ReConnex™

PRE-SUTURED TENDON

For ACL Reconstruction

OPERATIVE TECHNIQUE GUIDE KNEE

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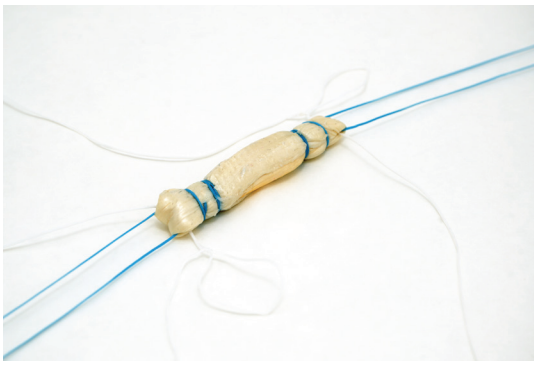
ABOUT

ReConnex™ Pre-Sutured tendon is a 510k cleared medical device intended for use as a construct in anterior cruciate ligament reconstruction utilizing the all-inside technique.



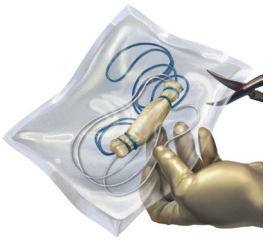
ReConnex consists of allograft tendons that have been cleansed and disinfected using AlloSource's proprietary process. These tendons are pre-sutured to lengths of 62-70 mm and diameters of 8.0-10.5 mm.

The tendons are pre-sutured with blue number 2 Force Fiber ultra-high molecular weight polyethylene (UHMWPE) non-absorbable sutures. The device includes white-loop passing sutures, for the addition of suspension fixation, and blue integrated sutures for pre-tensioning and may be used for button anchor or screw fixation.

OPERATIVE TECHNIQUE

STEP 1

Aseptic techniques must be maintained to minimize the risk of post-operative complications. Peel open outer package to expose the inner pouch and transfer inner pouch to sterile field. Immerse inner pouch completely in warm (37°C to 42°C) sterile isotonic solution. The recommended thawing time is 30-60 minutes, depending upon the size of the pre-sutured tendon device.

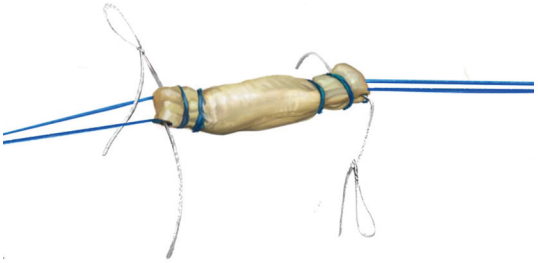


- Do not handle or manipulate until thawing is complete.
- Do not refreeze or refrigerate the graft after thawing has begun.

Aseptically remove pouch from solution and open using sterile cutting instrument.

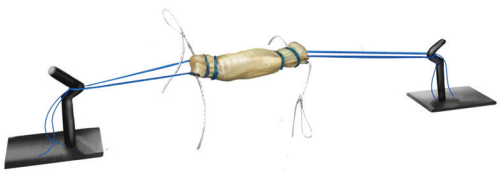
STEP 2

Once removed from the pouch, pre-tension ReConnex by pulling integrated blue sutures at each end until taut. Do not pre-tension by pulling the white loop passing sutures.



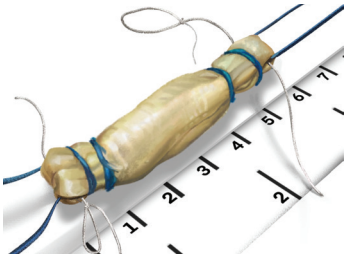
STEP 3

If desired, the long-tailing blue sutures, on each end of the device, can be utilized to suspend the allograft on a sterile tendon workstation.



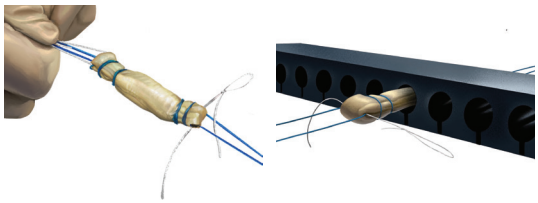
STEP 4

Verify the length of the device using a sterile ruler.



