

Synchfix™ EVT

Syndesmotic fixation device

**Technology overview for hospital
value analysis committee**



Elevating care with our next generation device
Experience. Vision. Technique.

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Letter to customer

December 15, 2025

Dear Value Analysis Committee Members,

I am pleased to share the enclosed materials for your review regarding **Synchfix EVT**, our second-generation, FDA-cleared solution for flexible syndesmotic fixation. **Synchfix EVT** builds on the success of our legacy Synchfix design, offering a simplified technique and reduced procedural complexity* to help surgeons perform syndesmotic repairs at the highest level.

This new, all-in-one system integrates suture tensioning directly into the implant instrumentation, delivering a streamlined experience with an ergonomic handle and a low-profile titanium medial implant.

We are also proud to announce that **Synchfix EVT** is the first ankle syndesmotic flexible fixation device cleared for use in adolescents, expanding treatment options for younger patients.

As your committee considers the utilization of innovative technologies to help improve patient care, optimize hospital efficiencies, and deliver long-term value, **Synchfix EVT** has been specifically developed to align with these goals. This packet is intended to provide a concise overview of its clinical benefits and operational efficiencies.

Thank you for your consideration and for your ongoing commitment to advancing high-quality patient care.

*as compared to the previous generation of device

Sincerely,



Robert Burns
Director, Marketing
robert.burns@stryker.com

Introducing Synchfix EVT

Introducing

Synchfix™ EVT

The best aspects of our legacy Synchfix design with a simplified technique and reduced procedural complexity*, helping you perform syndesmotic repairs at the highest level.



Elevated Experience

- Provides a seamless user experience with an ergonomic handle and a low-profile titanium medial implant
- Facilitates medial button placement without the need for medial incision
- Simplifies deployment* through an all-in-one system with integrated suture tensioning and one-handed implant delivery



Elevated Vision

- Sustainability for the future with new RFID packaging for inventory tracking
- May be used standalone or with titanium plates designed to accept 3.5mm nonlocking screws
- First ankle syndesmotic flexible fixation device on the market cleared for use in adolescents



Elevated Technique

- Handle design enables one-handed surgical implant deployment technique
- Knotless suture design provides a low-profile construct that eliminates knot tying and lateral knot prominence
- Engineered to eliminate knot-stacking that could cause soft tissue irritation

Part #	Description
86SYN205	Synchfix EVT inserter with implant construct

Foot & Ankle

Visit us at footankle.stryker.com

*As compared to the previous generation of the device.

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

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

Stryker Corporation or its divisions or other corporate affiliated entities own, use, or have applied for the following trademarks or service marks: Stryker, Synchfix, Synchfix EVT. All other trademarks are trademarks of their respective owners or holders.

510k letter



October 29, 2025

Wright Medical Technology, Inc (Stryker Corporation)
Rachel Warnock
Staff Regulatory Affairs Specialist
1023 Cherry Rd
Memphis, Tennessee 38117

Re: K251643

Trade/Device Name: Synchfix EVT
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN, HRS
Dated: September 19, 2025
Received: September 19, 2025

Dear Rachel Warnock:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory>-

[assistance/contact-us-division-industry-and-consumer-education-dice](#) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510k summary

510(K) SUMMARY: Synchfix™ EVT

(a)(1). Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	October 28 th , 2025
Contact Person:	Rachel Warnock Staff Specialist, Regulatory Affairs
Secondary Contact:	Alayne Melancon Manager, Regulatory Affairs
(a)(2). Proprietary Name:	Synchfix™ EVT
Common Name:	Washer, Bolt, Nut
Classification Name and Reference:	21 CFR 888.3030 – Single/multi component metallic bone fixation appliances and accessories
Device Product Code, Device Panel:	HTN – Orthopedic HRS – Orthopedic
(a)(3). Primary Predicate Device(s):	GRAVITY™ Syndesmosis LP (K170249)

(a)(4). Device Description

The subject device, Synchfix™ EVT, is a sterile, single-use, suture-button system intended to stabilize syndesmotic disruptions in the ankle. The subject system consists of a UHMWPE suture tensioned between two titanium alloy buttons and single use instruments to assist in implantation, including a pre-loaded inserter.

(a)(5). Indications for Use

Synchfix™ EVT is intended for soft tissue and bone fixation for ankle syndesmosis disruptions with or without ankle fractures and as an adjunct in connection with hardware for ankle fractures such as Weber B, Weber C and Maisonneuve in adult and adolescent patient populations.

(a)(6). Technological Characteristics Comparison

The subject Synchfix™ EVT is substantially equivalent to the predicate device in material and design.

There is no change in the fundamental scientific technology shared by both the subject and predicate devices. The subject and predicate implants have similar materials, design features, instrumentation, and performance characteristics. Mechanical testing has



confirmed substantial equivalence of the subject device, demonstrating that the technological characteristics do not raise new questions of safety or effectiveness.

