



**Intended use:** The Compression Orthoses are non-invasive devices intended to promote physical stability and postural control in children with impaired motor function as well as promote body awareness in children with impaired sensory function. The devices achieve their intended use through exerting pressure designed to provide and enhance deep pressure sensory input around and toward the midline of the patient's body. This mode of action is understood to improve dynamic stability and postural activation.

The Orthosis is designed to assist primary sensory deficit and improve gait. It provides full body stability and sensory input when combined with the Upper Body Orthosis. It is intended for patients with the following diagnosis: Cerebral Palsy, Down Syndrome, Autism, Sensory Processing Disorder, and various neurological disorders characterized by hypotonia, hypertonia, athetosis, muscular atrophy, poor core muscle activation, poor core stabilization, and weakness. The Orthosis can be worn at all times of the day, except under the following circumstances: 1) When the patient intends to sleep; 2) When the patient intends to be immersed in chlorinated water. There is no break-in period.

**Contraindications:** The use of the Compression Orthoses is contra-indicated in patients with seizure disorders triggered by heat or those who have cardiopulmonary impairments or ribcage restrictions.

In addition, anyone allergic to Lycra or Neoprene should not wear the Compression Orthoses.

## Warnings

Mild redness can occur at the point of the seams, this is normal, most clothing leaves red marks on the skin. However, if these red marks do not disappear within 15-20 minutes after the orthosis has been removed then the orthosis is too tight and should be exchanged for a larger size.

The Compression Orthoses should not be worn at night since they are not treated for fire resistance. In addition, the orthosis can twist while the patient is asleep leading to compression in areas or in ways not intended.

If the patient gets overly hot in the Compression Orthoses you can spray the patient with water to cool them down. If the patient is still hot you can remove the Compression Orthoses until the patient cools down and then put the Compression Orthoses back on.

If the Compression Orthoses causes the patient's feet to turn white or blue, or if the patient experiences a "tingle" sensation, remove the orthosis immediately. In this case, new measurements should be obtained. Blue or white feet are an indication that the orthosis is too small and should be exchanged for a larger size.

If the patient shows any discomfort in the Compression Orthoses or needs help with toileting, please watch the "Measuring and Fitting" video for fitting tips and suggestions. The video is on our website at <http://www.spioworks.com/pages/measuringandfitting>.

## How to Wear the Compression Orthoses

Compression Orthoses work when the patient has the correct fit providing the appropriate compression. When the Compression Orthosis is received, it will look small. However, have the patient try it on and follow the fitting recommendations and guidelines below to ensure a proper fit.

To determine if the Compression Orthosis is providing adequate compression, place your hand between the patient's body and the Compression Orthosis. When you pull your hand away from the patient's body you should feel significant resistance. If you can pull the fabric much more than 3-5 cm's from the patient's body, the system is too loose and you should go down to the next size. If you can pull away less than 3-5 cm's, the Compression Orthoses is too tight and you should go up to the next size.

## Putting the Compression Orthoses On

**Upper Body Orthosis (Long/Short Sleeve)** - Un-zip the Upper Body Orthosis and, if the patient is able, have the patient step into the Upper Body Orthosis and then feed the patient's arms through the sleeves. Remove all wrinkles from the sleeves by gradually working the fabric toward the wrists. Pull the Upper Body Orthosis back together and zip up to the top. Make sure that the sleeves are turned properly so they are not twisted. Twisted sleeves can lead to excessive compression and/or irritation in the armpits. If you slip your hand under the abdominal area, with proper tension, you should feel a snug compression. If you can pull the fabric away from the patient's body more than 3-5 cm's it is not tight enough. The hem of the Upper Body Orthosis should fit over the patient's buttocks and end at the trochanter.

**Lower Body Orthosis (Ankle/Knee Length)** - Gather each leg and thread the child's foot through the leg of the orthosis. Pull the leg up to the knee and repeat with the other leg. Gather and slowly work the Lower Body Orthosis up to the waist, then to the navel. If worn with an Upper Body Orthosis, the Lower Body Orthosis should be worn over the Upper Body Orthosis. This will allow for double compression across the hips and lower abdomen. Make sure the legs are turned properly so they are not twisted. The seams along the legs should be straight. Make sure all wrinkles are eliminated by working the excess fabric toward the ankles. If you slip your hand under the abdominal area, with proper tension, you should feel a snug compression. If you can pull the fabric away from the patient's body more than 3-5 cm's it is not tight enough.

