ottobock.

Genium | Genium X3

Clinically proven superiority

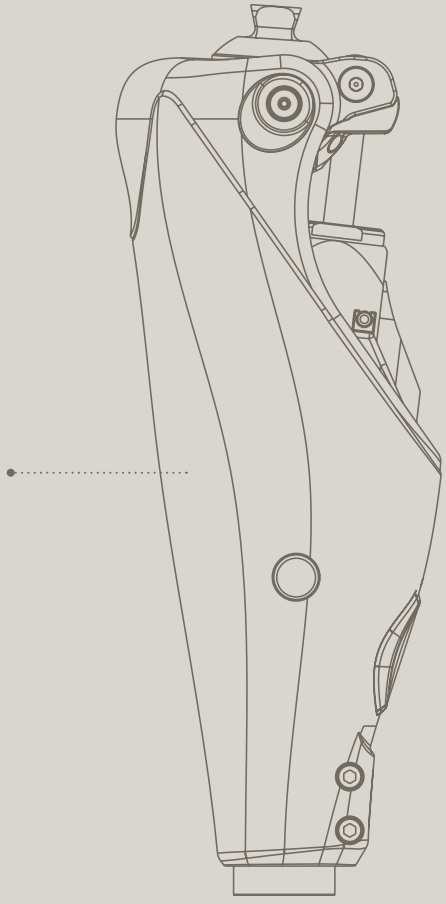
Incomparably close to nature

To this day, about 65 000 amputees around the world have been covering distances amounting to 180 million kilometers – using intelligent knee joints made by Ottobock. Altogether, they covered a distance larger than a one-way journey from the planet earth to the sun – not in a space shuttle, but with prosthetic legs.

C-Leg began to set a new standard in prosthetics in 1997 and still today, in its 4th generation, it is the most widely used and studied microprocessor-controlled knee on the market.

More than 40 studies prove the benefits of C-Leg over other prosthetic solutions.

The launch of the Genium was a breakthrough in the field of knee prosthetics. For the first time, a virtually natural replication of the physiological human gait was possible with a prosthetic leg. Valuable experience from technicians and users worldwide continually influenced the further development of the Genium product family.



The Genium X3 is based on the Genium but goes a few steps further. It is not only fully functional in fresh and salt water, but also extra-robust which makes it suitable for heavy-duty use in all sorts of jobs or family tasks.

10 publications from 2011–2015 clinically prove the superiority of the Genium family over C-Leg as a long-term industry standard.

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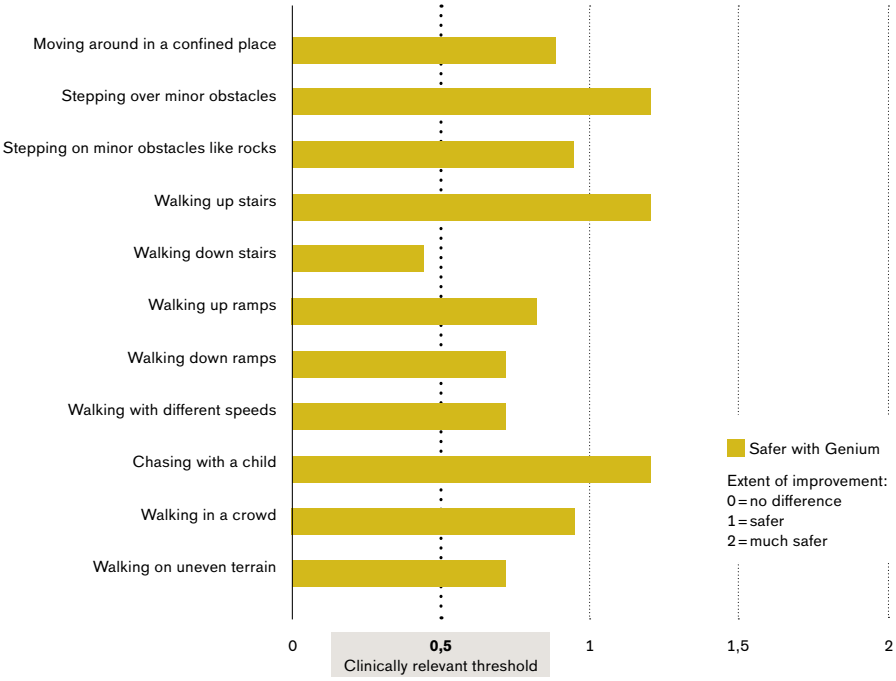
Safety

