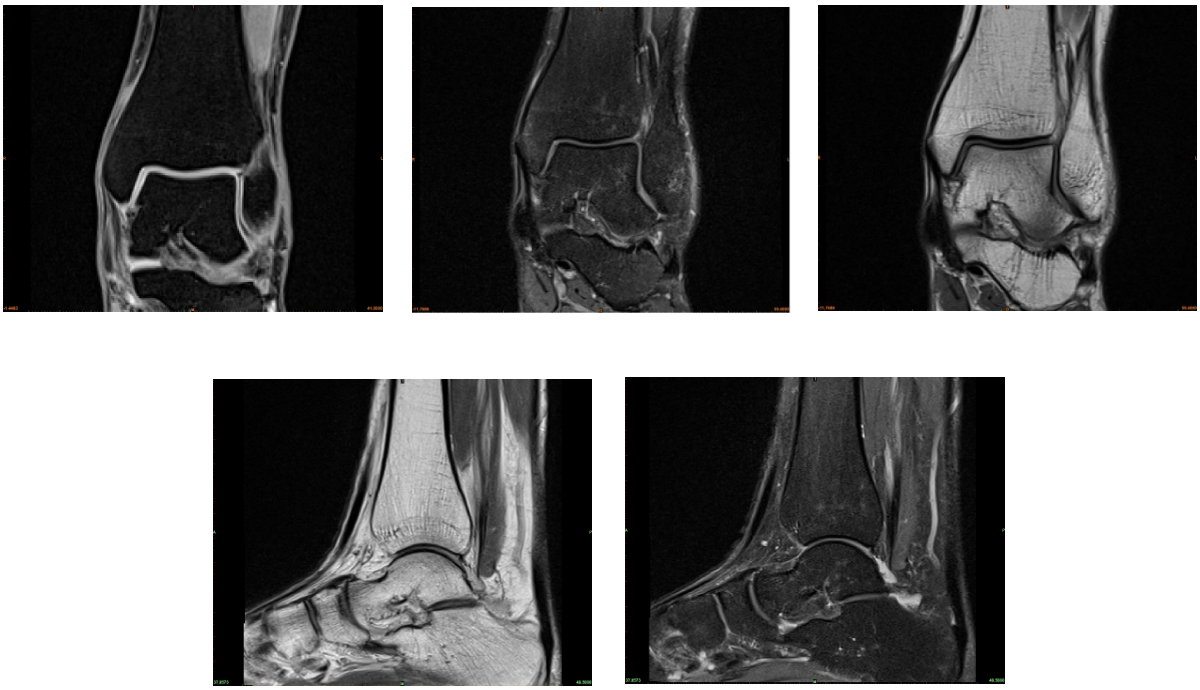
EPISURF Medical

EPISEALER® TALUS MRI PROTOCOL INSTALLATION GUIDE

PHILIPS

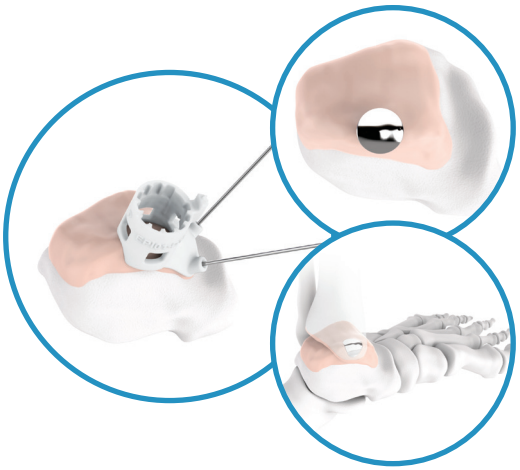


It is of outmost importance that the patient is scanned according to this MRI protocol. Please do not hesitate to reach out to an Episurf team member for assistance with the scanning process. If you encounter problems related to this protocol, please contact production@episurf.com.

CONTENT

Episurf Medical

Episurf designs and manufactures individualised solutions for osteochondral lesions in the medial and lateral talus. The design of the Episealer® Talus implant and associated surgical instrument kit is based on a virtual 3D visualisation of the patient's ankle. This visualisation is achieved by segmentation of CT or MR images of the patient's ankle using the Episealer Talus CT or MRI protocol. The MRI protocol consists of a 3D sequence and four MS sequences. It can be applied to Philips, Siemens and GE MRI scanners with a magnetic field strength of at least 1.5 T and an appropriate ankle coil.



