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OVERVIEW

Congratulations on purchasing the SELNERTX—the world’s first truly adjustable orthotic. This device can improve your lifestyle by helping realign how you stand, walk, and move. We spent six years and thousands of hours developing this revolutionary product based on the next generation of dynamic biomechanical research. Instead of merely trying to support the arch of the foot, the SELNERTX is designed to work with the complex biomechanics of the foot helping you achieve Optimal Clinical Alignment™. The SELNERTX can be customized to your alignment needs using the 19 settings of the

TXWHEEL. You can modify your alignment until you are most comfortable. We are very proud of the effectiveness of this revolutionary device. Because the SELNERTX is a powerful tool, **we highly recommend that you read the instructions carefully and follow the procedures to ensure proper use.**

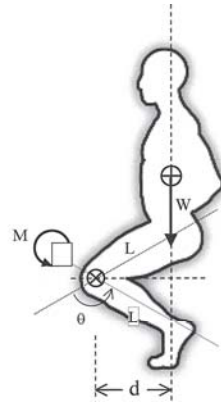
READ ALL INSTRUCTIONS BEFORE USE

The SELNERTX was designed to improve lower limb mechanical alignment, which is often helpful in allowing muscles and joints to work better. However, if you are diabetic, have poor circulation or numbness, chronic or persistent pain, or other medical problems, please check with your physician or podiatrist prior to using the SELNERTX.

Although we feel strongly that this device could make a significant difference in how you stand, walk, and move, it cannot replace the medical care provided by a physician or podiatrist.

UNDERSTANDING THE SELNERTX DIFFERENCE

When you walk, run, jump, swing, or throw, there are tremendous forces transmitted from your feet all the way up your body through your bones, muscles, and ligaments. These forces affect every aspect of your mobility, possibly leading to discomfort or even contributing to injury. These forces can affect aspects of your athletic performance as well. Too often we pay no attention to these forces or their constant effect on us. Through the use of cutting-edge biomechanical technology, we finally understand the impact of these forces on the body in motion. We have worked diligently to design and implement this first-to-market, truly



Forces Acting on Your Lower Body

reaction forces can often overload tissues if the forces are concentrated in one particular area. By realigning these forces, greater comfort and performance can often be achieved.

The SELNERTX uses a unique, highly resilient material to permit the device to flex easily, while allowing it to return to its original shape. Both the heel post and TXWHEEL bumper have a special combination of softness and resiliency. The TXWHEEL was designed to provide an audible click for precise use.

REFERENCES

1. Public Use File BGS98 Bundes-Gesundheitssurvey 1998. Berlin: Robert Koch-Institut, 2000.
2. Dreinhofer, K. E., Reichel, H., & Käfer, W. (2007). Lower limb pain. *Best Practice & Research Clinical Rheumatology*, 21(1), 135-152.

adjustable foot orthotic. The SELNERTX is a unique and powerful tool used to realign and redirect the forces acting upon the body.

The foot is an amazing and complex part of the body. The foot and ankle are comprised of 26 bones, 20 articulating joints, and hundreds of muscles, tendons, and ligaments. As a person moves, the foot interacts with the ground, and forces are created during these interactions; forces from the body to the ground and forces from the ground back to the body, which are called ground reaction forces. The structures of the foot influence the transmission of these forces through the leg. When the structures of the foot experience problems, an athlete's performance may suffer or a person may experience lower limb pain.

Unfortunately, lower limb pain is common. Studies show 1 out of 3 men and 1 out of 2 women experience some type of lower limb pain^{1,2}. There are many causes for this type of pain, including neuromuscular issues, disease, or injury². However, a common but typically overlooked reason is mechanical malalignment. Our joints are built to work in a particular manner, and when the structures of the foot are malaligned a person may experience a decrease in performance or increase in pain. We refer to pain aggravated by or resulting from malalignment as Mechanically Induced Pain™.

The SELNERTX was designed to realign the bones and ligaments of your foot, not support your arch. Realignment is a tremendous tool in helping redistribute the forces generated by walking. These ground

the arch of the foot too much. This can lead to malalignment problems and result in excessive forces moving up the leg, knee, and back. Think about it: Walking is actually falling from step to step. Each gait cycle occurs when your heel hits the ground, then your foot hits the ground, and then you push off your toes and repeat the cycle over and over. Maintaining your lower extremities in proper alignment while walking is essential for efficient gait.

