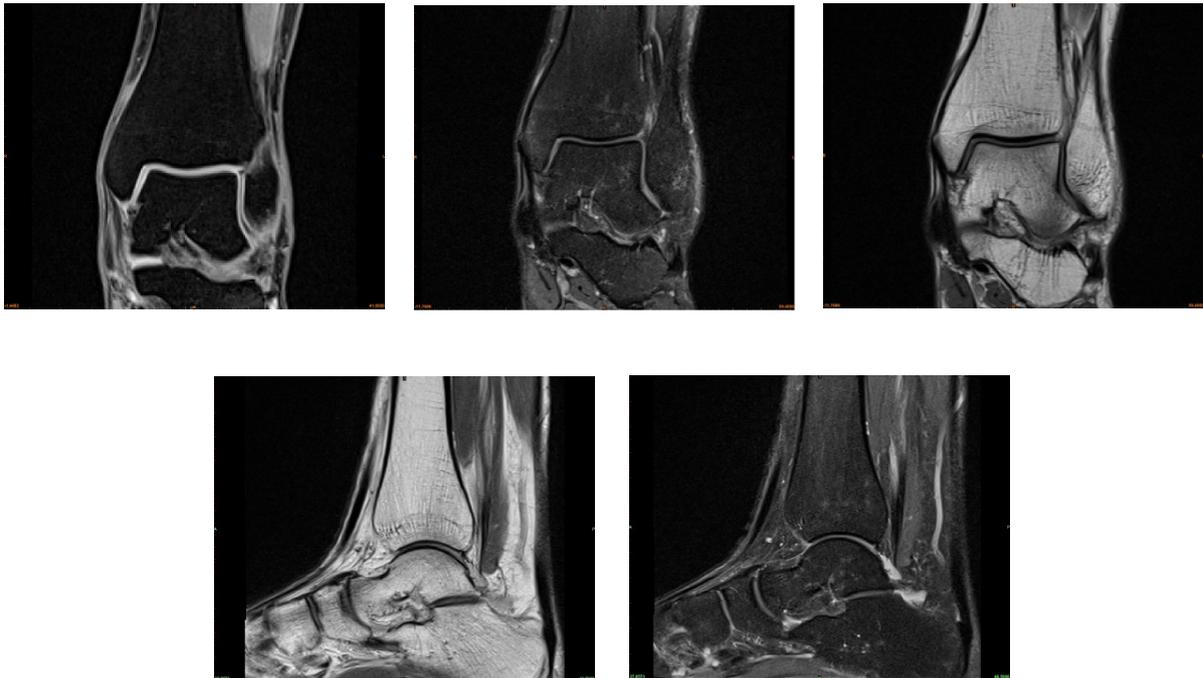




EPISEALER® TALUS MRI PROTOCOL
INSTALLATION GUIDE
SIEMENS



 **It is of utmost 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

INTRODUCTION *(PAGE 3)*

MANUAL PROTOCOL INSTALLATION - 3D SEQUENCE *(PAGE 4-5)*

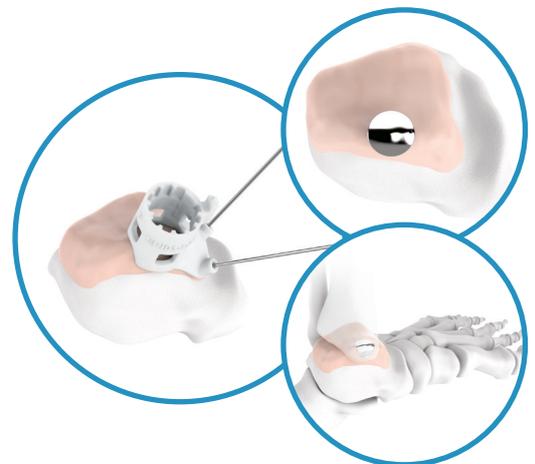
MANUAL PROTOCOL INSTALLATION - 2D SEQUENCES *(PAGE 6)*

EXAR1 FILE INSTALLATION *(PAGE 7)*

IMAGE ACQUISITION *(PAGE 8)*

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 2D sequences. It can be applied to Philips, Siemens and GE MRI scanners with a magnetic field strength of at least 1.5 T.



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 2D 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.

2D 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) 2D sequences.

Number	Type	Orientation	Pulse sequence	Optional pulse sequence
1	3D	Coronal	3D T1 WE Vibe	3D T1 FAT SAT FLASH (*3df1)
2	2D	Sagittal	TSE PD	
3	2D	Sagittal	TSE PD FS	
4	2D	Coronal	TSE PD	
5	2D	Coronal	TSE PD FS	

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. Any parameter not specified in the table below can be adjusted according to user preferences, provided that the image quality is maintained. Tips for improving image quality and/or reduce the scan time can be found on page 5.

