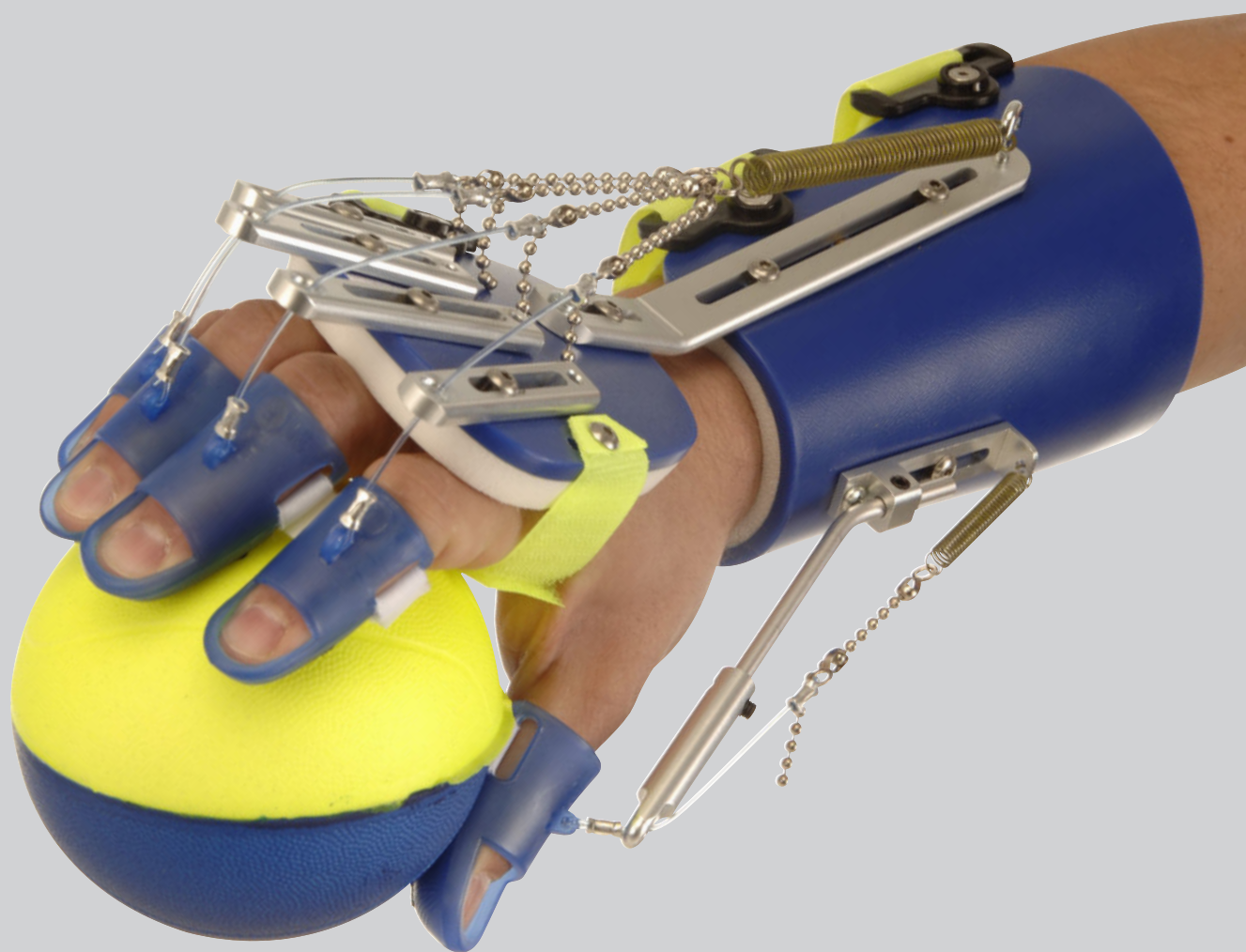


SaeboFlex[®]



 **Saebo**
Leaders In Stroke Rehabilitation

INTRODUCTION:

The **SaeboFlex**[®] is a custom fabricated, dynamic Wrist Hand Finger Orthosis (WHFO). It is finger and thumb driven in flexion, and cable driven in extension. The orthosis serves a dual purpose: to support the hand in a functional position while allowing the person to incorporate the hand in functional activities.

