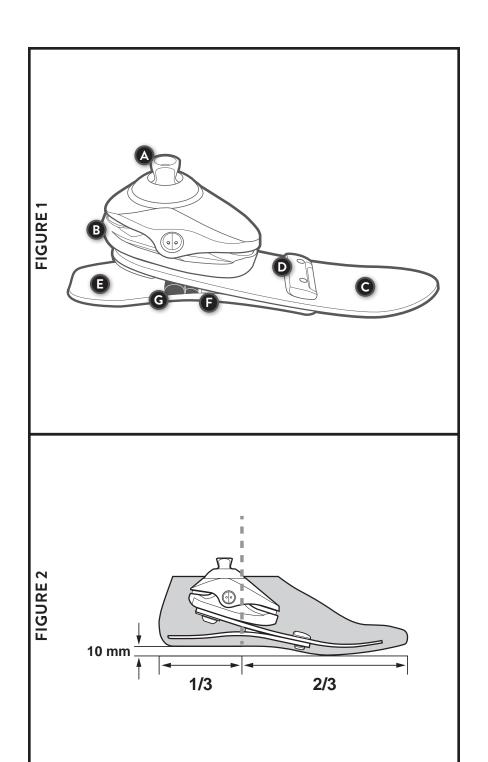






technical instructions

וניגוב - Ieknisk vejledning - Technische Anleitung
Τεχνικές οδηγίες - Instrucciones técnicas · Tekniset ohjeet
Instructions techniques - הוראות טכניות - Istruzioni tecniche
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Instruções técnicas · Технические инструкции · Technické pokyny
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ΕN

PACKAGE CONTENTS

(1) Terrain foot

(1) Foot Shell

(1) CPI Sock

(1) Horizon Wedge Kit

TOOLS REQUIRED

4mm Hex Key

TOOLS RECOMMENDED

(1) Foot Horn

This diagram (Figure 1) is to help familiarize you with the unique parts of the Terrain. These parts are referenced in the instructions and used when speaking with a technical service representative.

Key Components, FOOT (Figure 1)

A. Integrated Pyramid

B. Ankle-Housing Assembly

C. Toe Spring

D. Nut Plate

E. Heel Spring

F. Permanent Wedge

G. Rounded Heel Wedge (optional)

· CPI Sock (not shown)

• Foot Shell (not shown)

PRODUCT DESCRIPTION

This prosthetic foot device is constructed with an integrated pyramid, ankle-housing assembly, two composite springs, and heel wedge. The toe spring is secured to the housing and heel spring with fasteners.

INTENDED USE

The Terrain is a prosthetic foot designed to replace one or more functions of the biologic human foot.

⚠ INDICATIONS:

⚠ CONTRAINDICATIONS:

Lower limb amputations

None known

⚠ PROTECTIVE COVER ON DOME

Remove the protective cover on dome after alignment is completed and before patient leaves clinic.

TECHNICAL SPECIFICATIONS

FOOT SIZE	WEIGHT LIMIT	BUILD HEIGHT	FOOT WEIGHT*	
21-25 cm	330 lbs / 150 kg	3.4 in / 8.6 cm	815 g	
26-30 cm	365 lbs / 166 kg	3.6 in / 9.0 cm		

^{*26}cm foot w/shell

GAIT MATCHING® GUIDELINES

The gait match determines the firmness of the foot based on the user's specifications (foot size, patient weight, and impact level).

FIRMNESS CATEGORIES

Refer to the chart below to determine the correct firmness category.

Note: Incorrect category selection may result in poor device function. Contact College Park Technical Service if you have questions about category selection.

WEIGHT LBS	0-140	141-180	181-220	221-275	276-330	331-365
WEIGHT KG	0-63	64-81	82-100	101-125	126-150	151-166
SIZE CM	21-30					26-30
Low-Moderate Impact	1	2	3	4	5	7
High Impact	2	3	4	5	6	7

ASSEMBLY AND DISASSEMBLY (for sock replacement)

Use the Foot Horn to don and doff the foot shell. Remove the CPI sock and replace as needed. Any further disassembly or modification of components will void the warranty.

ENDOSKELETAL MOUNTING

Use only high quality proximal endoskeletal components.

STATIC ALIGNMENT

For optimal function, balance the patient's weight evenly between the heel and toe. (Figure 2)

- The Terrain was designed with a 3/8" (10.0 mm) heel rise.
- The load line divides the foot at 1/3 heel lever and 2/3 toe lever.

DYNAMIC ADJUSTMENTS				
DESIRED RESULT	ALIGNMENT CHANGE	COMPONENT CHANGE		
Firmer Toe Response	Plantarflex the Terrain or move load line posterior			
Softer Toe Response	Dorsiflex the Terrain or move load line anterior			
Firmer Heel Response	Dorsiflex the Terrain or move load line anterior	Add heel wedge		
Softer Heel Response	Plantarflex the Terrain or move load line posterior	Remove heel wedge		

^{*}To install or remove heel wedge, refer to the Horizon Wedge Kit Instructions.

WARNINGS

↑ WARNING

- Do not expose this product to corrosive materials, salt water or pH extremes.
- Any further disassembly or modification of components will void the warranty.

Failure to follow these technical instructions or use of this product outside the scope of its Limited Warranty may result in injury to the patient or damage to the product.

RESIDUAL RISK STATEMENT

NOTICE OF RESIDUAL RISK

During fitting process, ensure that CPI sock does not become pinched between foot and endoskeletal componentry.

WARRANTY INSPECTION / MAINTENANCE INFORMATION

College Park recommends that you schedule your patients for check-ups according to the warranty Inspection schedule below.

High patient weight and/or impact level may require more frequent inspections. Soft component wear depends on the patient weight, impact level and environment. We recommend you inspect the following applicable parts for excessive wear and fatigue at each warranty inspection and replace as needed.

- Composites and Adapters
- Foot Shell

CPI Sock

• Heel Wedge (if applied)

WARRANTY INSPECTION SCHEDULE FOR THE TERRAIN: SIX MONTHS, THEN ANNUALLY,

TECHNICAL ASSISTANCE / EMERGENCY SERVICE 24-7-365

College Park's regular office hours are Monday through Friday, 8:30 am – 5:30 pm (EST). After hours, an emergency Technical Service number is available to contact a College Park representative.

LIABILITY

The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.

↑ CAUTION

College Park products and components are designed and tested according to the applicable official standards or an in-house defined standard when no official standard applies. Compatibility and compliance with these standards are achieved only when College Park products are used with other recommended College Park components. This product has been designed and tested based on single patient usage. This device should NOT be used by multiple patients.

↑ CAUTION

If any problems occur with the use of this product, immediately contact your medical professional. The prosthetist and/or patient should report any serious incident* that has occurred in relation to the device to College Park Industries, Inc. and the competent authority of the Member State in which the prosthetist and/or patient is established.

*'Serious incident' is defined as any incident that directly or indirectly led, may have led, or might lead to any of the following; (a) the death of a patient, user, or other person, (b) the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health, (c) a serious public health threat.