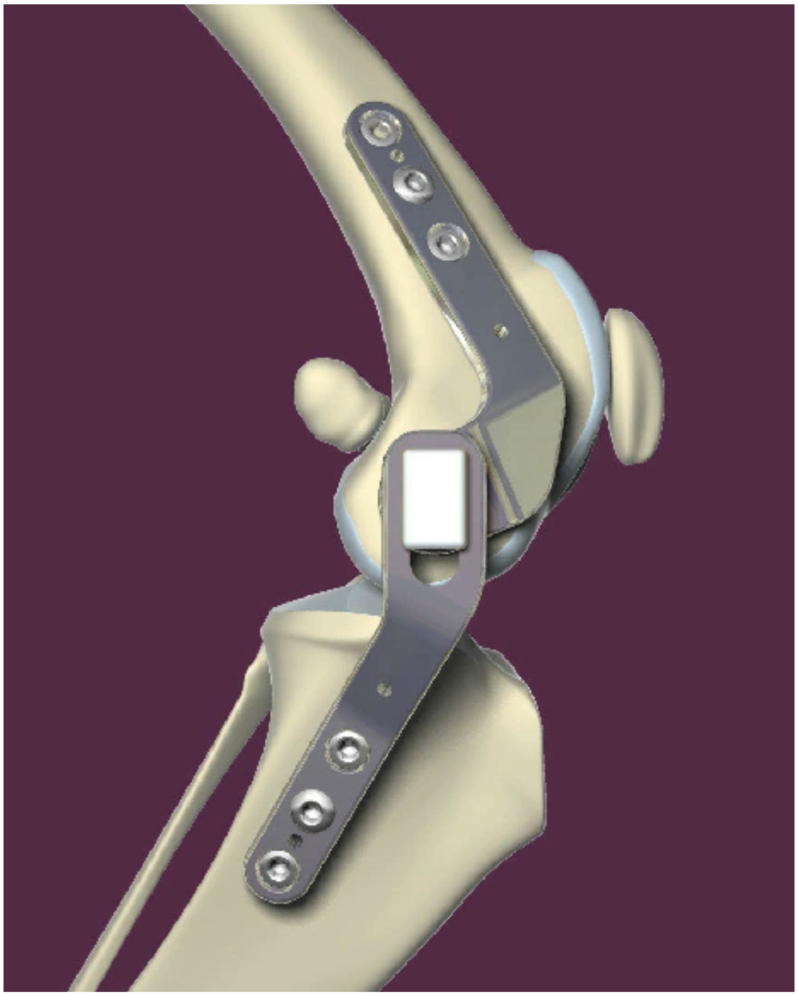
NEW GENERATION DEVICES
The Body Knows the Difference®

Simitri Stable in Stride®

Surgical Technique



Note: Although this technique contains descriptions of a particular surgical procedure, it is only to be used as a tool for licensed educated medical professionals. Ultimately, the surgeon should be guided by their own professional judgment in making any final determinations regarding product usage and technique.

Introduction:

The New Generation Devices (NGD) Simitri Stable in Stride™ internal stifle stabilization System is a patented three part modular system, designed to provide the surgeon with an option for the management of any form of canine stifle instability. Simitri may be of benefit in speeding up the recovery period by providing immediate stabilization upon repair. Laboratory and clinical research have shown Simitri to be an effective method of managing canine stifle instability.

Primary surgical indications:

(The damaged ligaments do not require a primary repair prior to Simitri implantation).

- Primary repair method for cranial cruciate ligament (CrCL) disruption. Either partial or complete.
- Primary repair method for caudal cruciate ligament (CaCL) disruption. Either partial or complete.
- Primary repair method for any combination of cranial and or caudal cruciate ligament disruption.

Secondary surgical indications:

(The damaged ligaments must undergo a primary repair using standard accepted surgical techniques prior to Simitri implantation).

