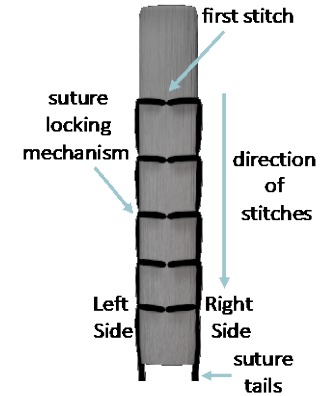
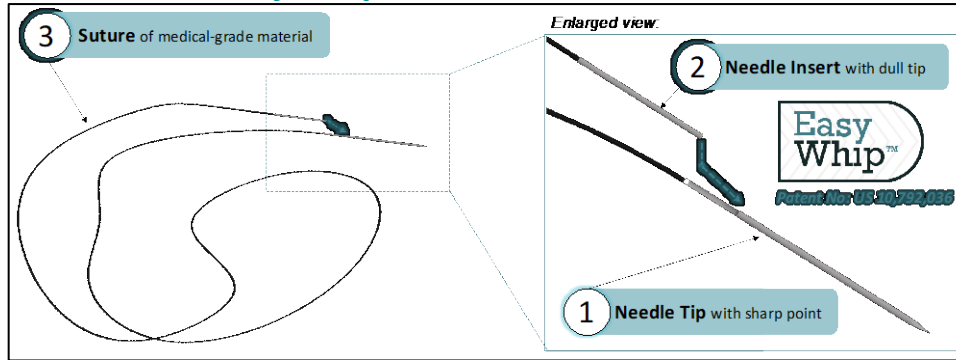
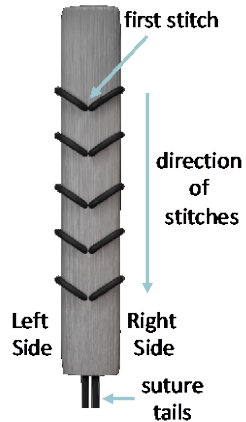
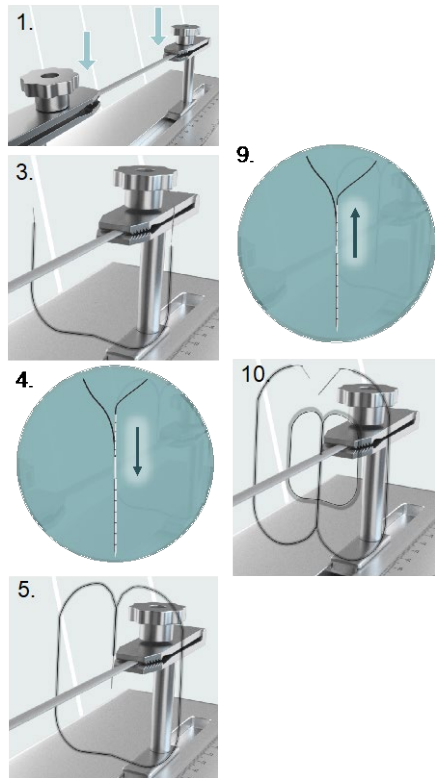


EasyWhip™ Instructions for Use



Whip Stitch



EasyWhip™ is a sterile, single use device intended for stitching in soft tissue approximation. EasyWhip™ consists of (1) a needle tip with a sharp point and a hollow receiver and (2) a needle insert, which is a rod with a dull tip that can be slid into the receiver. The two portions are attached to opposite ends of a length of (3) suture.

The choice of which stitch pattern to use is up to the clinician based on user needs and preferences.

Directions for creating both a Whip Stitch and WhipLock™ stitch pattern are outlined below.

The WhipLock™ stitch is a new hybrid locking stitch that combines elements of the Whip Stitch with a locking stitch such as the Krackow stitch.

Ex vivo porcine soft tissue testing demonstrated comparable mechanical properties of a Whip Stitch pattern created with EasyWhip™ and a Whip Stitch pattern created with conventional straight Whip Stitching needle.¹

Ex vivo porcine soft tissue testing on WhipLock™ and Krackow stitch patterns demonstrated comparable mechanical properties.¹ Mechanical properties of the WhipLock™ stitch have not been confirmed in human clinical studies.

