EPISURF

EPISEALER®
TALUS

SURGICAL TECHNIQUE

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THE EPISEALER TALUS CT AND MRI PROTOCOLS

The Episealer Talus implant and the Epiguide® are designed based on MRI or CT data. 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 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 Episealer 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 instruments and the individualised implants are designed using the data from the MRI to accurately reconstruct the patient´s unique anatomy.

CT sequences

As an alternative to MRI, a CT scan can be used to assess osteochondral defects and to create the virtual reconstruction of the patient´s unique anatomy for the design of the individualised implant and surgical instruments.

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 (of any human ankle) will need to be performed. This is to ensure that the correct quality images are produced. This is mandatory for MRI but optional for CT.
4. **Complete the set-up:** Episurf will confirm with you that the test scan is satisfactory. You are now ready to start scanning patients.

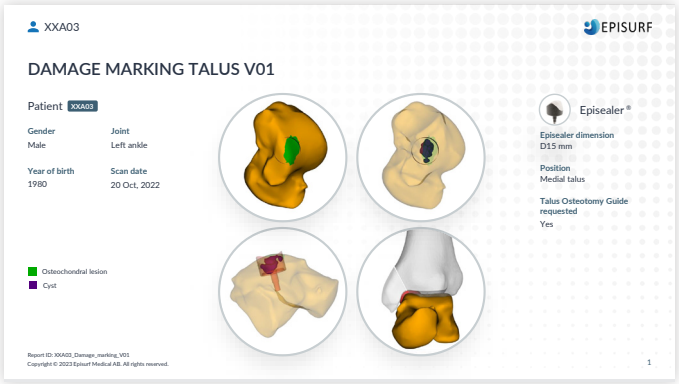
DAMAGE MARKING REPORT (DMR)

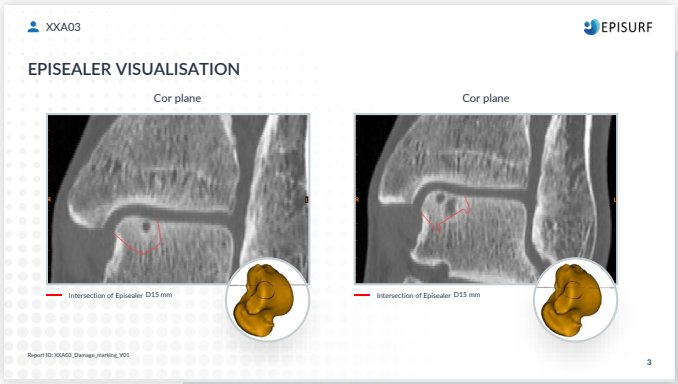
The patient's CT and/or MR images are used to create a detailed virtual model of the talus included in a Damage Marking Report (DMR). This report enables 3D visualisation of:

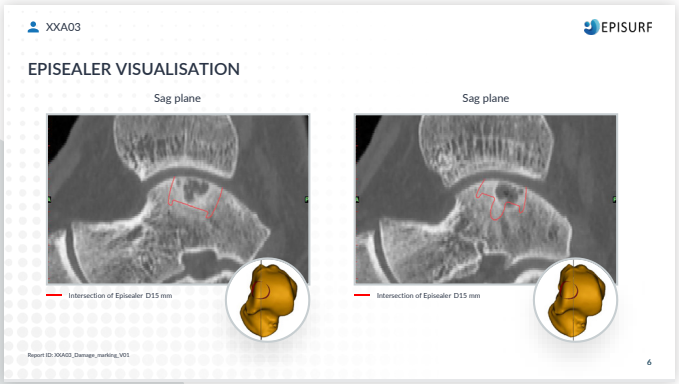
- osteochondral lesions
- bone marrow lesions such as bone edema
- signs from previous surgeries
- osteoarthritic signs
- other pathologies