- Medial collateral ligament (MCL) disruption. Either partial or complete.
- Lateral collateral ligament (LCL) disruption. Either partial or complete.
- Concurrent luxating patella.

Contraindications:

- Simitri is contraindicated in cases with neoplastic or infectious diseases of the stifle joint.
- As with all bone plates, Simitri is contraindicated when active infections are present at the implant site.

Design Features:

- Simitri can address instability of the diseased canine stifle, while allowing for normal range of motion, normal internal and external tibial rotation, normal joint compression and expansion and for normal varus and valgus tibial movement.
- Simitri is comprised of implant quality stainless steel femoral and tibial plates which are interconnected with an ultra high molecular weight polyethylene (UHMWPE) sliding articulation.
- Simitri's femoral and tibial plates each have two, 2mm holding pin holes. These are designed to accept a 5/64" pin and are used to hold the plates in place prior to final implantation.
- The plates can be independently contoured to allow for variations in anatomy and are designed to accept either cortical screws or NGD locking screws.
- Plates are available in a variety of sizes to accommodate varying anatomies and breeds.

Background:

The optimal surgical treatment for the cranial cruciate ligament (CrCL) deficient stifle should be to provide immediate stabilization to the unstable stifle joint while allowing normal joint contact mechanics and movement in all planes (1,2). Many studies have shown that the efficacy of current surgical techniques for treatment of the CrCL deficient stifle are similar and that progressive osteoarthritis is a common consequence regardless of the surgical procedure chosen (3-6). Current evidence suggests that there is no one surgical procedure that can claim superiority and consistently return dogs to normal function after CrCL injury and based on the goals of treatment described above, none of these current surgical techniques could be considered "optimal" (5,6).

Simitri, which can be utilized as a completely extra-capsular articulated stifle stabilizing implant, has been in development since 2012. The implant provides immediate and continuous cranial caudal and rotational stability, regardless of the phase of stride or position of the stifle.

1. Kim SE, Pozzi A, Banks S, Conrad B, et al. Effect of tibial plateau leveling osteotomy on femorotibial contact mechanics and stifle kinematics. J Vet Surg 2009; 38:23-32.

2. Johnston KA. The effect of stifle angle on stifle kinematic following TPLO: An in vitro experimental analysis, Masters Thesis Virginia Polytechnic Institute and State University April 2010 Blacksburg VA.

3. Morgan JP, Voss K, Damur D, Guerrero T, Haessig M, Montavon P. Correlation of radiographic changes after tibial tuberosity advancement in dogs with cranial cruciate deficient stifles with functional outcome. J Vet Surg 2010; 39: 425-432

4. Lineberger JA, Allen DA, Wilson ER, et al. Comparison of radiographic arthritic changes associated with two variations of tibial plateau leveling osteotomy. Vet Comp Orthop Traumatol 2005; 1: 13-17

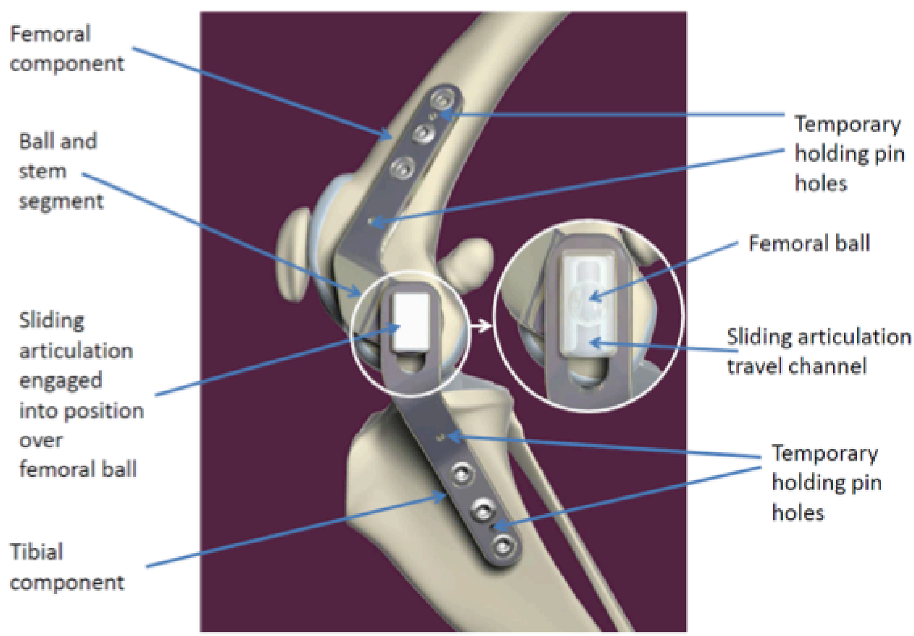
5. Budsberg SC, Aragon LA. Application of evidence-based medicine: cranial cruciate ligament injury repair in the dog. J Vet Surg 2005; 34: 93-98.

