

kneeGRIP II®

Knee Surgery + Arthroscopy Positioning Device

Design Rational Technical Instructions



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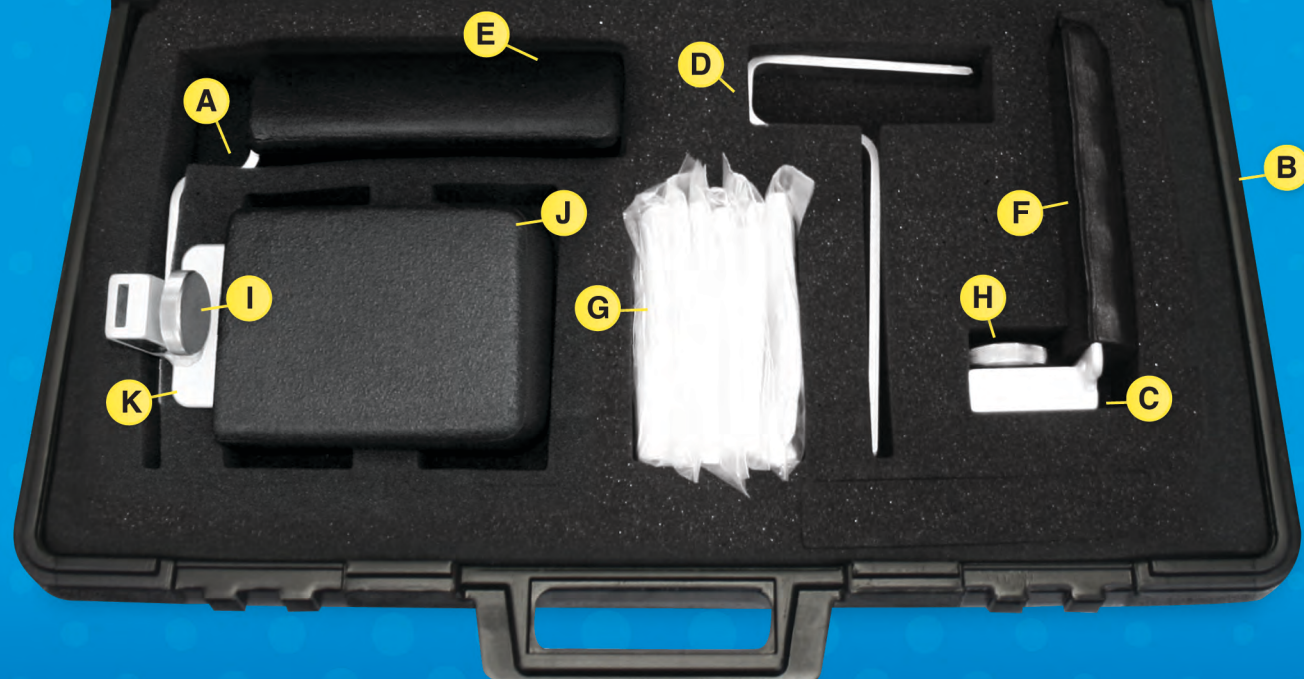
DESCRIPTION

The **kneeGRIP II®** is an intra-operative system of supports that is designed to hold the lower extremity for knee replacement surgery or arthroscopic knee surgery. When used for knee replacement surgery, the **kneeGRIP II®** is designed to hold the knee such that the assistant can better help the surgeon. In contrast to the **kneeGRIP®**, the **kneeGRIP II®** set includes the **kneeGRIP® Set** and additional contoured lateral **thighGRIP®** support. The **thighGRIP®** is used in arthroscopic surgery to better visualize the medial compartment.



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CARRYING CASE & PARTS DIAGRAM

kneeGRIP® + thighGRIP® = kneeGRIP II®

- A** kneeGRIP® Foot Support
- B** kneeGRIP® Carrying Case
- C** kneeGRIP® 8" Upright Support
- D** kneeGRIP® 8" Upright Support Bar & thighGRIP® Bar (AKA "?" Bar)
- E** kneeGRIP® Foot Support Foam Pad
- F** kneeGRIP® 8" Upright Support Pad
- G** kneeGRIP II® Coversets (6 Come in each set)
Also sold in Cases of 25 Set-ups. Each disposable Set-up is a ziploc baggie that contains enough covers for one surgery.
- H** kneeGRIP® Thumb Screw
- I** thighGRIP® Thumb Screw
- J** thighGRIP® Foam Pad
- K** thighGRIP® Upright Thigh Support

Intended Use

The kneeGRIP II® system is intended for use in surgery of the lower extremity. This device is to be used by a surgeon well trained in orthopedic surgery and with a working knowledge of the anatomy of the lower extremity. Specifically, the kneeGRIP II® system can be used with knee replacement surgery and arthroscopic knee surgery.