INTRODUCTION

Why a specific protocol?

MRI provides detailed images of the ankle anatomy and is used both for visualisation and assessment of e.g. lesions in the cartilage and the underlying bone. Episurf uses an MRI protocol with a tailored 3D sequence as well as conventional MS sequences. This particular combination is essential for the software and the design process in order to make precise, individualised implants and surgical instruments. It is mandatory to adhere to this protocol. An incorrect protocol can entail patient risks and will therefore not be accepted.

3D sequences

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 implant are designed using the data from the MRI to accurately reconstruct the patient's unique anatomy.

MS sequences (diagnostic sequences)

To make a complete damage assessment of the ankle, four (4) different conventional diagnostic sequences are required. Together with our radiological team, we identify cartilage and bone lesions and suggest individualised implant sizes and positions thereafter.

Episealer Talus MRI Protocol sequences

The Episealer Talus MRI Protocol consists of five (5) MRI sequences; one (1) 3D sequence and four (4) MS sequences.

Number	Type	Orientation	Pulse sequence	Optional pulse sequence
1	3D	Coronal	3D_WATSc	3DWATSf
2	MS	Sagittal	TSE PDW	
3	MS	Sagittal	TSE PDW SPAIR	TSE PDW SPIR
4	MS	Coronal	TSE PDW	
5	MS	Coronal	TSE PDW SPAIR	TSE PDW SPIR

The settings for these sequences will be described in further detail in this guide.

Setting up the protocol

The MRI protocol is put in place in **3 simple steps**:

1. **Configure the protocol**
   Load the specific settings on your MRI scanner. Your Episurf representative will be available to help you.

2. **Run a test scan**
   Once the MRI protocol has been correctly set up on the MRI scanner, a test scan must be performed (a scan of any human ankle) and assessed by Episurf. This is to ensure that the MRI data is producing the correct image quality.

3. **Complete the set-up**
   Episurf will inform you when the test scan is satisfactory. You are now ready to start scanning patients.

MANUAL PROTOCOL INSTALLATION - 3D SEQUENCE

Summary of 3D sequence settings

The table below summarises the settings for the 3D sequence. Tips for improving image quality and/or reduce the scan time can be found on page 5.

Tab	Setting	Value
Geometry	Uniformity	CLEAR
	FOV FH (mm)	≈ 130
	FOV AP (mm)	≈ 105
	FOV RL (mm)	≈ 100 (Avoid folding artefacts)
	ACQ voxel size FH (mm)	0.5
	ACQ voxel size AP (mm)	0.5
	ACQ voxel size RL (mm)	2
	Recon voxel size FH (mm)	0.5
	Recon voxel size AP (mm)	0.5
	Recon voxel size RL (mm)	1
	Reconstruction matrix	260
	Slice orientation	Coronal
	Fold-over direction	RL
Contrast	Scan mode	3D
	Technique	FFE
	Contrast enhancement	T1
	TE	shortest
	Flip angle (deg)	25
	TR (ms)	20 (user defined)
	Water-fat shift	1.5 T: min. 2 pixels (user defined) 3 T: min. 1 pixel (user defined)
	Fat suppression	ProSet
	Pulse type	121 or 1331
Motion	NSA	1

Accepted voxel size		
	Min	**Max**
Acquired voxel size	0.45x0.45x1.0 mm	0.55x0.55x1.0 mm
Reconstructed voxel size	0.45x0.45x1.0 mm	0.55x0.55x1.0 mm

MANUAL PROTOCOL INSTALLATION - 3D SEQUENCE

Tips for improving the image quality:

- Increase NSA
- Increase Water-Fat Shift without creating any geometrical distortions in the image

Tips for reducing the scan time:

IMPORTANT
Maintain Image Quality

- Set Fold-over suppression to “No” but make sure that folding artefacts do not interfere with the talar articulating cartilage
- Decrease FOV RL but make sure that the entire talar bone and cartilage are included and not affected by folding artefacts
- Decrease FOV AP but make sure that the talar bone and articulating cartilage are included

MANUAL PROTOCOL INSTALLATION - MS SEQUENCES

Summary of MS sequence settings

The table below summarises the settings for the MS sequences. Tips for improving image quality and/or reduce the scan time can be found at the bottom of this page. **Make sure to adjust the settings for all four sequences.**

