ToughWare Prosthetics

Humeral Suspension Cuff (HSC) Fitting & Usage Guide

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ToughWare Prosthetics

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Special Instructions & Notes

Storage & Transport – The Humeral Suspension Cuff (HSC) can be stored and transported in temperatures ranging from 22°F (-6°C) to 180°F (82°C).

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

Contraindications – HSC units are **NOT** recommended for use if any of these conditions are present:

- Wounds remain open for drainage or there exist 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 the HSC unit on the residual limb.
- Impaired ability to sense forces or mechanical loads applied to the HSC unit.
- 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 the HSC unit.
- Skin irritation, rash, bruising, or any condition that results in discomfort or an inability to acclimate to the HSC unit.

FOR THE USER'S SAFETY, THEY MUST BE ABLE TO PUT ON AND TAKE OFF THE HSC BY THEMSELVES WITHOUT THE USE OF TOOLS, HAVING TO LOOSEN PARTS OF THE HSC, AND/OR WITHOUT HAVING TO BEND OR DISTORT THE DEVICE. IF THEY ARE UNABLE TO DO SO, THE HSC IS UNSUITABLE FOR THIS INDIVIDUAL AND MUST NOT BE PRESCRIBED FOR THEIR USE OR BE USED BY THEM.

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 AND REMOVE THE DEVICE FROM THE USER'S RESIDUAL LIMB UNTIL THE CAUSE IS IDENTIFIED AND THE PROBLEM IS CORRECTED.

Introduction

ToughWare's Humeral Suspension Cuff (HSC™) is a fully adjustable supracondylar suspension system for upper-limb prostheses that preserves full range-of-motion (ROM) elbow flexion while providing an anchor point for the control cable housing required with many conventional body-powered (BP) configurations. HSCs are suitable for use with both BP and externally powered appliances and are ideal for achieving comfortable suspension where residual limb volume is in flux and frequent adjustments may be required. They also provide an option for clinicians dealing with difficult cases where some experimentation is necessary to achieve an overall optimal fit without requiring repeated casting and rectification. The HSC may be used alone to provide excellent suspension, or it may be combined with suction suspension at the clinician's discretion to provide additional support.

Purposely designed to be successfully fit and used with minimal training, the HSC is suitable for incorporation into upper-limb prostheses at the point of care (POC) and distributed through health care providers, government assistance programs, and humanitarian agencies worldwide. Field fitting in some cases eliminates the need for multiple clinical visits that may not be feasible or that present hardship for patients, thereby making assistive devices available to a wider audience of amputee end-users and providing broader access to an improved quality of life.

HSC units 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 helps users 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

Each HSC comprises a component, called the back, that rests on the user's olecranon; two (2) cushioned contacts that rest on the user's lateral and medial condyles with attached elbow straps; two (2) connecting shafts that join the components together; four (4) shaft clamps that provide adjustability; and an optional bicep strap. By loosening the shaft clamps, the relative positions and angles of the components may be adjusted to interface with a wide array of anatomical shapes. Correctly fit and used, the HSC can be donned (put on) or doffed (taken off) easily by the user alone and without the use of tools, having to loosen parts of the device, or bending or distorting the device.

Adjustments shown enable the HSC to accommodate a wide range of anterior-posterior (A-P) and medial-lateral (M-L) anatomical landmark configurations and contact angles. Bicep strap is not shown.

Sizing

The HSC is available in three (3) discrete sizes. Choosing the correct size HSC is important to assure proper fit and comfort for the user.

SMALL

Upper Arm Circumference ❶
7.0 > 9.0 in. (17.8 > 22.9 cm)

Total Weight (PLUG)
5.7 oz (162 g)
Add 0.4 oz (10 g) for SWIVEL or
Add 0.5 oz (14 g) for CROSSBAR

MEDIUM

Upper Arm Circumference ❶
8.0 > 10.5 in. (20.3 > 26.7 cm)

Total Weight (PLUG)
6.7 oz (190 g)
Add 0.4 oz (10 g) for SWIVEL or
Add 0.5 oz (14 g) for CROSSBAR

LARGE

Upper Arm Circumference ❶
9.0 > 12.0 in. (22.9 > 30.5 cm)

Total Weight (PLUG)
7.2 oz (204 g)
Add 0.4 oz (10 g) for SWIVEL or
Add 0.5 oz (14 g) for CROSSBAR

Humeral Suspension Cuffs (HSCs) are left-side / right-side indifferent and may be used on either side. Arm circumference should be measured just above the elbow as shown below.

Cable Housing Attachment

The HSC is available in three (3) control cable housing anchor configurations (i.e. Plug, Swivel, & Crossbar) to accommodate various prosthesis control setups.

PLUG: Use when no cable housing anchor point is required such as for passive or externally powered prostheses.

SWIVEL: Use with ToughWare's International Transradial Adjustable Limb (ITAL) System and applications where the control cable housing can be anchored to the HSC directly to preserve a slim, clean profile.

CROSSBAR: Conventional crossbar anchor for use with traditional or existing body-powered control cable arrangements. Use where some anchor point float is required.