BENEFITS:

- Designed to support the neurologically impaired wrist, hand, thumb, and fingers in a functional position
- Helps to prevent and correct contractures of the wrist, hand, thumb, and fingers
- Maintains and improves range of motion in the hand, thumb, fingers and throughout the entire upper extremity
- Improves strength in the wrist, hand, thumb, fingers and throughout the entire upper extremity
- Assists with performing functional grasp and release activities using the affected arm/hand

POSITIONING:

When wearing the **SaeboFlex** for positioning, the patient should gradually increase the wearing time. (This should be monitored by a licensed therapist/health care professional). This should be done during the waking hours, and it is not recommended that the **SaeboFlex** be worn while sleeping.

FUNCTIONAL ACTIVITIES:

We suggest two 45 minute sessions of functional grasp and release activities each day. Consult with your SaeboTrained therapist to help identify the best functional activities to match your specific needs. After each 45 minute session the *SaeboFlex* should be removed for at least 30 minutes. It is possible to do more than two 45 minute sessions each day.

INDICATIONS:

- Stroke
- Traumatic Brain Injury (T.B.I.)
- Incomplete Spinal Cord Injury
- Cerebral Palsy
- Individuals suffering from hemiparesis

CONTRAINDICATIONS:

- Severe joint deformities in the fingers and thumb secondary to hypermobile or lax joints
- Any type of inflammatory arthritis in the fingers or thumb
- Limiting fixed contractures in the fingers, thumb, and wrist
- Severe edema in the forearm and/or hand
- Open wounds or infected areas
- The *SaeboFlex* was not designed to be used on a normal hand as the dynamic resistive springs are not calibrated to accommodate normal tone and would be no functional benefit.

PRECAUTIONS:

1. If you experience any pain while wearing or using the *SaeboFlex*, stop immediately and contact a health care professional before resuming.
2. If unusual swelling, skin discoloration, discomfort, or numbness occurs, remove immediately and contact a health care professional before resuming.

3. Avoid wearing the **SaeboFlex** for longer than 45 minutes at a time while incorporating it functionally.
4. The **SaeboFlex** should fit snug, yet comfortably, without interfering with circulation.
5. Do not let unsupervised children play with the **SaeboFlex** as there are small parts which if removed may cause choking if swallowed.

MAINTENANCE:

The **SaeboFlex** should be cleaned with a damp cloth and allowed to air dry. Avoid chemicals/abrasives for cleaning which may damage and decrease the performance of the **SaeboFlex**.

DONNING THE SaeboFlex:

It is important for the patient and/or caregiver to understand how to correctly put on the **SaeboFlex** orthosis. The **SaeboFlex** needs to be donned at the same anatomical location every time to ensure correct performance. Below are suggested steps for putting on the **SaeboFlex**. If you continue to have difficulty with applying the **SaeboFlex**, please contact your therapist or call our clinical technical support team at 888-284-5433.

Step #1: Make sure all three straps (two forearm and one hand strap) are undone.

Step #2: Place your thumb over the bone at the wrist (ulnar head) (Fig#1). Place the **SaeboFlex** onto the forearm. Make sure the distal edge (the one closest to the wrist) of the forearm shell is just above the bone at the wrist (Fig #2).

