This brochure is presented to demonstrate the surgical technique utilized by Stephen M. Howell, M.D. Biomet Sports Medicine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient.

Rehabilitation activities vary depending on the individual patient and physician's recommendations.

The Howell™ 65° Tibial Guide was developed in conjunction with Stephen M. Howell, M.D., Sacramento, California.
Anatomic Transtibial Tunnel Technique

In vitro and in vivo studies have shown that the anatomic transtibial tunnel technique places the femoral tunnel without roof and PCL impingement and matches the tension of the native ACL, which are essential for restoring full function and stability. The key step is the use of the Howell™ 65° Tibial Guide to anatomically place the femoral tunnel through the tibial tunnel so that the following conditions are simultaneously met:

- Minimize an increase in anterior laxity from the ACL graft stretching-out from impinging against the PCL when flexing the knee.
- Minimize an increase in anterior laxity from the ACL graft stretching-out from impinging against the intercondylar roof when extending the knee.
- Reduce the tension in the graft throughout the range of motion.
- Avoid complications from placing the femoral tunnel through the anteromedial portal, which includes loss of fixation from purchasing soft cancellous-bone, impaired tendon-tunnel healing because of short tunnels, prominent painful hardware from deploying fixation device in soft tissue, and posterior backwall blowout.
The use of the Howell™ 65° Tibial Guide and transtibial technique to place the tibial and femoral tunnels enables an early recovery of motion, function, and early return to sport without a clinically important change in anterior laxity and with minimal slippage at the sites of fixation at one year after ACL reconstruction.1,2

The Howell™ 65° Tibial Guide reliably achieves the three principles for optimized placement of the tibial and femoral tunnels, which are:

• Prevention of PCL impingement by voiding a vertical femoral tunnel, which improves flexion, stability, and the mechanics of walking3-8 (Figure 1).

• Prevention of roof impingement by placing the tibial tunnel 1-2 mm posterior and parallel to the intercondylar roof in the extended knee, which improves extension, stability, and clinical MRI appearance of the graft5,9-15 (Figure 2).

• Replication of the tension pattern of the intact ACL in the ACL graft, which prevents the complications associated high tension in the ACL graft and minimizes slippage at the sites of graft fixation6,7,16-22 (Figure 3).

The transtibial technique has many advantages over the anteromedial and double-bundle techniques for placing the tunnels. The transtibial technique avoids potential complications from placing the femoral tunnel through the anteromedial portal, which include peroneal nerve injury, damage to articular cartilage, loss of fixation from purchasing soft cancellous-bone, impaired tendon-tunnel healing because of short tunnels, blowout of the backwall from placing the tunnel too obliquely, and prominent painful hardware from deployment of the fixation device in soft tissue.23-26 The use of the Howell™ 65° Tibial Guide with the transtibial technique avoids the high tension in extension in the posterolateral bundle in the double-bundle technique, which is associated with a high prevalence of posterolateral bundle failure in vivo.27-31
Definition, Complications, and Prevention of PCL Impingement: A Coronal Plane Issue

Premature contact of the ACL graft against the lateral edge of the PCL before the knee reaches full flexion is termed ‘PCL impingement’ and is determined by the position of the tibial tunnel in the coronal plane. PCL impingement causes either a loss of flexion because the tension in the ACL graft increases abnormally in flexion, or an increase in anterior laxity because the ACL graft gradually stretches around the PCL. Gradual stretching of the ACL graft from PCL impingement may result in a mild pivot shift with a firm endpoint during a Lachman test that may culminate in revision surgery. Knees without PCL impingement have better flexion and better anterior and rotational stability.

Preventing PCL impingement with the transtibial technique requires custom placement of the tibial tunnel in the coronal plane, and consists of three steps. First, widen the notch until the width between the PCL and lateral femoral condyle exceeds the diameter of the graft by 1 mm. Widening the notch is necessary because the intact ACL is several millimeters narrower than the typical 8-9 mm in diameter ACL graft.

