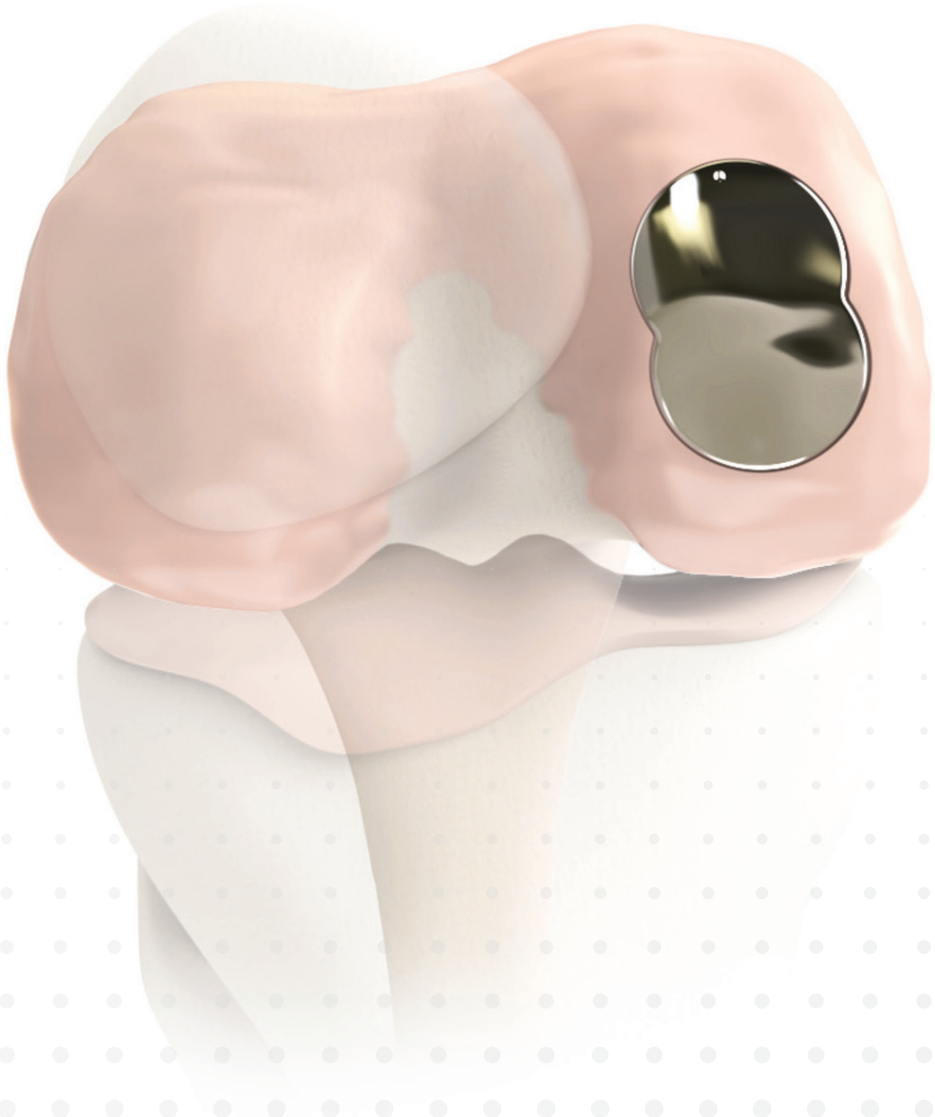
EPISURF

EPISEALER® KNEE

SURGICAL TECHNIQUE



SURGICAL TECHNIQUES:

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

TABLE OF CONTENTS

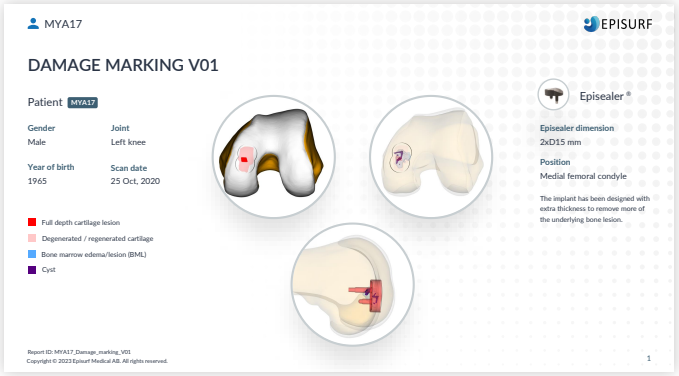
DAMAGE MARKING REPORT

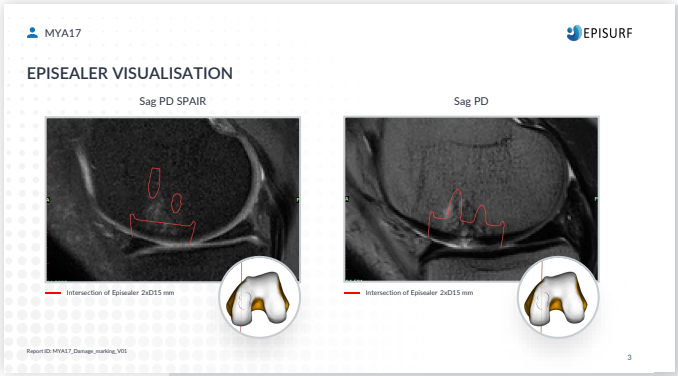
The patient's MR images are used to create a detailed virtual model of the knee included in a Damage Marking Report. This report enables a 3D visualisation of:

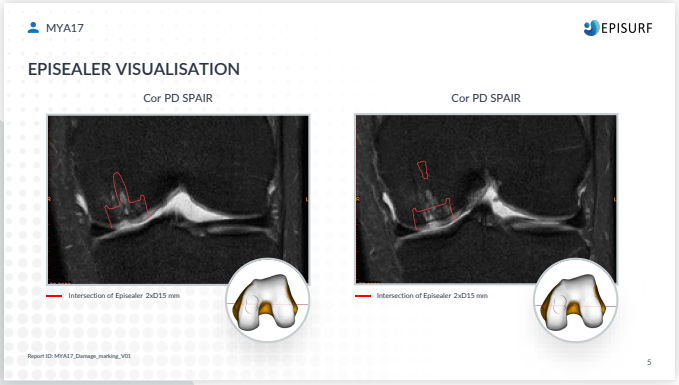
- cartilage damage
- subchondral bone damage
- bone marrow lesions such as bone edema
- previous surgeries
- osteoarthritic signs
- other pathologies

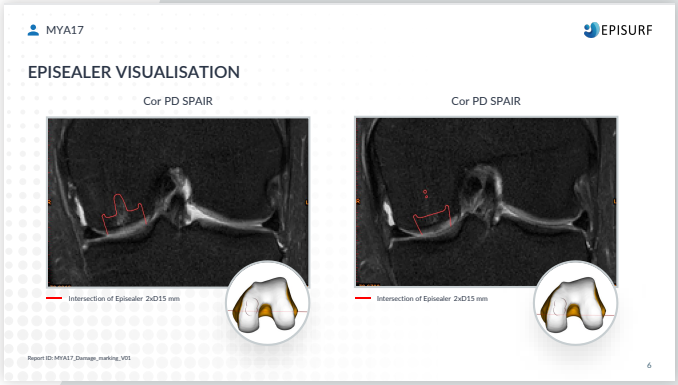
This virtual 3D visualisation will enable you to explore the patient's individual damage and assess the suitability for an Episealer implant. Based on this 3D presentation, you will be able to determine the level of damage and review any potential solutions that Episurf can offer. The implant position and size can be fine-tuned by working with Episurf if so needed.

If it is assessed that Episealer is a suitable therapeutic option for your patient, an order can be placed for the devices, to treat the specific (osteo)chondral defect. An Episealer 'Final Design' visualisation will be supplied, showing the exact position of the Epiguide and Episealer.









EPISEALER

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:

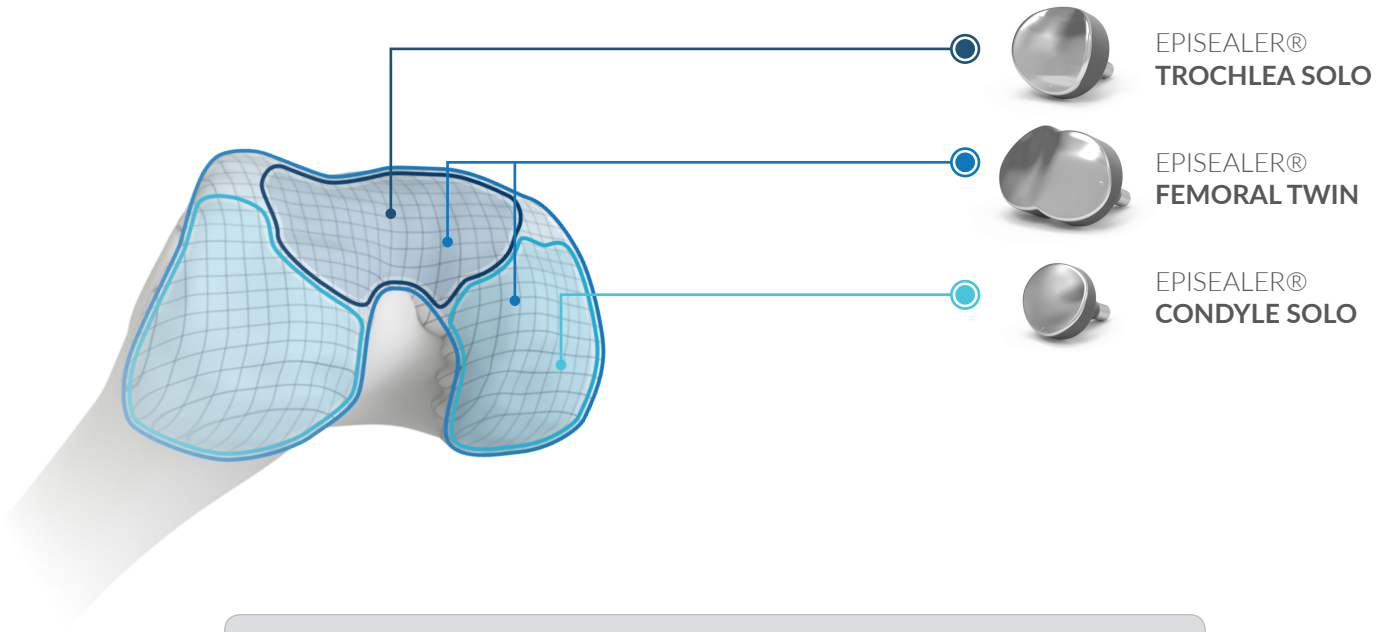
- **the hat** sits within the subchondral bone bed, loading in a physiological manner with the edges bonding to the patient's healthy cartilage.
- **the peg** gives initial stability and press-fits into the subchondral cortex allowing stable fixation and rapid recovery post-operatively.

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 customised 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 did not need any painkillers and that he had slept at night."

Orthopaedic Surgeon
Denmark

EPISEALER

Each individual Episealer implant is milled precisely from cobalt-chrome alloy. The top articulating surface has an individualised 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.

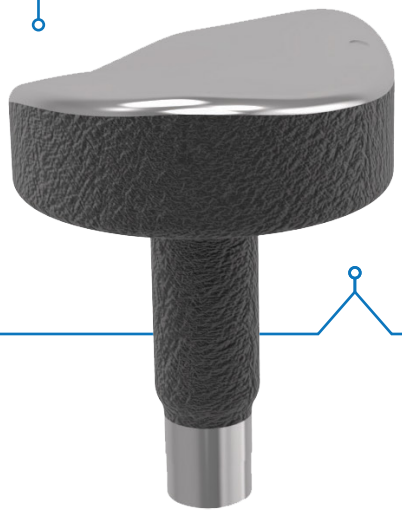
The undersurface and sides of the prosthesis have a coating of titanium and hydroxyapatite to biologically fix the implant to the patient's bone.

