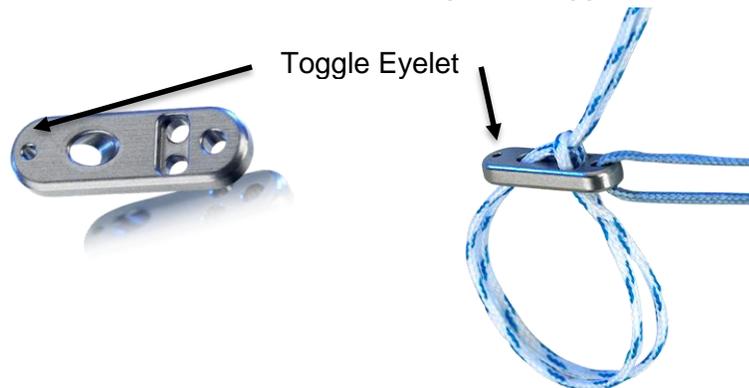
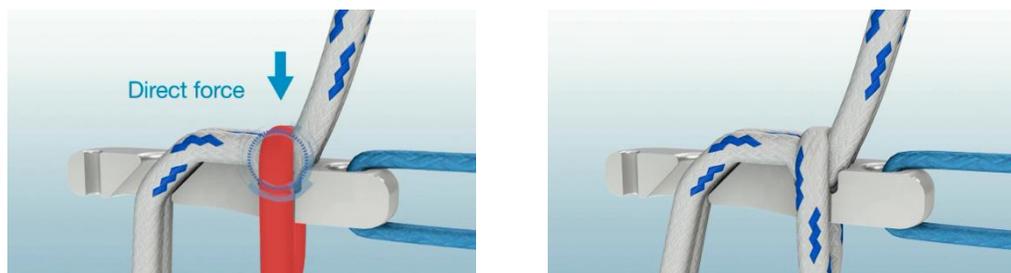


Frequently Asked Questions

1. Does the piercing of the suture through itself damage the suture?
Answer: No, piercing the suture through itself does not damage the suture. The fibers are not being cut, rather separated to allow one strand to pass through the other.
2. What size suture will fit through the Toggle Eyelet?
Answer: Suture size UPS 2 or smaller will fit through the Toggle Eyelet.

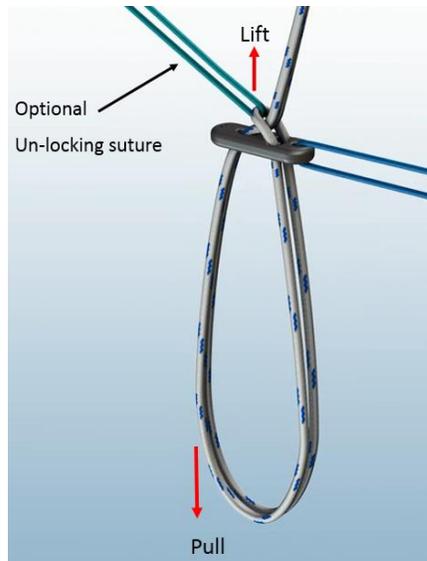


3. How much force is required to lock GraftMax Button Locking Loop into the Locking Pocket?
Answer: Very little force, only slight tension on the graft applies direct force to the locking loop pulling and locking the suture tails into the locking pocket. However, as the load on the loop increases, so does the locking force.



4. What is the “un-locking suture” and is it required?

Answer: An un-locking suture is optional. It can be added under the Locking Loop to easily lift the loop un-locking the suture tails. This makes it easier to enlarge the loop if needed.



5. Why does the graft shift backwards during tensioning of the graft and GraftMax Button?

Answer: When applying tension to the graft, the loop and graft travel slightly (approximately 2-3mm) as the Locking Loop locks down into the Locking Pocket.

Figure A: Locking loop before locked

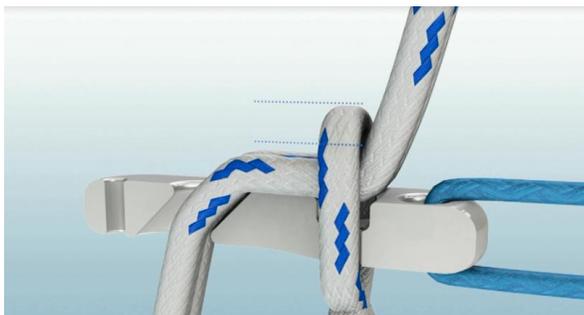
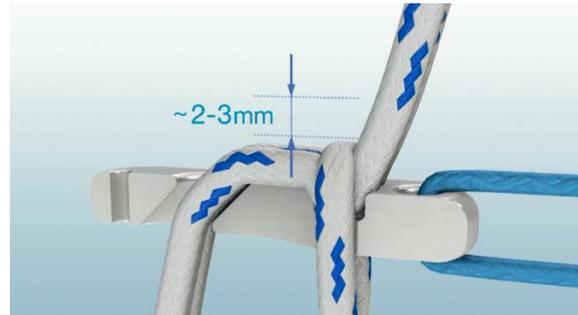


Figure B: Locking loop locked in locking pocket



6. What reaming method(s) can be used to prepare the femoral tunnel for ACL reconstruction using GraftMax™ Button for femoral fixation?

Answer: Any reaming method that prepares the appropriate size femoral socket and button channel can be used including: Trans-tibial, straight/standard medial portal, curved medial portal, outside-in.

