EPISURF Medical

# SURGICAL TECHNIQUE
# EPISEALER® KNEE

## SURGICAL TECHNIQUES:

- EPISEALER CONDYLE SOLO
- EPISEALER TROCHLEA SOLO
- EPISEALER FEMORAL TWIN

EPISEALER SURGICAL TECHNIQUE

# MAGNETIC RESONANCE IMAGING

**Magnetic Resonance Imaging - Why a specific protocol?**

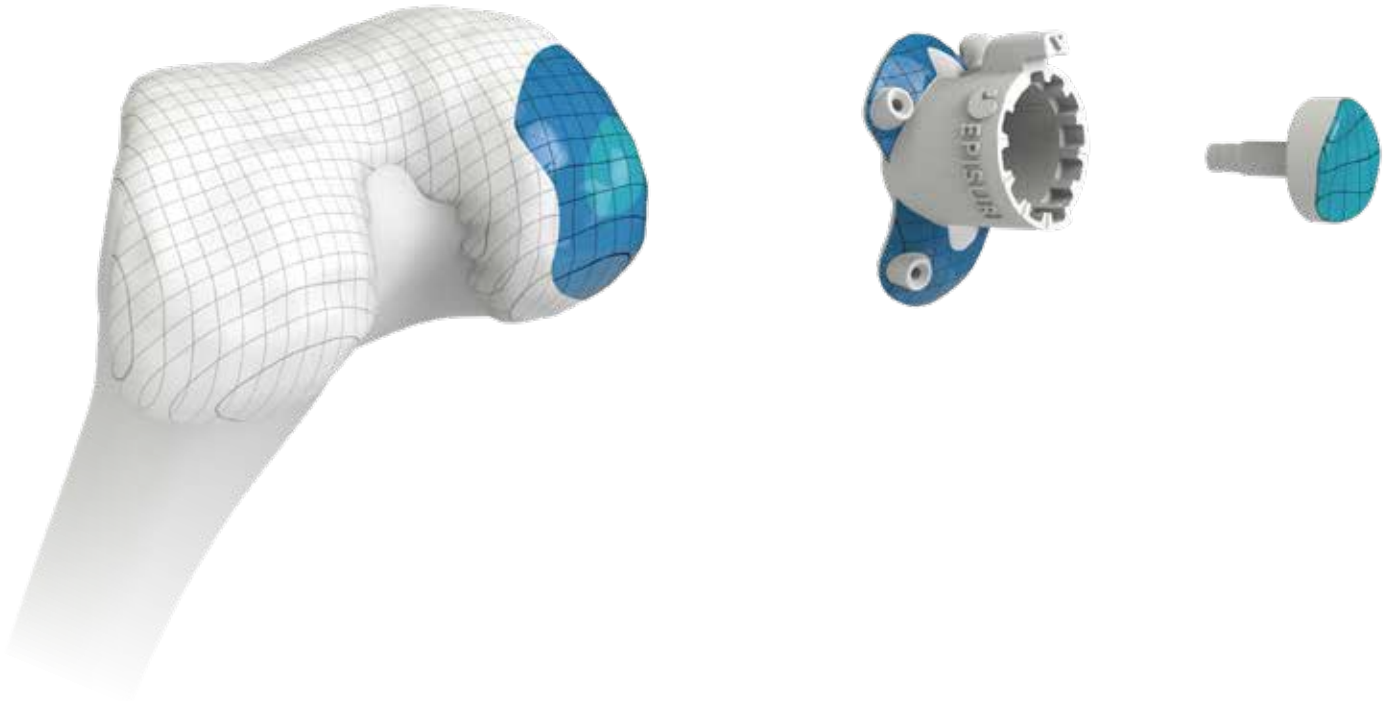
The Episealer implant and the Epiguide® surgical tool are designed based on MRI data. MRI provides a detailed profile of the anatomy and is used both for geometric acquisition and cartilage lesion assessment, using tailored 3D segmentations as well as conventional diagnostic sequences. The Episurf MRI protocol assesses all aspects of the patient's knee chondral and bony defects in a very precise way. From these detailed MRI sequences, patient-specific surgical implants and instruments can be precisely engineered.

The Episurf MRI protocol needs to be installed on an MRI scanner in your radiology department. The protocol is available from your local Episurf representative who will partner with your radiology team to get your scanner validated for the correct sequences.

**The protocol**

Episurf have developed an MRI protocol to be used when an Episealer implant is to be designed for a suitable patient. This is to ensure correct assessment and 3D representation.

The protocol does not need any special equipment to run the Episurf MRI protocol other than an MRI machine with a magnetic field strength of at least 1.5 T and an appropriate knee coil.



## MAGNETIC RESONANCE IMAGING

### How to set up the protocol

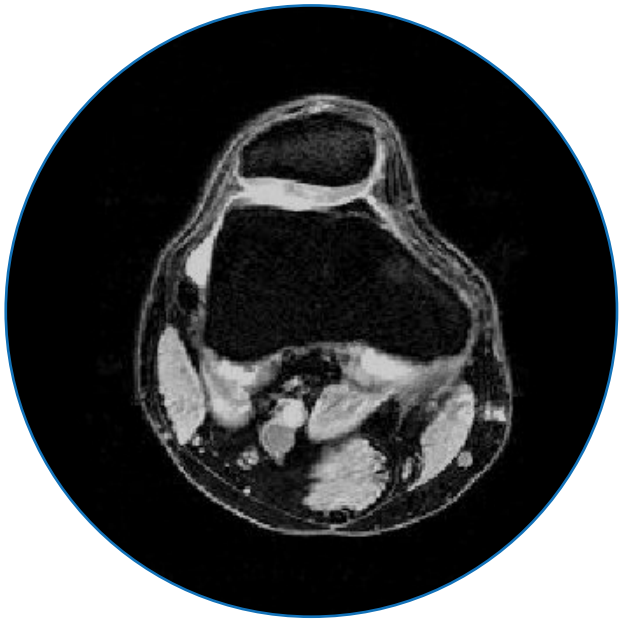
Working with your local Episurf representative, the MRI protocol is put in place in **4 simple** steps:

1. **Specify the MRI machine:** state which MRI machine you are using, so the correct protocol can be provided.
2. **Install the protocol:** once the Episurf representative has sent your MRI department the specific protocol, the specific settings can be simply loaded on your machine. Your Episurf representative will be available to help you.
3. **Run a test scan:** once the MRI protocol has been correctly set-up on the MRI scanner, a test scan will need to be performed. This is to ensure that the quality of the MRI data is producing the correct quality images.
4. **Complete the set-up:** Episurf will confirm with you that the test scan is satisfactory. You are now ready to start scanning patients.

### The sequences

#### 3D sequence

An SPGR (Spoiled Gradient Echo) fat-saturated sequence with **1 mm thick** slides with a **resolution of 0.5 x 0.5 mm** is used to reconstruct the joint anatomy. The surgical tools and the personalised implant are designed using the data from the MRI to accurately reconstruct the patient´s unique anatomy.



#### Diagnostic scans

In order to obtain a complete assessment of the cartilage defects, 4 or 5 different conventional diagnostic sequences are used. Together with our radiological team, we will identify cartilage and bony lesions and make suggestions on the size and position of any implant that may be required.

# DAMAGE MARKING REPORT

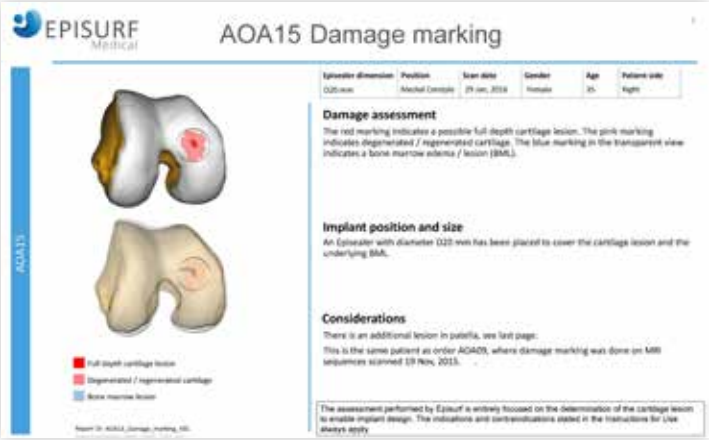
## Damage Marking Report (DMR)

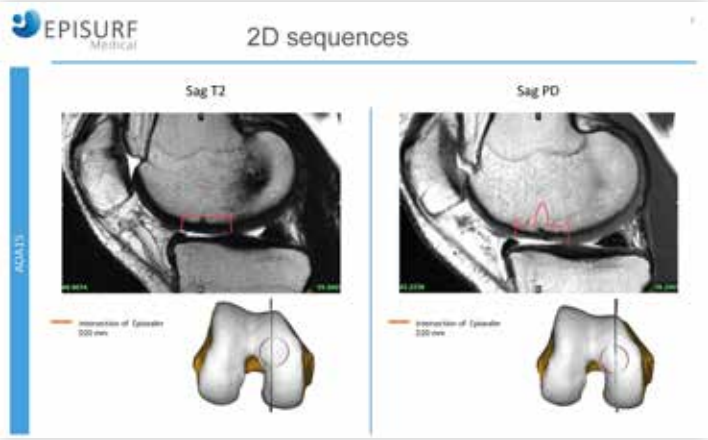
The patient's detailed MR images are used to create a detailed virtual model of the knee included in a Damage Marking Report (DMR). This report enables 3D visualisation of:

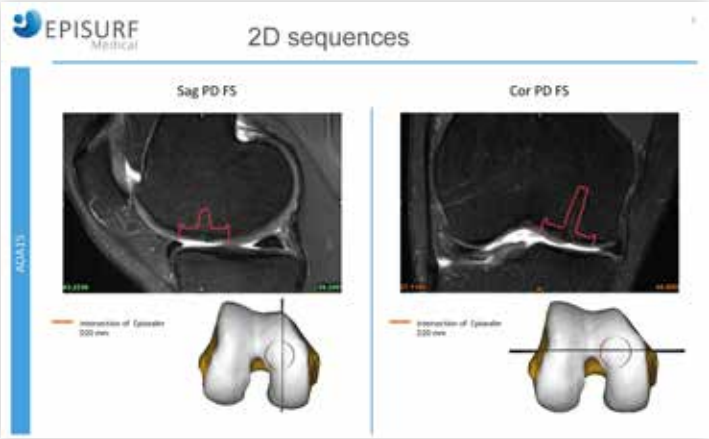
- cartilage damage
- subchondral bone damage
- bone marrow lesions such as bone edema
- previous surgeries
- osteoarthritic signs
- other pathologies

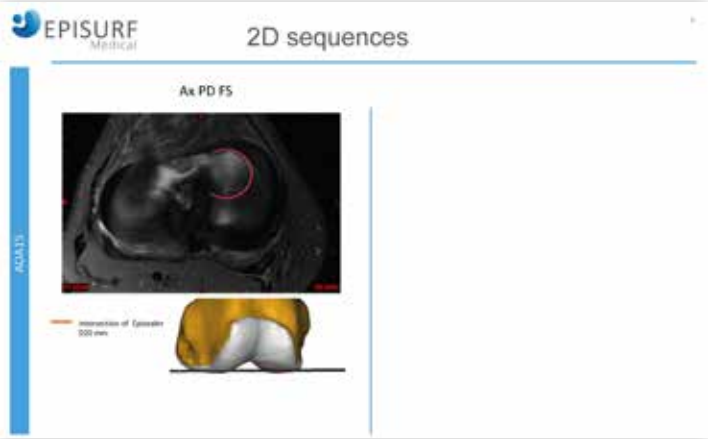
This 3D virtual visualisation will enable the clinical team to explore a patient's individual level of damage and assess their suitability for an Episealer implant. Based on this 3D presentation you will be able to determine the level of damage and review any potential solutions that Episurf can offer.

If it is assessed that Episealer is a suitable therapeutic option for a specific patient, an order can be created for devices to treat the specific osteochondral defect. The suggested Episealer 'Final Design', if appropriate, will be supplied, showing the exact position of the Epiguide and Episealer. This can be fine-tuned by working with Episurf if so needed.



