

**Smith & Nephew DonJoy Inc.**

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**Smith + Nephew**

K965073

Q. SUMMARY OF SAFETY AND EFFECTIVENESS

The 9 x 25mm S.I.S. ACL Fixation Screw is substantially equivalent to the Arthrex Inc. Cannulated Sheathed Interference Screw, the Concept, Inc. Cannulated Conical Tip Interference Screw, the Depuy Kurosaka Fixation Screw, and the Smith & Nephew RCI ACL Fixation Screw with regard to basic design, intended use, material, and size. The screws are made from implant grade titanium (T16A14V ASTM F136) which is a well know and accepted material for implantable devices. The 9 x 25mm S.I.S. ACL Fixation Screw for Tibial Fixation of Hamstring Tendons Grafts functions the same as the Smith & Nephew RCI ACL Fixation screw for Hamstring Tendons Graft Fixation in the Tibial Tunnel.

Smith & Nephew, Inc.  
DonJoy Division



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