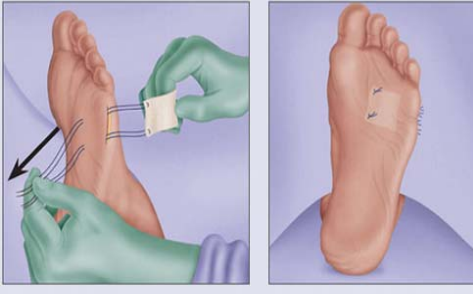


PATIENT INFORMATION SHEET

46	TOPIC	Plantar Fat Pad Thinning (Sole of Foot)
PROCEDURE		PLANTAR SOFT-TISSUE AUGMENTATION using GRAFTJACKET®
SPECIAL RISK TO CONSIDER	<p>GRAFTJACKET® is manufactured from human tissue. It is made from donated human skin supplied by USA tissue banks utilising the guidelines of the American Association of Tissue Banks (AATB) and the Food and Drug Administration's (FDA) applicable rules and regulations.</p> <p>It is approved for use in the EU and of course the UK. Processing of the tissue, laboratory testing, and careful donor screening minimize the risks of the donor tissue transmitting disease to the patient. As with any processed donor tissue, the GRAFTJACKET matrix cannot be guaranteed to be free of all pathogens. See the manufacturer's product leaflet (attached).</p>	 <p style="text-align: right;">Pictures courtesy of Wright Medical</p>
AIMS OF SURGERY	<p>To reduce pain To reduce the need for regular palliative treatment / use of insoles / orthoses</p>	
ADVANTAGES OF THIS OPERATION	<p>Replaces or supplements the lost plantar fat pad tissue N.B. The procedure may need to be undertaken in conjunction with an osteotomy if mechanical overload is associated with the area and may also require removal of any corny lesion if present.</p>	
SPECIFIC RISKS OF THIS OPERATION	<ul style="list-style-type: none"> <input type="checkbox"/> Infection associated with the components of human tissue (see SPECIAL RISK TO CONSIDER above and also summary of manufacturer's product leaflet on pages 3 & 4) <input type="checkbox"/> Hypersensitivity or allergy <input type="checkbox"/> Resorption of the GRAFTJACKET matrix & recurrence of symptoms <input type="checkbox"/> Non-integration of the matrix into host tissue & increase of symptoms 	
OVERVIEW		
Operation time	Usually between 15 – 30 minutes	
Incision placement	To one side of the area or lesion	
Stitches	Stitches are necessary and are usually simple stitches which require removal	
Fixation	None required for this procedure	
Will I have plaster?	This will usually be necessary	
Is this a Day Procedure?	Yes, you can usually go home the same day (you will usually be admitted for half a day)	
Estimated time off work	Non-manual work approximately 4-6 weeks Manual work 6-8 weeks	
INDICATIONS FOR THE PROCEDURE	A painful plantar area and/or plantar recurrent skin lesion which is associated with loss of plantar fat pad and which has not responded to other treatments	
ALTERNATIVE TREATMENTS	<p>Manage your symptoms by altering activity levels, using painkillers, changing footwear/ extra-width or special footwear possibly with an in-shoe foot support.</p> <p>Regular routine treatment</p>	
GENERAL RISKS OF SURGERY	<p>The anaesthetic options and general risks of foot surgery are outlined in the Generic Pre-operative Information Booklet for Patients with which you will have already been provided YOU SHOULD READ THIS LEAFLET IN CONJUNCTION WITH THE GENERIC PRE-OPERATIVE INFORMATION BOOKLET FOR PATIENTS (Numbered 1)</p>	
MORE INFO BY:	<ol style="list-style-type: none"> 1. Speaking with your consultant or one of the clinical team 2. Reading all the information provided including the attached manufacturer's product information which can also be found at http://www.wmt.com/literature/docs/129016-2GraftJacketPackageInsert.pdf 3. Looking at our Department's NHS Choices information or the Faculty of Surgery website 4. See our Podiatric Surgery public facing website pages on http://www.herefordshire.nhs.uk/ 5. The manufacturer's website http://www.wmt.com/footandankle/FA456-1207.asp 	

PLANTAR SOFT-TISSUE AUGMENTATION using GRAFTJACKET®

Answers to Common Questions

The Operation

The operation is usually performed under a local anaesthetic, usually around the ankle or behind the knee. Most patients find this to be more comfortable than a dental injection.

Although the operation is relatively short, you will be in the Day surgery Unit for longer. You must have a competent adult at home for the first day and night after surgery. This allows us to be sure you will be safe for the first night.

First 2-4 days

- This is the worse time for pain but you will be given painkillers to help. You must rest completely for 2-4 days.
- You should not bear any weight on the foot. You will need to be non-weightbearing for up to 3 weeks.
- You should restrict your walking to going to the bathroom and when getting about use your crutches in the way you will have been shown.
- You can get about a little more after 3 days.

3 to 5 days after surgery

- You will need to attend for your foot to be checked and re-dressed.
- You must remain non-weightbearing on the operated foot.

