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SURGICAL TECHNIQUE  
EPISEALER® TALUS



**SURGICAL TECHNIQUES:**

- TALUS OSTEOTOMY GUIDE
- EPISEALER TALUS



## EPISEALER SURGICAL TECHNIQUE

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## THE EPISURF MRI AND CT PROTOCOL

The Episealer Talus implant, the Epiguide® and Talus Osteotomy Guide (TOG) are designed based on MRI or CT data. While both MRI and CT can be used, MRI is preferred.

Episurf has developed specific protocols, which need to be installed on a scanner in your radiology department. These protocols are available from your local Episurf representative who will partner with your radiology team to get your scanner validated for the correct sequences. To run the Episurf MRI or CT protocols, no special equipment is needed. For MRI, the scanner must have a magnetic field strength of at least 1.5 T.

### MRI sequences

#### Diagnostic scans

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

#### 3D sequence

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

### CT sequences

#### Diagnostic scans

A conventional diagnostic sequence is used in order to obtain an assessment of the osteochondral defects. Together with our radiological team, we will identify bone lesions and make suggestions on the thickness and position of any implant that may be required.

### How to set up the protocol

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

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



## DAMAGE MARKING REPORT

### Damage Marking Report (DMR)

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

- osteochondral lesions
- 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 helped 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 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.

**EPISURF Medical** EPI20 Damage marking Episealer Talus

Episealer dimension	Position	Scan date	Gender	Age at scan date	Patient side
D15 mm	Medial Talus	15 Jan, 2020	Male	60	Left

**Damage assessment**  
The green marking indicates an osteochondral lesion.

**Implant position and size**  
An Episealer Talus with dimension D15 mm has been positioned to cover as much as possible of the osteochondral lesion on the medial talus. The implant has been made 1 mm thicker than normal in order to cover the osteochondral lesion.  
The Episealer Talus implant is only available in one implant size with dimension D15 mm.

**Malleolar osteotomy position**  
In order to access the medial talus, an osteotomy has been suggested with approximately a 30° angle from the tibial axis, aiming for the talus edge, see page 7. The position of the osteotomy can be adjusted upon the surgeon's request.  
The flexibility of the patient's joint needs to be considered to ensure the accessibility of the Epiguide drill tower.

Report ID: EPI20\_Damage\_marking\_V02  
Report template: DMR\_M001\_2020\_V02

**EPISURF Medical** 3D sequence

**Cor 3D**

Intersection of Episealer D15 mm

Report ID: EPI20\_Damage\_marking\_V02  
Report template: DMR\_M001\_2020\_V02

**EPISURF Medical** 3D sequence

**Sag 3D**

Intersection of Episealer D15 mm

Report ID: EPI20\_Damage\_marking\_V02  
Report template: DMR\_M001\_2020\_V02

**EPISURF Medical** Osteotomy

**Cor 3D**

Suggestion for the osteotomy position

Position of the Epiguide drill tower

Intersection of Episealer D15 mm

Report ID: EPI20\_Damage\_marking\_V02  
Report template: DMR\_M001\_2020\_V02



## EPISEALER TALUS OVERVIEW

Each Episealer is uniquely designed to perfectly fit a patient's individual talus osteochondral 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 and bone.
- **the peg** gives initial stability and press-fits into the subchondral cortex allowing stable fixation and rapid recovery post-operatively.

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

### Cobalt-chrome

- Can be polished to an ultra-smooth surface ( $R_a = 0.05\mu\text{m}$ )
- Low risk of metal debris
- Well-tested and proven medical device material

### Physiological surface

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

### Ti and HA coating

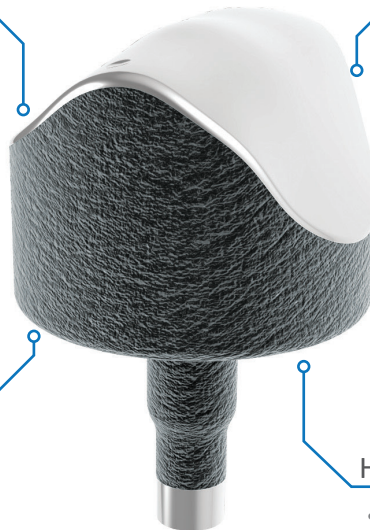
- Seals the Episealer to the cartilage
- Promotes healthy cartilage against the edge of the Episealer
- Prevents joint fluid penetration between the Episealer and surrounding tissue