The Indications for Use of the subject device differ from those of the predicate device in that the subject device is intended for use in both adolescent and adult patient populations. Additionally, the subject device's Indications for Use include the addition of Maisonneuve fractures.

(b)(1). Substantial Equivalence - Non-Clinical Evidence

Non-clinical performance bench testing (static pullout strength and dynamic fatigue mechanical testing) was performed to demonstrate substantial equivalence to the predicate device.

(b)(2). Substantial Equivalence - Clinical Evidence

N/A - Clinical testing was not necessary for the determination of substantial equivalence.

(b)(3). Substantial Equivalence - Conclusions

The subject device and predicate device share similar design features, basic fundamental scientific technology, principles of operation, materials, and intended use. The differences between the subject device and predicate device do not raise any new questions of safety or effectiveness. From the evidence submitted in this Traditional 510(k), the subject device can be expected to perform at least as well as the predicate device and are substantially equivalent.

Instructions for use

stryker

Synchfix™ EVT

EN

INSTRUCTIONS FOR USE

700004248053 Rev AA, 11-2025

**THIS DOCUMENT IS APPLICABLE TO
USA AND CANADA**

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Synchfix™ EVT



ALL OF THESE INSTRUCTIONS FOR USE AND LABELING MUST BE READ CAREFULLY PRIOR TO CLINICAL USE



CAUTION
Federal law in the USA restricts this device to sale by or on the order of a physician. See product label for information regarding the specific product referenced in this package insert.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

1 Description and Materials

The Synchfix™ EVT syndesmotic fixation device features sterile, single-use components that provide knotless, dynamic fixation for stabilizing the syndesmosis joint of the ankle. It is designed with an ergonomic all-in-one inserter, built-in suture tensioning handles, low-profile Ti6Al4V medial and lateral implants, and braided UHMWPE suture. The device can be used standalone or in conjunction with hardware designed for 3.5 mm nonlocking screws.

Synchfix EVT is composed of the following materials:

Component	Material	According to Standard
Medial Button	Ti6Al4V	ASTM F136
Lateral Button	Ti6Al4V	ASTM F136
Suture #5	WHITE UHMWPE	N/A
Washer	Ti6Al4V	ASTM F136

2 Indications / Intended Use

Synchfix EVT is intended for soft tissue and bone fixation for ankle syndesmosis disruptions with or without ankle fractures and as an adjunct in connection with hardware for ankle fractures such as Weber B, Weber C and Maisonneuve in adult and adolescent patient populations.

3 Contraindications

The physician's education, training, and professional judgement must be relied upon to choose the most appropriate device and treatment.

Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and / or fixation of the devices

- Material sensitivity, documented or suspected
- Patients having inadequate tissue coverage over the operative site
- Implant utilization that would interfere with anatomical structures or physiological performance
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

4 Warnings and Precautions

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection.

Users of this device should be familiar with the full labeling (e.g. Instructions for Use, Operative Technique, etc.) for each applicable product and should avail themselves of all publications offered.

This document and the immediate package label contain essential warnings, precautions, and contraindications for Synchfix EVT. Additionally, the operative technique should be referenced for detailed information about implant selection, relevant product details, recommended surgical instructions, and /or assembly use. Please contact Stryker and/or the legal manufacturer if further information on this product, including product related documentation (e.g., Operative Techniques), is needed.

In the case of damaged products (intra and/or pre operative), please contact Stryker and/or the legal manufacturer.

Surgeons must be familiar with the applicable operative technique and instructions for use for each product. This document and the immediate package label contain essential warnings, precautions, and contraindications for each product.

Additionally, the recommended surgical technique should be referenced for detailed information about implant selection, relevant product details, proposed surgical instructions, and/or assembly use. The surgeon should contact Wright for the recommended product-specific surgical technique.

WARNING

The licensed healthcare professional and operating room team must be thoroughly familiar with the operating technique, the instruments, as well as the range of implants to be applied. Complete information and labeling on these subjects must be readily available at the workplace.

⚠ CAUTION

- Avoid damaging the surface of implants
- Only use a device for its intended purpose. Improper use of devices may lead to loss in function or usage.
- Abnormal force loading and subsequent wear may be caused by patient misuse or overactivity
- Proper fixation at the time of surgery is critical to the success of the procedure
- The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection.
- Some preventative measures to consider to minimize the potential for complications include stabilizing collapsed deformities

NOTICE

If complications develop, possible corrective procedures include:

- Synovectomy
- Bone grafting of cysts
- Replacement of the implant
- Removal of the implant with fusion of the joint

4.1 Pre-Operative

⚠ CAUTION

Surgical devices should be handled with care and stored in an appropriate location, away from heat and moisture, in order to avoid damage, minimize time before cleaning and avoid drying of soil prior to cleaning. Devices should not be exposed to direct sunlight, ionizing radiation or particulate contamination. It is recommended to remove devices from plastic bags before storing them to avoid condensation. Devices must not be stored in contact with or near products that may have a corrosive effect.