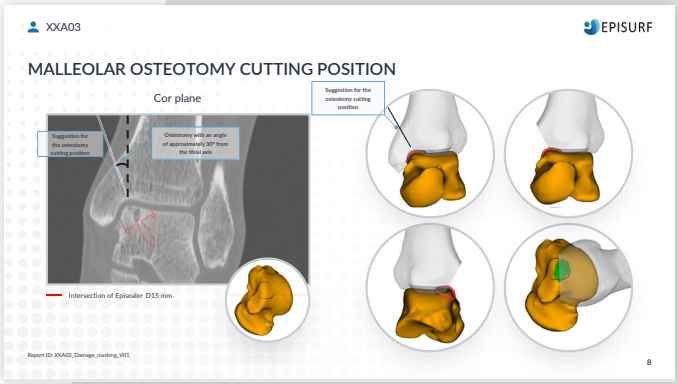
This virtual 3D visualisation will enable the clinical team to explore the patient's individual damage and assess the suitability for an Episealer implant. Based on this 3D presentation, you will be helped to determine the level of damage and review any potential solutions that Episurf can offer. The implant position 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 osteochondral defect. An Episealer 'Final Design' visualisation will be supplied, showing the exact position of the Epiguide and Episealer.









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.

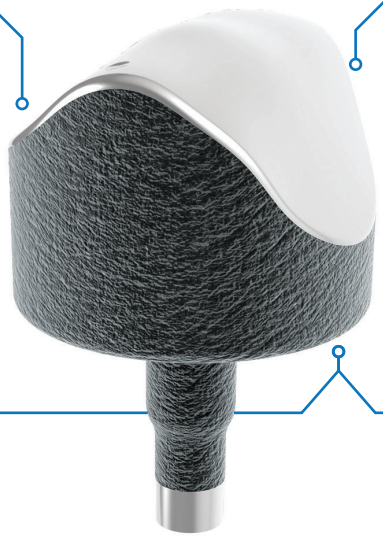
Each individual Episealer implant is milled precisely from a cobalt-chrome alloy. The top articulating surface has a patient-specific contour that precisely matches the geometry of the patient's talus. No two Episealer designs will ever be the same as they are personally produced, dependent on each individual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

Cobalt-chrome

- Can be polished to an ultra-smooth surface (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

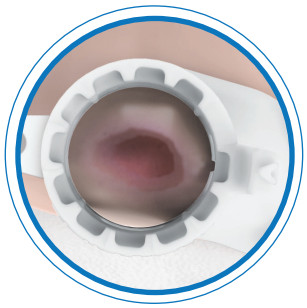
Hydroxyapatite outer coating

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

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 (or shelf, if a small shelf is present) facing the posterior direction. Identify the correct position by aligning the Epiguide's base to the anterior cartilage edge of the talar dome.

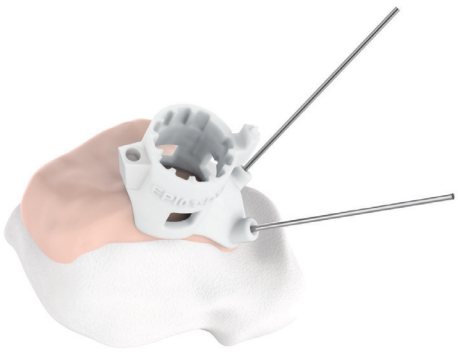


Look through the opening of the Epiguide and ensure the bottom surface is placed flush to the cartilage surface as shown on the Final Design document, which is provided by Episurf.

⚠ **WARNING!**

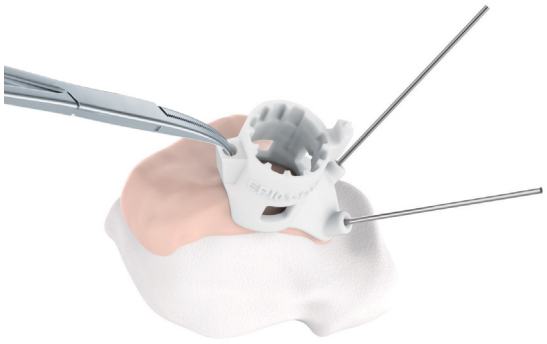
Make sure the Epiguide is placed flush on the cartilage surface all around the opening, without any gaps. Gaps between the inside of the Epiguide and the cartilage may lead to a poor anatomical alignment.

2 SECURING THE EPIGUIDE



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

If additional stability is desired to ensure that the Epiguide is flush with the cartilage, press on the guide or the shelf (if present). A chondral pick or a curved tip forceps can for example be used to facilitate pressing. Applying pressure to the shelf during the drilling process can enhance the stability of the Epiguide.



