Hansson Pinloc® System
For femoral neck fractures
The Hansson Pinloc System is an evolution of the Hansson Pin System. It has been developed to overcome the problem of fracture displacement after internal fixation and still maintain the same features as the Hansson Pin System.

Until 2011, the Hansson Pin System has been used in more than 250,000 patients with femoral neck fractures or slipped capital femoral epiphysis. The Hansson Pin System 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.

The problem

The femoral neck fracture is often referred to as the last unsolved fracture. Displacement of the fracture is one of the main complications associated with fixation of femoral neck fractures and occurs in about 5-8% of the undisplaced fractures and up to 20-30% of the displaced fractures.

Traditional fixation implants like cannulated screws or sliding hip screws will often fail to hold a fracture. These implants cannot provide enough mechanical stability to allow the fracture to heal in its reduced position.

Patents and patent applications:
SE532211C2 / EP2271274A1
SE535531C2
SE535436C2
WO2014/058367
SE533302C2 / EP2185092A1
SE533303C2 / EP2185089A1
The solution

By locking three Hansson Pins and a Plate into one dynamic unit, the Hansson Pinloc implant can recreate the stability of an unbroken hip. The Pins can not rotate in relation to each other as often is the case when independent screws are used. This means that the femoral head can only rotate if the bone cuts through all Pins simultaneously.

Our initial results indicate that the Hansson Pinloc System can reduce the occurrence of fracture healing complications and increase the quality of life for the patient.

The principle

After reduction of the fracture, three cylindrical Hansson Pins are inserted through a locking plate and into pre-drilled holes.

The Hansson Pins are atraumatically advanced into the femoral head. Fixation in the femoral head is achieved by pushing the inner sliding tongue out through the window of the outer Pin.
Product description

The Hansson Pinloc System consists of Plates, Pins and Pegs in different sizes which can be combined to fit each specific situation. The primary surgical technique for femoral neck fractures utilizes three Pins locked by a Plate. All implants are made from titanium alloy (Ti6Al4V) and available sterile for immediate use. The implants are MRI compatible.

Plates

- When the Pin has been fully seated in the Plate, the hook will automatically point towards the center of the femoral head. The distance between the anterior and posterior Pins are 4.5, 5.5 and 6.5 mm and between the inferior and the proximal Pins 6.0, 8.0 and 10.0 mm. The angle between the Pins and the Plate is 125° (CCD°).

Hansson Pins

- The Pin consists of three parts, an outer pin, an inner sliding tongue and an introduction screw. The Pins are available in 5 mm increments, from 70 to 140 mm. The diameter of the Pin is 6.5 mm.

- A short Anterior Peg can be used instead of the anterior Hansson Pin if the femoral neck is too narrow to allow insertion of three Hansson Pins. The Anterior Peg will stabilize the lateral cortex. The Anterior Peg is 40 mm in length and the diameter of the Peg is 6.5 mm.
Prevents non-union

Rotationally stable proximal and distal fixation

- **Strong resistance to rotation**
  By locking three Pins and a Plate into one dynamic unit, the Hansson Pinloc implant can recreate the stability of an unbroken hip. The Pins can not twist in relation to each other as often is the case when independent cannulated screws are used. This means that the femoral head can only rotate if all Pins cut through bone simultaneously.

- **Use of cortical bone for buttressing**
  Each Pin contacts strong cortical bone in three places to provide maximum stability. The Hansson Pinloc System does not rely on soft cancellous bone for support and the risk of displacement is thereby minimized.

- **Large contact area**
  It is important to have a large contact area at the fracture site in order to stabilize the fracture. The shaft diameter of the Pin is 6.5 mm. Most cannulated screws used for femoral neck fractures have a shaft diameter of only 4.5-4.8 mm.

- **Firm anchorage**
  The hook of each Pin engages in subchondral bone to provide secure anchorage and prevent migration or backing out.

Two Hansson Pins placed more than 8 mm apart have better rotational resistance than three cannulated screws (ACE-CHS)

Two Hansson Pins have greater fixation strength of the femoral head than three cannulated screws (ACE-CHS)


Prevents non-union

Prevents posterior tilt

- **The posterior Pin can not slide independent of the other Pins**

  Post-operatively, the Hansson Pinloc will allow the distal fragment to slide on the parallel Pins, compressing the fracture. By locking three Pins and a Plate together into one dynamic unit, the posterior Pin cannot slide independent of the other Pins. This prevents posterior tilt and shortening on the posterior side.

14/25 (0.6) of patients with posterior tilt of ≥ 20° were reoperated, as compared to 12/88 (0.1) of patients with tilt of < 20° (p < 0.001).

