



K041553: Arthrex Suture Graft Kit

The purpose of this Memo is to document the addition of the GraftLink, suture construct, as a line extension to the Arthrex FiberWire family cleared via 510(k) in K041553 (Arthrex Suture Grafting Kit).

The GraftLink is comprised of donated human tendon(s) which are pre-sutured with FiberWire Suture.

The GraftLink is intended for use in soft tissue approximation or ligation.

The product labeling and intended use, and the technology, engineering and performance of the **GraftLink** are the same as the *Arthrex Suture Grafting Kit*. The mechanical testing data demonstrated that the tensile strength of the proposed devices meet or exceed the minimum acceptance criteria.

The proposed changes to *Arthrex Suture Grafting Kit* are considered minor and do not significantly affect the safety or efficacy of the device. Additionally, the proposed changes were not in response to adverse events in the field. Arthrex, Inc. has determined that the **GraftLink** do not require a 510(k) submission at this time.

Sincerely,

Courtney Smith, RAC
Manager, Regulatory Affairs