### Titanium undercoating

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

### Hydroxyapatite outer coating

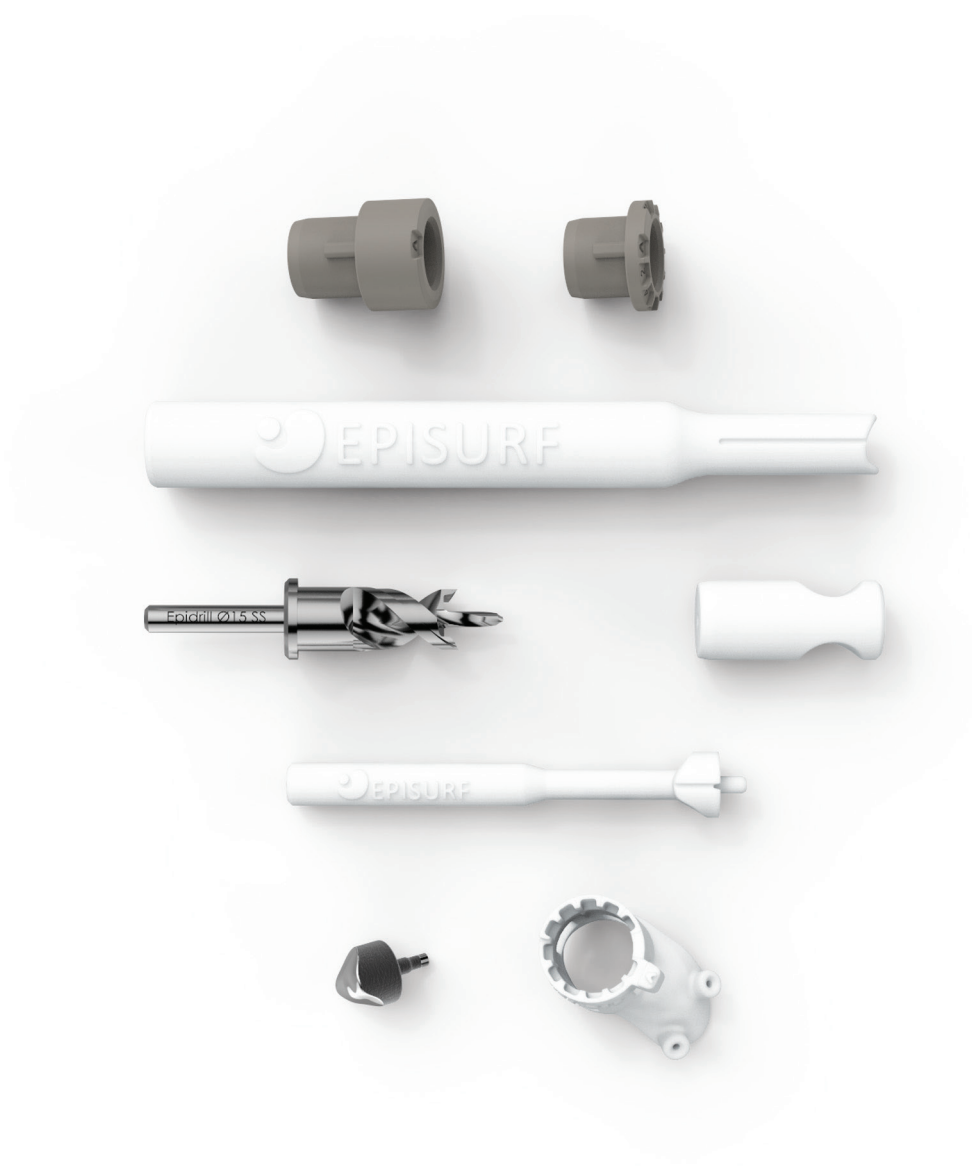
- In clinical use for over 30 years
- Rapid osseointegration
- Promotes bone ongrowth





