Hansson Pinloc® System
For slipped capital femoral epiphyses

The Hansson Pinloc System is an evolution of the Hansson Pin System.

The Hansson Pin was designed by Professor Lars-Ingvar Hansson at the University of Lund in Sweden. It was developed based on research concerning the effects of implants on the blood supply to the femoral head, with the objective to reduce the risk of femoral head necrosis. Thirty years of successful clinical use have led the Hansson Pin to its current form. Until 2011, more than 250,000 patients suffering from femoral neck fractures or slipped capital femoral epiphyses have been operated.

The late Professor Lars-Ingvar Hansson

Japanese patents
Patent Application No. 2010-534107 Pending
Patent Application No. 2011-515186 Pending
Patent No. 4917731
Patent No. 4421901
Slipped capital femoral epiphyses

The principle

The methodology involves a cylindrical Pin inserted in a drill canal which attaches to the femoral head via a hook. The drill canal and Pin run perpendicular to the growth zone and are, depending on the degree of slipping, relatively centrally located in the femoral neck and head. The Pin is 10-20 mm longer than the drill canal to allow continued growth in the length of the femoral neck. Slips of up to 60° can be stabilised by osteosynthesis.

The Hansson Pin consists of three parts, an outer Pin, an inner sliding tongue and a combined introduction and extraction screw. Fixation in the femoral head is achieved by pushing the inner sliding tongue out through the window of the outer Pin. All implants are made from titanium alloy (Ti6Al4V) and available sterile for immediate use. MRI scans can be undertaken without removal of the implant.
Features and benefits

Preventing diastasis and further displacement of the epiphysis

- The risk of further intraoperative displacement of the femoral head is reduced by drilling a canal for the Hansson Pin with the femoral head fixed with Guide Wires. The smooth outer Pin allows the surgeon to gently push the implant through the canal, reducing the risk of diastasis between the femoral neck and the head and the consequent danger of avascular necrosis.

Reducing the risk of unequal bone length

- The continued growth of the femoral neck in cases with slipped capital femoral epiphysis is an indication of undisturbed intra- and postoperative vascularization, as the nutrition for the proliferating cells of the growth plate is provided by the epiphysial vessels. By preserving the blood supply, the Hansson Pinloc System reduces the risk of unequal bone length.

A cylindrical Pin is inserted through a drilled hole and atraumatically advanced into the femoral head.

The hook is deployed by turning the T-handle clockwise whilst gently pushing medially on the introduction screwdriver. This minimizes disruption to the blood supply and the consequent danger of avascular necrosis.
Lasting stable fixation

- The hook resists loosening of the fixation to the femoral head as the longitudinal growth of the femoral neck retracts the Pin in the canal thereby stabilizing the femoral head. The risk of implant loosening is potentially reduced because of resorption and growth of the femoral neck under normal conditions.

Minimally invasive

- The complete procedure is carried out through a percutaneous incision.

Easy extraction

- The risk of the Pin being trapped in the bone is reduced as the Pin surface is smooth. The hook is easily withdrawn back into the outer pin, which can then be removed.

MRI compatible

- The Hansson Pin is made from titanium alloy (Ti6Al4V) and therefore MRI compatible.

Sterile implants

- All implants are available sterile packaged for immediate use.
References


Theses


Indications

Stable (Chronic) Slips

Eighty to ninety percent of slips are stable (or chronic).

**Stable slips are always pinned in situ. Any attempt to perform a closed reduction on a chronic slip may lead to avascular necrosis.**

Gradual bone remodelling has taken place as a response to the insidious slipping of the femur away from the femoral head. This is the body’s natural attempt to adapt the geometry of the proximal femur in order to maintain a functional hip joint. The remodelling is therefore ossified and reduction is not possible.

The stable slip is pinned with the intention of preventing further slippage, as well as preventing the possibility of acute-on-chronic traumatic changes, which could be devastating for the vascularization of the femoral head.

The surgical treatment of a stable slip can therefore be planned in advance but must be considered urgent.