## EPISEALER OVERVIEW

Each Episealer is uniquely designed to perfectly fit a patient´s individual knee cartilage and bone damage, determined by both the size and the location of the defect. The one-piece design of the Episealer has two functions:

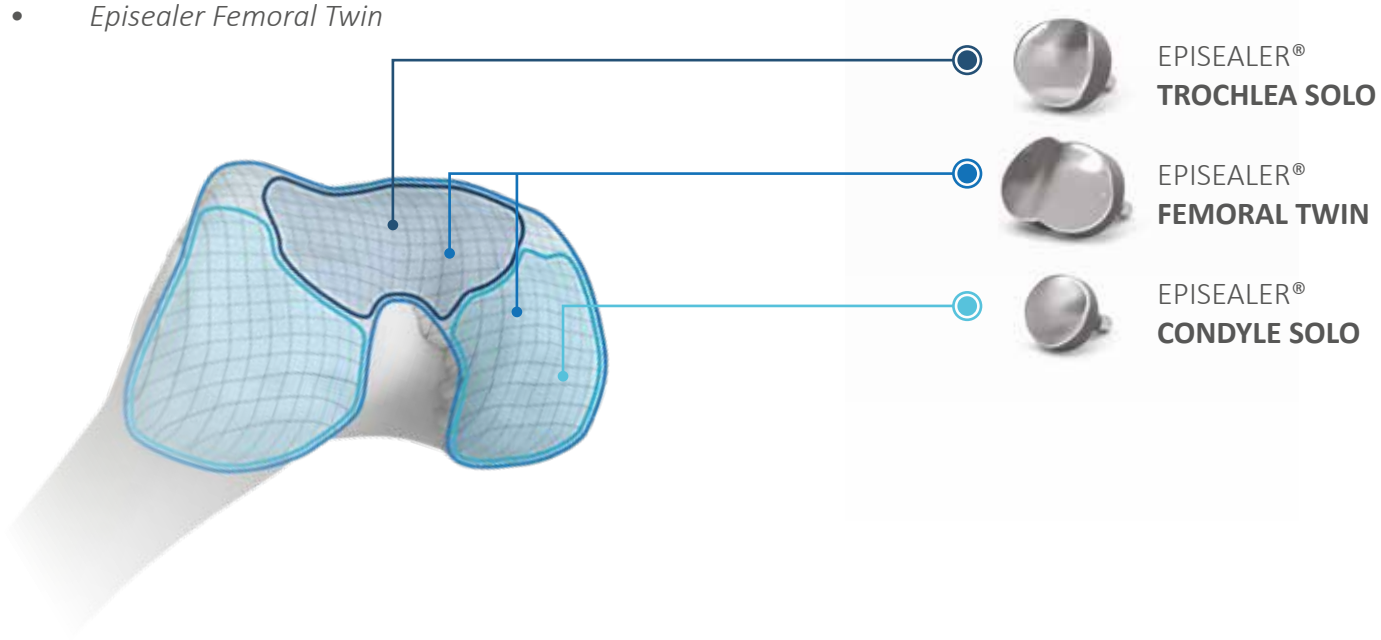
- **the hat** sits within the subchondral bone bed, loading in a physiological manner with the chondrophilic edges bonding to the patient's healthy cartilage.
- **the peg** gives initial stability and press-fits into the subchondral cortex allowing stable fixation and rapid recovery post-operatively.

An Episealer can be produced for defects on the medial femoral condyle, lateral femoral condyle or within the femoral trochlea.

*EPISEALER PRODUCT LINE*

*The Episealer product line consist of three product:*

- *Episealer Condyle Solo*
- *Episealer Trochlea Solo*
- *Episealer Femoral Twin*




*"What I thought was good with the implant is that it was customized so that it addressed both his lesion and anatomic proportions in the knee. This is the key difference, that you get an implant for the individual patient. I was astonished the day after the operation when he said that he didn´t need any painkillers and that he had slept at night."*

**Orthopaedic Surgeon**
Denmark

## EPISEALER OVERVIEW

Each individual Episealer implant is milled precisely from cobalt-chrome alloy. The top articulating surface has a personalised contour that precisely matches the geometry of the patient's knee. No two Episealer designs will ever be the same as they are personally produced, dependent on each indivual patient's unique pathology and position within the knee.

The undersurface and sides of the prosthesis have a coating of titanium and hydroxyapatite to biologically fix the implant to the patient's bone.

### Cobalt-chrome

- Can be polished to an ultra-smooth surface ($R_a$ = 0.5µm)
- Low risk of metal debris
- Well-tested and proven medical device material

### Physiological surface

- Articulates more naturally with opposing cartilage
- Recreates patient's natural morphology
- Allows an anatomical reconstruction

### Chondrophilic Ti and HA coating

- Seals the Episealer to the cartilage
- Promotes healthy cartilage against the edge of the Episealer
- Prevents joint fluid penetration between the Episealer and surrounding tissue

### Titanium undercoating

- Clinically proven long-term fixation
- Allows bone integration
- Roughness increases surface area and aids initial stability

### Hydroxyapatite outer coating

- In clinical use for over 30 years
- Rapid osseointegration
- Promotes bone ongrowth

| Name | Article number | Diameter implant hat | Surface size |
|---|---|---|---|
| Episealer Condyle Solo D12 | 11112 | 12 mm | 1.1 cm² |
| Episealer Condyle Solo D15 | 11115 | 15 mm | 1.8 cm² |
| Episealer Condyle Solo D17 | 11117 | 17 mm | 2.3 cm² |
| Episealer Condyle Solo D20 | 11120 | 20 mm | 3.1 cm² |
| Episealer Trochlea Solo D20 | 31120 | 20 mm | 3.1 cm² |
| Episealer Trochlea Solo D25 | 31125 | 25 mm | 4.9 cm² |
| Episealer Trochlea Solo D29 | 31129 | 29 mm | 6.6 cm² |
| Episealer Femoral Twin 2xD15 | 51115 | 15 mm (length: 23 mm) | 2.9 cm² |
| Episealer Femoral Twin 2xD17 | 51117 | 17 mm (length: 26 mm) | 3.7 cm² |
| Episealer Femoral Twin 2xD20 | 51120 | 20 mm (length: 29 mm) | 4.8 cm² |
| Episealer Femoral Twin 2xD25 | 51125 | 25 mm (length: 35 mm) | 7.3 cm² |

# EPISEALER TOOLKIT

| | Name | Available sizes (mm)/Article No | | | | | |
|---|---|---|---|---|---|---|---|
| | | D12 | D15 | D17 | D20 | D25 | D29 |
| 1 | Drilling socket Condyle Solo | 13112 | 13115 | 13117 | 13120 | | |
| 1 | Drilling socket Trochlea Solo | | | | 33120 | 33125 | 33129 |
| 1 | Drilling socket Femoral Twin | | 53115 | 53117 | 53120 | 53125 | |
| 2 | Adjustment socket Condyle Solo | 13412 | 13415 | 13417 | 13420 | | |
| 2 | Adjustment socket Trochlea Solo | | | | 33420 | 33425 | 33429 |
| 2 | Adjustment socket Femoral Twin | | 53415 | 53417 | 53420 | 53425 | |
| 3 | Epimandrel Condyle Solo | 17112 | 17115 | 17117 | 17120 | | |
| 3 | Epimandrel Femoral Twin* | | 57115-57125 | 57117-57217 | 57120-57220 | 57125-57225 | |
| 4 | Epimandrel Trochlea Solo | | | | 37120 | 37125 | 37129 |
| 5 | Epidrill Condyle Solo | 12115 | 12115 | 12117 | 12120 | | |
| 5 | Epidrill Trochlea Solo | | | | 32120 | 32125 | 32129 |
| 5 | Epidrill Femoral Twin | | 52115 | 52117 | 52120 | 52125 | |
| 6 | Epidummy Condyle Solo | 14112 | 14115 | 14117 | 14120 | | |
| 7 | Episealer Condyle Solo | 11112 | 11115 | 11117 | 11120 | | |
| 8 | Epiguide Condyle Solo | 13712 | 13715 | 13717 | 13720 | | |
| 9 | Epidummy Trochlea Solo | | | | 34120 | 34125 | 34129 |
| 10 | Episealer Trochlea Solo | | | | 31120 | 31125 | 31129 |
| 11 | Epiguide Trochlea Solo | | | | 33720 | 33725 | 33729 |
| 12 | Epidummy Femoral Twin | | 54115 | 54117 | 54120 | 54125 | |
| 13 | Episealer Femoral Twin | | 51115 | 51117 | 51120 | 51125 | |
| 14 | Epiguide Femoral Twin | | 53715 | 53717 | 53720 | 53725 | |
| 15 | Epiguide insert Femoral Twin | | Part of Epiguide | Part of Epiguide | Part of Epiguide | Part of Epiguide | |

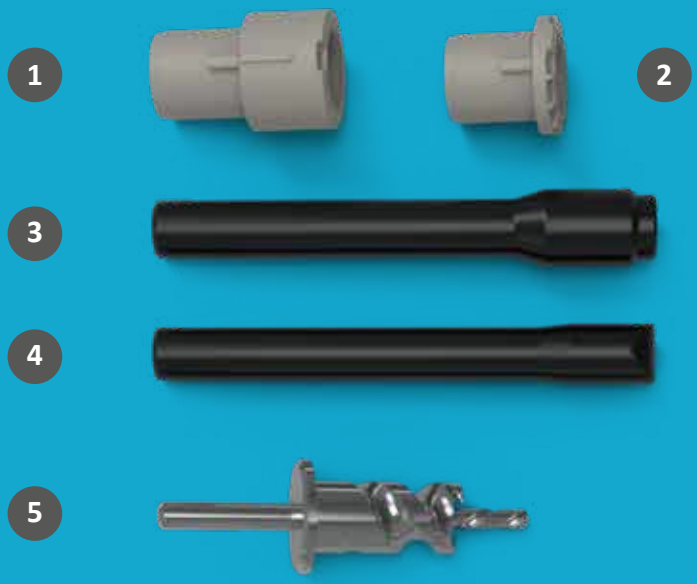
*The Epimandrel comes in two versions. The Toolkit includes either a flat or a round Epimandrel, depending on the patient-specific Episealer design (571XX=flat, 572XX=round)

Epidummy Condyle Solo
Episealer Condyle Solo
Epiguide Condyle Solo

Epidummy Trochlea Solo
Episealer Trochlea Solo
Epiguide Trochlea Solo

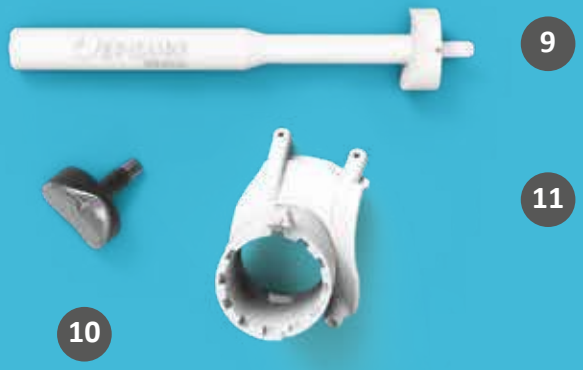
Epidummy Femoral Twin
Episealer Femoral Twin
Epiguide Femoral Twin

