Swemac

Swemac FNF System
Summary of Safety and Clinical Performance

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the Swemac FNF System. The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

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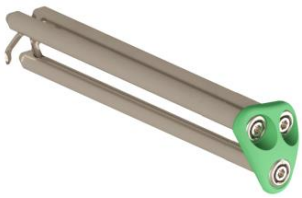
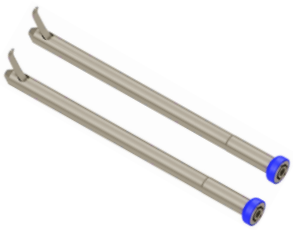
Information intended for healthcare professionals

Following this information there is a summary intended for patients in Annex B.

1 Device identification and general information

SSCP Document ID	SSCP-P205-EN		
Document Revision date	2025-03-05		
Device family, trade name:	Swemac Femoral Neck Fracture System (FNF)		
Included configurations of devices:	**Hansson Pinloc 2** 3 pcs Hansson Pin 2 1 pc Hansson Plate	**Hansson Pin 2** 2 pcs Hansson Pin 2 2 pcs Hansson End Cap	**Hansson Pin 2 for Slipped Capital Femoral Epiphyses** 1 pc Hansson Pin 2 1 pc Hansson End Cap
			
Basic UDI-DI:	Hansson Pin 2: 7340111700001Q3 Hansson Plate: 7340111700008QH Hansson End Cap: 7340111700003Q7		
EMDN:	Hansson Pin 2: P091299, Osteosynthesis devices, devices for tendon and ligament synthesis - other Hansson Plate: P09120501, Osteosynthesis compression plate Hansson End Cap: P0120502, Osteosynthesis neutralisation and support plate		
MDA/MDN/MDS/ MDT codes:	MDA: No applicable code MDN 1102: Non-active osteo- and orthopaedic implants MDS 1005: Devices in sterile condition (radiation sterilisation) MDT 2001: Devices manufactured using metal processing MDT 2011: Devices which require packaging, including labelling		
Class of the device:	Class IIb		
Manufacturer:	Swemac Innovation AB Cobolgatan 1, SE-583 30 Linköping, Sweden SRN: SE-MF-000000727		
Year when the first certificate (CE) was issued covering the device:	Hansson Plate: 2012 Hansson Pin 2: 2012 Hansson End Cap: 2022 Hansson Pin has been available on the EU market for more than 20 years in previous designs, see section 3.4 for more information.		
Authorised representative	Not applicable		
Notified body	Intertek Medical Notified Body AB SIN: NB2862		

2 Intended use of the device

2.1 Intended purpose

The Swemac Femoral Neck Fracture System (FNF) is intended for temporary stabilisation of femoral neck fractures in adults until bone consolidation has been achieved and for treatment of slipped capital femoral epiphysis in children. The device is intended for professional use only.

2.2 Indications

Femoral neck fractures in adults and slipped capital femoral epiphysis in children.

2.3 Contraindications

- Any active or suspected latent infection, sepsis or local inflammation in or around the surgical area.
- 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.
- 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.
- Basal fractures of the femoral neck.
- Other physical, mental, medical or surgical conditions that would preclude the potential benefit of surgery.

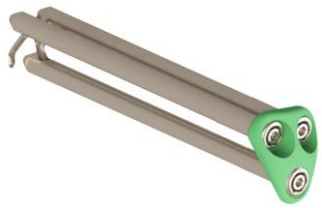
3 Device description

3.1 General description of the device

The Swemac FNF System consists of the Hansson Pin 2, Hansson Plate, and Hansson End Cap that are combined in the configurations shown in Table 1. A complete list of devices included in the Swemac FNF System is provided in Annex C. The configuration used for treatment of an individual patient is based on the fracture type, patient's physical status, the surgeons experience and current practice at the hospital. All implants in the Swemac FNF System are for single use, made from titanium alloy (Ti6Al4V) and delivered sterile. The method of sterilization is by exposure to gamma irradiation.

The devices in the Swemac FNF System do not contain medicinal substances, or tissues or cells of human or animal origin, or substances that are intended to be absorbed or dispersed in the human body. The devices do not contain carcinogenic, mutagenic, reproduction-toxic or endocrine-disrupting substances. In rare cases material sensitivity against titanium alloy may still occur and therefore documented or suspected material sensitivity is listed as a contraindication.

Table 1: Device configurations of the Swemac FNF System. SCFE = Slipped Capital Femoral Epiphysis.

Hansson Pinloc 2	**Hansson Pin 2**	**Hansson Pin 2 –for SCFE**
3 pcs Hansson Pin 2 1 pcs Hansson Plate	2 pcs Hansson Pin 2 2 pcs Hansson End Caps	1 pcs Hansson Pin 2 1 pcs Hansson End Cap
		

3.2 Hansson Pin 2 with Hansson End Caps

The Hansson Pin 2 is available in 70 – 130 mm lengths and consists of three parts, an outer pin, an inner sliding tongue and a combined introduction and extraction screw (Fig. 1). Fixation in the femoral head is achieved by pushing the inner sliding tongue out through the window of the outer pin. When the inner sliding tongue is pushed out through the window of the outer pin it creates a hook which is secured in the subchondral bone. The hook is intruded or extruded with the aid of a driver. The distal Pin thread can be covered by a Hansson End Cap to protect soft tissue structure and the lateral cortex from damage from the threads. The End Cap locks to the Pin by engaging to the Pin's distal threads.

Hansson Pin 2 is used in the configuration of two Pins with Hansson End Caps for the stabilisation of femoral neck fractures in adults or as one Pin with Hansson End Cap for the treatment of slipped capital femoral epiphysis in children (Fig. 2).