## EPISEALER TALUS TOOLKIT OVERVIEW

Name	Article Number
Episealer Talus D15	41115
Epiguide	43715
Pin socket	43815
Drilling socket	43115
Adjustment socket	43415
Epimandrel	47115
Epidrill	42115
Epidummy	44115





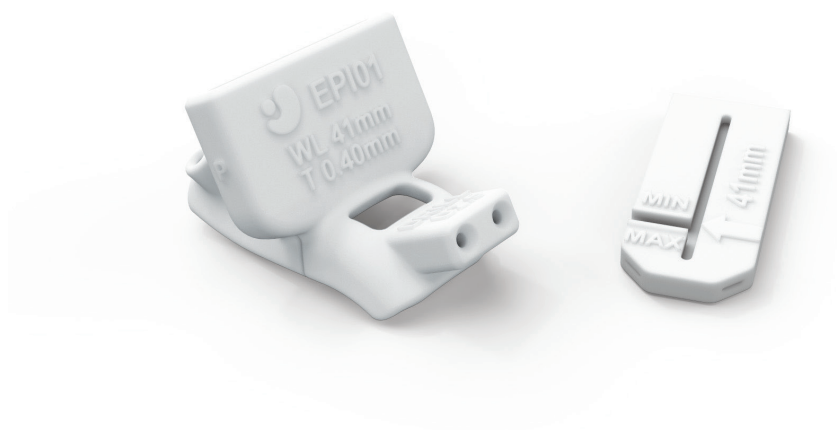
## TALUS OSTEOTOMY GUIDE OVERVIEW

Episurf's Talus Osteotomy Guide (TOG) is uniquely designed to perfectly fit the patient's distal tibia. This unique placement facilitates the osteotomy of the medial malleolus in preparation of the implantation of the Episealer Talus. The guide has two features

- **Saw guide** facilitates the detachment of the medial malleolus.
- **Drill holes** give a perfect placement of the fixation holes to re-fixate the medial malleolus to tibia after the implantation of the Episealer Talus.

Each TOG is designed to fit the patient's distal tibial anatomy and the sawblade used. Therefore it is important to inform Episurf about the sawblade dimensions and drill diameter used during the surgery. Prior to the surgery, the Osteotomy Depth Meter (ODM) is used to verify that the actual sawblade working length corresponds to the length the TOG was designed for.

The Talus Osteotomy Guide is an optional device. It can be ordered as a stand-alone product or in combination with the Episealer Talus implant for medial positions.



Name	Article Number
Talus Osteotomy Guide	48115
Osteotomy Depth Meter	48215



# Talus Osteotomy Guide

## **Procedure overview**

# 1

## CHECKING THE SAWBLADE LENGTH



Connect the sawblade to the power tool.

Insert the sawblade into the Osteotomy Depth Meter (ODM) until the power tool stops against the ODM. Verify that the tip of the sawblade is visible within the MIN/MAX markings.

### WARNING!

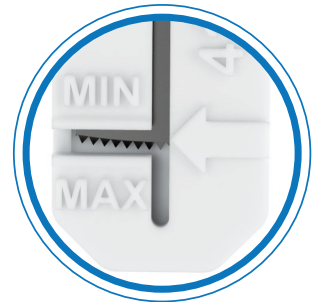
**Only use the Talus Osteotomy Guide (TOG) with the specified sawblade dimensions. If another sawblade is used, the TOG must not be used. If the sawblade is too short or too long, the TOG must not be used.**



Too short



Too long



OK

# 2

## PLACING THE TALUS OSTEOTOMY GUIDE (TOG)



Make an incision long enough to fully expose the operative field. The complete base of the TOG must be visible through the incision.

Liberate the tibia carefully from its connective tissue both anteriorly and posteriorly. Make sure not to damage any posterior tendons. The periosteum must stay intact.

Place the TOG in its unique position on the tibia. Use the window on the TOG to verify a proper anatomical fit without gaps.

### WARNING!

**Make sure not to damage posterior tendons.**

**Make sure the TOG is placed without gaps against the tibial surface. The periosteum must stay intact.**

# 3

## SECURING THE TOG



Attach and secure the TOG to the bone by inserting two 2 mm surgical pins in the pin holes on the proximal side of the TOG.

