

ITAL System

Fitting & Usage Guide

Version: 201603e



ToughWare Prosthetics

2514 West 104th Circle
Westminster, Colorado 80234-3508 USA
+1 (303) 635-1619
Info@ToughWarePRX.com
www.ToughWarePRX.com

Special Instructions & Notes



Storage & Transport – ITAL prostheses can be stored and transported in temperatures ranging from 22°F (-6°C) to 180°F (82°C).



Packaging – Each ITAL prosthesis and its associated items are packaged in a sealed polyethylene bag and, in some cases, a cardboard carton.



Contraindications – ITAL prostheses are **NOT** recommended for use if any of these conditions are present:

- Wounds left open for drainage or unhealed suture lines on the residual limb.
- Compromised or endangered blood circulation, neuropathy, insensate regions, or any condition impairing the ability to feel contact with a prosthesis on the residual limb.
- Impaired ability to sense forces or mechanical loads applied to the residual limb.
- Susceptibility to injury or re-injury, particularly of those anatomical structures of the neck, shoulder girdle, and/or spine.
- Cognitive deficits that impair understanding of putting on, taking off, and/or using a prosthesis use.
- Inability to assess whether the prosthesis is being used in a manner that protects the user's safety and that of others.

Introduction

ToughWare's ITAL system is an easy-to-fit, intuitive-to-use complete upper limb prosthesis designed for below-the-elbow amputees. Its simple but versatile body-powered design helps make the device affordable while enabling users to begin mastering operation in as little as one hour.

ITALs are fabricated from materials able to withstand extremes of temperature and humidity, submersion in water, and exposure to most biological fluids. Its field-tested, proven mechanical design enables users to get an early start, actively engaging the world head-on to do what they want to do—whether it be work, sports, household chores or recreational activities.

Form & Function

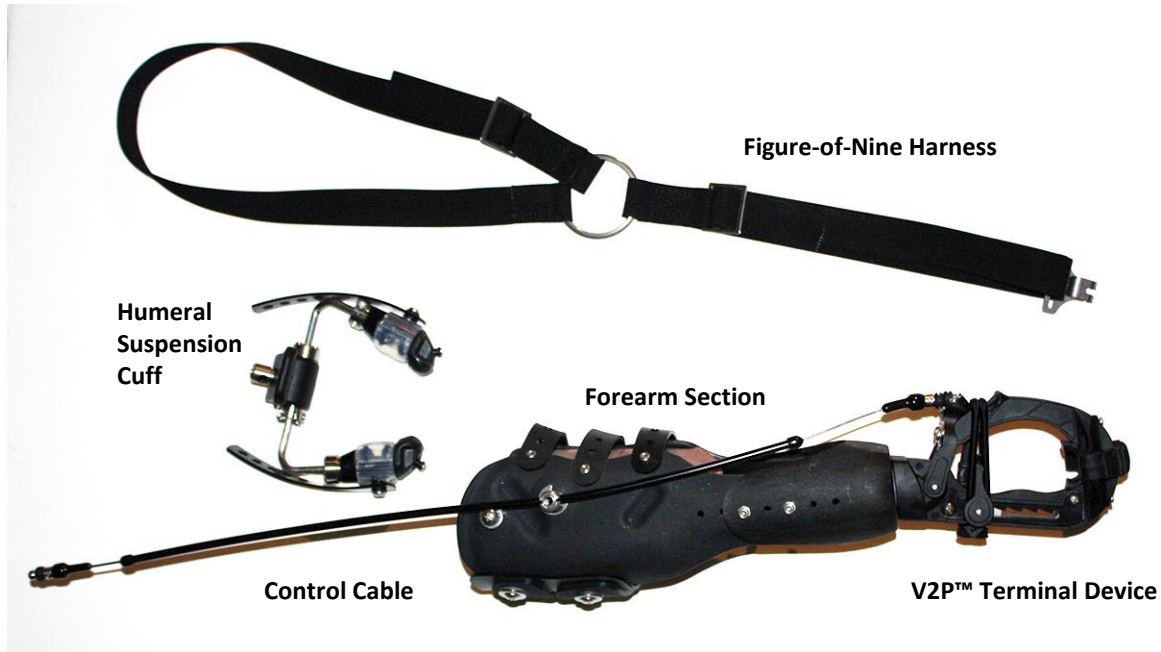
As a complete adjustable transradial prosthesis, each ITAL kit comprises four main components: 1) a fully adjustable humeral suspension cuff [HSC]; 2) a forearm shell section with attached distal cup; 3) a terminal device [the V2P™], and; 4) a Figure-of-Nine harness and control cable [shown below.] Also included are tools for fitting, adjusting, and maintaining the ITAL and a copy of this Fitting Guide. Correctly fit and adjusted, the system achieves a comfortable, secure, and stable fit. The ITAL restores functional grasp and promotes the use of both upper limbs for balanced upper-body anatomical performance, and is powered by the user's own muscles.