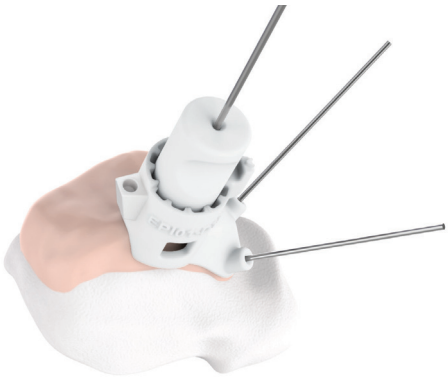
WARNING!

⚠ **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.

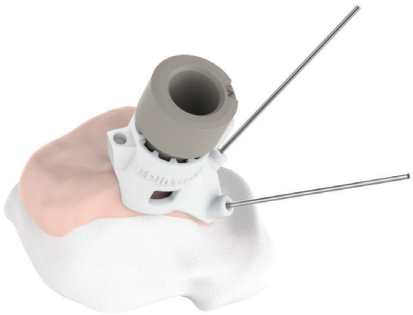
Attach a 2 mm surgical pin to the drill and insert the pin in the Pin socket. Start drilling and advance the drill approximately the same distance as the length of the implant.

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.

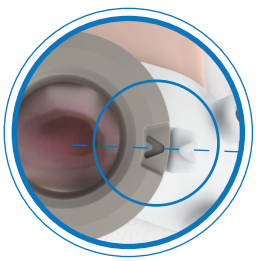
4 ASSEMBLING THE DRILLING SOCKET



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!**

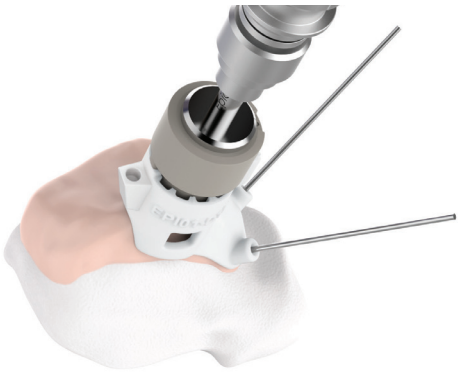
Ensure that the Drilling socket is in a correct position before drilling. Incorrect position may result in an incorrect drill depth and incorrect Episealer placement.



Start position

Drilling socket bottoming

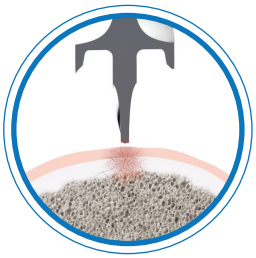
5 DRILLING PROCEDURE - STEP ONE



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.



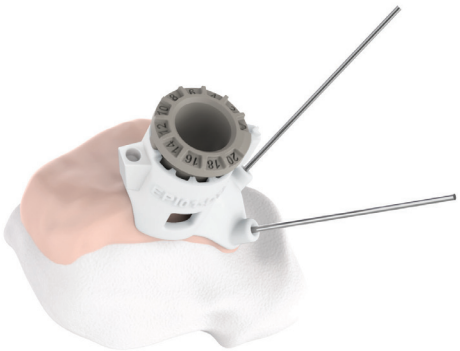
Start position

After pre-drilling

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.

6 DRILLING PROCEDURE - STEP TWO

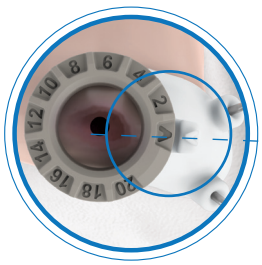


Remove the Drilling socket from the Epiguide and insert the Adjustment socket in the Epiguide in its START position. Make sure the Adjustment socket is inserted all the way to the bottom.

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!

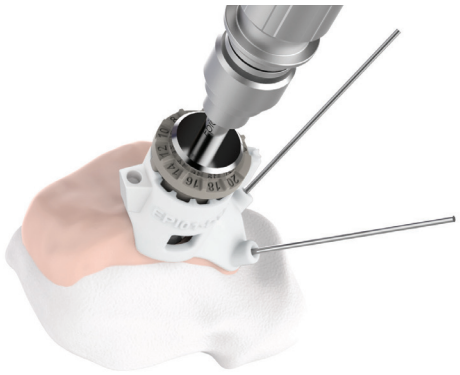
Ensure that the Adjustment socket is in a correct position before drilling. Incorrect position may result in an incorrect drill depth and incorrect Episealer placement.



