ITAL: FITTING AND USE
A GUIDE FOR USERS AND CAREGIVERS

Placing a World of Possibilities in Your Hands™
Special instructions for storage and use:

Storage conditions – the ITAL prosthesis may be safely stored and transported in temperatures ranging from 22°F (-6°C) to 180°F (82°C).

Packaging – each ITAL prosthesis is sealed in a polyethylene bag, packed in a cardboard carton.

Contraindications – the ITAL prosthesis is NOT recommended for use under the following conditions:

- After recent surgery on the residual limb, with the presence of draining wounds or suture lines, which are not yet healed.
- Compromised / endangered blood circulation, neuropathy, or any pathological condition which impairs the user’s ability to feel contact with the prosthesis on their residual limb, or sense the force of the mechanical load applied to the residual limb by the prosthesis during use.
- Physical conditions that render the user susceptible to injury, e.g., reconstructive surgery to the neck, shoulder girdle or spine following physical injury that has left the individual weakened or susceptible to re-injury.
Introduction

The ToughWare ITAL prosthesis is an easy-to-fit, easy-to-use upper extremity prosthesis designed to allow upper extremity, below-the-elbow amputees to perform typical activities of daily living and physical work – enabling full and productive lives.

Resistant to environmental extremes of temperature and humidity, and to corrosive biological and chemical fluids – the ITAL is made of resilient space age materials. The ITAL’s simple and ingenious form and function allow users to begin mastering its operation in as little as one hour.

Activities such as lifting, carrying, forceful grip and fine manual control are all within the capabilities of the ITAL user – for work, sports, household chores and recreational activities.

Form and function

Each ITAL, or adjustable transradial prosthesis, consists of four main components: 1) an adjustable upper arm cuff; 2) a forearm section; 3) a V2P™ terminal device, and; 4) a harness and control cable – all displayed below. Operating in unison, these components restore functional grasp and promote the use of both upper limbs for balanced upper body anatomical performance – completely powered by the user’s body.

The V2P™ terminal device offers users six (6) discrete levels of pinch force, to minimize muscular fatigue and overuse syndrome – permitting a full range of activities, from those requiring minimal force for handling of delicate or lightweight objects, to higher force for tasks demanding a powerful grip.

All ITAL components are fully adjustable for a comfortable, secure and stable fit – and optimal overall function.

Requiring minimal training to fit users, the ITAL is suitable for distribution, at the point of care, through health care providers, government assistance programs and humanitarian agencies worldwide. Field fitting eliminates the need for specialty clinics, making these assistive devices available to a wider audience of amputee end-users – providing broader access to an improved quality of life.
Contents of your ITAL kit

Each ITAL kit contains all of the components listed, and described below:

Flexible, cost-effective and easy to use

The ITAL’s unique characteristics make it the lowest cost, highest performance upper extremity prosthesis available. Following are just a few of its distinguishing features:

- Fits virtually all body types – available in small, medium and large
- Color selection – black or brown – custom colors on request
- Open construction allows for improved skin hygiene
- Suspension design protects shoulder muscles
- Can be used on left or right side
- Same-day fitting and use
- Modular design for easy servicing
- Meets design standards for use of other terminal devices
- Light weight
- Adjustable length
- Adjustable wrist design to allow position and task-specific functions
### Selecting the ITAL that’s right for you

Choosing the right device is critical to assure proper fitting and comfortable operation for the user. The following sizing guidelines and accompanying residual limb images assure selection of the correct ITAL and proper device settings for each user body type.

<table>
<thead>
<tr>
<th>SMALL</th>
<th>MEDIUM</th>
<th>LARGE</th>
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</thead>
<tbody>
<tr>
<td><strong>Upper Arm Circumference</strong>&lt;sup&gt;(1)&lt;/sup&gt;</td>
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</tr>
<tr>
<td>7.0 &gt; 9.0 in. / 17.8 &gt; 22.9 cm</td>
<td>8.0 &gt; 10.5 in. / 20.3 &gt; 26.7 cm</td>
<td>9.0 &gt; 12.0 in. / 22.9 &gt; 30.5 cm</td>
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<tr>
<td><strong>Forearm Length</strong>&lt;sup&gt;(2)&lt;/sup&gt;</td>
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<tr>
<td>Greater than 3.0 in. / 7.6 cm</td>
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<tr>
<td><strong>Forearm Width</strong>&lt;sup&gt;(3)&lt;/sup&gt;</td>
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<tr>
<td>2.3 &gt; 2.8 in. / 5.8 &gt; 7.1 cm</td>
<td>2.5 &gt; 3.0 in. / 6.4 &gt; 7.6 cm</td>
<td>2.8 &gt; 3.5 in. / 7.1 &gt; 8.9 cm</td>
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<tr>
<td><strong>ITAL Prosthesis Total Weight</strong></td>
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<tr>
<td>1.4 lbs. / 635 g</td>
<td>1.8 lbs. / 817 g</td>
<td>1.9 lbs. / 862 g</td>
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</table>

* All ITAL prostheses are shipped from the factory pre-configured for left or right side placement.
† Arm circumference should be measured just above elbow.
‡ To ensure adequate leverage, amputees should have at least 3 in. / 7.5 cm of residual limb below the elbow.
**Tools for fitting and adjustments**

Each ITAL comes equipped with a complete set of hand tools for fitting and adjustments of the device: 1/16” hex L-key; 5/64” hex L-key; 3/32” T-handle hex key; 7/64” hex L-key; #1 & #2 Philips screwdrivers; ¼” hex nut driver; ¾” hex nut driver.