Whip Stitch Directions

1. If preparing an autograft, clamp graft securely to prep stand posts on both ends. If stitching tissue *in situ*, grasp free end as desired.
2. Separate needle tip and needle insert
3. Pass suture under graft so that one needle portion is to the left of the graft and the other needle portion is to the right of the graft
4. Connect needle portions above the graft by sliding needle insert into hollow receiver on back end of needle tip
5. Use needle tip to penetrate through tissue
6. Pass connected needle tip and needle insert entirely through the graft
7. Grasp needle tip and needle insert below graft
8. Pull sutures through graft and tension
9. Separate needle tip and needle insert below graft
10. Pass one needle portion around left side of the graft and the other needle portion around the right side of the graft
11. Repeat steps 4-10 for desired number of stitches
12. Upon completion of stitch series, cut suture at desired length to remove needle tip and needle insert

¹ Data on file, Winter Innovations Inc.

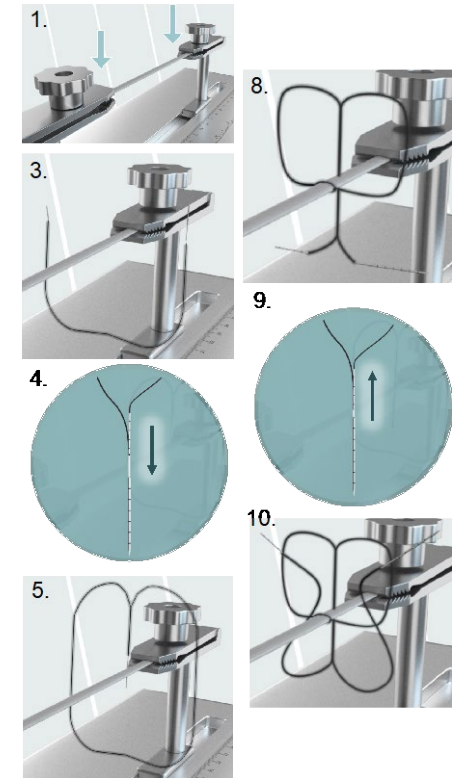
WhipLock™ Stitch Directions

1. If preparing an autograft, clamp graft securely to prep stand posts on both ends. If stitching tissue *in situ*, grasp free end as desired
2. Separate needle tip and needle insert
3. Pass suture under graft so that one needle portion is to the left of the graft and the other needle portion is to the right of the graft
4. Connect needle portions above the graft by sliding needle insert into hollow receiver on back end of needle tip
5. Use needle tip to penetrate through tissue
6. Pass connected needle tip and needle insert entirely through the graft
7. Grasp needle tip and needle insert below graft
8. Pull sutures through graft and tension slightly, but leave suture loops before tensioning fully
9. Separate needle tip and needle insert below graft
10. Pass needle tip through one suture loop and needle insert through other suture loop
11. Tension sutures
12. Pass one needle portion around left side of the graft and the other needle portion around the right side of the graft
13. Repeat steps 4-12 for desired number of stitches
14. Upon completion of stitch series, cut suture at desired length to remove needle tip and needle insert

Tip: Direction of passage should be in the same direction as stitches are progressing to create locking suture mechanism

Tip: Custom patterns may be desired, but to create full WhipLock™ stitch, needle portions should always be passed through the loop on the same side for each stitch. For example, if needle insert is passed through the right loop on first stitch, it must be passed through right loop for each subsequent stitch

WhipLock™ Stitch



DESCRIPTION

They EasyWhip™ device consists of a needle and non-absorbable suture assembly. The needle has two components: (1) *needle tip* with a receiver cut in one end to facilitate insertion of the needle insert as well as a sharp, tri-beveled tip on the other end, and (2) *needle insert* with a dull tip. The two needle components are attached to the ends of (3) suture. The *needle insert* is slid inside the *needle tip* to allow the two suture ends to be passed through the tissue simultaneously. The *needle insert* is removed from the *needle tip* to allow the suture ends to be separated. The suture is composed of braided Ultra High Molecular Weight Polyethylene (UHMWPE) that is dyed black (D&C Black #4 not to exceed 1.0% by weight). Additional materials in the EasyWhip™ device may include cyanoacrylate as well as a silicone coating. The EasyWhip™ size 2 suture is MR safe and meets or exceeds USP standards, except for oversize diameter (0.630mm maximum oversize average diameter, and 0.031mm maximum oversize from USP).