Tab	Setting	Value
Program	Pulse sequence	3D T1 WE Vibe or 3D T1 FAT SAT FLASH (*3df1)
Routine	Slabs	1
	Orientation	Coronal
	Phase enc. dir.	R>>L
	Slices per slab	104
	FoV read (mm)	128
	FoV phase (%)	≈ 0.8
	Slice thickness (mm)	1.0
Averages	Foot coil or 16 channel flex coil: Average = 1 4 channel flex coil: Averages =1 and activate elements in the spine coil	
Contrast	TE	Shortest possible
	TR (ms)	20.00
	Flip angle (deg)	25.0
Resolution	Base resolution	256
	Interpolation	OFF
	Slice resolution	Min. 50%
	PAT mode	None (<i>located in iPAT sub tab</i>)
	Distortion correction	Enable. Mode: "3D" or "2D + 3D" (if available, otherwise "2D") (<i>located in Filter Image sub tab</i>)
Sequence	Bandwidth (Hz/Px)	Max. 130 (for 1.5 T), max. 260 (for 3 T)
	Optimization	Min. TE

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 Averages
- Decrease Bandwidth without creating any geometrical distortions in the image
- Increase Slice Resolution

Tips for reducing the scan time:



IMPORTANT
Maintain Image Quality

- Set Phase Oversampling to 0% (in Routine tab) but make sure that folding artefacts do not interfere with the talar articulating cartilage
- Decrease FoV Phase but make sure that the entire talar bone and cartilage are included and not affected by folding artefact
- Decrease slices per slab but make sure that the talar bone and articulating cartilage are included

MANUAL PROTOCOL INSTALLATION - 2D SEQUENCES

Summary of 2D sequence settings

The table below summarises the settings for the 2D 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	Orientation	Pulse sequence
1	Sagittal	TSE PD
2	Sagittal	TSE PD FS
3	Coronal	TSE PD
4	Coronal	TSE PD FS

Tab	Setting	Value
Resolution	FoV read	128
	Slice thickness	3.0
	Base resolution	Recommended 320-384 (minimal value 256)
	Distortion Corr.	Enable. Mode: 3D if available, otherwise 2D (located in Filter Image sub tab)
Geometry	Slices	33
	Dist. factor (%)	10

Tips for improving the image quality:

- Increase Averages
- Decrease Bandwidth without creating any geometrical distortions in the image

Tips for reducing the scan time:

- Choose Phase Encoding Direction as following
 - Sag: A>>P
 - Cor: R>>L
- Use acceleration techniques such as GRAPPA
- Set Phase Oversampling to 0% (in Routine tab) but make sure that folding artefacts do not interfere with the talar articulating cartilage (see page 7 in this guide)
- Decrease FoV Phase 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
- Decrease Base resolution (however never below 256)



IMPORTANT
Maintain Image Quality

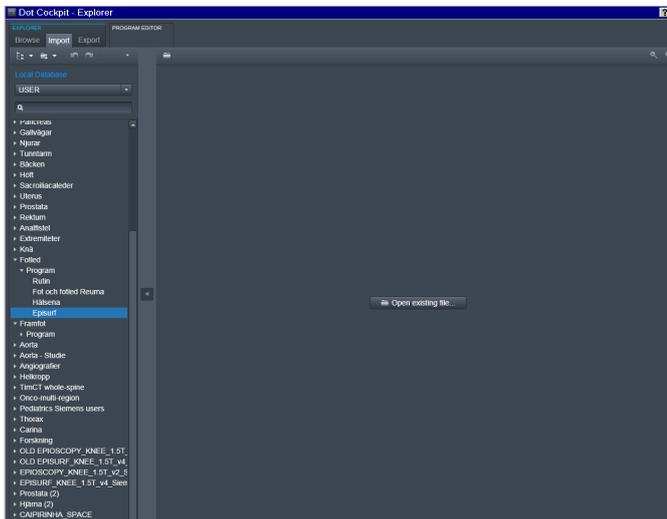
EXAR1 FILE INSTALLATION

Episurf provides two Episealer Talus MRI protocols for Siemens MRI machines according to the table below. This installation file can be provided by your local Episurf representative

