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Evidence Summary
Kenevo® Microprocessor Stance Control Knee

	Mobility need or deficit of the patient	Proven benefits of MPK/Kenevo in K2 patients
Safety	Patient often stumbles and/or falls	MPK have been demonstrated to significantly reduce falls by up to 80%, significantly improve indicators for the risk of falling, and to reduce the frequency of stumbles.
Safety	Patient avoids activities of daily living due to safety concerns and lack of balance and/or balance confidence	MPK/Kenevo have been shown to improve the risk of falling, balance and balance confidence. This may result in the patient doing more activities with the prosthesis.
Slope negotiation	Patient has to ambulate on slopes/hills on a regular basis and struggles with slope descent and/or has to descend slopes and hills faster.	MPK have been shown to improve slope and hill negotiation with a more natural gait pattern and to significantly improve downhill walking speed.
Stair negotiation	Patient has to ambulate on stairs on a regular basis and struggles with stair descent, needs to descent stairs faster.	MPK have been demonstrated to significantly improve the quality of stair descent. This is an indicator of improved balance confidence and allows for descending stairs much faster.
Negotiation of uneven terrain /obstacles in the walkway	Patient has to ambulate on uneven terrain and/or clear obstacles in the walkway on a regular basis and struggles to do so and/or has to ambulate faster (e.g. for chasing kids).	MPK have been shown to have superior safety and allows for significantly walking faster on uneven terrain and obstacle courses.
Cognitive demand/multi-tasking during walking	Patient has to do concurrent activities while walking with the prosthesis on a regular basis and struggles with these activities (e.g. needs to stop walking or walk slower)	MPK have been demonstrated to increase multitasking capacities and cognitive burden while walking with the prosthesis.
Overall mobility	Patient is a limited community ambulator (MFCL-2, K2)	MPK have been shown to reduce uncontrolled falls by up to 80%; improve validated indicators of the risk of falling; increase walking speed on level ground by 14-25%, on uneven terrain by up to 20%, and slope descent by 30%; and improve stair negotiation. About 50% of K2 patients in the studies were able to improve their mobility to K3. Kenevo has been found to reduce additional wheelchair use from 87% to 37%.

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Evidence Summary
Kenevo® Microprocessor Stance Control Knee

Safety: Reduced stumbles and falls

Several clinical and biomechanical studies have investigated the safety of prosthesis use as well as balance and balance confidence of individuals with patients with Medicare Functional Classification Level 2 (MFCL-2, K2, limited community ambulator) while walking with a prosthesis. A systematic review (1) analysed a total of six studies of sufficient methodological quality that compared the safety of microprocessor controlled prosthetic knees (MPK) with that of non-MP controlled prosthetic knees (non-MPK) in subjects with MFCL-2 mobility. Hafner et al. (2) and Kahle et al. (3) observed persons with a transfemoral amputation transitioning from a non-MPK to a C-Leg prosthesis to collect data on stumbles and falls. Hafner et al. (2) found a significant 80% reduction in the number of uncontrolled falls ($p<.01$) and a significant reduction in the frequency of stumbles ($p<.05$). Kahle et al. (3) reported a statistically significant 57% reduction in stumbles ($p=0.006$) and a significant 64% reduction in falls ($p=.03$) in their mixed sample of subjects with MFCL-2 and -3 mobility. A systematic review that analysed only the subgroup of this study with MFCL-2 mobility found a significant 80% reduction in falls ($p<.05$) in this patient subgroup (1). The significant reduction in falls was recently confirmed by a study of Kaufman et al. (4) that enrolled 50 patients with MFCL-2 mobility who were randomized to transition from their customary non-MPK to one out of four different MPK ($p=.01$). Burnfield et al. (5) and Lansade et al. (6) studied the effect of using MP stance control knees, the Ottobock Compact (5) or Kenevo (6), respectively, on validated indicators of the risk of falling in individuals with MFCL-2 mobility. Compared to non-MPKs, the use of the Compact significantly improved the average time to complete the Timed-up-and-go-test (TUG) by 28% from 24.5 sec to 17.7 sec ($p=.018$) (5). In the study with 27 subjects using the Kenevo, the median time required to complete the TUG was significantly reduced from 21.4 sec to 17.9 sec ($p=.001$) (6). Thus, in both studies, the TUG time decreased well below the established threshold of 19 sec that indicates an increased risk of multiple falls in below-knee amputees when using a MP stance control knee (7).