Number	Type	Orientation	Pulse sequence	Optional pulse sequence
2	MS	Sagittal	TSE PDW	
3	MS	Sagittal	TSE PDW SPAIR	TSE PDW SPIR
4	MS	Coronal	TSE PDW	
5	MS	Coronal	TSE PDW SPAIR	TSE PDW SPIR

Tab	Setting	Value
Geometry	Slice thickness (mm)	3
	Recon Voxel Size AP (mm)	0.2- 0.5 (maximum 0.5 mm allowed)
	Recon Voxel Size RL (mm)	0.2- 0.5 (maximum 0.5 mm allowed)
	Slices	33
	Slice gap	0.3 (user defined)

Tips for improving the image quality:

- **Increase NSA**
- **Increase Water-fat shift without creating any geometrical distortions in the image**

Tips for reducing the scan time:

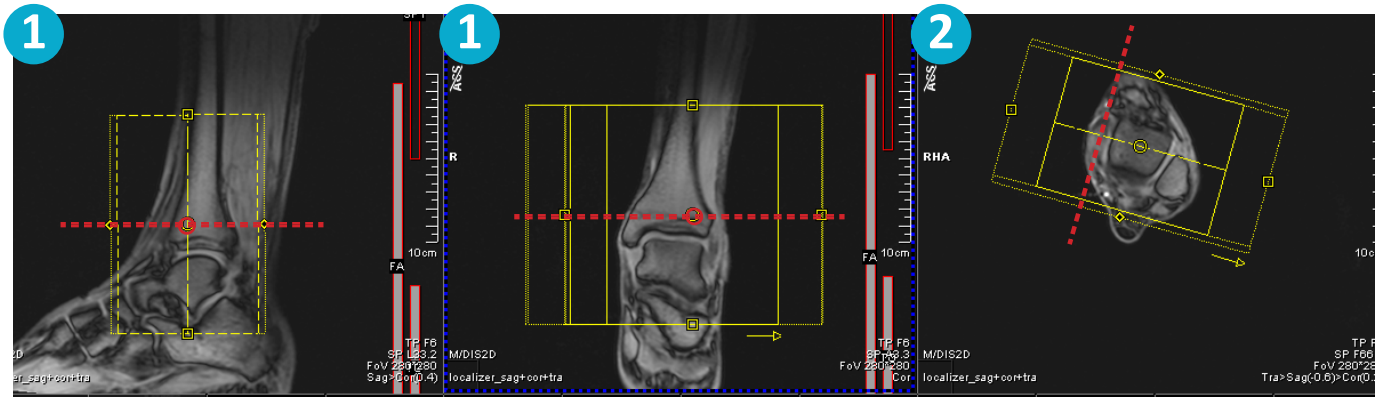
IMPORTANT
Maintain Image Quality

- **Choose Fold-Over Direction as following**
  - **Sag: A>>P**
  - **Cor: R>>L**
- **Use accelerations techniques such as SENSE**
- **Set Fold-Over Suppression to "No" but make sure that folding artefacts do not interfere with the talar articulating cartilage**
- **Decrease FOV RL but make sure that the entire talar bone and cartilage are included and not affected by folding artefacts**
- **Decrease Slices but ensure that the entire talar bone and cartilage are included**
- **Increase the pixel size (however never above 0.5x0.5 mm)**

IMAGE ACQUISITION

Angulation

Please follow the guiding images below when scanning a patient with the Episealer Talus MRI Protocol in order to achieve the correct FOV and angulation.



1) Include all of the talar bone and cartilage in the FOV. Place the centre of the FOV box just superior of the distal tibia in order to include 70 mm of the tibial bone.

2) Rotate the axial/transversal FOV box so that the vertical borders of the box are aligned with the talar edges

Acquisition Guidelines

When scanning a patient with the Episealer Talus MRI Protocol, please ensure to follow the guidelines below:

- Use a **foot coil** when available. Activate elements in the spine coil if a 4 channel flex coil is used
- Place the foot as close as possible to the **epicentre** of the main coil
- The protocol consists of one (1) 3D sequence and four (4) MS sequences: **5 sequences** in total
- All sequences must have a Field of View (FoV) that **covers the talar bone and articular cartilage**
- Include **70 mm of tibia** (only important for osteochondral lesions on the **medial** talar dome)
- Folding artefacts which are not interfering with the talar articular cartilage are accepted
- Tips for improving image quality and/or reduce the scan time can be found at pages 4 (for the 3D sequence) and 5 (for the MS sequences)

If you encounter problems related to this protocol, please contact production@episurf.com

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