# Episealer Toolkit
## **Product overview**



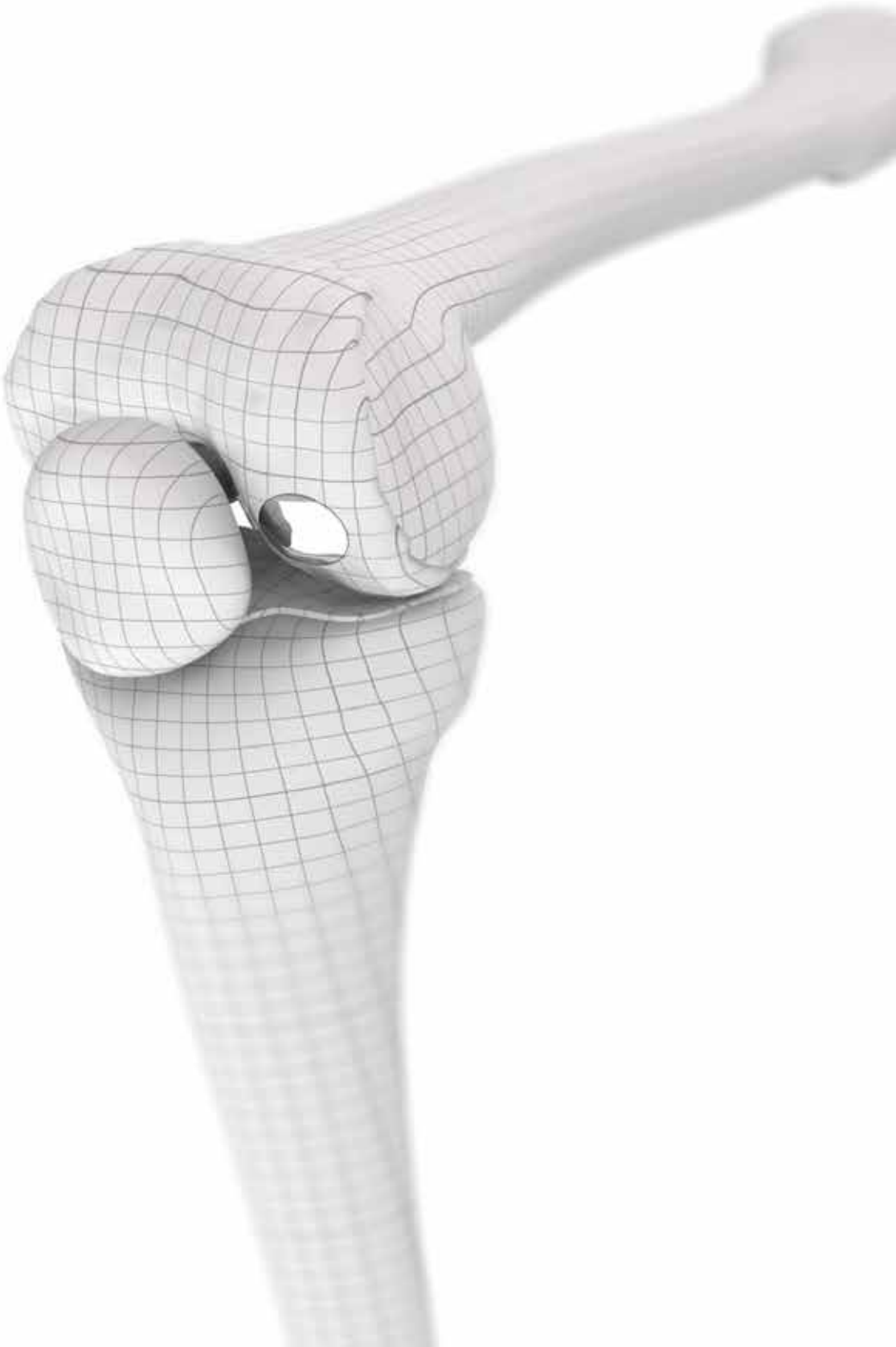

### Condyle Solo


### Trochlea Solo

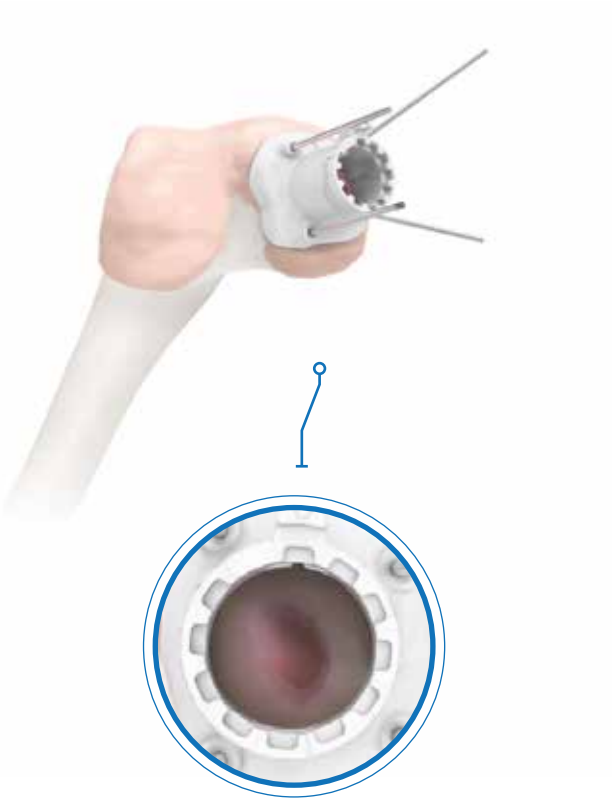



### Femoral Twin

# Episealer Condyle Solo
## **Procedure overview**



# 1 PLACING THE EPIGUIDE



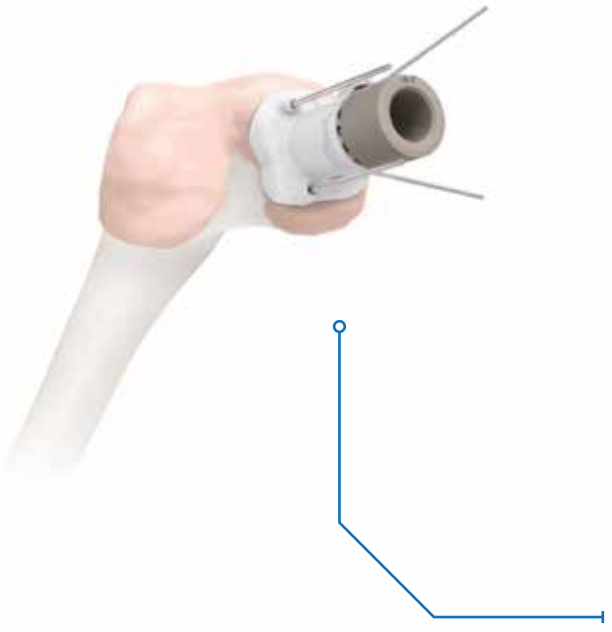
Make an incision long enough to fully expose the operative field. The complete base of the Epiguide must be visible through the incision. Place the Epiguide on the articular cartilage surface. Make sure to use the markings on the Epiguide, A (anterior) and P (posterior), to find the correct orientation when positioning the Epiguide.

Look through the circular opening of the Epiguide and make sure the bottom surface is placed flush to the cartilage surface all the way around the opening. This is important to achieve the correct drilling angle and depth.

Use a surgical drill and at least three surgical pins to attach and secure the Epiguide to the bone. After inserting the first pin, check that the Epiguide has not moved out of its unique position. Then insert the remaining pins.

**WARNING!**
**Make sure the Epiguide is securely fastened to the bone and that the bottoms surface is placed flush to the cartilage all way around the opening.**

# 2 ASSEMBLING THE DRILLING SOCKET



Mount the Drilling socket onto the Epiguide. The Drilling socket guides the first drill step.

Check that the Drilling socket is set in its correct position relative to the Epiguide; the arrow on the rim of the Epiguide must be in line with the marking on the Drilling socket.

Check that the Drilling socket is fully seated in the Epiguide.

**WARNING!**
**Ensure that the Drilling socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect Episealer placement.**

**Drilling socket fully seated**

**Start position**

# 3 DRILLING PROCEDURE - STEP ONE

Attach the Epidrill to the surgical drill and check that it is adjusted for drilling clockwise. Insert the Epidrill into the Drilling socket.

Use one hand to hold the Drilling socket steady in the Epiguide and the other hand to control the surgical drill. Start drilling and continue until the Epidrill stops at the top of the Drilling socket. Use moderate speed and keep the drill steady while applying only moderate force. Use vigorous lavage through the openings at the Epiguide during drilling to minimise heat effects to adjacent bone and cartilage tissue and to rinse away bone and tissue debris.

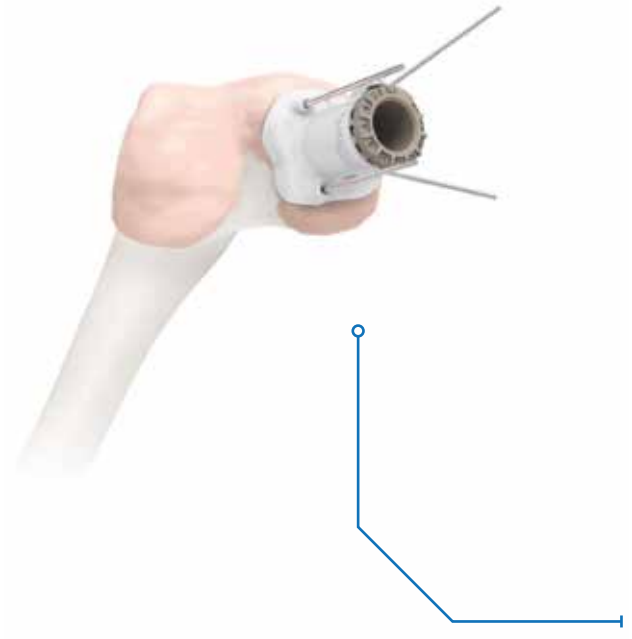
PRECAUTION
Make sure the Drilling socket is fully seated and is securely fastened in the Epiguide.

Make sure that the drill is correctly aligned in the drill guide to ensure drilling in the correct direction.

**Before drilling**

**After drilling**

# 4 DRILLING PROCEDURE - STEP TWO

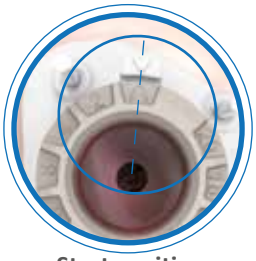


Remove the Drilling socket and insert the Adjustment socket aligned to the START position. Make sure the Adjustment socket is fully seated in the Epiguide.

Check that the surgical drill is adjusted for drilling clockwise and insert the Epidrill into the Adjustment socket. Use one hand to hold the Adjustment socket steady in the Epiguide and the other hand to control the surgical drill.

**WARNING!**
**Ensure that the Adjustment socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect implant placement.**

**Adjustment socket fully seated**



**Start position**

# 5 DRILLING PROCEDURE - STEP THREE

When inserting the Epidrill into the Adjustment socket, make sure that the tip of the Epidrill is inserted into the pre-drilled hole and that the large drill body is not in contact with the cartilage surface as the drilling starts.

Drill until the Epidrill stops at the top of the Adjustment socket. Use moderate speed and keep the surgical drill steady while applying only moderate force. Use vigorous lavage through the openings on the Epiguide during drilling. This will minimise heat effects to adjacent bone and cartilage tissues and will rinse away bone and tissue debris.

Remove the Epidrill.

PRECAUTION
If the drilling gets harder during the drilling process, residues may be stuck in the drilling channels. If this is the case, stop drilling, remove the Epidrill and remove all debris from the drilling channels. Re-insert the Epidrill all the way to the bottom of the drilled hole and continue the drilling process. Keep drilling until the Epidrill stops at the top of the Adjustment socket.

**Epidrill at start position**

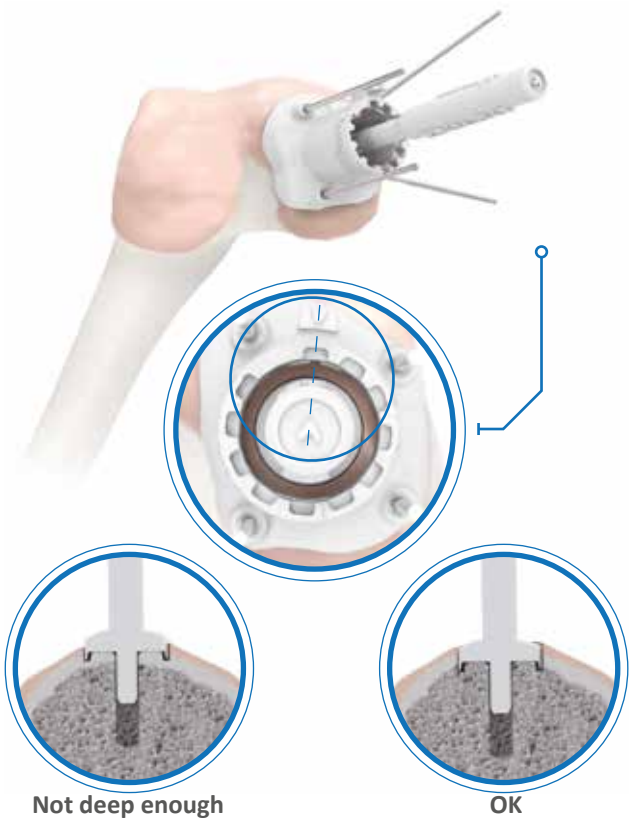
**Epidrill fully seated**

# 6 REMOVAL OF DEBRIS AND LOOSE CARTILAGE

Note the Adjustment socket position and remove the Adjustment socket from the Epiguide. Use adequate lavage en suction to clear all debris from the drilled hole.