Make sure the TOG does not move during fixation.

### **WARNING!**

**Make sure the TOG is securely fastened to the bone.**

# 4

## CREATING THE FIXATION HOLES



Make sure to use the same drill diameter as specified on the TOG. Attach the designated drill to the power tool. Use the distal guiding holes on the TOG to drill the fixation holes for refixation of the bone fragment after the procedure.

### **PRECAUTION**

Make sure to use the same drill diameter as specified on the TOG.



# 5

## SAWING



Attach the sawblade to the power tool. Insert the sawblade into the TOG and start sawing.

Make sure to keep surrounding tendons away from the sawing field.

The TOG will guide the sawing and controls the depth of the cut. Continue sawing until the saw bottoms on the top of the TOG.

### **WARNING!**

**Make sure to use the same sawblade as specified when placing the order.**



# 6

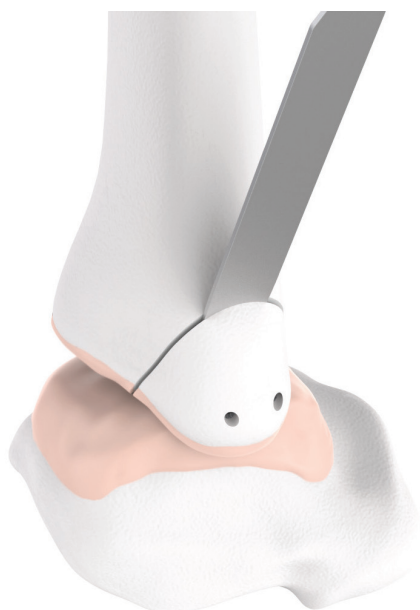
## REMOVING THE TOG



Remove the surgical pins and the TOG from the surgical field.

# 7

## BREAKING OFF THE BONE FRAGMENT



Perform the final break-off using an osteotome.

# 8

## FINAL RESULT



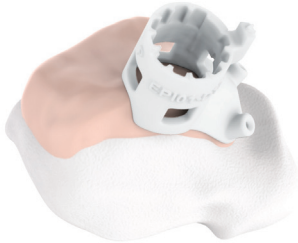


EPISEALER TALUS

## Episealer Talus **Procedure overview**

# 1

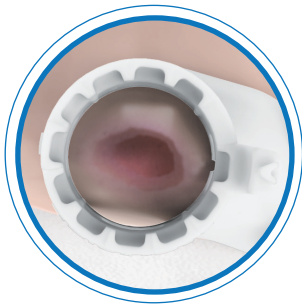
## PLACING THE EPIGUIDE



For improved talus exposure, a distractor forceps (e.g. Hintermann) can be used to separate the tibia and the talus. This is recommended to facilitate the placement of the Epiguide.

Place the Epiguide on the articular cartilage surface with the P facing the posterior direction. Identify the correct position by aligning the Epiguide's base to the anterior cartilage edge of the talar dome.

Look through the opening of the Epiguide and ensure the bottom surface is placed flush to the cartilage surface as shown on the Final Design document, which is provided by Episurf.

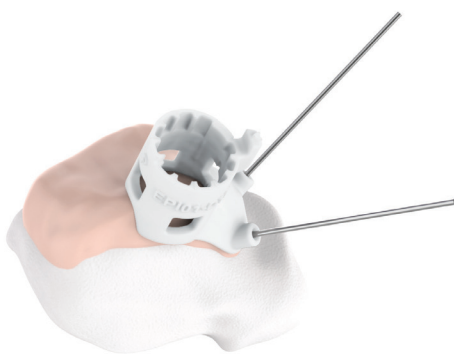


### **WARNING!**

**Make sure the Epiguide is placed flush on the cartilage surface all around the opening, without any gaps. Gaps between the inside of the Epiguide and the cartilage may lead to a poor anatomical alignment.**

# 2

## SECURING THE EPIGUIDE



Use two 2 mm surgical pins to attach and secure the Epiguide to the bone.