Conversion kits are available for each of these configurations and may be purchased from your distributor or ToughWare. Please don't hesitate to call us to discuss special requirements or other needs should they arise.

Adjustment Tools

For maximum convenience during fitting, ToughWare recommends having the following tools available.

Use a **9/64" Hex Key** to loosen or tighten the shaft clamps when adjusting the humeral suspension cuff (HSC) for fitting.

Use a **5/32" Hex Key** to loosen the SWIVEL clamp screw when adjusting or positioning the control cable housing.

Use a **5/64" Hex Key** to loosen the CROSSBAR clamp screw for adjusting or positioning the control cable housing.

Use a **3/32" Hex Key** (Small HSC) or **7/64" Hex Key** (Medium & Large HSC) to separate the HSC back halves to change the control cable housing anchor configuration.

Use a **#1 Philips Screwdriver** or **Hex Bit** to remove the shaft clamp mounting screws should it become necessary to replace a shaft clamp.

These tools may be purchased from your distributor or ToughWare if needed.

Fitting & Adjustment

Once the proper size HSC has been selected, follow the 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 HSC can in most cases be completed 30 minutes or less.*

Humeral Suspension Cuff (HSC) Adjustments

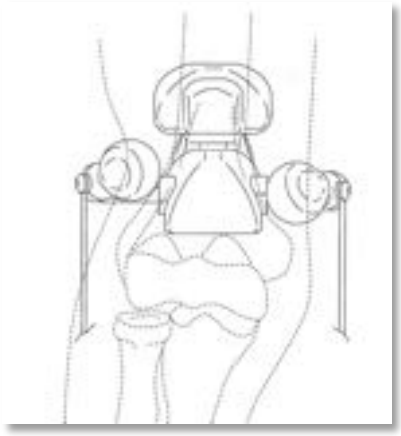
Step 1: Remove the bicep strap by pulling it off the posts. Loosen the shaft clamps slightly. Shafts should be moveable but not excessively loose.

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 shafts.

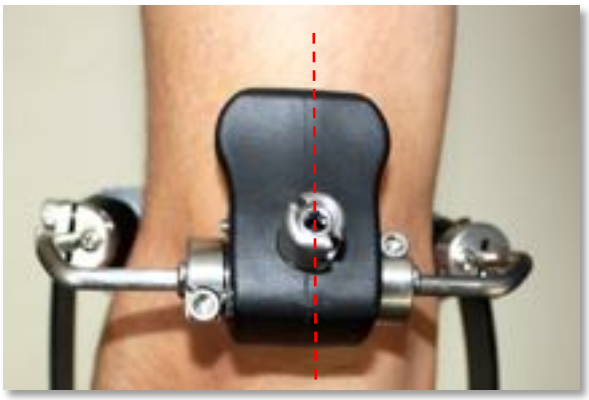
Step 3: Slip the HSC onto the user's arm above the elbow from the side. Ensure the space between the contacts is wide enough to pass over the upper arm from the side.

FOR THE USER'S SAFETY, IT MUST BE POSSIBLE TO PUT ON AND TAKE OFF THE HSC WITHOUT HAVING TO LOOSEN THE SHAFT CLAMPS, USE TOOLS, OR BEND OR DISTORT THE DEVICE.

Step 4: Rotate the HSC so the rear contact touches the back of the user's arm. The HSC should rest just above the olecranon and condyles to form a three-point mechanical lock on these bony prominences to provide suspension. The back tab helps stabilize the HSC and provides feedback. It may be rotated inward (more aggressive) or outward to suit the user's preference.



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



Step 6: Adjust the heights of the shafts and padded contacts so the HSC rear back 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 shaft clamps.

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 the fit is satisfactory, tighten all shaft clamps. *Note:* Use of the bicep strap is optional and left to the user's preference.

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, iteratively 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 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.

MAXIMUM PERMISSIBLE LOAD WILL VARY BY USER BUT MUST NOT EXCEED 40 LBF.

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

Step 10: Most users require time to fully acclimate to wearing the HSC. Minor skin redness and marks are normal; 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 CLAMPS, USE TOOLS, OR BEND OR DISTORT THE DEVICE.

IN THE EVENT A USER EXPERIENCES EXTREME SKIN IRRITATION, IMPAIRED CIRCULATION, PAIN, DISCOMFORT, OR ANY CONDITION THEY OR A CLINICIAN DEEMS EXCESSIVE OR UNSAFE, IMMEDIATELY DISCONTINUE USE OF THE HSC AND REMOVE THE DEVICE FROM THE USER'S RESIDUAL LIMB UNTIL THE CAUSE IS IDENTIFIED AND THE PROBLEM IS CORRECTED.

Control Cable Installation – PLUG Configuration

With the PLUG configuration, either no control cable is being used (i.e. passive prosthesis, external power) or the control cable is routed using an alternative path that does not require attachment to the HSC.

