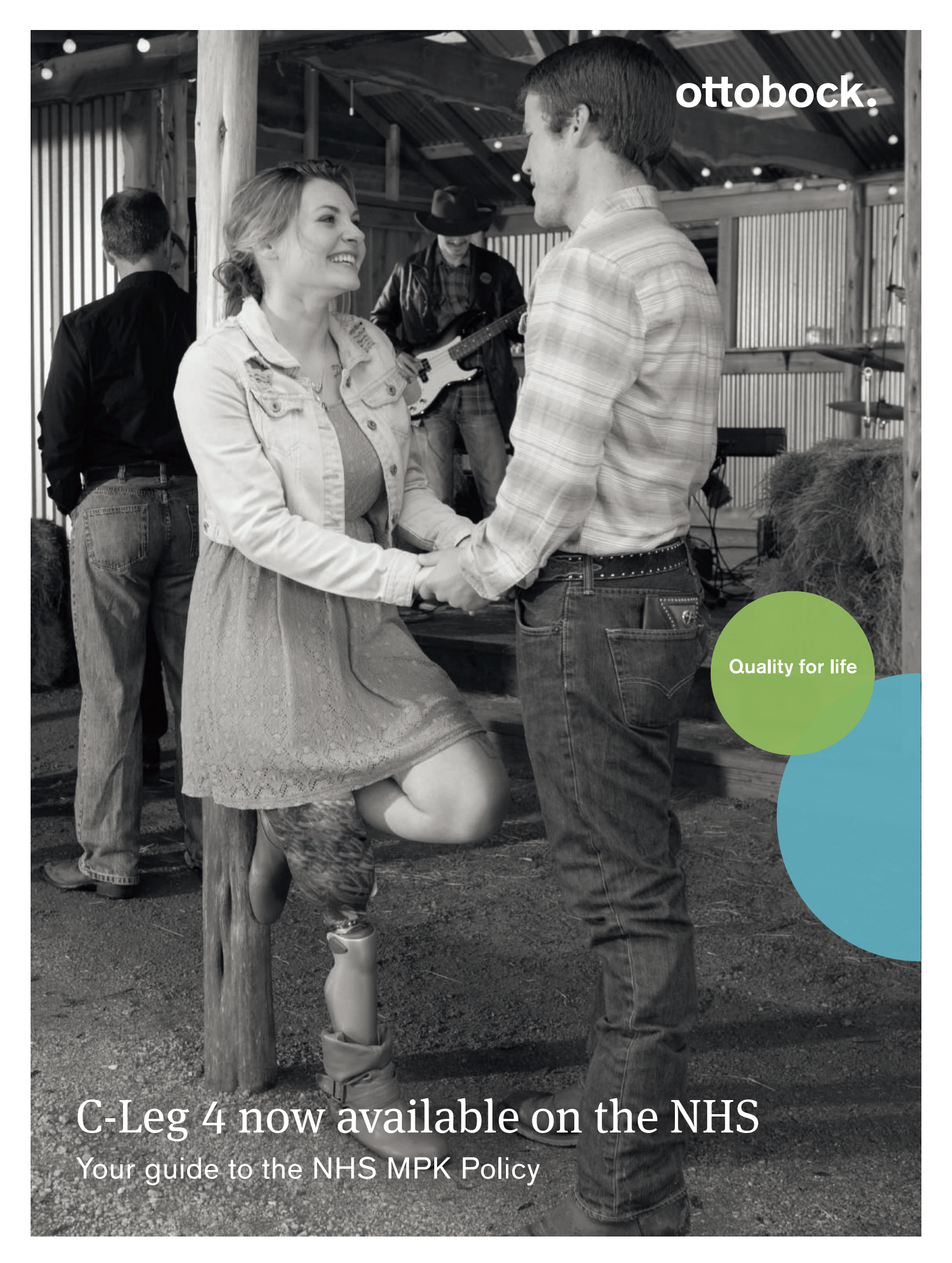




ottobock.

Quality for life

C-Leg 4 now available on the NHS

Your guide to the NHS MPK Policy

NHS Microprocessor Knee Funding

How you can be fitted with a C-Leg 4

NHS England has made the decision to approve the funding of microprocessor controlled knees (MPKs) for those living with above knee, through knee and hip disarticulation amputations.

This is a welcome step forward in improving the daily lives of many amputees and gives them the ability to benefit from the best possible prostheses available.