INDICATIONS

EasyWhip™ is indicated for use in approximation and/or ligation of soft tissues, including the use of allograft tissue for orthopedic surgeries.

PERFORMANCE

EasyWhip™ sutures do not exhibit a significant loss of tensile strength during the shelf life of 5 years (60 months). This product is intended for single use only.

CONTRAINDICATIONS

None known.

WARNINGS

- This product is intended for single use only and is supplied sterile (EO). DO NOT RESTERILIZE.
- Do not use if product sterilization barrier or package is damaged or compromised. Prior to use, inspect the packaging and product for signs of damage, tampering, or contamination.
- Do not use after the expiration date.
- It is the user's responsibility to be familiar with the appropriate surgical techniques prior to use of this device. Read instructions completely prior to use.
- The risk of wound dehiscence may vary with the site of application and the suture material used.
- As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

MRI SAFETY INFORMATION

EasyWhip™ sutures are manufactured from UHMWPE, may include a silicone coating and/or cyanoacrylate. EasyWhip™ is MR safe with the needle components removed.

PRECAUTIONS

- Strong familiarity with surgical procedures and techniques for non-absorbable sutures is required before use.
- Prior to use, inspect the device to ensure neither the device nor the packaging is not damaged. Do not use if damage is observed or suspected. Do not use after the expiration date.
- Tip is sharp. Care should be taken to prevent user needle sticks and inadvertent damage to surrounding tissue or suture material.
- Care should be taken to avoid damage from handling this device. Minimize crushing or crimping due to application of surgical instrument such as forceps or needle holders.
- Do not grasp the needle at the point or swage to avoid damage to these areas.
- Do not reshape or bend needles, as this may cause them to lose strength and be less resistant to breaking.
- Assure that all knots have been secured using accepted surgical knot tying techniques. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.
- Single Use Instruments are for single use only and are not Reusable. Do not attempt to re-clean or re-sterilize this product.
- After use, this device may be a potential biohazard and should be handled and disposed of in accordance with accepted medical practice and applicable local and national requirements.

CAUTION

- Federal Law (USA) restricts this device to sale by or on the order of a physician.

ADVERSE REACTIONS

- Adverse effects associated with the use of this type of suture include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occur, enhanced bacterial infectivity, minimal acute inflammatory reaction, pain, edema, transitory local irritation, and erythema at the wound site.
- This type of suture may elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue.
- Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

EasyWhip™ is supplied with needle components pre-attached to size 2 (5 metric) suture. The device is available individually packaged with one (1) EasyWhip™ device or as multipack carton containing ten (10) individually packaged devices.













STERILIZATION

EasyWhip™ is sterilized by Ethylene Oxide Gas (EO). Do not resterilize. Single use only.

STORAGE CONDITIONS

This device must be stored in the original unopened packaging in a cool, dry environment and should not be used after the expiration date.

SYMBOL GLOSSARY

Symbol Title	Symbol	Ref #	Symbol Description
Manufacturer		5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
Do Not Reuse		5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
Sterile EO		5.2.3	Indicates a medical device that has been sterilized using ethylene oxide.
Consult Instructions for Use		5.4.3	Indicates the need for the user to consult the instructions for use.
Use-by Date		5.1.4	Indicates the date after which the medical device is not to be used.
Caution		5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
Batch Code		5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified NOTE: Synonyms for "batch code" are "lot number" and "batch number"
Reference/Catalogue Number		5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
Do not resterilize		5.2.6	Indicates a medical device that is not to be reesterilized.
Do not use if package is damaged		5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.
Prescription Only		N/A	Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician
Quantity		N/A	Indicates the quantity