Contraindications

The kneeGRIP II® system is not designed or intended for any use except as indicated. The kneeGRIP II® system should not be used when a patient's skin is so fragile that the pressure from the supports may injure the skin. The kneeGRIP II® system puts pressure on the arch of the foot, over the greater trochanter and lateral thigh, therefore, conditions such as bursitis or arthritis of these areas could be aggravated by the use of this device. If a tourniquet is used, then the kneeGRIP II® system may put pressure on the lateral side of the tourniquet. The portal to the tourniquet should not be lateral as the pressure from the thigh part of the device may interfere with the tourniquet's function.

Warning

The kneeGRIP II® should be placed and adjusted properly. Improper placement or positioning may result in ineffective function of the device or injury to the lower extremity. The device needs to be used in conjunction with proper and appropriate surgical techniques. Only a qualified medical professional should position the kneeGRIP II® system.

Precautions

The kneeGRIP II® should be placed and adjusted properly. Improper placement or positioning may result in ineffective function of the device or damage to the lower extremity. The device needs to be used in conjunction with proper and appropriate surgical techniques. Only a qualified medical professional should position the kneeGRIP II® system. The directions for placement of the kneeGRIP II® system are only approximate, the optimal position of the system may need to be determined at the time of surgery. On occasion the device may be ineffective and a different means of holding the leg will need to be utilized.

Sterility

The kneeGRIP II® is generally a multi-use non-sterile device. The metal parts are either aluminum or stainless steel. The metal parts can be washed with soap/solvents or steamed for cleaning. Coversets help protect the closed cell foam pads which can be washed with soapy water. Do not autoclave the foam pads.

Disclaimer

SunMedica is not responsible for injury as a result of misuse or abuse of this product. Federal law restricts this device to use by or on the order of a physician. Call SunMedica for any questions regarding proper use.

DIRECTIONS FOR USE: Total Knee

Description:

The **kneeGRIP II®** system is designed to aid the Orthopedic Surgeon and the assistant in performing a primary total knee replacement. The **kneeGRIP II®** system provides support of the foot to keep the knee in a flexed position and support of the lateral proximal thigh to prevent hip abduction. This allows the surgeon and the assistant to direct their efforts toward the surgery.

Patient Position:

The **kneeGRIP II®** system is designed to work with the patient in the supine position. The pelvis should be level, especially if the bony landmarks are used as a reference for alignment of the knee replacement. The un-operated leg can be placed on pillows and secured to the operating table. It is also recommended that a pillow be placed distal to the foot support of the **kneeGRIP II®** to support the calf and foot of the operated leg when the knee is extended. This prevents all of the weight of the leg from being born on the foot support portion of the **kneeGRIP®** when the knee is extended. The tourniquet should be placed as far proximal as possible on the thigh.

Flex the knee and place the instep on the foot rest. Adjust the position of the foot support to reproduce the desired degree of flexion.

Sequence of Placing Positioner:

STEP 1

Position the **kneeGRIP®**
Foot Support

STEP 2

Position the **kneeGRIP®**
Upright Support



STEP 1:

Position the Foot Support

The **Foot Support** (Figure 1) requires a 1" x 1/4" bar support that attaches to the operating table (not provided).

For most patients, the mid portion of the **Foot Support** (A) should line up with the distal aspect of the patella with the knee straight.

The height of the support depends on the softness of the operating table surface, the size of the patient and the thickness of the drapes. Usually, the undersurface of the **Foot Support** is placed about an inch above the table padding for a firm table top and at the surface for a soft table top.

Flex the knee and place the instep on the foot support. Adjust the position of the **Foot Support** to reproduce the desired degree of flexion. This is illustrated in Figure 2.

