Diaped Duosoft Plus and Diaped Duosoft Therapeutic Insoles

Clinical evidence

Comfort evaluation, Off-loading and cushioning:

Refer to 'SATRA Report – Insock Comfort Index on two insocks for ATP Manufacturing LIc. where the products tested correspond to Duosoft Therapeutic Insoles (122-003) and Duosoft Plus Insoles (122-006).

Shock absorbency:

- Leber C, Evanski PM. A comparison of shoe insole materials in plantar pressure relief. Prosthet Orthot Int. 1986 Dec;10(3):135-8. doi: 10.3109/03093648609164517. PMID: 3808918.
- Rogers, K.; Otter, SJ. & Birch, I. The effect of PORON® and Plastazote® insoles on forefoot plantar pressures. British Journal of Podiatry November 2006; 9(4): 111-114.
- Pratt, D. J., and K. S. Sanghera. "Comparison of shock attenuating materials at in-shoe temperatures and humidity." The Biomechanics and Orthotic Management of the foot — 1. Orthotics and Disability Research Centre, Derbyshire Royal Infirmary, Pratt, DJ, Johnson, GR, Derby (1987): 35-44.

Rebound characteristics:

 Roozbeh Naemi, Peter Gerth, Philip Deeney, Aoife Healy, Nachiappan Chockalingam & Juliane Schulz (2013) The effect of temperature on the rebound characteristics of material combinations commonly used in diabetic insoles, Footwear Science, 5:sup1, S91-S93, DOI: 10.1080/19424280.2013.799576

Diabetic foot

- Viswanathan, V.; Madhavan, S.; Gnanasundaram, S.; Gopalakrishna, G.; Nath Das, B.; Rajasekar, S.; Ramachandran, A. Effectiveness of Different Types of Footwear Insoles for the Diabetic Neuropathic Foot: A follow-up study. Diabetes Care 2004, 27, 474–477.
- Lavery, Lawrence A. DPM, MPH; LaFontaine, Javier DPM, MS; Higgins, Kevin R. DPM; Lanctot, Dan R. BS; Constantinides, George BS. Shear-Reducing Insoles to Prevent Foot Ulceration in High-Risk Diabetic Patients, Advances in Skin & Wound Care: November 2012 - Volume 25 - Issue 11 - p 519-524 doi: 10.1097/01.ASW.0000422625.17407.93

<u>Arthritis</u>

- Raja K, Dewan N. Efficacy of knee braces and foot orthoses in conservative management of knee osteoarthritis: a systematic review. Am J Phys Med Rehabil 2011;90:247-62
- Rheumatoid diseases including Rheumatoid Arthritis Refer to studies commented further down.

Diaped Duosoft Plus and Diaped Duosoft Therapeutic Insoles

<u>Metatarsalgia (ball of foot pain) and other foot deformities requiring forefoot</u> <u>accommodation.</u>

- B.C. Chang, J.Y. Wang, B.S. Huang, H.Y. Lin, W.C. LeeDynamic impression insole in rheumatoid foot with metatarsal pain. Clin Biomech, 27 (2) (2012), pp. 196-201.
- Bao-Chi Chang, Ding-Hao Liu, Jeffrey Liao Chang, Si-Huei Lee, Jia-Yi Wang. Plantar pressure analysis of accommodative insole in older people with metatarsalgia, Gait & Posture, Volume 39, Issue 1 (2014), pp.449-454, ISSN 0966-6362, https://doi.org/10.1016/j.gaitpost.2013.08.027.
- Grifka, Joachim K., MD Shoes and Insoles for Patients with Rheumatoid Foot Disease, Clinical Orthopaedics and Related Research®: July 1997 - Volume 340 - Issue - p 18-25

<u>Plantar Fasciitis</u>

- Lim AT, How CH, Tan B. Management of plantar fasciitis in the outpatient setting. Singapore Med J. 2016;57(4):168-171. doi:10.11622/smedj.2016069
- Landorf KB, Keenan A, Herbert RD. Effectiveness of Foot Orthoses to Treat Plantar Fasciitis: A Randomized Trial. Arch Intern Med. 2006;166(12):1305–1310. doi:10.1001/archinte.166.12.1305
- Chia, J.K., Suresh, S., Kuah, A., Ong, J.L., Phua, J.M. and Seah, A.L., 2009. Comparative trial of the foot pressure patterns between corrective orthotics, formthotics, bone spur pads and flat insoles in patients with chronic plantar fasciitis. Annals Academy of Medicine Singapore, 38(10), p.869.

Morton's Neuroma

 Oliveira H, Jones A, Jennings F, et al. OP0337 HPR EFFECTIVENESS OF CUSTOMIZED INSOLES IN PATIENTS WITH MORTON'S NEUROMA: A RANDOMIZED, CONTROLLED, DOUBLE-BLIND CLINICAL TRIAL. Annals of the Rheumatic Diseases 2019;78:252.

Compatibility studies (connection to other devices)

There are no compatibility studies to date of the use of the Duosoft Plus and Therapeutic insoles in combination with other devices.

However, there is evidence of good results when soft insoles are used in combination with specialised shoes:

- Soon N, Hye J, Jung H, Mi E, Soo H. Randomized controlled trial for clinical effects of varying types of insoles combined with specialized shoes in patients with rheumatoid arthritis of the foot. Clinical Rehabilitation. 2009;23(6):512-521. doi:10.1177/0269215508101737
- The DARCO system: PegAssist® Insoles + DARCO shoes

Refer to: https://www.darco-europe.com/insoles-accessories-pegcontour-insole.html

Diaped Duosoft Plus and Diaped Duosoft Therapeutic Insoles

Evidence of the reduction in pressure seen in different shoes combined with this insole, measured by pressure analysis, can be downloaded:

https://www.darco-europe.com/pressure-analysis.html

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