Control Cable Installation — SWIVEL Configuration

If necessary, loosen the two fasteners holding the HSC back portions together to allow replacement of the PLUG or CROSSBAR strap attachments with the SWIVEL, then reinstall or tighten the fasteners. Contact your distributor or ToughWare if a SWIVEL conversion kit is needed.

Step 1: The control cable housing runs through the SWIVEL on the HSC back where it is clamped to establish a solid anchor point.

Step 2: Remove the jam nut and compression washer from the SWIVEL on the back of the HSC and set aside. Use caution to avoid losing small parts.

Step 3: Disconnect the control cable from the terminal device. Slide the cable housing cap towards the cable end and position the cable inside the SWIVEL as shown.

Step 4: Install the compression washer inside the SWIVEL and touching the cable housing as shown.

Step 5: Install the jam nut in the SWIVEL on top of the compression washer. Position the control cable with enough length to loop amply around the elbow. *Note:* Users should be able to flex their elbow without an excessively large cable loop outside the elbow.

Step 6: 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. Use caution to avoid overtightening and thereby crushing the housing or impeding free control cable motion.

Step 7: Reattach the cable terminations as required for correct prosthesis operation.

Control Cable Installation — CROSSBAR Configuration

If necessary, loosen the two fasteners holding the HSC back portions together to allow replacement of the PLUG or SWIVEL attachments with the CROSSBAR strap, then reinstall or tighten the fasteners. Contact your distributor or ToughWare if a CROSSBAR conversion kit is needed.

Step 1: Confirm CROSSBAR strap pivot post is securely captured between the two back halves of the HSC and that the two (2) back fasteners are tightened.

Step 2: Verify CROSSBAR strap pivots freely about the pivot post and that longer portion of strap slot faces outward.

Step 3: Loosen setscrew to leave cross-hole clear for cable housing to pass through. Insert CROSSBAR into strap and feed cable housing through cross-hole in CROSSBAR.

Step 4: Tighten setscrew to secure cable housing in CROSSBAR. Use caution to avoid overtightening and thereby crushing the housing or impeding free control cable motion.

Notice

ToughWare Prosthetics is a legally registered trade name of Invisible Hand Enterprises, LLC.
ToughWare Prosthetics reserves the right to change or discontinue products at any time without notification.

Limited Warranty

Invisible Hand Enterprises, LLC DBA ToughWare Prosthetics ("Company") warrants to the original owner-user that the purchased products will be free from defects in material or workmanship. This warranty and the implied warranties of merchantability and fitness for a particular purpose are limited to twelve (12) months from the date of purchase, whether or not actual use begins on that date, or twelve (12) months from date of shipment by Company, whichever occurs last. Some states may not allow limitations on how long implied warranties last, so the limitation of implied warranties may be limited in its applicability to you.

Limitations and Exclusions

Company's obligations under this warranty and the sole remedy for its breach are limited to repair, at its facility, of any part or parts of its products which are defective; or, in Company's sole discretion, replacement of such product. Notification shall be made to Company for all returns using one of the following means: correspondence by mail to ToughWare Prosthetics, PO Box 350055, Westminster, Colorado 80035-0055; email to Info@toughwareprx.com; or by calling 720-775-7884. Company shall subsequently provide notification of the address to mail the defective product, postage pre-paid, for service or repairs. Repaired or replacement parts will be return shipped by the Company.

1. The warranty provided herein covers any defects in materials or workmanship, charges for labor or other costs incurred in the troubleshooting, repair, removal, service or handling or parts or complete products.
2. The warranty provided herein shall be void and of no effect in the event that (a) the product has been subjected to misuse, neglect, accident, improper or inadequate maintenance, damaging environments [e.g. chemicals such as acids, alkalis, oxidizers; temperatures; electrical fields and/or currents; mechanical loads]; (b) unauthorized modifications are made to the product; or (c) the product is not installed or operated in compliance with the Company's printed instructions for use.
3. All claims under the warranty provided herein must be made within ninety (90) days from the date of discovery of the defect. Failure to notify the Company of a warranted defect within ninety (90) days of its discovery voids the Company's' obligations hereunder.
4. The warranty provided herein is for repair or replacement only. The Company shall not be liable for any loss, cost, damage, or expense of any kind arising out of a breach of the warranty. Further, The Company shall not be liable for any incidental, consequential, exemplary, special, or punitive damages, nor for any loss of revenue, profit or use, arising out of a breach of this warranty or in connection with the sale, maintenance, use, operation, or repair of any Company product. In no event will the Company be liable for any amount greater than the purchase price of a defective product. The disclaimers of liability included in this paragraph shall remain in effect and shall continue to be enforceable in the event that any remedy herein shall fail of its essential purpose. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.
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7. No person or entity is authorized to bind the Company to any other warranty, obligation, or liability for any Company product. Purchase or use of a Company product for which this warranty is issued shall constitute acceptance of the terms hereof.
8. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

Additional Information

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

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

For additional information about the ITAL™ (International Transradial Adjustable Limb™) or ToughWare's line of terminal devices, please contact your distributor or ToughWare Prosthetics directly.

Please visit our website at www.ToughWarePRX.com.

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