### **WARNING!**

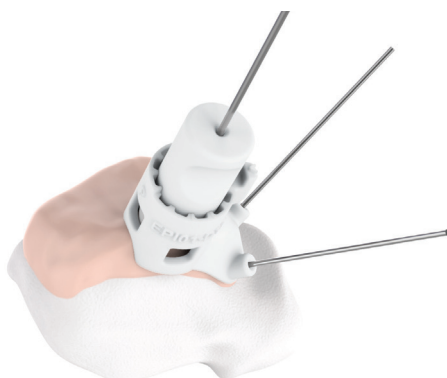
**Make sure that the Epiguide is securely fastened to the bone.**

### **PRECAUTION**

Make sure that tibia does not push against the Epiguide in any direction as this might result in an inaccurate Epiguide placement.

# 3

## CREATING THE CENTRE STEERING HOLE



Place the Pin socket in the Epiguide and make sure it bottoms on the cartilage surface.

Attach a 2 mm surgical pin to the drill and insert the pin in the Pin socket. Start drilling and advance the drill approximately the same distance as the length of the implant.

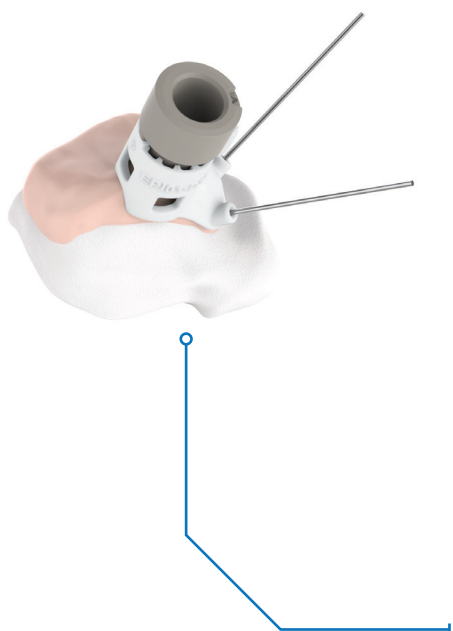
Remove the drill, surgical pin and the Pin socket from the Epiguide.

### WARNING!

**The surgical pin does not automatically stop on the Epiguide. Stop drilling when the pin has advanced approximately the same distance as the length of the implant.**

# 4

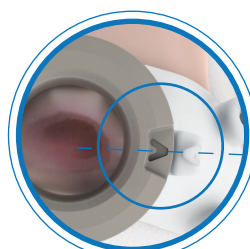
## ASSEMBLING THE DRILLING SOCKET



Mount the Drilling socket onto the Epiguide. The arrow on the top of the Drilling socket must be in line with the arrow on the Epiguide. Check that the Drilling socket has bottomed onto the Epiguide.

### WARNING!

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



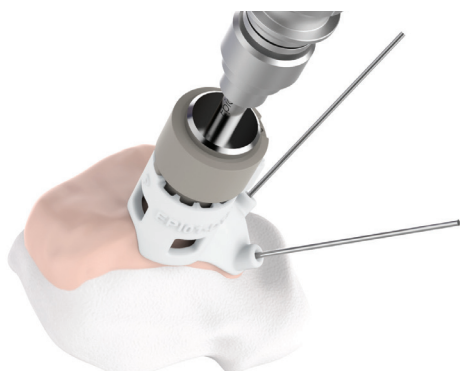
Start position



Drilling socket bottoming

## 5

### DRILLING PROCEDURE - STEP ONE



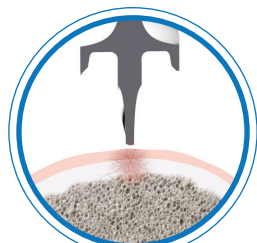
Attach the Epidrill to the drill and check that it is adjusted for drilling clockwise.

Insert the Epidrill into the Drilling socket. Start drilling at full speed before the Epidrill comes in contact with the cartilage. Keep the drill steady while applying only moderate force. Continue drilling until the Epidrill stops at the top of the Drilling socket.

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.

#### PRECAUTION

Make sure that the Drilling socket has bottomed in the Epiguide. Ensure that the drill is not misaligned and that it does not load the Epiguide in any direction.



