DIRECTIONS FOR USE

Indications:
- Arthropathies
- Muscular atrophy and reconditioning
- Deformities
- Joint replacements
- Neuromuscular

Contraindications:
- Sepsis
- Infection
- Diffuse cellulitis
- Tendinitis

Note: If signs of infection such as hyperthermia, infection, swelling, tenderness, or redness occur, therapy shall be stopped or discontinued until infection is controlled.

NOTE: Ensure Preparation of the Device (Steps 1–4) is complete prior to connecting the device to the patient's toe.

Preparation of the Device

Step 1: Range of Motion Selection
- There are five Range of Motion settings available on the Toe CPM device. The table below shows the recommended settings:
  - Loosen the Locking Knob.
  - Select the desired Range of Motion from the table.
  - Tighten the Locking Knob.

<table>
<thead>
<tr>
<th>Range of Motion Setting</th>
<th>Dorsiflexion</th>
<th>Plantar Flexion</th>
</tr>
</thead>
<tbody>
<tr>
<td>-15°</td>
<td>-1°</td>
<td>-1°</td>
</tr>
<tr>
<td>0°</td>
<td>0°</td>
<td>-1°</td>
</tr>
<tr>
<td>15°</td>
<td>0°</td>
<td>0°</td>
</tr>
<tr>
<td>30°</td>
<td>15°</td>
<td>15°</td>
</tr>
<tr>
<td>60°</td>
<td>30°</td>
<td>30°</td>
</tr>
</tbody>
</table>

*Using the ROM Endpoint Adjust, set the maximum and minimum degrees as listed in the table. The device can be positioned at maximum dorsiflexion by turning the actuator using the On/Off button.

Step 2: Softgoods / Orthopedic Shoe Selection
- Select the appropriate size to accommodate the patient.

Step 3: Assembly of Softgoods and Toe CPM Device
- The Orthopedic Shoe is attached to the Toe CPM device using four mounting bolts.
  - Secure the bolts between the mounting plate of the Toe CPM.
  - Align the Mounting Knobs with the shoe inserts which are visible on the sides of the shoe sole.
  - Depress each knob and turn clockwise to tighten.

*PLEASE REFER TO ENCLOSED INSERT FOR MAINTENANCE PROCEDURES, CAUTIONS AND WARNINGS. INFORMATION.

Fitting the Device to the Patient

Step 4: Alignment of the Metatarsal Head
- Correct anesthetized alignment of the Toe CPM with the patient is important for proper operation and comfort.
  - Pull out the Drive Rod.
  - Carefully fit the device to the patient's toe and secure with the two本事 belts around the proximal phalanx.
  - Loosen the four Mounting Knobs sufficiently to allow sliding of the device over the toe.
  - Align the Toe CPM FOOT Center line with the MP joint.
  - Tighten the Mounting Knobs.

Step 5: Attaching the Toe
- Before attaching the toe, verify that the softgoods selection, MP joint alignment and Range of Motion are correct.
- Attach the Metatarsal Head to the toe with the Drive Rod beneath the toe.
- Loosen the Drive Rod Clamp Knob.
  - Adjust the position of the Drive Rod Recaller such that the Drive Rod can be placed through the Drive Rod Centre the Drive Rod as shown below.

Specifications and Operating Limits
- Weight of Device: 1.4 kg (3 lbs.)
- Dimensions of Device: 38cm x 70cm x 11cm
- Range of Motion: Dorsiflexion 0° to 60°
- Plantar Flexion 0° to 60°
- Rate of Speed: 1.5 minutes for a complete cycle of motion
- Power requirement: 2 AA (alkaline) batteries, 3 volts
- Battery Life: Up to 4 days for alkaline batteries

Ordering Information
- ST-001 Toe CPM Kit
- ST-101A Disposable Orthopedic Shoe - Small
- ST-101B Disposable Orthopedic Shoe - Medium
- ST-101C Disposable Orthopedic Shoe - Large
- ST-101D Metatarsal Head Insertor - Small
- ST-101E Metatarsal Head Insertor - Medium
- ST-101F Metatarsal Head Insertor - Large

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EC REP

ISO 13849-1 for Quality Assurance

CE 0129