7. Can the GraftMax Button be used with the XO Button Holder to mark the sutures?
 Answer: Yes, the Graftmax Button fits in the XO Button Holder. Note: The button should be positioned upright, not flat in the XO Button holder, to mark the suture loop at the AC length corresponding to the button exiting the cortex (see figure A). This will result in approximately 10mm difference when the button is settled flat in the XO Button holder (see figure B) representing final button position.

Figure A: GraftMax Button sutures being marked at 30mm representing button exiting cortex.

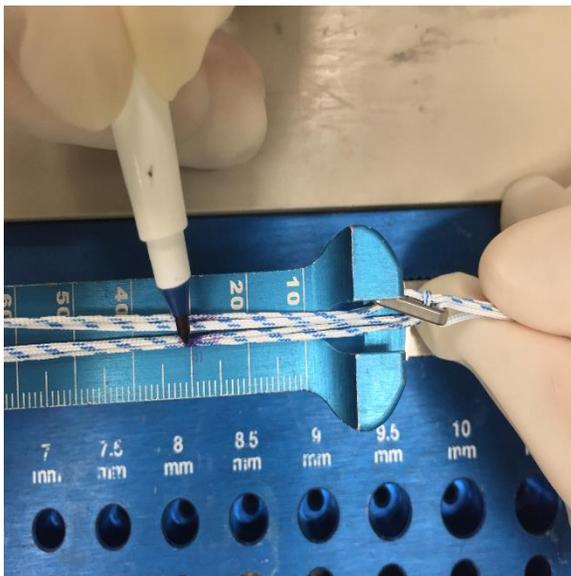
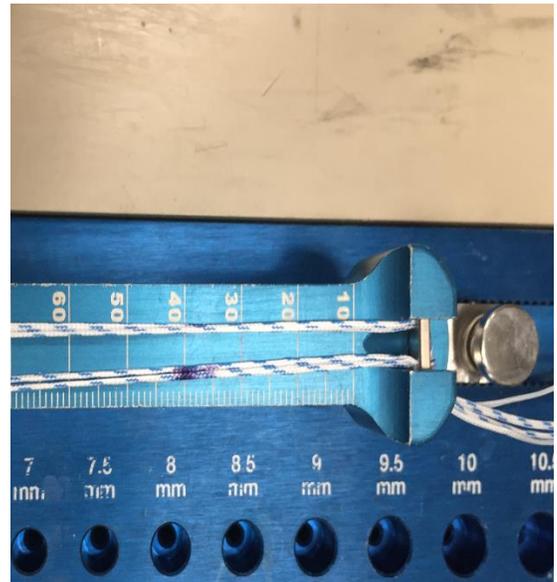
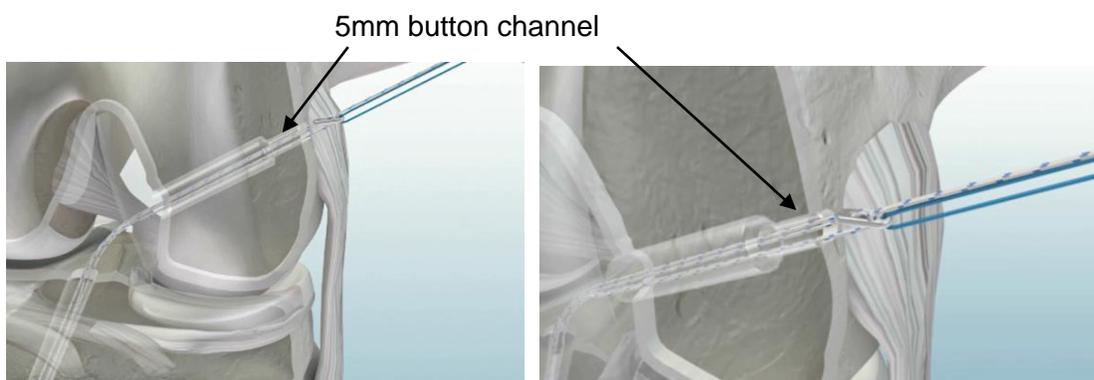


Figure B: 30mm suture marking with button flat in the XO Button holder.



8. What size channel does the GraftMax™ Button need to pass through?
 Answer: A 5mm button channel is required to pass the GraftMax™ Button.



9. Does GraftMax Button's #5 suture loop cause damage to the soft tissue graft?
Answer: No, the suture does not cause damage to the graft. Extensive performance testing has been conducted showing no damage. Twenty-two samples were tested and none of the samples exhibited graft damage. For each sample, a soft tissue graft loaded into the GraftMax Button loop, passed into the knee and fixed. The knee was then cycled for 1000 cycles from 60-200N.
10. Will the GraftMax Button become un-locked or loosen when lax?
Answer: No, the GraftMax Button will not un-lock or loosen when lax. Testing was performed with 1000 cycles of force from 0 – 250N with 1 minute of rest period (0 N) every 100 cycles then pulled to failure. This was to replicate real life scenario of walking during rehabilitation as well as simulate times of rest. The result was that the GraftMax Button met the ultimate failure strength and displacement requirements.

11. Is it necessary to tie a knot on top of the GraftMax Button?
Answer: No, it is not required to tie a knot on top of the button. This is an optional step for surgeons who prefer to tie a knot. All of the GraftMax Button functional data is performed without the optional step of tying a knot on top of the button.



12. If the suture tails are cut at skin level, doesn't that leave a suture tail?
Answer: Yes, however the suture will migrate below the skin and soft tissue and will not be exposed. This is the standard technique for competitive adjustable loop buttons.