The foot has a built-in stabilizing technology—the locking mechanism created by the subtalar joint. The alignment of the subtalar joint effects the performance of this locking mechanism. The key to improving the performance of your foot is to aid this natural mechanism. By aiding this mechanism with adjustments of the

TXWHEEL, a more optimal alignment can be achieved. We know that everyone's feet are different, just like everyone's eyes are different. You can buy reading glasses to improve your vision, and now you have the SELNERTX to improve your foot's alignment. This is why the SELNERTX has 19 settings to customize the device for each individual foot. Poor alignment of the foot can often lead to overloading the muscles and joints of the foot, knee, and back. Many people are walking around with malalignment problems that often go back to childhood, and yet are unaware that they even exist.

For the last 100 years, products have focused on supporting the arch of the foot. From an engineering perspective, supporting an arch is great for doors and coliseums—things that DO NOT move. Statically supporting the arch

in your foot is biomechanically incorrect, as the arch is constantly changing heights and shapes when you are moving.

The SELNERTX directly affects bone and joint alignment of the foot. Rotation of the TXWHEEL pronates or supinates the foot, essentially realigning the subtalar joint influencing the dynamic movement of the arch. After the user adjusts the TXWHEEL to the suggested range, the forces are redirected up the kinetic chain into a more natural position. While this will not necessarily repair damaged tissues, redirecting the forces to the natural position often reduces discomfort in joints, muscles, and ligaments. Therefore, by unlocking the Power of Alignment™, the SELNERTX can influence the forces moving up the kinetic chain to increase performance or reduce pain. The

unique adjustable TXWHEEL design of the SELNERTX gives the user the ability to control the forces acting upon his/her body.

GETTING ACCUSTOMED TO THE SELNERTX

The SELNERTX was designed to realign the bones, joints, and muscles of your foot and leg. Realignment occurs through positioning the TXWHEEL in one of 19 settings. Although realignment can be extremely valuable in improving comfort, it can dramatically change the demand on your muscles and joints. Because of these changes, there is an adaptation period necessary to train your body to this new alignment. Training could take as little as a few hours or as long as 3 to 4 weeks. Proceed slowly with your training

period. You should only wear the device for one hour the first day, two hours the second day, three hours the third day, etc. On the eighth day, you may begin wearing your SELNERTX full time. You should not wear your orthotics while running or participating in other sports or strenuous activity until after the first week and you are comfortable walking with the devices.

Please note that people who have less flexibility and/or more arthritic changes generally take a longer time to adapt to the new alignments. Also, we strongly recommend not going past TXWHEEL position 5 in either direction. Using the SELNERTX with the TXWHEEL in a position greater than 5 in either direction should be done carefully, slowly, and only after you have worn the SELNERTX in the lesser positions for

several weeks and your body has become accustomed to the device in lower settings. If you experience any pain or discomfort in the higher settings, please remove the SELNERTX, and move the TXWHEEL into the suggested range for your specific foot type (refer to the Foot Type Chart). When properly worn, with the TXWHEEL in the suggested range, the SELNERTX can help improve the function of your foot. By improving foot function, the SELNERTX may change the function of the muscles within your foot and the muscles entering the foot from the leg. In addition, by altering how much the foot rotates in or out, the SELNERTX can also help alter how the leg is positioned. It is important to note that damaged joints and muscles surrounding these joints are often overstressed. The power of realignment can shift the location of forces. While this device

is not intended to repair joint damage, shifting forces often reduces discomfort in the joints, muscles, and ligaments.

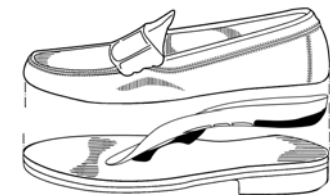
New orthotics may feel a bit odd at first, which is normal. After allowing your feet to become accustomed to the SELNERTX, use the provided Foot Type Chart to determine your foot type and adjust the SELNERTX to your desired setting based on comfort and foot type. Orthotics are not a cure-all, but proper alignment might be very helpful for Mechanically Induced Pain™.

