BioBrace® Augmentation in Anterior Cruciate Ligament Reconstruction Procedures

NCT06948591

Status	RECRUITING
Sponsor	CONMED Corporation
Enrollment	500 participants

Key Eligibility Criteria

Inclusion (11)

- Underwent ACL reconstruction with a tissue graft augmented with BioBrace® within the past 24 months from study start date or scheduled to undergo ACL reconstruction with a tissue graft augmented with BioBrace®.
- Between 14 and 70 years old at the time of surgery.
- Can understand the content of the subject information / Informed Consent Form (ICF) for the prospective portion of the study.
- Is willing and able to participate in the prospective data collection protocol and comply with the required data collection.
- If the subject has already undergone ACLR within the past 24 months, subject must have at least two (2) of the following measures at baseline and 1 year post-operatively:

... and 6 more (see full listing online)

Exclusion (4)

- Has other concurrent medical or other conditions (chronic or acute in nature) that in the opinion of the participating investigator may prevent participation or otherwise render subject ineligible for the study.
- Is currently participating in an investigational therapy (device and/or pharmaceutical) within 30 days prior to entering the study or such treatment is planned during the 3 years following enrollment into the study.
- Underwent or scheduled to undergo a multi-ligament reconstruction procedure (excluding cases where a torn MCL is treated non-operatively).
- Females of child-bearing potential who are either pregnant or breastfeeding at the time of surgery.

Locations (1 total)

ConMed, New Haven, Connecticut, United States