Second, position the lateral edge of the tibial tunnel so that it passes through the tip of the lateral tibial spine. Third angle the tibial tunnel to form an angle of 65 ± 5° with the medial joint line of the tibia (Figure 4). Widening the notch, positioning the tunnel lateral, and angling the tibia tunnel at 65 ± 5° in the coronal plane moves the femoral tunnel down the side-wall, which further protects the ACL graft from PCL impingement and restores the tension pattern to that of the intact ACL. Drilling the femoral tunnel through a tibial tunnel placed with these three steps creates a triangular space between the ACL graft and PCL. The triangular space between the ACL graft and PCL is a valuable arthroscopic checkpoint that indicates PCL impingement has been avoided (Figure 5).
Premature contact between the ACL graft and the intercondylar roof before the knee reaches full extension is termed ‘roof impingement’ and is determined by the position of the tibial tunnel in the sagittal plane. Roof impingement causes either a loss of extension because of premature contact between the graft and intercondylar roof prevents full extension, or an increase in anterior laxity because of abrasion between the graft and intercondylar roof ruptures the graft. Knees without roof impingement have better extension and better anterior and rotational stability.

Preventing roof impingement requires custom placement of the tibial tunnel in the sagittal plane. The principle for avoiding roof impingement and for placing the graft anatomically within the pathway of the original ACL (Figure 6) is to center the tibial tunnel 4–5mm posterior and parallel to the intercondylar roof with the knee in full extension. Because there is wide variability in the slope of the intercondylar roof (23-60°) and knee extension (-30 to 5°) between knees, each knee has a unique position and angle for the tibial tunnel in the sagittal plane. Because there is wide variability in the size and shape of the ACL insertion between knees, the use of the insertion of the ACL as an arthroscopic checkpoint is misleading and should be avoided.

Customizing the placement of the tibial tunnel in the sagittal plane eliminates the extra step and potential complications of a roofplasty, which include high graft tension, overstressing the graft and fixation, and interference with graft remodeling. The free passage an impingement rod that matches the diameter of the graft through the tibial tunnel and into the notch with the knee in maximum extension is a valuable intraoperative check that roof impingement has been avoided (Figure 5).
Replication of the Tension Pattern in the Intact ACL in the ACL Graft

Any tension in the graft between 10° and 120° of flexion is greater than the intact ACL and should be avoided.\textsuperscript{5,7,16} The penalties from tension in the ACL graft higher than the intact ACL includes excessive graft wear at the femoral tunnel,\textsuperscript{22} poor vascularity, myxoid degeneration, inferior mechanical properties of the graft,\textsuperscript{19,20} and posterior subluxation of the tibia.\textsuperscript{17,21}

The use of the Howell™ 65° Tibial Guide and the Size-Specific Femoral Aimer is a proven combination for positioning the tibial and femoral tunnels so that both the tension pattern of the ACL graft replicates the intact ACL and there is a reciprocal tensile behavior between anteromedial and posterolateral bundles in a single tibial and femoral tunnel.\textsuperscript{6,7,16-18} The use of the 6mm diameter Size-Specific Femoral Aimer through an 8–9mm in diameter tibial tunnel restricts the placement of the femoral aimer to the optimal location on the femur to replicate the tension pattern of the intact ACL in the ACL graft (Figure 3).\textsuperscript{6}

The key steps for restoring the normal tension pattern in the ACL graft are 1) custom placement of the tibial tunnel in the coronal and sagittal planes with use of the Howell™ 65° Tibial Guide and, 2) drilling the femoral tunnel with a 1 mm backwall with use of a Size-Specific Femoral Aimer.\textsuperscript{2,5,6} Because the normal ACL slackens 1–3mm as the knee is flexed from maximum extension to 150 of flexion with no change in length throughout the rest of flexion,\textsuperscript{40} a 1–3mm of movement of the ACL graft out of the tibial tunnel as the knee is flexed as a valuable intraoperative check that the tension pattern in the ACL graft has been replicated.
Description of Tibial and Femoral Guides
Three-Dimensional (3-D) Function of the Howell™ 65˚ Tibial Guide