Start position

Adjustment socket bottoming

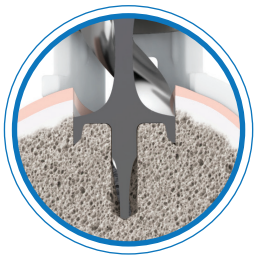
7 DRILLING PROCEDURE - STEP THREE



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.

Epidrill at start position



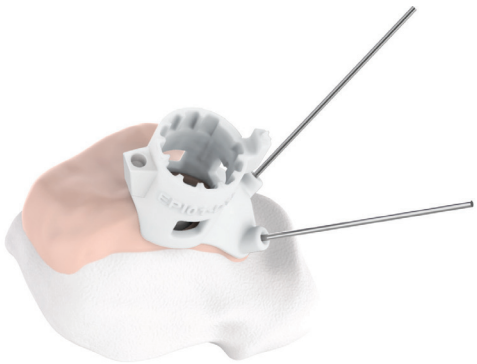
Epidrill bottoming

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.

8 REMOVAL OF DEBRIS AND LOOSE CARTILAGE

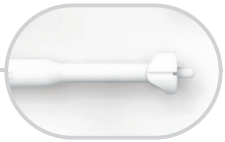


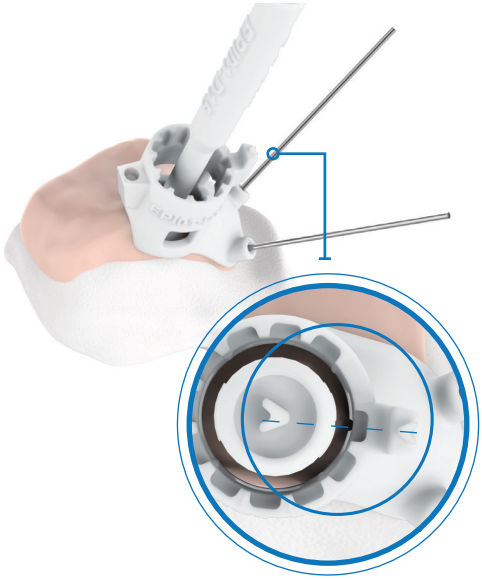
Note the Adjustment socket position and remove the Adjustment socket from the Epiguide.
Use the flushing device and suction to cleanse the drilled hole.

⚠ **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





Not deep enough

OK

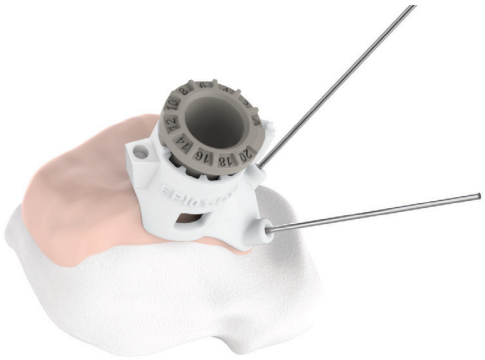
Insert the Epidummy into the drilled hole with its rotation mark aligned with the rotation mark of the Epiguide.

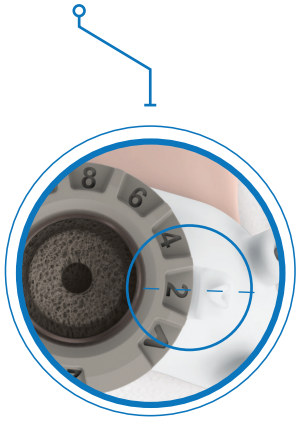
Compare the depth of the Epidummy top surface with the surrounding cartilage edge and assess the height difference. If the Epidummy top surface is positioned approximately 0.5 mm below the adjacent articular cartilage surface the drilling is finished, proceed to step 11. If not, continue adjusting the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





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 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.

