

# BADAL X<sup>®</sup>

BADAL X is a permanent fixation system to connect a leg prosthesis directly to the remaining leg bone of both above and below knee amputees. The BADAL X attachment method is also known as osseointegration.

OTN Implants





# Bone-anchored prostheses

## The problem

Leg amputees usually receive a prosthetic leg that is attached to the stump with a plastic socket. The use of a socket causes several problems:

1. Approximately one third of leg amputees wearing a socket develop chronic skin problems. Sweat, friction and pressure can irritate or even damage the stump skin.
2. The daily walking distance for leg amputees with a prosthetic socket is six times lower compared with the daily walking distance of people with two healthy legs.
3. The up-and -down movement of the stump in the socket may cause a limp. Large studies have shown that walking with a socket prosthesis costs 25-50% more energy compared to walking with two healthy legs.
4. Fifty percent of people with a transfemoral amputation do not use the leg prosthesis or use it for less than 7 hours daily.
5. Attaching and removing a socket prosthesis is tedious, time-consuming and difficult. A socket prosthesis is associated with poor sitting comfort.

## The solution

The leg prosthesis can be connected with a metal implant inserted into the bone of the residual limb without the use of a socket. The use of a metal implant spares the stump skin and the amputee can stand and walk much more comfortably. The click-mechanism makes it easier to attach the prosthetic leg and stability is superior compared to the use of a socket. Amputees no longer limp and can sit comfortably. They experience the prosthesis as a part of their own body. Daily activities such as walking, cycling and even sitting require significantly less energy. The technique of bone-anchored prostheses is by no means new. In dentistry, jaw implants have been used for decades to fix dental prostheses. In Europe bone implants have been used for amputees for approximately 30 years. The technique is very safe and effective and is recognised by physicians and health insurance providers.



# BADAL<sup>x</sup>

OTN Implants

BADAL X stands for 'Bone Anchoring Device for Artificial Limbs'. The product was developed and is manufactured in the Netherlands.

BADAL X is a complete system for transfemoral and transtibial amputees.

The BADAL X system consists of three main parts: Implant, Adapter and Connector.



## Implant

The implant is made from a titanium alloy and is firmly attached to the bone. The implants are available in an extensive range of sizes. All BADAL X titanium implants have a very rough surface which allows rapid ingrowth into the residual bone. Rehabilitation and full weight-bearing can therefore start one to three weeks after implantation.

## Adapter

The adapter is the connection between the implant and the leg prosthesis. This component is inserted into the implant through an opening in the skin (stoma) and links the implant to a connector to which the prosthesis can be attached.

## Connector

The BADAL X connector earned the system the nickname 'click prosthesis'. The connector allows the leg prosthesis to be attached and removed very quickly. The connector consists of a 'male part' and a 'female part'. The male part is the protruding part which is attached to the adapter. The female part is attached to the leg prosthesis. These two parts can be clicked together

with a simple hand grip. An 'offset plate' is attached to the Luci connector. The orthopaedic technician and physiotherapist select the correct offset size, i.e. the size that corresponds to the angle of the residual limb. This angle can change through training, and if needed a different size can simply be placed onto the connector. Five standard offset plate sizes are available.

## Safety First

BADAL X has been thoroughly tested and meets all European safety standards. BADAL X is CE certified according to the requirements of the Medical Device Regulation (MDR).

## Advantages of BADAL X

Studies have demonstrated that the use of the BADAL X system increases the prosthesis wearing time by 63% and the quality of life by 65%. The implant survival rate is 99% after two years of follow-up. Further advantages of the BADAL X system compared with the use of a socket include the ease of use, the safety, and the strengthening of the bones and muscles of the residual limb.

BADAL X users can carry out all normal daily activities. BADAL X even allows users to get wet: a bath or shower is no problem, and users can go swimming and visit the gym or sauna. BADAL X users can go hiking—even over longer distances, cycling, and sailing.

## Limitations of BADAL X

The stoma needs to be cleaned twice daily. In some cases, the skin around the stoma may become irritated and might need extra care.

Contact sports such as martial arts and football, and sports with a high risk of falling are however not recommended.

## Suitable Candidates

Suitable candidates for BADAL X:

- Have a leg amputation above or below the knee.
- Are in good health and are fit to undergo anaesthesia and surgery.
- Do not suffer from a severe form of diabetes or severe disease affecting the leg blood vessels.
- Do not take any medication that could prevent the ingrowth of the implant into the bone.



• The most recent chemotherapy or radiotherapy should be at least 2 years ago.

