stryker

Citrefix™
Suture Anchor System

Operative technique

Citrefix™
Suture Anchor System

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.

⚠ WARNING

All non-sterile devices must be cleaned and sterilized before use. Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly and cleaning and sterilization instructions provided in the Reusable Instruments Instructions for Use (IFU, Ref. No. PI-005) delivered with each instrument.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

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

⚠ WARNING

- 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.

For additional information including a complete list of adverse effects, adverse events, contraindications, warnings, and precautions, please refer to the instructions for use (IFU), Ref. No. PI-007 delivered with each implant and IFU, Ref. No. PI-005 delivered with each reusable instrument, and/or IFU, Ref. No. PI-008 delivered with each single-use instrument kit.

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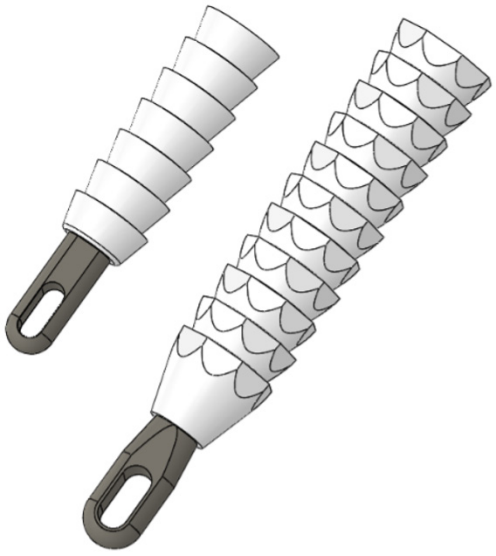


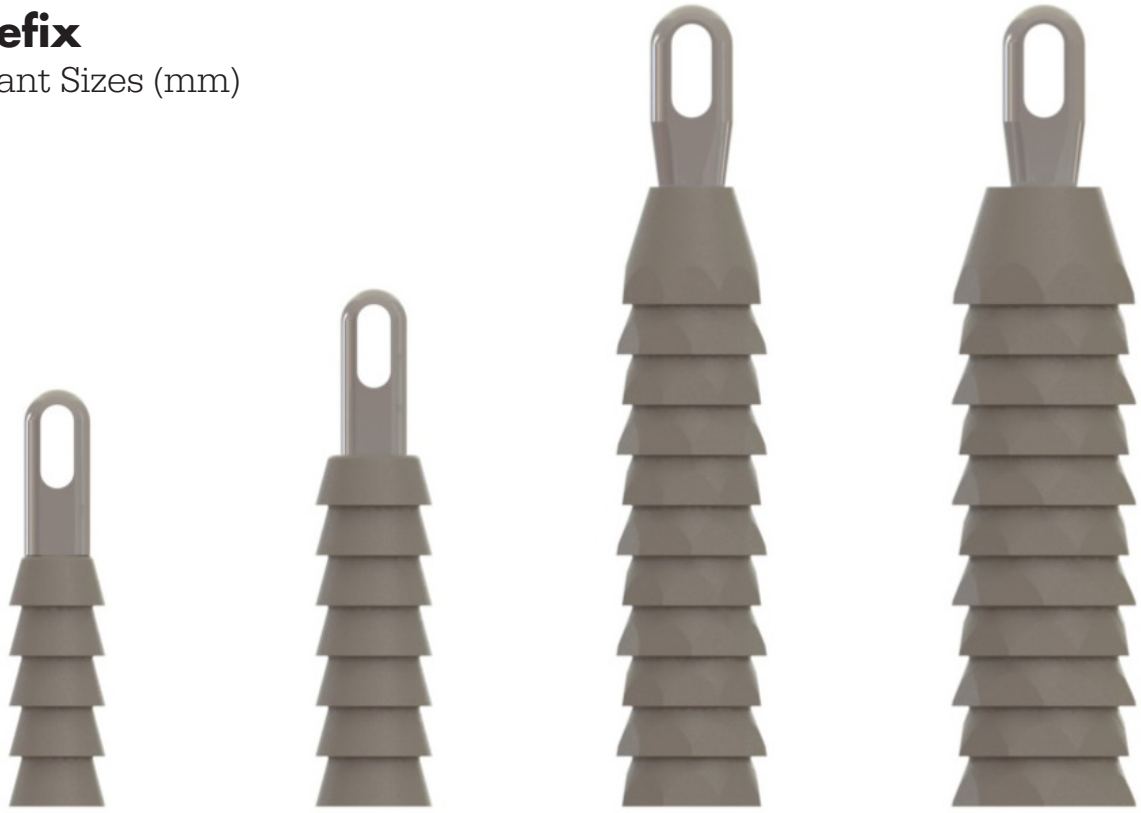
The surgeon must discuss all relevant risks with the patient when necessary, including the finite lifetime of the device, surgical risks, adverse effects, and make them aware of alternative treatments.