Do not exercise or perform strenuous activities when first using this device. Do not walk on uneven or difficult terrain when first using this device.

INSTRUCTIONS FOR USE OF THE SELNERTX

SHOES

The SELNERTX must be worn in shoes that properly fit, as the orthotic must be considered a part of your foot for proper function. Certain shoes may not be compatible with your orthotics. It is important to remember the shoe connects the orthotics to the ground and if it is incorrectly placed or does not fit into your shoe, the orthotics will not provide the benefit as intended.



SELNERTX Proper Fit Within Shoe

The SELNERTX was designed to sit completely flat within your shoe. If the device is tilted or sits unevenly in your shoe, the SELNERTX will not work properly and may result in discomfort. The SELNERTX is best used in walking or running shoes, or shoes with ample space. There is a left and right side specific SELNERTX orthotic.

There are two main features to look for when evaluating for proper shoes. These criteria are true for both athletic shoes and dress shoes. First, the area on the back of the shoe is called the "heel counter." The heel counter must be stable enough to support your foot and the orthotic. If the heel counter is soft/flexible, the SELNERTX may slide in the shoe reducing the effectiveness of the orthotic.

Second, the shoe should be torsionally stable— the front of the shoe should not twist easily with respect to the back. Also, make sure the shoe bends where your toes bend. Shoes should naturally bend where your toes bend – not in the middle of the shoe.

Fit

While sitting, take the right orthotic and properly place it under your right foot (see diagram). The forward edge of the SELNERTX should fit just behind the ball of the foot when the toes are flexed. Now repeat the same process for the left foot. If the orthotic does not fit as described, you may need a different size.

In fitting an orthotic properly, it is important to understand the value of your shoes. Fit is determined by how much volume your foot and the orthotic take up in the shoe. If you feel tightness when wearing the SELNERTX during the break-in phase, try removing the TXWHEEL and placing the orthotic (without the TXWHEEL) back in your shoe with the Dual Foam Insoles. This will allow the orthotic to flex more, reduce tightness, and may improve comfort. The TXWHEEL can be reapplied at a later time for more advanced use.

Place the left orthotic into the left shoe, and the right orthotic in the right shoe. It is important that the fit of the SELNERTX is stable in your shoe. Make sure that the heel sits all the way back against the heel

counter of the shoe. There should be no gap between the orthotic and the shoe. If there is a gap, the shoe may be too narrow for the orthotic and your foot.

You should wear stockings or socks with the orthotics to minimize the possibility of skin irritation. Occasionally, your orthotics may squeak, especially if your shoes are made from leather. If this occurs, remove the orthotics from your shoes and shake a little talcum or baby powder on the SELNERTX. Then, reinsert your orthotics and continue wearing.

If you are experiencing soreness and consistent pain, stop using the SELNERTX for a couple days. When the pain subsides, try walking with the orthotics again, but

only on even surfaces. If the soreness and/or consistent pain continues, then stop use and see your physician or podiatrist.

Your orthotics may feel unusual for several weeks. You may notice some pressure points that were not there before or the heels of your shoes may feel as if they are slipping. You will be using leg and foot muscles that may have been dormant for a long time and, as a result, you may experience some discomfort.

If you are experiencing chronic or severe pain that lasts more than a day, please remove the SELNERTX from your shoes and check with your physician or podiatrist.

Never attempt to force yourself to wear orthotics, especially if you are experiencing consistent discomfort.

STEPS FOR INSERTING & ADJUSTING THE SELNERTX

STEP 1.

Insert & Wear Dual Foam Insoles (DFI)

Please remove any existing insole or arch support from your shoe. Replace the insole with the Dual Foam Insole (DFI). The DFIs have two separate layers of special moldable foam. This will permit the insoles to adapt to your unique foot. Do not insert the SELNERTX yet, walk for a few hours while the DFI conforms to your foot. After walking with the DFIs for a few hours they will contour to your foot, providing more comfort and improving fit.



Dual Foam Insoles

STEP 2.