Cobalt-chrome

- Can be polished to an ultra-smooth surface (Ra ≤ 0.05 µm)
- Low risk of metal debris
- Well-tested and proven medical device material

Physiological surface

- Articulates naturally with opposing cartilage
- Recreates patient's natural anatomy



Titanium undercoating

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

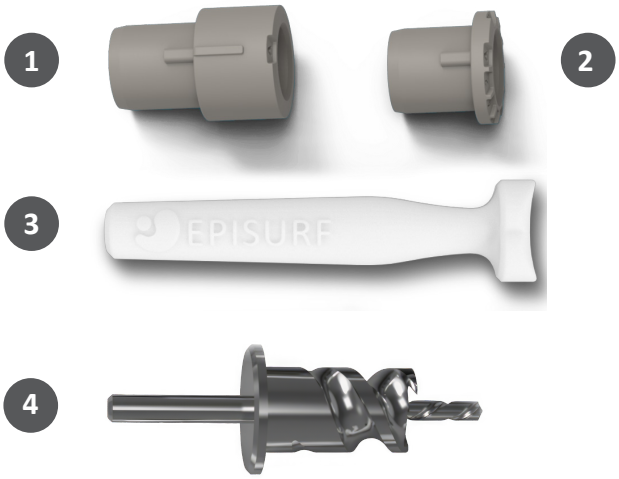
Hydroxyapatite outer coating

- 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 cm^2
Episealer Condyle Solo D15	11115	15 mm	1.8 cm^2
Episealer Condyle Solo D17	11117	17 mm	2.3 cm^2
Episealer Condyle Solo D20	11120	20 mm	3.1 cm^2
Episealer Trochlea Solo D20	31120	20 mm	3.1 cm^2
Episealer Trochlea Solo D25	31125	25 mm	4.9 cm^2
Episealer Trochlea Solo D29	31129	29 mm	6.6 cm^2
Episealer Femoral Twin 2xD15	51115	15 mm (length: 23 mm)	2.9 cm^2
Episealer Femoral Twin 2xD17	51117	17 mm (length: 26 mm)	3.7 cm^2
Episealer Femoral Twin 2xD20	51120	20 mm (length: 29 mm)	4.8 cm^2
Episealer Femoral Twin 2xD25	51125	25 mm (length: 35 mm)	7.3 cm^2

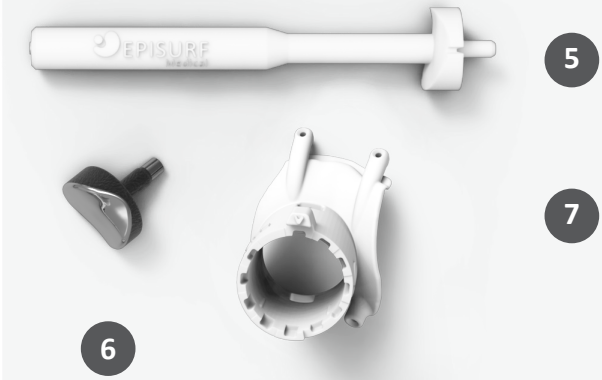
EPISEALER TOOLKIT

	Name
1	Drilling socket
2	Adjustment socket
3	Epimandrel
4	Epidrill
5	Epidummy
6	Episealer
7	Epiguide
8	Epiguide Insert

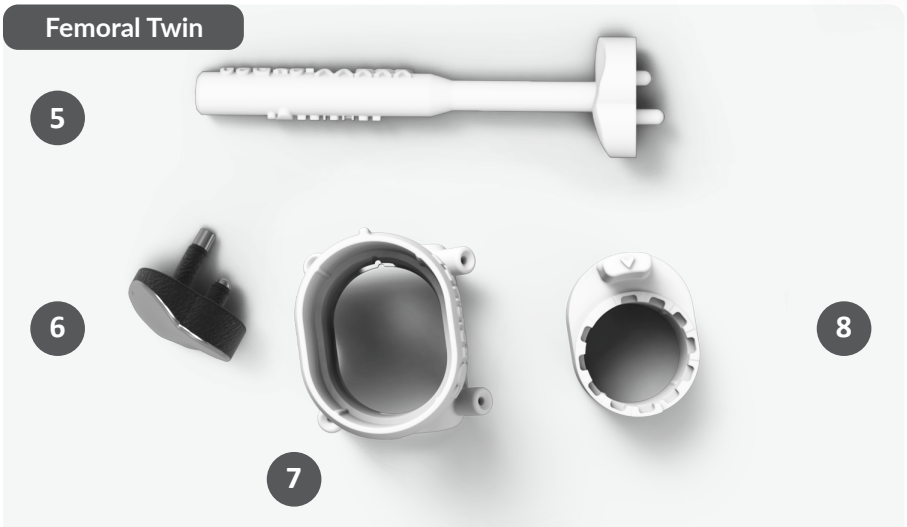


Condyle Solo

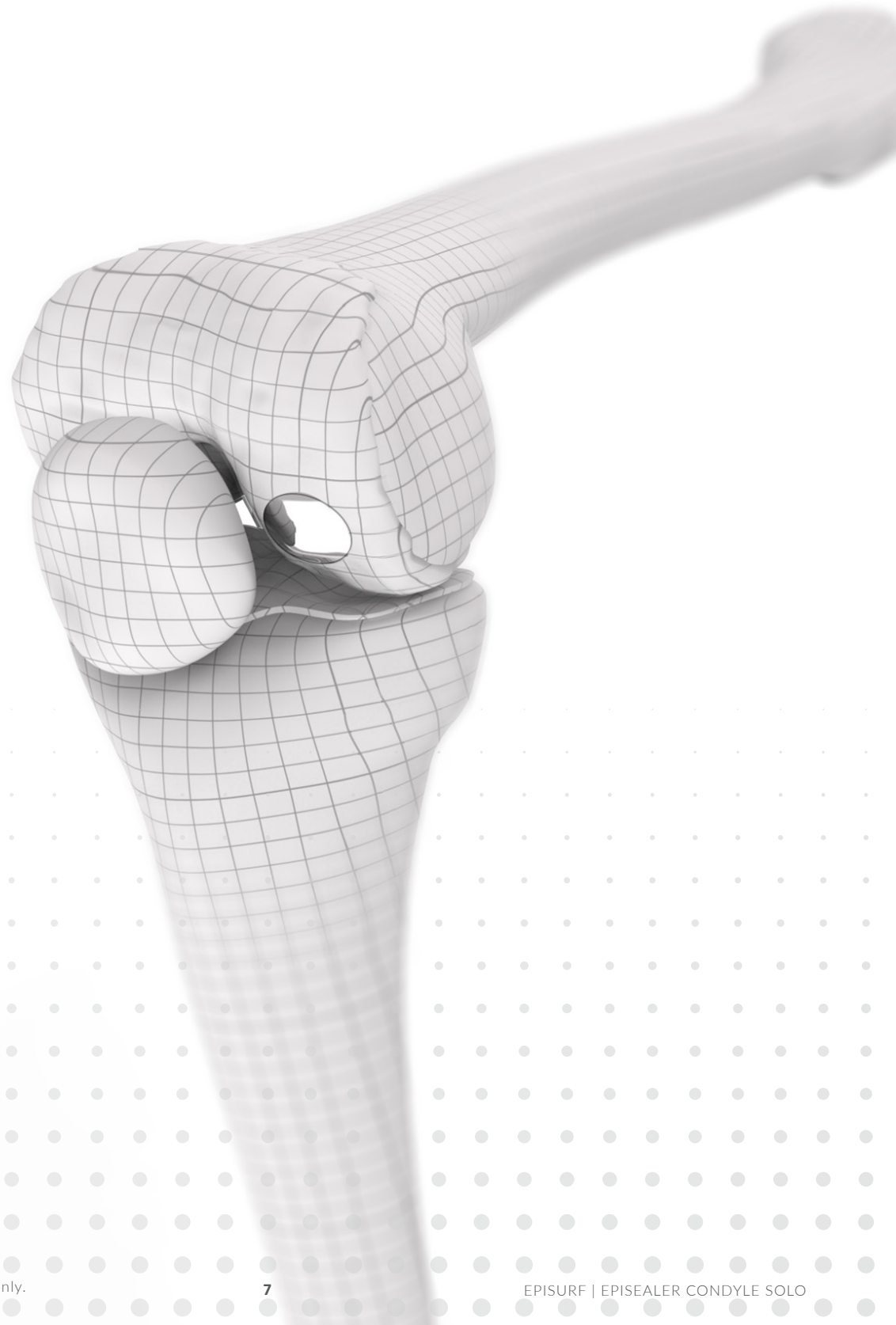
Trochlea Solo



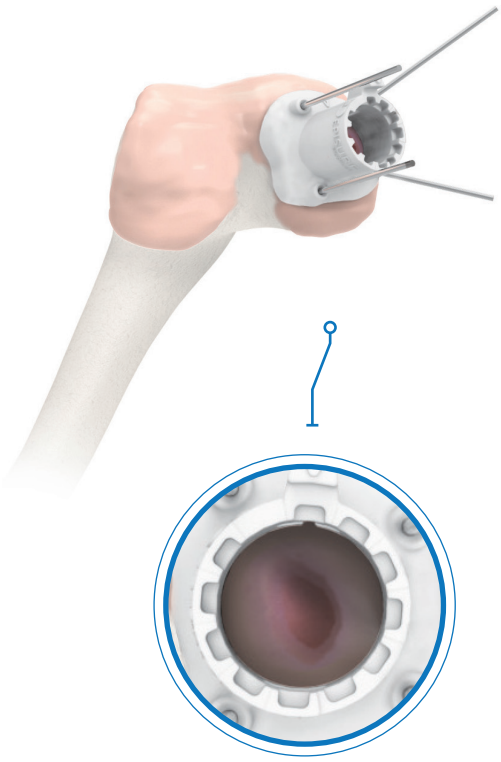
Femoral Twin



Episealer Condyle Solo
Surgical procedure



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. Use the markings on the Epiguide, A (anterior) and P (posterior), to find the correct orientation when positioning the Epiguide.

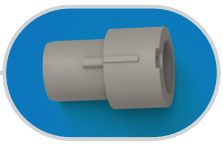
Look through the circular opening of the Epiguide and make sure the bottom surface is placed flush to the cartilage surface all the way around the opening. This is important to achieve the correct drilling angle and depth.

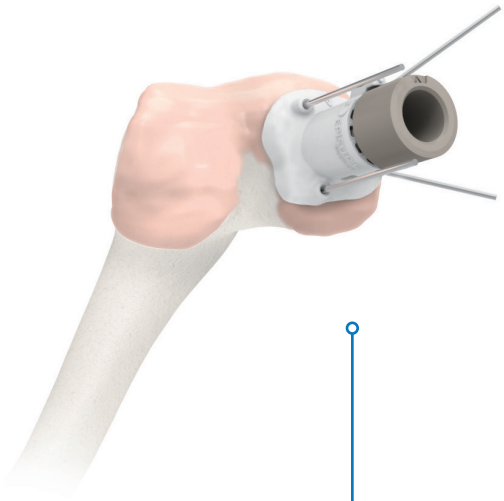
Use a surgical drill and at least three surgical pins to attach and secure the Epiguide to the bone. After inserting the first pin, check that the Epiguide has not moved out of its unique position. Then insert the remaining pins.

