

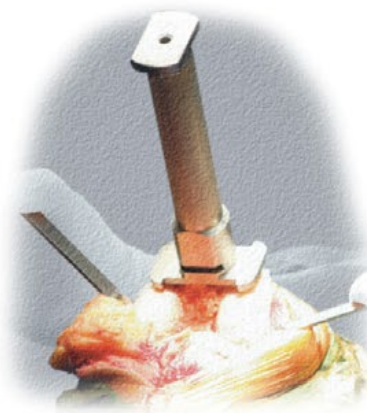
F R E E D O M[®]



K N E E



Freedom Total Knee[®] System Surgical Technique



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OVERVIEW

Surgical technique is an important factor in providing consistent and reproducible results. Basic principles of total knee replacement surgery should be maintained throughout the procedure. The surgeon must pay close attention to balancing the flexion and extension gaps, accurately sizing the femoral, tibial, and patellar components, positioning the femoral component in appropriate external rotation, removing excessive osteophytes of the posterior condyles, maintaining the joint line and implanting the final components using modern cementing techniques.

Preparation of the femur, tibia and patella can be achieved independently based on surgeon preferences. The instrumentation is not dependent on sequential steps during preparation of the three components. The principles of measured resection (replacing removed bone with equal amounts of implant) are used to provide this versatility during the operation. At the time of trialing the implants, we recommend that the surgeon assess overall alignment, extension angle, varus/valgus stability, flexion angle, patellofemoral tracking and anterior posterior stability.

PREOPERATIVE PLANNING

The angle between the mechanical and anatomic axis of the femur should be reproduced intraoperatively. You may contact your Maxx Medical representative for x-ray templates. The tibial component should be positioned perpendicular to the mechanical axis of the tibia. The final sizes must be determined intraoperatively as x-rays only provide an approximation. Please contact your Maxx Medical representative if you anticipate using the smallest or largest size, as it is our policy to provide components of every size in the system to accommodate any situation that may occur during the procedure.

The surgical technique outlined is specific to the Freedom Total Knee® System. The technique described uses the classical anterior midline incision to access the knee joint via a medial parapatellar arthrotomy. However the subvastus and midvastus approaches can readily be used with the same instrumentation. Your Maxx Medical representative can supply instrumentation to accommodate your preferred approach.

The **femoral A/P sizing guide** is an anterior referencing system that helps provide a consistent flexion gap. Regardless of the instrumentation used, equalization of the flexion and extension gaps is imperative to ensure knee stability.

INCISION AND EXPOSURE

Prior to incision, the superior pole of the patella is marked with the knee flexed at 30°. The tibial tubercle is identified and marked. An anterior midline longitudinal incision is made from a point slightly proximal to the superior pole of the patella passing just medial to the tibial tubercle at its distal margin. If significant tension is noted along skin edges, the incision should be extended to minimize risk of wound-edge necrosis.

Visualize the extensor mechanism without undermining the medial and lateral skin flaps. We recommend using a surgical marker to mark the medial parapatellar arthrotomy line starting from the medial edge of the extensor mechanism along the medial border of the patella to the medial edge of the patella tendon (Fig. 1). Be cautious not to transect the quadriceps in thinner patients with a small quadriceps tendon, as this could compromise postoperative rehabilitation protocols. Perform the arthrotomy with the knee in 30° of flexion.

Extend the leg and excise the fat pad under the patella tendon. Release excessive osteophytes along the margin of the patella. Retract the patella laterally with the knee in extension and release the patellofemoral ligaments. At this point, release of the anterior horn of the lateral meniscus will facilitate retraction of the extensor mechanism to the lateral side. Perform an abbreviated medial release of the proximal soft tissue attachments to the proximal tibia in standard fashion.



Figure 1

INCISION AND EXPOSURE (continued)

Release the anterior cruciate ligament and remove the medial and lateral meniscus. This will allow further edge exposure of the proximal tibia. Place retractors along the medial and lateral sides of the tibia for full visualization.

NOTE

If the Freedom® CR femoral component is being used, be careful not to disrupt the attachment of the posterior cruciate ligament (PCL) to the medial femoral condyle.

FEMORAL PREPARATION

Establishing femoral entry site

Using the **femoral step drill**, make an entry hole into the medullary canal of the femur (Fig. 2). The starting point should be anterior to the PCL attachment on the medial femoral condyle, just medial to the midline axis of the femur. Suction the medullary contents prior to insertion of the **distal femoral cutting guide (DFCG)** to reduce the potential of fat embolization.