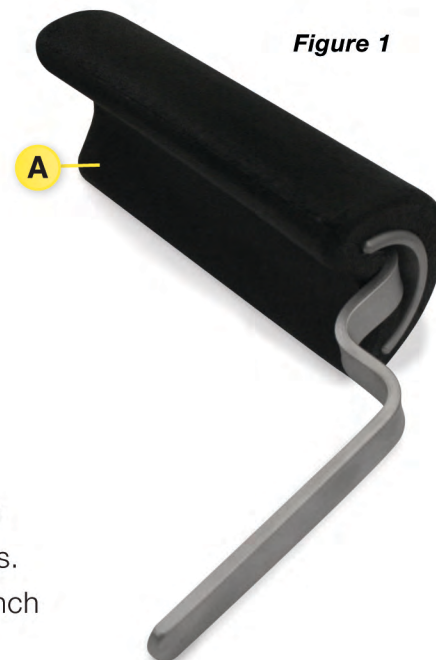


Figure 1



Figure 2

STEP 2:

Position the Upright Support

The **Upright Support** (Figure 3) is positioned so that with the knee and hip flexed, the proximal thigh (and tourniquet) is supported, preventing abduction of the hip. Place the cephalad border of the **Upright Support (C)** at the level of the greater trochanter. Slide the support toward the lateral thigh so that it just touches the tourniquet.

The **Upright Support Bar (D)**, also known as the “?” Bar should be used to allow appropriate adjustment. Flex the knee and place the foot onto the Foot Support. Allow the hip to abduct and be supported by the lateral thigh support. Adjust the lateral support to achieve the position of the flexed knee that will be optimal for surgical exposure. This is illustrated in Figure 4.

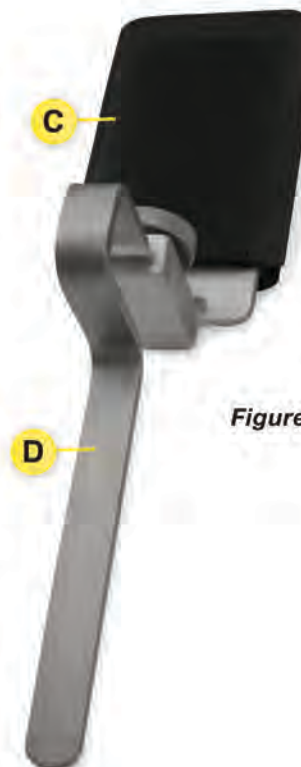


Figure 3

Precautions

- Do not widely abduct the thigh with the **kneeGRIP®** in place. This will lever the thigh against the lateral support and could injure the thigh or hip.
- Do not place the **kneeGRIP® Foot Support (A)** too far down the table such that the toes are blocked by the **Foot Support** rather than the instep of the foot. This may injure the toes.
- Do not place the tourniquet connection lateral such that it is against the lateral support. This may cause the tourniquet to malfunction.
- This device may not work well in markedly obese patients and a different method of support needs to be utilized.
- If the pad on the **Foot Support** or on the lateral support are damaged, replace prior to any subsequent use.

Plastic Drape

It is important that a plastic drape be placed between the lateral support and the tourniquet. This provides a number of benefits. The interposed plastic drape allows the tourniquet and thigh to slide easily over the lateral support as the knee and hip are changed from flexion to extension during the course of the surgery. The drape also protects the lateral support and tourniquet from the chemicals that are used to prep the skin. The preferred drape is a U-drape that also covers the Foot Support.

