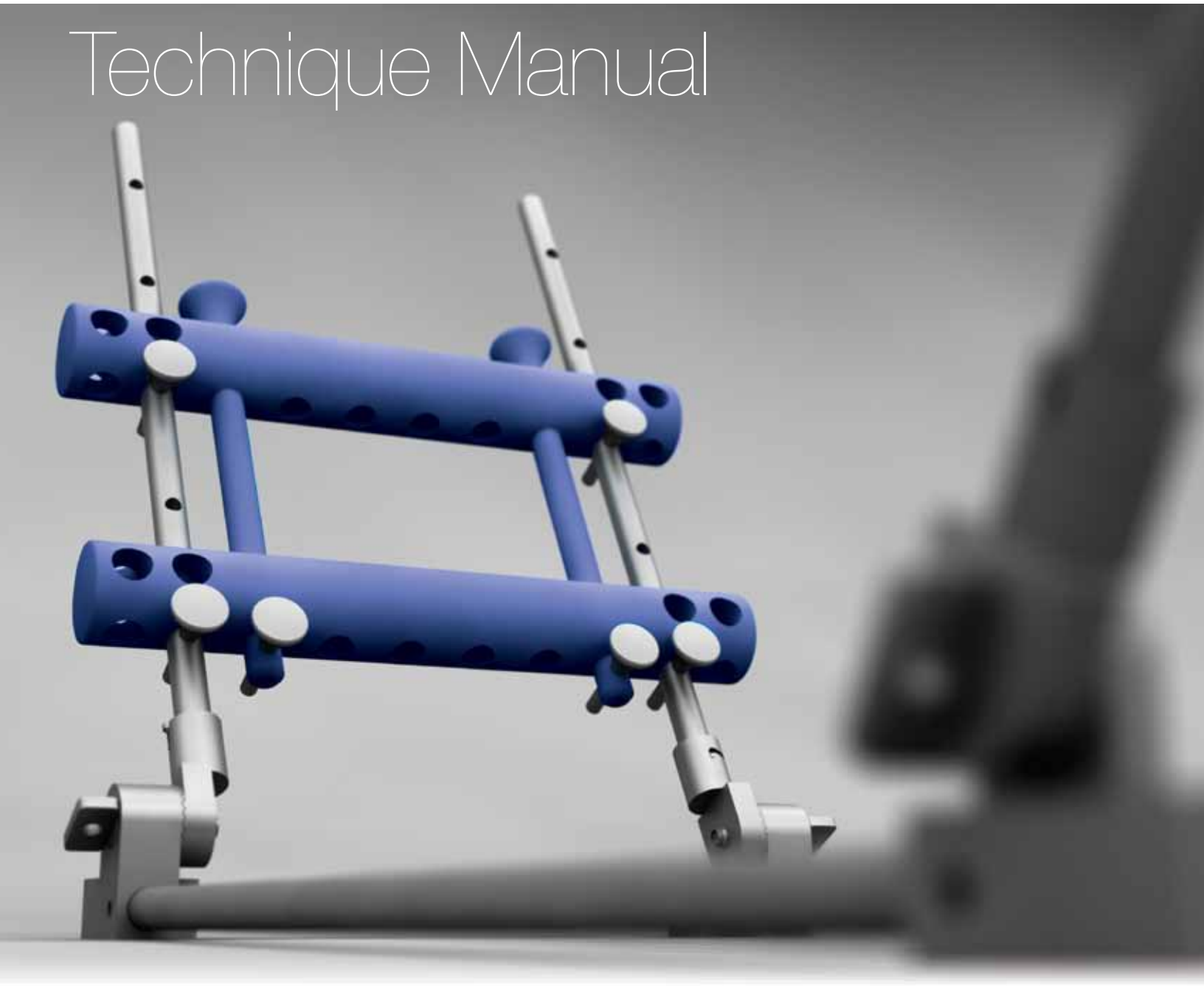
RUSSELL FRAME®

Technique Manual



Innovision

HELPING SURGEONS • HELPING PATIENTS

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Nota Bene

The technique description herein is made available to the healthcare professional to illustrate the author's suggested use and positioning of the patient for orthopaedic procedures. In the final analysis, the preferred use is under the surgeon's discretion.