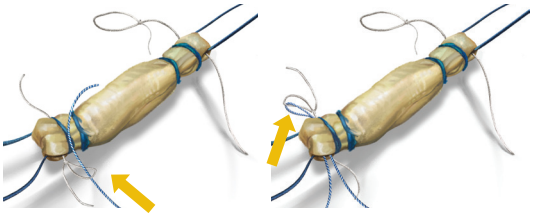
STEP 5

Verify the diameter of ReConnex using a sterile sizing block. On one end of the device, pull the white-loop passing sutures to align with the long blue tailing sutures. Pull all sutures through the slot in the sizing block and pull the device through the sizing block to verify the diameter listed on the package label (ensure the white-loop passing suture remains in place during measuring).



STEP 6

In order to add preferred suspension fixation, utilize the white-loop passing suture by placing the open loop suture of the fixation system through the white-loop of the passing suture. Next, pull the opposite side of the white passing suture to pull the white-loop with suspension fixation suture through the end of ReConnex. Repeat in the opposite direction, if needed, based on the fixation device.

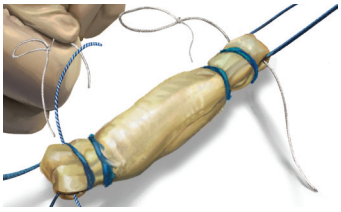


STEP 7

Remove the white-loop passing sutures from both ends of ReConnex prior to implantation of the allograft. The white-loop passing sutures are not to be implanted.

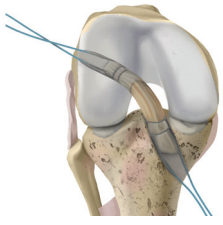
If using screw fixation, use manufacture's recommendations.

USE WARNING:
Do not utilize cortical screws with spiked washers as a fixation method.



STEP 8

Implant the ReConnex device utilizing the all-inside or preferred technique for ACL reconstruction.



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ReConnex™
PRE-SUTURED TENDON

LENGTH	HEAD DIAMETER	CONDITION	PRESERVATION	STORAGE	REF/ PRODUCT #
66 mm +/- 4 mm	8.0 mm	Sterile	Frozen	Frozen	PST17080
66 mm +/- 4 mm	8.5 mm	Sterile	Frozen	Frozen	PST17085
66 mm +/- 4 mm	9.0 mm	Sterile	Frozen	Frozen	PST17090
66 mm +/- 4 mm	9.5 mm	Sterile	Frozen	Frozen	PST17095
66 mm +/- 4 mm	10.0 mm	Sterile	Frozen	Frozen	PST17100
66 mm +/- 4 mm	10.5 mm	Sterile	Frozen	Frozen	PST17105

1.5-year shelf life at -40°C or colder

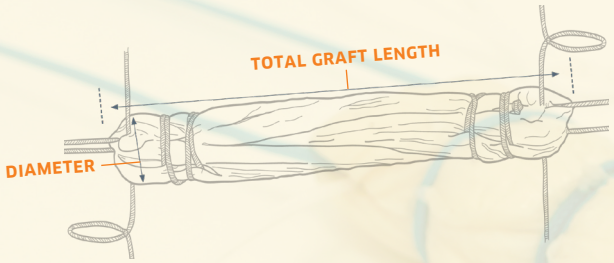
Manufactured with number 2 Force Fiber ultra-high molecular weight polyethylene (UHMWPE) non-absorbable surgical suture.

INDICATIONS FOR USE
ReConnex Pre-Sutured Tendons are intended for use as a construct for anterior and posterior cruciate ligament reconstruction.

This guide is intended solely for use by healthcare professionals. A surgeon must use sound clinical judgment when deciding whether to use a particular product, and treating a particular patient. AlloSource does not dispense medical advice. A surgeon should seek training for the use of any product before using it in surgery. The information provided is intended to demonstrate an AlloSource product. A surgeon should 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 AlloSource product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

MEASUREMENTS

Total Graft Length	Measured from end to end of the allograft.
Diameter	Measured by recording the smallest sizing-block hole through which the device will pass.



AlloSource, a life sciences organization, helps restore patient functionality by transforming the gift of human tissue donation into enhanced medical products that enable a life of movement, health, and wellbeing. We partner with medical professionals and biomedical companies who share our drive for innovation and quality in the use of human tissue allografts for medical advancements. Headquartered in Centennial, Colorado, we have served a global marketplace since 1994. Learn more at allosource.org.

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