Surgical Technique as described by:
Wayne Berberian, MD

System general considerations

Citrefix is utilized in soft tissue reconstruction procedures of the foot and ankle including but not limited to: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair.

Citrefix
Implant Sizes (mm)



2.9 x 12.5 **3.5 x 15.5** **4.5 x 24** **5.5 x 24**

Indications, precautions and contraindications

Indications

The Citrefix Suture Anchor is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction.

Precautions

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. The appropriate delivery system is required for proper implantation of the device. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. The manufacturer and/or distributor provides detailed surgical techniques in print, video, and electronic formats. Contact your local representative for an onsite demonstration.

Physician note: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patients.

MR Safety Information

The Citrefix Suture Anchor is MR Safe.

⚠ WARNING

No implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) can eventually occur. Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good alignment are important considerations in the success of surgery. Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of delayed healing. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for surgery.

Do not use devices that are received in open or damaged packages.

Do not use past the expiration date.

No implant should be reused once the sterile packaging has been opened.

Indications, precautions and contraindications (cont.)

Contraindications

Include, but are not limited to:

1. Fever or leukocytosis.
2. Infection, local to the operative site.
3. Mental illness.
4. Morbid obesity.
5. Pregnancy.
6. Insufficient quantity or quality of bone.
7. Signs of local inflammation.
8. Blood supply limitations and previous infections which may retard healing.
9. Any active infection or blood supply limitations.
10. Any patient unwilling to co-operate with postoperative instructions.
11. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
12. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
13. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
14. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
15. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant.
16. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in patients with such conditions must be made by the physician, taking into account the risks versus the benefits to the patient.
17. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, or alcoholism limits their ability to follow postoperative restrictions. These patients may place undue stresses on the implant during bony healing and may be at higher risk of implant failure.
18. Any condition not described in the indications for use.

Implant Selection

Surgeons must apply their professional judgment when determining the appropriate implant size based on the specific indication, preferred surgical technique, and patient history. The selection of the proper size of the implant for each patient is crucial to the success of the procedure. Polymeric implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Operative technique

1. Exposure

Physician preference can be utilized to expose the operative site. Care should be taken to avoid injuring tendons, blood vessels and peripheral nerves.

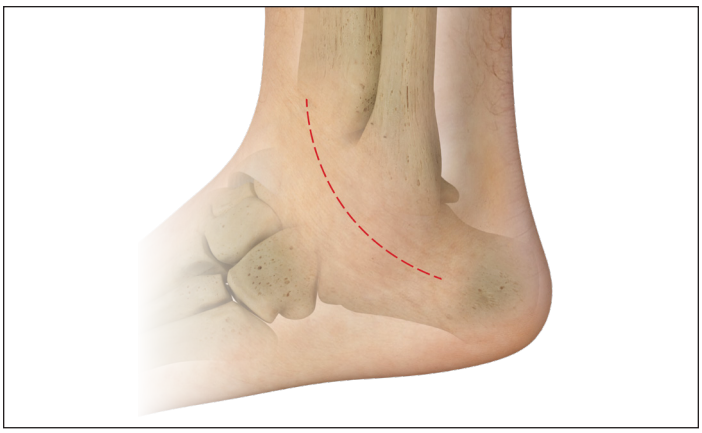


Figure 1

2. Isolation and preparation of tendons or ligaments

Dissection is performed to identify and define tendons or ligaments that are to be fixated (Figure 2). Osteophytes or loose bone fragments may be removed. The attachment site should be roughened with a rongeur to improve soft-tissue adherence. A light abrasion of the bone surface creates a bleeding base for tendon bonding. The cortical bone needs to bleed to bond to the tendon, but the bone cortex is needed to attain maximum strength for suture anchor fixation.

