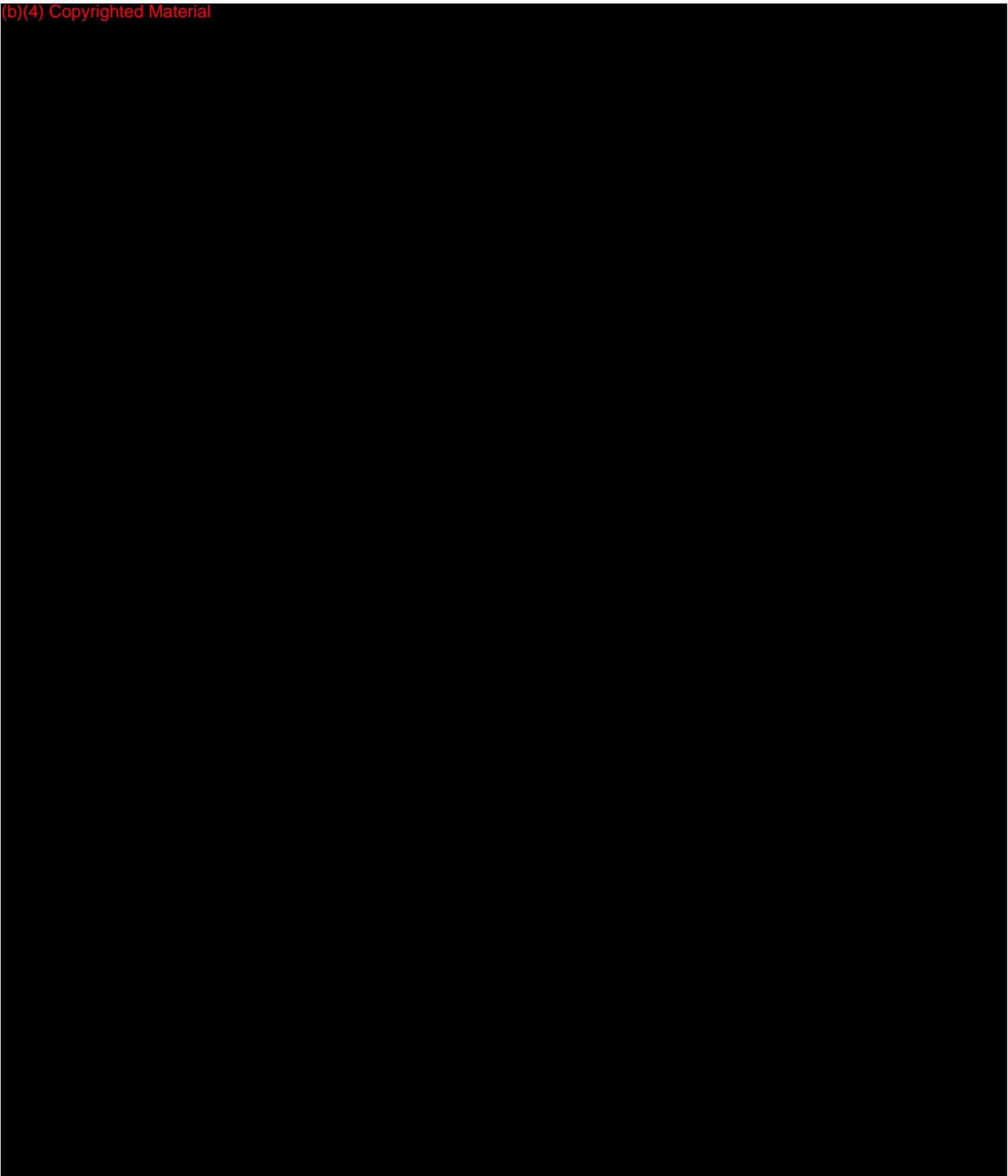
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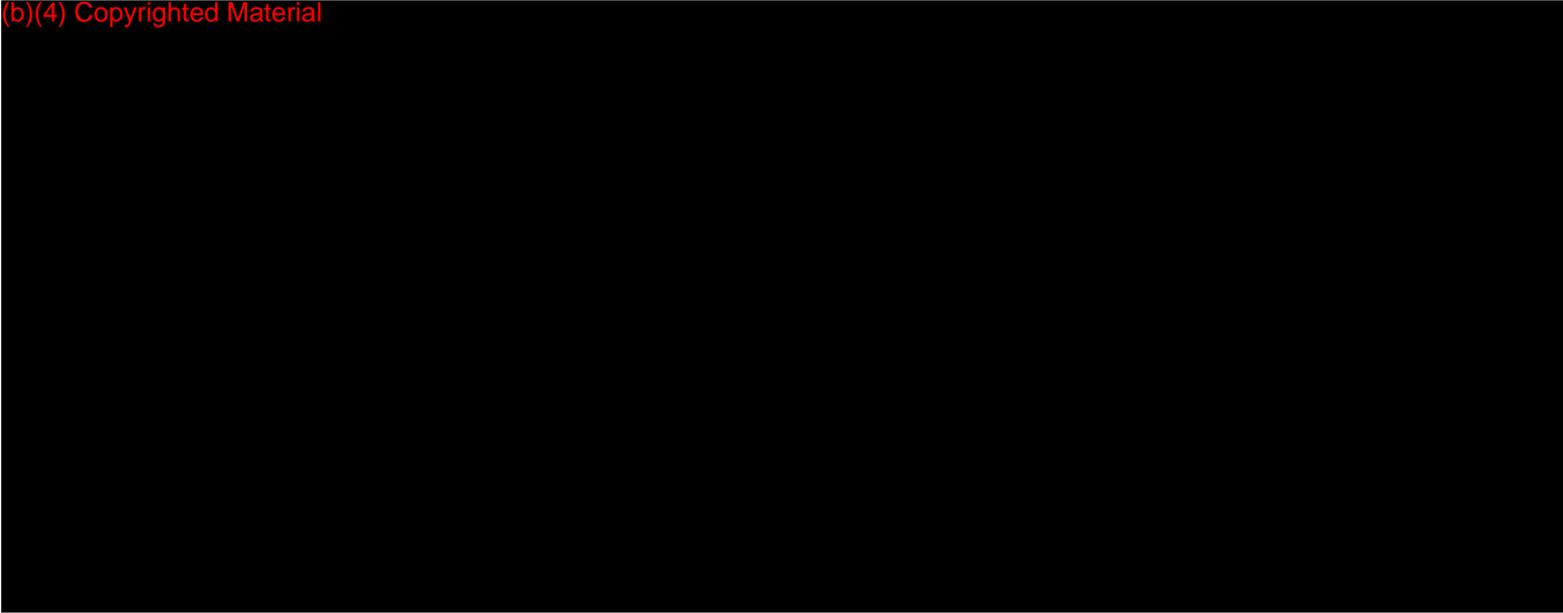
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**Appendix 2**  
**Bench Test Report ( (b)(4) )**





