**WARNING!**
**Ensure that there are no fringes or fronds on the cartilage edge after drilling. All debris along the cartilage edge should be removed using standard tweezers. Any residues of bone and/or cartilage that are left in the drilled hole may prevent the Episealer from becoming osseointegrated with the bone.**

# 7 EVALUATING THE DRILLED DEPTH

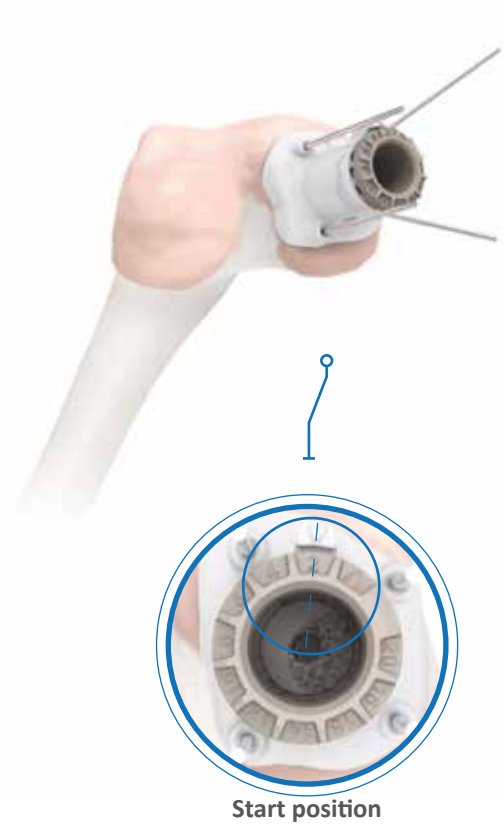



Insert the Epidummy into the drilled hole with its rotation mark aligned with the rotation mark of the Epiguide.

Compare the depth of the Epidummy top surface with the surrounding cartilage edge and assess the height difference. Use the openings in the Epiguide to evaluate the depth. If the Epidummy top surface is positioned approximately 0.5-1 mm below the adjacent articular cartilage surface, the drilling is finished. Proceed to step 9. If not, continue adjusting the drill depth according to step 8.

**WARNING!**
**Ensure that the top surface is positioned approximately 0.5-1 mm below the adjacent cartilage surface. If the Episealer is placed proud or too deep, it may damage surrounding and opposing soft tissues.**

# 8 ADJUSTING THE DRILL DEPTH




Re-assemble the Adjustment socket in the Epiguide. Adjust the drilling depth by turning the Adjustment socket to the desired setting; the desired setting on the Adjustment socket must be in line with the arrow on the Epiguide. The drill depth is increased by 0.2 mm in each step.

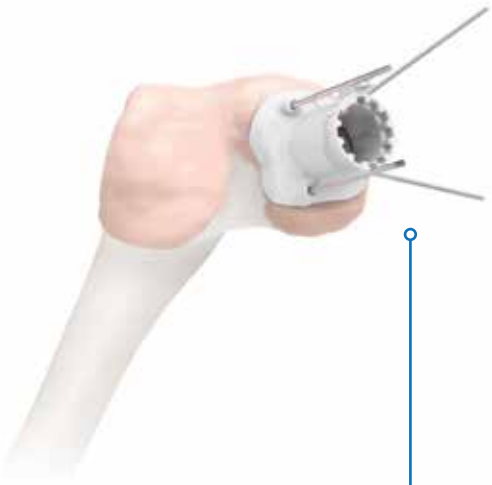
Repeat steps 5 through 7 until the Epidummy bottoms with its top surface approximately 0.5-1 mm below the surrounding cartilage.

PRECAUTION
It is recommended that any additional drilling is performed incrementally, increasing the drill depth by small increments at a time.

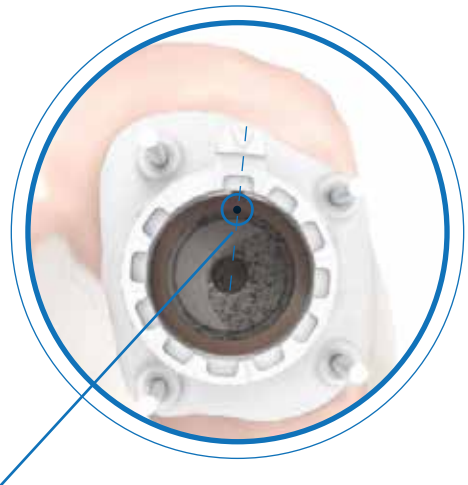
Note the drill depth setting. Upon removal and replacement of the Adjustment socket, it needs to be replaced at the correct depth to avoid unintentionally drilling too deep.

**WARNING!**
**Ensure that the Adjustment socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect Episealer placement.**

# 9 MARKING THE EPISEALER ROTATION



Use a sterile pen to mark the direction of rotation for the Episealer. Make the mark on the cartilage surface aligning the rotation mark of the Epiguide.

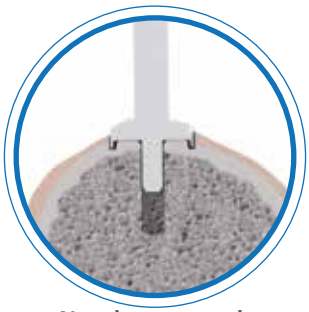


**Mark here**

# 10 FINAL CHECK

Remove the Epiguide and check the drill depth again. Insert the Epidummy into the drilled hole with its rotation mark aligned with the mark on the cartilage surface.

**WARNING!**
**Ensure that the top surface is positioned approximately 0.5-1 mm below the adjacent cartilage surface. If the Episealer is placed proud or too deep, it may damage surrounding and opposing soft tissues.**



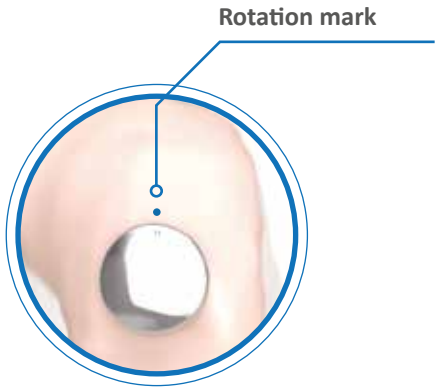
**Not deep enough**

**OK**

# 11 PLACING THE EPISEALER

Gently place the Episealer into the drilled hole. Check that the rotation mark on the Episealer is aligned to the rotation mark on the cartilage. if the rotation mark on the Episealer is not correctly aligned, use your fingers to gently turn it to the correct orientation.

Use your fingers to gently press the Episealer down into the drilled hole, ensuring the orientation is maintained.




# 12 DRIVING DOWN THE EPISEALER

Use the Epimandrel and a hammer to gently tap down the Episealer into the bone until bottomed. Make sure to tap evenly over the top surface of the Episealer. When fully seated, the top surface should be approximately 0.5-1 mm below the adjacent articular cartilage surface.

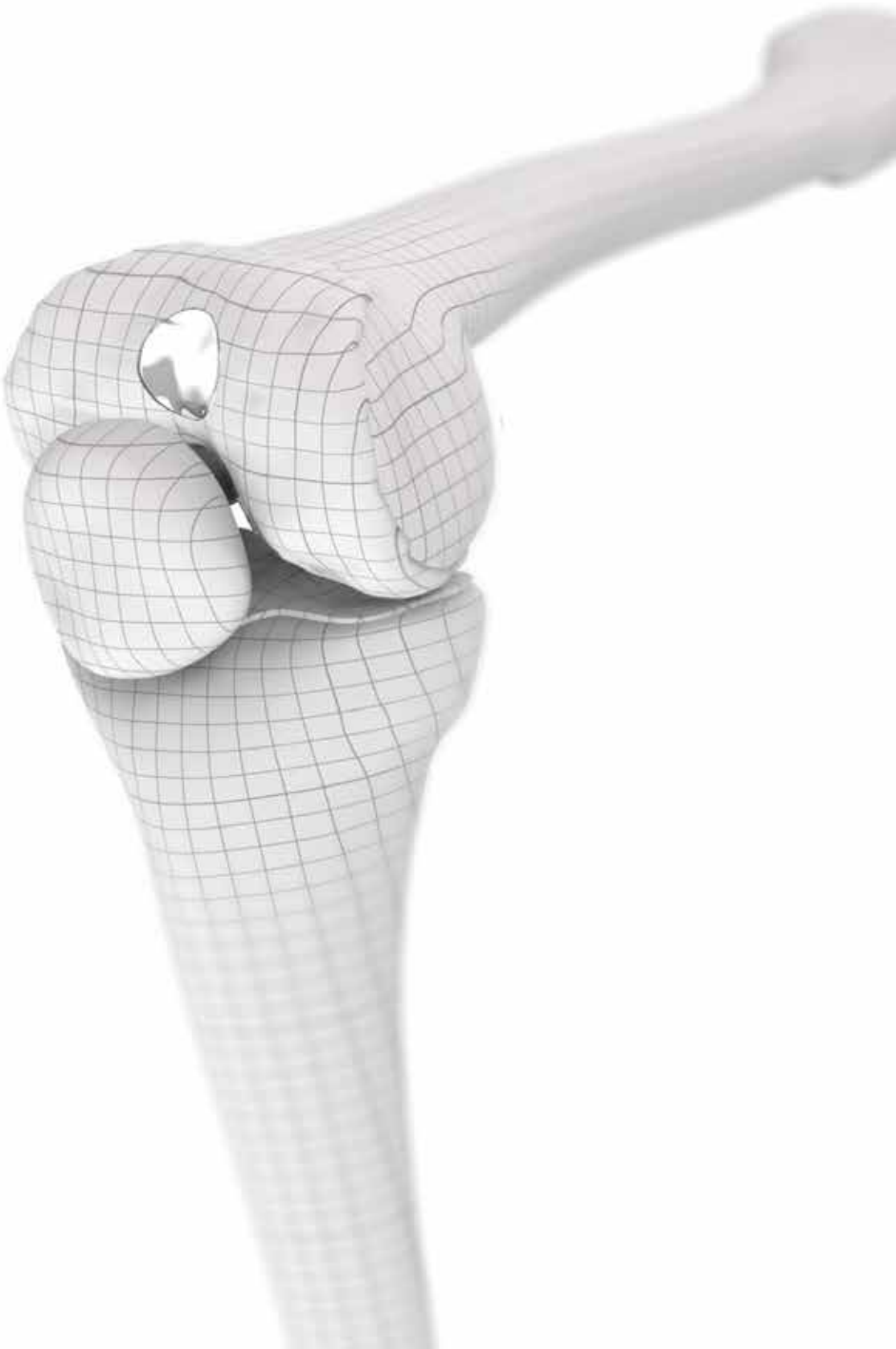
PRECAUTION
Make sure to gently tap the Episealer until fully seated. This is indicated by a more distinct sound.