⚠ WARNING!

Make sure the Epiguide is securely fastened to the bone and that the bottom's 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.

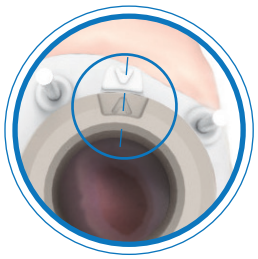
Check that the Drilling socket is set in its correct position relative to the Epiguide; the arrow on the rim of the Epiguide must be in line with the marking on the Drilling socket.

Make sure that the Drilling socket is fully seated in the Epiguide.

⚠ WARNING!

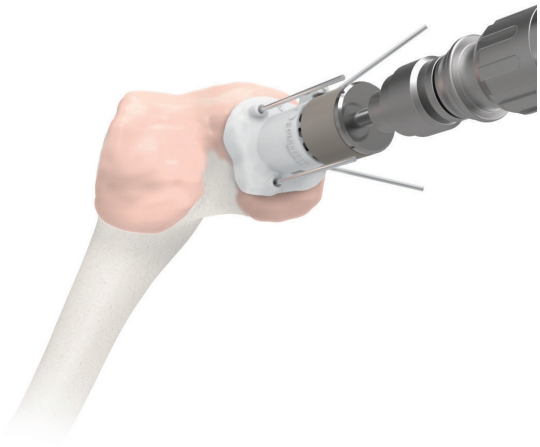
Ensure that the Drilling socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect Episealer placement.

Drilling socket fully seated



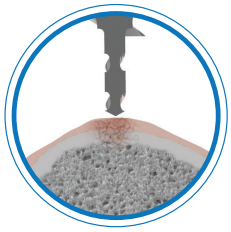
Start position

3 DRILLING PROCEDURE - STEP ONE



Attach the Epidrill to the surgical drill (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.



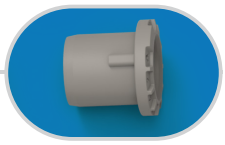
Before drilling

After drilling

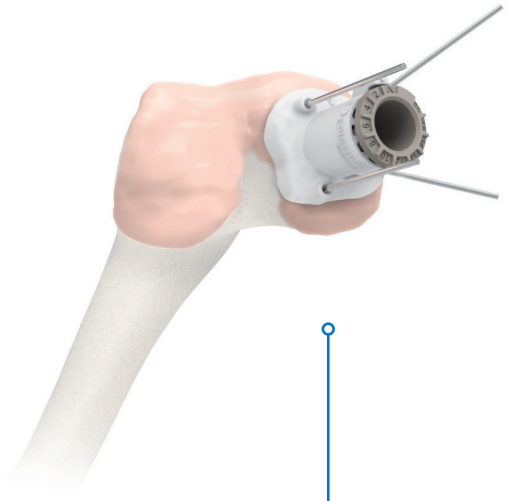
PRECAUTION

The Drilling socket must be fully seated and securely fastened in the Epiguide. Make sure that the drill is correctly aligned in the drill guide to ensure drilling in the correct direction.

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.

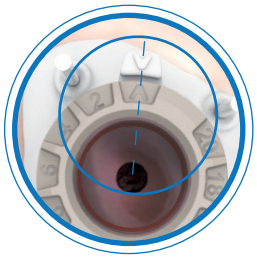


Check that the surgical drill is adjusted for drilling clockwise and insert the Epidrill into the Adjustment socket. Use one hand to hold the Adjustment socket steady in the Epiguide and the other hand to control the surgical drill.

⚠ **WARNING!**

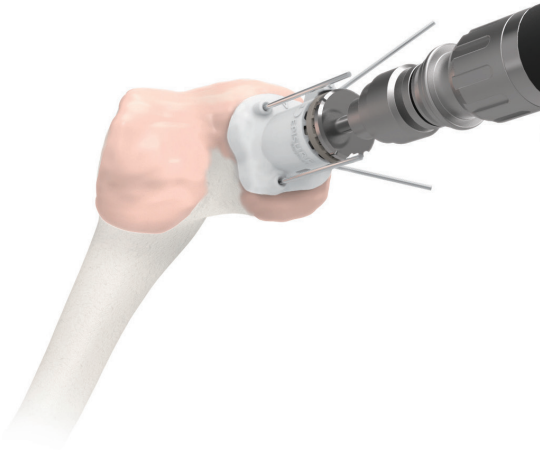
Ensure that the Adjustment socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect implant placement.

Adjustment socket fully seated



Start position

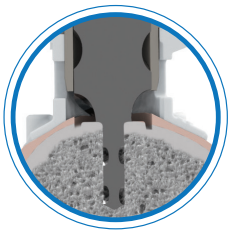
5 DRILLING PROCEDURE - STEP THREE



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.

Epidrill at start position



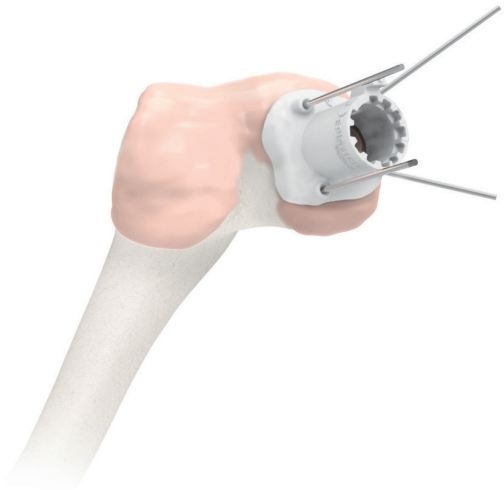
Epidrill fully seated

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

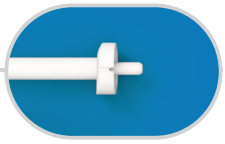


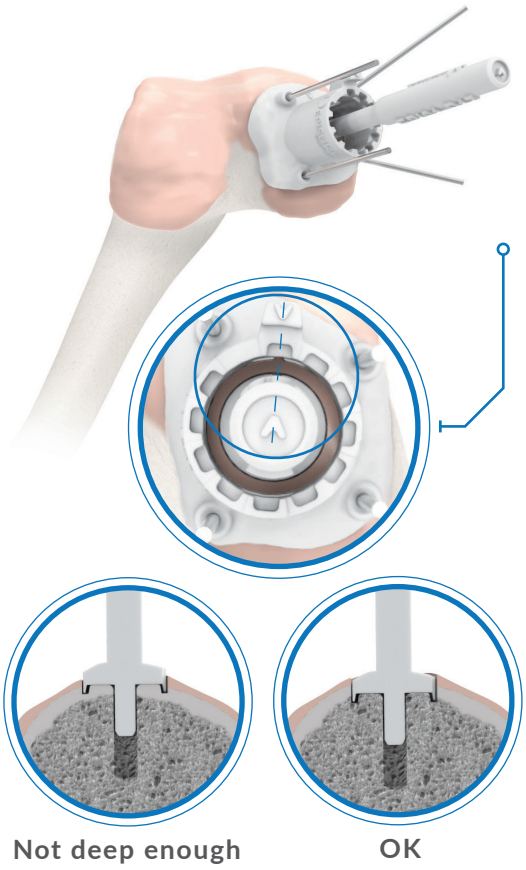
Note the Adjustment socket position and remove the Adjustment socket from the Epiguide.
Use adequate lavage en suction to clear all debris from the drilled hole.

⚠ 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





Not deep enough

OK

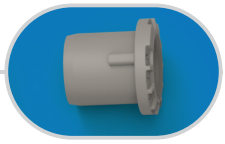
Insert the Epidummy into the drilled hole with its rotation mark aligned with the rotation mark of the Epiguide.

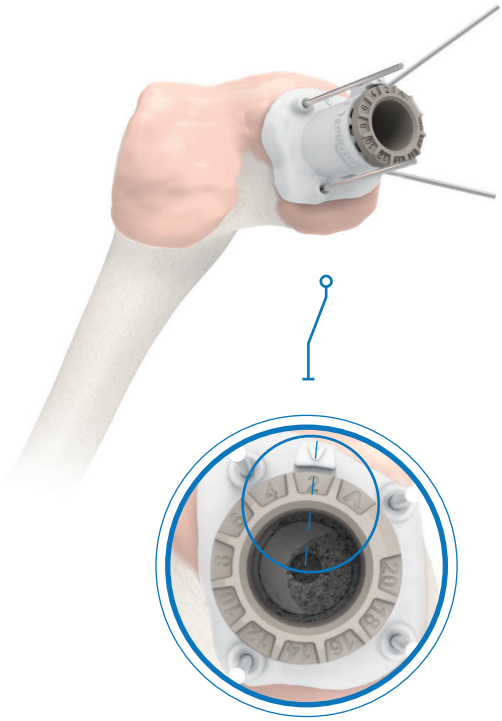
Compare the depth of the Epidummy top surface with the surrounding cartilage edge and assess the height difference. Use the openings in the Epiguide to evaluate the depth. If the Epidummy top surface is positioned approximately 0.5-1 mm below the adjacent articular cartilage surface, the drilling is 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





Drill depth increased 0.2 mm

Re-assemble the Adjustment socket in the Episealer guide. 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.

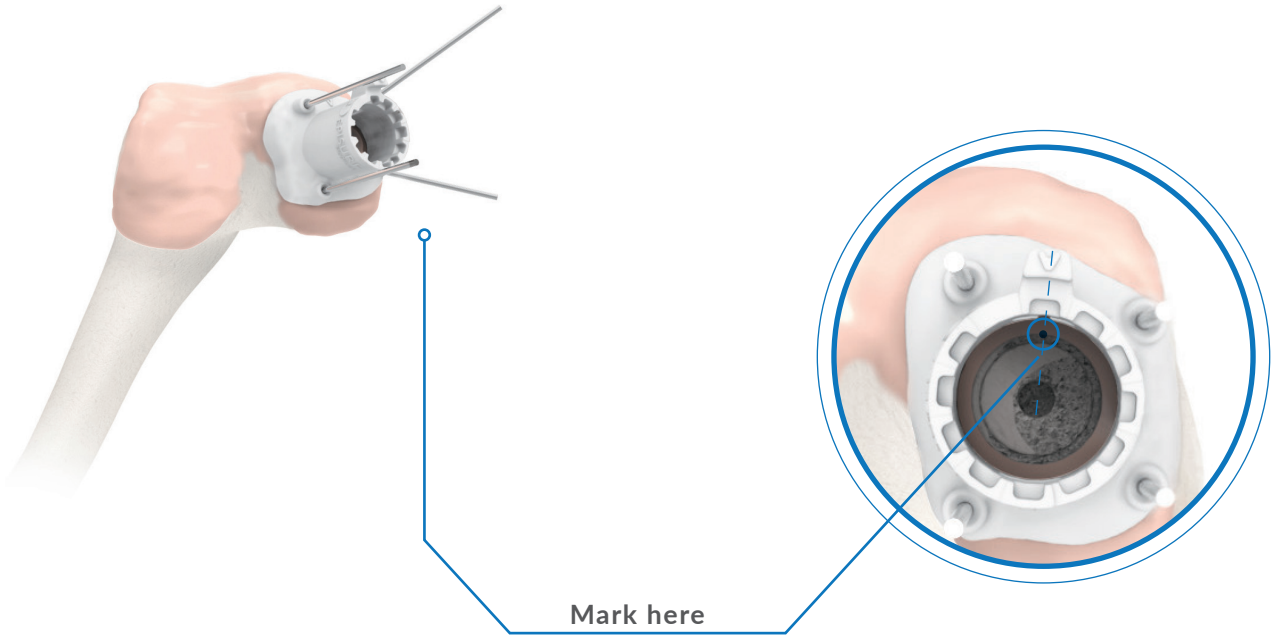
Note the drill depth setting. Upon removal and replacement of the Adjustment socket, it needs to be replaced at the correct depth to avoid unintentionally drilling too deep.