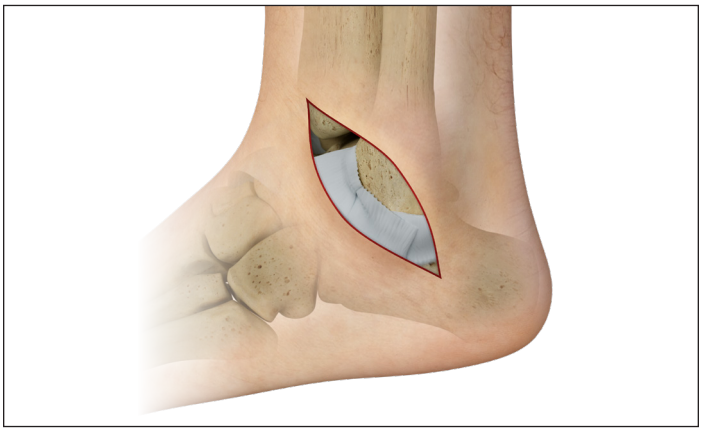


Figure 2

3. Preparation distal socket

The bone is prepared for anchor insertion. The surgeon can determine the number of anchors needed per their standard protocol. Once the surgeon has determined what size suture is required, the bone is predrilled with the corresponding drill bit for the selected anchor size. The surgeon can utilize the corresponding drill guide to set the location and trajectory of the anchor socket. The trajectory of the socket should be perpendicular to the surface to avoid drill skiving during preparation. The drill guide should be fully seated against the bony anatomy, and the drill bit should be advanced into the guide until the drill bit stop fully seats against the back of the drill guide (Figure 3). If the anatomy allows and surgeon preference is to use larger anchors, then the anatomical site may be prepared for larger implants. Care should be taken to ensure that multiple sockets do not interfere with each other as they converge.

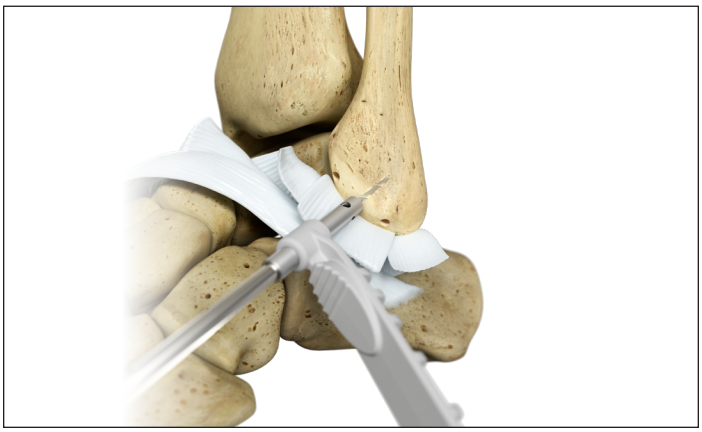


Figure 3

4. Loading suture and implant inserter

a) Open packaging containing the implant cartridge. Align the implant inserter with the suture anchor body on the cartridge and with the suture loading loop pointing away from the inserter tip (Figure 4.1). Advance the inner shaft of the inserter up through the suture anchor body and into the PEEK eyelet (Figure 4.2).

Figure 4.1

Figure 4.2

b) Select the preferred suture to be utilized for the repair (Table 1). Typically, one strand of #2 UHMWPE suture is utilized for most techniques. Load one tail of the selected suture through the suture loop on the implant cartridge (Figure 4.3). When the cartridge is removed in the next step (c), the suture loop will pull the suture through the PEEK eyelet. If one end of the suture contains a needle, then pull the end without the needle through the loop and into the eyelet.