**WARNING!**
**During insertion, carefully check that the rotational alignment of the Episealer has not changed.**

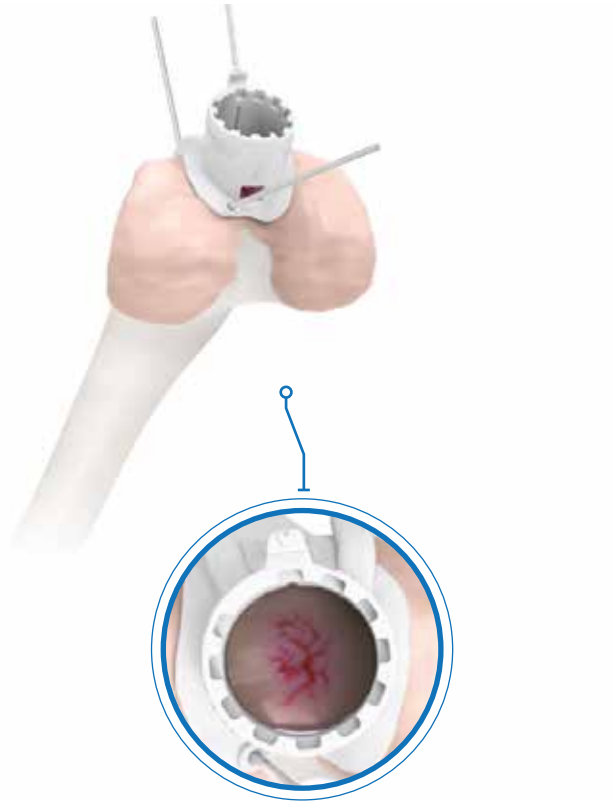
**Improper handling of the Episealer can cause scratches, nicks or dents that may have adverse clinical effects on opposing joint surfaces.**

## FINAL PLACEMENT

# Episealer Trochlea Solo
## **Procedure overview**



# 1 PLACING THE EPIGUIDE



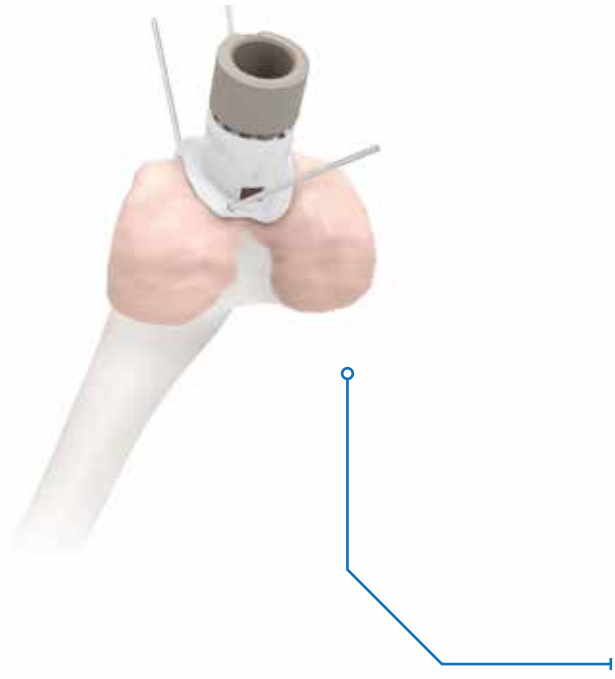
Make an incision long enough to fully expose the operative field. The complete base of the Epiguide must be visible through the incision. Place the Epiguide on the articular cartilage surface. Make sure to use the markings on the Epiguide, A (anterior) and P (posterior), to find the correct orientation when positioning the Epiguide.

Look through the circular opening of the Epiguide and make sure the bottom surface is placed flush to the cartilage surface all the way around the opening. This is important to achieve the correct drilling angle and depth.

Use a surgical drill and three surgical pins to attach and secure the Epiguide to the bone. After inserting the first pin, check that the Epiguide has not moved out of its unique position. Then insert the remaining pins.

**WARNING!**
**Make sure the Epiguide is securely fastened to the bone and that the bottoms surface is placed flush to the cartilage all way around the opening.**

# 2 ASSEMBLING THE DRILLING SOCKET

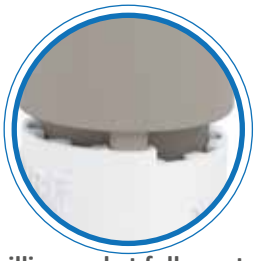


Mount the Drilling socket onto the Epiguide. The Drilling socket guides the first drill step.

Check that the Drilling socket is set in its correct position relative to the Epiguide; the arrow on the rim of the Epiguide must be in line with the marking on the Drilling socket.

Check that the Drilling socket is fully seated in the Epiguide.

**WARNING!**
**Ensure that the Drilling socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect placement.**



**Drilling socket fully seated**

**Start position**

# 3 DRILLING PROCEDURE - STEP ONE

Attach the Epidrill to the assigned surgical drill. Check that it is adjusted for drilling clockwise. Insert the Epidrill into the Drilling socket.

Use one hand to hold the Drilling socket steady in the Epiguide and the other hand to control the surgical drill. Start drilling and continue until the Epidrill stops at the top of the Drilling socket. Use moderate speed and keep the drill steady while applying only moderate force. Use vigorous lavage through the openings at the Epiguide during drilling to minimise heat effects to adjacent bone and cartilage tissue and to rinse away bone and tissue debris.

PRECAUTION
Make sure the Drilling socket is fully seated and is securely fastened in the Epiguide.

Make sure that the drill is correctly aligned in the drill guide to ensure drilling in the correct direction.

Before drilling

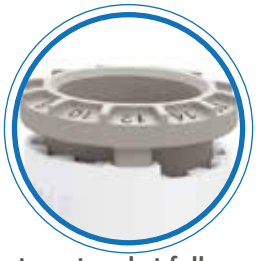
After drilling

# 4 DRILLING PROCEDURE - STEP TWO

Remove the Drilling socket and insert the Adjustment socket aligned to the START position. Make sure the Adjustment socket is fully seated in the Epiguide.

Check that the surgical drill is adjusted for drilling clockwise and insert the Epidrill into the Adjustment socket. Use one hand to hold the Adjustment socket steady in the Epiguide and the other hand to control the surgical drill.

**WARNING!**
**Ensure that the Adjustment socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect Episealer placement.**



Adjustment socket fully seated

Start position

# 5 DRILLING PROCEDURE - STEP THREE

Epidrill at start position

Epidrill bottoming

When inserting the Epidrill into the Adjustment socket, make sure that the tip of the Epidrill is inserted into the pre-drilled hole and that the large drill body is not in contact with the cartilage surface as the drilling starts.

Drill until the Epidrill stops at the top of the Adjustment socket. Use moderate speed and keep the surgical drill steady while applying only moderate force. Use vigorous lavage through the openings on the Epiguide during drilling. This will minimise heat effects to adjacent bone and cartilage tissues and will rinse away bone and tissue debris.

Remove the Epidrill.

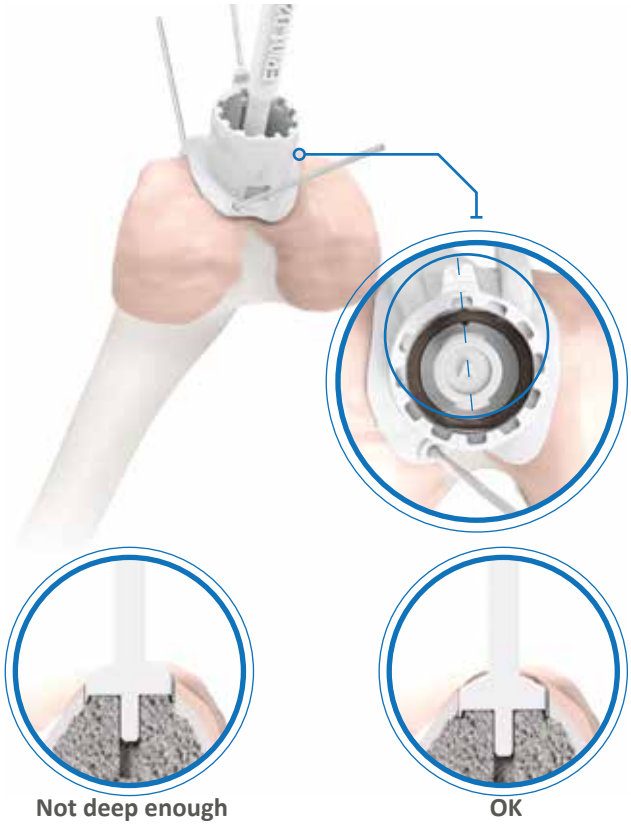
PRECAUTION
If the drilling gets harder during the drilling process, residues may be stuck in the drilling channels. If this is the case, stop drilling, remove the Epidrill and remove all debris from the drilling channels. Re-insert the Epidrill all the way to the bottom of the drilled hole and continue the drilling process. Keep drilling until the Epidrill stops at the top of the Adjustment socket.

# 6 REMOVAL OF DEBRIS AND LOOSE CARTILAGE

Note the Adjustment socket position and remove the Adjustment socket from the Epiguide. Use adequate lavage en suction to clear all debris from the drilled hole.

**WARNING!**
**Ensure that there are no fringes or fronds on the cartilage edge after drilling. All debris along the cartilage edge should be removed using standard tweezers. Any residues of bone and/or cartilage that are left in the drilled hole may prevent the Episealer from becoming osseointegrated with the bone.**

# 7 EVALUATING THE DRILLED DEPTH

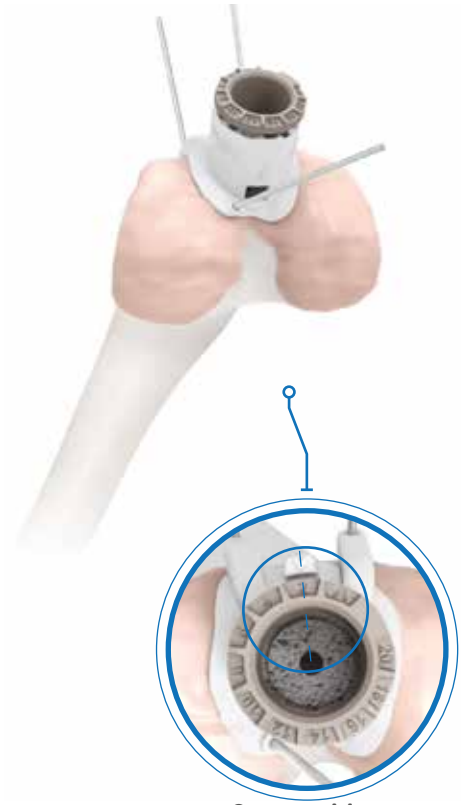



Insert the Epidummy into the drilled hole with its rotation mark aligned with the rotation mark of the Epiguide.

Compare the depth of the Epidummy top surface with the surrounding cartilage edge and assess the height difference. Use the openings in the Epiguide to evaluate the depth. If the Epidummy top surface is positioned approximately 0.5-1 mm below the adjacent articular cartilage surface, the drilling is finished. Proceed to step 9. If not, continue adjusting the drill depth according to step 8.

**WARNING!**
**Ensure that the top surface is positioned approximately 0.5-1 mm below the adjacent cartilage surface. If the Episealer is placed proud or too deep, it may damage surrounding and opposing soft tissues.**

# 8 ADJUSTING THE DRILL DEPTH




Re-assemble the Adjustment socket in the Epiguide. Adjust the drilling depth by turning the Adjustment socket to the desired setting; the desired setting on the Adjustment socket must be in line with the arrow on the Epiguide. The drill depth is increased by 0.2 mm in each step.

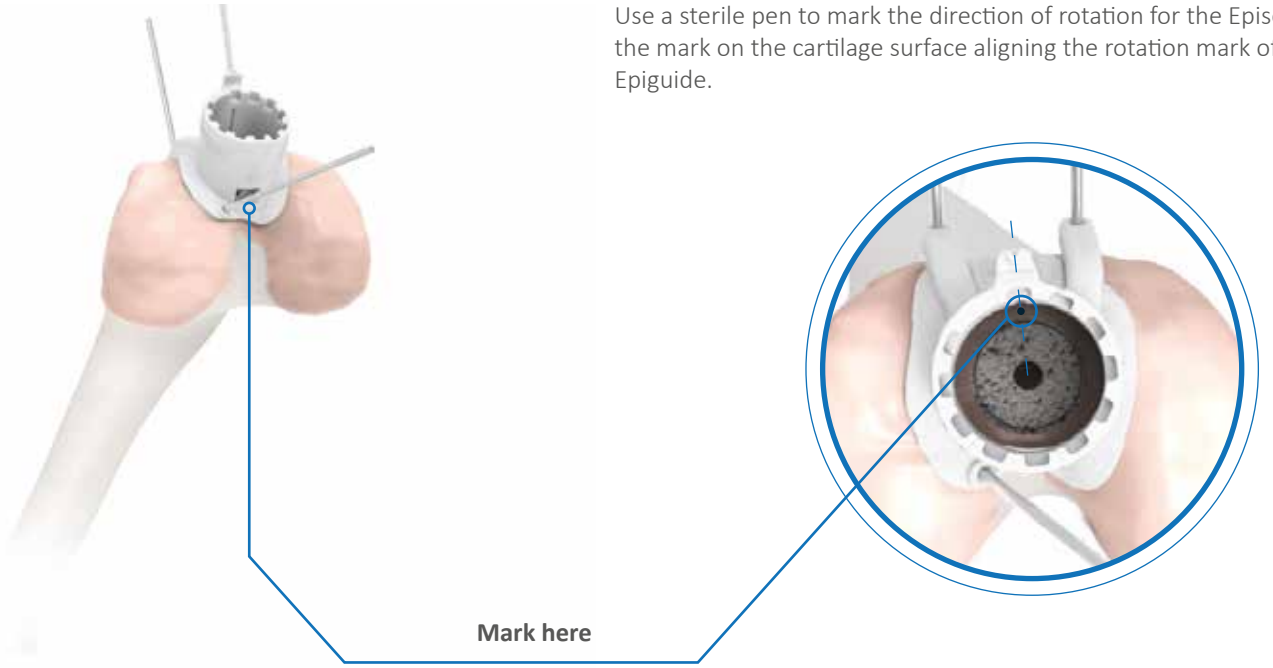
Repeat steps 5 through 7 until the Epidummy bottoms with its top surface approximately 0.5-1 mm below the surrounding cartilage.