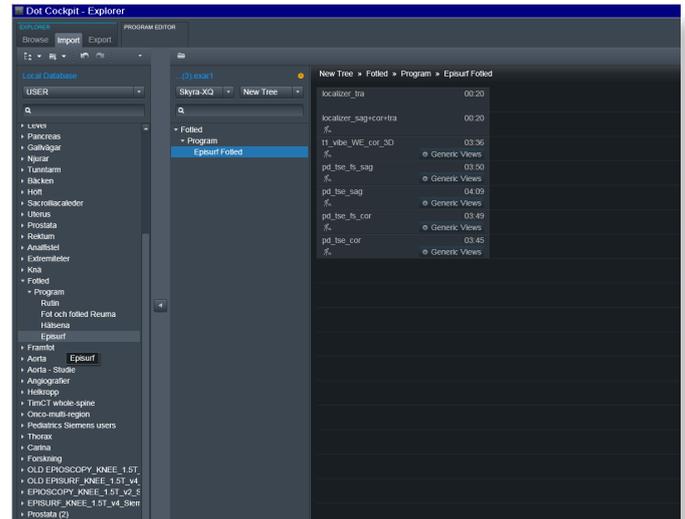
Tab	Setting	Software version	
1.5 T	EPISURF_ANKLE_1.5T_V01_Siemens Protocol	11C	Aera, Avanto Fit
3 T	EPISURF_ANKLE_3T_V01_Siemens Protocol	11C	Skyra, Prisma

Instructions

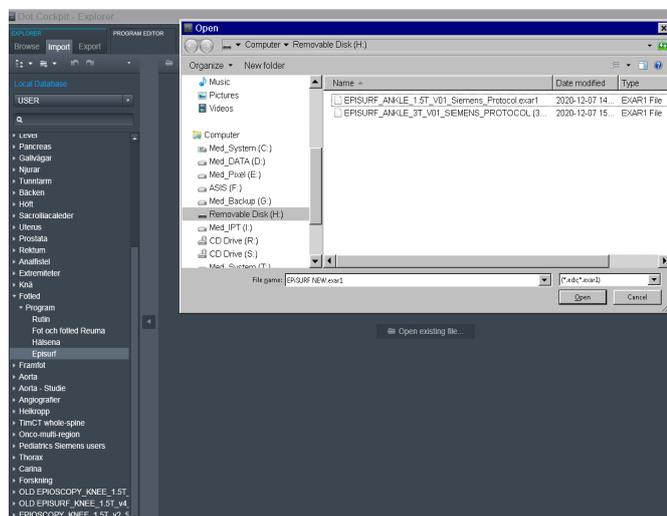
- 1 Insert the USB stick and open Dot Cockpit and choose "Import". Choose "Open existing file...".



- 3 Select the protocol and press the small arrow button to transfer the protocol to the local database..



- 2 Locate the USB stick, select the appropriate Episurf Protocol and press "Open".



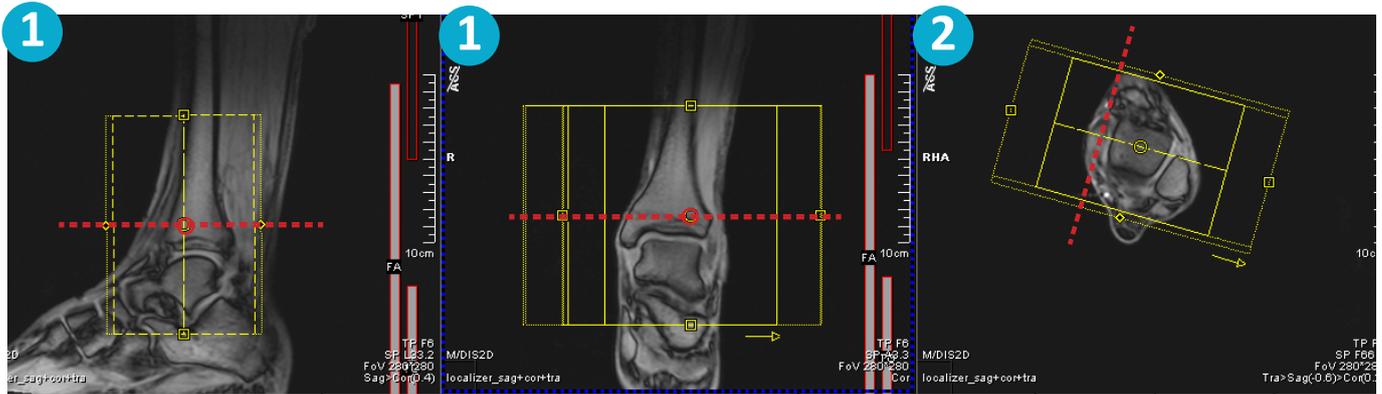
- 4 Depending on machine configuration, minor changes may occur in the protocol during the USB installation. Once the protocol is installed, check if any changes were made. If necessary, adjust the parameters according to the settings described in the manual protocol installation guide (pages 4-6).

- 5 Check that all sequences were installed.

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) 2D 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 5 (for the 3D sequence) and 6 (for the 2D sequences)

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



CONTACT INFORMATION

KARLAVÄGEN 60 | 114 49 STOCKHOLM | SWEDEN

+46 8 612 00 20

WWW.EPISURF.COM