⚠ CAUTION

- Always exercise care in selecting the proper type and size of implant. Improper selection, placement and/or fixation of the implant components may result in early implant failure. Implants may be available in different versions, varying for example in length, diameter, angle, left and right specific options, versions, material and number of drilled holes. The correct selection of the fracture fixation device is extremely important. Failure to use the appropriate device for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.
- Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome.

4.2 Intra-Operative

⚠ CAUTION

- Ensure that all components needed for the operation are available in the operation theatre.
- Careful handling and storage of the product is required. Scratching or damage to the implants can significantly reduce the strength and fatigue resistance of the product.
- Visually inspect devices prior to use for damage, debris, dirt, flaws, or if the device was stored past the shelf life expiration date. Do not use them.

4.3 Post-Operative

⚠ WARNING

- The implant is intended for temporary bone fixation. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example, breakage or loosening of the implant or instability of the implant system. The surgeon must advise the patient to attend all follow-up examinations as directed.

⚠ CAUTION

- After the procedure, check that all implants are positioned correctly using an image intensifier.
- Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone, or soft tissue damage.

5 MRI Safety Information



The Synchfix EVT is MR Conditional. A patient implanted with a Synchfix EVT implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Device name	Synchfix EVT
Static Magnetic Field Strength (T)	1.5 T and 3.0 T
Maximum Spatial Field Gradient	30 T/m (3000 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR (W/kg)	2 W/kg
Scan Duration	2 W/kg whole-body average SAR for 1 hour (or 60 minutes) of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

⚠ CAUTION

The MRI safety information provided is based on testing which included compatible systems listed in the Instructions for Use. If there are supplementary devices (i.e. plates, screws, wires, etc.) present in proximity to the system, this could result in additional MRI effects and the information provided above may not apply.

6 Informing the Patient

⚠ CAUTION

Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant. Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Inadequate soft tissue support

The surgeon must advise patients of surgical risks, and make them aware of adverse effects and/or alternative treatments.

⚠ CAUTION

Post-operative patient activity:

- These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason, post-operative instructions and warnings to patients are extremely important. During the post-operative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioural requirements. External immobilization (e.g., bracing or casting) may be employed until X-rays or other procedures confirm adequate healing.
- The patient should be advised that the device cannot and does not replicate a normal healthy soft tissue, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life. Removal or revision of the device may be required sometime in the future due to medical reasons.
- The risk of post-operative complications (e.g. failure of an implant) is higher if patients are obese, have a mental or neuromuscular disorder and are unable to follow the post-operative care plan. For this reason, for these patients the HCP may consider additional post-operative follow up.
- Explain the need to report unusual changes in the surgical site as well as falls or accidents, even if the device or the site of operation did not appear to be harmed.

The healthcare professional is responsible for filling out the Medical Device Card, providing the Medical Device Card to the patient, as well as informing the patient about the availability of the Medical Device Card on the website www.patientinfo.stryker.com.

Print a copy Medical Device Card which is available on www.patientinfo.stryker.com.

To retrieve the Medical Device Card, follow the instructions on the website. Copy the catalogue number(s) (REF) of the implanted device(s) on the dedicated empty lines of the Medical Device Card.

You can find the catalogue number(s) (REF) on the package label(s) of the implanted device(s).

- Inform the patient to store the Medical Device Card in a safe place.
- Instruct the patient to consult the healthcare professional prior to an MR exam and to provide a copy of the Medical Device Card to the MRI site personnel before an MR exam.

7 Adverse Events and Adverse Effects

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Breakage of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism or deep vein thrombosis
- Bone damage
- Malreduction
- Malpositioning of the medial endobutton

8 Sterility, Cleaning and Sterilization

This product is delivered sterile and has been sterilized using ETO.

WARNING

- The packaging of all sterile products should be inspected before opening.
- If the packaging is flawed (damaged), was opened prior to planned use, or the device was stored past the shelf life expiration date, the product must be assumed to be non-sterile. Do not re-sterilize and do not use. If any of these conditions occur, contact the manufacturer.
- The implants should be opened using aseptic technique
- Devices delivered sterile must be stored in their sealed package of origin.
- The implant is for single use only
- Single use devices shall not be reused, as they are not designed to perform as intended after the first use. Mechanical, physical or chemical properties of single use device may be compromised after first use. In this case, the safety and performance of the devices are not supported by the manufacturer, and compliance to relevant specifications cannot be ensured.

Single use is defined as a device that is intended for use on one single patient and one procedure only.