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: minimal force (~ 3 lbf / 13N) for handling delicate or lightweight objects, stepping up to a maximum force (~ 9 lbf / 40N) for tasks requiring more powerful grip.

Purposely designed to be successfully fit and used with minimal training, the ITAL is suitable for distribution at the point of care (POC), 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.

Package Contents

In addition to this Fitting Guide and a set of tools, each ITAL kit contains the components shown below:



Versatile, Cost-Effective, & Intuitive to Use

The ITAL's unique characteristics make it the lowest cost, highest performance upper limb prosthesis available. Some of its distinguishing features include:

Available in Small (SM), Medium (MD), and Large (LG) sizes to fit a wide spectrum of body types • Open frame construction allows for sweat drainage and air circulation to promote skin health • Suspension design protects neck and shoulder muscles • Available for left or right side use • Same-day fitting • Simple modular design makes field servicing easy • User-selectable pinch force settings mitigate sound-side overuse • Light weight • Adjustable length • Friction wrist • User adjustable socket compression

ITAL Selection & Sizing

Choosing the right size device is important to assure proper fit 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.

SMALL

Upper Arm Circumference ①
7.0 > 9.0 in. / 17.8 > 22.9 cm

Forearm Length ②
Greater than 3.0 in. / 7.6 cm

Forearm Width ③
2.3 > 2.8 in. / 5.8 > 7.1 cm

ITAL Prosthesis Total Weight
1.4 lbs. / 635 g

MEDIUM

Upper Arm Circumference ①
8.0 > 10.5 in. / 20.3 > 26.7 cm

Forearm Length ②
Greater than 3.0 in. / 7.6 cm

Forearm Width ③
2.5 > 3.0 in. / 6.4 > 7.6 cm

ITAL Prosthesis Total Weight
1.8 lbs. / 817 g

LARGE

Upper Arm Circumference ①
9.0 > 12.0 in. / 22.9 > 30.5 cm

Forearm Length ②
Greater than 3.0 in. / 7.6 cm

Forearm Width ③
2.8 > 3.5 in. / 7.1 > 8.9 cm

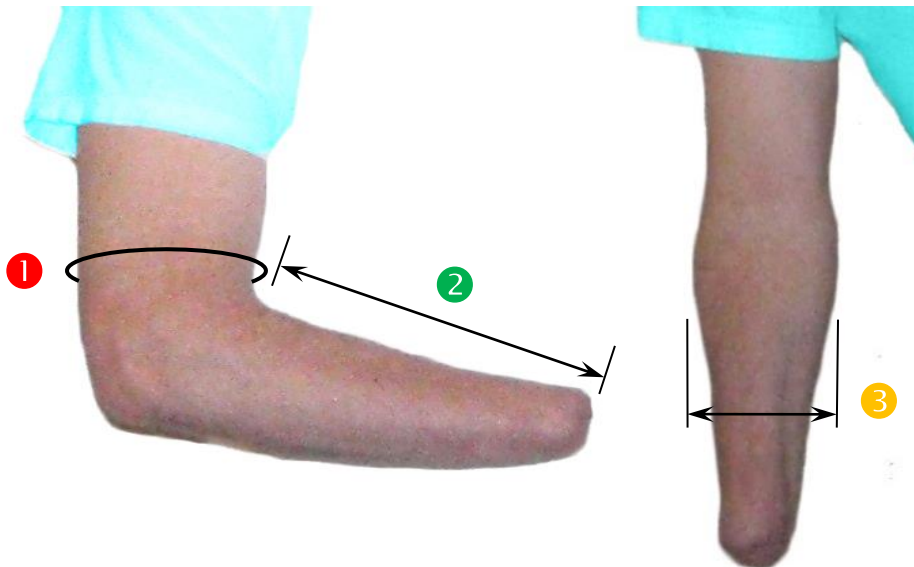
ITAL Prosthesis Total Weight
1.9 lbs. / 862 g