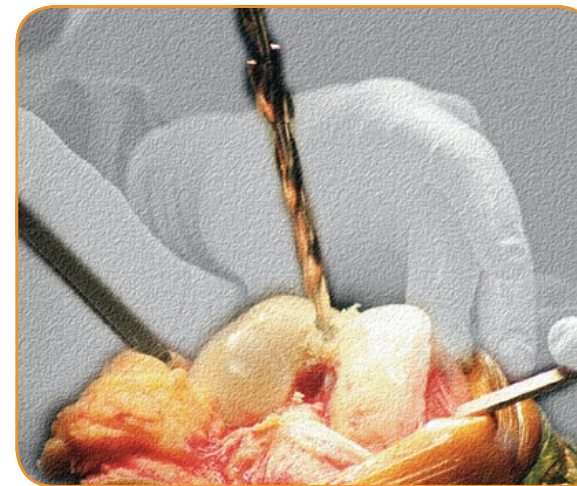


Figure 2

FEMORAL PREPARATION (continued)

Distal femoral valgus angle preparation

Confirm that the correct side (Right or Left) is oriented on the guide (Fig. 3). Slowly insert the **DFCG**. Advance the **DFCG** until the endplate rests securely on the condyles. Secure the **distal femoral cutting jig** to the distal femur with **pins**. Release the **adapter** and remove the **distal femoral cutting guide** using the **detachable slap**, if necessary.

NOTE

The **distal femoral cutting jig** (Fig. 4) cuts the distal femur in a measured resection. The standard cut is 9mm. An optional cut slot is available which provides an additional 4mm of resection. Additional holes allow the block to be repositioned in 2mm increments.

Use the **oscillating saw** to make the distal femoral face cut at 6° valgus (Fig. 5 and 5A). Additional valgus adaptors are available to provide 4° and 8° valgus cuts as well.

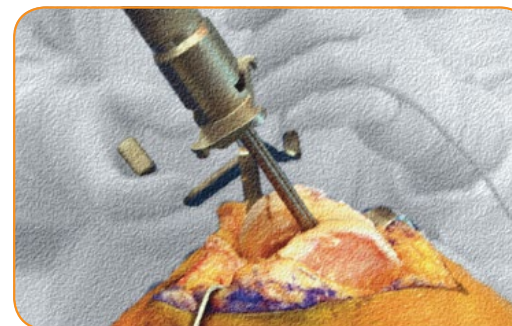


Figure 3



Figure 4



Figure 5



Figure 5A

FEMORAL PREPARATION (continued)

Sizing the distal femur

Secure the **femoral A/P sizing guide** to the distal face of the femur and confirm that the correct side is read (Right or Left). Use the **stylus** to adjust the height of the sizing guide to the highest point on the anterior aspect of the distal femur. Once adjusted, place **headless pins** into the two 3° external rotation slots (Fig. 6) Read the size using the indicator.

NOTE

The **femoral A/P sizing guide** is a single-unit, reversible anterior referencing instrument (Fig. 7). It allows for sizing of both the right and left femur based on the orientation of the guide. It also allows the surgeon to set the femur in 3° or 6° of external rotation, based on the posterior condylar axis. Intraoperatively, the rotation can be verified using the anteroposterior axis (Whiteside line) (Fig. 7A) or the surgical transepicondylar axis of the femur.

Completing the distal femoral preparation

Position the **5-in-1 cutting block** over the **headless pins**, centering the block on the M/L dimension of the femur (Fig. 8).



Figure 6

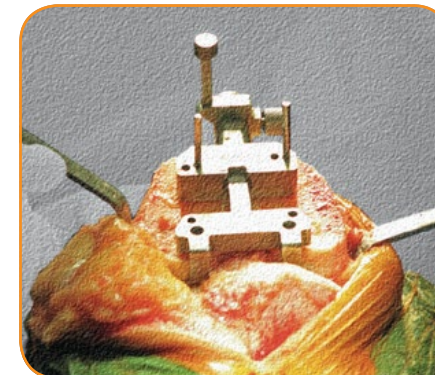


Figure 7



Figure 7A

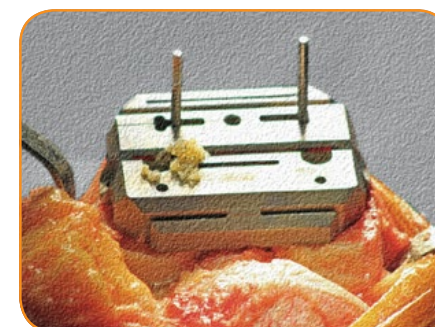


Figure 8

FEMORAL PREPARATION (continued)