 **WARNING**

- Sterile packed, ETO.
- Single use only.
- DO NOT flash or reprocess

9 Notification

Please inform the manufacturer, if a product related incident has occurred while using this device. Retain damaged devices and return them to Stryker and/or the legal manufacturer to assist with their analysis of the event.

 **WARNING**

Do not use if damaged, dirty or expired.

10 Transport and Storage Information

The device is individually packed in protective packaging that is labelled according to its contents. Store and transport the device in the original protective packaging or the appropriately marked storage module/tray. Do not remove the device from the packaging until it is planned to be used or it is ready to be placed in the storage module/tray. Store the devices in standard hospital environmental conditions (cool and dry) unless specific requirements are defined and described on the product label.

11 Special Training

The healthcare professional must be licensed to perform surgery in the respective field of medicine and must be familiar with the principles of the surgical procedure. No mandatory training is required for the intended user group before using the devices of the Synchfix EVT System.

12 For Further Information

Ensure that you are familiar with the intended purposes, indications/contraindications, compatibility and correct handling of the implants which are described in the operative technique manual for the product system. Please remember that product systems may be subject to alterations that affect the compatibility of the implant with other implants or with instruments. For your information, avail yourself of the publications offered (e.g. operative techniques).

Important information for doctors and operating room (OR) staff: This document does not include all of the information necessary for selection and use of a device. Please see full labeling for complete information!

Instructions for Use, Operative Techniques, "Instructions for Cleaning, Sterilization, Inspection and Maintenance" (OT-RG-1) and other associated labeling may be requested online at www.ifu.stryker.com.

The use of the system is described and/or illustrated in the operative technique of the product system. The applicable Operative Techniques for the Synchfix EVT System can be found on wwwifu.stryker.com.

For a symbol explanation please refer to the glossary OT-IFU-210 on wwwifu.stryker.com.

Please contact Stryker if further information on this product is needed.

If the product does not function satisfactorily, please contact your local Stryker representative or call Stryker Customer Service.

13 Disposal

The hospitals should follow the national regulations in force for medical waste disposal.

Contaminated units should be decontaminated before they are discarded.

Operative technique

stryker

Synchfix™ EVT

Syndesmotic fixation device

Operative technique



Important

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. Consult Instructions for Use (wwwifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.

The surgeon must advise patients of surgical risks and make them aware of adverse effects and alternative treatments.

 **CAUTION**

The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life. Removal or revision of the device may be required sometime in the future due to medical reasons.

 **WARNING**

The licensed healthcare professional and operating room team must be thoroughly familiar with the operating technique, the instruments, as well as the range of implants to be applied. Complete information and labeling on these subjects must be readily available at the workplace.

The following guidelines are furnished for information purposes only.

Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience.

All instructions for use and labeling must be read carefully prior to clinical use.

Users of this device are encouraged to contact their (Stryker) representative concerning any and all missing documents (e.g., Instructions for Use, Operational Technique, etc.), in the case of damaged products (intra and/or pre operative), or if they require a more comprehensive explanation of the technique to be used with this device. Contact information can be found in this document and the package insert.

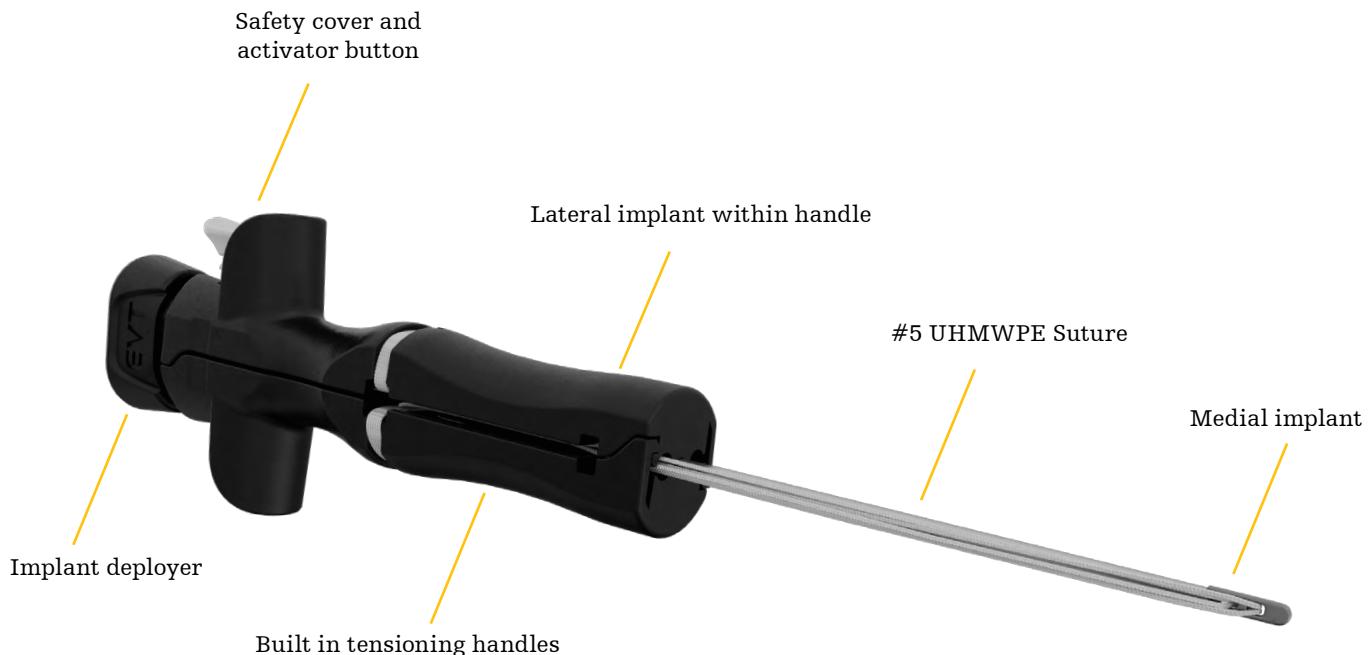
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Introduction