Two weeks after surgery

- You must attend again. Alternate sutures may be removed.
- You must remain non-weightbearing on the operated foot.

Three weeks after surgery

- The remaining sutures will be removed.
- You will be able to start to walk carefully on the foot with use of the protective walking boot

6-8 weeks after surgery

- There may be residual swelling.
- You may return to work but may need longer if you have an active job
- You may return to driving if you can perform an emergency stop. You must check with your insurance company before driving again.
- Sport can generally start between 8-12 weeks.

Six months after surgery

- You will have a final review between 3- 6 months following surgery.
- The swelling should now be slight and you should be getting the full benefit of surgery.

Twelve months after surgery

- The foot has stopped improving with all healing complete.

Please note; if a complication arises, recovery may be delayed.

PATIENT INFORMATION SHEET

The information on the following pages is a summary of information relevant to patients considering PLANTAR SOFT-TISSUE AUGMENTATION using GRAFTJACKET® and is extracted from the manufacturer's information leaflets for clinicians.

GRAFTJACKET Regenerative Tissue Matrix (129016-2)

Wright Medical Technology, Inc. 5677 Airline Road, Arlington, TN 38002 901-867-9971

Processed from Donated Human Tissue for Wright Medical Technology, Inc. by LifeCell Corporation

DESCRIPTION:

The GRAFTJACKET™ Regenerative Tissue Matrix is processed from donated human skin supplied from U.S. tissue banks utilizing the guidelines of the American Association of Tissue Banks (AATB) and the Food and Drug Administration's (FDA) applicable rules and regulations. The allograft skin is minimally processed to remove epidermal and dermal cells through a patented method while preserving the remaining bioactive components and structure of dermis. The resulting allograft serves as a framework to support cellular repopulation and vascularization.

Histology and immunohistochemistry are performed on the GRAFTJACKET™ matrix to confirm the presence of intact basement membrane complex, retention of collagen, and an absence of cells. Microbiological cultures are performed on each lot to assure the absence of bacterial and fungal pathogens. Residual moisture of the GRAFTJACKET™ matrix is less than 5%.

REGULATORY CLASSIFICATION:

The GRAFTJACKET™ Regenerative Tissue Matrix is regulated by FDA as human tissue for transplantation. GRAFTJACKET™ matrix is processed in accordance with the FDA's requirements for the procurement and processing of banked human tissues (CFR Title 21, Part 1270 and 1271) and standards and guidelines of the AATB.

WARNING:

Processing of the tissue, laboratory testing, and careful donor screening minimize the risks of the donor tissue transmitting disease to the patient. As with any processed donor tissue, the GRAFTJACKET™ matrix cannot be guaranteed to be free of all pathogens. No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of the GRAFTJACKET™ Regenerative Tissue Matrix.

PATIENT INFORMATION SHEET

DONOR SCREENING AND TESTING:

Donor tissue undergoes several levels of testing and screening to assure its safety. Blood samples from each skin donor for the GRAFTJACKET™ matrix are screened by a certified laboratory [Clinical Laboratory Improvement Amendments of 1998] and found to be negative when tested for:

- Hepatitis B surface antigen (HBsAg);
- Antibody to hepatitis C (HCV);
- Antibody to human immunodeficiency virus (HIV) types 1 and 2;
- Antibody to human T-lymphotropic virus (HTLV) type I and II;
- Syphilis (RPR or VDRL).

All tests are FDA-licensed, except the Center for Disease Control (CDC)-approved syphilis tests. A licensed physician further determines donor suitability after review of all donor screening and testing records. Donor screening includes history (including medical and social) and physical examination, serology and microbiology, and cause of death. Samples of the donor skin are tested for and shown to be free of bacterial and fungal pathogens; normal non-pathogenic skin bacteria may be present. Existing tests cannot provide absolute assurance that human source material will not transmit disease.

INDICATIONS FOR USE:

The GRAFTJACKET™ matrix is used for the repair or replacement of damaged or inadequate integumental tissue.

CONTRAINDICATIONS:

Note to Surgeon: It is the responsibility of the physician to determine the appropriate size and thickness of GRAFTJACKET™ matrix for each application. GRAFTJACKET™ matrix should only be used where physical properties are appropriate.

The GRAFTJACKET™ matrix is contraindicated for use in any patient in whom soft tissue implants are contraindicated. These patients and conditions include:

- Patients diagnosed with autoimmune connective tissues diseases;
- Infected or nonvascular surgical sites, unless specifically prescribed by a physician;
- Sensitivity to specific antibiotics listed on the package;
- Any pathology that would limit the blood supply and compromise healing;
- Poor nutrition and/or poor general medical condition.

Ancillary agents or procedures that may cause inflammation at the treatment site should be avoided.

The GRAFTJACKET™ Regenerative Tissue Matrix is processed by LifeCell Corporation, One Millennium Way, Branchburg, NJ, 08876 U.S.A.

GRAFTJACKET™ is a trademark of Wright Medical Technology, Inc.