Introduction

The Russell Frame from InnoVision is a surgical assist device that offers the surgeon the following benefits:

- Provides stability and control of the lower extremity for fixation
- Utilized and adjustable within the sterile field after prep and drape
- Easy to disassemble, clean and sterilize
- Built with durable and long lasting materials
- Allows for 360˚ access to the lower extremity
- Holds the lower extremity in a stable position allowing the C-arm to rotate easily between AP and Lateral positions
- Provides hands-free support of the lower extremity
- Clinically proven to be nonmagnetic for use with computer assisted navigation and targeting systems

Indications

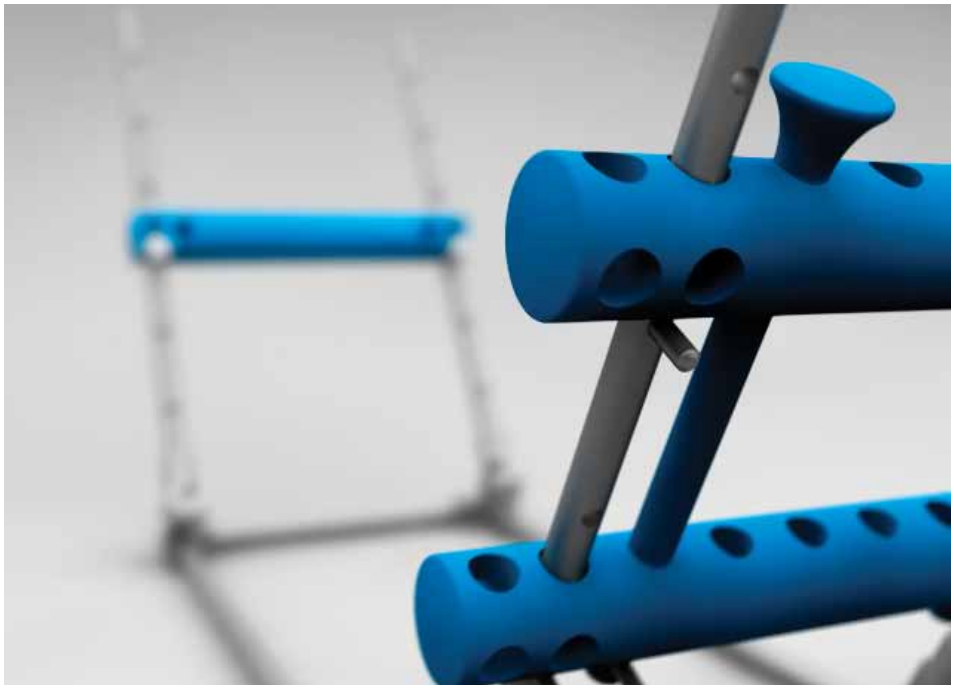
The Russell Frame from InnoVision is intended to be used as a surgical assist device. The patients leg is positioned on the frame to provide a stable platform and easy access to the leg during Orthopaedic procedures of the lower leg.