Safety: Improved balance and balance confidence

Balance and balance confidence with the prosthesis are related to and/or associated with falling, fear of falling, and activity avoidance in persons with an above-knee amputation (8-14). Burnfield et al. assessed balance confidence in subjects with MFCL-2 mobility with the validated Activity-specific balance confidence (ABC) scale that improved significantly from 60.1 to 75.7 ($p=.001$) when using the MP stance control knee Compact as compared to non-MPKs (5). Scores below 67 indicate an increased risk of falling (8-10) and are associated with fear of falling and avoidance of activities (8, 15, 16). Kaufman et al., in their study that had enrolled 50 subjects with MFCL-2 mobility, saw a significant increase in median activity per day ($p=.02$) and spent significantly less time sitting ($p=.01$) when using a MPK, indicating an improved confidence in the prosthesis (4). This is supported by the findings of Theeven et al. (17) who found significantly improved performance in activities of daily living (ADL) and community ambulation in their study with 30 individuals with MFCL-2 mobility when using a MPK compared to their customary non-MPK. The biggest improvements were seen in activities that were performed with the arms and hands but required good lower body stability to execute (17). Likewise, Lansade et al. demonstrated a significant improvement in ADL performance assessed with the Locomotor Capabilities Index (LCI-5) in their study with 27 patients with MFCL-2 mobility using Kenevo as compared to non-MPKs (6). Similarly, Hafner et al. found a significantly increased multi-tasking ability (p=.04) of individuals with MFCL-2 mobility while walking with the C-Leg, indicating an improved confidence in the prosthesis (2). An observational study with 29 subjects assessing Kenevo as compared to NMPK typically prescribed and fit in patients with MFCL-2 mobility found that the percentage of participants who experienced no falls at all within 8 weeks increased from 45% to 72% (n.s.), the percentage of subjects who experienced no stumbles at all increased from 8% to 50% (p=.044), and 50% of individuals reported a reduction in the fear of falling when using the Kenevo (18).

Summarizing all studies with individuals with MFCL-2 mobility that had investigated the safety of MPKs compared to non-MPKs, a systematic review of the literature (1) and two more recent bigger clinical studies (4, 6) have concluded that MPK significantly reduced falls and significantly improved indicators for the risk of falling as well as balance and balance confidence.

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Improved slope descent

Ambulation on sloped terrain such as ramps and hills is associated with increased potential for slipping, loss of balance, and falling. Among the many causes for this is the fact that ramp and slope walking requires changes in the range of motion and strength compared to traditional stepping patterns used to traverse flat ground (2, 6). Able-bodied people use reciprocal (step-over-step) slope and hill descent, in which the supporting leg lowers the whole body down using knee flexion controlled by an eccentric contraction of the quadriceps muscle while the swinging leg swings and lands past the supporting leg. Usually, the step length is even between both legs. In above-knee amputees, most non-microprocessor controlled prosthetic knee mechanisms do not allow for any or enough knee flexion during weight-bearing to lower the body with the supporting prosthetic leg or are too difficult to control for most patients to do so safely (2, 7). That's why above-knee amputees usually use a step-to or even a side-step pattern to descend slopes and hills. In the step-to pattern, the supporting sound leg lowers the body using knee flexion controlled by an eccentric contraction of the quadriceps while the prosthetic leg swings and lands past the sound leg. Then the sound leg is positioned next to the prosthetic leg to become the supporting leg again for lowering the body down for the next step with the prosthetic limb (5, 6). The side-step pattern is similar to the step-to pattern, but in addition the patient turns the whole body to one side to descend the slope not with a straight but oblique step-to pattern to further reduce the downhill-slope force to be controlled (3, 4, 6). Both patterns allow for only slow slope and hill descent, with the side-step pattern being even slower than the straight step-to pattern and expose the patient as a disabled person to the public. In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1, 3, 8, 9), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (5, 11), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (5). Consequently, patients with MFCL-2 mobility have been demonstrated to significantly improve their downhill gait pattern and significantly increase their downhill walking speed by 27-36% ($p=.002/<.001$) when using a MPK as compared to a non-MPK (1, 3, 5).

Evidence Summary
Kenevo® Microprocessor Stance Control Knee

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Improved negotiation of uneven terrain and obstacles in the walkway

Negotiation of uneven terrain and clearance of obstacles in the walkway are common activities in daily living. As most non-microprocessor controlled knee mechanisms have been designed for ambulation on level ground (7-9), uneven terrain and obstacles in the walkway expose above-knee amputees to an increased risk of stumbling and falling (8-9). Therefore, many patients usually avoid walking on uneven terrain or walkways with obstacles, or negotiate them very cautiously and slowly. In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1-4), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (5, 6), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (5). Consequently, timed walk tests on uneven terrain and obstacle courses have shown that patients with MFCL-2 mobility using MPK are able to negotiate these terrains at significantly faster walking speeds (2, 3). Uneven terrain may be negotiated 20% faster ($p=.001$) (3) and obstacle courses 11% faster ($p=.02$) without and 12 faster ($p=.02$) with a concurrent mental task (2). Thus, above-knee amputees with MFCL-2 mobility are able to negotiate uneven terrain and clear obstacles in the walkway significantly better and faster with a MPK than with any non-microprocessor controlled knee.