The reliability and accuracy of the Howell™ 65˚ Tibial Guide is determined by the 3-D function of the tip of the guide. The tip of the guide assists the surgeon in the prevention of PCL impingement, the prevention of roof impingement, and the customization of the placement of the tibial tunnel for variability in notch width, roof angle, and knee extension between patients. The prevention of PCL impingement begins by recognizing a narrow notch, which is detected by the 9.5mm tip of the tibial guide not fitting between the PCL and lateral femoral condyle. A few millimeters of bone are removed from the lateral wall (i.e. wallplasty) until the width between the PCL and lateral femoral condyle exceeds the diameter of the graft by 1mm. The lateral femoral condyle and PCL centers the tip of the guide in the customized space (Figure 4). An alignment rod, inserted in the handle of the guide, is used to orient the angle of the tibial tunnel with respect to the medial joint line in the coronal plane. Orienting the alignment rod parallel to the medial tibial joint line aligns the tibial tunnel at 65˚ (Figure 7).

The use of the lateral hole in the bullet moves the tibial tunnel lateral away from the PCL so that the lateral edge of the tunnel passes through the tip of the lateral tibial spine.

The last step in the prevention of PCL impingement is to insert an over-the-top femoral aimer through the tibial tunnel and laterally rotate the femoral aimer away from PCL, which creates the triangular space between the ACL graft and PCL (Figure 8).

The prevention of roof impingement begins by placing the tip of the tibial guide inside the widened notch. The knee is maximally extended and the heel is placed on a Mayo stand, which allows gravity to reduce the tibia with respect to the femur. The surgeon lifts the guide until the bump on the tip of the guide abuts the intercondylar roof, which customizes the sagittal position of the center of the tibial tunnel 4–5mm posterior and parallel to the intercondylar roof and simultaneously accounts for variability in roof angle and
knee extension for each patient’s unique knee anatomy so that a roofplasty is avoided (Figure 9).\textsuperscript{2,5,6,9,10,12,13,15,38}

After drilling the tibial tunnel an impingement rod the same diameter as the graft, should freely pass through the tibial tunnel and into the notch with the knee in extension, which is a manual check that roof impingement is prevented (Figure 10).\textsuperscript{2,4-7,9,12,13,38}

**Design Features of Size-Specific Femoral Aimers**

The Size-Specific Femoral Aimers work in conjunction with the Howell\textsuperscript{TM} 65° Tibial Guide and is designed to create a 1mm thick backwall in the femoral tunnel without blowing out the posterior wall. The offset of the femoral aimer is 1mm greater than the radius of the graft, which means the size of the femoral aimer is selected to match the diameter ACL graft. The prevention of a blow-out of the femoral tunnel requires the use of an angled curette to remove remnants of the ACL origin from the over-the-top position. Complete removal of the remnant of the ACL origin allows the tip of the Femoral Aimer to rest directly on bone creating a thin 1mm thick backwall and a normal tension pattern in the ACL graft (Figure 11).\textsuperscript{2,5,6,41}
Surgical Technique

Place the Medial Portal
Mark the medial and lateral edge of the patellar tendon. Place the medial portal at the medial edge of the patellar tendon (Figure 12a). The guide will not stay in the intercondylar notch if the portal is 1cm or more medial to the patellar tendon (Figure 12b). Alternatively, the guide can be inserted through the patellar tendon defect if a BTB graft is harvested.

Widen the Notch
Remove the remnant of the torn ACL so that the lateral edge of the PCL is clearly seen. Insert the tibial guide through the medial portal or patellar tendon defect with the knee in flexion. Use the 9.5mm wide tip of the guide to gauge the width between the PCL and lateral femoral condyle. Remove bone from the lateral femoral condyle (i.e. wallplasty) with use of the using the angled osteotome through the medial portal until the width between the PCL and lateral femoral condyle exceeds the diameter of the graft by 1mm (Figure 13). Do not perform a roofplasty because this changes the reference for the tibial guide in the sagittal plane.
Insert the Howell™ 65° Tibial Guide
Reinsert the tibial guide through the medial portal. Position the tip of the guide between the PCL and the lateral femoral condyle (Figure 14). Position the bump inside the notch facing the intercondylar roof. Slowly extend the knee while arthroscopically visualizing that the bump on the tip of the guide remains inside the notch (Figure 15). Maintain the knee in hyperextension by placing the heel on a raised Mayo stand. Suspending the knee by placing the heel on the Mayo stand allows gravity to reduce the tibia on the femur.\textsuperscript{13,15}