The Synchfix EVT syndesmotic fixation device provides a seamless user experience with an ergonomic handle and a low-profile titanium medial implant. Designed for standalone use or compatibility with 3.5mm non-locking screw hardware, it ensures precise, knotless, and secure dynamic fixation across the syndesmosis joint. Its all-in-one integrated design incorporates built-in tensioning handles for a streamlined and efficient technique.

Synchfix EVT Inserter



All of the instruments contained in the Synchfix EVT syndesmotic fixation device kit are disposable.

Indications and Contraindications

Indications

Synchfix EVT is intended for soft tissue and bone fixation for ankle syndesmosis disruptions with or without ankle fractures and as an adjunct in connection with hardware for ankle fractures such as, Weber B, Weber C and Maisonneuve in adult and adolescent patient populations.

Contraindications

The physician's education, training, and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area;
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site;
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and / or fixation of the devices;
- Material sensitivity, documented or suspected;
- Patients having inadequate tissue coverage over the operative site;
- Implant utilization that would interfere with anatomical structures or physiological performance;
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care;
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications, and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Magnetic Resonance Imaging (MRI) Information



The Synchfix EVT is MR Conditional. A patient implanted with a Synchfix EVT implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

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Maximum Whole-Body SAR (W/kg)	2 W/kg
Scan Duration	2 W/kg whole-body average SAR for 1 hour (or 60 minutes) of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.



The MRI safety information provided is based on testing which included compatible systems listed in the Instructions for Use. If there are supplementary devices (i.e. plates, screws, wires, etc.) present in proximity to the system, this could result in additional MRI effects and the information provided above may not apply.

General Considerations

Syndesmotic reduction

⚠ CAUTION

The reduction of the syndesmosis is necessary before fixation, and it should be verified through fluoroscopy, arthroscopic confirmation, direct visualization during open reduction, or a combination of depending on the surgeon's preference and the severity of the injury.

Ankle fractures

Anatomic fixation of unstable and/or displaced fractures in the distal two-thirds of the fibula enables restoration of proper fibular length and rotational alignment. In higher fibula fractures, such as Maisonneuve injuries, treatment often includes fibular shaft open reduction and internal fixation (ORIF) combined with syndesmotic stabilization, depending on the specific injury pattern. The procedure may utilize one or multiple Synchfix EVT implants based on the extent of syndesmosis disruption and the surgeon's preference.

In-plate Surgical Technique

Step 1: Incision and bone prep

Stabilize any associated fractures prior to drilling. Through a lateral incision, use the 3.5mm drill bit (solid or cannulated) to create a pathway through the plate hole, fibula, and tibia — drilling all four cortices at or slightly above the tibial incisura. The drill trajectory should allow for fixation in the center of the tibia. **(Figure 1)**

Optional: The use of a drill guide.

NOTICE

Flexible fixation should be at the centroidal axis of the syndesmosis, which minimizes the likelihood of mal-reduction.



Figure 1

Optional: A guide wire with insert and cannulated 3.5mm drill bit can also be used to confirm accurate positioning. **(Figure 2)**

NOTICE

When using a cannulated drill, trajectory can be confirmed by obtaining fluoroscopic imaging with the temporary K-wire in place. Proper positioning is indicated when the K-wire is centered within the fibular diaphysis.



Figure 2

Step 2: Implantation of construct

Position the gray safety cover on the black inserter handle anteriorly (this will help align the medial button with the axis of the tibia after deployment). Advance the Synchfix EVT implant system through the fibula and tibia bone tunnel, passing through all four cortices. **(Figure 3)**

NOTICE

Use fluoroscopy in the anterior-posterior view to ensure that the distal end of the most proximal translucent window on the shaft of the inserter is aligned with the edge of the cortex.