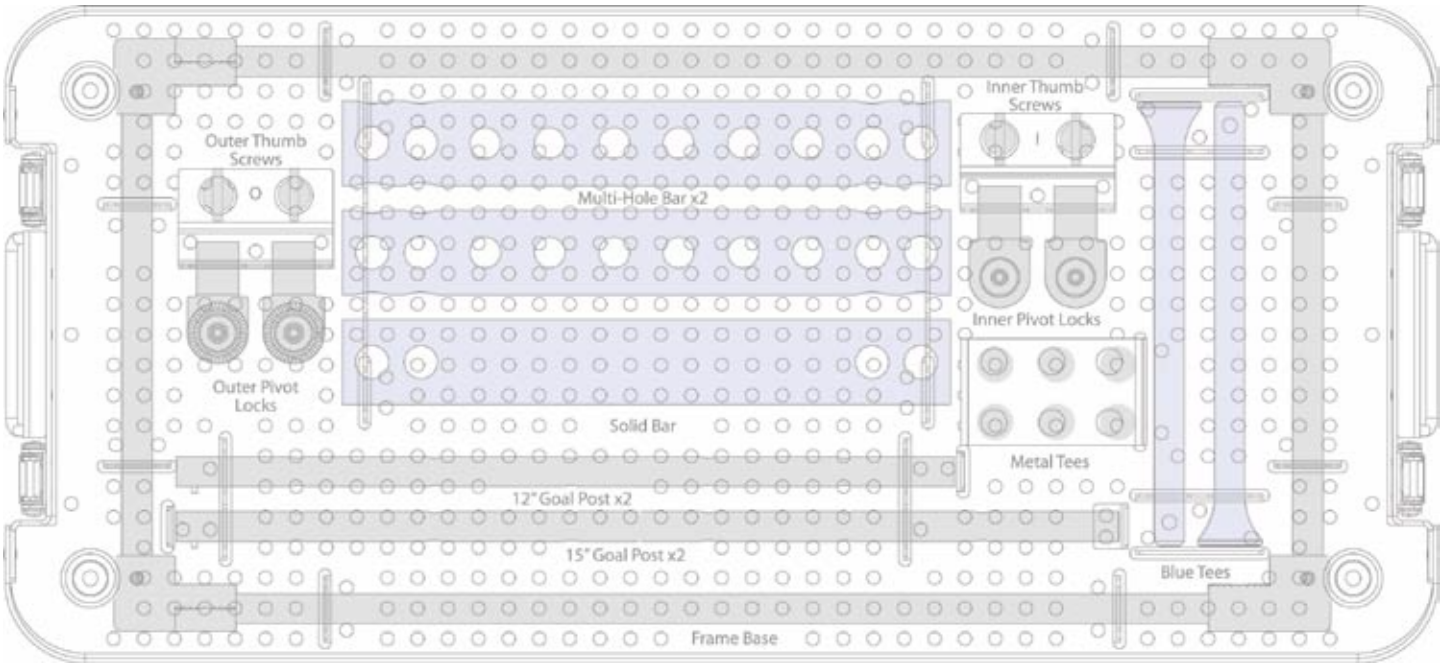
These procedures include, but are not limited to:

- Care of both closed and open fractures of the lower extremity
- Intramedullary nailing of the tibia (Peri-patellar and Supra-patellar entry portal)
- Retrograde intramedullary nailing of the femur
- Open reduction and internal fixation of the distal femur
- Open reduction and internal fixation of the proximal tibia
- Open reduction and internal fixation of the distal tibia
- Open reduction and internal fixation of the ankle
- Open reduction and internal fixation of the foot
- Application of external fixation of the lower extremity
- Open reduction and internal fixation of the patella
- Soft tissue and ligament procedures of the knee and lower extremity

Instrumentation

The Russell Frame is made from instrument grade Titanium and USP Class VI thermo polymer which has been clinically proven to be non-magnetic for use with computer assisted surgical navigation and targeting systems.





The frame is provided in a sterilization tray designed for easy access and identification of all components.

Frame Assembly

1. Place Frame Base flat on the sterile back table.

2. Notice that there are pivots on one end that are attached on the inside (Marked I) and on the opposite end attached on the outside (Marked O). The end where the pivot locks attach on the outside is wider and accommodates the thigh more easily.

3. Attach the correct Pivot Lock with the corresponding Thumb Screw.

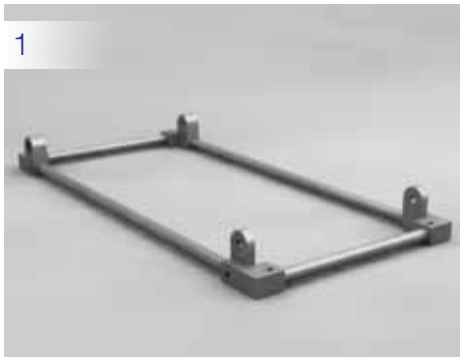
4. Slide the 12” Goal Posts into the Pivot Locks (I) attached on the inside and twist into place to lock.

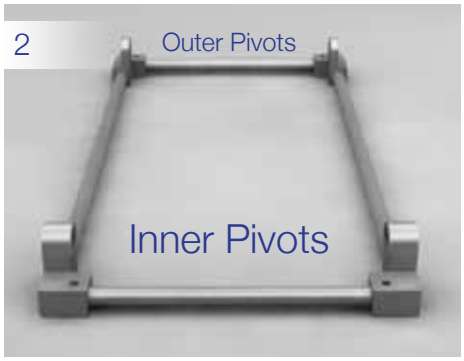
5. Slide the 15” Goal Posts into the Pivot Locks (O) attached on the outside and twist into place to lock.