All tools and their use are described below.

<table>
<thead>
<tr>
<th>Tool Description</th>
<th>Image</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>A ¾” hex nut driver is required to tighten or loosen the ½-20 UNF nut that connects the terminal device (V2P) to the forearm section.</td>
<td><img src="image1.png" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>A 3/32” T-handle hex key is needed to adjust the upper arm suspension cuff.</td>
<td><img src="image2.png" alt="Image" /></td>
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<tr>
<td>A 1/16” hex L-key is needed to install or remove the control cable ball terminations.</td>
<td><img src="image3.png" alt="Image" /></td>
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<tr>
<td>A 1/4” hex nut driver is required to install, remove, or adjust the cup furthest from the point of attachment on the forearm section.</td>
<td><img src="image4.png" alt="Image" /></td>
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</tr>
<tr>
<td>A 5/64” hex L-key is used to loosen the swivel clamp screw to adjust and position the control cable housing.</td>
<td><img src="image5.png" alt="Image" /></td>
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<tr>
<td><strong>A #2 Philips screw driver</strong> is required to adjust the sizing plate on the rear of the forearm section and a <strong>#1 Philips screw driver</strong> to install or remove the swivel caps.</td>
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<tr>
<td><strong>A 7/64&quot; hex L-key</strong> is used to loosen the screws holding the rear upper arm contact halves together that encase the cable swivel.</td>
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Adjusting and fitting the ITAL

Once the proper size ITAL has been selected, follow the simple steps below to complete the pre-fitting adjustments of the prosthesis and the fitting process.

*With minimal experience and use, the entire process of initial adjustment and fitting of the ITAL prosthesis can be completed in one (1) hour, or less.*

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**The Upper Arm Cuff**

**Step 1:** Loosen the shaft collars with a 3/32” T-handle hex key. Adjust the space between the upper arm cuff halves by sliding them on the stainless steel rods.

**Step 2:** Estimate the distance between the contacts on the stainless steel rods to allow placement of the upper arm cuff on the user’s arm, just above the elbow, to permit additional adjustment, if needed.
**Step 3:** Slip the cuff onto the arm from the side. Make sure the space between the contacts above the elbow is wide enough to pass over the upper arm from the side.

**Step 4:** Rotate the cuff to move the back piece behind the back of the arm. This positioning acts as a mechanical lock on the rear portion of the upper arm and provides suspension for the ITAL. *Note:* Placement and removal of the cuff must be possible without loosening the shaft collars.

**Step 5:** Turn the contacts on the stainless steel rods just above the elbow so that their padded surface is rotated to a slightly downward angle, cushioning the bony prominences on either side of the elbow. *Note:* As the bony prominences are not symmetrical, the outside contact above the elbow is often higher than the inside contact.
Step 6: Once the cuff is in place, fine adjustments can be made without removing it from the upper arm. Adjust the cuff several times to achieve the best fit. Have the user flex and extend their arm between adjustments.

Step 7: Have the user fully extend and flex the elbow, loosening or tightening the cuff, as necessary, to allow unimpeded movement of the elbow.

Step 8: Lightly pull down on the elbow straps to place a physical load on the upper arm cuff. Note: The cuff will move and stabilize at a fixed position on the arm.

Step 9: Adjust the heights of the stainless steel rod contacts so the back contact of the upper arm cuff aligns with the axis of the upper arm and makes contact with the back of the arm. Note: Mild initial contact imprint patterns on the arm indicate a good load distribution. Do not fully tighten the shaft collars.
The Forearm Section

**Step 10:** Users require time to become fully accustomed to wearing the ITAL. This is normal. Optional: The bicep strap may be tightened, loosened, or removed, according to user preference.

**Step 11:** Soft sleeves on the stainless steel rod contacts may be replaced if damaged or worn.

**Step 12:** Adjust the length by selecting the proper hole used to attach the forearm shells to the end cup.

**Step 13:** Remove the straps on the top of the arm section.
**Step 14:** To check the forearm section for correct length, hold it beside the residual limb. *Note:* The distance from the tip of the elbow to the rear edge of the width adjustment plate should be approximately 1” (2.5 cm).

**Step 15:** The end cup is designed to tilt the terminal device (V2P) toward the body midline. *Note:* If necessary, remove the 4 screws from the side pieces secured to the end cup. Be careful not to misplace parts. If necessary, select a new hole position to achieve the correct length.