6. Conzemius MG, Evans RB et al. Effect of surgical technique on limb function after surgery for rupture of the cranial cruciate ligament in dogs. J Am Vet Med Assoc 2005; 226: 232-236.

Design Rationale and Proposed Advantages:

- Provide immediate and continuous cranial caudal and rotational stifle stability regardless of the phase of stride or position of the stifle
- Have minimal impact on normal stifle kinematics
- Can be used completely extra-capsular
- Less invasive (no osteotomy required)
- Does not require any specialized implantation equipment

Simitri Implant



Designed by Neil Embleton, B.Sc., DVM, Veronica Barkowski, DVM, Helivet Mobile Surgical Services, Sundre, Alberta, Canada

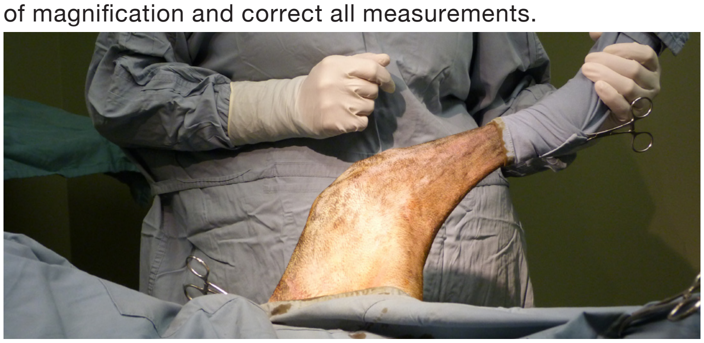
1. Preparation

Preoperative planning is important for implant selection and determining plate positioning. Simitri has been designed to fit a wide weight range of patients, however, due to great variability in femoral condyle sizes between breeds, selection of the appropriate sized implant is primarily determined by the size and shape of the medial femoral condyle.

Two pre-surgical radiographs of the stifle are required; an extended lateral view with the femoral condyles superimposed and a cranial caudal view. Measurements made on the lateral view include: Femoral diaphysis width and dimensions of the medial femoral condyle. These measurements aid in the selection of an appropriately sized femoral implant. The cranial caudal view is used to assess tibial component size (offset), approximate the length of screws required and assess any anatomical abnormalities that may adversely affect the procedure.

The extended lateral radiograph is also used to predetermine the ideal placement of the implant with the goal of placing the femoral ball at the theoretical center point of the medial condyle. Measurements made on this radiograph will be used during surgery to find this location on the patient.

It is important to remember that all radiographic images are magnified (range of 5% to 25%) and therefore all measurements made on a radiograph must be corrected for this magnification. To determine magnification, radiograph a metal object of a known length or diameter at the same height as the patient's stifle joint, determine the percentage of magnification and correct all measurements.