Secure the **5-in-1 cutting block** to the femur using **threaded pins** (Fig. 9, 10). Confirm that the anterior cut will not notch the anterior cortex of the femur. Remove the **headless pins**. Additional stability is achieved with the use of two 6.5mm **cancellous screws** placed through the lug holes.

Using an **oscillating saw with a 1.27mm thickness blade**, prepare the femur in the following order (Fig. 11, 12).

1. Anterior cut
2. Posterior condylar cut
3. Superior champher cut
4. Inferior champher cut
5. Trochlear cut

NOTE

If positioned in external rotation correctly on the distal face of the femur, then more posteromedial femoral condyle would be removed compared to the posterolateral femoral condyle. Be careful not to transect the attachment of the medial collateral ligament or the lateral collateral ligament during resection of the posterior condyles.

If screws have not been used to hold the 5-in-1 cutting guide, then use a **5mm peg drill** to make the two lug holes at the appropriate locations of the distal femur.

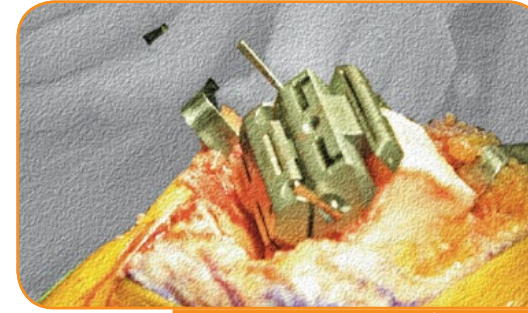


Figure 9

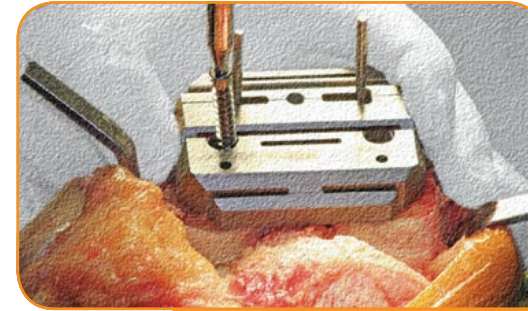


Figure 10

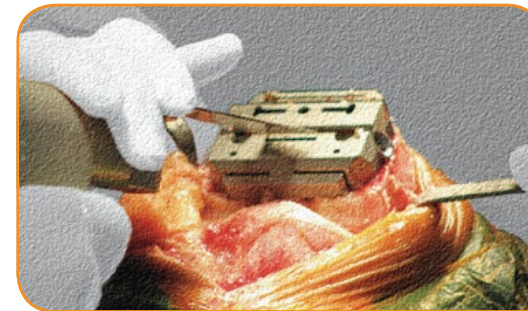


Figure 11

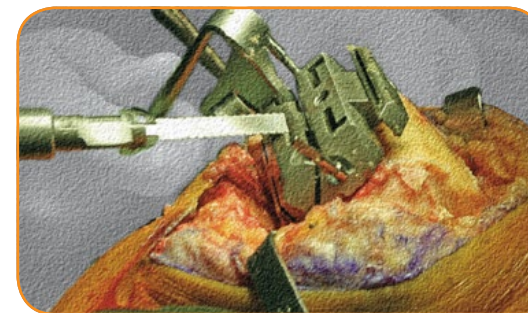


Figure 12

FEMORAL PREPARATION (continued)

If implanting a posterior stabilized (PS) design, see “PS box cut preparation” below. If opting to use the cruciate retaining (CR) design, proceed to “Removing the posterior osteophytes” section.

PS box cut preparation

Secure the same size **box cut guide** to the femur. With a **reciprocating saw**, use the guide to make the box cut on the distal femur (Fig. 13). Be careful not to undermine the medial or lateral condyles and risk fracture.

Remove posterior osteophytes

Using an **osteotome** or **rongeur** (Fig. 13A), remove any posterior osteophytes. The femur is now prepared to accept either the cruciate retaining (CR) or posterior stabilized (PS) **femoral component**. The preparation should be done in a measured resection so the amount of bone removed will be duplicated by the implant when positioned on the distal femur.