A posterior tilt of ≥ 20° was the only significant predictor of reoperation.

Palm H, Gosvig K, Krasheninnikoff M, Jacobsen S, Gebuhr P.

A new measurement for posterior tilt predicts reoperation in undisplaced femoral neck fractures: 113 consecutive patients treated by internal fixation and followed for 1 year.


The Hansson Pinloc has the ability to compress the fracture, maintain length and prevent posterior tilt.
Simple instrumentation ensures precise parallel placement. The parallel placement of the Pins does not depend on thin Guide Wires.

6.7 mm Drills are introduced through deep parallel drill tubes ensuring parallel placement of the Pins.

Maintains contact with bone

- **Precise parallel placement**
  Precise parallel placement allows for fracture dynamization thus ensuring continuous contact with bone, even during resorption. This reduces the risk of implant breakage and cut-out of the femoral head.

> "Convergence has been reported to increase the incidence of non-union. Therefore, placement of parallel peripheral pins, is considered ideal"

  Bray T.J, Smith-Hoefer E, Hooper A, Timmerman L.


> "The positioning of the osteosynthesis material was significantly (P=0.042) better for the hook-pins"

  Mjørud J, Skaro O, Solhaug JH, Thorngren KG.


> "The hook pin was considered easier to use by the surgeons due to more easy handling and better guide instrument"

allows early mobilisation

- **Strong stable fixation with continuous compression at the fracture site** allow most patients to be mobilized during their first postoperative day and to be discharged early.
Finite element analysis

The Plate acts as a load transmitter reducing stress and deformation at the fracture site both on the implant and the implant / bone interface. Stress and deformation in the fracture is reduced with more than 50% compared to isolated Hansson Pins. (Ref. 9-10)

Torsional analysis

Position of the Pins and centre of rotation (Fig.1). Photograph of an assembled specimen and indication of the driving direction (Fig.2). Photograph of the test model in action (Fig.3).

Conclusion

The torsional analysis show that the Hansson Pinloc (with three Hansson Pins locked in a Plate) provide 9 x higher torsional resistance than two (2) isolated Hansson Pins. (Ref. 13)
Biomechanical analysis

A dynamic validation of two (2) isolated Hansson Pins and three (3) Hansson Pins locked in a Plate was performed at Elos Medtech in Timmersdala, Sweden. 6 pcs of the 4:th generation femur composite bones (manufactured by Sawbones AB) was used in each of the two validation groups. A transcervical fracture with a 10 mm inferior wedge was made to all sawbones.

The following set-up of the Instron machine was used:
- Dynamic load: 1900 N (Ref. 12).
- Cycles: 1 Hertz.
- Load corresponding to 159° JRF.

The following stop criteria was used:
- Fracture surfaces compacted
- Displacement > 9 mm
- Max 10,000 cycles

2 isolated Hansson Pins in standing position:
1332 cycles until failure

3 Hansson Pins with a Plate in standing position:
10,000 cycles without failure

Conclusion

The dynamic validation show that the Hansson Pinloc (with three Hansson Pins locked in a Plate) is superior to two (2) isolated Hansson Pins. (Ref. 11)
Reduces the risk of femoral head necrosis

Preserves the blood supply

- **Minimum surgical trauma**
  The smooth profile of the Pins allows for sliding into final positioning without applying torque forces or hammering. This minimizes disruption to the blood supply and the consequent danger of avascular necrosis.

- **Prevents further damage to the lateral epiphyseal arteries**
  By preventing rotation of the femoral head and avoiding the area where the lateral epiphyseal arteries enter the femoral head, the Hansson Pinloc can prevent further damage to the lateral epiphyseal arteries.

  *The difference in the incidence of necrosis of the femoral head was significantly lower in the Hook Pin group for displaced fractures (odds ratio 3.5 p = 0.036).*


A Pin is inserted through a drilled hole and atraumatically advanced into the femoral head. The proximal Pins are placed just above the central axis of the femoral neck.

The hook is deployed by turning the introduction screwdriver clock-wise whilst gently pushing medially on the T-handle. This minimizes disruption to the blood supply and the consequent danger of avascular necrosis.
Preserves bone integrity

- **Reduced bone disruption**
  By using only three 6.5 mm Pins, the cancellous bone within the femoral head and neck is preserved.

- **Enters the lateral femoral cortex at a point opposite the lesser trochanter**
  Reducing the risk of subtrochanteric hip fractures.

Minimal invasive surgery

- **Small incision**
  The complete procedure is carried out through a 30-40 mm skin incision.