Unstable (Acute) Slips

Unstable slips (where the event is recent, the child cannot weight-bear and the threat of avascular necrosis of the femoral head is an immediate danger) must be pinned without delay from the moment of the patient’s arrival in the clinic.

**This is an emergency situation.**

Some chronic remodelling may be noted on X-ray and again, this ossified modification of the hip joint cannot be reduced in surgery.

The acute or unstable portion of the slip is treated with closed reduction by internal rotation and then pinned. The chronic portion is left as it is.

Contraindications

Due to a lack of any supportive clinical experience, the Hansson Pinloc System is not recommended for use with pediatric hip fractures.

The physician’s education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of implant failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the surgical site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Detailed information is included in the instructions for use being provided with each implant. See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the service life of the device and the need for postoperative protection of the implant with the patient, when necessary.
Surgical technique

1. Patient positioning

Place the patient in supine position on an extension table. Position the leg on the healthy side with the hip in flexion and slight abduction so that the C-arm can be adjusted intra-operatively for both the anterior/posterior and the lateral/medial views. This is necessary to obtain a true lateral view of the femoral neck and head.

Position the hip in full extension with neutral position between abduction and adduction. Furthermore, again for avoiding pin penetration, the surface of the femoral head must be seen continuously when moving the C-arm from the horizontal to vertical position.

2. Maintain the leg in the horizontal plane

Apply the surgical boot to the foot. **Mild traction is applied for the sole purpose of maintaining the leg in the horizontal plane.**

Additional support under the thigh may be necessary.

Rotate the foot internally by 30 to 60° and fix in position, so that the femoral neck is parallel to the radiation beam in the lateral view.
3. Locate the optimal point for skin incision

The Hansson Pin positioning template is temporarily placed onto the monitor of the image intensifier in AP-view. The line should be placed central through the femoral neck and head.

A Guide Wire, (1) is held under AP-view of the image intensifier, above the skin anterior to the hip joint and in line with the medial cortex of the femoral neck. A Guide Wire is placed along the line under image intensification. A second Guide Wire (2), is held in a vertical position to the femoral shaft and directed against the point where the first Guide Wire and the skin meet, (A).

A third Guide Wire (the first Guide Wire can be used) is placed along the midline axis of the femoral shaft. The point where the second and the third Guide Wires cross, (B), is the optimal starting point for a stab incision.
4. Make skin incision

A percutaneous stab incision is made through the soft tissues down to the lateral cortex in about 130° to the length axis of the femoral shaft.

5. Stabilization Guide Wire insertion

When treating unstable (acute) slips a Guide Wire may be used. Using image intensification in both AP and lateral view, it is inserted percutaneously in the trochanteric region into the femoral neck and head for intraoperative stabilization.
6. Guide Wire insertion

A Guide Sleeve with handle and the Drill Sleeve with handle are introduced together with a Guide Wire through the incision. A Guide Wire Adapter can be used to facilitate the insertion of the Guide Wires.

Slipping of the femoral head occurs in a true posterior direction. The Hansson Pin must be positioned in the central part of the femoral head. To achieve this, the Pin must be inserted anterior-laterally in the greater trochanter and then directed posteriorly. In the AP-view, the tip of the 3.2 mm Guide Wire should be at the level, but not below, the lower edge of the lesser trochanter.

Using a power drill, begin insertion from the anterio-lateral cortex, crossing the epiphysis and targeting the center of the femoral head. Depending on the severity of the slip, the guide wire will be in an oblique position in the femoral neck.

Frequently use fluoroscopic control (preferably biplanar) to verify the alignment of the Guide Wire in both the anterior/posterior and lateral/medial plane. This is to ensure that the centre of the femoral head will be reached. Advance to within 5 mm of the subchondral bone. It is important to make sure that there is enough space for the hook to be extruded. The Guide Wire Sleeve is then removed.
7. Drilling

The Cannulated Drill is inserted over the Guide Wire. The Drill Sleeve with Handle is pushed forward and maintained against the lateral cortex.