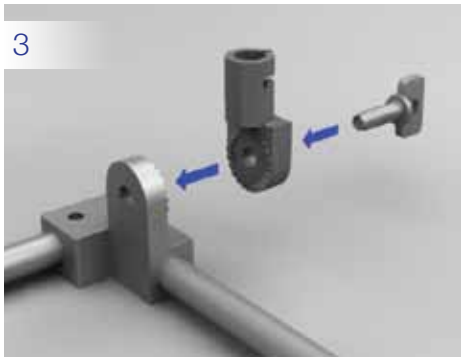
6. Place the Solid Support Bar (four holes) and secure at the desired level with Metal Tees on the femoral side (O).

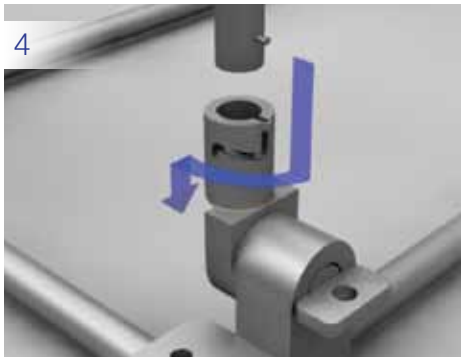
7. Slide the Multi-Hole Support Bar on the 12” Goal Post and secure with Metal Tees.

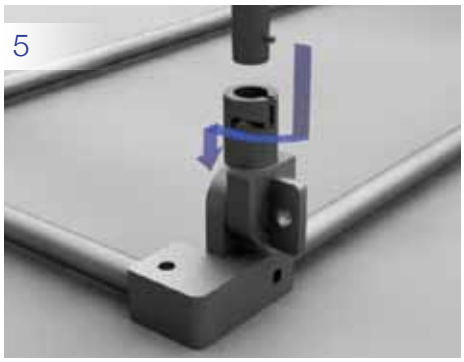
8. The foot and ankle can be locked into place by sliding the second Multi-Hole Support Bar over the ankle and locking together with the Blue Tees secured by a set of Metal Tees.



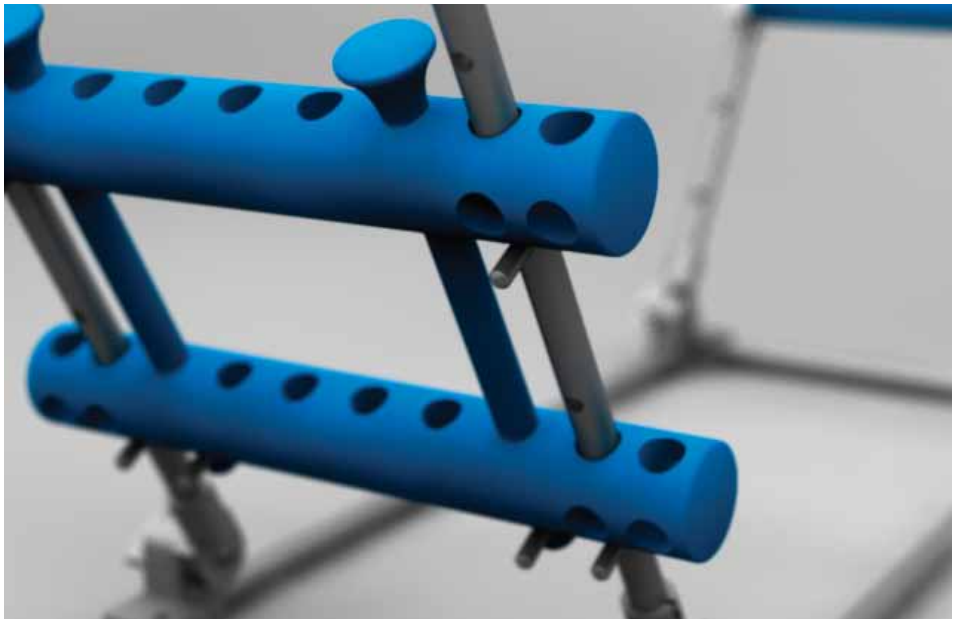








Position Guide



Testimonials from surgeons provide feedback that a consistent benefit in using the Russell Frame is the fact that the frame gives a dependable, stable base on which to perform lower extremity surgery. The use and positioning of the patient is based on the preference of the surgeon.