PRECAUTION
It is recommended that any additional drilling is performed incrementally, increasing the drill depth by small increments at a time.

Note the drill depth setting. Upon removal and replacement of the Adjustment socket, it needs to be replaced at the correct depth to avoid unintentionally drilling too deep.

**WARNING!**
**Ensure that the Adjustment socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect Episealer placement.**

# 9 MARKING THE EPISEALER ROTATION




Use a sterile pen to mark the direction of rotation for the Episealer. Make the mark on the cartilage surface aligning the rotation mark of the Epiguide.

# 10 FINAL CHECK

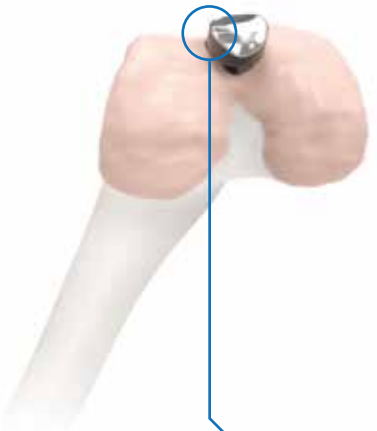
Not deep enough

OK

Remove the Epiguide and check the drill depth again. Insert the Epidummy into the drilled hole with its rotation mark aligned with the mark on the cartilage surface.

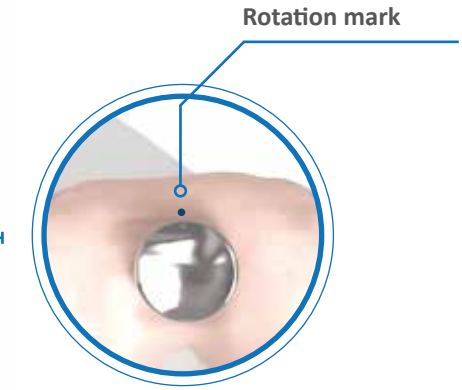
**WARNING!**
**Ensure that the top surface is positioned approximately 0.5-1 mm below the adjacent cartilage surface. If the Episealer is placed proud or too deep, it may damage surrounding and opposing soft tissues.**

# 11 PLACING THE EPISEALER



Gently place the Episealer into the drilled hole. Check that the rotation mark on the Episealer is aligned to the rotation mark on the cartilage. if the rotation mark on the Episealer is not correctly aligned, use your fingers to gently turn it to the correct orientation.

Use your fingers to gently press the Episealer down into the drilled hole, ensuring the orientation is maintained.




# 12 DRIVING DOWN THE EPISEALER

Use the Epimandrel and a hammer to gently tap down the Episealer into the bone until bottomed. Make sure to tap evenly over the top surface of the Episealer. When fully seated, the top surface should be approximately 0.5-1 mm below the adjacent articular cartilage surface.

PRECAUTION
Make sure to gently tap the Episealer until fully seated. This is indicated by a more distinct sound.

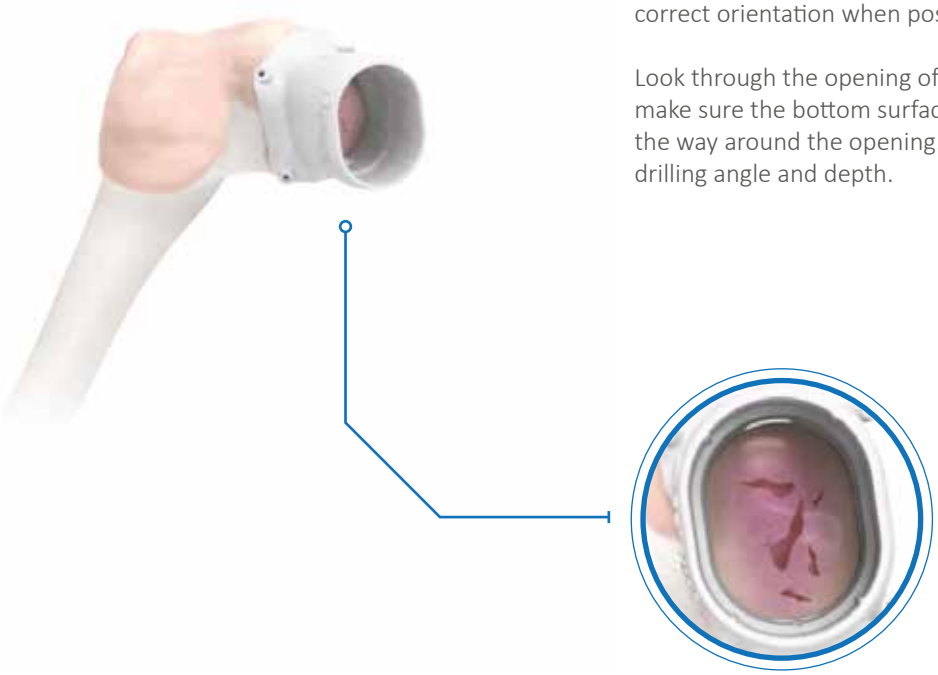
**WARNING!**
**During insertion, carefully check that the rotational alignment of the Episealer has not changed.**

**Improper handling of the Episealer can cause scratches, nicks or dents that may have adverse clinical effects on opposing joint surfaces.**

## FINAL PLACEMENT

# Episealer Femoral Twin
## **Procedure overview**

# 1 PLACING THE EPIGUIDE



Make an incision long enough to fully expose the operative field. The complete base of the Epiguide must be visible through the incision. Place the Epiguide on the articular cartilage surface. Make sure to use the markings on the Epiguide, A (anterior) and P (posterior), to find the correct orientation when positioning the Epiguide.

Look through the opening of the Epiguide without the insert in place and make sure the bottom surface is placed flush to the cartilage surface all the way around the opening. This is important to achieve the correct drilling angle and depth.

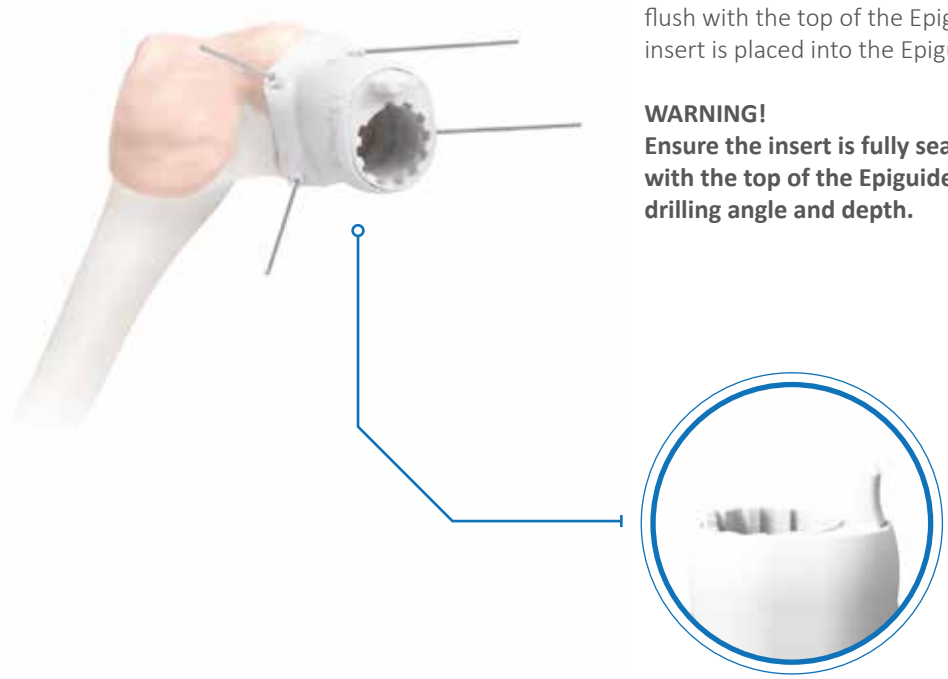


# 2 SECURING THE EPIGUIDE

Use a surgical drill and four surgical pins to attach and secure the Epiguide to the bone. After inserting the first pin, check that the Epiguide has not moved out of its position. Then insert the remaining pins.

**WARNING!**
**Make sure the Epiguide is securely fastened to the bone and that the bottoms surface is placed flush to the cartilage all way around the opening.**

# 3 ASSEMBLING THE EPIGUIDE



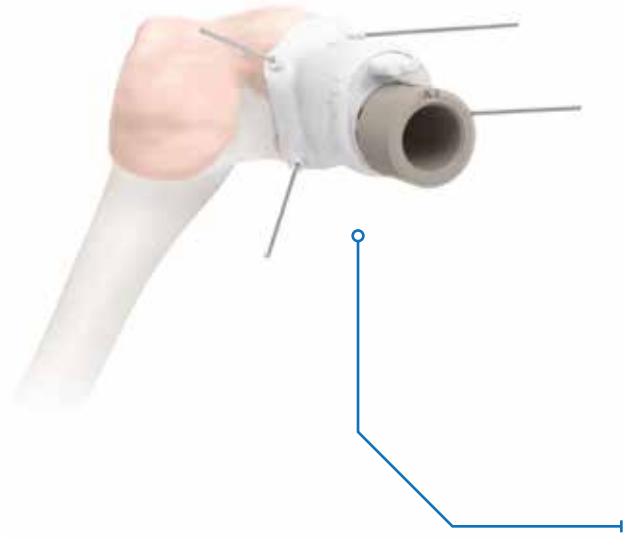
Place the insert in the Epiguide in either of the two positions. The insert is used during the drilling of both holes.

Check that the insert is fully seated in the Epiguide with its top surface flush with the top of the Epiguide. This must be checked every time the insert is placed into the Epiguide.

**WARNING!**
**Ensure the insert is fully seated in the Epiguide with its top surface flush with the top of the Epiguide. This is essential to achieve the correct drilling angle and depth.**



# 4 ASSEMBLING THE DRILLING SOCKET



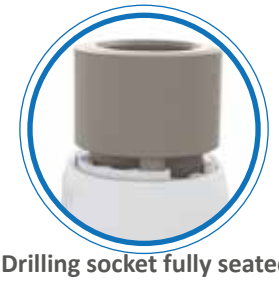
Mount the Drilling socket into the Epiguide. The Drilling socket guides the first drill steps.

Check that the Drilling socket is set in its correct position relative to the Epiguide; the arrow on the rim of the Drilling socket must be in line with the arrow on the insert.

Check that the Drilling socket is fully seated in the Epiguide.

**WARNING!**
**Ensure the Drilling socket is in a correct position before drilling. Incorrect position may result in an incorrect drill depth and incorrect Episealer placement.**

**Start position**



**Drilling socket fully seated**

# 5 DRILLING PROCEDURE - STEP ONE

Both holes are always drilled to the same depth before any adjustment is made to another depth.

Attach the Epidrill to the assigned surgical drill and check that the drill is adjusted for drilling clockwise. Make sure the insert is fully seated in the Epiguide and that the Drilling socket is correctly mounted into the insert. Ensure that both insert and Drilling socket are fully seated correctly.