Activities of daily living

Increased safety

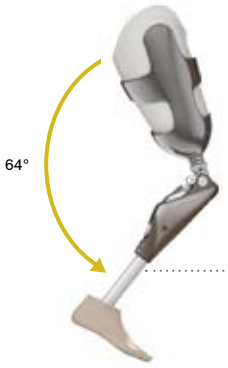
In a clinical study[1] amputees were asked to rate the importance and safety of 45 activities of daily living when using C-Leg and Genium. After 3 months of Genium use all 45 activities were rated as safer with Genium. The graph shows some examples.



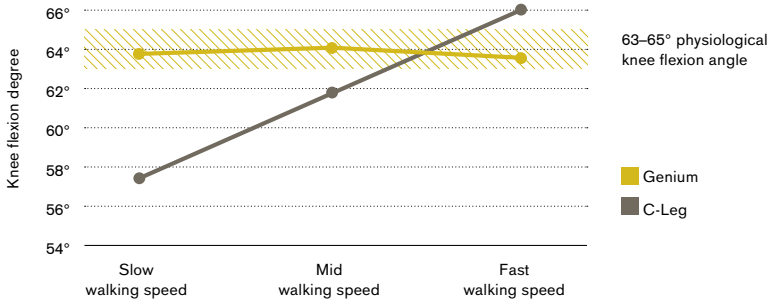
Background: Studies have investigated the risk of falling and fear of falling in lower limb amputees. Out of 435 lower limb amputees that were surveyed in a study, approximately 50 % reported falling in the past year or a fear of falling.[10] Another study reports that 50 % of the participants had a fall in the last month.[11] Fear of falling can have a big impact on a person's daily living and lead to activity restriction and loss of independence. A person's fear of falling is also highly associated with its balance confidence.[12] It was shown that the balance confidence of people with a lower limb amputation is diminished in a lot of activities as walking up and down stairs and ramps, walking in a crowed mall, picking up something from the floor or simply walking around the house.[13] Genium can reduce the risk of falling and increase the safety in activities of daily living.[1, 2]

Toe Clearance

Genium may reduce the risk of stumbling and falling



A study has shown that with Genium the maximum knee flexion angle is at approximately **64°** during swing phase at slow, mid and fast walking speed. This knee angle ensures an adequate toe clearance across all walking speeds that may result in a further reduction of stumbling and falling.[2] Also the knee demonstrated an increased adaptability and toe clearance during ramp ambulation and when wearing shoes with different weights.[3]



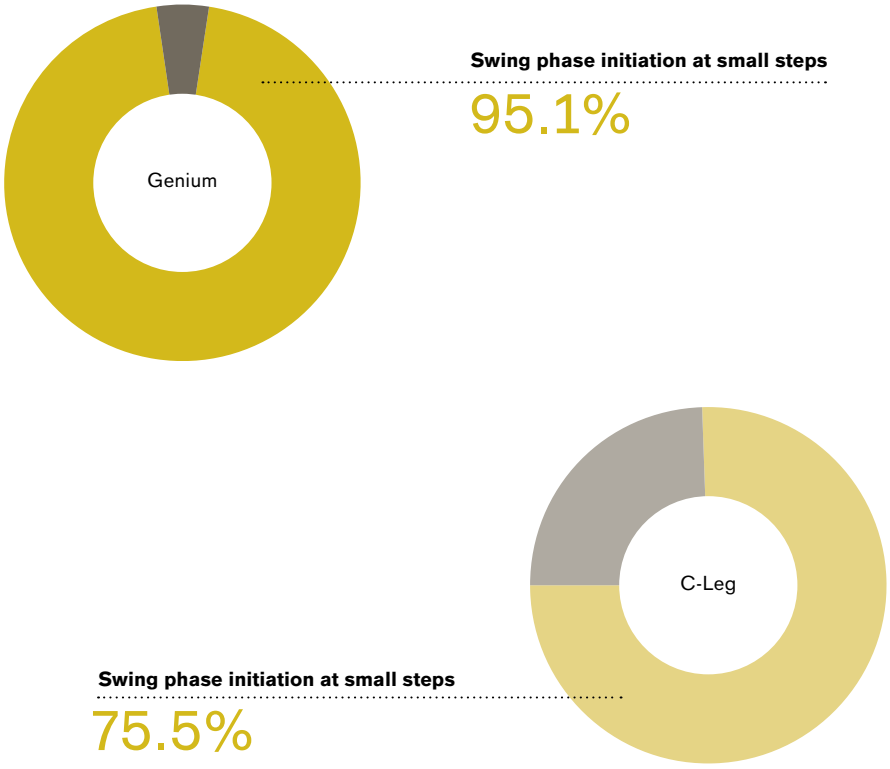
Background: Tripping is known to be a major reason of falling. A low toe clearance (the space between the tip of the toe and the floor while walking) or a high variability in toe clearance is associated with tripping.[14] Wearing heavy shoes additionally decreases the toe clearance.