**If the Guide Wire has been bent during insertion, it is important to remove the Guide Wire and re-insert it, to avoid pushing the Guide Wire forward during drilling.**

Drilling is carried out, using image intensification to ensure that the Cannulated Drill follows the line of the Guide Wire accurately and does not penetrate the hip joint.

8. Measuring

The required Pin length is read off the scale on the Measuring Sleeve against the end of the Cannulated Drill protruding from the inferior Drill Sleeve. If the measured value is between two pin lengths, always choose the shorter pin length. Make sure that the Pinloc Plate is in contact with the bone when reading the scale.

The drilling depth can be adjusted manually if possible, using the Tri-Lobe Driver Handle attached to the Cannulated Drill. The Drill Sleeve Handle is used to push the Pinloc Plate forward when reading the length against the Drill Sleeve. The Tri-Lobe Driver Handle can be used to remove the Cannulated Drill. The inferior Drill Sleeve can then be removed.

Choose a Hansson Pin which is 10 to 15 mm longer than the measurement read off the scale.

This allows the femoral neck to continue its growth along the Pin and to ease Pin removal once the physis has closed and growth is completed.

Depending on the amount of subcutaneous tissue which covers the Greater Trochanter, a longer pin protruding from the patient’s lateral cortex may not be tolerated. In such a case, a shorter Pin is used, and a future operation to replace the Pin with a longer one may be necessary.

**NOTE: The Drill and the Drill Sleeve are then removed by pulling the Drill backwards using clockwise rotation. This will clean the bone canal.**
9. Instrument-to-Pin Assembly

Mount the Pin on the T-handle Hex
Verify that the Inner Pin does not protrude from the window of the Outer Body and is in correct position. The T-handle Hex is introduced into the Pin.

There are several arrows (guide lines) on the T-handle Hex that when introduced into the outer Pin should be in line with the window of the outer Pin to ensure the direction in which the hook will be deployed.

⚠️ Do not hammer on the T-handle Hex during insertion of the Pin.
⚠️ Do not over-tighten the introduction screw.
10. Check the position of the Hansson Pin

Before closing the skin incisions, it is important to make sure that the Pin have not penetrated the joint. This can be done by removing traction and rotating the hip under image intensification in both AP and lateral view.

Lateral view.

10. Insertion of the Hansson Pin

Insert the chosen Hansson Pin with the introducer assembly into the pre-drilled canal. Ensure that the Pin is fully inserted and in good position using image intensification. The guide line on the T-handle Hex must point superiorly, giving the direction in which the hook will point.

Insert the Ratchet Handle with the Screwdriver Hex through the T-handle Hex cannulation. The hook is deployed by turning the Ratchet Handle clockwise whilst gently pushing medially on the T-handle Hex. Continue turning the Ratchet Handle under image intensification to completely deploy the hook using image intensification. The hook is fully extruded when the introduction screw reaches its mechanical stop. After deployment of the hook, the introducer assembly shall be removed.
Postoperative regime

Stable slip

The patient is allowed to start walking using crutches and partial weight bearing on the operated side the first day after surgery. Usually the patient can be discharged from the ward one to two days after surgery when he or she is capable of walking with crutches. Full weight bearing is possible after one week.

Bilateral Slips

Periodic X-Ray images should be taken of both hips to facilitate early detection of contralateral slips.

Unstable slip

The patient is allowed to start walking using crutches and partial weight bearing on the operated side the first day after surgery. Full weight bearing on the operated leg is not allowed until after six weeks.

Follow-up examination – stable and unstable

A six-week post-op follow-up medical and radiological examination is recommended. When assessing the follow-up X-ray, the surgeon must look for:

- Reliable anchorage of the hook in the femoral head.
- Protrusion of the end of the pin through the lateral cortex of the thigh.

The most accurate angle to view the protrusion of the pin is the lateral position, due to the insertion angle. Walking is permitted if the X-rays are satisfactory. Repeated X-rays are necessary every 6 months or until the physes have closed.