Insert the SELNERTX

Make sure the TXWHEEL is securely fastened to the base orthotic in the orientation depicted in the attached diagram. Once the TXWHEEL is in proper neutral position (position 0, TXWHEEL at the '6 o'clock' position), place the SELNERTX orthotic within the shoe under or on top of the DFI (you can choose the placement of the DFI based on comfort). Make sure the SELNERTX lies flat within the shoe, TXWHEEL side down, and the heel of the orthotic is positioned at the very back of the inside of your shoe. The heel of the inside of your shoe should be flush with the back of your orthotic.



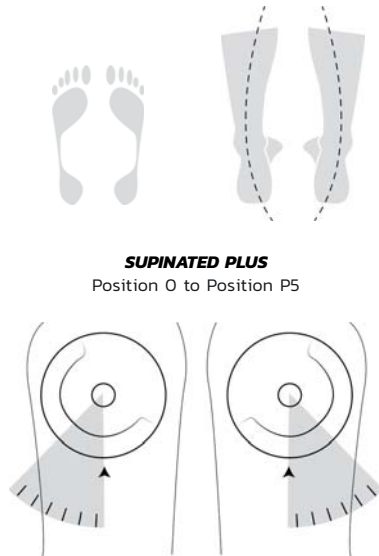
Base View of SelnertX

The TXWHEEL on the SELNERTX is removable. However, when replacing the TXWHEEL (after removal), it is essential to make sure it is properly attached. To do this, place the hole in the center of the TXWHEEL over the stem on the orthotic, using both thumbs press the TXWHEEL against the orthotic until

STEP 4.

Determine Foot Type

Every individual has a different foot type. The SELNERTX can be adjusted to your specific foot type and preferred comfort. Please refer to the Foot Type Chart to determine your foot classification. Based on your foot type, use the suggested TXWHEEL range. Keep in mind that this range is only a recommendation. The user may decide to adjust the TXWHEEL to a setting they feel most comfortable.



SUPINATED PLUS

Position 0 to Position P5

you will hear a snap indicating the TXWHEEL is securely attached to the orthotic. Make sure that the "0" on the TXWHEEL is aimed at "6 o'clock," or straight down, as shown in the Foot Type Chart indicating the "Starting Position".

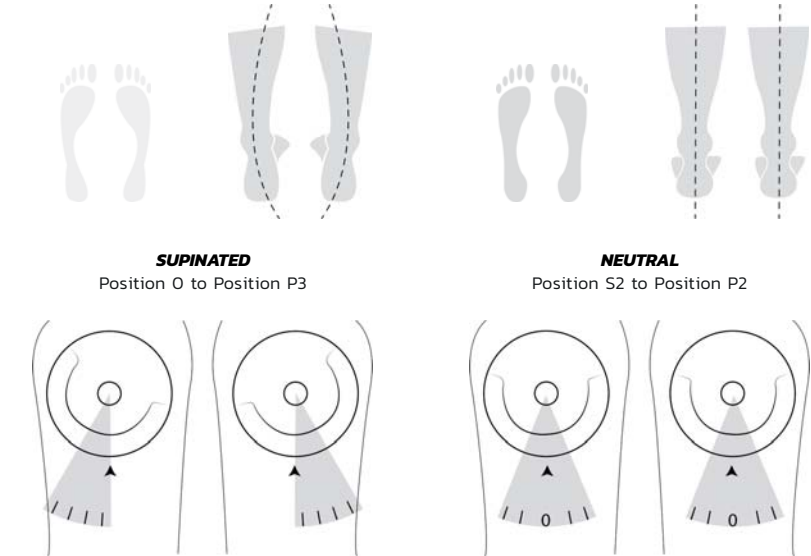
STEP 3.

Adapting to the SELNERTX

When first wearing the SELNERTX, we recommend that you start with position 0, neutral position. Starting with this position allows you and your body to become accustomed to the device and trains your body to acclimate to the SELNERTX. Since your body is training, just like exercise, you may feel minor discomfort.

The training period allows your body to adapt to a new alignment. It is important to go slowly. You should only wear the device for one hour the first day, two hours the second day, three hours the third day, etc. On the eighth day, you may begin wearing your SELNERTX full time. You should not wear your orthotics while running or participating in other sports until after the first week and you are finding them comfortable for walking.