NOTE

The above femoral preparation was done in a measured resection. Trial components can be used for gap balancing, after tibial preparation.

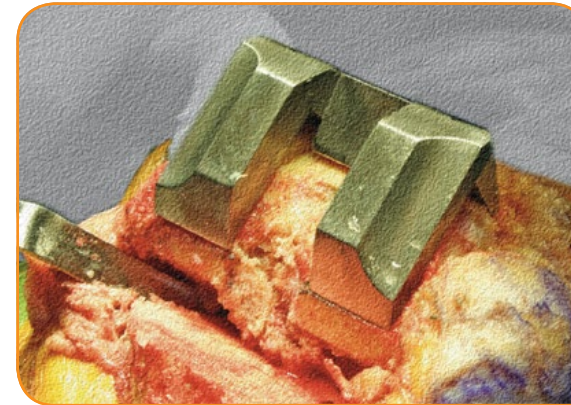


Figure 13

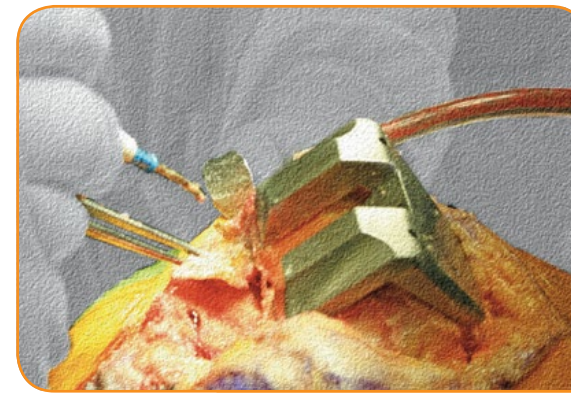


Figure 13A

TIBIAL PREPARATION

Extramedullary tibial alignment and proximal tibial resection

Align the **tibial cutting guide (TCG)** and stabilize the guide using the spring around the ankle (Fig. 14). Use the **gross adjustment knob** and align the **TCG** with the mechanical axis of the tibia in the coronal and sagittal planes. Secure the guide with one **pin**. At this time, confirm parallel alignment of the **TCG** to the mechanical axis in both planes. Use the **fine adjustment knob** at the proximal end of the **TCG** to adjust the height of the cutting slot (Fig. 14A). A **tibial stylus** can be used at this point to approximate resection height at either 2mm below the lowest point or 9mm below the highest point on the proximal tibia. Secure the **TCG** to the bone with two **pins**. Tighten all **knobs**.

OR

Intramedullary tibial alignment

Access to the intramedullary canal of the tibia is made with the **8mm femoral step drill**. The fluted rod from the **IM tibial alignment assembly** is advanced into the canal and the collar of the assembly is brought to rest on the surface of the tibia (Fig. 14B). An external drop rod can then be used to verify alignment with the mechanical alignment axis of the tibia. A stylus is placed into the cut slot to approximate either a 2mm cut from the lowest point of the proximal tibia or 9mm from intact cartilage (Fig. 14B). The **tibial cut block** is pinned in place, and all adjustment knobs are released. The assembly is disengaged from the cut block and removed. The proximal tibial cut is made in the standard fashion.

NOTE

The cutting slot on the **TCG** is angled to provide a 3° posterior slope. If the PCL is being retained, be cautious not to transect the PCL with the saw blade. We recommend placing a ¼-inch osteotome in front of the PCL to ensure it is protected from inadvertently passing the saw blade too far posterior (Fig. 15).



Figure 14

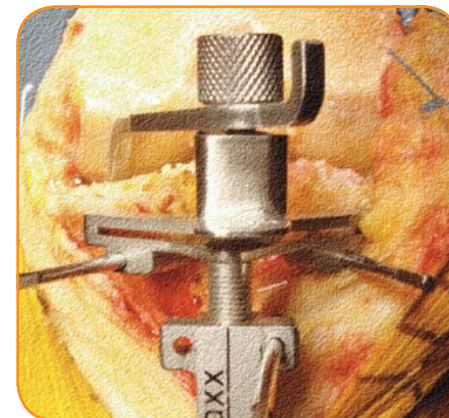


Figure 14A



Figure 14B

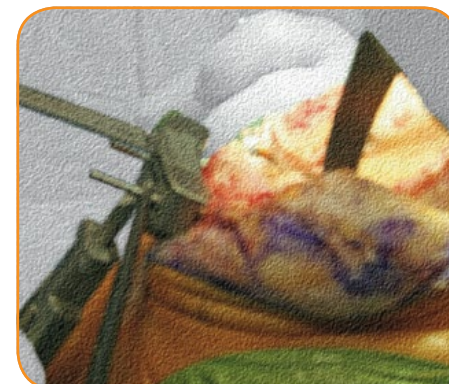


Figure 15

TIBIAL PREPARATION (continued)