Figure 3

In-plate Surgical Technique (continued)

Step 3: Deploy implant

- A. Lift the gray safety cover up to expose the activator button. **(Figure 4)**
- B. Press the gray activator button once, to activate the deployer. **(Figure 5)**
- C. Using the palm of your hand, squeeze the black implant deployer into the handle to deploy and flip the medial implant. **(Figure 6, 7, & 8)**

NOTICE

Fully advance the deployer until it contacts the back of the handle. This indicates the medial implant is fully deployed.



Figure 4



Figure 5

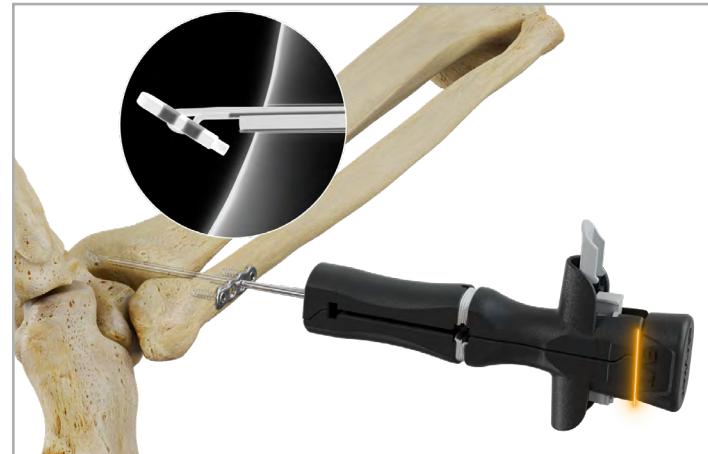


Figure 6

Figure 7

Figure 8



Figure 9

- D. After deployment, pull back on the inserter handle and check under fluoroscopy to confirm that the medial implant is fully deployed and seated flat against the medial tibial cortex. **(Figure 9)**

In-plate Surgical Technique (continued)

Step 4: Remove inserter

A. After deploying the medial implant, press the gray activator button a second time to release the implant deployer from the Synchfix EVT inserter. (**Figure 10**)

B. Slide the medial implant deployer fully out of the Synchfix EVT inserter to disengage the tensioning handles, then discard it. (**Figure 11**)

C. Grip the Synchfix EVT inserter with both hands and rotate each half of the handle in opposite directions (one counterclockwise and the other clockwise) to separate the halves and prepare for tensioning. (**Figure 12**)

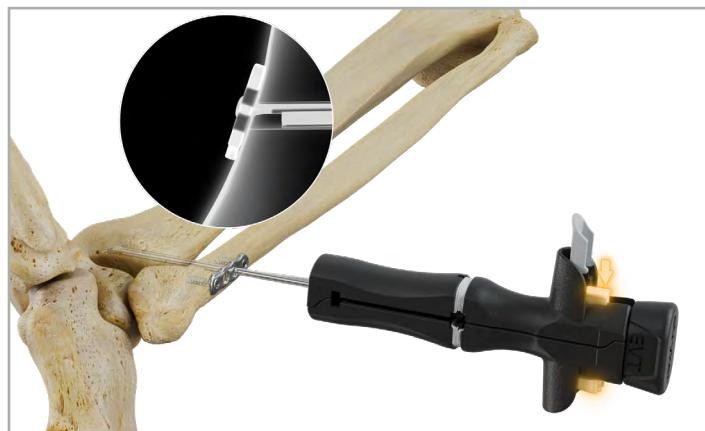


Figure 10



Figure 11



Figure 12

In-plate Surgical Technique (continued)

Step 5: Final tensioning and fluoro check

A. To begin final tensioning, grasp the two built-in tensioning handles, holding one in each hand. (Figure 13)

NOTICE

For optimal lateral button advancement, pull the tensioning handles straight back toward the operator, alternating tension from one side to the other to gradually "walk" the lateral button down to the plate until fully seated.



Figure 13

B. After seating the button, pull the two suture strands outward, keeping them in the same plane as the plate surface, until the desired tension is achieved. (Figure 14)

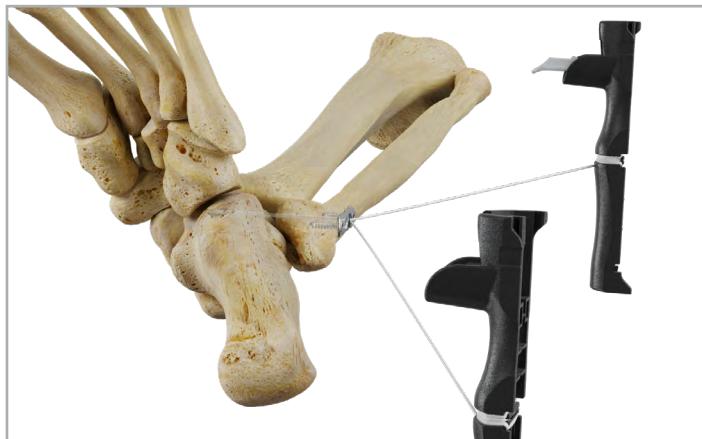


Figure 14

In-plate Surgical Technique (continued)

Step 6: Trim

 **CAUTION**

Once the desired tension is reached, the suture may be carefully cut at the edge of the outer diameter of the lateral implant leaving at least 2mm of suture tail to ensure the implant sutures remain intact and undamaged.