**TLSO** - The TLSO is worn on the trunk of the body covering the shoulders, chest, abdomen and hips of the patient. The lycra panel should be worn on the front of the body. The neoprene panel should be worn on the back of the body. The neoprene panel should be attached at the sides to the lycra front panel. When donning the TLSO, attach one shoulder strap and the same side panel to the neoprene back. The patient can be standing, sitting or lying down on their back, depending on their comfort level. Slide the patient's arm through the fastened opening and attach the other shoulder strap. Place the patient on his or her stomach, on your lap, or on the floor (sitting, standing or kneel-stand are also possible). To attach the side panel, pull the TLSO down over the hips and wrap the panel snugly around the patient. Fasten the crotch strap so it is snug, not tight. The crotch strap is designed to prevent the TLSO from riding up. The TLSO should fit snugly and firmly. You may have to adjust it a few times after the initial donning to optimize the fit. If you slip your hand under the abdominal area, with proper tension, you should feel a snug compression. If you can pull the fabric away from the patient's body more than 3-5 cm's it is not tight enough. Once you have the proper compression use the small, white "Sure Fit Tabs" as markers to indicate where the panels should be attached the next time the TLSO is worn.

**Quest, TLSO With Heat Moldable Kydex Stays** - This TLSO includes two ridge heat-moldable Kydex stays. When donning the TLSO, attach one shoulder strap and the same side panel to the neoprene back. The patient can be standing, sitting or lying down on their back, depending on their comfort level. Slide the patient's arm through the fastened opening and attach the other shoulder strap. Place the patient on his or her stomach, on your lap, or on the floor (sitting, standing or kneel-stand are also possible). To attach the side panel, pull the TLSO down over the hips and wrap the panel snugly around

the patient. Fasten the crotch strap so it is snug, not tight. The crotch strap is designed to prevent the TLSO from riding up. The TLSO should fit snugly and firmly. You may have to adjust it a few times after the initial donning to optimize the fit. If you slip your hand under the abdominal area, with proper tension, you should feel a snug compression. If you can pull the fabric away from the patient's body more than 3-5cm it is not tight enough. Once you have the proper compression use the small, white "Sure Fit Tabs" as markers to indicate where the panels should be attached the next time the TLSO is worn. Once the TLSO is properly on the patient you can attach the Kydex stays where needed. The Kydex stays can be heated in an infrared or convection oven and then molded to the child's body for more intimate support. The stays should be heated between 350 - 380 F (176 -193 C) for 10-15 minutes. Check the stays often while heating. Do not heat stays unattended. **Warning: Do not heat Kydex stays above 400 F (204 C) as it could melt and give off cyanide gas.** Stays must be heated in a well ventilated area. Do not put Kydex stays into a microwave oven. When heating is complete check the stays to be sure there are no hot spots before applying to patient. Keep patient in desired position until stays cool and harden. An ice bag may be used to accelerate cooling of the stays. Once set, allow 15 minutes to completely harden. If the correct fit is not obtained, remove the product and repeat above procedure or spot treat specific areas with a heat gun.

**Expedition, TLSO With Heat Moldable Kydex X Panels** - This TLSO includes two rigid X panels that can be heat molded and inserted into the back pocket of the TLSO. Follow the donning instructions for the TLSO above, but remove the plastic X panels from the pocket before fitting. Once the front panel and pocketed back panel are attached and on the patient, select the X panel(s) that provide the appropriate level of support. The X panels are made from heat-moldable Kydex material and can be heated in an infrared or convection oven and then molded to the child's body for more intimate support. Kydex can be heated between 350 -380 F (176 -193 C). **Warning: Do not heat Kydex panels above 400 F (204 C) as it could melt and give off cyanide gas.** Panels must be heated in a well ventilated area. Do not put Kydex panels into a microwave oven. When heating is complete check the panel to be sure there are no hot spots before applying to patient. Keep patient in desired position until panel(s) cool and harden. An ice bag may be used to accelerate cooling of the panel(s). Once set, allow 15 minutes to completely harden. If the correct fit is not obtained, remove the panel(s) and repeat above procedure or spot treat specific areas with a heat gun. For maximal support mold and insert both X panels into the pocket. For significant support mold and insert the wide X panel, and for minimum support mold and insert the narrow X panel. For spot heating use a heat gun to re-mold specific areas of the panel. When the patient is no longer in need of the support provided by the X panels, they can be removed.

