

PROVEN Precision Sizing

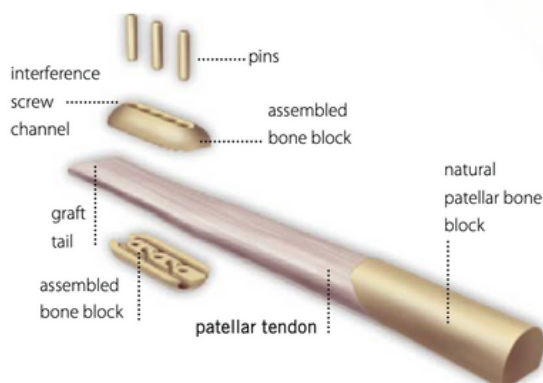
BTB Select™



BTB Select™ allograft is an innovative solution that allows for precision-sized matching relative to the intra-articular length of BTB allografts. The BTB Select allograft is sterilised without the use of irradiation through RTI's BioCleanse® process, which inactivates or removes potential pathogens from tissue using a specific formula while maintaining the tissue's biomechanical properties.

Features:

- Assembled technology provides precision-sized matching relative to the intra-articular length of BTB allografts.
- Natural patellar bone block allows for multiple fixation types.
- Assembled cortical bone block is constructed with proprietary anti-slip design, to keep tendon from slipping through bone blocks.
- Assembled cortical bone block is secured with three interference fit machined cortical bone dowels to ensure maximum stability of the construct.
- Interference screw channel on assembled cortical bone block aids with interference screw fixation.
- Assembled bone block allows for use in a standard 10mm tibial bone tunnel.
- Graft tail allows for supplemental fixation.

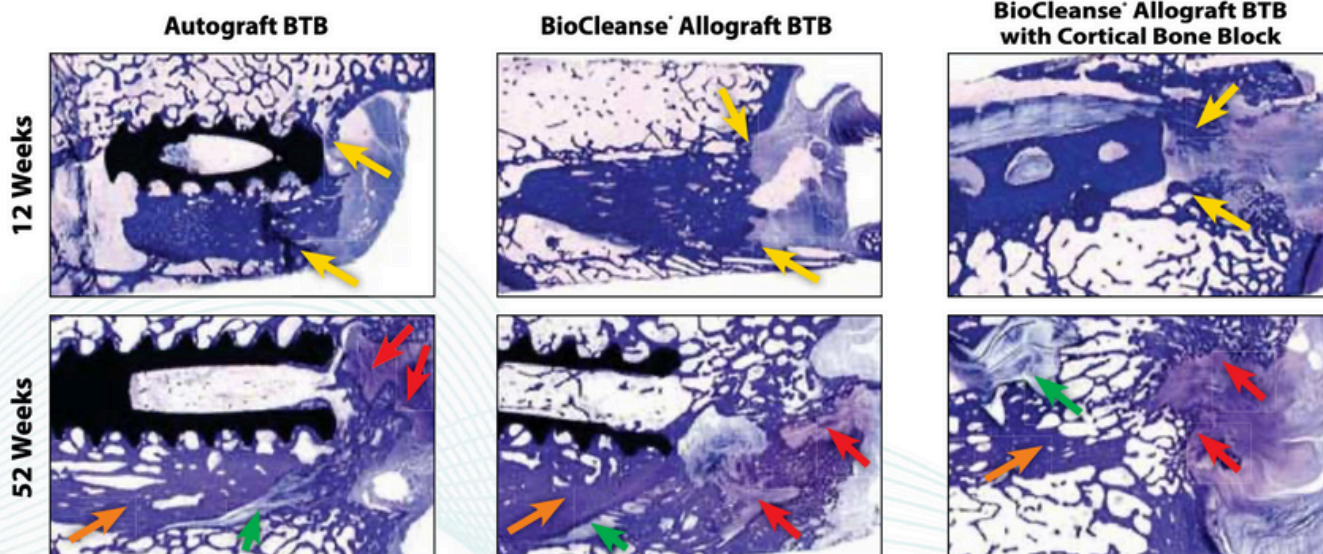


BTB Select Assembly

Biomechanical properties:

- Assembled cortical bone block load to failure (LTF) is similar to interference screw LTF (650N average LTF in a bench top study; data on file).
- Mid substance LTF of the BTB Select is typical of a patellar tendon

BioCleanse® Allograft Sheep Study



NOTE: The heterochromatic purple staining of the tendons towards the tunnel opening indicates the presence of a cartilaginous transition zone. At higher magnification, a dense band of Sharpey's fibers anchoring the tendon to the newly formed bone is visible.

- ➔ Infiltration of woven bone
- ➔ Neo-ligament attached to newly formed
- ➔ woven bone Graft incorporation
- ➔ Original tendon

- An ovine model (four animals per time point/group) of ACL reconstruction was used to compare and assess graft incorporation and remodeling in the tunnel.
- Three groups were examined 1) Autograft BTB 2) BioCleanse-processed allograft BTB 3) BioCleanse-processed allograft BTB with assembled cortical bone blocks.
- At 12, 24, and 52 weeks, graft incorporation and remodeling were examined. The implants were also tested by pulling the tibia and femur apart until implant failure.
- At 12 weeks, all three groups indicated similar incorporation and remodeling in the tunnel, characterised by infiltration of woven bone into the tunnel.
- At 12 weeks, all three groups failed by avulsion.
- Between 24 and 52 weeks, all three groups showed neo-ligament attached to newly formed woven bone and significant graft incorporation.
- At 24 and 52 weeks, all three groups failed mid-substance.

Conclusion:

In this model, the results of this study suggest that neither the BioCleanse® Tissue Sterilisation Process nor the use of assembled cortical bone blocks negatively impact the overall success of an ACL reconstruction procedure when compared to using an autograft BTB. At 12 weeks, bone incorporation was not the mode of failure in any of the three groups.

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