 **NOTICE**

The Synchfix EVT device uses a self-locking (knotless) suture, so tying a knot over the lateral implant is not necessary.

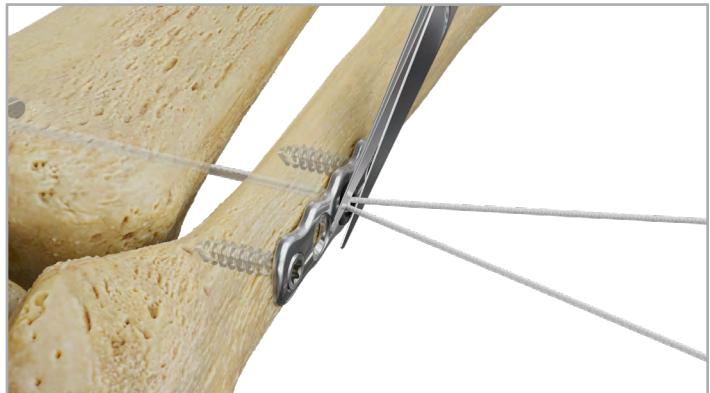


Figure 15



Figure 16



Figure 17

Non-plate Surgical Technique

The Synchfix EVT syndesmotic fixation device may be used without plate fixation by following the previously outlined steps.

The use of a washer is recommended. (**Figure 18**)

Prior to completing the previously outlined **steps 1-6**, slide the Synchfix EVT lateral implant washer over the medial implant inserter and suture lines prior to inserting the medial implant through the bone tunnel.

If using a drill guide without a plate, ensure the toothed side is positioned against the bone to provide stable interface during drilling.

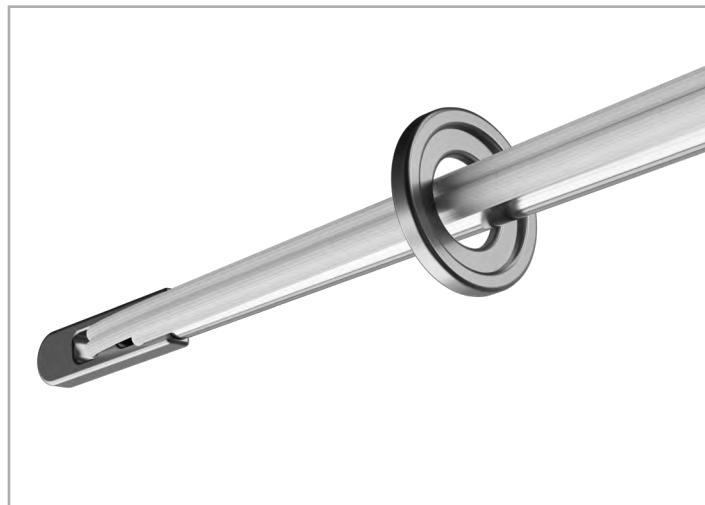


Figure 18

Removal

Explant information

Removal of the Synchfix EVT syndesmotic fixation device, like all flexible syndesmotic fixation, should not be required in most instances and is therefore left to the discretion of the surgeon. If removal is deemed necessary, then a small incision on the lateral and medial side is needed to expose the medial and lateral implants. Once both ends of the construct are exposed, cut the suture and remove the medial implant, followed by the lateral implant and remaining suture.

Ordering Information

Synchfix EVT syndesmotic fixation device sterile packed, single-use implant/instrument kit

Part number	Description
86SYN205	Synchfix EVT inserter with implant construct
	Drill guide
	1.6mm guide wire
	Guide wire adapter for drill guide
	3.5mm solid and cannulated drills
	Washer

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Manufacturer:



Wright Medical
Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
800 238 7117
901 867 9971