- **Short procedure**
  Simple instrumentation and a reproducible procedure allows fixation to be achieved within an adequate time frame.

- **Easy extraction**
  The procedure for Pin removal is quick and straightforward. The risk of the Pin being trapped in the bone is reduced as the Pin surface is smooth. The Pin has been treated with anodization type II which prevents bone ongrowth. The hook is easily withdrawn into the body of the Pin, which can then be pulled out.

\[
\pi \times r^2 = \text{Total area of destroyed bone}
\]

Three 6.5 mm Pins destroy 21% less bone area than three 7.3 mm cannulated screws.

\[
\begin{align*}
\text{Three 6.5 mm Pins} & = 99.5 \text{ mm}^2 \\
\text{Three 7.3 mm cannulated screws} & = 125.6 \text{ mm}^2 \\
\end{align*}
\]
Case 1

Pre-op. Garden 1 fracture.

Two days post-op. The patient was operated with the Hansson Pinloc.

Two months post-op. The fracture has found a stable position. ~2 mm shortening.

Case 2

Pre-op. Garden 2 fracture.

Four days post-op. The patient was operated with the Hansson Pinloc.

One month post-op. The fracture has found a stable position. ~3 mm shortening.
Case 3

Pre-op. Garden 4 fracture. Hip prosthesis could not be used. Patient is severely sick – High risk of mortality.

One week post-op. The patient was operated with the Hansson Pinloc after a successful reduction.

Two months post-op. The fracture has found a stable position. ~6 mm shortening.

References


9. Jönsson A (MD, PhD), Mellgren M (M.Sc.), Theodorsson J (M.Sc.). Analysis of Hansson Pinloc System for femoral neck fractures. The fracture gap modeled by a very elastic material. 12702.02.06-TR-01, XDIN® Develop and Deliver. (Data on file)

10. Jönsson A (MD, PhD), Mellgren M (M.Sc.), Theodorsson J (M.Sc.). Torsional rigidity of Hansson Pinloc System for femoral neck fractures. 12702.02.04-TR-01, XDIN® Develop and Deliver. (Data on file)

11. Jönsson A (MD, PhD), Lannergård A. Biomechanical test – Hansson Pinloc; standing case. (Data on file)


Indications

Femoral neck fractures in adults (complete Hansson Pinloc system).

Slipped capital femoral epiphysis in children (one isolated Hansson Pinloc pin).

Contraindications

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, 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.
- 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.
- Previously implanted or extracted osteosynthesis implants of the diaphyseal or proximal femur increases the risk of secondary fracture.
- Obesity. An obese patient can produce loads on the implant that can lead to device/treatment failure.
- Fractures where the inferior pin would not achieve sufficient contact with the inner medial cortex in the distal fragment.

Detailed information is included in the instructions for use being provided with each implant. 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.

This information is also available on www.swemac.com.
Surgical technique

1. Position the patient

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

2. Reduce the fracture

Reduction should be obtained by gentle manipulation according to the normal procedure for displaced fractures. The fracture position should be anatomical or with a slight valgus tilt and held by immobilization on an extension table. The femoral head and neck should be positioned parallel to the floor.

The foot should therefore be rotated inwards and fixed between 15° and 30° of internal rotation. The patella should have an either horizontal or slightly inward position. The patient is then prepared and draped.
Optimal implant position

The inferior Pin

1. Enters the lateral femoral cortex at a point opposite the lesser trochanter.
2. Touches the internal surface of the medial cortex in the femoral neck below the fracture.
3. Reaches the subchondral bone in the femoral head just below the centre.

The posterior Pin

The posterior Pin is placed parallel to the inferior Pin.

4. Enters the lateral femoral cortex.
5. Touches the internal surface of the posterior cortex of the femoral neck below the fracture.
6. Reaches the subchondral bone of the femoral head.

In a lateral projection the Pin is placed slightly posteriorly to the central femoral axis line.

The anterior Pin

The anterior Pin is placed parallel to the posterior and the inferior Pin.

7. Enters the lateral femoral cortex.
8. Touches the internal surface of the anterior cortex (if possible) of the femoral neck below the fracture.
9. Reaches the subchondral bone of the femoral head.

In the lateral projection the Pin is placed slightly anteriorly to the central femoral axis line.
3. Locate the optimal point for skin incision

The Hansson Pinloc positioning template is temporarily placed onto the monitor of the image intensifier in AP-view. The horizontal line (1) should be at the level, but not below, the lower edge of the lesser trochanter. It is essential to have the 125° line (2) close to the inner inferior cortex. The silhouette of the Plate (3) should be positioned against the lateral cortex.