⚠ 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.

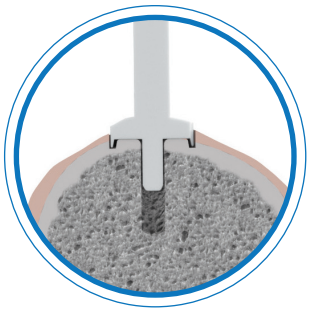
9 MARKING THE EPISEALER ROTATION

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.

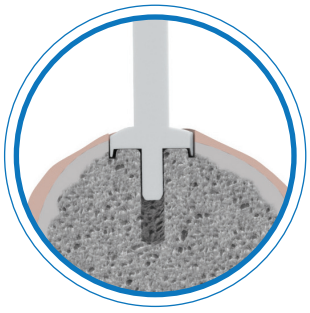


10 FINAL CHECK

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.



Not deep enough

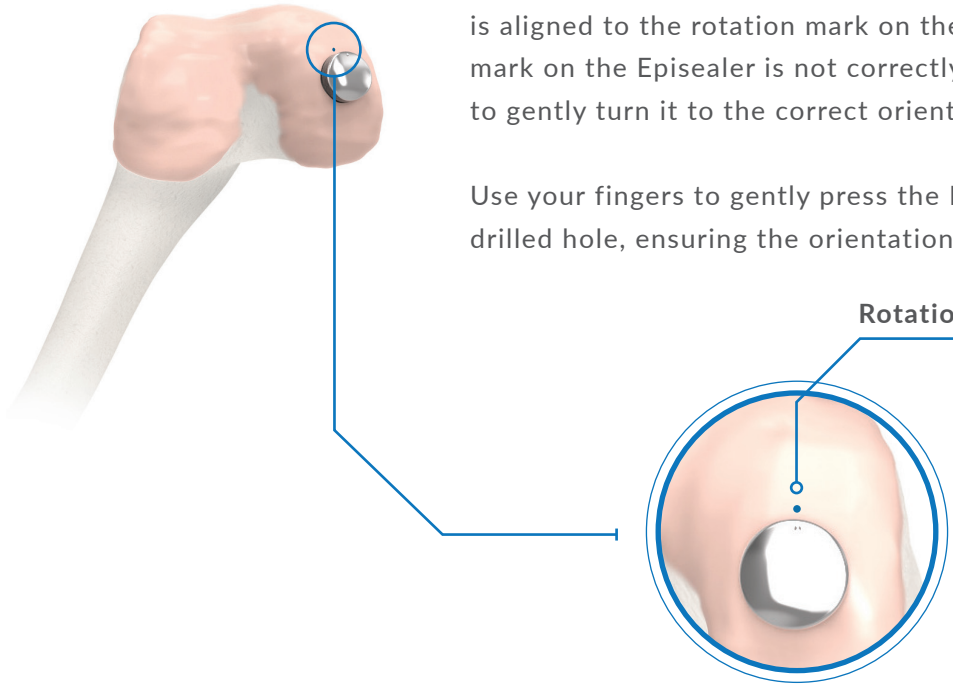


OK

⚠ **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.

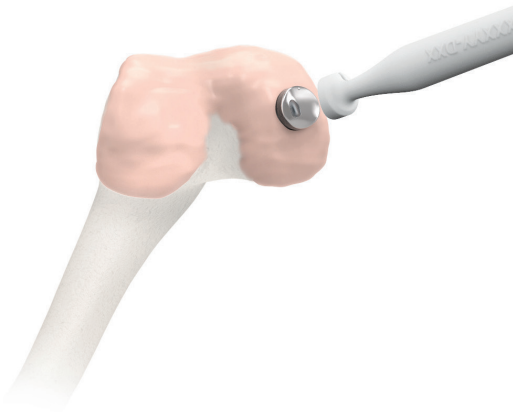
11 PLACING THE EPISEALER



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



For the final placement, use the Epimandrel and a hammer to gently tap down the Episealer into bone until fully seated. Ensure Epimandrel's anterior marking is aligned with the rotation mark on the Episealer and the cartilage surface. When fully seated, the top surface of the Episealer should be approximately 0.5-1 mm below the adjacent articular cartilage surface.

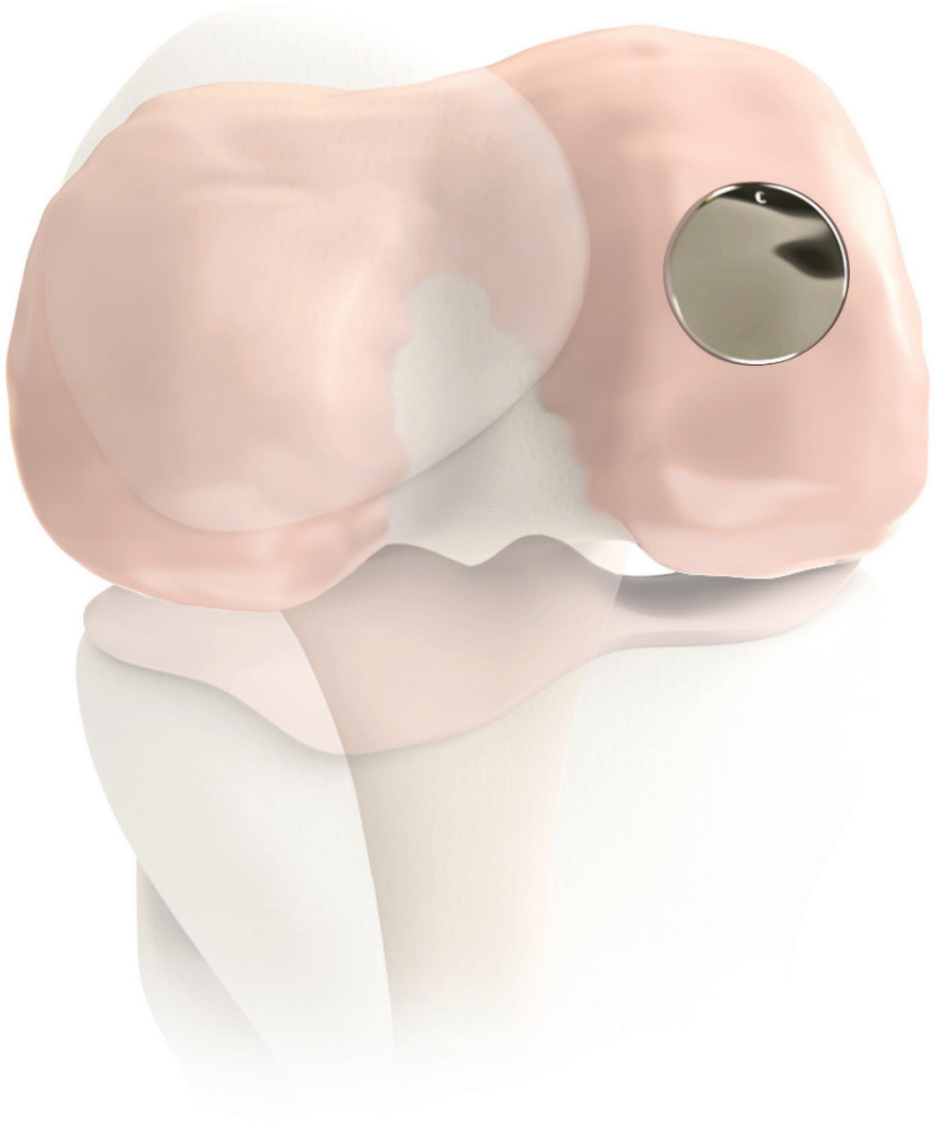
PRECAUTION

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

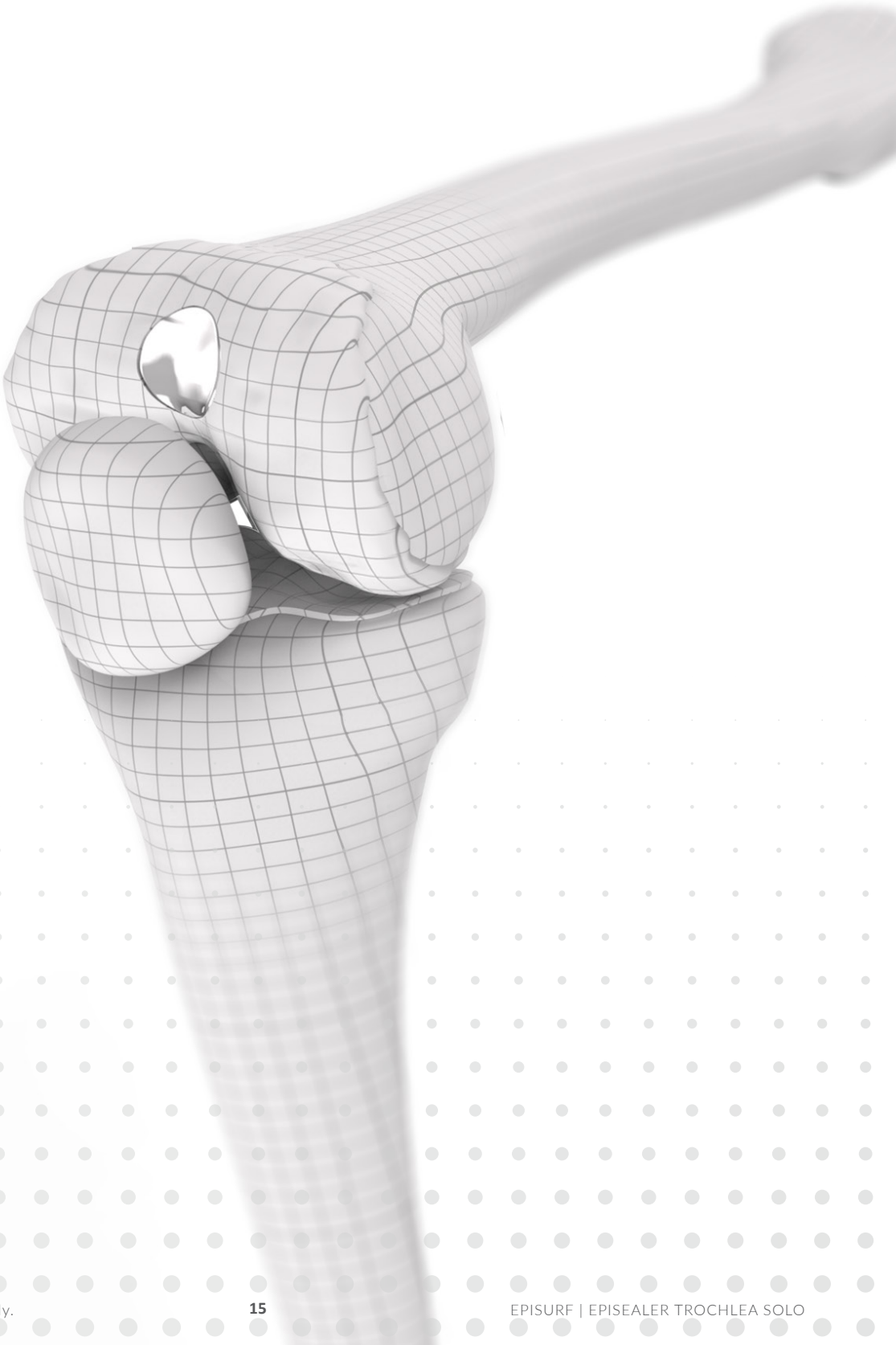
⚠ WARNING!