Toe clearance is among other things ensured through an adequate knee flexion angle. If the knee flexion angle is too low, the risk of stumbling is increased. If it is too high, the leg might not be ready for the next step at the end of the swing phase. Sufficient toe clearance is especially critical for transfemoral amputees because of the lack of compensation mechanisms of the foot.

Swing phase initiation

Reliable swing phase initiation while taking small steps

An investigation with eleven transfemoral amputees showed that with Genium the swing phase is initiated very reliably when walking with small steps. Furthermore it was shown that it was easier for users to initiate the swing phase.[2]



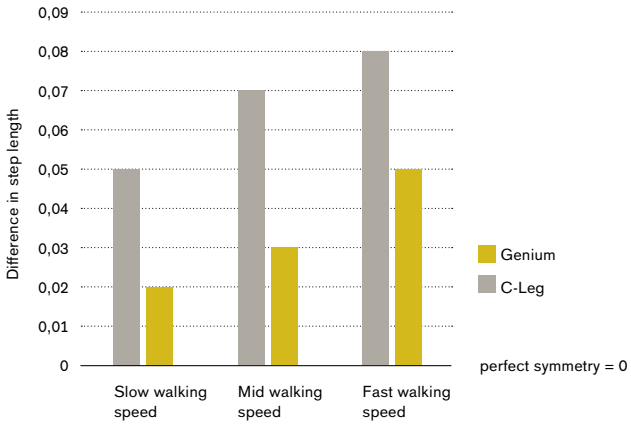
Background: A reliable swing phase initiation is very important for walking without having to concentrate too much on the prosthesis while still maintaining safety. There are some situations in daily life where it is necessary to walk with small steps. A survey of lower limb amputees showed that moving around in a confined space or walking in a crowd are such situations that are rated as very important.[1] Moreover, initiating the swing phase should not be too exhausting for the users in order to conserve other body parts as the hip and the back.

Protection

Gait Symmetry

More symmetrical gait pattern protects the body

Bellmann et al. (2012) investigated the step length symmetry of patients walking with Genium and C-Leg. With Genium walking was more symmetrical than with C-Leg.[2]



Background: People with a unilateral lower transfemoral amputation generally have an asymmetrical gait.[15] Walking with such a gait pattern can lead to some secondary problems in the sound leg, the residual limb and the back. Clinical studies have shown that lower limb amputees could have an increased risk of

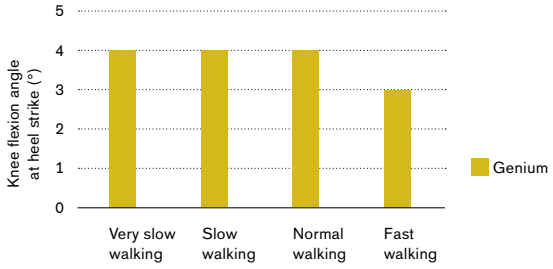
- osteoarthritis in the sound leg.[16,17]
- osteoporosis in the residual limb.[16]
- pain in the back and in the sound leg.[16,17]

Osteoporosis, osteoarthritis and pain may lead to difficulties in activities of daily living and a reduced quality of life.[19,20] Therefore it is important for lower limb amputees to decrease the risk of those secondary problems. Genium can reduce gait asymmetries and enable amputees to walk with a more natural gait pattern.[2,3] This is an important contribution to keep the sound leg healthy.