Go slowly and be patient. If you experience pain or significant discomfort, please remove the orthotic immediately and contact your physician or podiatrist.

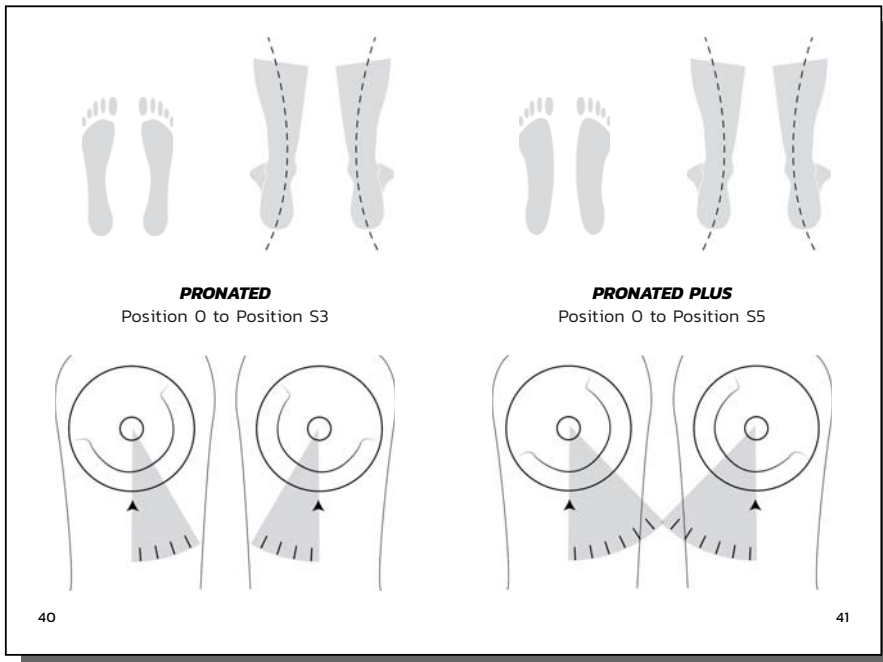


SUPINATED

Position 0 to Position P3

NEUTRAL

Position S2 to Position P2



If you have experienced any discomfort or instability you may want to return to the TXWHEEL to its original position. The Foot Type Chart suggested TXWHEEL range provides a baseline of TXWHEEL positions that may be best for you.

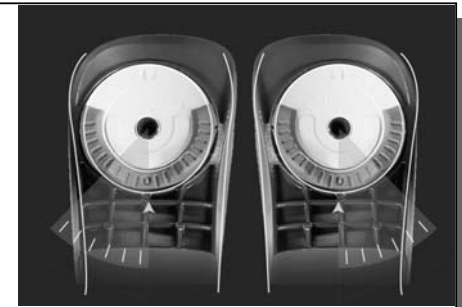
We do not recommend setting the TXWHEEL in position 6, 7, 8, or 9 until you have worn the device with the TXWHEEL in the lesser positions for several weeks and your body has become accustomed to the device in these lower settings. Never exceed TXWHEEL position 9 on either side. During the training period, refrain from high risk or strenuous physical activity such as running while wearing the SELNERTX. If at any time you experience persistent pain or significant discomfort, remove the orthotic immediately and contact your physician or podiatrist.

It is unusual for anyone to need to move the TXWHEEL past position 5 for normal use. If you want to test position 6 or higher, only do so carefully and slowly, as such positions could cause some discomfort. If you experience pain or discomfort while wearing the SELNERTX with the TXWHEEL in a position greater than 5 in either direction, remove the device and move the TXWHEEL into the suggested range for your foot type.

STEP 5.

Adjust TXWHEEL to Desired Setting

Once you have become accustomed to the SELNERTX, you can begin to improve your alignment using the TXWHEEL. The TXWHEEL has 19 different settings allowing you to adjust the orthotic to your specific foot type and comfort. If you feel that neutral position is best for you, you may continue using the device with this setting. If you would like to adjust the TXWHEEL to change your alignment, first remove the SELNERTX from your shoe. You can adjust the TXWHEEL by putting pressure on its bumpers to rotate. An audible click will be heard with each adjustment of the TXWHEEL, but be sure to turn the TXWHEEL slowly, one position



at a time. Since your body is undergoing a training period and needs to adapt to the mechanical changes, you should make adjustments gradually and with great care. It is recommended that you start by only adjusting the TXWHEEL one or two positions in either direction at any given time. Please use the device carefully for about a week prior to making any additional changes.

