



### The function of the REHA soles water-filled patented membrane

The construction of the water-filled membrane is essential for the function of the MEDICOVI insoles. There has therefore been an ongoing development with regard to the construction of the membrane sides throughout the years. In 1998, the idea of constructing membranes made from several layers of materials started. This development has since continued so that today the membrane sides are built up of 9 layers of materials.

With the current construction, a relatively rigid membrane is obtained, which barely changes shape when put under load and retains the structure. This means that, under load, a large hydraulic pressure is enabled to momentarily build up in the water inside the membrane. This high hydraulic pressure will then force a water film under most of the sole of the foot.

Physically, there can be only one specific pressure in a liquid. Therefore, the water film will immediately distribute the pressure load over a larger area of the sole of the foot and thus reduce the painful pressure load on exposed areas.

At the slightest movement of the body, ultra-rapid pressure changes will occur in the water film, which sensorily affects the soles of the feet with a stronger and clearer signal of the body's movement. It is this purely mechanical function that evokes the balance-improving function of the MEDICOVI insoles. The sum of the ultra-fast pressure changes forms a type of massaging movement of the soles of the feet. The high hydraulic pressure in the membrane causes this movement to occur while the weight of the body loads the sole of the feet.

The constant massaging movement of the soles of the feet increases the blood circulation and adds greater strength and endurance to the soles of the feet. Additionally, the shoe's often one-sided load on the balls of the feet will be stopped. Overall, a reduction in pressure pain is thus achieved via the construction of the membranes.

The structure of the membrane is protected through patenting (EP3082489A4, US 10,413,014 B2 and WO2015090331A1)

Over the years, the surface of the membranes has been supplemented with both a coating of cotton fabric and soft EVA top-layers. The clinical studies of diabetics' use of the MEDICOVI insoles have, however, shown a strong need for further relief of the balls of the feet through the Metatarsal Pad and arch support. Therefore, the surface coating of the membranes has now been changed to a textile / PU coating, so that the REHA insoles can be delivered with Metatarsal Pads REHA-1 and with both Metatarsal Pads and arch support REHA-2.



REHA-1



REHA -2



## Documentation of MEDICOVIS patented water-filled membrane sensory and pressure-distributing function

### Sensory Massage of the Sole of the Foot by using MEDICOVI's water filled insoles

#### Clinical study conducted in collaboration with University of Copenhagen and University of Aalborg

The function of the MEDICOVI-insoles is defined as sensory massage, which covers a new type of foot massage consisting of the following three components:

- Continuously variable pressure relief of the area under the sole of the foot.
- Constant stimulation of muscular activity and movement of the sole of the foot.
- Increased awareness relating to posture and balance.

It is not only the movement of the feet that influence the distribution of pressure on the soles of the feet thus activating the water's movement in the sole of the feet but any movement of any part of the body has the same effect. In this way the MEDICOVI-insole does not only maintain foot movements but also movement of all parts of the body.

### MEDICOVI-H20\*INSOLES (The patented water-filled membrane) Variability Of Centre of Pressure in Healthy People During Standing and Walking

#### Clinical study of University of Aalborg

Conclusion: The analysis of complexity and variability of the center of pressure movement during single-leg standing and walking revealed significant effects of the Medicovi (H20\*) insoles. The observed reduction may be a direct mechanical effect of the insert in providing a less fluctuating center of pressure movement which may indirectly increase the margin of stability **and thus may have a protective function in situations where balance is challenged.**

### Study of the effect of MEDICOVI-insoles continuous intensive sensorimotor activation and special mechanical movements of the soles of the feet in diabetics burdened with DPN (Diabetic Peripheral Neuropathy) and PDN (Painful Diabetic Neuropathy).

#### Clinical study by A. Waagstein Madsen, C. Bendix, C. K. Green, M. Johansen, S. Vindriis

**The study shows:** That the membrane-soles largely **immediately (milliseconds)** improved the balance of the most participants.

That most participants who were burdened with PND **quickly (days)** achieved a reduction and in some cases complete absence of problems with both cold feet and restlessness and pain in feet and legs at night.

That the membrane-soles during **long-term use (months)** seemed to build up more energy (glucose etc.) in the soles of the feet, as a markedly reduced growth of hard skin, increased flexibility and movement in the feet and toes, and increased sensitivity in the soles of the feet has been registered.



