



college park
TECHNOLOGY for the HUMAN RACE

technical instructions

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FIGURE 1

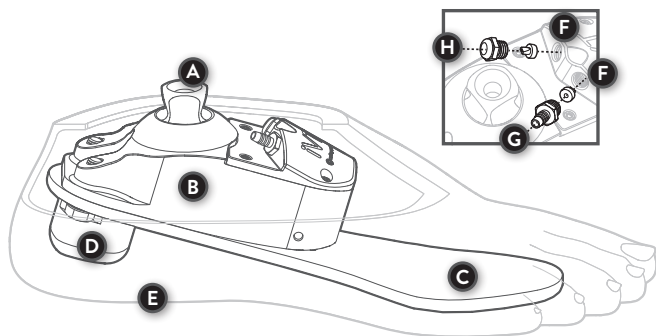


FIGURE 2

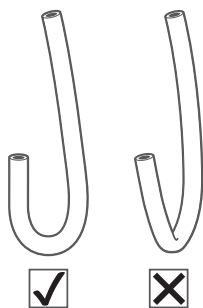


FIGURE 3

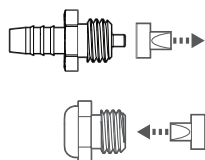


FIGURE 4

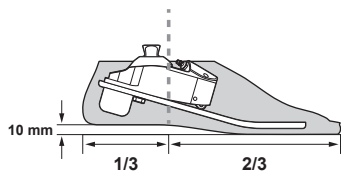
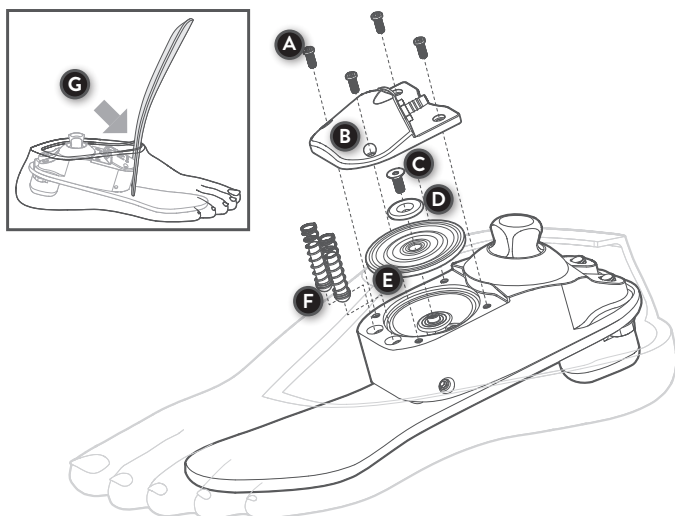


FIGURE 5



Package Contents

- (1) Tempo iVT foot with bonded foot shell
- (1) iVT Tube Kit

Tools Required

- (1) 4 mm Hex Key

Tools Recommended

- (1) Foot Horn

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

Key Components (Figure 1)

FOOT

- A. Integrated Pyramid B. Housing C. Toe Spring D. Heel Bumper
- E. Bonded Foot Shell F. iVT Check Valves G. iVT Hose Connector H. iVT Exhaust Vent

PRODUCT DESCRIPTION

This prosthetic foot device is constructed with an integrated pyramid, mechanical vacuum pump, housing, composite toe spring, and heel bumper. The toe spring is secured to the housing with fasteners. The foot shell is bonded to the toe spring and is not removable.

INTENDED USE

The Tempo iVT is a prosthetic foot designed to replace one or more functions of the biologic human foot. The device incorporates a vacuum pump to draw air from the socket for the purpose of suspension.



INDICATIONS:

- Lower limb amputations



CONTRAINDICATIONS:

- Make sure that the socket is well fitting before any use; Never use a loose fitting or leaking socket with the Tempo iVT Foot.

TEMPO iVT OVERVIEW

- During full dorsiflexion the maximum attainable vacuum ranges from 18-22inHg.
- Vacuum suspension is generated when the user applies a load to the toe. The integrated pump draws air from the socket during each step until elevated vacuum is achieved inside the socket.
- The firmness category of the foot can affect the number of steps needed to reach maximum vacuum pressure.
- Liner selection is the sole responsibility of the provider. College Park recommends against the use of Copolymer Gel liners with the Tempo iVT Foot.

TECHNICAL SPECIFICATIONS

| FOOT SIZE | WEIGHT LIMIT | BUILD HEIGHT | FOOT WEIGHT* |
|-----------|------------------|-----------------|--------------|
| 21-24 cm | 300 lbs / 136 kg | 2.5 in / 6.4 cm | 635 g |
| 25-30 cm | 330 lbs / 150 kg | | |

*26cm 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 | 221-300 | 301-330 |
|------------|-------|---------|---------|---------|---------|
| WEIGHT KG | 0-63 | 64-81 | 82-100 | 101-136 | 137-150 |
| SIZE CM | 21-30 | | | | 25-30 |
| LOW IMPACT | 1 | 2 | 3 | 4 | 5 |

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 4).