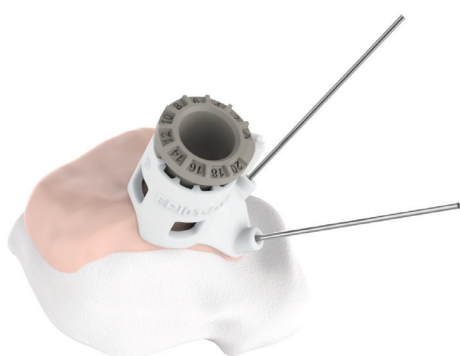
Start position



After pre-drilling

## 6

### DRILLING PROCEDURE - STEP TWO

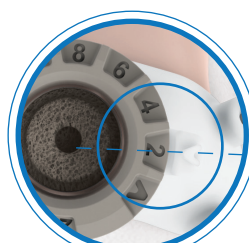


Remove the Drilling socket from the Epiguide and insert the Adjustment socket in the Epiguide in its START position. Make sure the Adjustment socket is inserted all the way to the bottom.

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

#### WARNING!

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



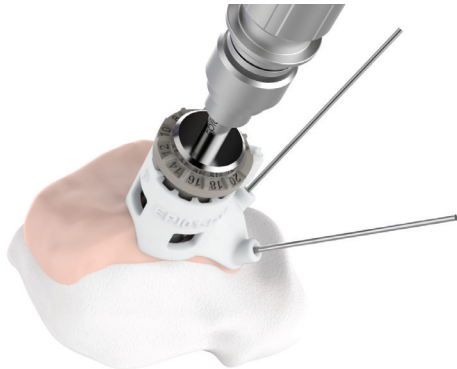
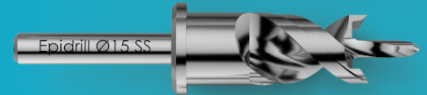
Start position



Adjustment socket bottoming

# 7

## DRILLING PROCEDURE - STEP THREE



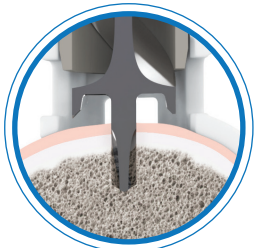
When inserting the Epidrill into the Adjustment socket, make sure that the tip of the Epidrill is inserted into the pre-drilled hole but that the drill body is not in contact with the cartilage surface when the drilling procedure starts.

Drill until the Epidrill stops at the top of the Adjustment socket. 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 tissues and to rinse away bone and tissue debris.

Remove the Epidrill.

### PRECAUTION

If the drilling gets harder during the drilling process, residues might be stuck in the Epidrill channels. If that is the case, stop drilling and cleanse the Epidrill from residues. 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.



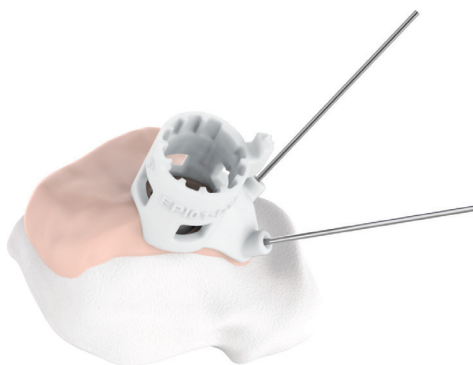
Epidrill at start position



Epidrill bottoming

# 8

## REMOVAL OF DEBRIS AND LOOSE CARTILAGE



Note the Adjustment socket position and remove the Adjustment socket from the Epiguide. Use the flushing device and suction to cleanse the drilled hole.

### WARNING!

Ensure that there are no fringes on the cartilage edge after drilling. Fringes on the cartilage edge should be removed using standard tweezers. If residues of bone and/or cartilage are left in the drilled hole, the implant may be prevented from becoming osseointegrated with the bone.