Position the Guide in the Sagittal Plane
Grasp the handle of the guide with the long and ring fingers and rest the hypothenar area of the hand on the patella. Seat the tibial guide by gently lifting the handle toward the ceiling until the arm abuts the trochlear groove. Simultaneously press the patella toward the floor hyperextending the knee (Figure 16). This maneuver customizes the angle and position of the guide in the sagittal plane to the roof angle and knee extension of the patient.
Adjust the Angle of the Tibial Tunnel in the Coronal Plane

From the lateral side of the guide, insert the alignment rod into the proximal hole in the handle. Position the alignment rod parallel to the joint line and perpendicular to the long axis of the tibia, this angles the tibial tunnel at 65˚ with respect to the medial joint line (Figure 17). Insert the drill sleeve until it touches the superficial MCL overlying the posteromedial tibia. Drill a 2.4mm drill tip guide pin through the lateral hole in the drill sleeve until it stops at the broad tip of the guide. Remove the tibial guide.

Assess Placement of Tibial Guidepin

Flex the knee, insert the arthroscope, and tap the guidepin into the notch. Assess the coronal plane placement of the guide pin with the knee in 90˚ of flexion. With respect to the tibial plateau, the custom placement of the guidepin is midway between the lateral edge of the PCL and the lateral femoral condyle (Figure 18). With respect to the femur, the custom placement of the guidepin is pointing down the sidewall of the lateral femoral condyle midway between the apex and base of the notch. Assess the sagittal plane placement of the guide pin with the knee in full extension.

The correct guidepin placement is when a 2mm wide nerve hook pistons 2mm between the anterior surface of the guide pin and intercondylar roof with the knee in full extension (Figure 19).
Consider the use of intraoperative radiography or fluoroscopy on the rare occasion when there is uncertainty concerning whether the tibial guide pin was correctly placed. Obtain an A/P and lateral image with the knee in full extension with the tibial guide, alignment rod, and guide pin in place.

In the coronal plane, the guidepin is properly placed when it forms an angle of $65 \pm 5^\circ$ with the medial joint line, and the projected lateral edge of the tibial tunnel passes through the tip of the lateral spine (Figure 20). In the sagittal plane, the guidepin is properly placed when the center of the guide pin is 4–5mm posterior and parallel to the intercondylar roof (Figure 21).
Surgical Technique

Check for Roof Impingement
Drill the tibial tunnel with a cannulated reamer that matches the diameter of the graft. Place the knee in maximum extension and insert an impingement rod the same diameter as the ACL graft through the tibial tunnel and into the notch. Free passage of the impingement rod indicates prevention of roof impingement. A roofplasty is rarely required with the Howell™ 65° Tibial Guide (Figure 22).

Remove ACL Origin from Femur
Insert the angled curette through the medial portal and into the over-the-top position on the femur. Remove the remnant of the ACL origin down to bone. Removing the remnant of the ACL origin allows the tip of the femoral aiming to rest on bone instead of soft tissue, which prevents blow-out of the posterior wall of the femoral tunnel (Figure 23).
Position Size-Specific Femoral Aimer
Select the Size-Specific Femoral Aimer that corresponds to the diameter of the ACL graft. Insert the Femoral Aimer through the tibial tunnel and into the notch. Adjust knee flexion until the tip of the aimer passes into the over-the-top position. Allow gravity to flex the knee and lock the aimer in place (Figure 24). The flexion angle that locks the aimer in place ranges from 60–100˚. Laterally angulate and externally rotate the Femoral Aimer farther away from the PCL and drill a 5mm deep pilot hole with the guide pin.

Redirect the Femoral Guide Pin with the Knee in 90˚ or more of Flexion
Surgeons that use the EZLoc™ Femoral Fixation Device redirect the femoral guidepin to keep the length of the femoral tunnel between 35–50mm. Reinsert the femoral guide pin through the tibial tunnel and into the pilot hole in the femur. Flex the knee to 90˚ or more and angulate the guide pin distal medial to proximal lateral. Drill the guide pin in this orientation to create a femoral tunnel between 35–50mm in length.