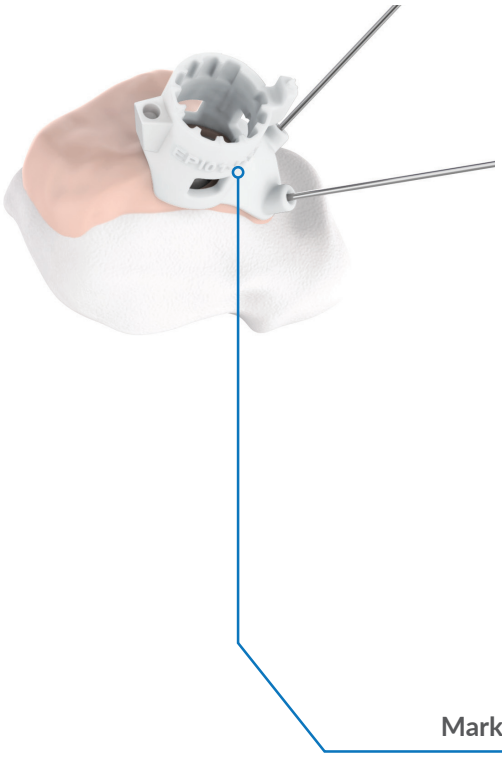
PRECAUTION

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.

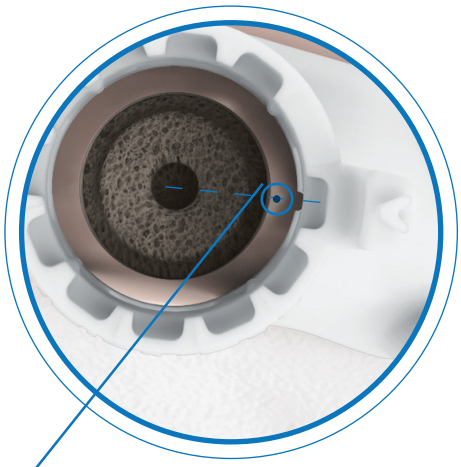
⚠ **WARNING!**

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

11 MARKING THE EPISEALER ROTATION

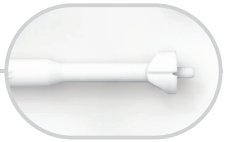


Use a sterile pen to mark the direction of rotation for the Episealer. Make the mark on the cartilage surface aligned with the rotation mark of the Epiguide.



Mark here

12 FINAL CHECK



Not deep enough

OK

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.

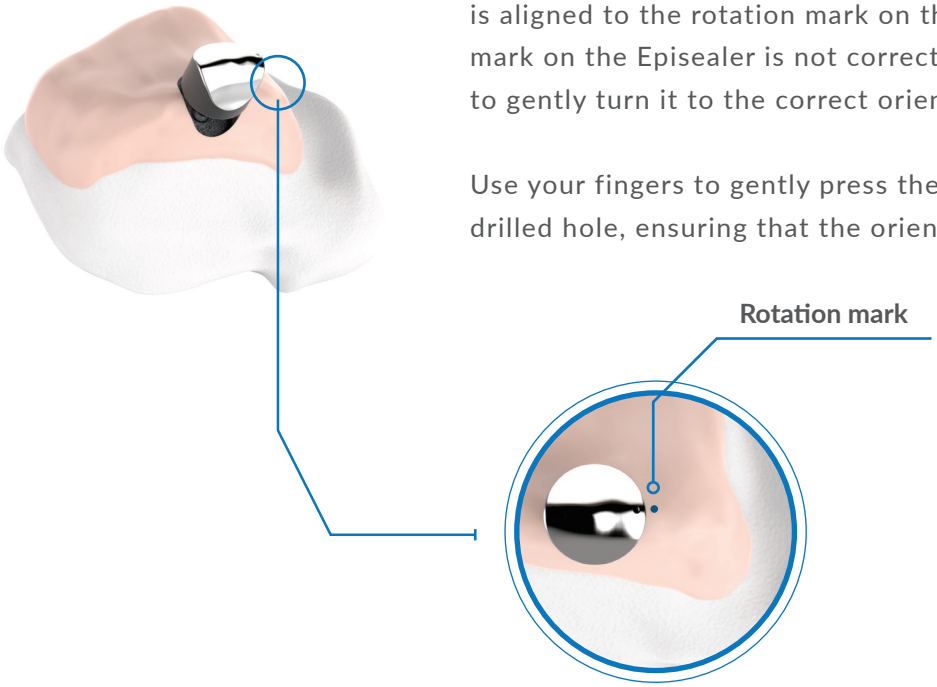
⚠ **WARNING!**

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.

15 FINAL PLACEMENT

NOTES

NOTES

EPISURF

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