The Russell Frame is designed with flexibility and adjustability to fit the size and shape of the patient and desired position for the particular surgery that is being performed.

Hyper-Flexed Position

The hyper-flexed position of the Russell Frame is used for:

- Standard nailing of the tibia
- Soft tissue & ligament reconstruction around knee
- Arthroscopically assisted knee surgery

Place the femoral Goal Posts at the appropriate angle and height for the size of the patient and the desired amount of hyper-flexion. The foot can be rested on the table for full flexion or the two Multi-Hole Support Bars can be joined together on the ankle Goal Posts for an excellent footrest (as shown).

Semi-Extended Position

The semi-extended position is the most common position and can be used for a number of different surgeries that may include:

- Supra-patellar tibial nailing
- Retrograde femoral nailing
- ORIF distal femur
- ORIF proximal tibia
- Debridement and Irrigation of lower extremity
- Fasciotomy
- External Fixation

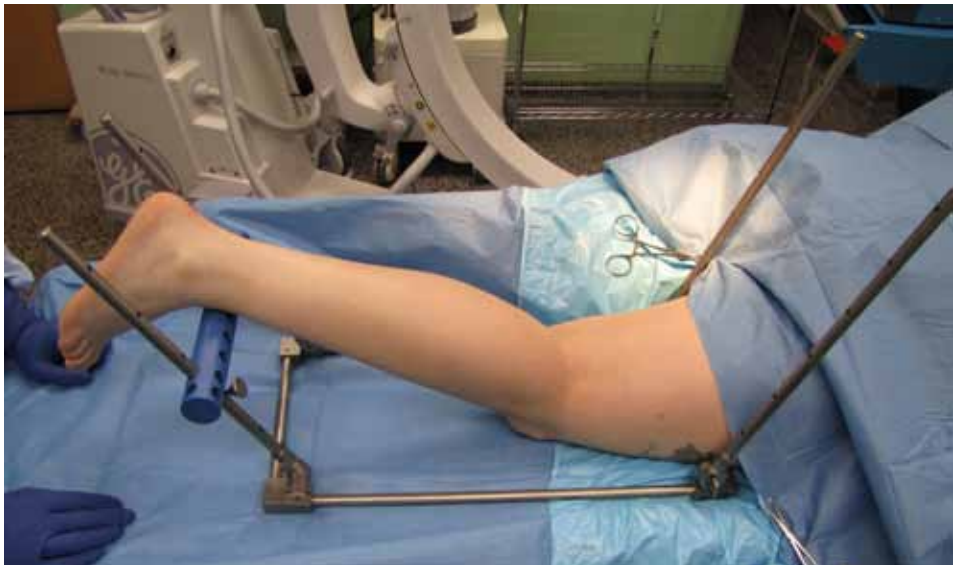
Place the femoral Goal Post at approximately 30° cephalad with the Solid Support Bar midway on the Goal Post. Lock the support bar at the desired height with the Metal Tees. With the tibia parallel to the floor, adjust the ankle Goal Post to the desired angle and the ankle Support Bar to the appropriate height.

Prone Position

The prone position is useful for the following procedures:

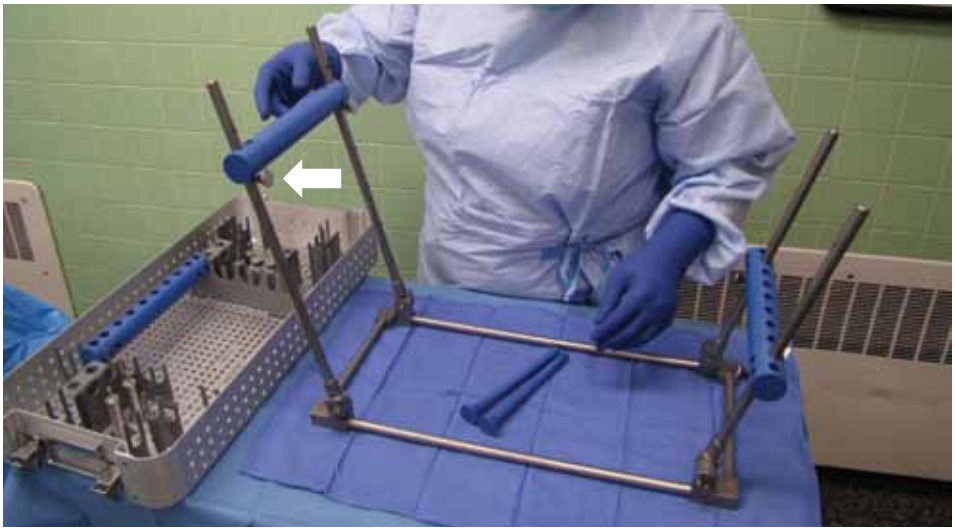
- Posterior approach to the knee and lower extremity
- ORIF of the distal tibia and ankle when a posterior approach is necessary

In the prone position, the Solid Support Bar can be removed completely or placed on the lowest level. The ankle Goal Post is place at approximately 30° caudad and the Multi-Hole Support Bar is placed at the desire height.



Tips and Tricks:

It is best to assemble the Russell Frame during the standard OR set-up time. When adjusting the angle of the Goal Post, hold the Support Bar with one hand, loosen each Thumb Screw at least one turn. Place Pivot Lock at desired angle and retighten Thumb Screws.



The Support Bars rest on Metal Tees which lock into place by the weight of the leg. To prevent Tees from loosening without the weight of the leg, the Tees should be placed on the inside slope of the angle.

The Russell Frame is assembled on the back table and placed under the leg after prep and drape.

Tips and Tricks:

The Russell Frame allows for excellent access to the leg for debridement and irrigation of open fractures or irrigation and closure of the surgical wound. Placement of a wound vac is simplified by 360˚ access to the lower extremity.

It is recommended that the Support Bars be padded with blue towels (shown here), sterile cast padding or other suitable material.

Tips and Tricks:

With the leg in a stable position, the X-Ray Technologist adjusts the C-arm and anesthesia adjusts the table height which allows the C-arm to simply roll back and forth from AP to Lateral.

Surgeons find that the Russell Frame provides hands-free support of the lower extremity. As shown here, it can assist in holding a retractor. It can also hold the foot in internal rotation by utilizing a hemostat attached to the Coban and hooked to the frame. The Blue Tees can be locked into place with the smaller Metal Tees.

Tips and Tricks:

The femur can be locked into place. Surgeons have found that the Support Bars can be helpful in fracture reduction. For example, the femoral Support Bar in this position helps reduce a distal femur fracture where the distal femur sags posteriorly.

The ankle can be locked into place using the second Multi-Hole Support Bar with the Blue Tees. This locks the rotation and provides a slight amount of traction which helps in fracture reduction.

Cleaning

The Russell Frame must be thoroughly cleaned before each use. Decontamination and disinfection of the frame should occur immediately after completion of the surgical procedure, according to the medical facility standard protocol.

Sterilization

The Russell Frame is provided non-sterile. Sterilization must be performed prior to surgery using one of the following methods:

1. Flash Sterilization - unwrapped: Temp 270˚F (132˚C) for 10 minutes with 1 minute dry time.

2. Gravity Sterilization - wrapped in two layers of 1-ply polypropylene wrap using sequential wrapping techniques with a surgical towel placed between the wraps and the bottom of the tray. Temp 270˚F (132˚C) for 15 minutes with 30 minutes dry time.