In the following pages you will find information about MPKs, the NHS MPK policy, eligibility criteria, the funding process and an overview of the most popular MPK on the market - C-Leg 4. You will also find the latest clinical evidence surrounding C-Leg.

Should you need any more information or have any questions please do not hesitate to get in touch. You will find our contact details at the end of this brochure.



Bailey's day with the C-Leg
With the C-Leg 4, Bailey can walk on uneven surfaces such as straw or the wooden floor in the barn. "The C-Leg 4 lets me walk backwards so I can keep an eye on my horse," she says. Her Prosthetist set one of the C-Leg's modes for riding so her knee stays at a right angle. Another mode makes dancing easier.



Microprocessor Knees

Unlike mechanical knees, microprocessor knees use an internal computer and sensors to monitor each step of the wearer's walking pattern (gait cycle) and use this information to make real-time adjustments to the knee.

These adjustments typically involve changes to resistance. This makes walking at various speeds easier, allows wearers to manoeuvre ramps and challenging terrain as well as walk down stairs step-over-step. Another important feature is being able to walk backwards in a safe and physiological manner.

As a result of this technology, patients often comment that their energy levels are much higher, they can do more, walk further and more often. Because of the enhanced safety systems in place within the knee, wearers also note a reduction in back pain; which is very common within the amputee population.

For patients with hip disarticulation amputations, this ultimate level of security given by microprocessor knees is an absolute must in order for them to walk safely and confidently.

These are only a handful of benefits microprocessor knees can offer a patient and is truly what sets them apart from their mechanical counterparts.

Ottobock's C-Leg is the most used MPK across the world, with more than 60,000 fittings carried out since 1997. Extensive clinical research has shown the C-Leg as the safest microprocessor-controlled knee joint, extremely reliable and helps amputees achieve greater independence.



The Policy

Available within NHS England centres only, the policy aims to help patients recover from the effects of amputation with improved rehabilitation and prosthetic choice. Patients will be prioritised for funding based on clinical need. Along with their clinical team, amputees will now be able to select the right prosthesis based upon their needs and will not be limited to mechanical options.

There has been much documented evidence on the benefits and advantages of microprocessor knees compared to mechanical alternatives. MPKs provide wearers with more safety and stumble recovery software. This can reduce the risk of falls and their related injuries significantly.

Patients who have trialled both mechanical and microprocessor knees also noted their improved mobility and independence when wearing an MPK.

The policy will allow above knee, through knee and hip disarticulation amputees, with a medium to high ability level, the opportunity to be fitted with a fully funded microprocessor knee on the NHS.

All patients will need to follow the outlined treatment pathway, in order to qualify for MPK provision.



"I suppose the world sees me as disabled but I don't see myself as disabled if I'm wearing my C-Leg"

Gillian



Gillian and her C-Leg

C-Leg 4 has allowed Gillian to reclaim her determination and the confidence to explore the world, without having to think about her walking. "You can walk and take in the scenery around you because you are not thinking about every step. I can do anything I want to do. It has opened up a whole new world. I just go out and do what I want and live life to the fullest and my leg comes too".

Eligibility Criteria

In order to qualify for an MPK, you must be able to meet specific indications.

Amputation Level

You must meet at least one of the below:

- Single, above knee amputation
- Hip disarticulation amputation
- Knee disarticulation amputation
- Double lower limb amputee with a least one above knee amputation

Activity + Mobility

You must meet the below criteria:

At a minimum, you should have the potential to walk with a mechanical knee at differing speeds as well as be able to overcome most environmental obstacles. You should also be capable of walking more than 50 yards on level ground.

If your mobility is lower than the above, you can also be considered for funding. You should be able to demonstrate through a C-Leg 4 trial, improved mobility and environmental obstacle negotiation to the levels described above.

Further Criteria

You must meet all of the below:

- Commitment to prosthetic rehabilitation through active participation with the therapy team.
- Adequate strength and balance to be able to activate the microprocessor knee unit.
- Rely on the MPK as your main day to day prosthesis.
- Cognitive reasoning to master control, operation and care of the MPK.
- Sufficient cardiovascular abilities to meet the fitness demands of ambulating outdoors with a free knee.