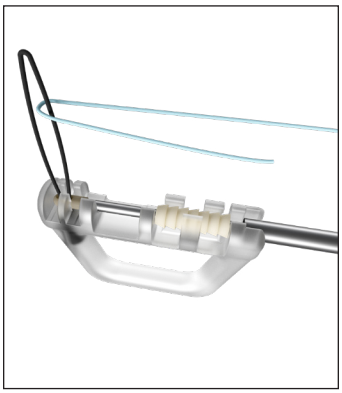


Figure 4.3

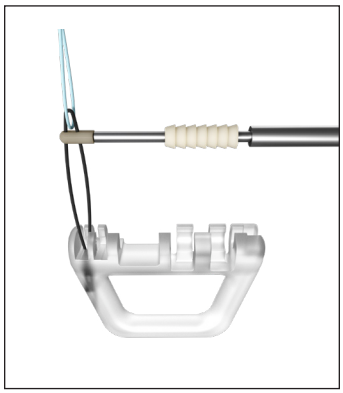


Figure 4.4

c) Gently pull the cartridge from the inserter to release the implant and pull the suture through the PEEK eyelet (Figures 4.4 and 4.5). Care should be taken during this step to avoid pulling the eyelet off the inserter wire. Pull the cartridge off to the side and ensure the suture is loaded into the eyelet. Once the cartridge has been removed and the suture passed through the eyelet, and if the surgeon desires, the two ends of the suture can be wrapped around the handle cleats (Figure 4.6).

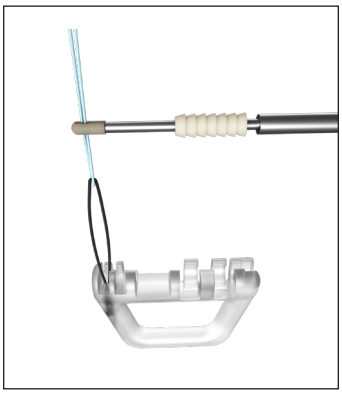


Figure 4.5

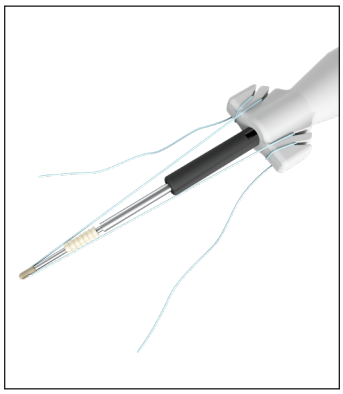


Figure 4.6

Table 1 – Suture Configurations for Anchor Size

Suture Size	No. Strands for 2.9mm and 3.5mm anchors	No. Strands for 4.5mm and 5.5mm anchors
2-0	4	4
0	4	4
2	1	2
1.5mm tape	2	2
2mm tape	1	2
The system can also accommodate a suture with double-ended needles. The following needle sizes will fit through the eyelet: CT-3, T-5, KC-7		

5. Implanting anchor

Insert the Citrefix anchor into the prepared holes. A larger Suture anchor may be used in softer bone. Place the tip of the inserter containing the eyelet into the socket and then remove the orange safety clip from the inserter (Figure 5.1). Using a mallet, tap the plunger on the back of the implant inserter handle until the anchor body is flush with the bone (Figure 5.2). The plunger on the back of the inserter will not be fully flush with the handle. However, the laser mark on the plunger should be below the surface of the back of the inserter handle as an indication that the anchor is fully seated. Remove the inserter with gentle twisting and tension until it releases from the eyelet and suture anchor body.