Use one hand to hold the Drilling socket steady in the Epiguide and the other hand to control the surgical drill. Insert the Epidrill into the Drilling socket. Start drilling and drill until the Epidrill stops at the top of the Drilling socket. Use moderate speed and keep the surgical drill steady while applying only moderate force. Use vigorous lavage through the openings of the Epiguide during drilling to minimise heat effects to the adjacent bone and cartilage tissue, and to rinse away bone and tissue debris.

**WARNING!**
**Make sure that the drill is correctly aligned in the drill guide to ensure drilling in the correct direction.**

Before drilling

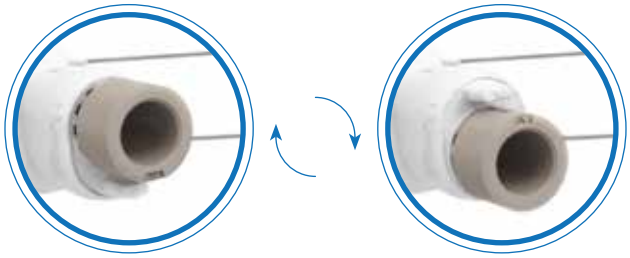
After drilling

# 6 DRILLING PROCEDURE - STEP TWO

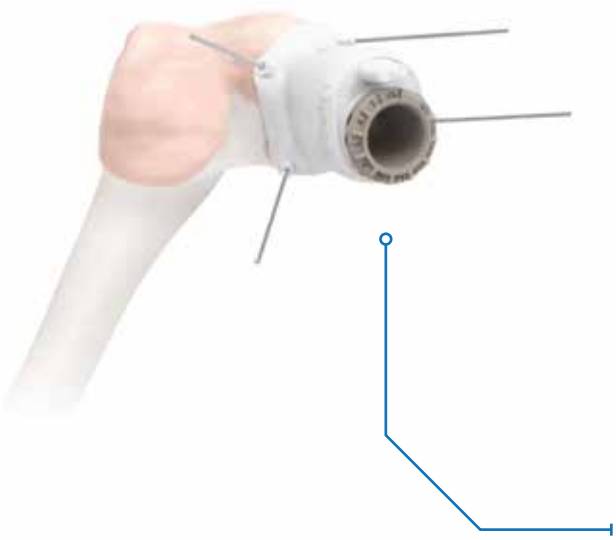
Lift up the insert from the Epiguide, turn it 180° and re-mount it in the Epiguide. Check that the insert is fully seated in the Epiguide and that the Drilling socket is correctly mounted into the insert. In order to achieve the correct drilling depth, it is important that the Drilling socket is always placed correctly, with its arrow in line with the arrow on the insert.

Drill the second hole, repeating the instructions as for the first one.

Remove the Drilling socket from the Epiguide.

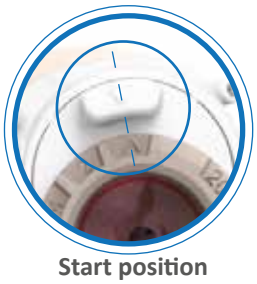


# 7 ASSEMBLING THE ADJUSTMENT SOCKET



Remove the Drilling socket and insert the Adjustment socket aligned to the START position. Make sure the Adjustment socket is fully seated in the Epiguide.

**WARNING!**
**Ensure the Adjustment socket is in a correct position and that the insert is fully seated in the Epiguide before drilling. Incorrect positions may result in an incorrect drill depth and incorrect Episealer placement.**



**Start position**

**Adjustment socket fully seated**

# 8 DRILLING PROCEDURE - STEP THREE

**Epidrill at start position**

Insert the Epidrill into the Adjustment socket making sure that the tip of the Epidrill is positioned within the pre-drilled hole but that the drill body is not in contact with the cartilage surface when the drilling starts. Use one hand to hold the Adjustment socket steady in the Epiguide and the other hand to control the surgical drill.

Drill until the Epidrill stops at the top of the Adjustment socket. Use moderate speed and keep the surgical drill steady while applying only moderate force. Use vigorous lavage through the openings of the Epiguide during drilling to minimise heat effects to adjacent bone and cartilage tissues and to rinse away bone and tissue debris.

Remove the Epidrill.

PRECAUTION
If the drilling gets harder during the drilling process, residue might be stuck in the drilling channels. If this is the case stop drilling, remove the Epidrill and cleanse the Epidrill from residue. Re-insert the Epidrill all the way to the bottom of the drilled hole and continue the drilling process. Keep drilling until the Epidrill stops on top of the Adjustment socket.

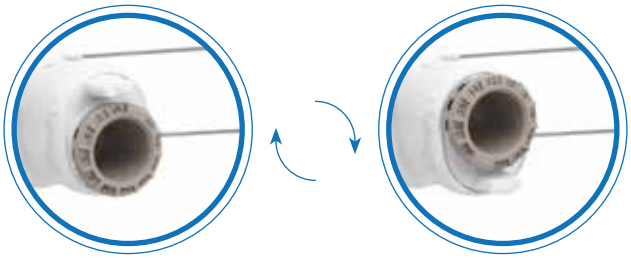
# 9 DRILLING PROCEDURE - STEP FOUR

Remove the insert from the Epiguide, turn it 180° and re-mount it in the Epiguide.

Perform the adjustment drilling for the second hole, repeating the instructions as for the first hole.

**WARNING!**
**Ensure both holes are drilled with identical Adjustment socket drill depth setting. Different hole depths may prevent the Episealer from being placed correctly and/or becoming osseointegrated.**

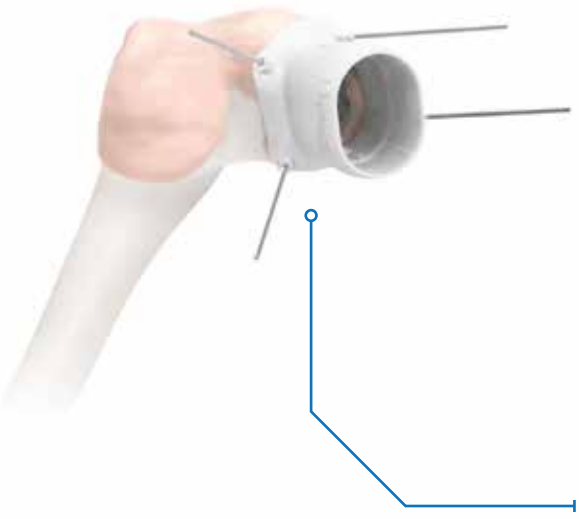
**Epidrill fully seated**



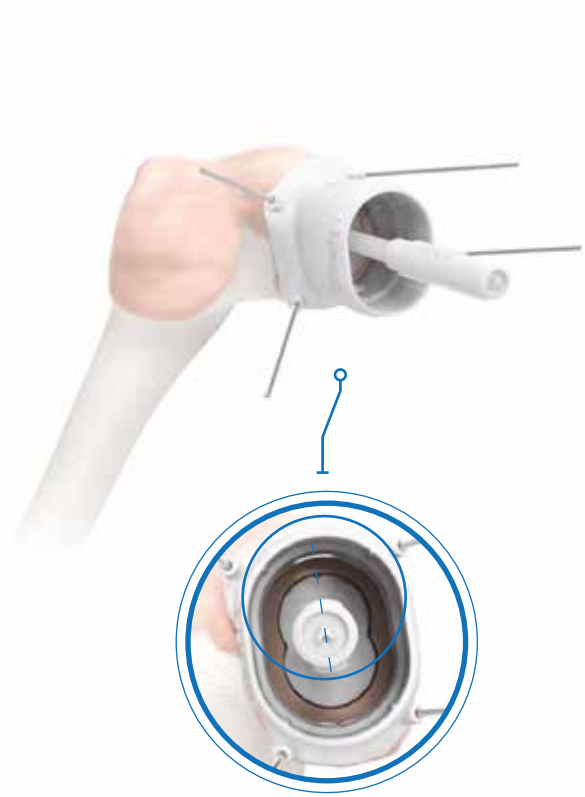
# 10 REMOVAL OF DEBRIS AND LOOSE CARTILAGE

Note the Adjustment socket position and remove the Adjustment socket and insert from the Epiguide. Use the pulse lavage and suction to cleanse the drilled hole.

**WARNING!**
**Ensure there are no fringes or fronds on the cartilage edge after drilling. Rough edges on the cartilage edge should be removed using a standard tweezer. If residue of bone and/or cartilage are left in the drilled hole, the Episealer may be prevented from becoming osseointegrated.**



# 11 EVALUATING THE DRILLED DEPTH



Insert the Epidummy into the drilled hole with its direction mark aligned with the direction mark of the Epiguide.

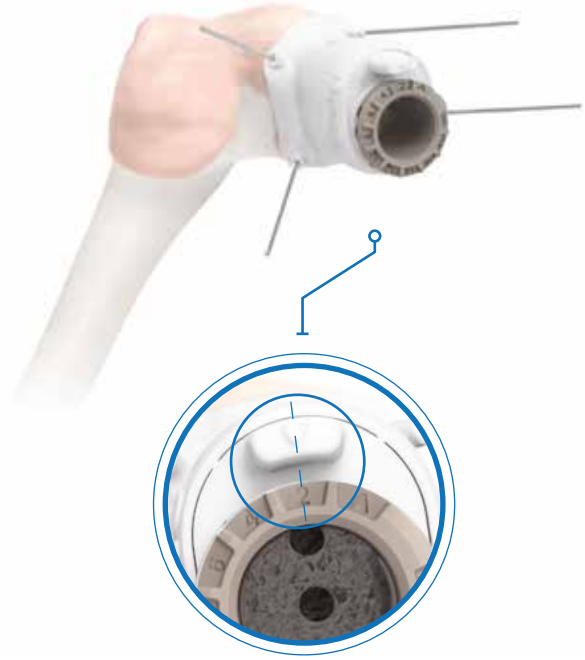
Compare the depth of the Epidummy top surface with the surrounding cartilage edge and assess the height difference. Use the openings in the Epiguide to evaluate the depth. If the Epidummy top surface is positioned approximately 0.5-1 mm below the adjacent articular cartilage surface the drilling is finished. Proceed to step 13. If not, continue adjusting the drill depth according to step 12.

**WARNING!**
**Ensure the top surface of the Epidummy is positioned approximately 0.5-1 mm below the adjacent cartilage surface. If the Episealer is placed proud or too deep it may damage surrounding and opposing soft tissues.**

**Not deep enough**

**OK**

# 12 ADJUSTING THE DRILL DEPTH



Re-assemble the Adjustment socket and insert in the Epiguide. Adjust the drilling depth by turning the Adjustment socket to the desired setting; the desired setting on the Adjustment socket must be in line with the arrow on the insert. The drilling depth is increased by 0.2 mm in each step. Check that the insert is fully seated in the Epiguide and that the Adjustment socket has bottomed-out in the insert.

Repeat steps 8 through 11 until the Epidummy top surface is positioned approximately 0.5-1 mm below the adjacent articular cartilage surface.

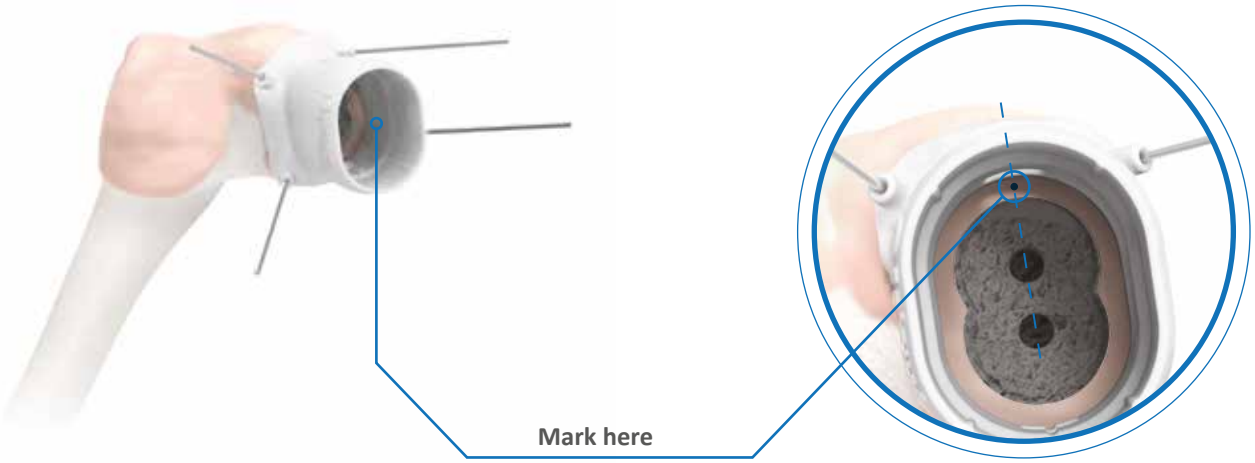
It is recommended that additional drilling is performed incrementally, increasing the drill depth by small increments at a time.