A Guide Wire is placed along the 125° line (2) under image intensification. A second Guide Wire, is held in a vertical position to the femoral shaft and directed against the point where the 125° line (2) and the skin meet, (A).

NOTE: When using the positioning template, always lock the wheels of the image intensifier.

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 the skin incision.
4. Make incision

A 40 mm longitudinal incision is made, in the proximal direction from point B through the skin. The deep fascia is divided in the direction of the fibres. The lateral cortex of the femur may be approached either directly or posterior-laterally by lifting the vastus lateralis muscle. The area of the femur where the plate is to be positioned is cleared with a raspatorium.

NOTE: The Guide Wire should not enter the lateral cortex distal to the lesser trochanter.

5. Introduce the inferior Guide Wire

Once the Guide Wire is aligned with the 125° line of the Hansson Pinloc Positioning Template, the Guide Wire is advanced to the subchondral bone of the femoral head.

In the lateral view, it should be central in relation to the femoral head and neck.

If the Guide Wire is placed in the wrong position, it is possible to open up the lateral cortex with an Awl through the opening created by the Guide Wire. This allows for adjustment at the Guide Wire angle without making any additional holes in the lateral cortex.
6. Drill the inferior canal

Introduce the Cannulated Drill over the Guide Wire and through the Drill Sleeve with handle. A Drill Adapter should be used to facilitate the insertion of the Drills.

Image intensification is used to ensure that the Cannulated Drill follows the Guide Wire accurately and does not cut through the calcar.

As a safety precaution, the Drill is not advanced (using the power tool) further than 10 mm from the subchondral bone of the femoral head.

The inferior Drill is left in position.

**NOTE:** It is important to ensure that the Guide Wire or the Drill does not penetrate the hip joint. If drilling is carried out over a bent Guide Wire, there is a high risk of femoral head penetration.
7. Select and introduce the Parallel Guide

There are three Parallel Guides with different distances between the sleeves (6, 8 or 10 mm). Select the Parallel Guide which gives the widest possible separation of the Pins without cutting through the posterior or anterior cortex.

The fixed Guide Wire Sleeves of the Parallel Guide has the same outer diameter as the Hansson Pin (Ø 6.5 mm). It is therefore possible for the surgeon to assess if the Hansson Pins can be inserted through the femoral neck without cutting through the posterior and/or the anterior cortex. Based on this assessment, the correct plate can be selected. If unsure, start by introducing the 8 mm Parallel Guide.

In the frontal view, the posterior Guide Wire should be positioned just above the center of the femoral neck and head. It is important to avoid the area where the lateral epiphyseal arteries enter the femoral head (A).

The selected Parallel Guide is pushed over the inferior Drill and rotated, to ensure that the posterior Guide Wire is situated posteriorly and proximally. The teeth of the Parallel Guide are pushed into the cortex to enhance stability.
8. Introduce the posterior Guide Wire

The posterior Guide Wire is introduced through the Parallel Guide. Once the alignment of the Guide Wire is satisfactory, the Guide Wire is advanced to the subchondral bone of the femoral head.

If the Guide Wire touches the internal posterior cortex and bends, it is important to remove the Guide Wire and rotate the Parallel Guide in such a way that it is possible to reinsert the Guide Wire parallel to the inferior Drill. If necessary, select a smaller Parallel Guide.

It is also possible to use a Solid Drill after removing a bent Guide Wire.

9. Introduce the anterior Guide Wire

The anterior Guide Wire is introduced through the Parallel Guide.

Once the alignment of the Guide Wire is satisfactory, the Guide Wire is advanced to the subchondral bone of the femoral head.

**NOTE:** If the femoral neck is too narrow to allow insertion of an anterior Hansson Pin, a short Anterior Peg can be inserted to stabilize the lateral cortex without passing through the femoral neck.
10. Assemble the Plate and the Drill Sleeves

Place the chosen Plate in the corresponding plate holder (inside the instrument set), introduce the three Drill Sleeves over the pegs into the threaded holes of the selected Plate. The Drill Sleeve Handle or the T-handle Hex 6.0 is used to tighten the Drill Sleeves.

The assembled Plate is introduced over the inferior Drill and the proximal Guide Wires.

11. Drill the posterior canal

The second Cannulated Drill is introduced over the posterior Guide Wire.

Image intensification is used to ensure that the Drill does not cut through the posterior cortex. As a safety precaution, the Drill is not advanced (using the power tool) further than 10 mm from the subchondral bone of the femoral head. The posterior Drill is left in position.
12. Drill the anterior canal

The third Cannulated Drill is introduced over the anterior Guide Wire.