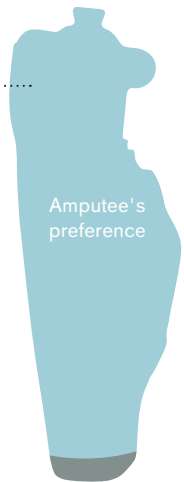
Clinical Indications

You must meet at least one of the below:

- Clinical presentation of an unstable gait, evidenced by a history of frequent falls, stumbles or near misses. A trial is required to prove a reduced risk of falls.
- When the risk of injury from a fall is very high due to a co-existing medical condition (e.g. upper limb joint replacements, inability to protect head in case of fall due to upper limb impairment, increased risk fracture). A trial is required to prove reduced risk of injury.
- When the reduced energy requirements for walking would allow you to improve your mobility/activity level and environmental obstacle negotiation. For example, being able to carry out additional duties at work.



94%
of trialed amputees
preferred C-Leg 4
over their previous prosthesis¹



■ C-Leg 4
■ previous prosthesis



95%
of trialed practitioners would
recommend a
C-Leg 4 for their
patients
to replace their previous prosthesis (94%
previous C-Leg version)¹

Contra-indications

In order to be considered for C-Leg 4 provision you must have none of the following contra-indications:

- Limited cognitive ability to understand the operation and care requirements of an MPK
- You use your daily prosthesis to participate in highly active activities (e.g. running) unless the manufacturer specifically states the limb is suitable for highly active activities
- Low activity level - you have no or limited ability or the potential to walk on level ground at fixed speed
- Your weight or height falls outside of manufacturer's recommendations
- Water related activities, unless the MPK manufacturer specifically states the MPK is waterproof
- Not enough space to fit the MPK, or where cosmetic appearance will be an issue for you
- Failure to achieve good socket fit or comfort
- Low mobility level, which can't be improved through an MPK trial
- You're not able to tolerate weight of unit
- Inability to regularly charge batteries
- Issues preventing correct knee alignment and MPK activation as per manufacturer's recommendations
- You're unable to commit to regular maintenance as recommended by manufacturer



Patient Pathway

If you wish to be fitted with an NHS C-Leg 4 you need to contact your local NHS Prosthetist. You will then be assessed individually by your centre’s multi-disciplinary team (MDT). This could include your Prosthetist, Consultant, Physiotherapist and Occupational Therapist.

The assessment will aim to gather your full patient history as well as understand the daily activities, needs and challenges you may face as an amputee. A physical examination may also be required. You will need to be able to demonstrate commitment to the rehabilitation programme required for fitting. You will then, along with your care team, outline clear rehabilitation goals you would like to achieve. The goals will be centred around your ability, needs, aspirations and must be able to justify the need for a C-Leg.

Upon the successful completion of the above, your MDT can then organise a C-Leg 4 trial. Prior to your trial, you may need to be fitted with a new socket. The trial will last four weeks, allowing you to take the prosthesis home and get the feel of what using a C-Leg in daily life is like. During the trial you may need to attend some physiotherapy sessions, where you will be taught how to get the most out of your C-Leg.

You will also need to prove that you have enough strength and balance to activate the knee as well as sufficient physical fitness to walk outdoors with the prosthesis. You must also be able to master the control, operation and care of a C-Leg 4.

Your Physiotherapist may also record how you walk on your current prosthesis, compared to your performance on the C-Leg following the trial. Referred to as outcome measures, these may include information on your mobility and noticeable changes that have taken place as a result of wearing your C-Leg.

For example, if you have a history of instability documented through falls, stumbles or near misses it is imperative you share this information with your Prosthetist prior to your trial. Studies have found 64% of C-Leg wearers had a reduction in falls compared to wearing a mechanical knee². If the results of your C-Leg trial illustrate a higher level of stability for you, this will be a key finding to support your need for a C-Leg. The easiest way to keep track of this is by keeping a diary of your daily activity.

Upon successful trial completion and based on your care team’s recommendations, you may then be eligible to be fitted with an NHS funded C-Leg 4. Once fitted, you should also expect follow-up appointments.