# 9

## EVALUATING THE DRILLED DEPTH

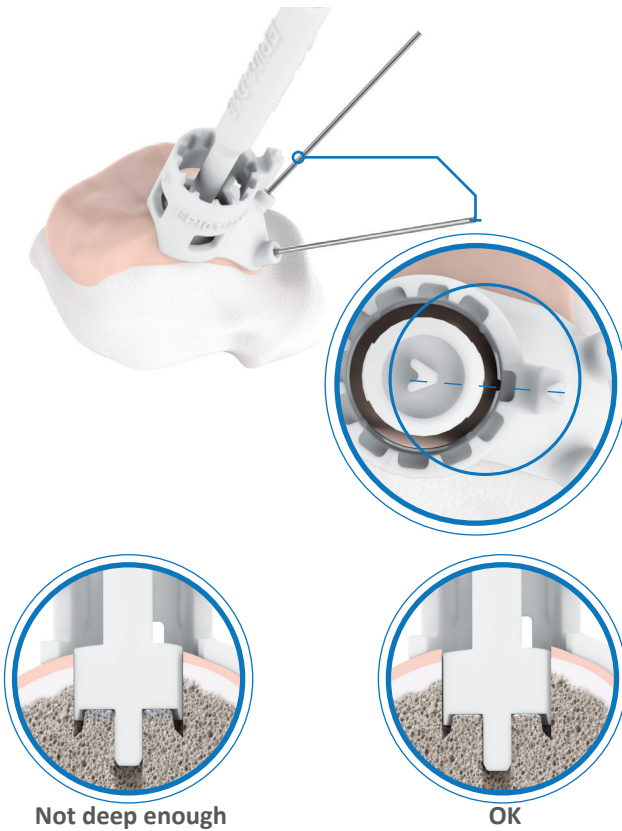


Insert the Epidummy into the drilled hole with its rotation mark aligned with the rotation mark of the Epiguide.

Compare the depth of the Epidummy top surface with the surrounding cartilage edge and assess the height difference. If the Epidummy top surface is positioned approximately 0.5 mm below the adjacent articular cartilage surface the drilling is finished, proceed to step 11. If not, continue adjusting the drill depth according to step 10.

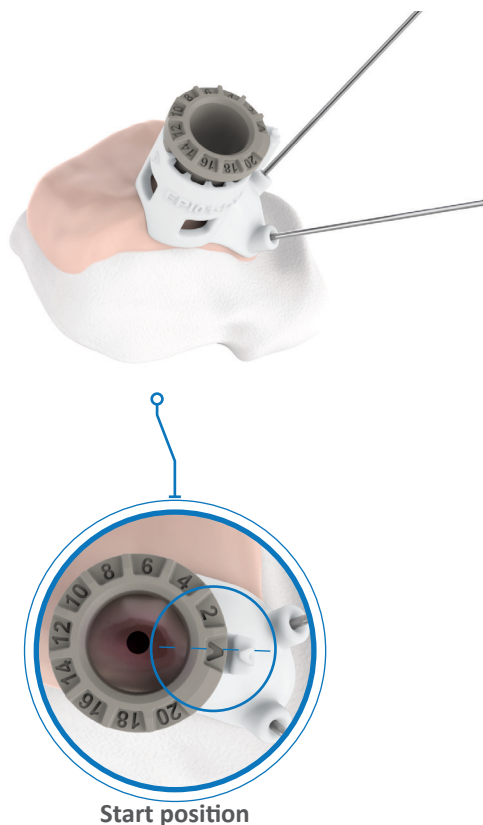
### WARNING!

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



# 10

## ADJUSTING THE DRILLED 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 drilling depth is increased by 0.2 mm in each step.

Repeat steps 7 to 9 until the Epidummy top surface is positioned approximately 0.5 mm below the surrounding articular cartilage surface.

### PRECAUTION

It is recommended that the additional drilling is performed incrementally, increasing the drill depth by small increments at a time. Note the drill depth setting. In case of removal of the Adjustment socket it needs to be replaced at the correct depth to avoid unintentionally drilling too deep.