CLEANING AND MAINTENANCE

SELNERTX with TXWHEEL Removed



- 1** To clean the SELNERTX, remove the TXWHEEL from the orthotic.
- 2** Use mild soap with a damp cloth to gently wipe down orthotic and TXWHEEL. Using only a damp cloth, wipe down the Dual Foam Insole.
- 3** Rinse the SELNERTX and TXWHEEL in room temperature water.
- 4** Do not submerge the Dual Foam Insole in water.
- 5** Allow SELNERTX and TXWHEEL to dry completely and reassemble before continuing use.
- 6** Do not expose the SELNERTX to extreme temperatures.

*Should the teal colored material on the SELNERTX or TXWHEEL appear to wear or should any part of the device break, contact us at support@mechanicalmedicine.com.

DISCLAIMER

Medical Information

SELNERTX and the SELNERTX User Manual (the "Manual") does not provide medical advice. Information in this Manual is general in nature and is provided for informational purposes only. Our content is in no way intended to substitute for consulting a medical professional. Always consult a trained medical professional with any questions you may have regarding a medical condition. Never disregard medical advice as a result of something which you may have read in the Manual. Recommendations expressed in the Manual are the opinions and recommendations of the authors. We do not assume liability for any of the content of the material presented in the Manual. Rather, the Manual and the SELNERTX attempts to only help treat Mechanically Induced Pain™ by changing mechanical forces. The Manual and the SELNERTX does not attempt to cure or treat any other medical condition and does not represent that it shall be a cure for all pain.

If you think you may have a medical emergency, call your doctor or 911 immediately. The Manual and the owners of the SELNERTX do not recommend or endorse any specific tests, physicians, products, procedures, opinions, or other information that may be mentioned in the Manual. Reliance on any information provided in the Manual, or by the owners, directors, officers, employees, affiliates, or licensors and licensees of the SELNERTX (collectively "SELNERTX") is solely at your own risk.

Product Descriptions

We attempt to be as accurate as possible in the Manual. However, we do not warrant that product descriptions or other content of this manual are accurate, complete, reliable, current, or error-free. If the SELNERTX is not as described, your sole remedy is to return it in an unused condition.

The decision to rely on information found in the Manual is solely at your own risk. SELNERTX accepts no liability for injury or damage resulting from your decision to use any product, information or instruction by SELNERTX or found in the Manual. It should be noted that specific devices presented by SELNERTX and the Manual may not yet be specifically cleared by the FDA for use in the United States. It is emphasized that package inserts must be referred to for labeling limitations for products used in the United States.

Disclaimer of Warranties

THE SELNERTX AND THE MANUAL AND ALL CONTENT RELATED THERETO IS PROVIDED "AS IS" EXCEPT AS OTHERWISE STATED HEREIN. SELNERTX AND THE MANUAL MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO THE MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, TITLE, NON-INFRINGEMENT OR ANY OTHER WARRANTY, CONDITION, GUARANTY, OR REPRESENTATION, WHETHER ORAL, IN WRITING OR IN ELECTRONIC



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Indemnification

You hereby agree to indemnify, defend and hold SELNERTX and all its officers, directors, owners, agents, information providers,

affiliates, heirs, successors, assigns, licensors and licensees (collectively, the "Indemnified Parties") harmless from and against any and all claims, demands, liabilities, lawsuits, or costs incurred by the Indemnified Parties in connection with any claim arising out of any breach by you of the Instructions for Use in the Manual or otherwise arising from your use of the SELNERTX including, without limitation, reasonable attorneys' fees and expert fees. You shall cooperate as fully as reasonably required in the defense of any claim. SELNERTX and the Indemnified Parties reserve the right, at its own expense, to assume the exclusive defense and control of any matter otherwise subject to indemnification by you.