BADAL X is especially recommended for people who have difficulties to wear a socket prosthesis. If the residual limb is very short, wearing a socket is often not possible. For people with very short stumps, BADAL X may provide the solution.

## Experiences

BADAL X system users give very positive feedback. After rehabilitation many

report that they can resume their pre-amputation lifestyle. Users have more energy to pursue life-enhancing activities.

The prosthesis feels part of their own body. The way the prosthesis is attached to the stump enhances confidence when walking—some users even manage some very long-distance hikes!



## The Experience

*‘I quickly realised that I had my old life back!’*

Thieu Rijnders is a married 59-year-old living in the Netherlands where he runs a mechanical carpentry workshop. Two years ago he was involved a motorcycle accident.

“I have ridden motorcycles from a young age, both on the road and on tracks. I crashed on the Assen circuit and the person coming up from behind rode over me whilst braking. My left leg was completely broken. Surgeons tried to save my leg, but this was not successful and after a week the leg was amputated above the knee. This was very traumatic; the accident was already traumatic and my time in hospital was very intense. I was in a lot of pain and was emotional and anxious. I had always been independent and suddenly I had become dependent, and I struggled with that. I talked a lot and had a lot of support from my wife, our children and other people around me. And then you have to decide: what am I going to do? When you experience something like that you can either keep moping or jump in front of a train, but for me the only choice was: go ahead and make the best of it. My work helped a lot. I am a stickler for getting out of bed every morning at six-thirty. Things went rapidly in the right direction and suddenly you notice that it is simply possible to live with a prosthesis. I basically did everything I did before. I did stop riding a motorcycle: enough is enough!”

### Working alone

Thieu works long hours in the mechanical carpentry workshop, which involves a lot of walking and standing. “I’m very active and people commented: That Thieu does everything

with his prosthesis. But they didn’t see that I was completely worn out at the end of the day. There’s a piece on my stump with transplanted skin which caused a lot of trouble. In the evening all I could do was lie on the couch, and I went to bed at half past nine at the latest. My life was only work, I couldn’t do anything else. Every step was painful, and I suffered from blisters and backache”. “Cycling was not possible, sitting on a hard surface was only possible with a cushion and matters went from bad to worse. At one point I had to go to the prosthetist every week, there was always a problem with the socket. In a year and a half I had four new sockets fitted.”

### Realistic

Thieu started to study the possibilities of a bone anchored prosthesis. “I read about it and looked up people who have such a prosthesis. It is important to make a well-considered choice and to be realistic, consider the risks and disadvantages. A bone anchored prosthesis is quite drastic and it is not a solution for everyone. For example, people with poor blood vessels or severe diabetes are not eligible, just like people who smoke or are overweight. I think it’s good that doctors decide about this, to prevent risks.”

Thieu consulted orthopedic surgeon Dr Jan Paul Frölke, who introduced BADAL X in the Netherlands about ten years ago. It soon became clear that Thieu was perfectly healthy and eligible for the procedure.

At the end of May 2021, Thieu had single stage implantation of BADAL X. The surgery took approximately two hours. “I was very pleased with it. You hear from some people that they are in a lot of pain, but that was not the case with me. Two days after admission I was able to go home. I immediately started training to make my muscles - also in the stump - strong and flexible, because I wanted to move forward. After

three weeks I had my first rehabilitation session and I was immediately allowed to put full weight on the leg. Thanks to the training I had done, it went smoothly and I was immediately ahead of schedule. Soon I noticed: I have my life back! It is a liberation, a relief. The best thing is: you are standing on your skeleton again, nicely upright. I no longer have pain, I have energy, I can sit on a hard chair again. The quality of my life has improved so much, despite the fact that I’m still rehabilitating.”

### ‘Everyone should get this chance’

Thieu comments that the post-op recovery went very well: “It usually takes a while before people can start their rehabilitation. When walking with a socket prosthesis your muscles are inactive, but with BADAL X they have to start working again - and working hard. That causes a type of muscle pain. Luckily I didn’t have any problems, nor any infections or complications”. Thieu’s fit condition certainly helped. “They did say ‘take it easy’, but that’s not for me. During physiotherapy I was constantly pushing myself. And I kept going, because I wanted to move forward quickly”

### Goals

Thieu went through the rehabilitation at breakneck speed. “When they asked what my goals were, I replied that I wanted to be able to do everything as much as possible as before, meaning walking upright, climbing stairs, walking on unpaved terrain, up and down hills, cycling. We have practiced all



those things and I have progressed at a very fast pace. Rehabilitation usually takes three months, but after two months I was ready. At the Military Rehabilitation Center, where AOFE clinic does the rehab, they have an assault course and I tried that at the end. Not everything worked out: it is impossible to climb into car tyres or up a rope with a prosthesis. But most of it worked and I really liked that.”