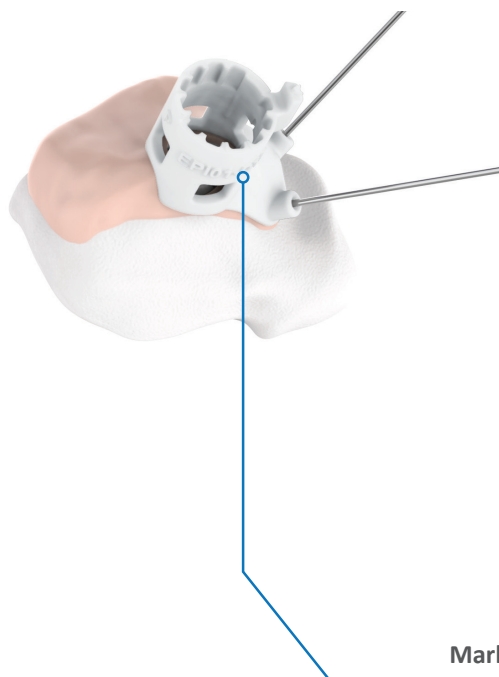
### WARNING!

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

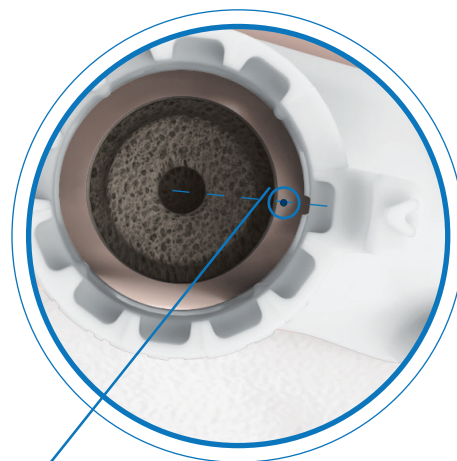
Start position

# 11

## MARKING THE EPISEALER ROTATION



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



Mark here

# 12

## FINAL CHECK



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



Not deep enough



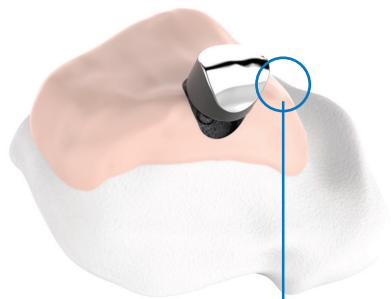
OK

### WARNING!

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

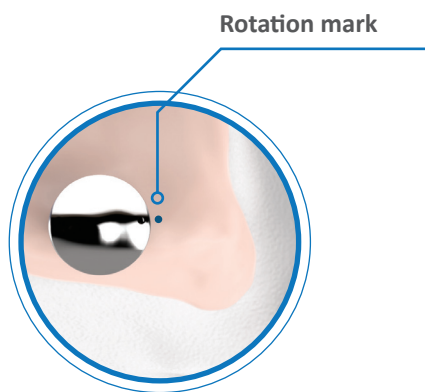
# 13

## PLACING THE EPISEALER



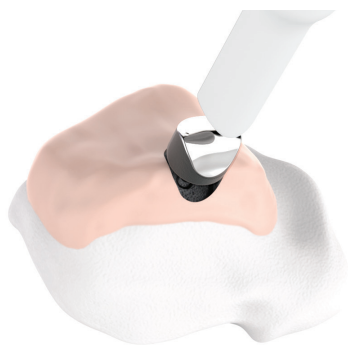
Gently place the Episealer into the drilled hole. Check that the rotation mark on the Episealer is aligned to the rotation mark on the cartilage. If the rotation mark on the Episealer is not correctly aligned, use your fingers to gently turn it to the correct orientation.

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



# 14

## DRIVING DOWN THE EPISEALER



For the final placement, use the Epimandrel and a hammer to gently tap down the Episealer into bone until bottomed. Ensure Epimandrel's anterior marking is aligned with the rotation mark on the Episealer and the cartilage surface.

When bottomed, the top surface of the Episealer should be approximately 0.5 mm below the adjacent articular cartilage surface.

### PRECAUTION

Check that the rotation mark on the Episealer is aligned with the rotation mark on the cartilage. Ensure the Episealer top surface ridge is aligned with the talar dome ridge. Make sure to gently tap the Episealer until bottomed. This is indicated by a more distinct sound.

### WARNING!

**During insertion, ensure the rotational alignment of the Episealer is 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





## NOTES



## NOTES



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## CONTACT INFORMATION

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