**Step 16:** For maximum strength, screws should be installed with at least one hole separating them, not in adjacent holes.

**Step 17:** Loosen the screws securing the width adjustment plate and spread the sides as wide as possible.
**Step 18:** Place the forearm section on the user’s residual limb. *Note:* Make certain the tongue is positioned fully inside the forearm section, resting flat against the user’s skin.

**Step 19:** Loosen the screws on the underside of the width adjustment plate, to apply comfortable light compression on the residual limb.

**Step 20:** Keeping the adjustment plate centered between the forearm shells, retighten the screws.

**Step 21:** Reinstall the top forearm straps to increase or decrease compression on the user’s residual limb, as desired. *Note:* The control cable attachment swivel is located on the outer side of the ITAL, positioned in the opposite direction from the terminal device (V2P) tilt.
Connection of Upper Arm Suspension Cuff to Forearm Section

**Step 22:** Place the upper arm suspension cuff and forearm section on the user at the same time.

**Step 23:** On both sides, select the elbow strap hole that aligns with the space between the upper arm cuff and the forearm section. Note: The attachment should be free of any tension and the cuff should not be pushed upward. This will prevent the entire device from becoming loose and unstable.

**Step 24:** Place one elbow strap washer between the strap and the forearm shell, and another washer on top of the strap before installing the retaining screw. Install screws on both sides of the elbow.
**Step 25:** Gently pull on the forearm section, as if trying to pull the device off the user’s arm. The entire prosthesis will move a short distance before the upper arm cuff comes to rest on the bony prominences. This movement is normal. However, there should not be excessive movement in the prosthesis, which can cause chaffing of the user’s skin. Repeated strap adjustments may be necessary to achieve the most comfortable fit. **Note:** Users should be able to fully flex and extend their elbow without the device pinching or binding.

**Step 26:** Tighten all shaft clamp hex screws on the upper arm cuff. The gap in each shaft clamp should be evenly spaced on either side of the rod, to ensure the strongest clamping force.
Control Cable Installation and Positioning

Step 27: The ITAL control cable attaches at two swivel points. One is located on the outer side of the forearm. The other is located on the back of the upper arm suspension cuff. Note: ITAL units are shipped with the cable attached to the forearm swivel.

Step 28: To install the cable into the cuff swivel, remove the black cap and its retaining screw from the swivel on the back of the upper arm cuff.

Step 29: Disconnect the control cable from the terminal device. Thread the opposite end of the exposed cable through the slot in the upper arm cuff swivel.

Step 30: Position the control cable with sufficient length, to allow for an ample loop around the elbow. Note: Users should be able to flex their elbow without an excessively large cable loop outside the elbow.
**Step 31:** Make note of the point on the cable housing located inside the upper arm cuff swivel. Position the thin metal compression sleeve on the cable housing at this point.

**Step 32:** Position and center the compression sleeve and cable housing in the cuff swivel.

**Step 33:** Tighten the set screw in the swivel, to clamp the housing and anchor in place.

**Step 34:** Install the black cap on the swivel, matching the hole in the side of the swivel to the hole on the side of the swivel that does not have a setscrew in place. Install the retaining screw. *Note:* The same procedure can be used to adjust the forearm swivel, if necessary.
Terminal Device Installation and Adjustment

Note: Each ITAL is supplied with a Vari-Pinch Prehensor™ (V2P) installed. The following steps are only required if adjusting, replacing or exchanging the terminal device. The ITAL may be used with terminal devices from other manufacturers, if they attach using a standard ½-20 UNF threaded post.

The arrangement of a spring washer, plastic washer and hex nut allow for friction adjustment and variable wrist functionality.

Step 35: The plastic washer is installed between the terminal device and the end cup of the forearm section. The conical spring washer is installed inside the end cup, with its convex side facing the hex nut. Note: If desired, removable thread lock compound, or plumber’s Teflon® sealing tape may be placed on the threaded post of the terminal device, before installing the hex nut.

Step 36: Tighten the hex nut until the terminal device turns with the desired level of resistance.

Step 37: Attach the control cable to the terminal device using the ball termination with the bend in it. Note: This bend relieves flexing movements that place stress on the cable.
Harness Adjustments

Note: Each ITAL is supplied with a figure-of-nine harness, designed to be worn on the shoulder of the arm opposite the amputation.

Step 38: Adjust the axilla shoulder loop, locating the ring as close as possible to the center of the user’s back.

Step 39: Adjust the cable attachment extension to allow attachment of the control cable. Note: Confirm that the user can open and close the terminal device using shoulder and arm movements. The fitting is now complete!

Encourage the user to practice with the device, performing activities they enjoy. Motivate him/her to speak with other ITAL users, to share their combined experience and knowledge, and to provide psychological support.

Fitted with their new prosthesis, the ITAL user can go on to a productive and fulfilling life – taking part in all the possibilities the world has to offer.
Additional information

For additional information about the ITAL™ (International Transradial Adjustable Limb™), contact your local distributor or ToughWare Prosthetics.

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