Refining the proximal tibial face cut

Confirm alignment using the **tibial alignment block** and **tibial alignment rod**. Make adjustments to the proximal tibial face cut, if necessary, to ensure alignment of the rod with the mechanical axis of the tibia (Fig. 16).

NOTE

Rotational alignment can also be adjusted using the optional **free-floating baseplate**. The baseplate can be freely placed on the proximal surface with an articular surface liner of the appropriate thickness. The knee is reduced and taken through a range of motion. This allows the baseplate to freely locate on the proximal surface of the tibia. With the knee in extension, mark the midline of the baseplate on the bone corresponding to the laser etch mark found in the front of the baseplate. This serves as a guide to reproduce the rotation of the baseplate.

Tibial baseplate preparation and rotational alignment

Place the appropriately sized **tibial baseplate** (Fig. 17) on the resected surface of the proximal tibia. The appropriately sized baseplate should have bony support on all sides with no overhang (Fig. 17A). Use the **tibial alignment rod** through the **tibial tray coupler** to adjust rotation of the **tibial baseplate**. The medial $\frac{1}{3}$ of the tibial tubercle should serve as an anatomic landmark to guide rotational placement of the baseplate. Secure the **tibial baseplate** with **long pins** (Fig. 17B) and disengage the **tibial tray coupler**.



Figure 16



Figure 17



Figure 17A



Figure 17B

TIBIAL PREPARATION (continued)

Place the **tibial broach housing** on the **tibial baseplate** (Fig. 18).

Reaming the proximal tibia

Using the **tibial entry reamer**, gently ream the proximal tibia until the marked groove on the reamer reaches the top of the **tibial broach housing** (Fig. 19). If the **metal-backed tibia tray** is being used, go to “Broaching the tibia.” Otherwise, skip to “Trialing the tibial components.”

Broaching the tibia

Gently tap the **tibial broach** (Fig. 20) through the **tibial broach housing** until it reaches the endpoint (Fig. 20A). Use the **detachable slap** to remove the **tibial broach**. Release the guide.

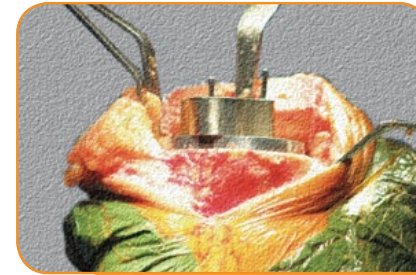


Figure 18



Figure 19

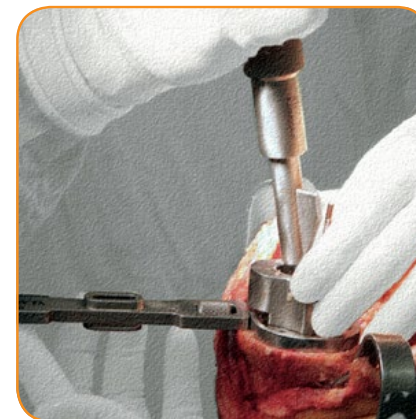


Figure 20



Figure 20A

TIBIAL PREPARATION (continued)

Trialing the tibia components

Place and impact the appropriate **femoral component**, followed by the **tibial baseplate**, insert thickness trial **tibial insert** into the **tibial baseplate** (Fig. 21). Reduce the knee and trial the components (Fig. 21A).



Figure 21



Figure 21A

PATELLA PREPARATION

The preparation of the patella should be done with the patella everted and the knee flexed to 30°. The minimum thickness of the resected patella should be 8mm. Overstuffing the patellofemoral joint may lead to flexion loss, while leaving a thin patella may lead to fracture or early loosening. Use a **caliper** to help decide the amount of resection that is required.