Knee flexion at heel strike

More natural walking with PreFlex

A biomechanical study confirmed that with Genium the knee is 3 – 4° pre-flexed at heel strike across different walking speeds.[3]



Background: During normal gait, the knee is flexed a few degrees at the beginning of the stance phase. This is done for reasons of shock absorption, stabilisation of the knee and forward progression.[21] With most knee joints this is not possible and people step on a fully extended or even hyperextended leg.[22, 23] With Genium PreFlex the knee is already flexed at 4° at heel strike and also allows controlled flexing of the knee during stance phase.

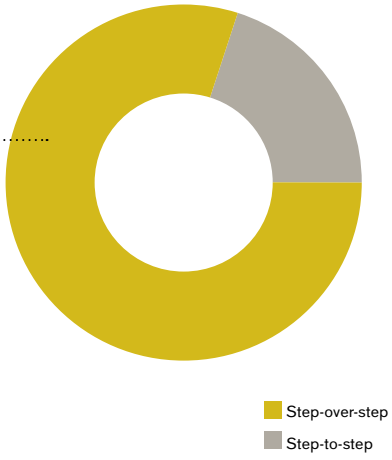
Climbing stairs

Climbing stairs with a natural step-over-step pattern

With most conventional as well as the majority of microprocessor controlled knees it is only possible to climb stairs with a step-to-step pattern. This obviously puts a higher stress on the sound leg. Since 2011 Genium allows users worldwide to walk upstairs in a well-proven, natural step-over-step pattern relieving the sound side.[4,5,6,7]

Out of all users who were not able to walk step-over-step before

80% could use this pattern with Genium within one day.[4] This walking pattern was shown to reduce the loading of the sound leg to a more physiological range.[4,5]



Endurance

Exhaustion while walking

Walking is perceived as less exhausting with Genium

Study participants were asked to rate their perceived exhaustion while walking with Genium and C-Leg at different speeds and distances. Walking with Genium was ranked as less exhausting than with C-Leg.[8]

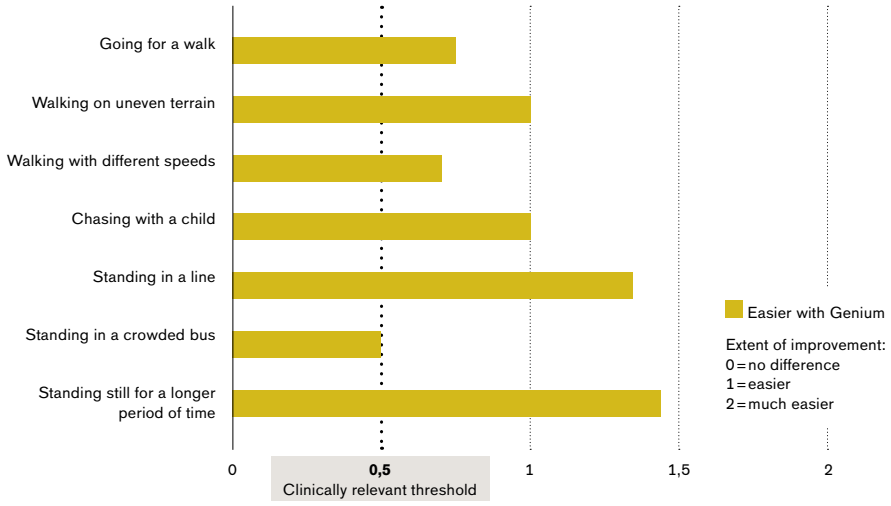
Background: Lower limb amputees need up to 34% more energy while walking than non-amputated individuals.[24] Especially on inclines and declines the energy expenditure is even higher. This can lead to a limitation in the activities of daily living for people walking with a lower limb prosthesis.

With Genium walking becomes more efficient as part of the energy at heel strike is converted into a forward movement.[25]

Difficulty of activities of daily living

Daily activities are perceived as less difficult with Genium

Amputees rated the perceived difficulty of activities of daily living with C-Leg and Genium.[1]
The graph shows some activities that are expected to require a high level of endurance and that were rated to be easier with Genium at a clinically relevant level.