### Minimal restrictions

At home it became clear that Thieu’s wish - to be able to do everything as far as possible again - has really come true. “I’m back in the workshop working from 7:30 to 4:30 without any problems. When we last looked I had taken more than 10,000 steps in one day. And in the evening I have energy to do other things. I recently cycled 40 kilometers for charity; cycling with the socket prosthesis was impossible because the socket was really uncomfortable. I am also very happy that I can now visit the toilet at night or take a shower in the morning. Previously I had to go to the shower or toilet with my crutches; now I click on the bath prosthesis and I am showering on two legs. Of course there are limitations, but they are minimal. I hope to be able to walk longer distances; at the moment I have to rest after four or five kilometers. But the walking is still improving, and that counts. Some things remain difficult. Working on a staircase to measure something or to place glass is difficult because of the balance. Working low to the ground is a problem because I have to get down on my knees. But if that’s all...”

### Disabled

Thieu says that it’s the difference between night and day. “It is only afterwards that you really notice how bad it actually was and how disabled I was. My quality of life has not improved by steps, but by leaps and bounds. I can do everything myself and we have a social life again. It has also been very important for my relationship with my wife. She has a life of her own again and our relationship is equal. I do understand that relationships break down when people become disabled. You start to lean more and more on your partner and rebecome dependent on their help. That is no longer necessary. I really hope that the reimbursement of bone anchored prosthetics will soon be better arranged. Anyone who wants to and who qualifies should be offered this opportunity, without endless waiting lists. It actually saves money in the long run.”

*This is a summary of two articles published in ‘Kort&Krachtig!’, September and December 2021. ‘Kort&Krachtig!’ Is the magazine of the Dutch amputee society KMK. If you are looking for a reference to your national amputee association please go to <https://www.ic2a.eu/members/>.*