- The Tempo iVT 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 |
|-----------------------------|---|
| Firmer Toe Response | Plantarflex the Tempo iVT or move load line posterior |
| Softer Toe Response | Dorsiflex the Tempo iVT or move load line anterior |
| Firmer Heel Response | Dorsiflex the Tempo iVT or move load line anterior |
| Softer Heel Response | Plantarflex the Tempo iVT or move load line posterior |

INSTALLING THE TEMPO iVT

College Park recommends the iVT valve kit to connect the system to the socket. Use of other products is the sole responsibility of the provider.

TUBE CONNECTION

1. Attach the tube to the hose connector.
2. Cut the tube to a proper length and connect to the socket.
3. Use the supplied tube retainer to secure the tube to the pylon or other adapter.
4. Position the tube on the medial side to avoid damage.
5. Once assembled verify the pump is working properly; creating vacuum during gait and not leaking air.

TUBE INSPECTION

The tube is the most sensitive part of the Tempo iVT and should be fitted carefully. Verify the tube is NOT:

- Folded or pinched (Fig 2).
- Contacting sharp objects.
- Punctured.
- Dangling or hanging during gait.
- Located laterally, to avoid damage.

CHANGING HOSE CONNECTOR SIDE

The hose connector is pre-assembled for a left foot and can be reconfigured for a right foot.

1. Use a 5/16 wrench to loosen the hose connector and exhaust vent.
2. Switch the positions. Ensure the check valves are oriented in the correct direction for proper function (Fig. 3).
3. Retighten. Torque to 35 in-lbs (4 N-m).

PUMP DISASSEMBLY AND REASSEMBLY (FOR MAINTENANCE) DISASSEMBLY

1. Disconnect the tube from the hose connector.
2. Use a Foot Horn or similar blunt tool to fold the opening of the foot shell and access the pump area.
3. Use a T9 torx wrench to loosen the housing cap fasteners, remove the fasteners (Fig 5-A).
4. Release the housing cap (Fig 5-B).
5. Use a T9 torx wrench to loosen the air bladder fastener and remove the washer (Figs 5-C & 5-D).
6. Gently pull the air bladder from the housing (Fig 5-E).
7. Remove the return spring assemblies (Fig 5-F).

Note: Do not disassemble the pump or foot module further. Additional disassembly will void the warranty.

REASSEMBLY

1. Install new return spring assemblies.
2. Insert a new air bladder into the housing.
3. Replace the washer and air bladder fastener. Torque to 5 in-lbs (0.6 N-m).
4. Replace the housing cap.
5. Thread the fasteners into the housing. Torque to 5 in-lbs (0.6 N-m).
6. Reconnect the tube to the hose connector and use the tube retainer to secure the tube to the pylon or other adapter.

PUMP INSPECTION

Verify the following:

- Make sure that the pump is functioning properly, and the system is not leaking.
- Confirm the CPI sock does not interfere with the Tempo iVT as it could compromise the function of the pump.
- Are the check valves oriented in the correct direction (Fig 3)?
- Is the air bladder fully inserted into the housing?
- Are the inlet and outlet ports tightened?
- Is the tube fully inserted on the inlet port? (Check both at the socket valve and at the bladder housing)

CLEANING

Components may be cleaned with mild soap or isopropyl alcohol and rinsed with water. DO NOT use solvents stronger than isopropyl alcohol as it might degrade the material or get through the valve and into the socket.

WARNING

- Make sure that the socket is a close fit to prevent blistering and/or wounds.
- The tube must be well secured at all times.
- Never operate this product if it is not working properly. Users should report any concerns to their prosthetist immediately, including but not limited to: loose fit, noise, sudden loss of function, etc.
- Contaminants such as dirt and the use of lubricants or powder may affect the function of the prosthesis and lead to a lack of proper function.
- Do not expose this product to corrosive materials, salt water or pH extremes.
- Misuse of this product may result in loss of vacuum, leading to loss of suspension and potential fall.
- Any further disassembly or modification of components will void the warranty.

The following activities will void the warranty:

- Usage with Copolymer Gel liners.
- Usage without liners or other means which can lead to sweat or other fluids entering the system.
- Exposure to environment with extreme airborne particle contamination.

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 per the warranty inspection schedule below.

High patient weight or activity level may require more frequent inspections. We recommend you visually inspect the following applicable parts for excessive wear and fatigue at each warranty inspection.

- | | | |
|---------------------------|------------------|----------------------------|
| ▪ Composites and Adapters | ▪ Hose Connector | ▪ Tube |
| ▪ Foot Shell | ▪ Exhaust Vent | ▪ Return Spring Assemblies |
| ▪ Air Bladder | ▪ Check Valves | |

WARRANTY INSPECTION SCHEDULE FOR THE TEMPO iVT: 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.

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