Additional Notes

ITAL prostheses ship from the factory pre-configured for left or right side placement.

Arm circumference should be measured just above the elbow.

To ensure adequate leverage, amputees should have at least 3 in. / 7.5 cm of residual limb below the elbow.











Fitting & Adjustment Tools

Each ITAL comes equipped with a set of hand tools for fitting and adjusting the device:

Folding hex key set; separate 5/64" hex L-key; 1/4" hex bit holder; #1 & #2 Philips screwdriver hex bits; 9/64" hex bit; 3/4" hex nut wrench.

All tools and their use are described below.

	 <p>Use a 3/4" hex nut driver to tighten or loosen the 1/2-20 UNF nut that connects the terminal device (V2P) to the forearm section.</p>
	 <p>Use a 1/4" hex bit holder and 9/64" hex bit to adjust the humeral suspension cuff (HSC).</p>
	 <p>Use a 1/16" hex key to install or remove the control cable ball terminals.</p>
	 <p>Use a 1/4" hex bit holder (as a nut driver) and 5/64" hex L-key to adjust the forearm section length.</p>
	 <p>Use a 5/32" hex key to loosen the swivel clamp screw for adjusting or positioning the control cable housing.</p>

	 <p>Use a 1/4" hex bit holder and #2 Philips screwdriver hex bit to adjust the forearm width dimension and attach HSC elbow straps to the forearm shell.</p>
	 <p>Use a 3/32" hex key (Small HSC) or 7/64" hex key (Medium & Large HSC) to separate the HSC rear contact halves to remove or replace the cable swivel.</p>
	 <p>Use a 1/4" hex bit holder and #1 Philips screwdriver hex bit to remove shaft clamping collar screws when replacing the collars.</p>

Control Cable Ball Terminals

The ITAL uses ball terminals on its control cable. There are two (2) types:



The *bent* ball terminal attaches to the terminal device. Its curved shape reduces stress in the control cable to help prevent fraying and breakage.



The *straight* ball terminal is shorter and attaches to the harness hanger on the Figure-of-Nine harness.

Both types use four (4) set screws that require a 1/16" hex key, and both have black strain relief boots that help preserve cable life. When removing or installing the ball terminals, use caution to avoid damaging or stripping the small set screws.

Fitting & Adjustment

Once a proper size of ITAL has been selected, follow the simple steps below to complete pre-fitting adjustments and begin the fitting process. *With minimal experience and use, this process of initial adjustment and fitting of the ITAL prosthesis can in most cases be completed in one (1) hour or less.*

Humeral Suspension Cuff (HSC) Adjustments



Step 1: Remove the bicep strap by pulling it off the posts. Loosen the clamping collars with a 9/64" hex bit inserted into the hex bit holder. Rods should be moveable but not loose.



Step 2: Estimate the distance needed between the padded contacts to allow placement of the HSC just above the user's elbow. Adjust the space between the contacts by moving them on the rods.

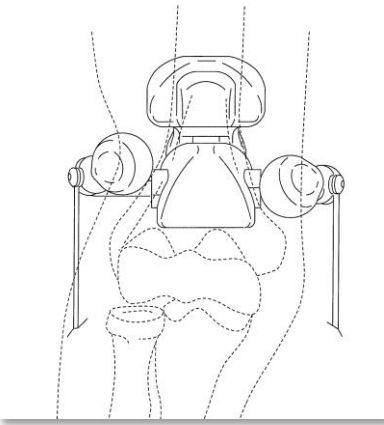


Step 3: Slip the HSC onto the user's arm above the elbow from the side. Ensure the space between the contacts is wide enough to pass over the upper arm from the side.