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.

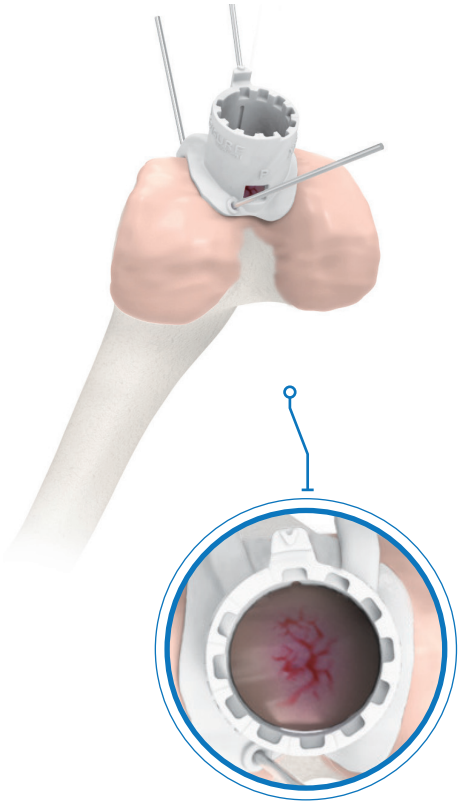
13 FINAL PLACEMENT



Episealer Trochlea Solo
Surgical procedure



1 PLACING THE EPIGUIDE



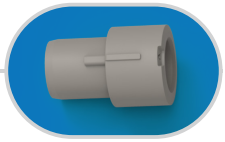
Make an incision long enough to fully expose the operative field. The complete base of the Epiguide must be visible through the incision. Place the Epiguide on the articular cartilage surface. Use the markings on the Epiguide, A (anterior) and P (posterior), to find the correct orientation when positioning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

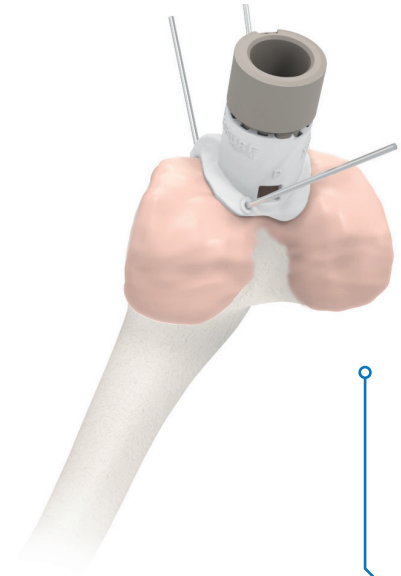
Look through the circular opening of the Epiguide and make sure the bottom surface is placed flush to the cartilage surface all the way around the opening. This is important to achieve the correct drilling angle and depth.

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 bottom's surface is placed flush to the cartilage all way around the opening.

2 ASSEMBLING THE DRILLING SOCKET



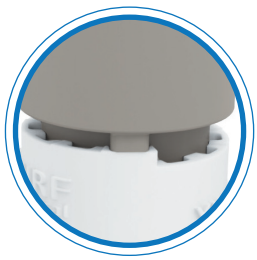


Mount the Drilling socket onto the Epiguide. The Drilling socket guides the first drill step.

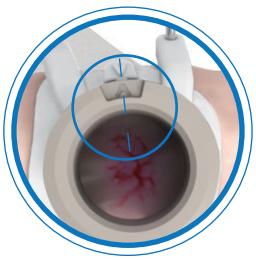
Check that the Drilling socket is set in its correct position relative to the Epiguide; the arrow on the rim of the Epiguide must be in line with the marking on the Drilling socket.

Make sure 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.

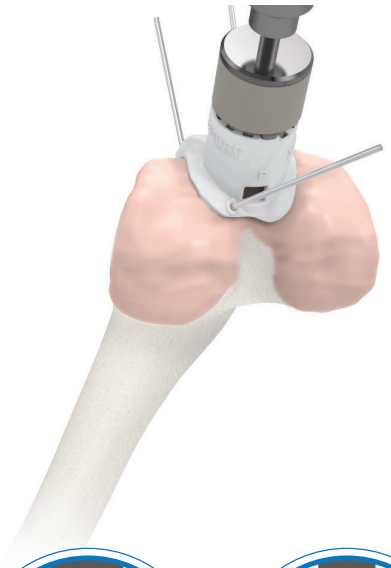


Drilling socket fully seated



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.

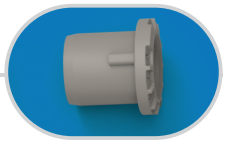
Before drilling

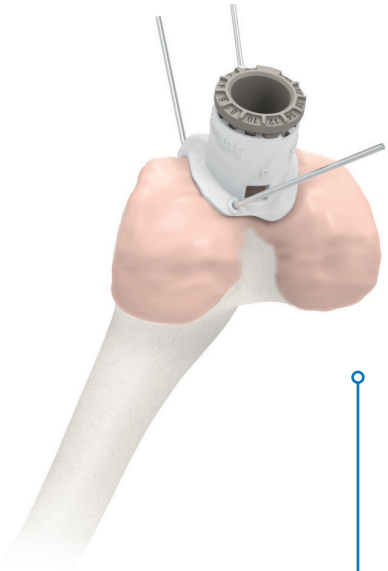
After drilling

PRECAUTION

The Drilling socket must be fully seated and securely fastened in the Epiguide. Make sure that the drill is correctly aligned in the drill guide to ensure drilling in the correct direction.

4 DRILLING PROCEDURE - STEP TWO





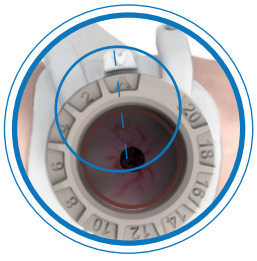
Remove the Drilling socket and insert the Adjustment socket aligned to the START position. Make sure the Adjustment socket is fully seated in the Epiguide.

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!**

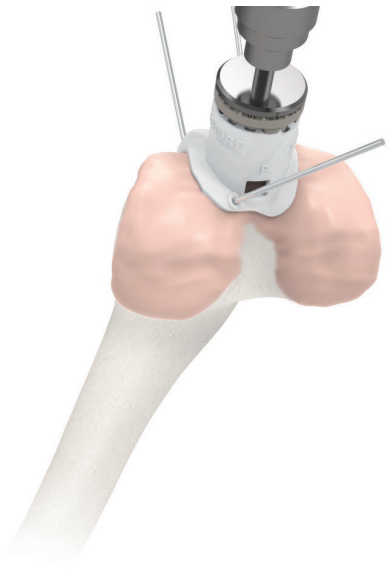
Ensure that the Adjustment socket is in a correct position before drilling. Incorrect positions may result in an incorrect drill depth and incorrect Episealer placement.

Adjustment socket fully seated



Start position

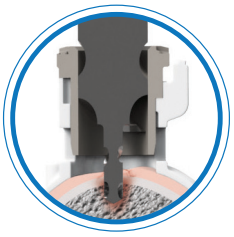
5 DRILLING PROCEDURE - STEP THREE



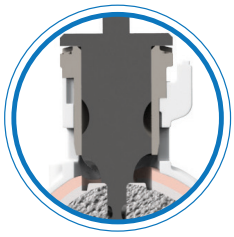
When inserting the Epidrill into the Adjustment socket, make sure that the tip of the Epidrill is inserted into the pre-drilled hole and that the large drill body is not in contact with the cartilage surface as the drilling starts.

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.



Epidrill at start position

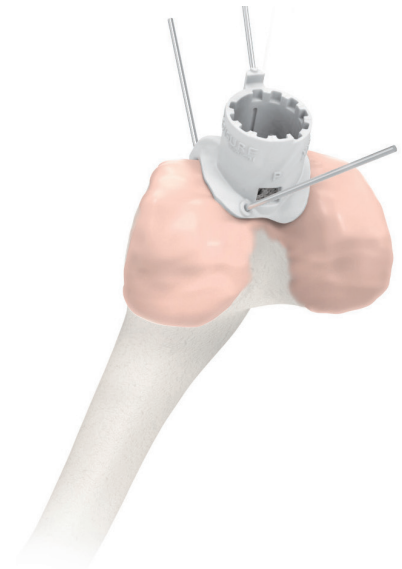


Epidrill bottoming

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

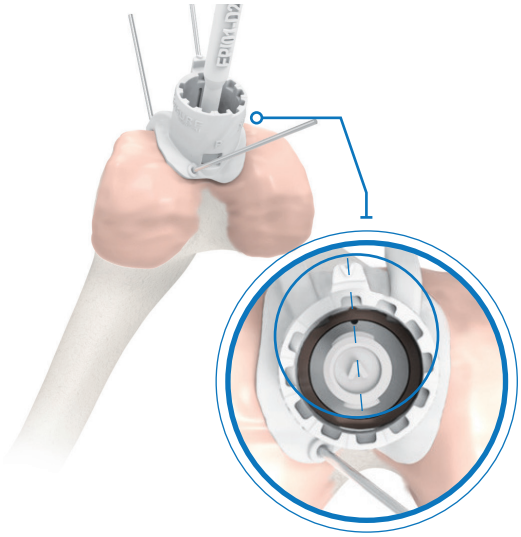


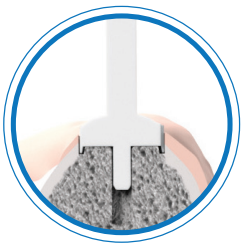
Note the Adjustment socket position and remove the Adjustment socket from the Epiguide.
Use adequate lavage en suction to clear all debris from the drilled hole.

⚠ WARNING!

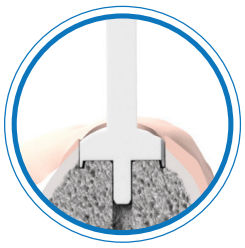
Ensure that there are no fringes or fronds on the cartilage edge after drilling. All debris along the cartilage edge should be removed using standard tweezers. Any residues of bone and/or cartilage that are left in the drilled hole may prevent the Episealer from becoming osseointegrated with the bone.

7 EVALUATING THE DRILLED DEPTH





Not deep enough



OK

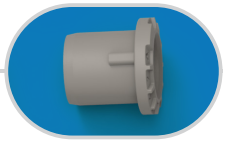
Insert the Epidummy into the drilled hole with its rotation mark aligned with the rotation mark of the Epiguide.

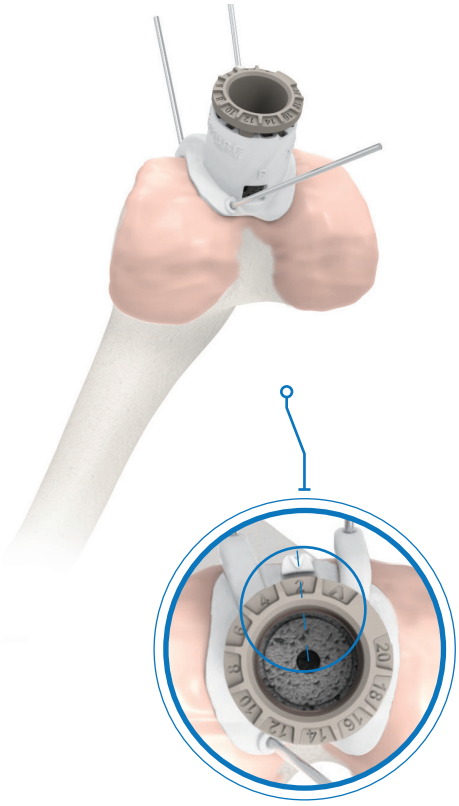
Compare the depth of the Epidummy top surface with the surrounding cartilage edge and assess the height difference. Use the openings in the Epiguide to evaluate the depth. If the Epidummy top surface is positioned approximately 0.5-1 mm below the adjacent articular cartilage surface, the drilling is 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





Drill depth increased 0.2 mm

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.