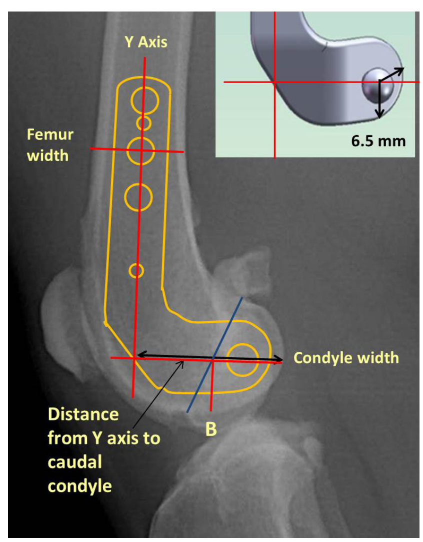


2. Implant Size Selection

It is important to select an appropriately sized implant to fit the medial femoral condyle of each patient. With the screw segment of the femoral plate parallel to the diaphysis of the femur, the ball on the plate will be centered over the medial condyle where the medial collateral ligament attaches, which is in a position caudal to Blumensaat's line. If the distal portion of the femoral plate is wider or deeper that the medial condyle, then the plate is too large. When the ball is in the correct location, the screw segment of the femoral shaft will fit within the limits of the femoral diaphysis. The tibial plate offset size is selected based upon the difference between measurements of the width of the proximal tibial epiphysis and the diaphysis.

3. Patient Preparation and Positioning

The patient is induced and maintained using a balanced anesthetic protocol. Epidural and preoperative antibiotics are administered. The surgical limb is prepped from the greater trochanter to the distal tibia using aseptic technique. The patient is positioned in dorsal recumbency and the limb is draped in a standard fashion.



Surgical tip: Placing the patient's back in an appropriately sized V trough will aid in positioning.

4. Surgical Approach

A 15cm curvilinear incision is made on the medial aspect of the surgical limb. The incision is centered over the stifle and extends equidistant both proximally and distally (Figure A). Arthroscopy or arthrotomy is performed as required. Meniscal release is not required as further meniscal damage has not been associated with Simitri cases.

Exposure to the proximal tibia is made with a 6 cm incision through the conjoined tendons of the Sartorius, Gracilis and Semitendinosus. The incision begins at the level of the proximal tibia and extends distally while remaining parallel to the tibial crest. Caudal reflection of the incised tendons exposes the proximal tibia and medial collateral ligament. This ligament will be used as a landmark for plate location (Figure B).

For exposure of the distal femur, extend the facial incision proximally between the bellies of the cranial and caudal Sartorius muscles, exposing the Vastus musculature (Figure C).

Using palpation, locate the tendon of the Pectineus, place a pair of scissors cranial to this landmark and bluntly dissect and expose the Vastus Medialis. Be cautious to preserve the descending Genicular artery and medical articular nerve. Cranial reflection of this muscle will expose the medial femur (Figure D).

In order to place the femoral plate in close contact with the medial femoral diaphysis, a periarticular soft tissue tunnel must be created. Using a heavy pair of curved Mayo scissors, they are introduced at the level of the femoral exposure, deep to the descending genicular artery and medical articular nerve. While remaining superficial to the joint capsule, the scissors exit distally at the level of the distal patella, cranial to the medial collateral ligament. The tunnel remains extracapsular and allows for the femoral plate to be implanted in close contact with the condyle (Figure E).

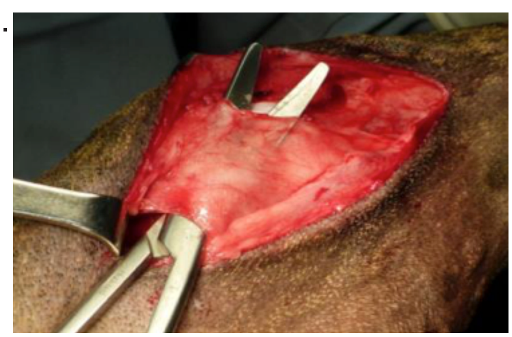
A.

B.

C.

D.

E .