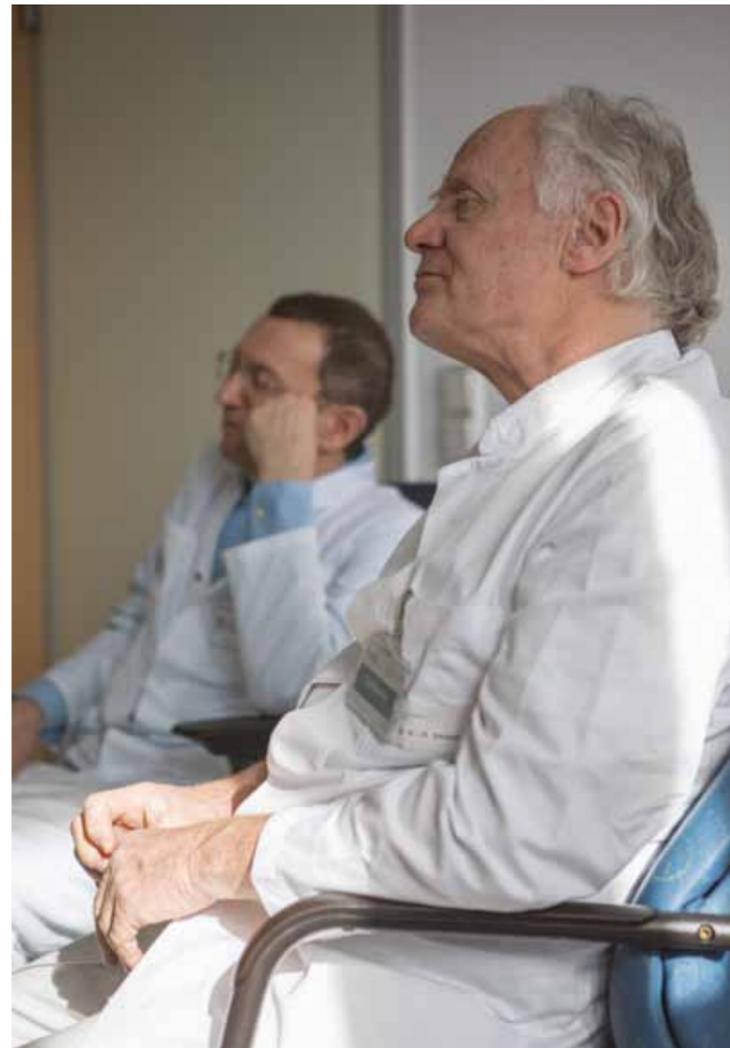
## The Specialists



### Dr Jan Paul Frölke

My close collaboration with my tutor and dear friend Dr Horst Aschoff enabled me to introduce bone anchored prosthetics in the Netherlands in 2009. Since then, I have been closely involved in all aspects of this promising development as the orthopedic surgeon of almost 300 patients. Bone anchored prosthetics were a novel method in the Netherlands, and the Radboud UMC in Nijmegen provided the opportunity to advance implant techniques. Improved surgical instruments and techniques benefitted our patients, and improved safety and efficiency. I have been working closely with OTN implants (the suppliers of BADAL X) since the company was founded. It has quickly grown into a world-class player in the field of bone anchored prostheses, because of the brilliant people who work there. The intense gratitude of patients that we treat and claim to 'have their own leg back' always makes a deep impression on me and is my greatest motivation. I look forward to working with OTN implants in the future on further improvements and to make bone anchoring for arm amputees with intuitively guided prostheses a reality.

*The intense gratitude of patients that we treat and claim to 'have their own leg back' always makes a deep impression on me and is my greatest motivation.*



### Dr Horst Aschoff

I have 20 years of experience with transcutaneous, bone anchoring systems for prosthetics. These systems have evolved from being a pioneering technique into a firmly established method. Initial concerns about the risk of ascending infections from the skin stoma into the intramedullary space have proven unfounded, with intramedullary infections being extremely rare. Bone anchoring has been a very valuable addition in the rehabilitation of arm or leg amputees. I personally supervised 300 amputees fitted with bone anchoring systems; 95% of patients were happy with their choice of prosthesis and would not consider changing it for an alternative. Increased comfort was the main factor. This finding is corroborated by the improved K-level in most patients fitted with a bone anchoring system prosthesis.

*Having worked with different types and generations of bone anchoring systems, BADAL X could now be considered the most advanced system for leg amputees.*

Having worked with different types and generations of bone anchoring systems, BADAL X could now be considered the most advanced system for leg amputees. The system has opened up a whole new range of possibilities in amputee rehabilitation. As the system becomes more established, it is likely that new indications for use will develop. Together with further improvements in surgical techniques this will ultimately lead to even greater patient satisfaction. I am honoured to be involved in working with such an innovative system- it is more than I could have hoped for when starting my career as a surgeon.

# The Treatment Process

## The Admission Procedure

The surgeon assesses the candidate's suitability for the BADAL X system during one or more interviews. The treatment is explained in detail and, if the candidate is deemed suitable, a CT examination (CT scan) is performed. This scan allows the most suitable implant to be selected.

## Surgery

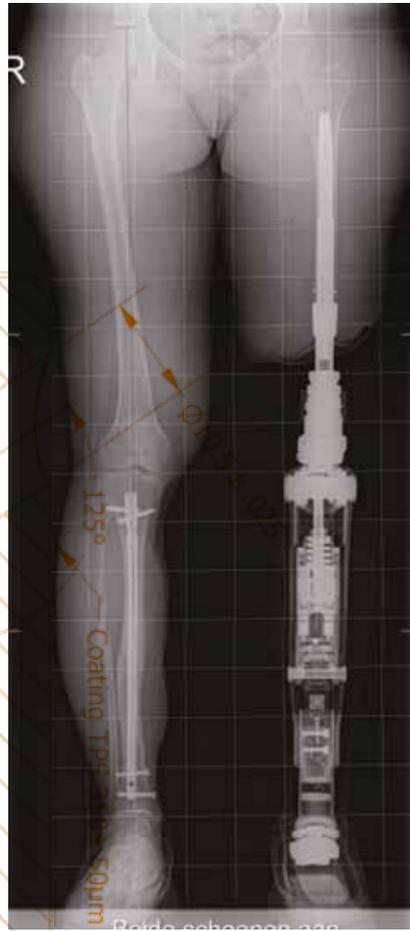
The BADAL X system is placed during one or two operations. During the procedure, the titanium implant is inserted into the stump bone. This may require a slight shortening of the bone in order to place the implant correctly. It may be necessary to remove excess tissue. Subsequently, a stoma is created and the adapter is attached. After the operation patients stay in hospital for one to two days before being referred to an orthopaedic technician. The orthopaedic technician attaches the connector and aligns the prosthesis.

## Rehabilitation

Rehabilitation starts one week post-op. Step by step you will learn how to put weight on the prosthesis. Crutches are used in the early stages and gradually you will learn to walk without support. The rehabilitation of transtibial amputees generally takes approximately four weeks, and the rehabilitation of transfemoral amputees six to twelve weeks.

## The Stoma

Inserting the implant creates a permanent artificial opening in the body. The stoma needs daily care. It is recommended to clean the stoma twice daily with water and soap- compare it to brushing your teeth. Some people with an implant use a water sprayer that is marketed for dental care. The surgeon will inform you in detail about stoma care.



