

July 2016

SIMITRI STABLE IN STRIDE® IMPLANT

The Simitri Stable in Stride® implant was designed to stabilize the canine stifle. This module will cover the following information:

- Implant design
- Implant testing
- Implant Indications contraindications

A. Implant design

The cranial cruciate ligament performs two main functions: It limits cranial translation and internal rotation of the tibia relative to the femur. As the level of disease increases within the ligament, its ability to perform these functions diminishes. This leads to progressive stifle instability, the consequence of which is increasing lameness, progressive degenerative joint disease, loss of comfortable range of motion, decrease in affected limb thigh circumference and a compensatory increase in thigh circumference of the unaffected limb. Current surgical techniques affect stifle kinematics and or alter stifle geometry.

The Simitri Stable in Stride implant is a three-part modular implant with surgical grade stainless steel femoral and tibial plates and an ultra high molecular weight polyethylene articular insert. The femoral plate has a ball and stem and interdigitates with the tibial plate via a travel channel.

The femoral plate is currently available as 2.7 mm, 3.5 mm small and 3.5 mm standard. A 3.5 mm broad plate is in the design stages. Each plate size has a maximum patient body weight (Table 1-1). Tibial plates are currently available in 2.7 mm (10 mm offset) and 3.5 mm (10, 13 and 16 mm offset). The small and standard 3.5 femoral plates can be used with any of the 3.5 tibial plate offset sizes.

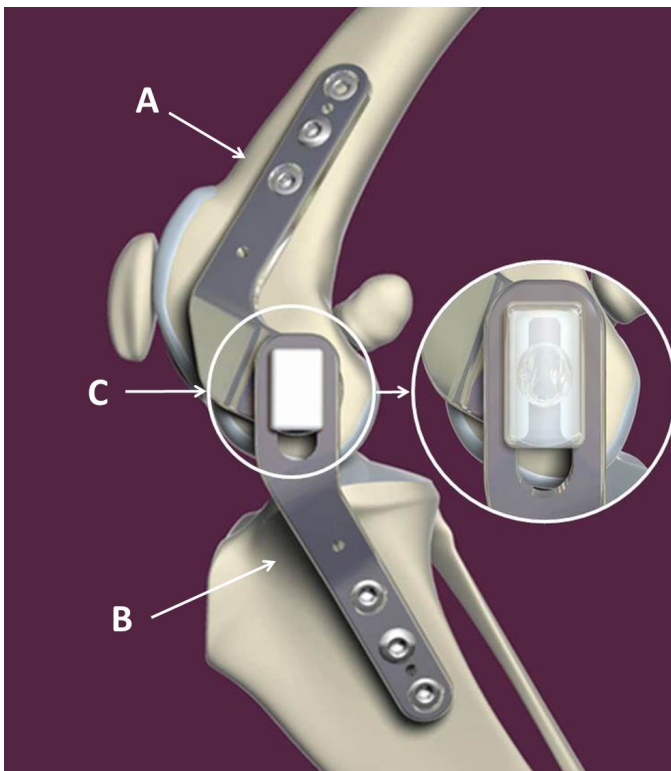


Figure 1: Simitri Stable in Stride® implant. A. Femoral plate. B. Tibial plate C. articular insert. Note: Each plate has three screw holes and two, 2 mm holding pin holes for temporary implantation. The screw holes are number # 1 to # 3, the hole closest to the joint is # 1. 3.5 mm plates accept 3.5 or 4.0 mm cortical locking screws. 2.7 mm plates only accept 2.7 mm screws.

Permanent implantation is achieved via three bicortically placed locking screws of appropriate size for patient (Table 1-1). The implant is positioned on the inside of the affected limb and remains completely extracapsular. Once implanted it provides immediate and continuous translational and rotational stability while minimally affecting stifle kinematics.

B. Implant Testing

The Simitri Stable in Stride® implant has undergone biomechanical testing, 3D computer modelling and clinical trials.

Biomechanical testing of the implant was conducted using and Instron 3343 at the New Jersey Institute of Technology. Static and dynamic biomechanical tests included:

- Range of motion – flexion/extension and axial twist
- Tibial thrust
- Wear testing

Results of biomechanical tests indicated that the implant would allow for functional range of motion (flexion, extension and axial twist) within the normal canine biomechanical ranges and provide the strength required to prevent tibial thrust in the canine patient. Tibial thrust was tested out to 1000 N with no failure of the EAI. Wear testing showed structural stability through 1,000,000 cycles at 250 N with loss of stability occurring at 791,373 cycles at 350 N.

Based on an *in silico* comparison using a 3D computer model of a 33 kg Golden retriever, stifle joint biomechanics were improved in the EAI-managed stifle compared to the CrCL-deficient stifle joint and the EAI treated CrCL deficient stifle was predicted to return ligament loads and tibial kinematics closer to the state of the intact CrCL stifle than did the TPLO managed (Bertocci et al, Vet Surg April 2016).

Cadavers were used in the early stages of design and through out the testing procedure to refine the design and surgical procedure prior to beginning clinical trials.

The results of the first 66 implantations will be published in the August 2016 issue of Veterinary Surgery.

C. Indications and Contraindications

The Simitri stable in Stride® implant is **indicated** as a primary treatment in dogs with:

- partial or complete tears of the cranial cruciate ligament
- partial or complete tears of the caudal cruciate ligament
- partial or complete tears of both the cranial and caudal cruciate ligaments

The implant can be used in patients with concurrent collateral ligament injuries or luxating patella. However, these injuries must undergo a primary repair prior to implantation of the Simitri Stable in Stride® implant.

The Simitri stable in Stride® implant is **contraindicated** in cases:

- where stifle instability is associated with either infection or neoplasia.
- with excessive tibial torsion.
- that exceed the recommended patient body weight of the implant.

	2.7 mm standard	3.5 mm small and standard	3.5 mm broad
Maximum patient weight	≤ 12 kg (25 lb)	≤ 34 kg (75 lb)	≤55 kg (120 lb)
Locking screw sizes	2.7 mm only	4.0 mm screws are always used in hole #1 patients > 30 kg - assuming sufficient bone size, use 4.0 mm screws in all screw holes patients < 30 kg - 3.5 mm can be used in holes #2 and #3	

Table 1-1 Maximum patient body weight and locking screw sizes for different implant sizes, all screws are cortical locking screws.