Assess Placement of Femoral Guidepin
The femoral guide pin is incorrectly placed when the guidepin is placed vertical, near the the roof of the notch (Figure 25). The femoral guide pin is correctly placed when the guide pin is placed further down the sidewall of the lateral femoral condyle midway between the apex and base of the notch (Figure 26). Insert the one-inch femoral reamer into the notch and assess its relationship to the PCL. The reamer tip should easily pass the PCL without touching it. The shaft of the reamer should form a triangle with the lateral border of the PCL.

Drill the Femoral Tunnel
Drill the femoral tunnel to the desired depth. The posterior wall of the femoral tunnel should be 1mm thick (Figure 26).
Surgical Technique

Post-Operative Radiographic Assessment of Tibial and Femoral Tunnel Position

In the coronal plane the lateral edge of the tibial tunnel should pass through the tip of the lateral tibial spine at an angle of $65 \pm 5^\circ$ with the medial joint line. The femoral tunnel should be in line or slightly lateral to the axis of the tibial tunnel. In the sagittal plane the tibial tunnel should be 1–2mm posterior and parallel to the intercondylar roof with the knee in full extension. The posterior edge of the femoral tunnel should be flush with the posterior cortex of the femur (Figure 27).


Surgical Instruments and Instrument Cases

DESCRIPTION
Biomet® instruments and instrument cases are generally composed of aluminum, stainless steel, and/or polymeric materials. The cases are multi-layered with various components designed for surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and slides/mine. The instrument cases are perforated to allow steam to penetrate these various materials of aluminum, stainless steel, and/or polymeric materials. The instrument cases are designed to fit within a supplied reusable rigid sterilization container, the following sterilization cycle parameters are the minimum for instrument cases up to 25 lbs (11 kgs).

PRE-VACUUMED STERILIZER (HI-VAC)
270°F - 275°F (132˚C - 135˚C) – Double or single wrapped or unwrapped 10 minutes exposure time - 8 minutes drying time

Reusable Rigid Sterilization Containers
In some instrument case designs, two or three individual instrument cases may be supplied with an outer transportation container. These instrument cases may be sterilized individually following the instructions above, or may be sterilized by placing the individual cases within the supplied transportation container. To sterilize two or three instrument cases within the supplied outer transportation container, the following sterilization cycle parameters are recommended. The following cycle parameters are the minimum for instrument cases up to 35 lbs (16 kgs).

PRE-VACUUMED STERILIZER (HI-VAC)
270°F - 275°F (132˚C - 135˚C) – Double or Single Wrapped or unwrapped 5 minutes exposure time - 8 minutes drying time

Since Biomet is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Biomet assumes no responsibility for sterilization of product by a hospital even if the general above guidelines are followed.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding Biomet® devices or instruments can be directed to: Regulatory Dept, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

Authorized Representative: Biomet U.K., Ltd.
Waterstone Industrial Estate, Bridgend, South Wales CF33 3XG, U.K.

Biomet Orthopedics
56 E. Bell Drive
PO. Box 587
Warsaw, IN 46581 USA

Recommendations for the Care and Handling of Biomet® Surgical Instruments and Instrument Cases

1. General
Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including prolonged use, misuse, and rough or improper handling. Care must be taken to avoid compromising the exacting performance. To minimize damage and risk of injury, the following should be done:

- Inspect the instrument case and instruments for damage upon receipt and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned. Instruments in need of repair should be set aside for repair service or returned to Biomet (Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for return, or contact Biomet or your distributor for further instruction).
- Only use an instrument for its intended purpose.
- When handling sharp instruments, use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
- General Cleaning. Clean instruments prior to initial sterilization and as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Wash all instruments whether or not they were used or inadvertently came into contact with blood or saline solution.
- Ultrasonic Cleaners can be used with hot water per manufacturer’s recommended temperature (usually 90-140°F or 32-60°C) and specially formulated detergents. Follow manufacturer’s recommendations for proper cleaning solution formulated specifically for the equipment. Be aware that loading patterns, instrument cassettes, water temperature, and other external factors may change the effectiveness of the equipment.

2. Washer-Decontamination Equipment will wash and decontaminate instrument of soil from corrosive and serations depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, as well as the manufacturer’s recommendations for proper cleaning solution formulated specifically for the equipment. Be aware that loading patterns, instrument cassettes, water temperature, and other external factors may change the effectiveness of the equipment.