Once the patellar surface is resected (Fig. 22), use the **patellar drill guide** to assess the size of the patella. Using the **patellar drill guide** and the **peg drill** (Fig 22A), drill three holes in the remaining patellar bone. Place the **patella trial** (Fig. 22B) onto the resurfaced patella and begin range of motion to evaluate patellar tracking.



Figure 22



Figure 22A



Figure 22B

TRIAL REDUCTION AND GAP BALANCING

Perform a trial reduction of the components (Fig. 23). Check alignment, varus/valgus stability, extension, patellofemoral tracking, anteroposterior stability and flexion degrees. Use a gap balancing chart to adjust and modify any imbalance in the knee. Soft tissue releases can be performed as necessary to allow for fine tuning the tension in extension and flexion.

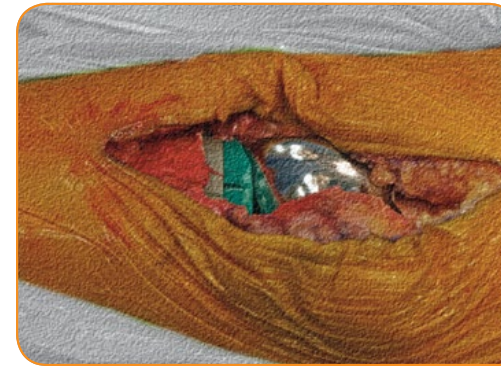


Figure 23

IMPLANTATION

Using the standard mixing protocol for the bone cement, mix and prepare the bone cement for cementing the implants.

We recommend the following order of implantation.

1. Tibial component
2. Femoral component
3. Patellar component
4. Tibial articulating surface

Prior to cementing, irrigate the bone surfaces and drill sclerotic areas with a $\frac{1}{8}$ " **drill bit** to a depth of approximately $\frac{1}{8}$ ". Firmly press cement into the bone surfaces (Fig. 24), including the reamed keel entry hole, to allow for adequate interdigitation. Place cement on the undersurface of the **tibial component** and firmly impact the **tibial component** (Fig. 25) into place using the **tibial impactor**. Remove excess cement.



Figure 24



Figure 25

IMPLANTATION (continued)

Hyperflex the knee and dry the distal femoral bone cuts (Fig. 25A). Finger pressurize the posterior condyles with cement. Apply bone cement to the undersurface of the **femoral component**. Firmly impact the **femoral component** into place using the **femoral impactor**. Remove excess cement.

If the **metal-backed tibial tray** is being used, irrigate the surface of the tray and remove any excess debris to clear the locking mechanism. Firmly impact the selected **articular surface liner** into place (Fig. 26) and check to see that the locking mechanism is engaged.

Reduce the knee and place into extension. Evert the patella. Dry the bony surface of the patella. Place cement into the bone surfaces. Apply bone cement to the undersurface of the **patella implant**. Place the **patella implant** in the resected bone. Use the **patella clamp** to secure the **patella implant** (Fig. 26A). Trim excess osteophytes and remove excess cement.

Closure is performed in the usual manner (Fig. 27).



Figure 25A

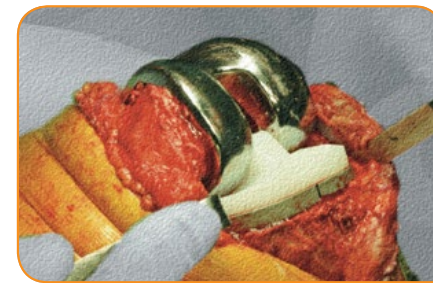


Figure 26



Figure 26A

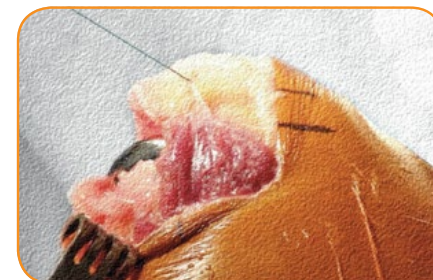


Figure 27

Pursue Life™

For more information about Freedom Knee®
please contact your local representative.

Freedom Total Knee® System (CR and PS)

Rx only



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Carefully read all instructions and be familiar with the surgical techniques prior to use.

Please see the package insert for complete device description, product selection information, indications, contraindications, precautions, adverse effects, warnings, materials, sterilization and patient guidance associated with the Freedom Total Knee® System.

CAUTION: THIS DEVICE IS RESTRICTED TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

WARNING: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY

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