5. Femoral Plate Contouring

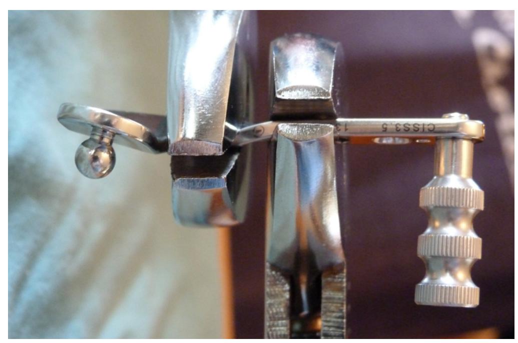
The goal of the contouring is two fold: (1) to ensure that throughout the full range of motion, the two plates remain as parallel as possible where they are in contact at the articulation and then (2) to ensure that the screw segment of each plate is implanted in close contact with the diaphysis. The femoral plate comes pre-contoured. However, depending on the position of the screw segment on the femoral diaphysis, adjustments may be required to maintain the correct position of the ball relative to the long axis of the femur. Contouring does not need to be exact, as the plate uses locking screws. Place locking plugs in the screw holes prior to significant contouring. This will prevent damage to the screw holes which may affect screw locking.

Bend

Generally a 1-2 mm concave bend located between the screw segment and the ball segment is needed to accommodate varying shaped distal femora. The goal of this bend is to ensure that the femoral plate follows the contour of the distal femur and that the ball and stem are as perpendicular as possible to the long axis of the femur. Be conservative with the amount of bend induced as it can greatly affect the proximal distal orientation of the femoral ball.

Twist

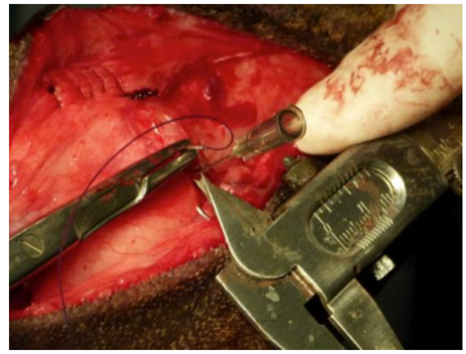
Femoral plates come pre-contoured such that the screw segment and ball segment are essentially parallel. The degree of twist adjustment is determined by the position of the screw segment relative to the midpoint of the femoral diaphysis. If the screw segment is located cranial to the midpoint the twist is decreased. If the screw segment is located caudal to the midpoint then the degree of twist is increased. This ensures that the screw segment is in close contact with the femur and the ball and stem are neither deflected cranially or caudally relative to the femur.



6. Femoral Plate Positioning

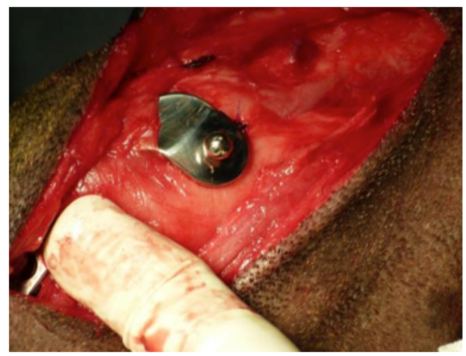
It is important that the stifle is held in full extension during femoral plate positioning. To determine the distal extent of the femoral plate, locate the most proximal aspect of the tibial plateau at the level of the MCL. Using a 25 ga. needle, walk along the cranial edge of the MCL until it enters the joint. Using the measurement obtained during preoperative planning, measure proximal to the needle with a caliper/ruler and place a stay suture centered over the MCL (Figure F). The screw segment of the femoral plate is slide into the soft tissue tunnel, aligned parallel to the long axis of the femur and positioned as predetermined during the preoperative planning. The femoral plate is positioned such that the distal edge of the plate is in contact with the stay suture with the ball located over the center of the MCL (Figure G).

F.