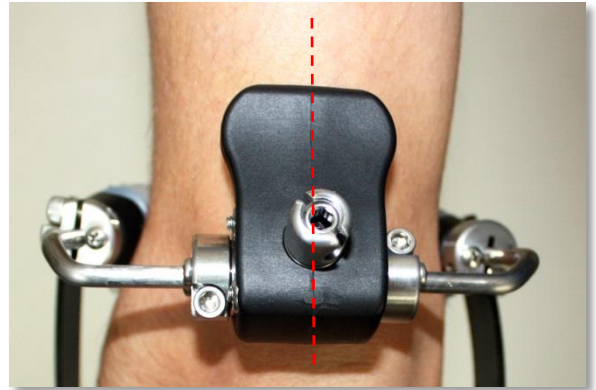
Note: For the user's safety, it **MUST** be possible to put on and take off the HSC without having to loosen the shaft collars, use tools, or bend or distort the device.



Step 4: Rotate HSC so the rear contact touches the back of the user's arm. The HSC should rest just above the olecranon and epicondyles to form a mechanical lock on these bony prominences. The HSC provides suspension for the ITAL.



Step 5: Turn the contacts on the rods so the padded surfaces face slightly downward to cushion the bony prominences on both sides of the elbow. *Note:* These bony prominences are not symmetrical. The outside lateral contact may be higher than the inside medial contact.



Step 6: Adjust the heights of the rods and padded contacts so the HSC rear contact touches the upper arm and aligns axially. *Note:* Mild initial contact imprint patterns on the arm indicate a good load distribution. Do not yet fully tighten the clamping collars.

Step 7: Once the HSC is in place, fine adjustments can be made without removing it from the user's arm. While communicating with the user, adjust the HSC several times to achieve a comfortable fit. *Note:* Comfort and stability of the prosthesis depend upon the HSC. Taking time to ensure a correct fit at this point will increase the likelihood of achieving a satisfactory fit and will save time.



Step 8: Have the user fully extend and flex their elbow. Adjust the HSC as necessary to allow unimpeded movement over a full range of motion (ROM). If fit is satisfactory, tighten all clamping collars. *Note:* Use of the bicep strap is optional and left to the user's preference.

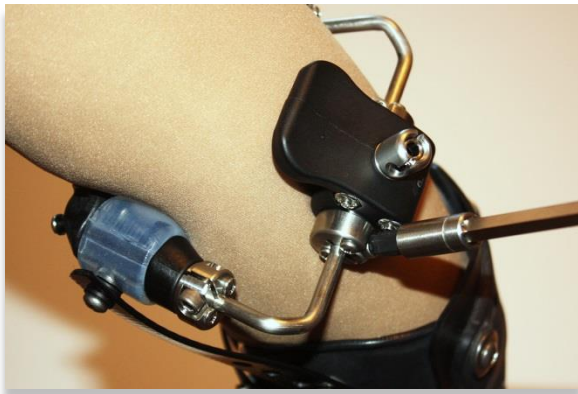


Step 9: Lightly pull down on the elbow straps to place a physical load on the HSC. *Note:* The HSC will stabilize at a fixed position on the arm. It should be possible to apply a substantial load without causing discomfort.



Step 10: Users require time to fully acclimate to wearing the HSC and the ITAL. Minor skin redness and marks are normal, and a sock may be used if desired.

VERIFY the user is able to comfortably put on and take off the HSC. For the user's safety, it **MUST** be possible to put on and take off the HSC without having to loosen the shaft collars, use tools, or bend or distort the device.