Image intensification is used to ensure that the Drill does not cut through the anterior cortex. As a safety precaution, the Drill is not advanced (using the power tool) further than 10 mm from the subchondral bone of the femoral head. The anterior Drill is left in position.

13. Reduce traction on the operating table

By reducing traction on the operating table, it is possible for the fracture to compress in the axis of the femoral neck. The three 6.7 mm Drills and the 3.2 mm Guide Wires will maintain the fracture reduction. This step will minimize unnecessary post-operative lateralisation of the Plate.
14. Adjust drill depth and measure the inferior canal

The inferior Drill is manually advanced to the subchondral bone using the Tri-lobe Driver Handle attached to the Cannulated Drill. The required Pin length is read off the Drill against the end of the Drill Sleeve. If the measured value is between two pin lengths, the drilling depth is adjusted. Make sure that the Plate is in contact with the bone when reading the scale.

15. Instrument-to-implant Assembly

Instrument and implant overview

- T-handle Hex 6.0 mm
- Hansson Pin
- Plate
- Screwdriver Hex 3.0 mm
- Tri-lobe Driver Handle

Exploaded view of the Pin and the instrument assembly

- Screwdriver Hex 3.0 mm
- Introduction Screw
- T-Handle Hex 6.0 mm
- Snap-lock
- Outer pin

When using an isolated Hansson Pin (without the Plate)
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. This is not necessary when using the Plate.

The Tri-lobe Driver Handle can be used to remove the Cannulated Drill. The inferior Cannulated Drill should ALWAYS be removed before removing the inferior Drill Sleeve. This will minimize the risk of the drill damaging the internal threads of the Plate. It will also make sure that they are clean from bone substance.
16. Introduce the inferior Pin

The T-handle Hex is introduced into the Pin which will snap and lock into place. Verify that the Inner Pin does not protrude from the window of the Outer Body and is in correct position. Do not introduce the assembled screwdriver into the T-handle Hex before the Pin is properly locked in the Plate.

If necessary, use suction to remove bone substance trapped in the threads of the inferior hole. A Pin of the length required for the inferior canal is mounted on the T-handle Hex and inserted into the inferior pre-drilled canal. The T-handle Hex is turned clockwise as far as it will go.

When the Pin is properly locked in the Plate, the hooks will automatically point towards the center of the femoral head. Ensure that the Pin is fully inserted and in good position using image intensification. The T-handle Hex is left in position.

**NOTE:** Do not hammer on the T-handle Hex during insertion of the Pin.
17. Deploy the hook of the inferior Pin

The assembled screwdriver is introduced into the T-handle Hex and rotated as far as it will go. This will deploy the hook.

Assemble the Screwdriver Hex and the Tri-lobe Driver Handle. Insert the tip of the assembled screwdriver through the hole in the T-handle Hex. The hook is deployed by turning the assembled screwdriver whilst pushing medially on the T-handle Hex.

Continue turning the assembled screwdriver 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.

NOTE: Do not over-tighten the introduction screw.
18. Introduce the posterior Pin and then the anterior Pin

The same procedure as used when measuring the length and introducing the inferior Pin (steps 14-18) are repeated when introducing the posterior and then the anterior Pin.

19. Check the position of the Pins

Before closing the skin incision, it is important to make sure that none of the Pins have 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.

Postoperative regime

Full weight-bearing as tolerated by the patient may be allowed in elderly patients. In younger patients, partial weight-bearing is preferable.
Implant extraction

1. Retract the hook of the inferior Pin

Image intensification is used to locate the Plate and a 40 mm skin incision is made. The T-handle Hex is introduced into the inferior Pin. The Screwdriver Hex and the Tri-lobe Driver Handle are assembled.

The assembled screwdriver is introduced into the T-handle Hex and rotated counter-clockwise to retract the hook.

2. Remove the inferior Pin

Check under image intensification that the hook is fully retracted prior to the removal of the Pin. The Pin is removed by rotating the T-handle Hex counter-clockwise. Once the hook is fully retracted, the Pin is removed along with the assembled extractor. The Pin Remover can be used to remove the Pin.

The same procedure as used when removing the inferior Pin (steps 1-2) is repeated when removing the posterior and then the anterior Pin.

In patients with poor bone quality, it is possible to remove the Plate together with all Pins after retraction of the hooks.
## Product Information

### Hansson Pins

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### Plates

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For the latest version of this Instruction For Use. Please visit: http://download.swemac.com/Hansson-Pinloc-System