With the limb in full extension, place a k-wire in the proximal pin hole and engage through the first cortex. Flex and extend the leg and visualize the stay suture following along the distal portion of the plate. If the stay suture's position remains constant, then the ball is in an isometric position. If the suture moves away during flexion, the ball is in a cranial position and should be moved caudally. If the suture moves under the implant during flexion, the ball is in a caudal position and should be moved cranially. If after position adjustment the ball is located either too far caudal or cranial to the MCL, re-evaluate and adjust the proximal distal position of the femoral plate. Once acceptable placement is confirmed, place a k-wire in the distal pin hole and engage both cortices.

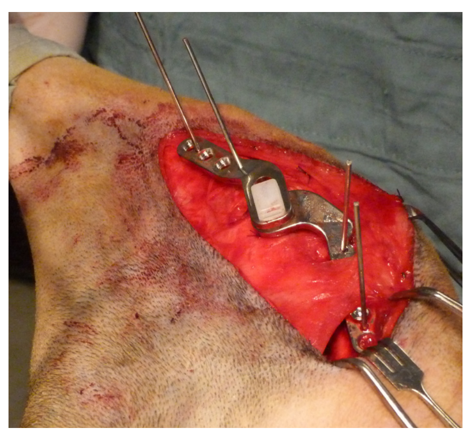
G.



7. Tibial Component Positioning

With the limb held in full extension and the tibia in a neutral position, place the tibial plate by sliding the ball from the femoral plate into the articulation. The shaft of the tibial plate is aligned over the thickest part of the tibia. Ideally, the ball should be located roughly in the middle of the sliding articulation and the tibial and femoral plates should be as parallel as possible. If the screw segment is not in contact with the tibial diaphysis, a contouring adjustment to one or both of the tibial bends may be needed. Correct placement is confirmed when there is no resistance felt within the stifle and the ball movement is minimal and does not come within 1-2mm of either the top or the bottom of the articulation (Figure H).

H.

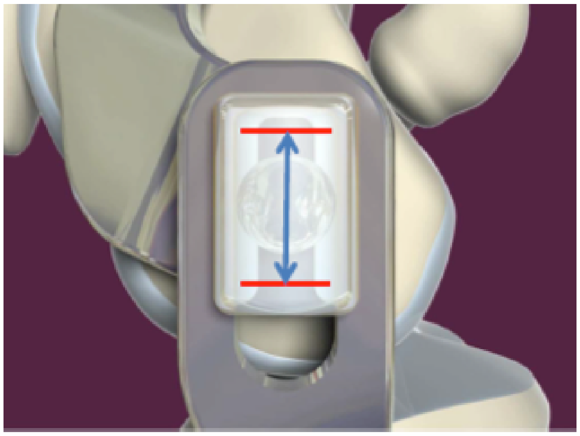


Once placement is correct, place a k-wire in the distal hole, reduce the cranially subluxated tibia and then place an additional k-wire in the proximal hole. At this point, both plates have been provisionally fixed in the proper location.

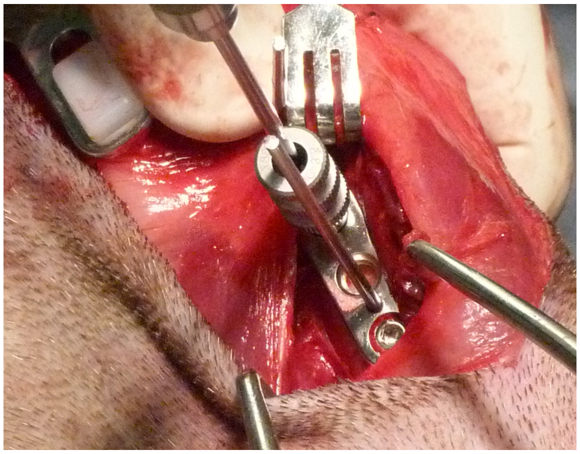
8. Confirmation of Placement

Fully flex and extend the stifle with the components temporarily fixed in place. There must be absolutely no interference with full flexion and full extension. The ball should not travel closer than 1-2mm to either end of the travel channel. Any interference with normal stifle flexion or extension suggests incorrect placement of the implant (Figure I). The femoral and tibial plates around the area of the articulation section should remain as parallel as possible throughout the full range of motion. If the articulation does not remain parallel, adjustments must be made to either the position of the components or the tibial offset. Typically, the femoral plate positioning or contouring is the likely cause.