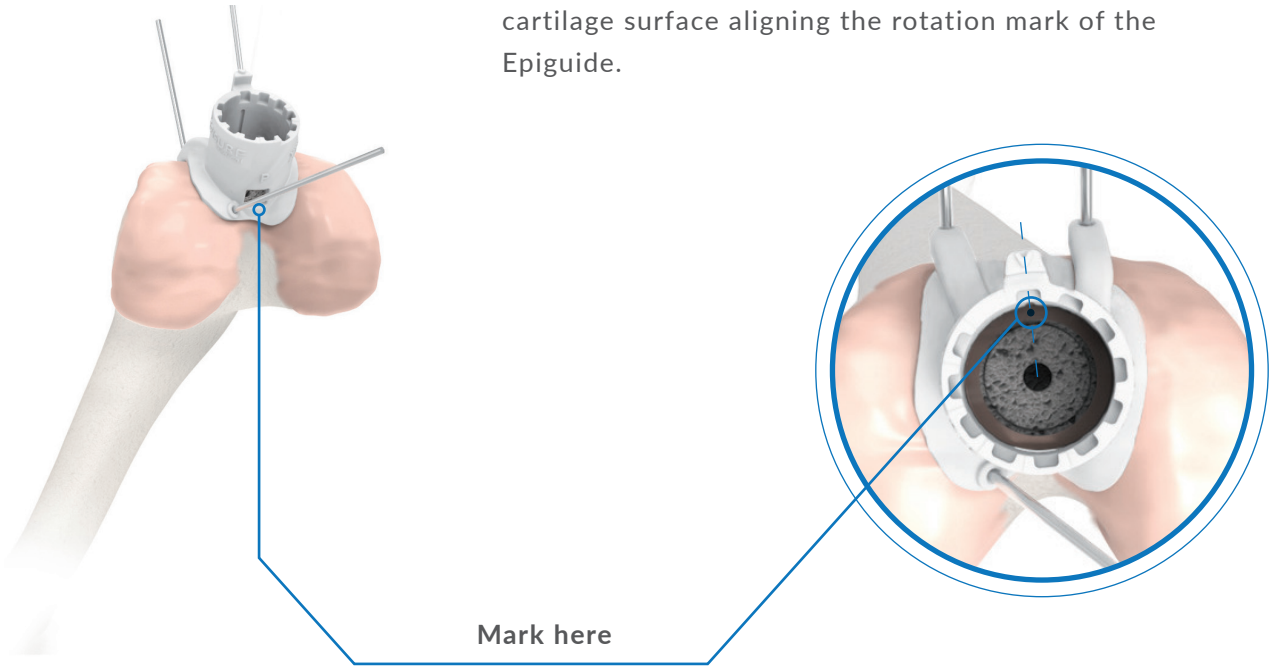
Note the drill depth setting. Upon removal and replacement of the Adjustment socket, it needs to be replaced at the correct depth to avoid unintentionally drilling too deep.

⚠ **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.

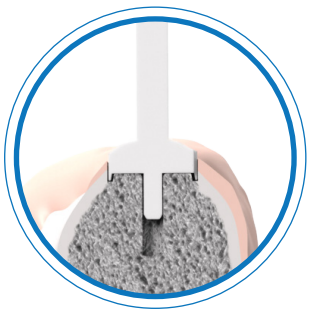
9 MARKING THE EPISEALER ROTATION

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.

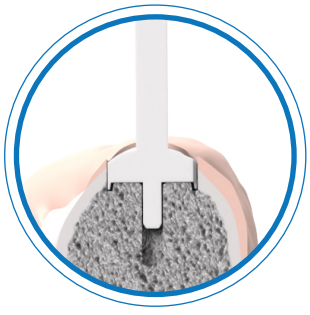


10 FINAL CHECK

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.



Not deep enough



OK

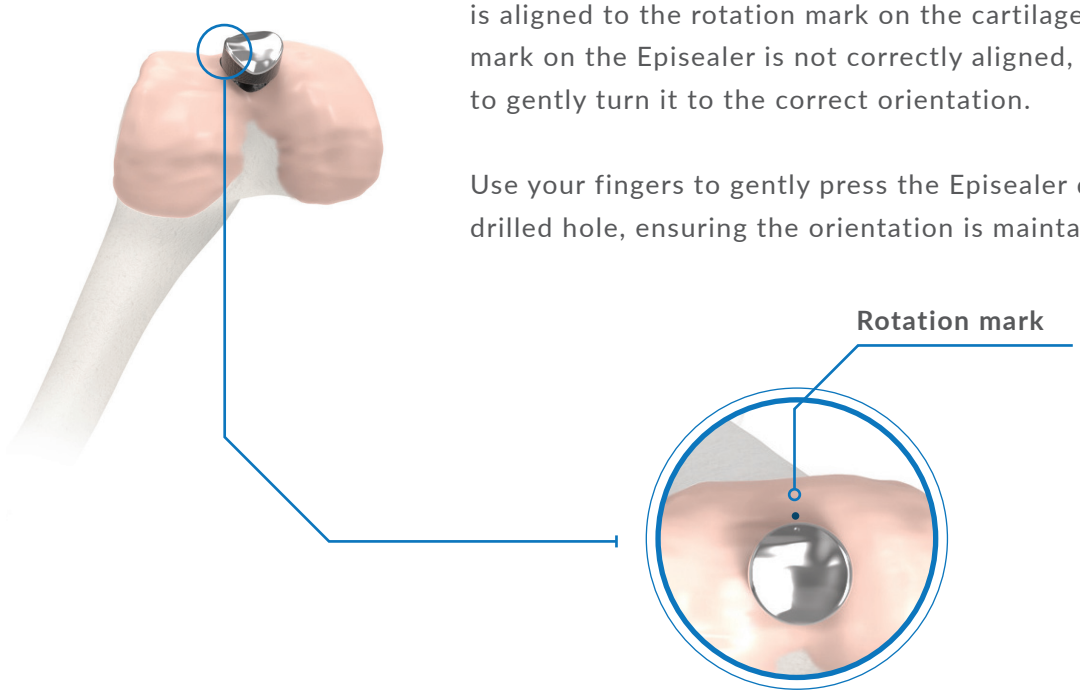
⚠ **WARNING!**

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

For the final placement, use the Epimandrel and a hammer to gently tap down the Episealer into bone until fully seated. Ensure Epimandrel's anterior marking is aligned with the rotation mark on the Episealer and the cartilage surface. When fully seated, the top surface of the Episealer should be approximately 0.5-1 mm below the adjacent articular cartilage surface.