**Collins, Virginia \***

---

**From:** Collins, Virginia \*  
**Sent:** Tuesday, March 04, 2014 2:58 PM  
**To:** 'a.memmol@allenmedical.com'  
**Cc:** DCCLetters  
**Subject:** K133858 SE Letter  
**Attachments:** K133858.pdf

**Tracking:**

**Recipient**

**Delivery**

'a.memmol@allenmedical.com'

DCCLetters

Delivered: 3/4/2014 2:58 PM



## COVER SHEET MEMORANDUM

Food and Drug Administration  
Office of Device Evaluation &  
Office of In Vitro Diagnostics and  
Radiological Health

**From:** Reviewer Name Daniel Ramsey  
**Subject:** 510(k) Number K133858  
**To:** The Record

**Please list CTS decision code:** SE - Substantially Equivalent

- Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page ( <i>Attach IFU</i> )	X	
510(k) Summary or 510(k) Statement ( <i>Attach Summary or Statement</i> )	X	
Truthful and Accurate Statement ( <i>Must be present for a Final Decision</i> )	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach <u>Form 3654</u> .)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices</u> .)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? ( <a href="#">Medical Device Tracking Guidance</a> )		X

**Regulation Number:** 21 CFR 888.3030  
**Class:** II  
**Product Code:** HTN  
**Additional Product Codes:**

<b>Digital Signature Concurrence Table</b> (Not all signatures may be required)	
Branch Chief Sign-Off	<p>Casey Hanley-S                        2014.02.28 15:29:42 -05'00'</p>
Division Sign-Off	<p>Vincent J. Devlin-S                        2014.02.28 15:58:48 -05'00'</p>

K133858/S001

dallen  
MEDICAL

FDA CDRH DMC

JAN 03 2014

Received

1046 Calle Recodo, Suite G  
San Clemente, CA 92673

January 2, 2014

Mr. Daniel S. Ramsey  
U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**RE: 510(k) K133858–Tensyn Band\_Amendment 1 (Rev 1-2-14)**

Dear Mr. Owens:

In response to your request for additional information dated on December 27, 2013, we are enclosing the information you requested. We have included each question in **bold type**, followed by our response. Two additional copies of this amendment are provided. Enclosed is an eCopy. **The eCopy is an exact duplicate of the paper copy.**

Thank you for your attention to this matter. Please direct further questions or comments to my attention at [a.memmolodallenmedical.com](mailto:a.memmolodallenmedical.com) or by telephone at 949-218-0030.

Sincerely,  
(b)(6)  
(b)(6)  
Al Memmolo  
Chief Operating Officer

Enclosures

10



1046 Calle Recodo, Suite G  
San Clemente, CA 92673

January 2, 2014

Mr. Daniel S. Ramsey  
U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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Sincerely,

(b)(6)

(b)(6)

Al Memmolo  
Chief Operating Officer

Enclosures

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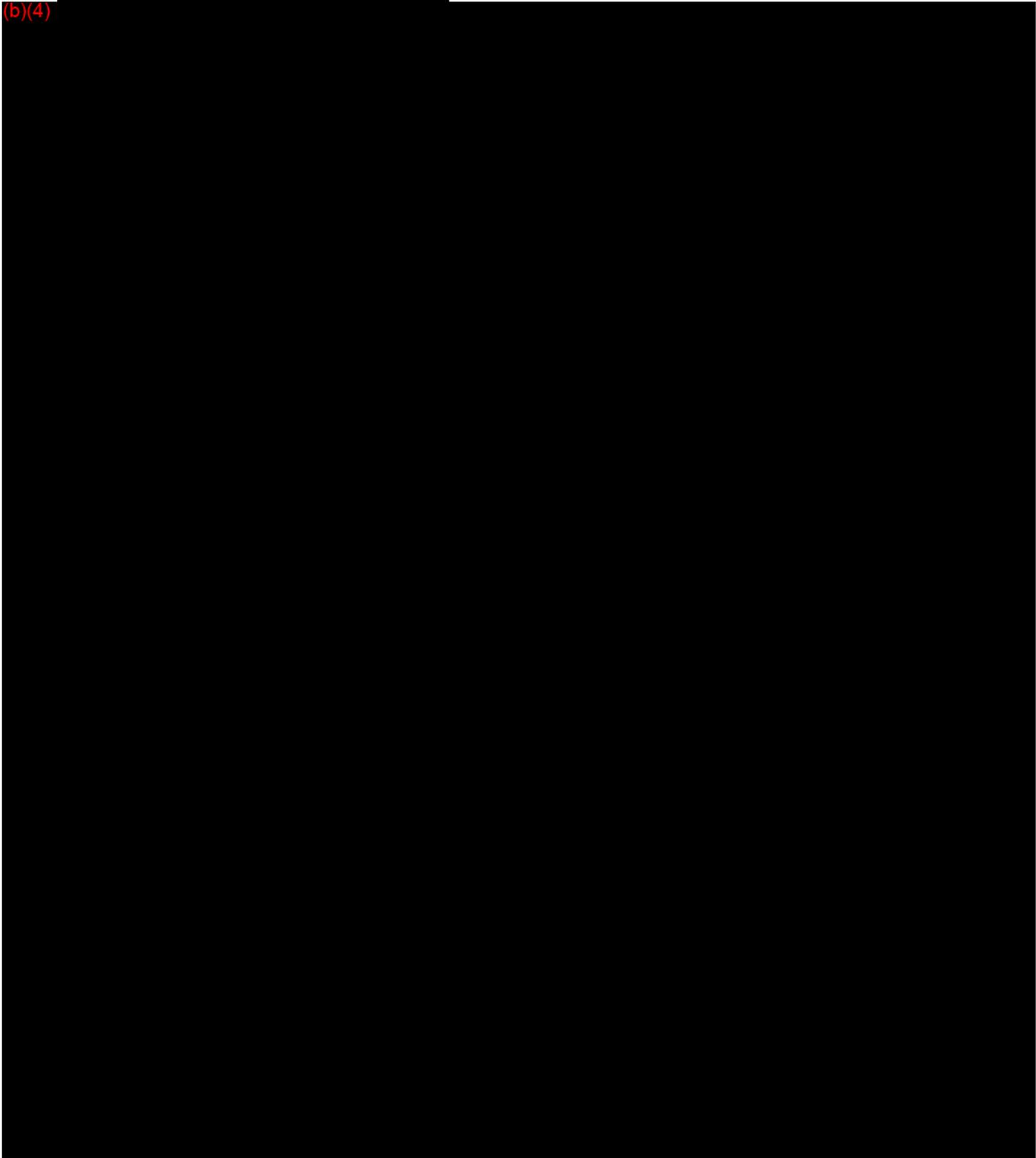
**ATTACHMENTS:**