I.



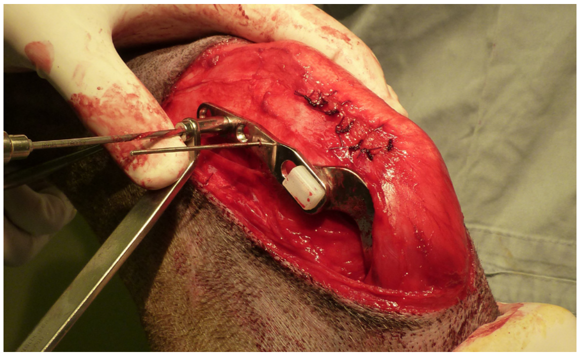
J.



9. Permanent Implantation

The femoral component is implanted first. Three bicortically placed 3.5 or 4.0 mm cortical locking screws are used in the femoral plate. The screw holes are numbered 1, 2 and 3. Screw hole #1 is closest to the joint. A 3.5 mm non locking cortical screw is initially used to compress the plate to the femur. Screw holes 2 and 3 are then drilled and 3.5 or 4.0 mm cortical locking screws are then inserted. The cortical screw in hole #1 is then exchanged for a 4.0 mm cortical locking screw. Holding pins are removed once two of the three screws have been placed (Figure J). The process is repeated for the tibial component where three locking screws are to be used (Figure K). The tibial plate is generally not compressed prior to locking screw insertion. As with the femoral plate, hole #1 always uses a 4.0 mm cortical locking screw. Prior to closure, reconfirm correct positioning by placing the stifle through full flexion and extension. The stifle should move freely with no interference felt within the joint.

K.

