INTRODUCTION

The Gunslinger is a sturdy, lightweight, fully adjustable orthosis which immobilizes the shoulder, elbow, wrist, and hand. This shoulder “airplane design” orthosis provides 90° of shoulder abduction from the torso.

INDICATIONS

Reconstruction surgery/shoulder replacement, traumatic injuries/fractures to the proximal humerus and shoulder, reduction of shoulder luxation, post operative repair of rotator cuff, Bankart lesions.

Selection

Model Number	**Description**
GS102L	Gunslinger, Left
GS102R	Gunslinger, Right

FITTING

1. Familiarize yourself with the adjustment capabilities before applying device to the patient. See **FIGURE 2** and **FIGURE 3** for a diagram of adjustments.

Note: Each quick release clasp is number coded with a round dot on the male and female parts for correct mating. Begin with hip (“1”), followed by the shoulder (“2”), then thoracic (“3”) FIGURE 1. Sit patient or flex patient hip if supine to ensure pelvic portion does not interfere with hip flexion. Re-adjust straps if necessary for proper length. Secure straps to a snug fit. Cut off excess strap if necessary and melt the end to prevent fraying. Refer to adjustments on the next page for continuing steps.

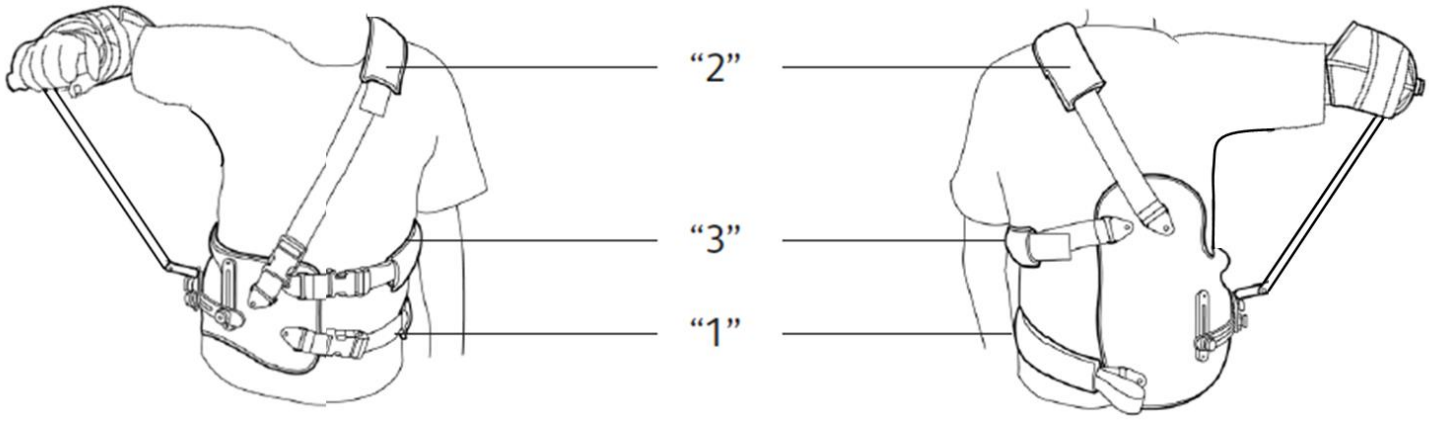

Figure 1 (Three extension posts shown)

A - Forearm Section

1&3 Forearm AP position
2 Elbow flexion/extension humeral abduction (minimal)
3&2 Humeral flexion/extension
4 Hand rest quick release

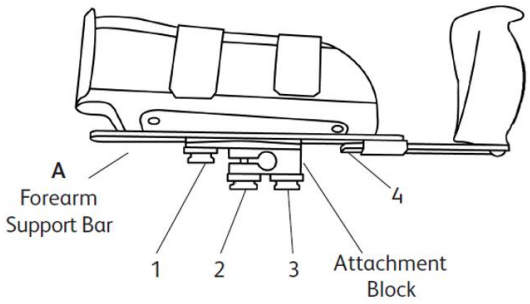

Figure 2

B – Pelvic Section

5 Anterior/posterior positioning
6&5 Shoulder elevation
7 Forearm support shaft

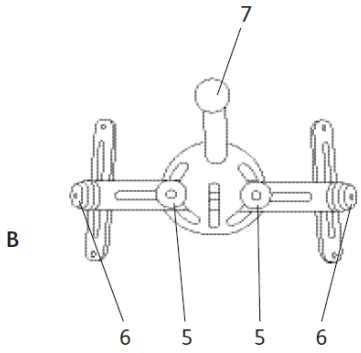

Figure 3

2. Using Allen wrench provided set the outrigger with no angle or straight (neutral position).
3. With patient supine or standing, apply the pelvic portion of the brace. Assure comfort by aligning the iliac crest with the plastic contour and secure the lower (hip) strap.
4. Loosen wing nuts (1), (2), and (3). Note that the forearm support bar and the attachment block slide independently of each other.
5. With patient's elbow flexed, place forearm in support. The elbow should be positioned about 1" posterior of the plastic cuff.
6. Position the attachment block with respect to the forearm so that the support shaft (7) is 1" proximal of the midpoint between the wrist and elbow.
7. Adjust forearm length and loosely hand tighten wing nut (3). Remove hand grip by squeezing tips of quick release fork (4) to unlock. Check the wrist to ensure unrestricted flexion.
8. Accommodate flexion, rotation, and abduction adjustments accordingly and hand tighten wing nuts (1), (2), and (3).
9. Secure contact closures over forearm and readjust posterior plastic overlap for comfort as necessary. Attach hand grip by sliding tips of fork through quick release bracket until a 'click' is heard.
10. While supporting the forearm, loosen the socket head cap screw on the outrigger bar to allow angulation.

⚠ **Loosen the screw enough to avoid damaging the serrations when making positional adjustments.**

11. With wing nuts (6) and (2) loose enough to allow motion, angle the shaft upward while sliding the forearm outward. You will notice, depending on the amount of abduction required, the attachment at the pelvic section B (6) will compensate elevation to maintain appropriate arc required in abduction.
12. Using the Allen wrench, securely tighten the socket head cap screw to lock angle of outrigger.

⚠ **Care should be taken to avoid mismatching the serrations when securely tightening.**

13. Hand tighten wing nuts (2) and (6).
14. Loosen wing nuts (5) for anterior/posterior positioning and finer elevation adjustments then hand tighten.

Note: To minimize shoulder adduction, remove the second extension post and reattach the plastic end cap.

Note: To maximize shoulder adduction, add the provided extension post and reattach the plastic end cap. See Figure 1.

15. If two or three extension posts are used, disassemble them using the provided wrench. Each extension post will have an exposed set screw that is firmly cemented into it. Do not try to remove these. Apply the provided red thread locking compound to the exposed threads. Reattach and securely tighten with the provided wrench.

⚠ **Step 15 must be followed to prevent loosening during use.**

16. Secure all wing nuts, especially (2), with the wrench provided when all adjustments have been completed.

STORAGE AND USE

There are no identified restrictions on the temperature of storage and use.

DISPOSAL

There are no hazardous materials in the device. Comply with local and national laws and regulations.

LEGAL INFORMATION

MD The use of this class 1 medical device is subject to the respective national laws of the country of use and may vary accordingly. The user of this device should report any serious incident to Trulife and the competent authority of the country of use.

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LIMITED WARRANTY

Trulife warrants that the PRODUCT will be free from defects in material and workmanship from the date of installation for the warranty period stated on the PRODUCT warranty card.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by a certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

1 As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.

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