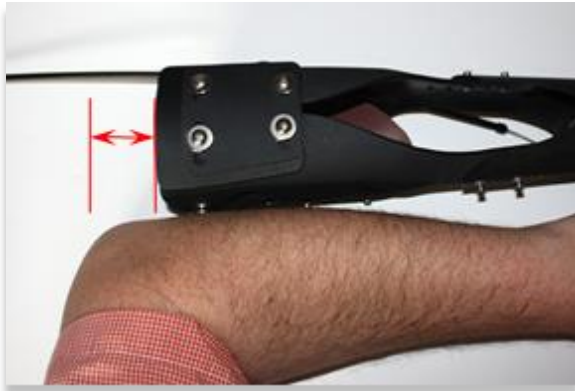


Step 11: Confirm all clamping collars on the HSC have been tightened to avoid inadvertent loss of adjustment.

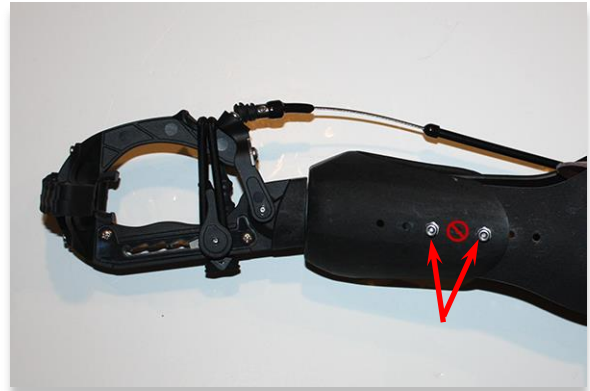


In the event a user experiences extreme skin irritation, impaired circulation, pain, or any condition they or a clinician deems excessive or unsafe, immediately discontinue use of the HSC or full ITAL and remove the device from the user's residual limb until the problem is corrected.

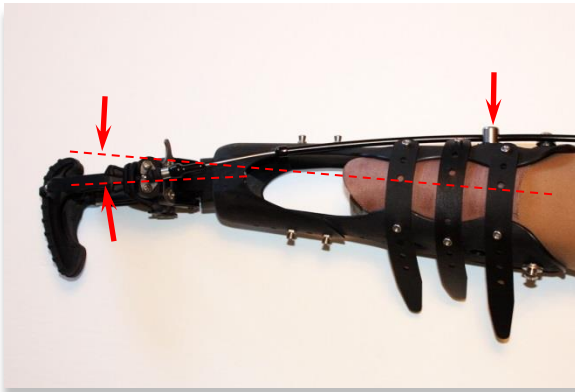
Forearm Shell Adjustment



Step 12: Check for correct length. *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).



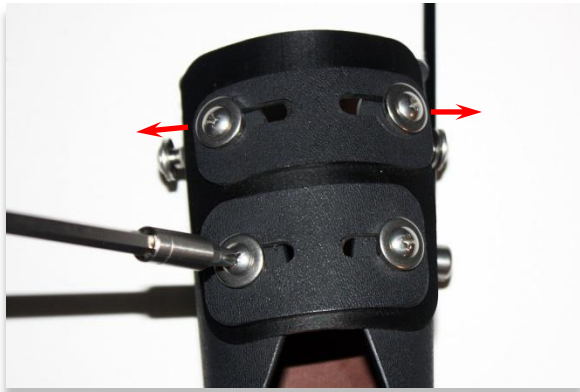
Step 13: Adjust length by selecting and matching holes in the forearm shells and distal cup. For maximum strength, two (2) screws should be installed per side with at least one hole separating them, not in adjacent holes.



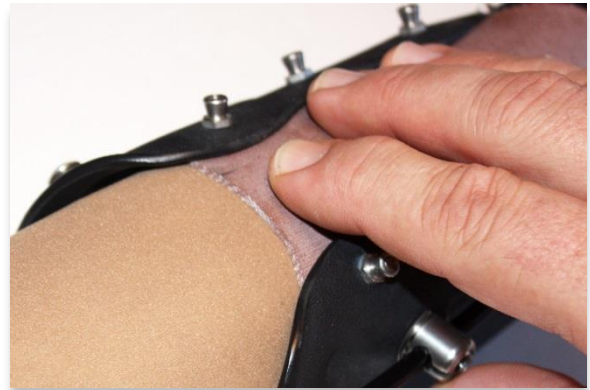
Step 14: The distal cup is designed to tilt the terminal device (V2P) toward the body midline, away from the outer lateral side (cable swivel side).