# OTN Implants

OTN Implants B.V. is an innovative medical device company. The company was founded in 2016 by medical specialists from Radboud UMC in Nijmegen (The Netherlands).

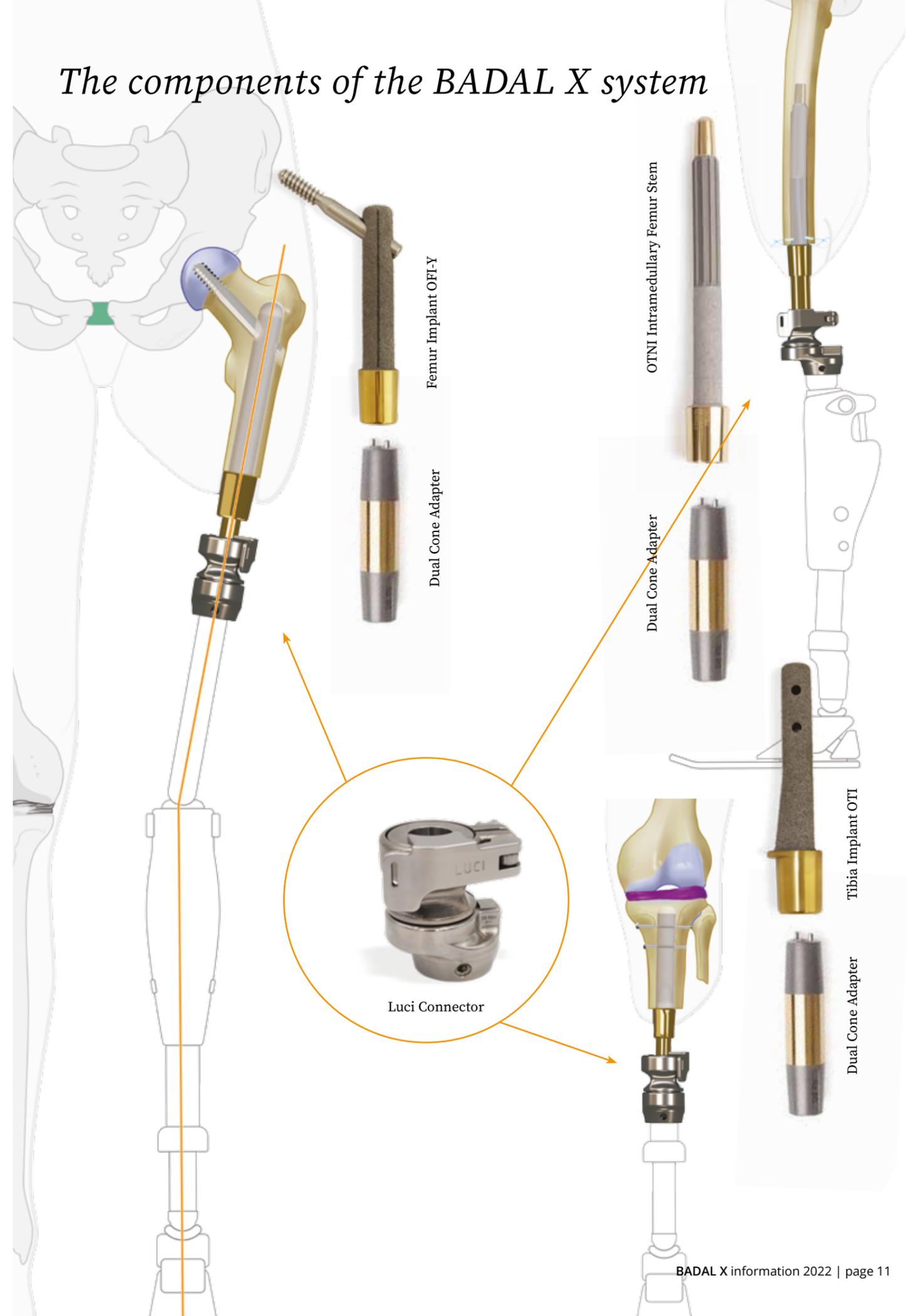
OTN Implants is ISO 13485 certified and is the manufacturer and distributor of the groundbreaking medical device BADAL X for people with transtibial or transfemoral amputation.

BADAL X is already used in several hospitals in Europe. In Canada and the USA, OTN Implants supplies limited quantities to orthopaedic clinics with an exemption for custom-made products.

BADAL X is CE certified and recognised by health authorities and health insurance funds in several European countries.



# The components of the BADAL X system





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