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INSTRUCTIONS

Patent no.:

ToeOFF[®], ToeOFF[®] 2.0, ToeOFF[®] Short, ToeOFF[®] NFR, BlueROCKER[®], BlueROCKER[®] 2.0, BlueROCKER[®] NFR, KiddieGAIT[®], NFR: AU736950, BE1005297, BE1114526, INO5297, OKI 114526, FIL005297, FIL114526, FIL005297, FIL114526, FIL005297, FIL114526, IE1005297, IE1114526, INO5297, IT1114526, CA2279225, CNZL971B1689.1, NL1105297, NL1114526, NO313656, PL194247, CH1005297, CH1114526, ES1005297, ES1114526, GB1005297, GB1114526, SE1005297, SE1114526, DE697091B4.8-08 DE69732541.5-08ATE210417, ATE289187

Ypsilon®,Ypsilon®NFR,Ypsilon® Flow: GE60208889.5-08, GB1379201, IT1379201, US6887213

Single Patient Use

Because Professional Customization is Required - a Prescription is also Required for the COMBO[™] Orthosis.

The product must be fitted by or under the supervision of a certified Prosthetist or Orthotist.

CAREFULLY READ THESE INSTRUCTIONS BEFORE USE!

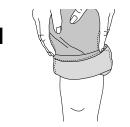
INTENDED USE

COMBOTM is intended for Hyperextension in combination with footdrop. This product is intended ONLY to be used together with a ToeOFF[®] or BlueROCKER[®]. No other combination is allowed.

The brace that you have received is actually two braces in one. The lower part, the ToeOFF[®] or BlueROCKER[®] (AFO), and the upper part, the COMBO[™] (Thigh cuff with extension control uprights). They should preferably be used together to provide increased ankle stability and/or dynamic walking assist, and help prevent hyperextension of your knee. The lower part (AFO) can also be used as a separate item when desired and authorized by your orthotist and physician.

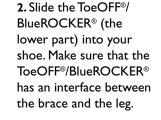
Each brace should always have an interface between the front of the brace and the leg. Tall cotton socks are suggested for increased comfort. They also keep the brace padding protected from perspiration and soiling. The COMBO[™] part has been shaped and adjusted to fit your leg. You should not make any adjustment to the COMBO[™] on your own. If you feel any discomfort or experience any skin irritation, you should immedi-ately remove the brace and contact your orthotist.

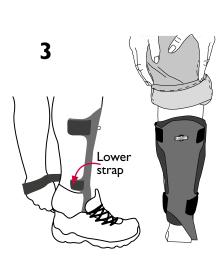
PUTTING ON YOUR BRACE



I. Pull trousers or slacks up above your knee.







3. Slide your foot into the shoe, attach and wrap the lower strap around the back of your leg and secure on the opposite side.



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4. Slide your trousers/slacks down below your knee.



5. A properly assembled COMBO[™] has two uprights joined at top with thigh cuff and at lower end with a tibia connector. Make sure that all textile parts are in place. End of uprights should have textile covers to protect skin from brace. 6

6. Position the thigh cuff on your thigh and then follow the illustrations 7 A-D below to connect the two parts as shown on this illustration.

CONNECTING THE TWO PARTS



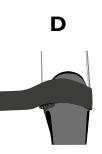
Place the Tibial Connector over the Thumb Screw.



Turn Thumb Screw 90° to the vertical position.



Place rubber molded end of strap over the Thumb Screw.



Secure strap completely around the leg so that it overlaps the Thumb Screw.

8 7. Attach the buckles for the Hyperextension Support Pad (soft pad that goes behind your knee).

REMOVING YOUR BRACE



I. Remove the strap that is wrapped around your calf.



2. Turn Thumb Screw 90° and remove the strap from the upper section and release the buckles on <u>one side</u> of the Hyperextension Support Pad.

ADAPTING TO YOUR NEW BRACE

Follow the fitter/prescriber's recommendations for gradually increasing wearing time to help become accustomed to your new brace.

DRIVING

Consult your fitter/prescriber regarding any driving limitations.

SKIN MONITORING

Check the condition of your leg and foot daily, especially if you are suffering from loss of feeling on your lower leg. In the case of skin irritation or discoloration discontinue use immediately and contact your fitter/prescriber immediately. If your ability to monitor your foot and leg is reduced, ask for assistance.

STORAGE

Take care not to leave your brace laying down to reduce possibility of someone stepping on or sitting on it. Do not expose your brace to temperature extremes. (Don't store in the car trunk on summer days or leave outdoors during freezing nights).

Also read the User Instructions for the ToeOFF[®]/BlueROCKER[®].

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Your COMBO[™] was fitted by:

MAINTENANCE

Inspect the brace daily. Make sure all parts are secure and screws properly thread into the brace. Discontinue use immediately and report any signs of damage on the product, signs of wear or any change in the performance of the device to the fitter. If your ability to monitor the brace is reduced, ask for assistance.

CLEANING

It is recommended to wash liners and straps approximately twice per week. Follow washing instructions on liner.

Remember to re-attach the liner/straps to the brace. Extra sets of straps/pad may be purchased from your fitter in order to decrease laundering frequency. The brace can be gently cleaned with mild soap and water.

Do not open the C-Shaped Velcro tabs on the Hyperextension Support Pad. Open buckles only on one side when donning and doffing. Wash the Hyperextension Support Pad with the buckles still in place. Use a washing bag.

DISPOSAL

The product shall be disposed of in accordance with relevant national and local laws and regulations. If the product may have been exposed to infectious substances or bacteria, the product should be destroyed according to relevant national and local laws and regulations covering disposal of contaminated materials.

I have reviewed and understand these instructions.

Patient Name (Print)

Parent, Caregiver, or Guardian Name

Date_

Signature (Patient, Parent, Caregiver, or Guardian)

ATTENTION ORTHOTIST OR PROSTHETIST: Make a copy of these instructions for your records and give original to patient.



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