Sensory Massage of the Sole of the Foot by using MEDICOVI's water filled insoles



MEDICOVI-H20\*INSOLES Variability Of Centre of Pressure in Healthy People During Standing and Walking



Study of the effect of MEDICOVI-insol's continuous intensive sensorimotor activation and special mechanical movements of the soles of the feet in diabetics burdened with DPN (Diabetic Peripheral Neuropathy) and PDN (Painful Diabetic Neuropathy).



Study of water-filled membrane insoles effect on 3 diabetics with diabetic peripheral neuropathy (DPN) in the soles of the feet for a period of 8 months.



Study of the water-filled membrane-insoles effect on 3 diabetics with Diabetic Peripheral Neuropathy

### **Clinical study based on electronic balance measurement**

A collaboration with the local Diabetes Association and S. Vindriis

**The study shows:** That all 3 participants have gained better and better balance over the duration of the study. The improved balance proved both with and without membrane insoles. The use of the insoles has thus over time developed a better sensory response from the soles of the feet, which is made probable by:

- That one of the participants after approx. 7 months could began to feel the floor heat. A feeling that had been lacking for the last 10 years.
- That another got the feeling and the movement in the toes back relatively quickly.

*The use of the insoles thus seems over time to elaborate on the harmful effects of neuropathy.*

One of the participants, who had tended to drop foot, got a normal walk.

The pain caused by Morton's Metatarsalgia disappeared within the first 14 days.

The problems of pain, restlessness and tingling in the feet, respectively cold feet at night, which greatly reduced the night's sleep, disappeared relatively quickly.

Two of the participants were severely bothered by the growth of calluses. After approx. 3 months was recorded a reducing growth. At the end of the study, they no longer considered this problem to be significant.

## Balance Training - Multiple Sclerosis

### **Clinical study in cooperation with the Sclerosis Society of Denmark and S. Vindriis with 86 participants**

60% of the participants in the questionnaire survey registered an immediate balance improvement and a further improvement after 6 weeks. Another 20% registered a small positive change of the balance.

The balance effect was completely absent for approx. 11% of the participants, which is most likely due to a very low intensity in the sensory nerves of the feet, as a result of the disease.

9% of participants could not tolerate the soles activation of the sole of the foot.

The study also shows:

- That the use of the insoles provides a sustained self-reinforcing balance training, as almost everyone in the test period responded that their walking distance without aids was increased.
- That even participants with very poorly stated mobility in the beginning have had a surprisingly large improvement in both balance and mobility.
- That the insoles provide an increased blood circulation in the feet with consequent warm feet, which is highlighted by many positively.
- That the insoles for many have provided a pain-relieving effect in the musculoskeletal system.
- That the two participants who used the drop foot splint(s) with the insoles could go without the drop foot splint(s).



Balance Training - Multiple Sclerosis



### Balance Training - Parkinson's patients

#### **Clinical study based on electronic balance measurement**

A collaboration with the local Parkinson's Association

The study shows the MEDICOVI-insoles can provide an immediate improvement in balance for many Parkinson's patients, which can and has provided increased safety and greater mobility.

At the same time, the pain relief of the MEDICOVI-insoles in the feet and the musculoskeletal system proved to be beneficial for several of the participants.

Many Parkinson's patients are at high risk for falls. In order to both reduce the risk of falling and improve the balance, the reaction speed of the MEDICOVI-insoles must be ultra fast.

In this study, it is therefore shown that the reaction speed of the MEDICOVI-insoles is so fast that the insoles can continuously improve the balance through a golf drive (swing) with a duration of 0.5 sec



Balance Training -  
Parkinson's patients

### Balance training after a stroke

#### **Clinical study of the effect of the MEDICOVI-insoles in relation to the retraining of the balance of patients after a stroke, by using the Berg's Scale.**

In an exam assignment at the Århus School of Physiotherapy.

**Conclusion:** Relating the control group to the intervention group found a change in the score of 2.11 point after a period of three weeks where the BBS scores of both groups had increased. Based on a level of significance of  $\alpha = 0.05$ , the result is statistically significant.

#### **Additional**

In addition to improved balance in the study conducted, interviews with the intervention group show that the MEDICOVI-insole is a potential prevention and health improvement tool among elderly as, according to some participants, the soles gave warm feet and an increased level of activity in the form of more walks. One walked without a walking stick, and one was free from tingling in his legs. The increased number of walks in itself helps prevent inactivity.



Balance training after  
a stroke