Clinically proven benefits

68% of low mobility patients were able to **reduce their walking effort**

when wearing C-Leg compared to a mechanical knee³

50% of low mobility patients **improved their mobility level**

when wearing C-Leg⁴

90% of lower mobility patients improved in a **variety of walking speeds**

with C-Leg compared to mechanical knees⁵

When wearing C-Leg, 90% of lower mobility patients **felt safer**

compared to wearing a mechanical knee⁵

Patient falls reduced by 64% with C-Leg compared to a mechanical knee²

The **walking speed** of bilateral knee disarticulation patients **improved by 73%**

with C-Leg when compared to a mechanical knee⁷

In a study evaluating 1200 C-Leg patients an overall relief of the sound leg was seen in 95% of patients⁶

94% of patients reported to be **very satisfied** or satisfied with C-Leg 4, with no patients reported as unsatisfied¹

Standing comfort on slopes, while standing and perceived **safety** while standing were rated as **improved** by 70% of all patients with C-Leg¹

Swing phase control was rated as more **consistent** with C-Leg compared to other microprocessor knees⁸

C-Leg 4 has the **highest recorded safety** of all assessed MPKs⁹

56% of C-Leg patients are **less dependent on hand rails** during ramp descent compared to other microprocessor knees¹⁰



The best C-Leg of all time



The C-Leg is a microprocessor-controlled knee joint. This means a small computer continually responds to how you are moving and supports you accordingly.

The C-Leg story

No other knee joint of this type is worn by as many people worldwide: More than 60,000 fittings have taken place since its market launch. In 1997, it set new standards in terms of safety and freedom of movement. Numerous studies have proven its benefits; no other knee joint has been the subject of scientific research so frequently.* We are also continually developing the C-Leg's technology. This led to new generations of the product in 2006 and 2011.

And now the C-Leg 4.

*International C-Leg Studies, published by Otto Bock Healthcare GmbH, 3rd Edition, 2014, 646B33=GB-05-1403.



1997

The C-Leg sets a new standard as the first fully microprocessor-controlled leg prosthesis system



Colour and extras such as the remote control modernise the C-Leg

2006



2011

Important functions including an optimised stumble recovery feature and improved swing phase control mark the start of a new generation



The C-Leg 4 marks the start of a new era: It is the best C-Leg of all time. With important new features for users and Prosthetists.

2015

How can C-Leg 4 help you?

More dynamic

The most natural walking pattern

C-Leg 4 is closer than ever to replicating normal anatomical movement. The on-board sensors and computers within C-Leg 4 are constantly measuring information from the knee joint in real-time. Unlike other microprocessor knees, there is absolutely no delay from detecting a change, to adapting the settings to the new situation. Whether you're walking down a slope, quickly changing your direction and pace of walking, or stopping abruptly to avoid danger, the C-Leg 4 has the technology to provide you with the most natural and responsive walking pattern.

C-Leg 4's internal computers are also able to detect when you are walking backwards. Even if the knee bends whilst walking backwards, C-Leg 4 will never catch you off guard and will maintain the highest level of safety. This unique function ensures a normal physiological backwards walking pattern and ultimate safety in every situation.



The C-Leg continues its evolution with numerous new features: It's the best C-Leg of all time.

It's not all about walking!

New functions for everyday life

Life isn't always about moving around. Sometimes the hardest thing for an amputee is to stand still in a comfortable and relaxed position, without having to waste energy controlling the movement in the knee. Without a C-Leg, simple things like standing outside on uneven ground, holding your child at the park or certain jobs that require you to stand and face people can become a daily struggle. These situations can often generate significant back problems along with joint aches and pains. With C-Leg 4's unique stance function, it naturally and intuitively allows you to stand completely safely on a slightly bent knee joint. When you are then ready to move, this movement is detected and will allow you to walk off without you having to think twice.

C-Leg 4 also carries the additional benefit of an IP rating of 67. This rating means C-Leg 4 is protected from damage due to incidental contact with or temporary submersion in fresh water. Simple things that were previously avoided like bathing the children, getting caught in the rain or washing the car are no longer a problem.



More advanced

Smart control via app

You can control your C-Leg 4 with your smart-phone. The C-Leg 4 lets you connect via Bluetooth to your knee by using the Cockpit App on your mobile device. Information such as remaining battery life and step count can be easily viewed and tracked. Patients can also use the app to activate and deactivate the C-Leg 4's sitting function. This is extremely helpful when sitting in confined spaces, such as on the train, where you may need to reposition your leg. Another feature of the app is its ability for users to switch between modes. No matter whether your hobby is golfing, dancing or riding a bike, C-Leg 4 allows amputees to programme their knee to a specific mode, so you can continue doing what you love.