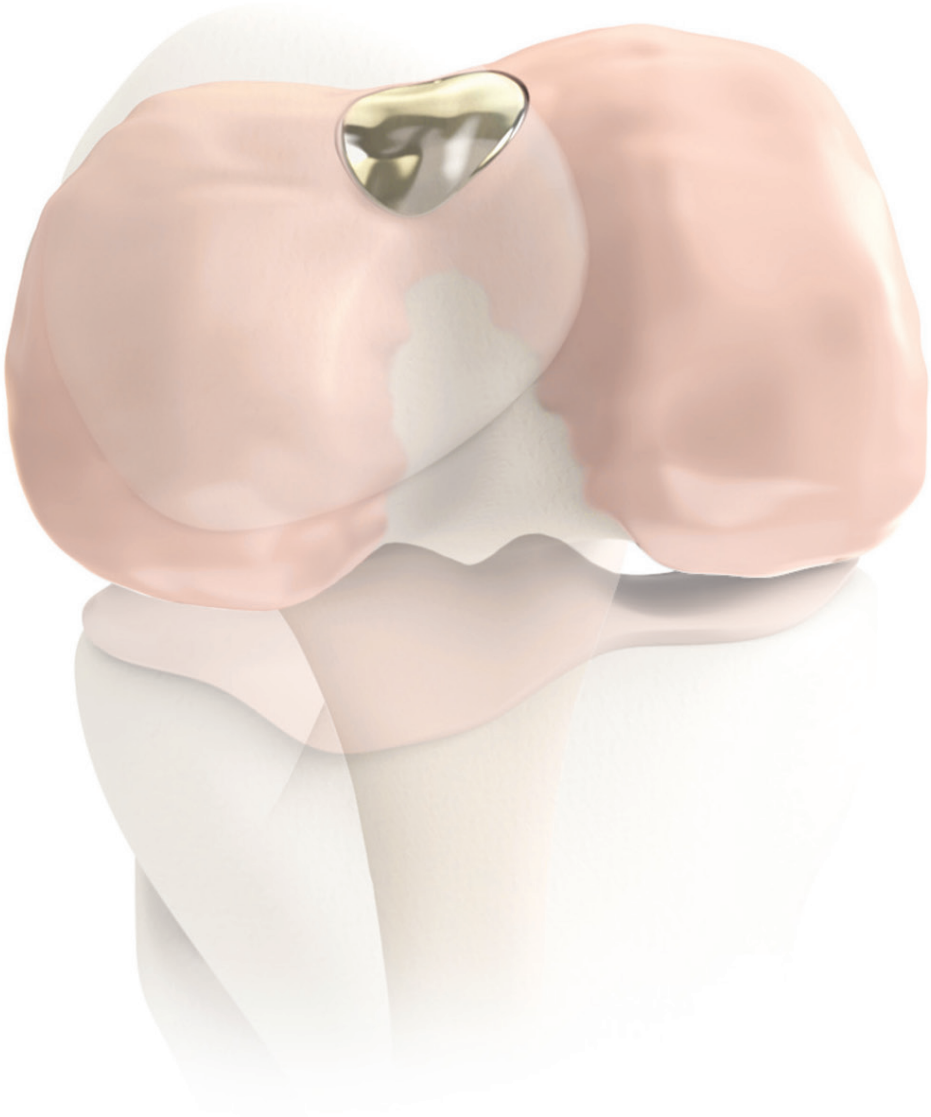
PRECAUTION

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

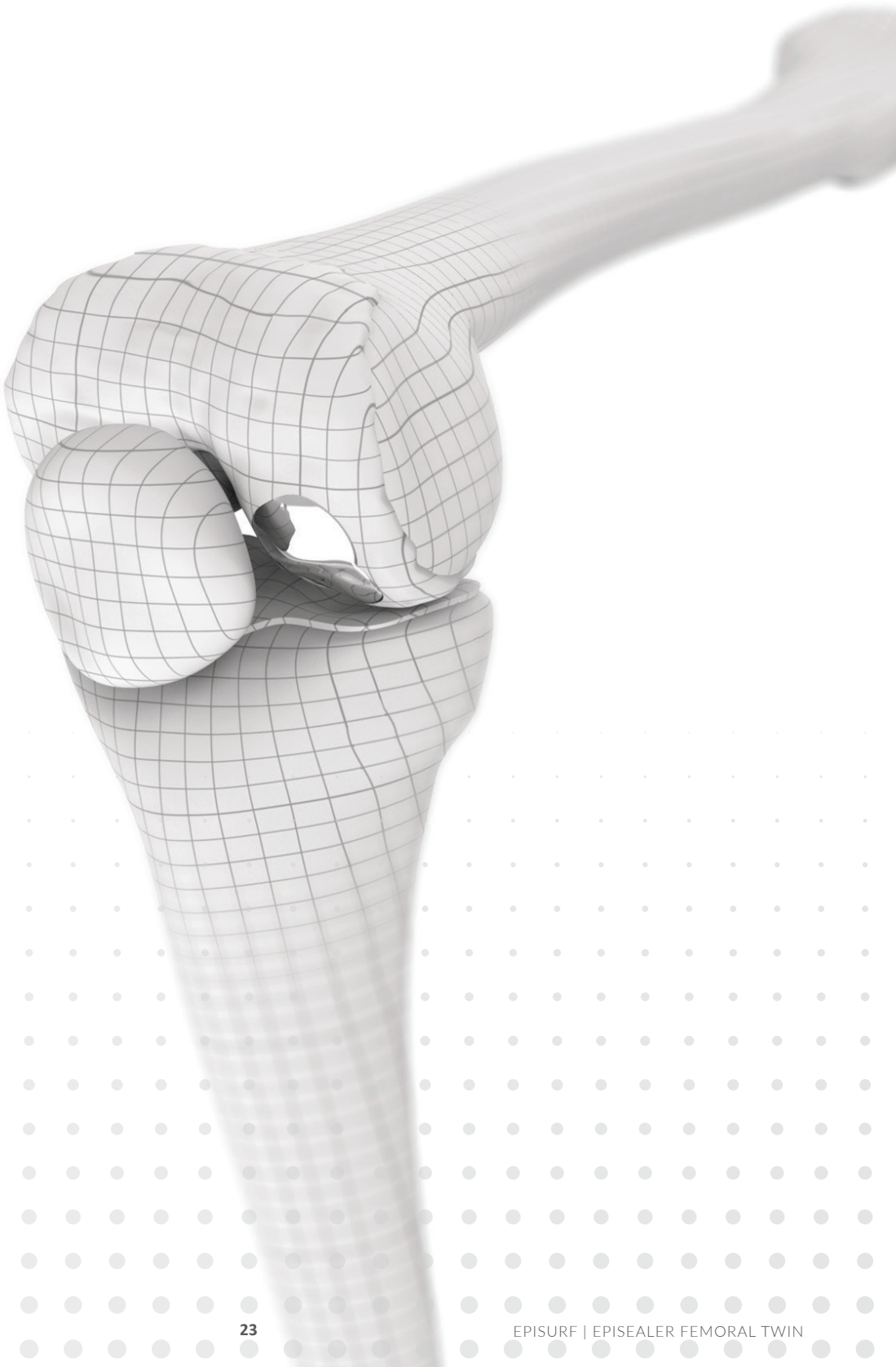
⚠ WARNING!

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.

13 FINAL PLACEMENT

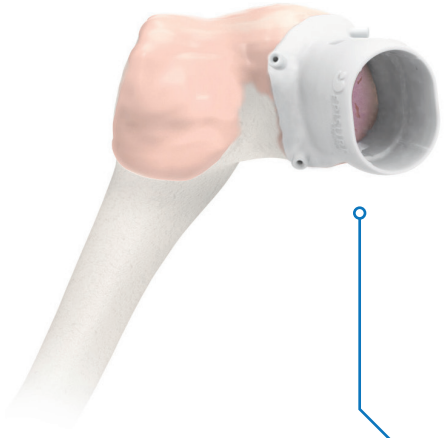


Episealer Femoral Twin
Surgical procedure



1 PLACING THE EPIGUIDE

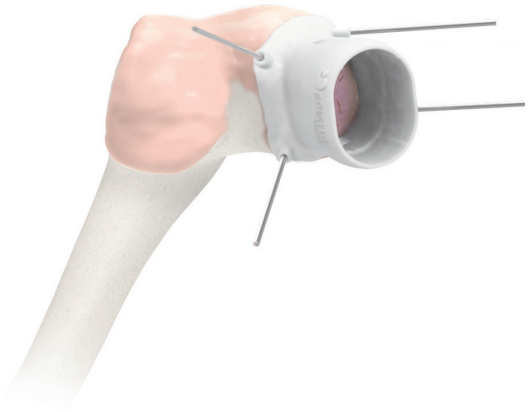
Make an incision long enough to fully expose the operative field. The complete base of the Epiguide must be visible through the incision. Place the Epiguide on the articular cartilage surface. Use the markings on the Epiguide, A (anterior) and P (posterior), to find the correct orientation when positioning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

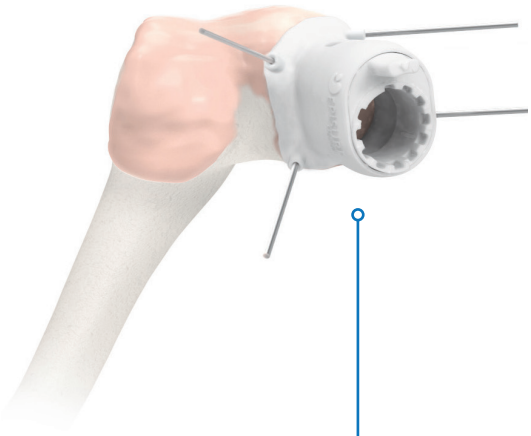


⚠ **WARNING!**

Make sure the Epiguide is securely fastened to the bone and that the bottom's 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.

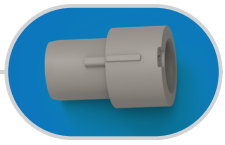


Check that the insert is fully seated in the Epiguide with its top surface flush with the top of the Epiguide. This must be checked every time the insert is placed into the Epiguide.

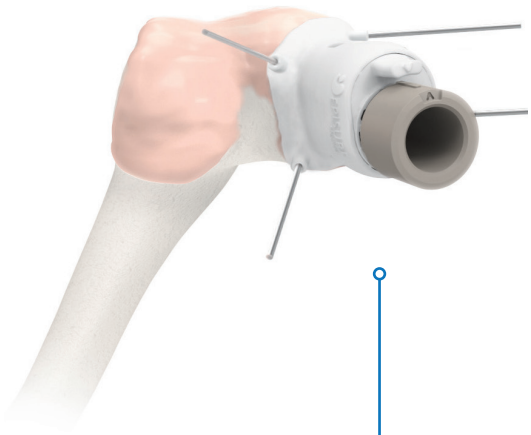
⚠ **WARNING!**

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.

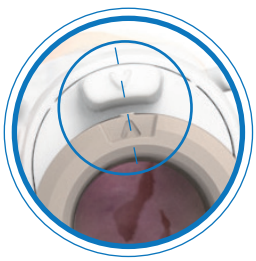


Check that the Drilling socket is set in its correct position relative to the Epiguide; the arrow on the rim of the Drilling socket must be in line with the arrow on the insert.

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

⚠ **WARNING!**

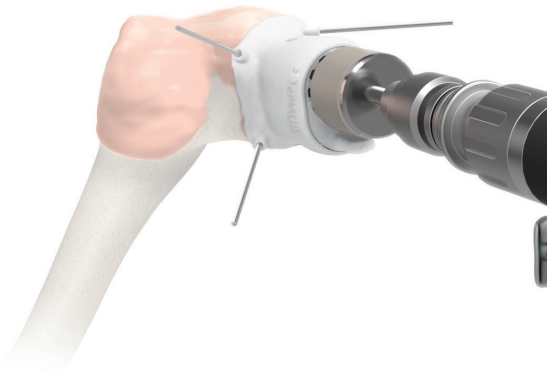
Ensure the Drilling socket is in a correct position before drilling. Incorrect position may result in an incorrect drill depth and incorrect Episealer placement.



Start position

Drilling socket fully seated

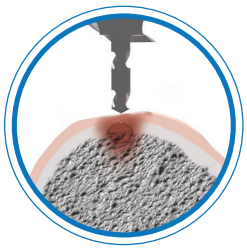
5 DRILLING PROCEDURE - STEP ONE



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 (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. Both insert and Drilling socket must be 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.



Before drilling

After drilling

⚠ **WARNING!**

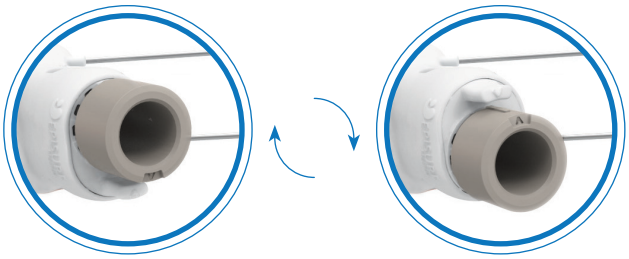
Make sure that the drill is correctly aligned in the drill guide to ensure drilling in the correct direction.

6 DRILLING PROCEDURE - STEP TWO

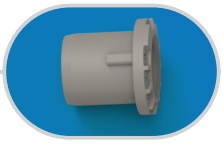
Lift up the insert from the Epiguide, turn it 180° and re-mount it in the Epiguide. Check that the insert is fully seated in the Epiguide and that the Drilling socket is correctly mounted into the insert. In order to achieve the correct drilling depth, it is important that the Drilling socket is always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

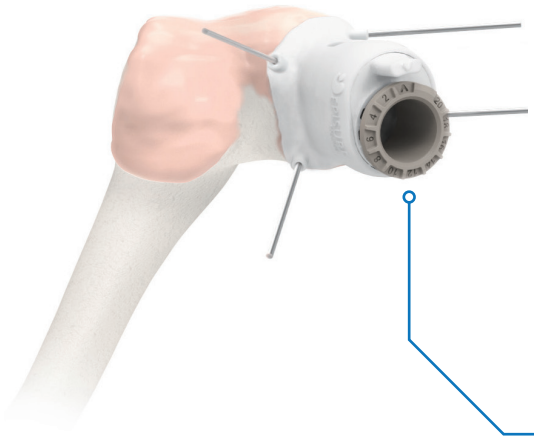
Drill the second hole, repeating the instructions as for the first one.

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

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.

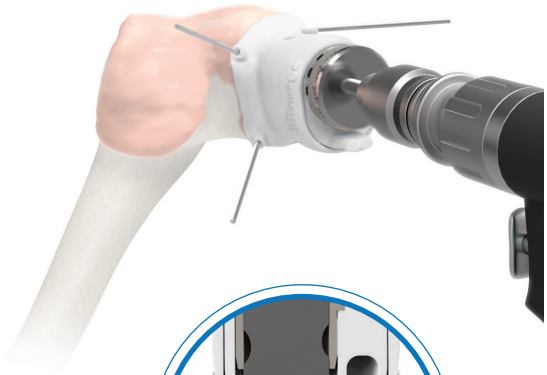
Remove the Epidrill.

Epidrill at start position

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



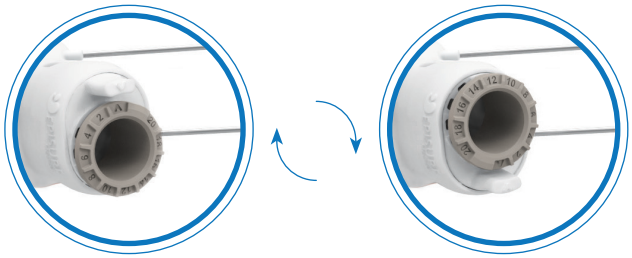
Epidrill fully seated

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

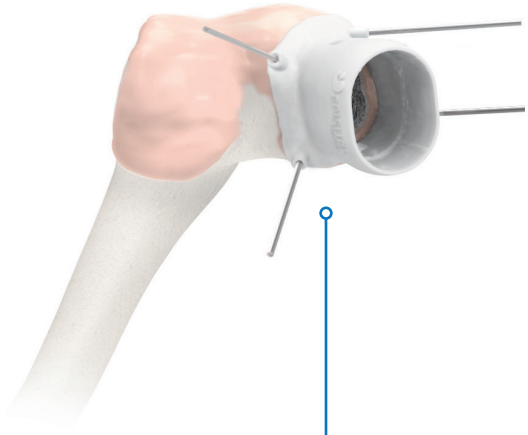
Perform the adjustment drilling for the second hole, repeating the instructions as for the first hole.