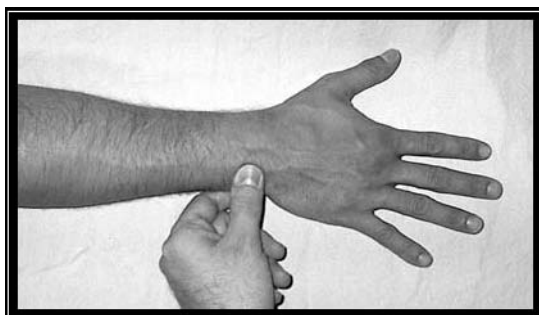


Fig #1

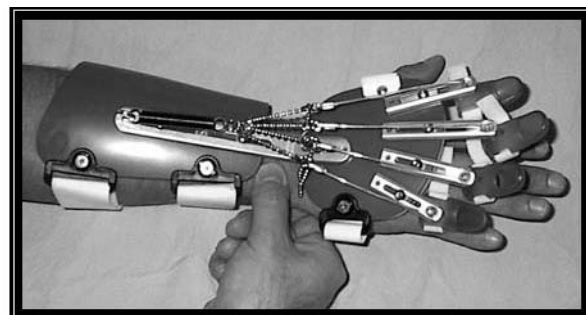
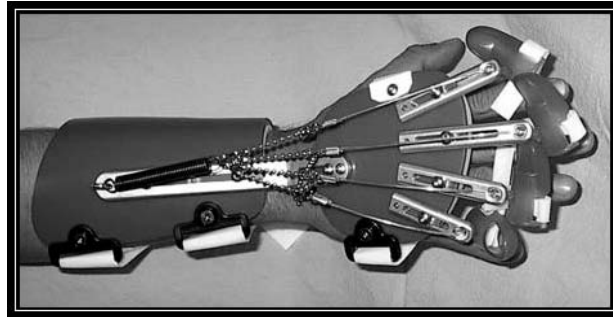


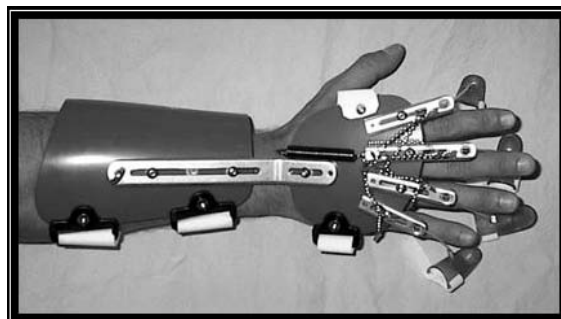
Fig #2

Step #3: Once you have the forearm shell in the correct position, secure the two forearm straps. Make sure they are secure so the forearm shell does not migrate down over the bone at the wrist (Fig #2).

Step #4: In order to apply the hand strap, bring the back of the hand and fingers up against the hand piece. Once they are positioned with the hand centered under the hand piece, secure the hand strap.

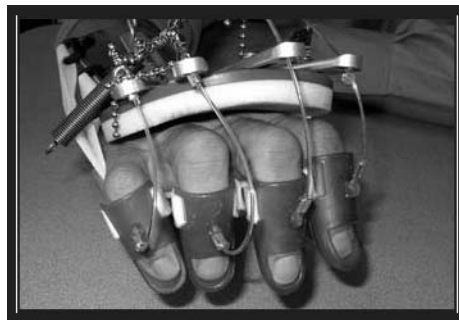


Step #5: When all three straps are secure, remove the finger spring from the hook on the wrist mount located on the forearm shell by turning the hook a half-turn so the opening is facing to the side. Remove the spring allowing the digit caps to fall down.



Step #6: Starting with the index finger and finishing with the little finger, slide each finger into the appropriate digit cap. Make sure the tip of the finger comes to the end of the digit cap. Depending on the tone in the hand and fingers, this step may be difficult for some people.

In the beginning, it may be necessary to open the white Velcro strap that holds the digit cap securely to the finger. Eventually, it will be possible to slide the finger into the digit cap without opening the Velcro straps. Trim any excess length from the digit cap straps. (Your therapist should have trimmed these straps at the clinic.)



Step #7: Once all four digit caps are securely on the fingers, bring the fingers up against the finger lead mounts (Fig #3). Reattach the finger spring onto the eye hook on the wrist mount located on the forearm shell (Fig #4).