New design

More choice for patients

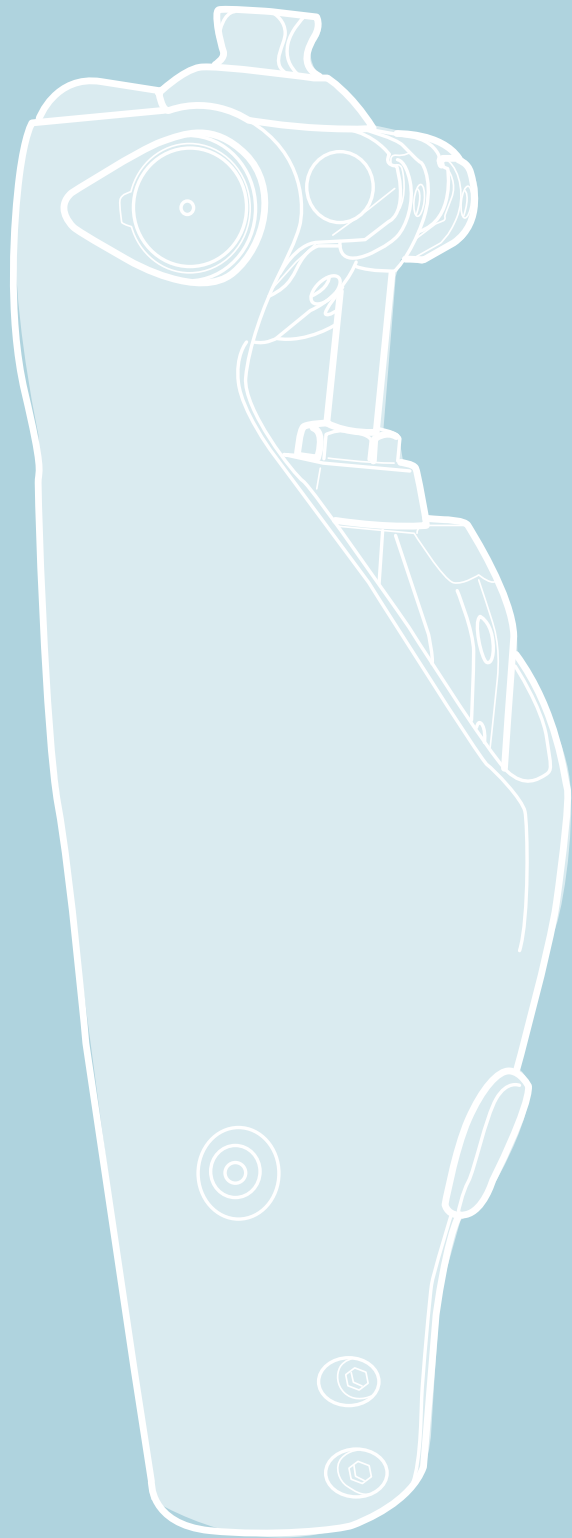
C-Leg 4 also boasts a sleek modern design with contours modelled on the human body and more discreet colours. You can choose between the anthracite Volcano Shadow tone or the champagne-coloured Desert Pearl. The shield inserts for the protective cover are also available in three different versions. The protective cover safeguards the C-Leg against external influences such as dirt and wear-and-tear. It also gives the leg a more natural volume under long clothing.



Scientifically proven; World Class Safety!

An even better stumble recovery function

During normal daily life, safety is of the utmost concern to those who use a prosthesis. The C-Leg 4 has a unique precise and extremely safe Stumble Recovery feature, built into the knee joint. Unlike other microprocessor knees, the C-Leg 4's Stumble Recovery function is armed with an additional level of safety before a stumble is even detected. Without the need to detect a stumble in order to provide this heightened level of safety, the C-Leg 4 is certainly best in class. A large number of scientific research studies have proven that the number of falls in people with transfemoral amputations is significantly lower with the C-Leg in comparison to conventional prostheses.



OneFit

The most convenient way to trial an MPK

If you are fitted with a C-Leg 4 by the NHS, Ottobock has developed a new trial process known as OneFit.

OneFit will allow you to be fitted with a brand new C-Leg 4 for your four week trial. Following a successful trial, you will then be able to stay on the trial limb as your definitive prosthesis.

By using this process, you can reduce the number of appointments needed by removing the need to transfer back onto your mechanical prosthesis in between your trial and ordering of a new limb.

During your trial, we're sure you'll become accustomed to the additional safety C-Leg 4 provides you. The OneFit process removes the safety risk of having to change back to your old prosthesis.

If you have any questions regarding the NHS MPK policy please do not hesitate to get in touch. Our Customer Support team are on hand to assist you through the entire process:

Customer Support

Email: bockuk@ottobock.com

Tel: +44 (0) 1784 744 900

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