Note the drill depth setting. Upon removal and replacement of the Adjustment socket, it needs to be replaced at the correct depth to avoid unintentionally drilling too deep.

**WARNING!**
**Ensure the Adjustment socket is in the correct position and that the insert is bottomed-out in the Epiguide before drilling. Incorrect positioning may result in an incorrect drill depth and incorrect Episealer placement.**

# 13 MARKING THE DIRECTION OF THE EPISEALER POSITION

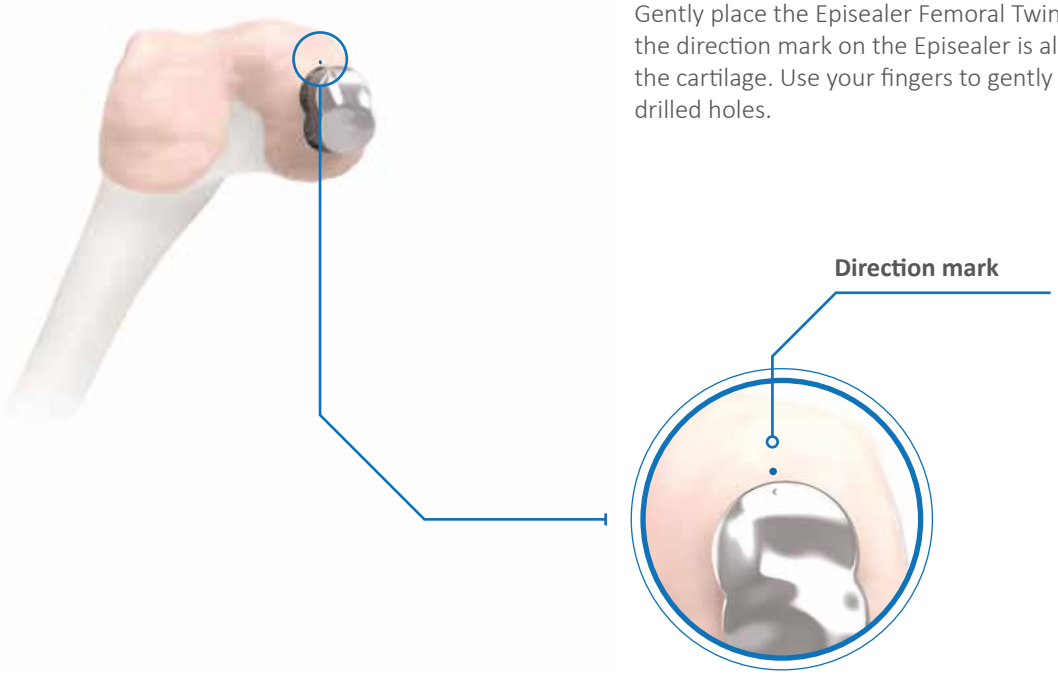
Use a sterile pen to mark the direction of the Episealer. Make the mark on the cartilage surface aligned with the direction mark of the Epiguide.




# 14 FINAL CHECK AND PLACING THE EPISEALER

Remove the Epiguide and check the drill depth again. Insert the Epidummy into the drilled hole with its direction mark aligned with the mark on the cartilage surface

Gently place the Episealer Femoral Twin into the drilled hole. Check that the direction mark on the Episealer is aligned with the direction mark on the cartilage. Use your fingers to gently press the Episealer down into the drilled holes.



# 15 DRIVING DOWN THE EPISEALER

Use the Epimandrel and a hammer to gently tap down the Episealer into the bone until bottomed. Make sure to distribute the tapping evenly over the top surface of the Episealer. When fully seated, the top surface of the Episealer should be approximately 0.5-1 mm below the adjacent articular cartilage surface.

**WARNING!**

**Make sure to gently tap the Episealer until fully seated. This is indicated by a more distinct sound.**

**Improper handling of the Episealer can cause scratches, nicks or dents that may have adverse clinical effects on the opposing joint surfaces.**

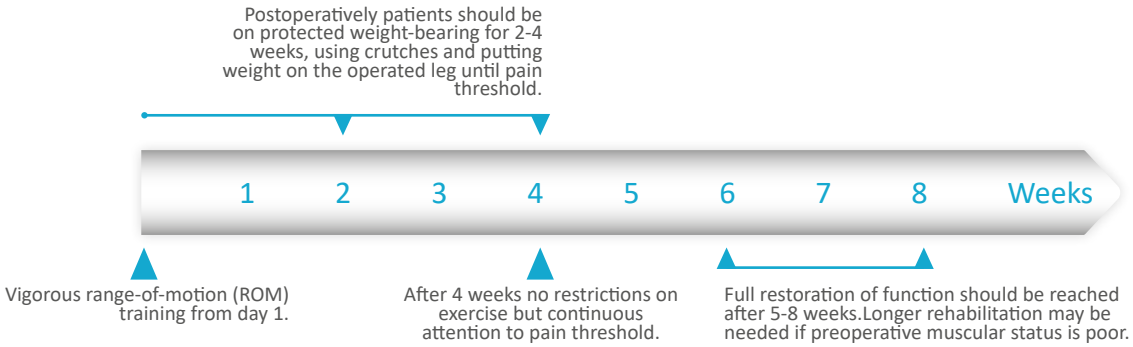
## FINAL PLACEMENT

# REHABILITATION

## The short rehabilitation period

After the surgery, the patient should start moving and exercising the operated knee. It is recommended that the knee is exercised as instructed. Early use of the knee promotes the healing process and encourages the biological coating on the implant to integrate quickly with the bone, resulting in long term fixation of the implant.

Together with the physiotherapy team at University Hospital Coventry and Warwickshire NHS trust, Episurf Medical has produced a dedicated prehabilitation and rehabilitation programme. Contact your Episurf representative for more information.




# CASE STUDIES

## PATIENT #1

**Age:** 38
**Gender:** Female
**Occupation:** Nurse
**Diagnosis:** ICRS 3-4 lesion on medial femoral condyle

### PRE-OPERATIVE

- Previous surgeries including arthrosopies, mosaicplasty and ACI
- Unresolved pain, no resolution of symptoms and inability to work

### TREATMENT

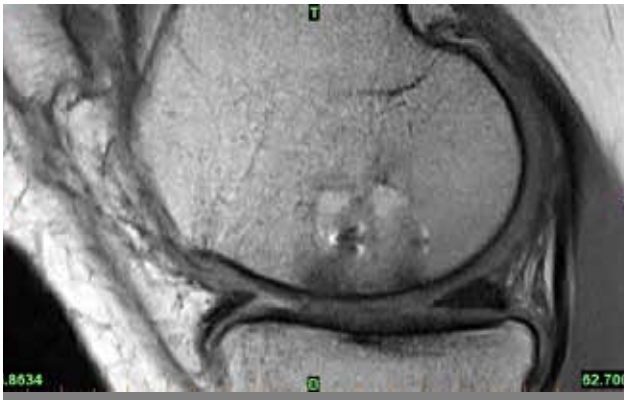
- Episealer Condyle Solo

### POST-OPERATIVE

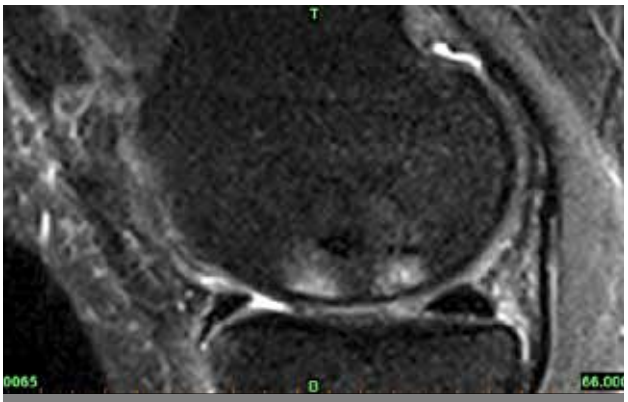
- Weight-bearing after 10 days
- Immediate pain reduction
- Able to return to work after 3 months

### FOLLOW-UP

- 6 months, no reported pain and full function
- 12 months, no reported pain and full function
- 24 months, no reported pain and full function



MRI 1



MRI 2


X-ray 2

X-ray 1

# CASE STUDIES

## PATIENT #2

**Age:** 40
**Gender:** Male
**Occupation:** Sales man
**Diagnosis:** ICRS 3-4 lesion on femoral trochlea following an ice-hockey injury at the age of 13

### PRE-OPERATIVE

- 9 previous surgeries including multiple arthrosopies and ACI
- Unresolved pain, no resolution of symptoms
- Large dosis of oral analgesics
- Suggested treatment with total knee replacement (TKR)

### TREATMENT

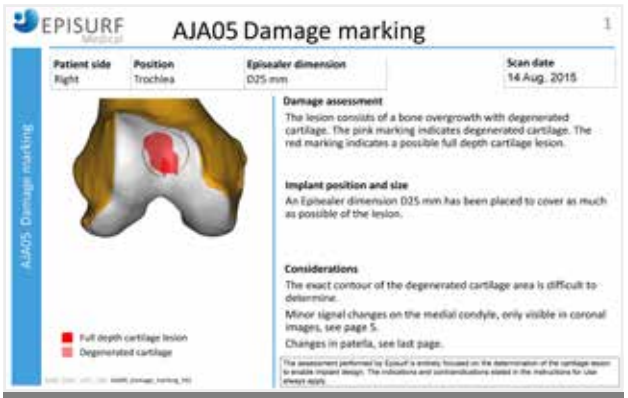
- Episealer Trochlea Solo

### POST-OPERATIVE

- Partial weight-bearing immediately post-op
- Immediate cessation of oral analgesia
- Able to return to work within 1 month of surgery

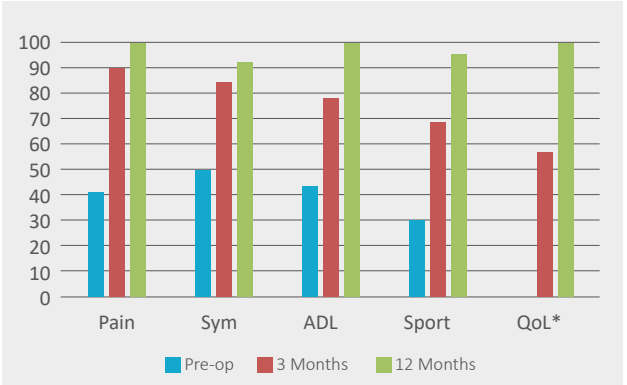
### FOLLOW-UP

- Rapid and marked improvement in all KOOS subsets at 3 months
- Return to sporting activity and no quality-of-life limitations

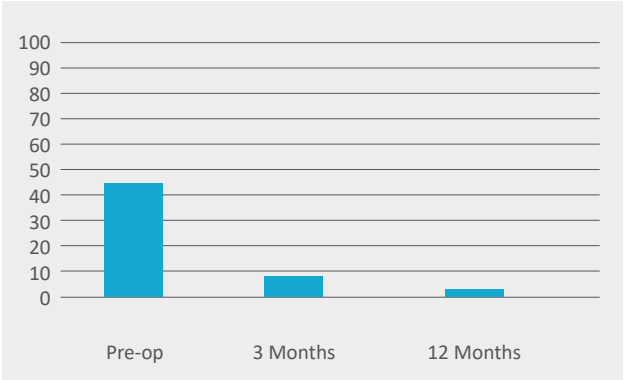


Damage Marking Report


Intra-surgical findings



KOOS AJA05 (*insufficient pre-operative QoL subset data)



VAS AJA05

# NOTES

EPISURF Medical

## CONTACT INFORMATION

KARLAVÄGEN 60 | 114 49 STOCKHOLM | SWEDEN
+46 8 612 00 20 | INFO@EPISURF.COM
WWW.EPISURF.COM

NASDAQ OMX-B-SHARE

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