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Kit component guide

Synchfix™ EVT

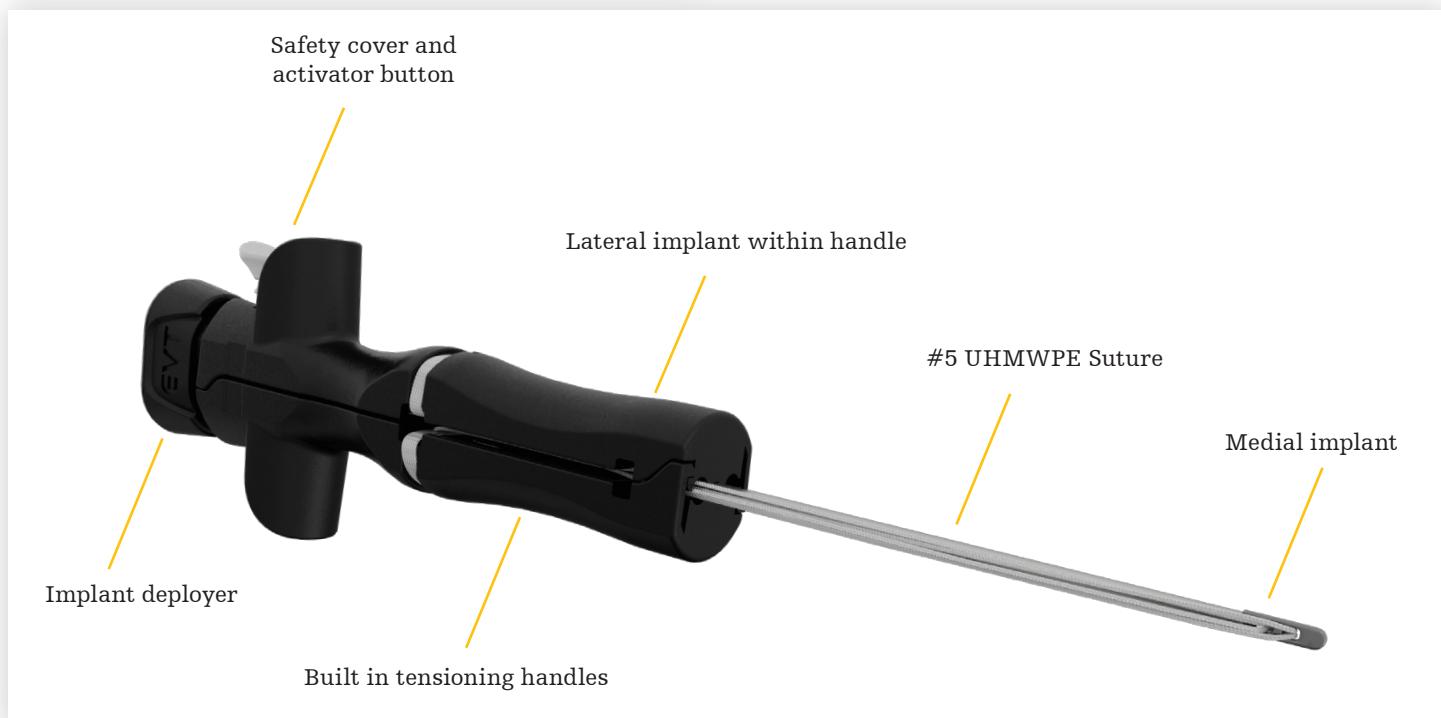
Syndesmotic fixation device

Kit component guide

Synchfix EVT syndesmotic fixation device sterile packed, single-use implant and instrument kit



Part #	Description	Qty
86SYN205	Synchfix EVT inserter with implant construct	1
	Drill guide	1
	1.6mm guide wire	1
	Guide wire adapter for drill guide	1
	3.5mm solid drill	1
	3.5mm cannulated drill	1
	Washer	1



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Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
800 238 7117
901 867 9971

stryker.com

Plating compatibility guide

Synchfix™ EVT

Syndesmotic fixation device

Plating compatibility guide

Synchfix EVT may be used standalone or with titanium plates designed to accept 3.5mm non-locking screws

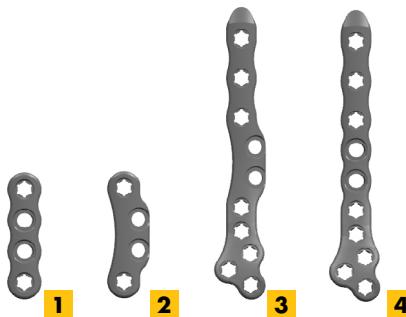


Internal options

Ortholoc 2 Ankle Fracture LP

Syndesmosis holes are located in Ortholoc 3Di lateral fibula plates and the 4 hole syndesmosis plate

1.3mm thick



Pangea



Distal cluster: 2mm thick

Shaft: 2.6mm thick

Distal Lateral Fibula and Distal Posterolateral Fibula Plates



VariAx 2

Distal lateral fibula plate

Distal end: 1.3mm thick

Shaft: 2.0mm thick

Straight fibula plate

2.0mm thick

One third tubular plates

1.7mm thick

Fibula and One Third Tubular Plates



Part #	Description
RSAM	VariAx 2 Small Fragment add-on tray

1. Distal lateral fibula plate
2. Straight fibula plate
3. One third tubular plate

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