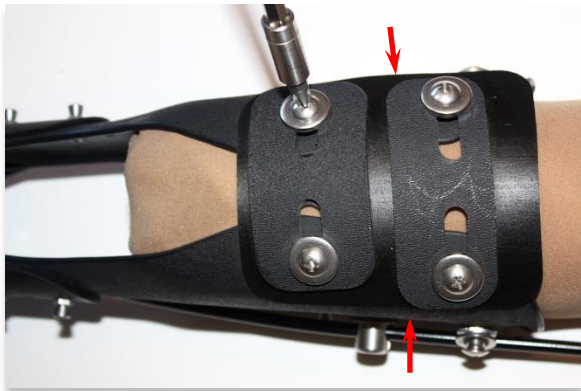
Step 15: Remove compression straps from the forearm section by lifting them off the posts and set them aside.



Step 16: Loosen the screws securing the width adjustment plates and spread the side shell pieces apart as wide as possible.



Step 17: Place the forearm section on the user's residual limb and position it correctly. Ensure the tongue is positioned fully inside the forearm section, resting flat against the user's residual limb.



Step 18: Loosen the screws on the width adjustment plates and press the shell sides together to apply comfortable light compression on the user's residual limb. While keeping the plates and cushion pad centered, retighten the screws.

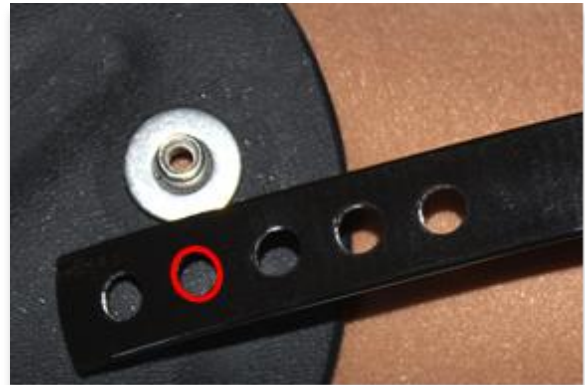


Step 19: Reinstall the compression straps to increase or decrease pressure on the user's residual limb to the level desired. *Note:* Various strapping configurations may be used according to user preferences.

Connection of Humeral Suspension Cuff (HSC) to Forearm Section



Step 20: Place the HSC and forearm section on the user at the same time.



Step 21: On both sides, select the elbow strap hole that aligns with the space between the HSC and the forearm section. *Note:* The attachment should be free of any tension and the HSC should NOT be pushed upward. This will prevent the entire device from becoming loose and unstable.



Step 22: 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.

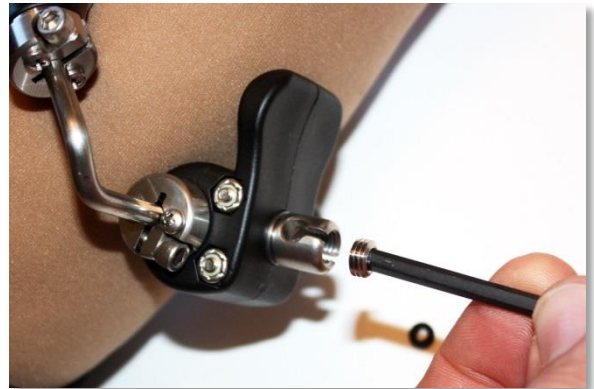


Step 23: Gently pull the ITAL as if trying to pull it off the user's arm. After moving a short distance, the HSC should engage the bony prominences. This movement is normal, but excessive movement can cause skin irritation. If necessary, adjust the elbow straps to achieve a more stable fit. *Note:* User should be able to fully flex and extend their elbow comfortably without pinching or binding.