Postoperative activities – stable and unstable

Surgeons should instruct parents regarding appropriate and restricted activities during the treatment in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons should also instruct parents to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

Postoperative regime is a recommendation by MD, PhD Göran Hansson, The Queen Silvia Children’s Hospital. The hospital is a part of Sahlgrenska University Hospital (SU), Gothenburg.
Implant extraction

1. Retract the hook

Image intensification is used to locate the end of the Pin and a 20 mm skin incision is made. The T-handle Hex is introduced into the Pin. The Screwdriver Hex and the Tri-Lobe Driver Handle are assembled. The Screwdriver with Tri-Lobe Handle is introduced into the T-handle Hex and rotated counter-clockwise to retract the hook.

Assemble the Extractor and the Tri-Lobe Driver Handle. The Extractor is inserted through the T-handle Hex and rotated clockwise as far as it will go. This will retract the hook.

2. Remove the Hansson Pin

Check under image intensification that the hook is fully retracted prior to removing the Hansson Pin.

The Pin is removed by rotating the T-handle Hex. The Hansson Pin is now loose in the canal and can be removed by using a grasping instrument.
## Product information

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<tr>
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<td>Cannulated Drill</td>
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<td>Screwdriver Hex</td>
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<td>Guide Wire Sleeve with handle</td>
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<td>Drill Adapter</td>
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<td>62-3034</td>
<td>Guidewire Adapter</td>
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<td>62-3090</td>
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<td>Parallel Guide</td>
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<td>62-3062</td>
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<td>Hansson Pin Positioning Template</td>
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Instruction For Use

– Osteosynthesis implant, non active implant

FURTHER INFORMATION
This Instruction For Use is only provided in English. Other languages of this leaflet and the recommended surgical technique as well as detailed instructions for cleaning, sterilization and re-sterilization can be downloaded in PDF format from the Swemac website http://www.swemac.com/ru/IFU-0102/. Printed documentation can be provided free of charge upon request. Delivery time is max 7 days.

DESCRIPTION
The Hansson Pinloc system is an implant system intended for temporary stabilization of femoral neck fractures in adults until bone consolidation has been achieved and for treatment of slipped capital femoral epiphysis in children. The implants are single-use devices, made of implantable Ti6Al4V (ISO 5832-3). The system consists of three pins intended to be used together with a plate. The pins and plates are available in different sizes. The system includes specific instruments for the procedure. The device is for professional use only.

COMPATIBILITY
The implants are safe for the patient undergoing an MR procedure, but depending on the implant materials, image artifacts may occur.

INDICATIONS
Femoral neck fractures in adults:
• One plate with three pins (primary choice)
• One plate with two pins and a peg
• One plate with two pins
• Two isolated pins
Slipped capital femoral epiphysis in children:
• One isolated pin

CONTRAINDICATIONS
The physician’s education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:
• Any active or suspected latent infection, sepsis or marked local inflammation in or around the surgical area.
• Severe osteoporosis, insufficient quantity or quality of bone/soft tissue.
• Material sensitivity documented or suspected.
• Physical interference with other implants during implantation or use.
• Obesity. An obese patient can produce loads on the implant that can lead to device/treatment failure.
• Compromised vascularity, inadequate skin or neurovascular status.
• Compromised bone stock that cannot provide adequate support and/or fixation of the device due to disease, infection or prior implantation.
• Patients who are unwilling or incapable of following post-operative care instructions.
• Other physical, medical or surgical conditions that would preclude the potential benefit of surgery.