Quality of Life

Impact on quality of life and overall satisfaction

Genium has the ability to improve the quality of life

20 amputees were asked to rank their quality of life using the Prosthesis Evaluation Questionnaire. Genium was compared to C-Leg. There was a gain in quality of life when using Genium.[10]

Item	Significantly improved	Improved
Natural standing with the prosthesis	✓	
Feeling of balance		✓
Ability to walk in confined spaces	✓	
Going down stairs	✓	
Ability to walk up steep hills	✓	
Ability to walk down steep hills	✓	
Ability to walk on slippery surfaces	✓	
Satisfaction with the prosthesis		✓
Satisfaction with walking in general	✓	

Background: It is known that lower limb amputees are at risk to have a reduced quality of life.[26] People often suffer from skin related problems, inability to navigate in certain environments or to walk quickly or they experience pain in the residual limb, the sound leg or phantom pain. These and other factors can affect the quality of life negatively.

Genium has the ability to improve the general well-being and the satisfaction with walking while reducing social burden.[9]

References of studies investigating Genium

1. Kannenberg, A.; Zacharias, B.; Mileusnic, M.; Seyr, M.; Kannenberg, Andreas; Zacharias, Britta et al. (2013): Activities of Daily Living: Genium Bionic Prosthetic Knee Compared With C-Leg. In: JPO Journal of Prosthetics and Orthotics 25 (3), S. 110 – 117. DOI: 10.1097/JPO.0b013e31829c221f.
2. Bellmann, Malte; Schmalz, Thomas; Ludwigs, Eva; Blumentritt, Siegmar (2012): Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. In: Arch Phys Med Rehabil 93 (3), S. 541–549. DOI: 10.1016/j.apmr.2011.10.017.
3. Lura, Derek J.; Wernke, Matthew M.; Carey, Stephanie L.; Kahle, Jason T.; Miro, Rebecca M.; Highsmith, M. Jason (2015): Differences in knee flexion between the Genium and C-Leg microprocessor knees while walking on level ground and ramps. In: Clinical Biomechanics 30 (2), S. 175 – 181. DOI: 10.1016/j.clinbiomech.2014.12.003.
4. Bellmann, Malte; Schmalz, Thomas; Ludwigs, Eva; Blumentritt, Siegmar (2012): Stair ascent with an innovative microprocessor-controlled exoprosthetic knee joint. In: Biomed Tech (Berl) 57 (6), S. 435 – 444. DOI: 10.1515/bmt-2011-0029.
5. Blumentritt, Siegmar; Bellmann, M.; Ludwigs, Eva; Schmalz, Thomas (2012): Zur Biomechanik des mikroprozessorgesteuerten Prothesenkniegelenks Genium. In: Orthopädie-Technik 01 (12), S. 24 – 35.
6. Highsmith, M. Jason; Kahle, Jason T.; Lura, Derek J.; Lewandowski, Amanda L.; Quillen, William S.; Kim, Seok Hun (2014): STAIR ASCENT AND RAMP GAIT TRAINING WITH THE GENIUM KNEE. In: Technology & Innovation 15 (4), S. 349–358. DOI: 10.3727/194982413X13844488879267.
7. Aldridge Whitehead, Jennifer M; Wolf, Erik J.; Scoville, Charles R.; Wilken, Jason M. (2014): Does a microprocessor-controlled prosthetic knee affect stair ascent strategies in persons with transfemoral amputation? In: Clinical orthopaedics and related research 472 (10), S. 3093–3101. DOI: 10.1007/s11999-014-3484-2.
8. Highsmith, M. Jason; Kahle, Jason T.; Lura, Derek J.; Dubey, Rajiv V.; Carey, Stephanie L.; Quillen, William S.; Mengelkoch, Larry J. (2014): Short and Mid-Distance Walking and Posturography With a Novel Microprocessor Knee. In: Technology & Innovation 15 (4), S. 359–368. DOI: 10.3727/194982413X13844488879302.
9. Highsmith, M. Jason; Kahle, Jason T.; Miro, Rebecca M.; Lura, Derek J.; Dubey, Rajiv V.; Carey, Stephanie L. et al. (2014): Perceived differences between the Genium and the C-Leg microprocessor prosthetic knees in prosthetic-related function and quality of life. In: Technology & Innovation 15 (4), S. 369–375. DOI: 10.3727/194982413X13844489091297.