Control Cable Installation & Positioning



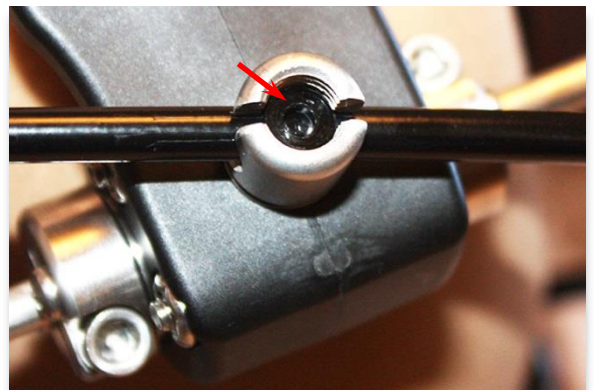
Step 24: The ITAL control cable attaches at two swivel points. One is located on the outer lateral side of the forearm. The other is located on the back of the HSC. *Note:* ITAL units ship with the cable attached to the forearm swivel only; the HSC is kept separate to facilitate fitting.



Step 25: Remove the jam nut and compression washer from the cable swivel on the back of the HSC and set aside. Use caution to avoid losing small parts.



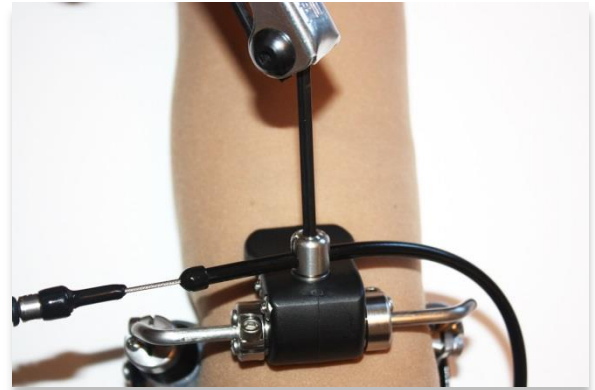
Step 26: Disconnect the control cable from the terminal device. Slide the cable housing cap towards the straight ball cable terminal and position the cable inside the cable swivel as shown.



Step 27: Install the compression washer inside the cable swivel and touching the cable housing as shown.



Step 28: Install the jam nut in the cable swivel on top of the compression washer. 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 29: Gently tighten the jam nut to lock the control cable position in the cable swivel. Large torque is not necessary to lock the cable in position. Avoid excessive torque to prevent damaging the cable housing.



Step 30: Reattach the bent ball cable terminal to the terminal device.

Terminal Device Installation & Adjustment

ITALs are supplied with a factory installed Vari-Pinch Prehensor™ (V2P). The following steps are only required if adjusting, replacing or exchanging the terminal device. The ITAL may be used with other manufacturers' terminal devices if they use the standard ½-20 UNF threaded post for mounting.

The spring washer, plastic washer, and hex nut allow for friction adjustment of the wrist and allow it to be turned without loosening.



Step 31: Install the plastic washer between the terminal device and the distal 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.

Do NOT use Loctite® RED thread lock compounds on the terminal device.



Step 32: Tighten the hex nut until the terminal device turns with the desired level of resistance.



Step 33: Attach the control cable to the terminal device using the bent ball cable terminal. *Note:* This bend relieves flexing movements that place stress on the cable and preserves service life.

Harness Adjustments

ITALs are supplied from the factory with a Figure-of-Nine harness, intended to be worn on the shoulder of the arm opposite the amputation.



Step 34: Adjust the axilla shoulder loop, locating the ring as close as possible to the center of the user's back.



Step 35: 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. Fitting is now complete!

Encourage users to practice with their device and explore ways to perform activities they enjoy. Experience has shown that interacting with other ITAL users results in a sharing of experience and knowledge, more rapid recovery, and helps users achieve a more positive self-image and outlook.

Fitted with their new prosthesis, ITAL users are better equipped and prepared to lead productive and fulfilling lives while enjoying all the possibilities the world has to offer.

Additional Information

ITAL™, V2P™, and HSC™ are in use as trademarks of ToughWare Prosthetics.

The ITAL, HSC, and V2P are manufactured in the USA under one or more of the following US patents:
8,052,761; 8,414,658; Other Patents Pending


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

Please visit our website at www.ToughWarePRX.com.



ToughWare Prosthetics

P.O. Box 350055
Westminster, Colorado 80035-0055
U.S.A.

 +1 (303) 635-1619

E-mail inquiries to:
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