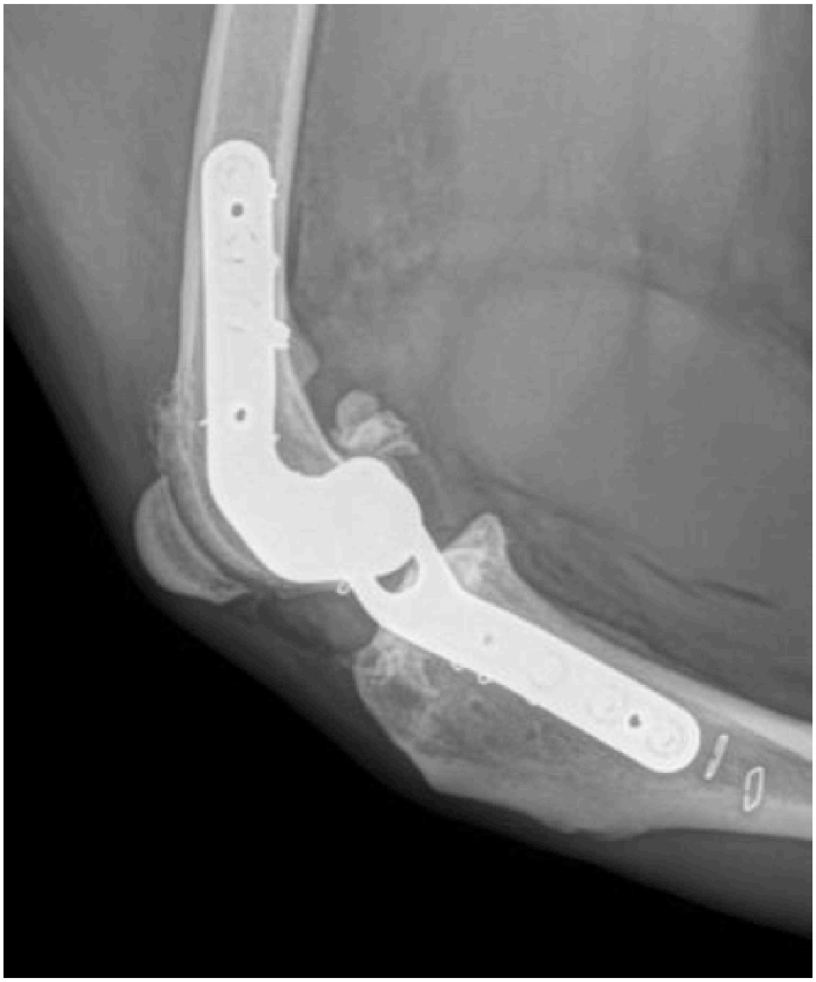


10. Closure

Routine closure of the soft tissues is performed using a continuous pattern of an appropriate suture. The skin is closed with surgical staples or as per surgeon's preference (Figure L).

L.

Post-operative Radiographs



Simitri Plate Ordering Information

Plates		
Cat#	**Description**	
SIMI2.7L	2.7mm Simitri Plate Left	
SIMI2.7R	2.7mm Simitri Plate Right	
SIMI3.5-10L	3.5mm Simitri Plate with 10mm offset Left	
SIMI3.5-10R	3.5mm Simitri Plate with 10mm offset Right	
SIMI3.5-13L	3.5mm Simitri Plate with 13mm offset Left	
SIMI3.5-13R	3.5mm Simitri Plate with 13mm offset Right	
Screws		
Cat#	**Description**	**Length**
LSTCBS2.7-xx	2.7mm Locking Self-Tapping Screws	10mm-34mm in 2mm increments
LSTCBS3.5-xx	3.5mm Locking Self-Tapping Screws	12mm-40mm in 2mm increments
LSTCBS3.5-xx	3.5mm Locking Self-Tapping Screws	40mm-60mm in 5mm increments
LSTCBS4.0-xx	4.0mm Locking Self-Tapping Screws	20mm-40mm in 2mm increments
LSTCBS4.0-xx	4.0mm Locking Self-Tapping Screws	40mm-60mm in 5mm increments
Instruments		
Cat#	**Description**	
LDG2.7S	Locking Drill Guide for 2.7mm Screws	
LDG3.5S	Locking Drill Guide for 3.5mm Screws	
LDG4.0S	Locking Drill Guide for 4.0mm Screws	
DBQC2.0	2.0mm Drill Bit with AO Quick Coupling	
DB2.0	2.0mm Drill Bit	
DBQC2.5	2.5mm Drill Bit with AO Quick Coupling	
DB2.5	2.5mm Drill Bit	
DBQC3.2	3.2mm Drill Bit with AO Quick Coupling	
DB3.2	3.2mm Drill Bit	

US Pat. D735, 861S   Additional Patents Pending

Simitri Surgical Equipment List

Scalpel handles: Standard with a # 10 blade. Beaver handle with a # 64 blade
Hemostats: 6 curved, 1 straight
Mayo scissors: 1 straight, 1 curved (heavy)
Towel clamps: 6-8 small
Periosteal elevator
Meniscal probe
Retractors: Weitlaner, Senn, US Army, Hohmann, Gelpi
Needle driver
Tissue forceps: 1 Addison, 1 tissue (rat tooth), 1 Allis
IM pins. 5/64th Three trocar / trocar cut in half
Metal ruler or calipers
Assortment of appropriate drills, taps, hex head screwdrivers and drill guides appropriate for 2.7 mm, 3.5 mm and 4.0 mm cortical locking screws
Quick connect chuck
Drill, key
Plate bender, twisting irons
2.7, 3.5 and 4.0 mm cortical, cancellous and cortical locking screws
22, 25 gauge needle (3/4-1 inch)
35 cc syringe and 22 gauge needle (1.5 in.) for drill cooling