Other references

10. Miller, W. C.; Speechley, Mark; Deathe, B. (2001): The Prevalence and Risk Factors of Falling and Fear of Falling Among Lower Extremity Amputees. In: Arch Phys Med Rehabil 82 (8), S. 1031–1037.
11. Gauthier-Gagnon, C.; Grisé, M. C.; Potvin, D. (1999): Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. In: Arch Phys Med Rehabil 80 (6), S. 706–713.
12. Myers, A. M.; Powell, L. E.; Maki, B. E.; Holliday, P. J.; Brawley, L. R.; Sherk, W. (1996): Psychological indicators of balance confidence: relationship to actual and perceived abilities. In: The journals of gerontology. Series A, Biological sciences and medical sciences 51 (1), S. M37-43.
13. Miller, W. C.; Speechley, Mark; Deathe, A. B. (2002): Balance Confidence Among People With Lower-Limb Amputations. In: Phys Ther 8 (9), S. 856–865.
14. Begg, Rezaul; Best, Russell; Dell'Oro, Lisa; Taylor, Simon (2007): Minimum foot clearance during walking: Strategies for the minimisation of trip-related falls. In: Gait & Posture 25 (2), S. 191–198. DOI: 10.1016/j.gaitpost.2006.03.008.
15. Jaegers, S.M.H.J; Arendzen, J.H; Jongh, H.J de (1995): Prosthetic Gait of Unilateral Transfemoral Amputees: A Kinematic Study. In: Arch Phys Med Rehabil 76, S. 736–743.
16. Burke, M. J.; Roman, V.; Wright, V. (1978): Bone and joint changes in lower limb amputees. In: Ann. Rheum. Dis. 37 (3), S. 252–254.
17. Kulkarni, J.; Adams, J.; Thomas, E.; Silman, A. (1998): Association between amputation, arthritis and osteopenia in British male war veterans with major lower limb amputations. In: Clin Rehabil 12 (4), S. 348–353.
18. Ephraim, Patti L.; Wegener, Stephen T.; MacKenzie, Ellen J.; Dillingham, Timothy R.; Pezzin, Liliana E. (2005): Phantom Pain, Residual Limb Pain, and Back Pain in Amputees: Results of a National Survey. In: Arch Phys Med Rehabil 86 (10), S. 1910–1919. DOI: 10.1016/j.apmr.2005.03.031.
19. Kotz, Krista; Deleger, Stephane; Cohen, Richard; Kamigaki, Alisa; Kurata, John (2004): Osteoporosis and health-related quality-of-life outcomes in the Alameda County Study population. In: Preventing chronic disease 1 (1), S. A05.
20. Jakobsson, Ulf; Hallberg, Ingalill Rahm (2002): Pain and quality of life among older people with rheumatoid arthritis and/or osteoarthritis: a literature review. In: Journal of clinical nursing 11 (4), S. 430–443.
21. Winter, David A. (1991): The biomechanics and motor control of human gait. Normal, elderly and pathological. 2nd ed. Waterloo, Ont: University of Waterloo Press.
22. Kaufman, K. R.; Levine, J. A.; Brey, R. H.; Iverson, B. K.; McCrady, S. K.; Padgett, D. J.; Joyner, M. J. (2007): Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. In: Gait & Posture 26 (4), S. 489–493. DOI: 10.1016/j.gaitpost.2007.07.011.
23. Segal, Ava D. Orendurff Michael S.; Klute, Glenn K.; McDowell, Martin L.; Pecoraro, Janice A.; Shofer, Jane; Czerniecki, Joseph M. (2006): Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. In: JRRD 43 (7), S. 857–870.
24. Chin, Takaaki; Sawamura, Seishi; Shiba, Ryouichi; Oyabu, Hiroko; Nagakura, Yuji; Takase, Izumi et al. (2003): Effect of an Intelligent Prosthesis (IP) on the Walking Ability of Young Transfemoral Amputees. In: American Journal of Physical Medicine & Rehabilitation 82 (6), S. 447–451. DOI: 10.1097/01.PHM.0000069191.20125.38.
25. Kampas, Ph.; Seyr, M. (2011): Technologie und Funktionsweise des Genium-Prothesenkniegelenks. In: Orthopädie-Technik 12 (11), S. 898–903.
26. Hagberg, K.; Brånemark, R. (2001): Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems. In: Prosthet Orthot Int 25 (3), S. 186–194.

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