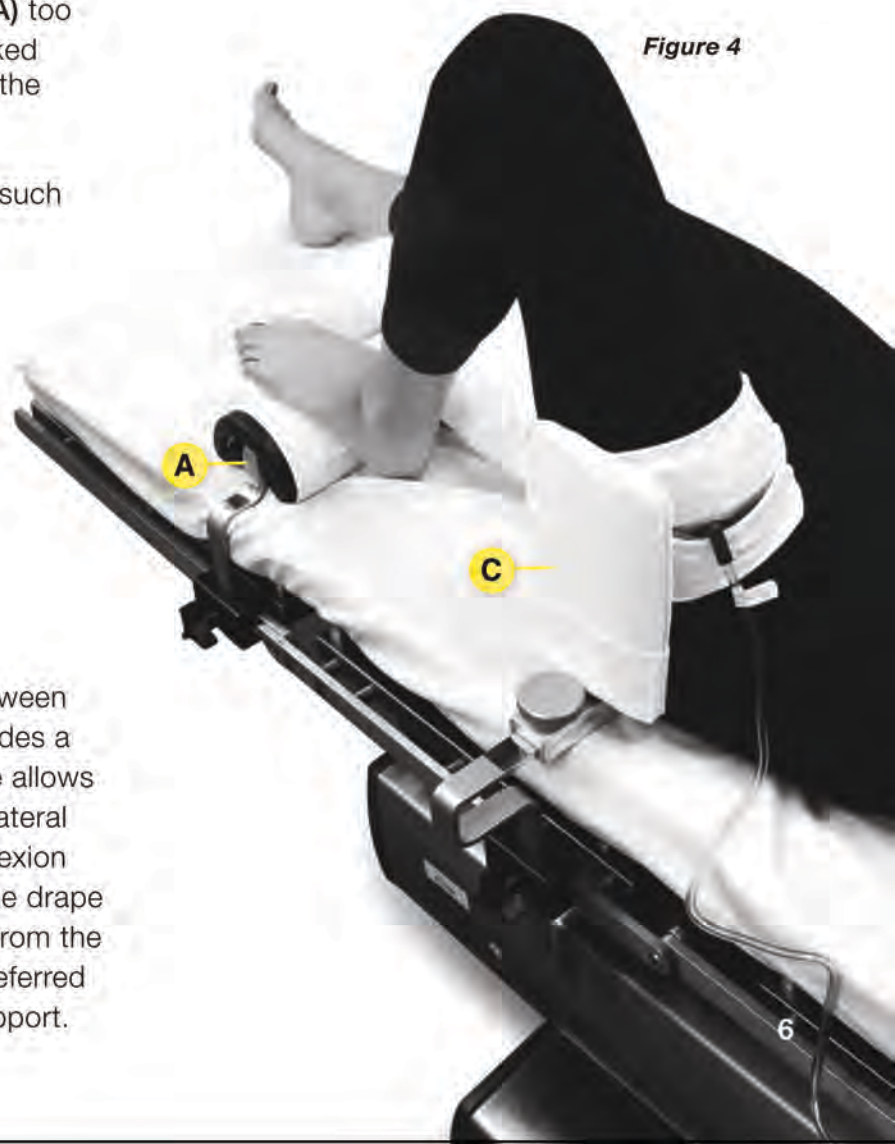


Figure 4

DIRECTIONS FOR USE: Knee Arthroscopy

Description:

The lateral thigh is supported by the **thighGRIP®** upright support. With valgus force on the leg, the thigh is blocked and opens the medial compartment for arthroscopic surgery. The **thighGRIP®** is attached to the operating room table by the **thighGRIP®** support bar (AKA “?” Bar) that allows the **thighGRIP®** to be adjusted to fit the patient. The foam is contoured to decrease the pressure over the lateral thigh.

Patient Position:

The **thighGRIP®** is designed to work with the patient in the supine position. The **thighGRIP®** attaches to the table at about mid thigh. The foot of the table may be up or down according to the surgeons preference.

Sequence of Placing thighGRIP® Positioner:

STEP 1: knee Arthroscopy

Position the thighGRIP®
lateral thigh support



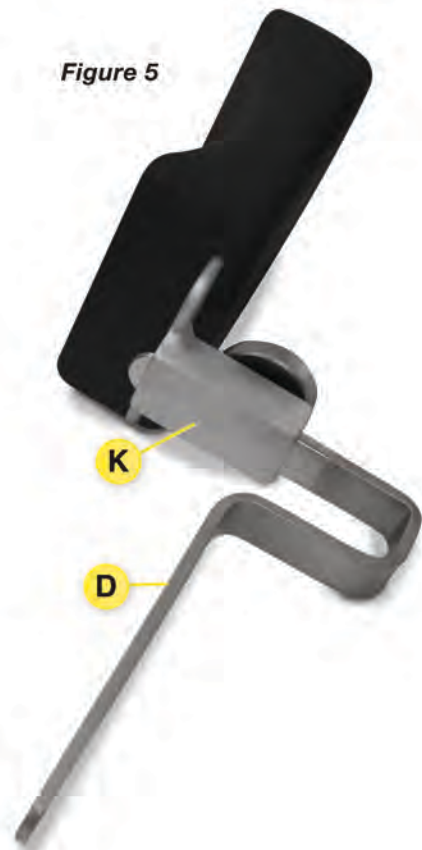
STEP 1:

Position the thighGRIP®

The **thighGRIP®** (Figure 5) is generally placed at about mid thigh, and is attached to the operating room table with the **Upright Support Bar (D)**. The Upright Support Bar allows adjustment of the **thighGRIP®** to accommodate patient size.

If a tourniquet is used, then the **thighGRIP® Upright Thigh Support (K)** can be placed at the level of the tourniquet so that the pressure is transferred through the tourniquet. Overall, the position must be checked by the surgeon to assure that the desired effect is achieved. Isolate the lateral **Upright Thigh Support** with a drape to keep preparation fluids from damaging the **thighGRIP®**. See Figure 6.

Figure 5



Precautions

- Do not use if the femur or tibia integrity is compromised, such as tumor, fracture or infection.
- Do not place the tourniquet connection lateral such that it is against the lateral support. This may cause the tourniquet to malfunction.
- This device may not work well in markedly obese patients and a different method of support needs to be utilized
- If the pad is damaged, replace prior to any subsequent use

Figure 6



Plastic Drape

It is important that a plastic drape be used. Pads should be protected from prep solutions to prevent skin damage or damage to the **thighGRIP®**.

kneeGRIP II® CLEANING INSTRUCTIONS

The **kneeGRIP II®** is a non-sterile device. The metal parts consist of both aluminium or stainless steel.

Foam Pads

The foam pads are closed-cell polyurethane foam. Before use, cover the foam pads with SunMedica's disposable **kneeGRIP II®** Coversets.

Clean the kneeGRIP II® after each operative procedure and before returning parts to the storage case.

What are Coversets?

Coversets (Figure 7) are latex-free and are made of mostly cotton. They are specially designed to easily protect the foam pads as well as conduct body moisture away from the pad's contact areas. This protects the patient's skin from maceration. The Coversets DO NOT protect the foam pads. It is recommended that you use a U-drape to protect the pads from body fluids.

kneeGRIP II® Coversets Item# D-070-011:

Sold by the box/case. Includes 25 "Set-ups".

Each "Set-up" is a ziploc baggie that contains the appropriate number of covers per surgery.

The recommended method for cleaning the foam pads is to use soapy water and then rinse with clean water. Thoroughly dry the pads prior to use. Operating room cleaners can be used but test the cleaner on a small non-contact area of the pad prior to use. It is very important to rinse with clean water as no cleaner residue should be left on the pad surfaces.



SunMedica has coversets available for all positioning devices. Each ziploc baggie is a "set-up".

Metal Parts

The metal parts can be cleaned with soapy water, alcohol, standard operating room cleaners or even steam cleaned.



Figure 7



INSTRUCTIONS FOR REPLACING FOAM PADS

Upright Support & thighGRIP®

- Remove old pad from support.
- Clean and lubricate surface with soap, wax or KY jelly (Figure 1).
- Place the thick side of pad on the opposite side of Thumb Screw and slide on (Figure 2).

Foot Support

- Remove old pad from Foot Support.
- Clean surface.
- Place the curved pad on the Foot Support and slide on (Figure 3).

Figure 1



Figure 2



Figure 3



IMPORTANT MESSAGE: FOAM PAD MAINTENANCE

To maintain soil free positioner pads you must take the following precautions:

- Use a U-DRAPE or similar drape to protect the positioner pads from solutions used in skin preparation and body fluids.
- Use the Coversets to conduct body moisture and prevent skin irritation. These covers DO NOT protect the foam pads from body fluids or skin preparations.

- Pads must be replaced when contaminated with patient body fluids; become hard or loose their resilience after extensive repeated use; damaged in any way that compromises the intended use.

Save Replacement Costs

You can save money on replacement costs by taking the above precautions to help avoid contamination of the foam pads from blood, body fluids or skin preparation solutions.