Attachment 1 ..... 5

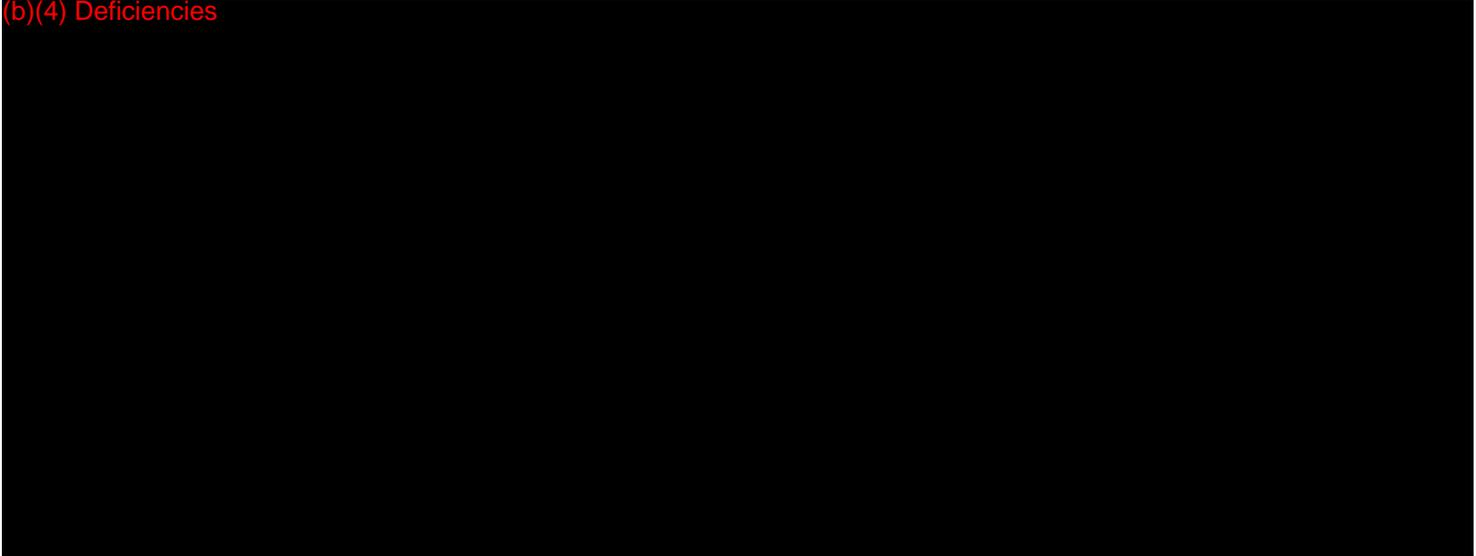
(b)(4) Deficiencies

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(b)(4)