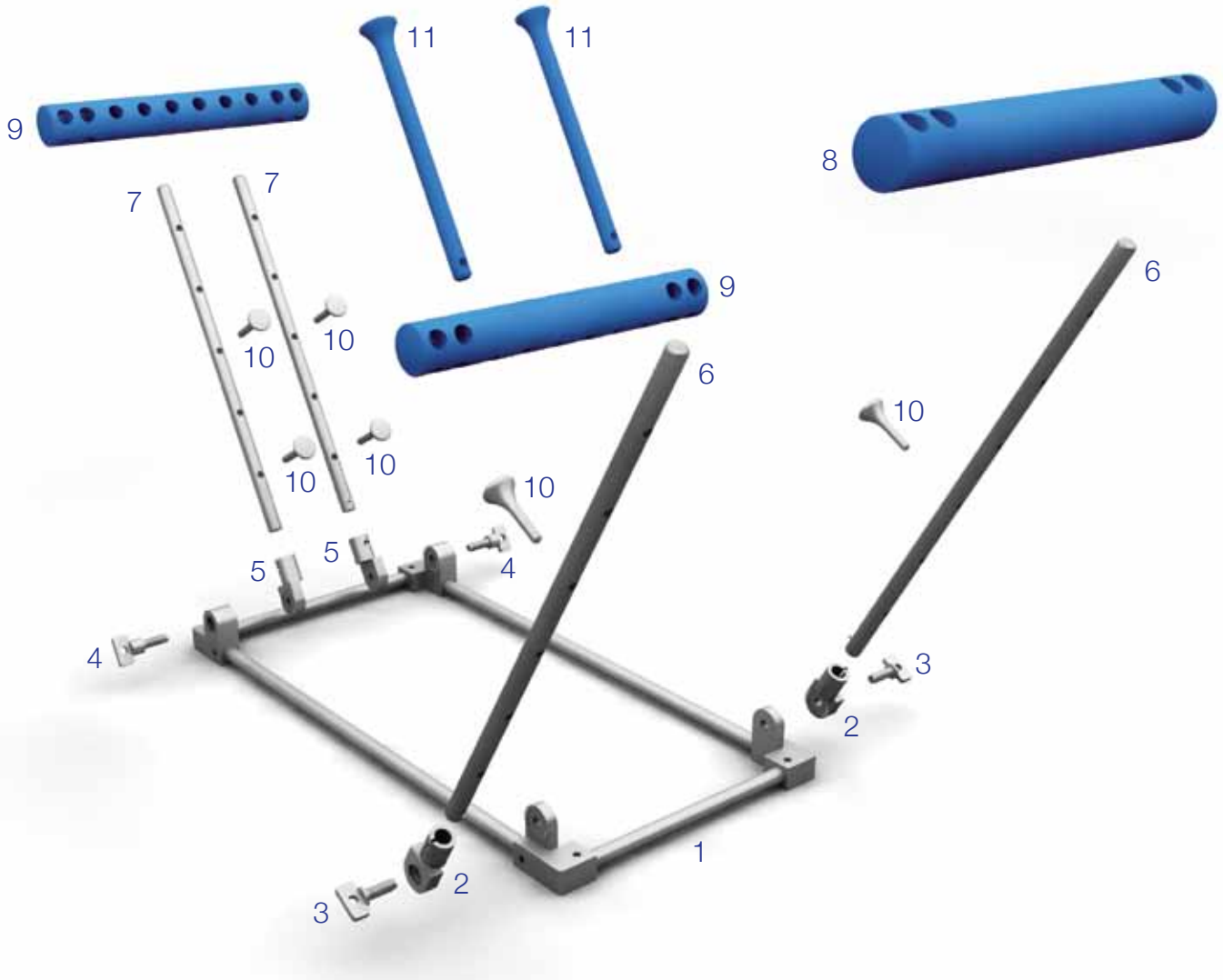
Storage Instructions

Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, damage or water contamination.

Warning and Precautions

For safe and effective use of this product, the surgeon must be thoroughly familiar with the Russell Frame, the method of application, and recommended surgical technique of this device. The Russell Frame is to be used as a surgical assist device only and is not meant for implantation.

Replacement Part List



#	ITEM #	ITEM DESCRIPTION
1	IN004-01	RF BASE
2	IN004-02	RF OUTER PIVOT LOCK
3	IN004-03	RF OUTER THUMB SCREW
4	IN004-04	RF INNER THUMB SCREW
5	IN004-05	RF INNER PIVOT LOCK
6	IN004-06	RF 15” GOALPOST ASSEMBLY
7	IN004-07	RF 12” GOALPOST ASSEMBLY
8	IN004-08	RF SOLID SUPPORT BAR
9	IN004-09	RF MULTI-HOLE SUPPORT BAR
10	IN004-10	RF METAL TEE
11	IN004-11	RF BLUE TEE
12	IN004	RUSSELL FRAME

The Russell Frame should be inspected for wear or damage prior to use. Please contact InnoVision for replacement parts if needed.

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