Figure 5.1

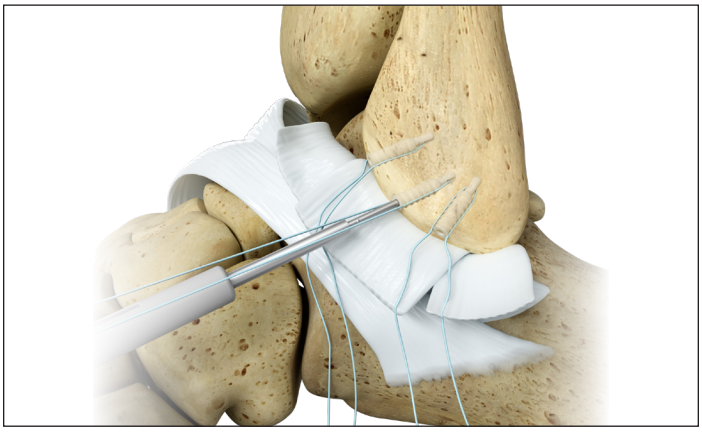


Figure 5.2

6. Capturing the selected ligament using sutures

Pass the selected suture through the desired ligaments (example: ATFL, CFL, and the capsule) and advance attachment site using preferred knots to tie the sutures (Figure 6). If the ligaments/ capsule appear to be excessively thin or stretched out, consider making several passes through the tissue with one suture strand prior to tying the knot. The ankle and foot should be placed in optimal position for each specific procedure before tying the sutures. In cases of severe tissue attenuation, consider the use of a ligament augmentation procedure using suture or adding a tendon graft (allograft or a split peroneal tendon autograft). At this point, the surgeon may consider performing adjunctive procedures (such as calcaneal osteotomy, Achilles' lengthening, spring ligament reconstruction, cotton osteotomy, lateral column lengthening, etc.).

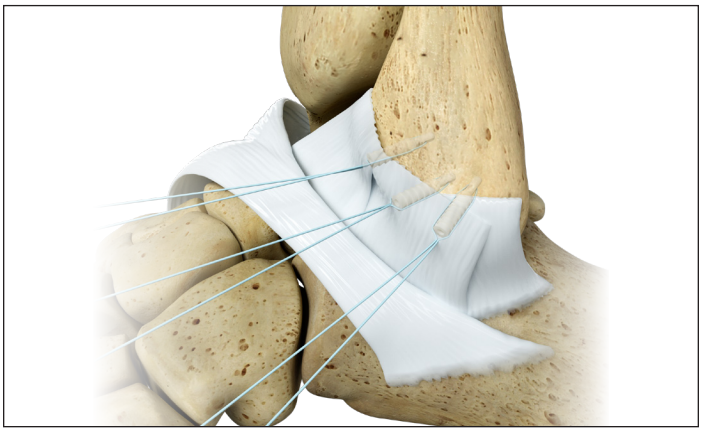


Figure 6

7. Preparing proximal sockets (optional)

If the surgeon desires to perform a bridge technique, adjacent sockets may be prepared as in Step 3. The two drill holes should be placed 1cm apart and parallel to the prior sockets. One suture from each of the distal anchors is passed into the eyelet of the selected Citrefix anchor. The sutures are tensioned, and the anchor is inserted. While tension is maintained on the sutures, remove the safety clip and using a mallet tap the plunger (located on the back of the implant inserter handle) until the anchor body is flush with the bone. The plunger on the back of the inserter will not be fully flush with the inserter handle. However, the laser mark on the plunger (indicated as a light band in Figure 5.1) should be below the surface of the back side of the inserter handle as an indication that the anchor is fully seated. Remove the inserter with gentle twisting and tension until it releases from the eyelet and suture anchor body.

Figure 7

8. Completing the repair and closure

Trim the excess sutures at the level of the cortex (Figure 7). If desired, check the location of the implant under x-ray. After completing insertion of the Citrefix implant, wound closure is performed according to the surgeon's standard protocol.

9. Removal

If, for any reason, the clinician determines that the implant should be removed after it has been seated, it can be drilled out under fluoroscopy using a burr that is smaller in diameter than the implant.

10. Ligament augmentation option

Citrefix may also be used to augment a ligament repair in procedures employing sutures or braided tape, such as Brostrom ATFL, Achilles, Spring Ligament, and AITFL support. For an augmentation technique, an anchor is inserted with the attached suture or tape into the first site, and then the tails of the suture can be loaded onto another suture anchor to provide counterforce and fix into position. The augmentation technique is only intended to augment the primary repair or reconstruction by expanding the area of tissue approximation during the healing period and is not intended as a replacement for the native ligament.

Notes

Notes

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Foot & Ankle

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 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.

Operative Techniques, patient information leaflets and other associated documents may be requested online at www.stryker.com. If saving the Instructions for Use, operative techniques, or cleaning instructions, please make sure you always have the most up to date version prior to use.

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