Evidence Summary
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Improved stair descent

Stairs are often encountered barriers in daily living and require greater lower-extremity range of motion and strength to negotiate, compared to level ground walking. Able-bodied people use reciprocal (step-over-step) stair descent, in which the supporting leg lowers the whole body down to the next step where the swinging leg becomes the supporting leg after landing. In above-knee amputees, most non-microprocessor controlled prosthetic knee mechanisms do not allow for any or enough knee flexion during weight bearing to lower the body with the supporting prosthetic leg or are too difficult to control for most patients to do so safely (4-6). That´s why above-knee amputees usually use a step-to pattern to descend stairs: The supporting sound leg lowers the body down using an eccentric contraction of the quadriceps to control knee flexion allowing the patient to land on the next step with the prosthetic leg. Then the sound leg is positioned on the same step next to the prosthetic leg to become the supporting leg again for lowering the body down to the next step (2, 4, 5, 6). This step-to pattern allows for only slow stair descent and exposes the patient as a disabled person. In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1-3, 8), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (7, 9), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (7). Consequently, patients with MFCL-2 mobility have been demonstrated in several studies to significantly improve their gait quality when descending stairs ($p=.04$ / $p=.008$) and adopt a significantly more natural stair descent pattern in which the supporting prosthetic leg may even be used to lower the body down to the next step (1-3). This gait pattern is considerably faster than a step-to pattern and does not expose them as disabled persons to the public.

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Reduced cognitive demand / Improved multitasking capacity while walking

The need to execute a concurrent task while walking is a common activity in daily living. As most non-microprocessor controlled knee (NMPK) mechanisms have been designed for ambulation on level ground and require a permanent alertness of the patient to actively stabilize the knee (5-7), above-knee amputees usually spend a lot of concentration and mental energy on screening their walkway for any kind of perturbation (2, 5, 6, 7). Therefore, their capacity to execute a concurrent task while walking with the prosthesis is considerably limited. In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (2, 3, 8, 9), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (4, 10), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (4). Consequently, tests assessing the self-reported ability for multitasking while walking with the prosthesis demonstrated a significant improvement by 21% ($p=.04$) when patients with MFCL-2 mobility were using the C-Leg as compared to NMPK (2). An observational study with 29 subjects assessing Kenevo as compared to NMPK typically prescribed and fit in patients with MFCL-2 mobility found that 79% of participants reported much less or less concentration required to walk with Kenevo (1). Thus, MPK may reduce cognitive demand and improve capacity for multitasking while walking with the prosthesis in patients with MFCL-2 mobility.

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Improved overall mobility, especially in K2 patients

The more proximal the amputation, the greater is the physical and functional impairment to the individual, including a decreased likelihood of regaining household or community ambulation and an increased risk of falling (13-15). In subjects with an above-knee amputation, the prosthetic knee is a very important component, tasked with restoring knee biomechanics while at the same time providing maximum stability and safety. Most non-microprocessor controlled knee mechanisms have been designed for ambulation on level ground and require a permanent alertness of the patient to actively stabilize the knee in case of any pertubations (8-10). In subjects with MFCL-2 mobility, MPK have been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1-3, 16), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$ / $p=.001$) (4, 17), and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (4). Consequently, many patients are able to improve their overall mobility when using the C-Leg. Two studies demonstrated that 44% (3) or 50% (2), respectively, of patients with MFCL-2 mobility increased their overall mobility level to MFCL-3. Performance-based outcome measures suggest that these patients may be able to walk about 14-25% faster (p=.01 to .000) on level ground (1, 3, 5), around 20% quicker (p=.008) on uneven surfaces (1, 3), and descend a slope 30% faster (p=.002 to .001) when using the C-Leg (1, 2, 4). Furthermore, negotiation of stairs is significantly improved (p=.04 to .008) (1-3) and patients are enabled to perform many activities of community ambulation and in the house that are considered typical of MFCL-3 mobility (1, 6, 7). In addition, an observational study with 29 subjects assessing Kenevo as compared to NMPK typically prescribed and fit in patients with MFCL-2 mobility found that when using the NMPK, 87% of patients reported to use a wheelchair with their prosthesis. When using Kenevo, only 37% of subjects (p=.0046) still required an additional wheelchair (18). It is therefore no longer justified to generally withhold microprocessor-controlled prosthetic knees from patients with MFCL-2 mobility.

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