3. Cleaning/Decontamination. The health care facility is responsible to issue that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, services followed by sterilization.

Sterility. Users should conduct testing in the health care facility to ensure that contamination can be achieved and that specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. ANSI/AAMI ST35 Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities covers the selection and use of reusable rigid sterilization container systems. Guidelines are provided by this standard for cleaning and decontamination, preparation and assembly, sterility testing and tracking, and use in applications for other uses of sterilization.

4. STERILITY

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use. Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided. Unwrapped instrument cases DO NOT maintain sterility. A cannula set needs to be repaired and/or replaced when the fluid flow through the cannula around the scope is decreased.

STORAGE AND SHELF LIFE
Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instrument cases based upon the type of sterilization wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is even related and that the probability of occurrence of a contaminating event increases over time with handling, and whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

Dental instruments and instrument cases may be reassembled and placed in their proper locations in the instrument cases. Materials

Aluminum
Stainless Steel
Polymeric Materials

STERILIZATION

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use. Biomet® instruments can be steam autoclaved and repeated autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using Biomet® instruments or instrument cases, please bring this to Biomet’s or Biomet’s distributors’ attention when you return them. (Instruments returned to Biomet or its distributors should be cleaned and sterilized, prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for return, or contact Biomet or your distributor for further instruction).

Unlimited duration, instruments must be thoroughly cleaned, rinsed, and sterilized prior to surgical use. Set forth below is a recommended minimum cycle for steam sterilization that has been validated by Biomet under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on sites, including the on-site validation of the recommended minimum cycle parameters described below.

Surgical instruments may be autoclaved using a full cycle. Instruments that have been in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST35 Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended. The following cycle parameters are the minimum instrument cases up to 35 lbs (16 kgs).

PRE-VACUUMED STERILIZER (HI-VAC)
270°F - 275°F (132˚C - 135˚C) – Double or Single Wrapped or unwrapped 5 minutes exposure time - 8 minutes drying time

Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended. The following cycle parameters are the minimum for instrument cases up to 35 lbs (16 kgs).

PRE-VACUUMED STERILIZER (HI-VAC)
270°F - 275°F (132˚C - 135˚C) – Double or Single Wrapped or unwrapped 12 minutes exposure time - 8 minutes drying time

GRATIY DISPLACEMENT STERILIZER (Full Cycle)
270°F - 275°F (132˚C - 135˚C) – Double or single wrapped or unwrapped 12 minutes exposure time - 8 minutes drying time

Multi-Level Instrument Cases
In some instrument case designs, two or three individual instrument cases may be supplied with an outer transportation container. These instrument cases may be sterilized individually following the instructions above, or may be sterilized by placing the individual cases within the supplied transportation container. To sterilize two or three instrument cases within the supplied outer transportation container, the following sterilization cycle parameters are recommended. The following cycle parameters are the minimum for instrument cases up to 35 lbs (16 kgs).

PRE-VACUUMED STERILIZER (HI-VAC)
270°F - 275°F (132˚C - 135˚C) – Double or Single Wrapped or unwrapped 10 minutes exposure time - 8 minutes drying time

Reusable Rigid Sterilization Containers
In some instrument case designs, an instrument case may be designed to fit within a supplied reusable rigid sterilization container for sterilization. These instrument cases may be sterilized individually following the instructions above, or may be sterilized by placing the individual case(s) within the supplied reusable rigid sterilization container. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. The following cycle parameters are the minimum for instrument cases in rigid container systems up to 35 lbs (16 kgs).