⚠ WARNING!

Both holes must be drilled with identical Adjustment socket drill depth setting. Different hole depths may prevent the Episealer from being placed correctly and/or becoming osseointegrated.



10 REMOVAL OF DEBRIS AND LOOSE CARTILAGE

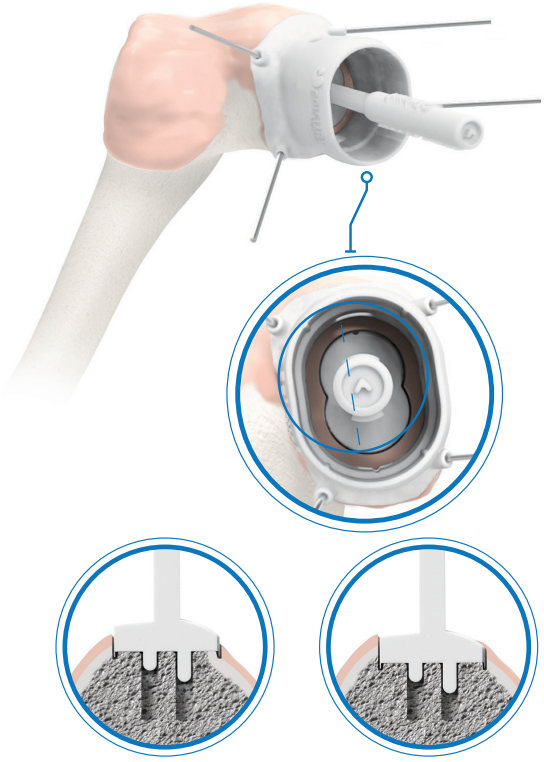


Note the Adjustment socket position and remove the Adjustment socket and insert from the Epiguide. Use the pulse lavage and suction to cleanse the drilled hole.

⚠ 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



Not deep enough

OK

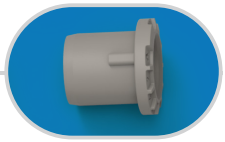
Insert the Epidummy into the drilled hole with its direction mark aligned with the direction mark of the Epiguide.

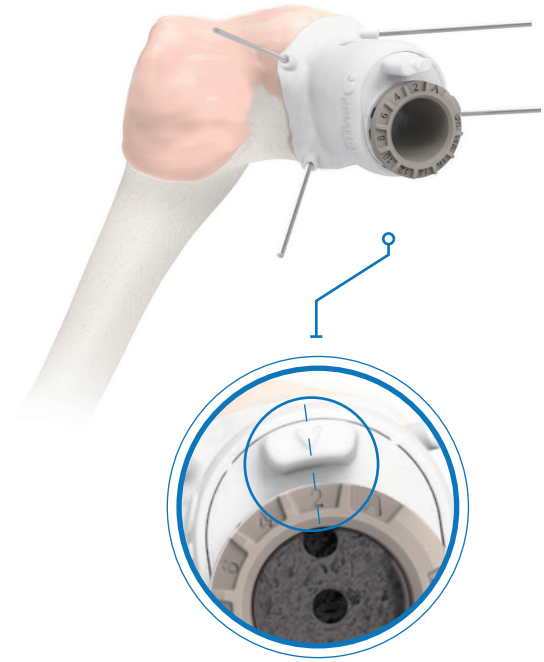
Compare the depth of the Epidummy top surface with the surrounding cartilage edge and assess the height difference. Use the openings in the Epiguide to evaluate the depth. If the Epidummy top surface is positioned approximately 0.5-1 mm below the adjacent articular cartilage surface the drilling is finished. 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.

12 ADJUSTING THE DRILL DEPTH





Drill depth increased 0.2 mm

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.

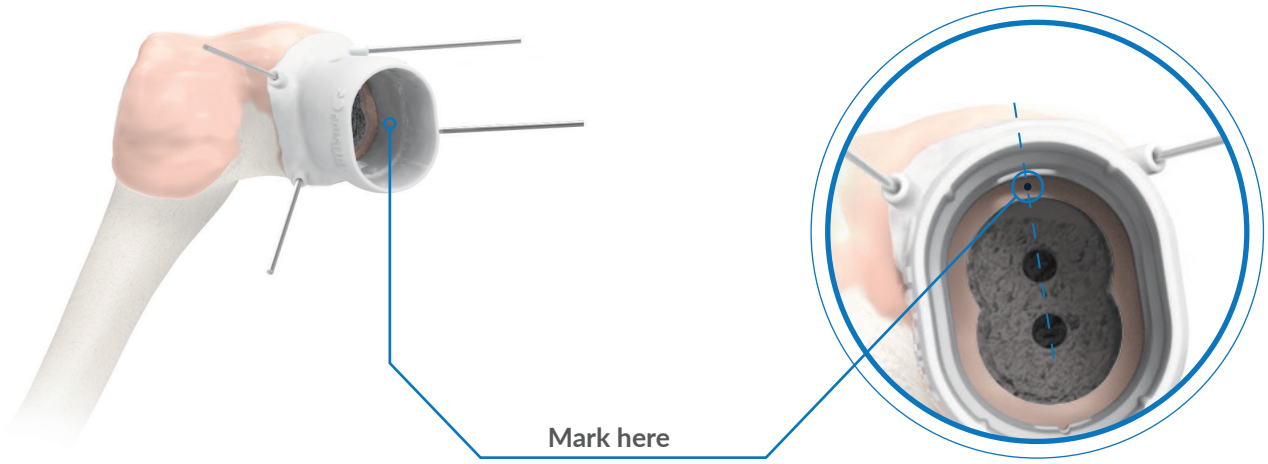
Note the drill depth setting. Upon removal and replacement of the Adjustment socket, it needs to be replaced at the correct depth to avoid unintentionally drilling too deep.

⚠ **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

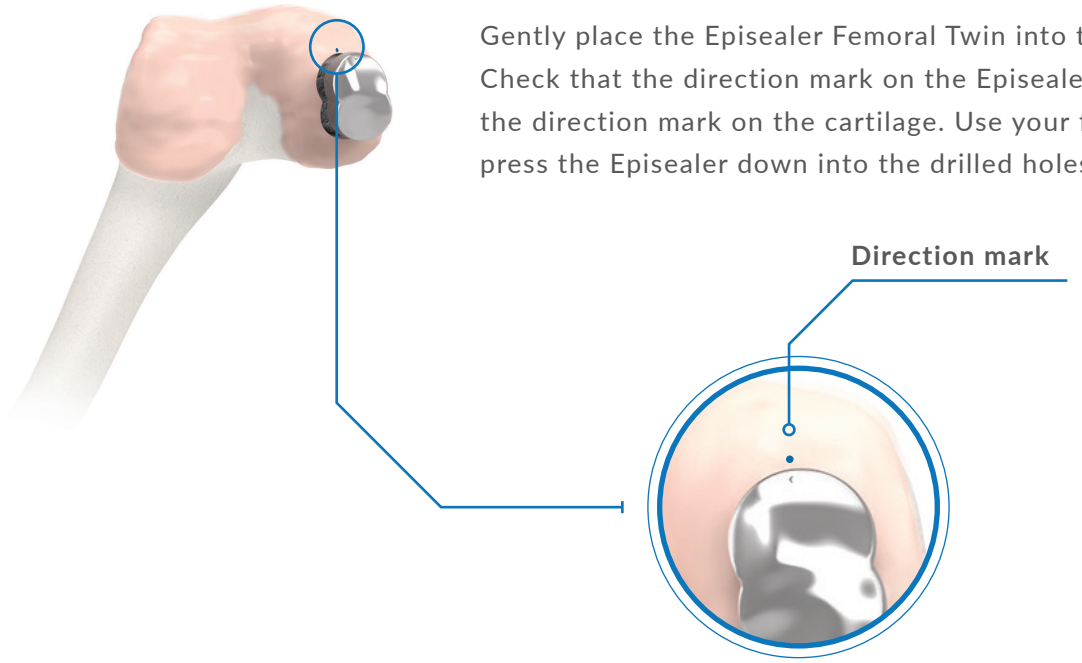
Use a sterile pen to mark the direction of the Episealer. Make the mark on the cartilage surface aligned with the direction mark of the Epiguide.



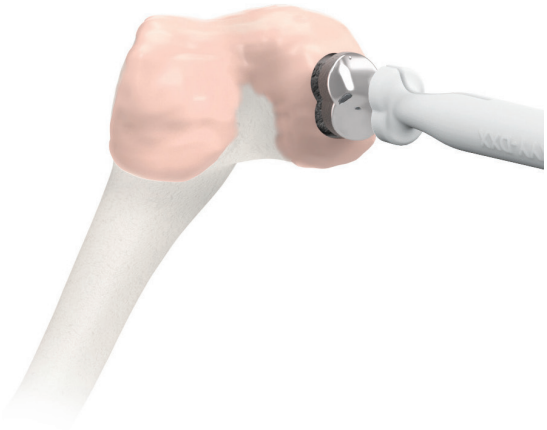
14 FINAL CHECK AND PLACING THE EPISEALER

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



For the final placement, use the Epimandrel and a hammer to gently tap down the Episealer into bone until fully seated. Ensure Epimandrel's anterior marking is aligned with the direction mark on the Episealer and the cartilage surface. When fully seated, the top surface of the Episealer should be approximately 0.5-1 mm below the adjacent articular cartilage surface.

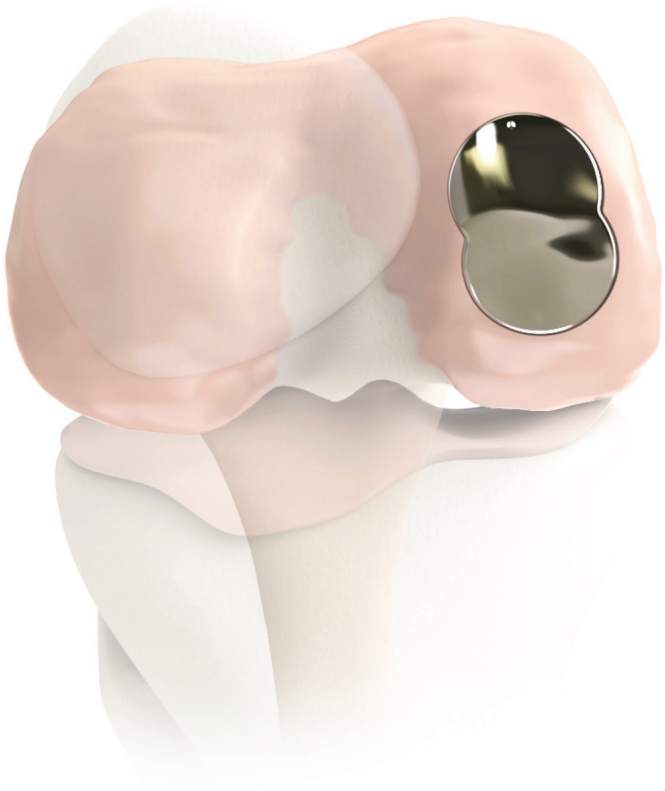
PRECAUTION

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.

16 FINAL PLACEMENT



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