**X Back Panel** - The X back panel can be used in place of the standard neoprene back panel that comes with the TLSO. Remove the single layer neoprene back panel from the lycra front panel of your TLSO. Attach the back panel to the front panel around the patient. Attach one shoulder strap and the same side panel to the neoprene back. The patient can be standing, sitting or lying down on their back, depending on their comfort level. Slide the patient's arm through the fastened opening and attach the other shoulder strap. Place the patient on his or her stomach, on your lap, or on the floor (sitting, standing or kneel-stand are also possible). To attach the side panel, pull the TLSO down over the hips and wrap the panel snugly around the patient. Fasten the crotch strap so it is snug, not tight. The crotch strap is designed to prevent the TLSO from riding up. The TLSO should fit snugly and firmly. You may have to adjust it a few times after the initial donning to optimize the fit. If you slip your hand under the abdominal area, with proper tension, you should feel a snug compression. If you can pull the fabric away from the patient's body more than 3-5cm it is not tight enough. Once you have the proper compression use the small, white "Sure Fit Tabs" as markers to indicate where the panels should be attached the next time the TLSO is worn. Once the front panel and pocketed back panel are attached and on the patient, select the X panel(s) that provide the appropriate level of support. The X panels are made from heat-moldable Kydex material and can be heated in an infrared or convection oven and then molded to the child's body for more intimate support. Always remove the X panels from the neoprene pocket before heating. Kydex can be heated between 350 -380 F (176 -193 C). **Warning: Do not heat Kydex panels above 400 F (204 C) as it could melt and give off cyanide gas.** Panels must be heated in a well ventilated area. Do not put Kydex panels into a microwave oven. When heating is complete check the panel to be sure there are no hot spots before applying to patient. Keep patient in desired position until panel(s) cool and harden. An ice bag may be used to accelerate cooling of the panel(s). Once set, allow 15 minutes to completely harden. If the correct fit is not obtained, remove the panel(s) and repeat above procedure or spot treat specific areas with a heat gun. For maximal support mold and insert both X panels into the pocket. For significant support mold and insert the wide X panel, and for minimum support mold and insert the narrow X panel. When the patient is no longer in need of the support provided by the X panels, they can be removed.

**Thermoplastic Back Panel** - Remove existing neoprene back panel from the TLSO front panel and save for future use. Remove the thermoplastic back panel from the packaging. Heat the panel at 195 F to 205 F for up to 10 minutes. **IMPORTANT STEPS:** Check the back panel often. Do not leave back panel unattended while heating. When heating is complete check the inside of the back panel to be sure there are no hot spots before applying it to patient. Keep the patient in the desired position until back panel cools and hardens. An ice bag may be used to accelerate the cooling of the thermoplastic panel. Once set, remove the panel from the patient and allow 15 minutes to completely harden. If the correct fit is not obtained, remove the product and repeat above procedures or spot treat specific areas with an iron set to medium.

**Wrist Hand Orthosis** - The Wrist Hand Orthosis can be worn on either the right or the left hand. Feed the fingers and the palm into the large opening of the Wrist hand orthosis and feed the thumb into the smaller opening. If you slip your hand under the fabric, with proper tension, you should feel a snug compression. If you can pull the fabric away from the patient's body more than 3-5 cm's it is not tight enough.

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#### **After Taking the Compression Orthoses Off**

After removing the Compression Orthoses inspect the patient's skin for red marks. Mild redness is expected. If redness is excessive and does not resolve in 15 minutes, the Compression Orthoses may be too small. Contact us to discuss an exchange for next larger size.

If the inside seams irritate the patient's skin, you may turn the Compression Orthoses inside out. This will not compromise the compression or function of the Compression Orthoses.

#### **How to Care for the Compression Orthoses**

The patient or care-giver is responsible for the proper cleaning of the product. Wash the Compression Orthoses daily, or at minimum every other day, in a washing machine with cold or warm water, 30-90 F. The motion of the machine will realign the fabric fibers to obtain optimal compression. For this reason hand washing is not effective. After 3 days of wear the Compression Orthoses will be significantly stretched out if it has not been washed.

Do not use detergents with bleach and do not tumble dry. Do not use fabric softener.

After one year of daily wear and washing the device materials tend to break down, therefore, the TLSO should be discarded and a new one purchased if necessary.

**Storage**

Compression Orthoses must be stored between 30 F and 110 F with humidity between 0% and 90%, without conditioning. Keep the Compression Orthoses in the plastic bag until you are ready to put the item on the patient. Compression Orthoses must be kept away from direct sun light before use. Compression Orthoses should not be used repeatedly in chlorinated water, such as a chlorinated pool, since chlorine will break down the fabric.

**Warranty**

Each system is guaranteed for fit, materials, and workmanship for 90 days. Abuse, altering, or undue rough wear and tear will void the warranty. This includes improper washing and drying in a dryer. To provide maximum benefit a physician or therapist should monitor the use and the effect of the Compression Orthoses. If you have any questions or want to report a complaint, please contact us at the address below.