WARNINGS:
• Do not use the device without reading the surgical manual, which has been provided to the clinic separately.
• Do not use the Hansson Pinloc System with paediatric hip fractures.
• The device must only be used by a professional surgeon who is thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique of the device.
• The correct selection of the fracture fixation application is extremely important. Failure to use the appropriate application for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone.
• The implant can be available in different sizes and versions. It is important to select the appropriate combination of implant components and sizes taking into consideration the length, body weight, anatomy and functional demands of the patient. Implants which consist of several components must only be used in the prescribed combination (see surgical manual).
• Improper insertion of the device during implantation can increase the possibility of loosening or migration.
• Improper positioning of the device may lead to clinical failure.
• It is important to ensure that the guide wire or the drill does not penetrate the hip joint.
• Do not reuse the implants, since previous stresses may have created imperfections, which can lead to a device failure.
• Do not touch sharp edges of instruments or implants.
• The device is not designed to immediately withstand the stress of weight bearing, load bearing or excessive activity.
• If either the product or package seems damaged, contaminated or if sterility is questioned for any reason, the product shall not be used.
• Do not reuse Guide Wires, these are single use only. Guide Wires may be damaged of bent during surgical procedures. If a Guide Wire is reused it may become lodged in the instruments or the drill and could be advanced in to the pelvis, damaging large blood vessels or vital organs.
• Drills and reamers with measuring function must not be re-sharpened.
• Do not over-tighten the introduction screw.

PRECAUTIONS
• Ensure that all components needed for the operation are available in the surgical theatre.
• Inspection is recommended prior to surgery to determine if implants have been contaminated or damaged during storage.
• Instruments should be examined for wear or damage prior to surgery.
• Avoid surface damage to the implant and discard all damaged or mishandled implants.
• After the procedure check the proper positioning of all implants using an image intensifier. Correct positioning of the implant parts is extremely important for the outcome (see surgical manual).
• Do not use components from Swemac in combination with components from other manufacturer’s system.

ADVERSE EFFECTS
• Pain, discomfort, abnormal sensations, nerve damage, soft tissue damage, infections, necrosis of bone, bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.
• Treatment failure such as fracture or loosening of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, delayed union, non-union or excessive force exerted on the implant during insertion.
• Implant migration and/or loosening may occur.
• Mal-union may occur.
• Shortening of the affected bone/fracture site.
• Metal sensitivity, histological or allergic reaction resulting from implantation of a foreign material may occur.

POSTOPERATIVE CARE INSTRUCTIONS:
Postoperative care is extremely important. The patient must be cautioned about the use, limitations and possible adverse effects of this implant. The patient must also be warned that the implant and/or treatment might fail if he/she neglects the postoperative care instructions.
• The implantation affects the patient’s ability to carry loads and her/his mobility and general living circumstances. For this reason, each patient needs individual instructions on correct behavior after implantation.
• The device is not designed to immediately withstand the stress of weight bearing, load bearing or excessive activity.
• Explain the need to report unusual changes in the implantation area as well as falls or accidents even if the device or the surgical area did not appear to be harmed at the time.

STERILITY
The implants are provided sterile or non-sterile.
Sterile devices have been exposed to a minimum dose of 25.0 kGy gamma irradiation. If either the implant or the package appears damaged, or if sterility is questioned for any reason, the implant shall not be used.
Non-sterile implants must be sterilized by using a validated sterilization process following EN ISO 17665 prior to use.

CLEANING AND DISINFECTION
The instruments should be disassembled before cleaning. Cleaning shall be performed in accordance with ISO 15883. Cannulated instruments must be visually inspected after cleaning.

STERILIZATION AND RE-STERILIZATION OF INSTRUMENTS
The instruments and non-sterile implants shall be sterilized and re-sterilized by using a validated sterilization process in accordance with ISO 17665. Sterile packaging shall be done in accordance to EN ISO 11607-1.

The following sterilization parameters are recommended

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<td>121 °C</td>
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* Holding time. These times do not include air removal or penetration times.

STORAGE INSTRUCTIONS
Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect the product package for signs of tampering, or water contamination.

SYMBOLS USED ON THIS DEVICE

Stabilized by radiation
Do not use if package is damaged
Consult instruction for use
Warning
Non-sterile

CAUTION: Federal law (USA) restricts this device to sale by or on order of a licensed physician or hospital

19
Swemac develops and promotes innovative solutions for fracture treatment and joint replacement. We create outstanding value for our clients and their patients by being a very competent and reliable partner.

Hansson Pinloc System

Manufacturer: Swemac Innovation AB
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