NICE National Institute for Health and Care Excellence

NICE guidance

# Direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant

HealthTech guidance

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# Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guidance replaces IPG795 and IPG270.

# 1 Recommendations

1.1 Direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant can be used in the NHS while more evidence is generated. It can only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Healthcare professionals wanting to do direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- ensure systems are in place that support healthcare professionals to collect and report data on outcomes and safety for everyone having this procedure
- regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team with specific training and experience in the procedure and should include:

- an orthopaedic surgeon experienced in amputation and device implantation

- a plastic surgeon with experience in the necessary bone and soft tissue reconstruction
- an anaesthetist, and
- rehabilitation specialists including:
  - experts in prosthetics
  - occupational therapists, and
  - clinical psychologists.

1.5 The procedure should only be done in specialised centres by a multidisciplinary team with specific training and experience in the procedural techniques, and management and rehabilitation after the procedure.

**Why the committee made these recommendations**

The evidence for this procedure is limited in quality and mainly from observational studies. Short-term evidence suggests that people who have it after an amputation above the knee:

- have improvements in quality of life and
- are better able to carry out normal daily activities.

But there is evidence of serious complications such as fractures and infections. These can lead to additional treatments and surgery, which can have significant impact on a person's mental health.

It is unclear how well the procedure works in the long term or who would benefit most from having it. So, this procedure can only be used with special arrangements.

# 2 The condition, current treatments and procedure

## The condition

2.1 Limb amputation is traumatic and affects quality of life. Lower-limb amputation (above or below the knee) is the most common reason for a person to use a prosthetic limb (customised prosthesis). The most common reason for lower-limb amputation is peripheral vascular disease. Other causes include trauma, infection, diabetes and cancer. Upper-limb amputations are less common and are mainly a result of trauma. A small proportion of people need prosthetic limbs because of congenital limb loss or deformities.

## Current treatments

2.2 The customised prosthesis is fitted to replace the function of the missing limb and provide cosmesis for major amputations. The type of prosthesis depends on what part of the limb is missing. Conventionally, the prosthesis is attached to the residual stump by belts and cuffs, suction, or by a suspension system. The conventional prosthesis usually has a socket, which is custom made from a plaster cast of the stump. Every effort is made to ensure people have sockets that fit well and are comfortable. One of the main problems with this type of prosthesis is rubbing between the stump and the socket. This can cause pain, ulceration and improper distribution of body weight that can affect balance and lead to falls. This may mean the user has limited use of the prosthesis or may have to abandon it for a period because of poor fit. For most people a conventional prosthesis is appropriate and well tolerated. But, when a conventional socket prosthesis is unsuitable or causes problems, direct skeletal fixation of limb prostheses using an osseointegrated implant may be an option for some people.

# The procedure

2.3 The procedure aims to surgically insert an osseointegrated implant, producing a secure connection between the remaining bone and the implant for prosthetic attachment. The implant may be in 1 piece or modular with a separate small, metal extension (abutment).

2.4 The advantages of direct skeletal fixation of an osseointegrated implant are:

- proper transfer of load from the prosthesis to the person's body
- better function and mobility (such as walking)
- improved comfort while sitting
- better balance
- fewer stump problems
- increased prosthesis use, and
- improved quality of life.

The potential problems are:

- soft-tissue infection where the skin and the prosthesis meet
- deep infection
- fracture or loosening around the implant, and
- implant failure.

2.5 Direct skeletal fixation of limb prostheses using an osseointegrated implant is done under general or regional anaesthesia (depending on the level of amputation). The procedure can be done all in 1 stage or in 2 stages separated by a period of time. In the first stage, a metallic implant (with either an outer surface threaded like a screw or a press-fit design) is inserted into the medullary cavity of the residual bone. Then healing components are attached to the implant to secure the bone graft during healing. The second stage of the procedure is usually done about 2 to 6 months later, after the implant has integrated into the

bone (osseointegration) and the stump wound is completely closed and healed. It involves surgically removing the healing components and re-exposing the distal end of the implant. It is then attached to an abutment with an abutment screw or bridge component. The wound is closed with the abutment penetrating the skin. The external limb prosthesis can then be attached to the osseointegrated implant using various components, depending on the level of amputation.

2.6 A period of extensive physiotherapy and rehabilitation follows the procedures, and the load on the prosthesis is gradually increased until full weight-bearing is allowed a few weeks later.

# 3 Committee considerations

## The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 1 HTA, 3 systematic reviews, 2 retrospective cohort studies, 2 retrospective reviews, and 1 cross-sectional observational study. It is presented in the summary of key evidence section in the overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts, patient representatives and the committee considered the key efficacy outcomes to be: improvement in mobility, reduction in falls and quality of life.

3.3 The professional experts, patient representatives and the committee considered the key safety outcomes to be: pain, infection, fractures, implant failure, osteomyelitis, need for device removal and potential limb shortening.

3.4 Seventeen commentaries from people who have had this procedure were discussed by the committee. Submissions provided by 1 patient organisation representing people who have had this procedure were discussed by the committee.

## Committee comments

3.5 Most of the evidence reviewed was from people who had above-knee amputations.

3.6 This procedure could provide significant benefit in some people who are unable to tolerate a conventional prosthesis and could provide a dramatic improvement in quality of life.

3.7 This procedure may be paired with a microprocessor prosthetic.

3.8 People being considered for the procedure should be informed of the significant risk of serious complications including the need for repeated operations, removals and infections.

3.9 Long-term outcomes, particularly in young people, need to be carefully monitored.

3.10 Appropriate post-operative care including management of soft tissues and long-term rehabilitation is important.

3.11 Patient commentary was mixed and included examples of both profoundly positive and negative experiences, but all people responding to the survey said they would recommend this procedure to others in the same situation.

3.12 The patient experts explained how the procedure could be life-changing for some people but there is always a risk of complications. One patient expert said that infection can be extremely serious and lead to further loss of bone. Both experts agreed that patient selection was a vital factor in deciding who has the procedure, but that age should not predetermine whether someone is able to adhere to rehabilitation or recovery.

3.13 There is more than one device, and the technology and procedure are evolving.

3.14 The committee were informed that it is more difficult to secure an implant in a tibia than a femur, because of the shape of the bone.

# Update information

**Minor changes since publication**

**January 2026:** Interventional procedures guidance 795 has been migrated to HealthTech guidance 732. The recommendations and accompanying content remain unchanged.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.