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(b)(4) Deficiencies

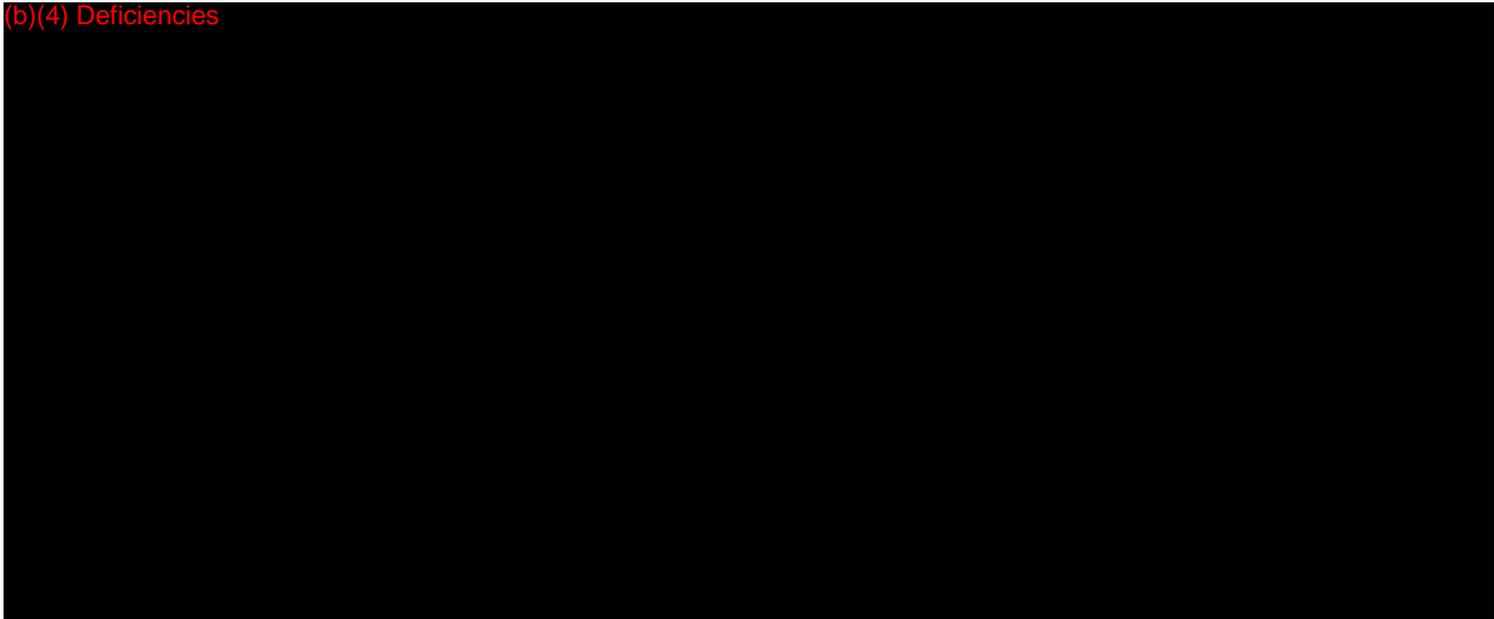


# Attachment 1

## Clinical Literature

**Clinical Literature Review:**  
**Syndesmotic Repair adjunct to fracture repair Independent of a Plate System**

(b)(4) Deficiencies



The proposed use of the Tensyn™ Band for syndesmotic repair adjunct to fracture repair is supported by clinical literature.

<sup>1</sup> Frania SJ, Judge MS, Meszaros A, Canales MB and Masdeh S. *Technique of Syndesmotic Repair: Investigating the Innovative Tightrope™ in Treatment of Syndesmotic Injuries*. Vickers NS (editor), *Reconstructive Surgery of the Foot and Leg*, Update 2006. Podiatry Institute Publishing Co., Tucker, GA, pp. 37-43.

<sup>2</sup> Cottom JM, Hyer CF, Philbin TM, Berlet GC. *Treatment of syndesmotic disruptions with the Arthrex Tightrope: a report of 25 cases*. *Foot Ankle Int.* 2008 Aug;29(8):773-80.