Care should be taken to avoid pulling the fingers up with the spring as this practice may overstretch the spring or pull open the split ring (the round ring at the end of the spring).

We suggest you extend the fingers and hold them into extension by placing them against your thigh or a table.

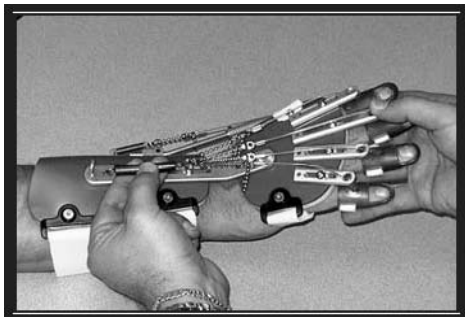


Fig #3

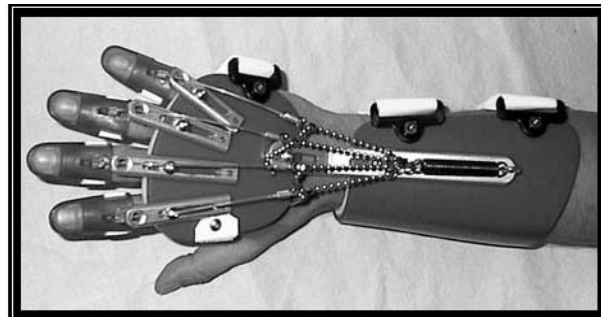


Fig #4

Step #8: To apply the thumb digit cap, unhook the thumb spring attached to the thumb mount on the forearm shell. Let the digit cap hang down toward the thumb.



Step #9: Slide the thumb into the digit cap. Make sure the tip of the thumb is at the end (tip) of the inside portion of the digit cap and no space can be seen.



Step #10: Once the thumb digit cap is securely on the thumb, re-attach the thumb spring onto the thumb mount. Be careful not to overstretch the spring.



Care and Cleaning of the Kit Style SaeboFlex and SaeboReach

- Kit style devices are fabricated so that the foam liners can be removed and replaced with the replacement foam liners provided in the Saebo kit. Replacement straps for the digit caps, hand pieces, and forearm shells are also included.
- The remainder of the parts/pieces can be cleaned with the same cleaning solutions used for other rehabilitation equipment and supplies such as Dispatch.
- Spray or apply solution to a clean cloth and wipe down.
- If the device was only used a few times, the foam liner, which is closed cell, can be re-used after wiping down and cleaning with the same solution.

Care and Cleaning of Custom Fabricated SaeboFlex and SaeboReach

- Use Dispatch or other hospital grade disinfectant liquid or spray applied to a clean cloth and wipe down.
- Foam padding is closed cell and non- absorbent and can also be wiped down with disinfectant cleaning solution as well as using a clean cloth.

If you have questions or require further information, please contact:



Saebo, Inc.
2459 Wilkinson Blvd
Suite 120
Charlotte, NC 28208
Tel: 888.284.5433
www.saebo.com



www.saebo.com
888-284-5433

With Saebo . . . There Is No Plateau In Sight®

WARNING
This product can expose you to Diisononyl Phthalate (DINP),
which is known to the State of California to cause cancer.
For more information go to WWW.P65Warnings.ca.gov

Manufactured and distributed by:

Saebo, Inc.
2459 Wilkinson Blvd
Ste. 120-B
Charlotte, NC 28208

888-284-5433
sales@saebo.com
www.saebo.com

GMDN: 41457
BUDIDI/GMN: 0850331006SaeboFlexPH



European Healthcare & Device Solutions (Ireland) Ltd.
info@europeandevicesolutions.co.uk
www.europeandevicesolutions.co.uk

Australian Sponsor:
Ausmedic Australia Pty Ltd
Unit 3, 3 Basalt Road Pemulwuy NSW
2145 1300 473 422
Performhealth.com.au



Rev. 02|2023