PRE-VACUUMED STERILIZER (HI-VAC)
270°F - 275°F (132˚C - 135˚C) – Double or Single Wrapped or unwrapped 5 minutes exposure time - 8 minutes drying time

Since Biomet is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Biomet assumes no responsibility for sterilization of product by a hospital even if the general above guidelines are followed.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding Biomet® devices or instruments can be directed to: Regulatory Dept, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

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Authorized Representative: Biomet U.K., Ltd.
Waterstone Industrial Estate, Bridgend, South Wales CF33 3XG, U.K.
**CLEANING AND STERILIZATION METHODS**

<table>
<thead>
<tr>
<th>Biomet® Rigid Instrument Cases—Suitable for Steam Autoclaving Aluminum, Stainless Steel, and Polymeric</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Processing Steps</strong></td>
<td><strong>Suggested Method</strong></td>
</tr>
<tr>
<td>Removal of gross contamination &amp; disassembly</td>
<td>By hand, submerged in water with continuous flow with mechanical aid (e.g. brush) wearing protective gloves &amp; goggles. Disassemble instruments into individual parts.</td>
</tr>
<tr>
<td>Washing &amp; Disinfecting</td>
<td>Automatic washer-disinfection unit utilizing thermal disinfection (ultrasonic or continuous tunnel process preferable). Temperatures, cycles &amp; disinfectant type used as instructed by manufacturer of washer-disinfection unit.</td>
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<td>Sterilization</td>
<td>Steam autoclav</td>
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### Steam Autoclave Cycle Parameters*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
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<tbody>
<tr>
<td>Gravity Displacement Sterilizer (Full Cycle)</td>
<td>270°-275° F (132°-135° C) – Double or single wrapped or unwrapped 12 minutes exposure time – 8 minutes drying time</td>
</tr>
<tr>
<td>Pre-Vacuumed Sterilizer (HIVAC)</td>
<td>270°-275° F (132°-135° C) – Double or single wrapped or unwrapped 5 minutes exposure time – 8 minutes drying time</td>
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</tbody>
</table>

*Validated by Biomet under laboratory conditions, however, these cycles must be re-validated by the end-user to ensure that sterility can be achieved on site.

### Precautions

- When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
- Unless otherwise indicated, instrument sets are NOT Sterile and must be thoroughly cleaned and sterilized prior to use.
- Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided, whenever possible.
- Unwrapped instrument cases DO NOT maintain sterility.

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**Symbol Legend**

- **Manufacturer**
- **Date of Manufacture**
- **Do Not Reuse**
- **Caution**
- **STERILE EO** Sterilized using Ethylene Oxide
- **STERILE R** Sterilized using Irradiation
- **STERILE** Sterile
- **STERILE A** Sterilized using Aseptic Processing Techniques
- **STERILE ▪** Sterilized using Steam or Dry Heat
- **Use By**
- **WEEE Device**
- **Catalogue Number**
- **Batch Code**
- **Flammable**
- **Authorized Representative in the European Community**

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The information contained in this package insert was current on the date this launch packet was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet Sports Medicine at the contact information provided herein.
## Ordering Information

<table>
<thead>
<tr>
<th>Howell™ 65 Tibial Guide</th>
<th>909601</th>
</tr>
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<tbody>
<tr>
<td>Sharp Drill Guide Bullet—Calibrated (for Howell™ 65 Guide)</td>
<td>909602</td>
</tr>
<tr>
<td>Drill Point K-Wire</td>
<td>909827 2.4mm</td>
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<tr>
<td>15˚ Angled Osteotome</td>
<td>909871</td>
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<td>Curved Roofplasty Gouge</td>
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<tr>
<td>Howell™ Tibial Guide Cross Pin</td>
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<td>Cannulated Drill Bit</td>
<td>909911 7mm, 909913 8mm, 909915 9mm, 909917 10mm, 909919 11mm, 909921 12mm</td>
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<td>Impingement Rod</td>
<td>909931 7mm, 909933 8mm, 909935 9mm, 909937 10mm, 909939 11mm, 909941 12mm</td>
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<td>Sizing Sleeve/Skin Protector</td>
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<tr>
<td>Cannulated End Cutting Reamer</td>
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<tr>
<td>Femoral Aimer Handle</td>
<td>909623</td>
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| Femoral Aimer Replacement Ring Nut | 909627–03 |
| 3/32” Guide Pin/Graft Passing Pin | 909640 |
| 60˚ Curette | 906988 |
| Femoral Aimer Tip | 909627 7mm, 909628 8mm, 909629 9mm, 909630 10mm, 909631 11mm, 909632 12mm |
| Femoral Aimer Tip | 909627 7mm, 909628 8mm, 909629 9mm, 909630 10mm, 909631 11mm, 909632 12mm |

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