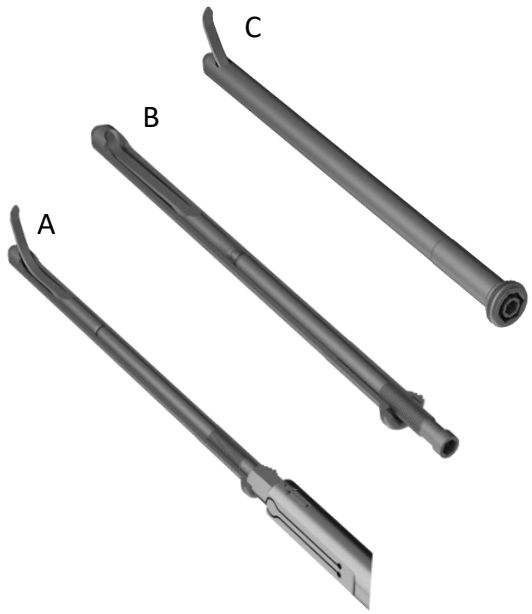


Figure 1: The anatomy of a Hansson Pin 2.

A) With driver attached and the inner sliding tongue extruded

B) Cross-sectional view revealing the mechanism of the inner sliding tongue and the threaded interface.

C) Fully assembled with inner tongue extruding through window of outer pin.

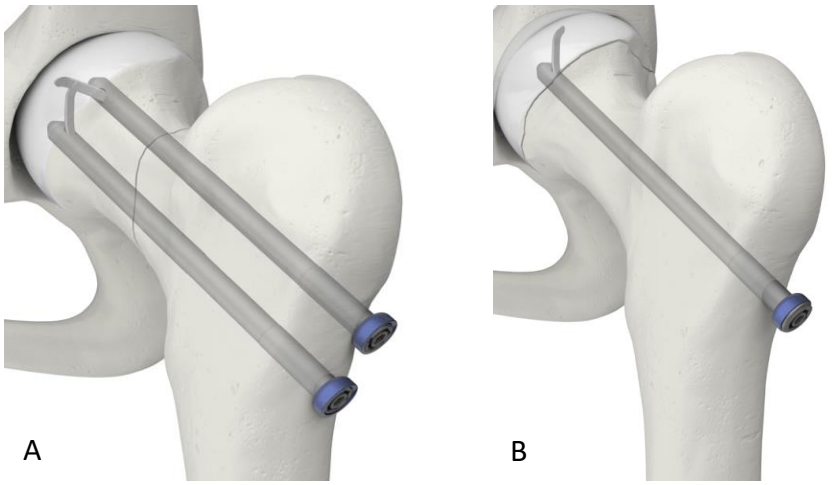


Figure 2:

A) Two Hansson Pin 2 with End Caps implanted in the femoral neck for stabilisation of a femoral neck fracture in adults.
B) One Hansson Pin 2 with End Cap implanted in the femoral neck for treatment of slipped capital femoral epiphysis in children.

3.3 Hansson Pin 2 with Hansson Plate

Hansson Pin 2 can be used together with Hansson Plates in the Hansson Pinloc configuration. Hansson Plates are available in three different sizes (6 mm, 8 mm and 10 mm), each with a 120° angle between the Pins and the Plate. The Hansson Plate is triangular because in most cases it will need to be slightly rotated for the Pins to fit the offset of the femoral neck from the femoral shaft which is different for each patient.

In the Pinloc configuration, Pins are locked to the Plate, by threads, creating one dynamic unit, where the Pins are unable to rotate independently from one another (Fig.3). By locking the Pins and the Plate together, the Plate will act as a load transmitter, reducing stress and deformation at the fracture site both on the implant and at the implant/bone interface.

Figure 3:

Hansson Plate used together with three Hansson Pin 2 in the Pinloc configuration for stabilisation of femoral neck fractures in adults.

3.4 Previous versions of the device

3.4.1 Previous versions of Hansson Pin

The Hansson Pin in stainless steel has been on the market since the 1970's (under previous legal manufacturers). It received the CE-mark for the first time in the 1990's and the design of the Hansson Pin has been without major changes since. However, around the year 2000, a titanium alloy version of the Pin was released to meet requests from the Japanese market. Swemac Innovation AB assumed the role as a legal manufacturer of the Hansson Pin device in 2018 and both the titanium and the stainless-steel versions are still marketed. So far, Hansson Pin 2 is only available in titanium alloy. Other differences between Hansson Pin and Hansson Pin 2 are the addition of a thread on the distal end of the Hansson Pin 2 that provides dual functionality of the Pins to be used in the configuration of two Hansson Pin 2 or together with

a Hansson Plate to achieve a Pinloc configuration. Hansson End Caps were added to the Hansson Pin 2 in 2022 to protect soft tissue from the threads of the Pins when used without the Hansson Plate. The Hansson Pin 2 also have a different design of the inner pin compared to the Hansson Pin and the instrumentation used with Hansson Pin 2 has been improved to reduce the number of instruments needed for the introduction and extraction of the implants.

3.4.2 Previous version of Hansson Plate

The Hansson Plate was CE-marked in 2012 and is still on the market. The original version of the Plate had an angle between the Pins and the Plate of 125°. In 2015, this angle was reduced to 120° to achieve a lower position of the implants in the femoral head and a higher position of the Plate on the femoral lateral wall. These changes were implemented to reduce the risk of interfering with blood supply in the femoral head and to reduce stress on the lateral wall. At the same time, the shape of the Plate was trimmed to reduce pain caused by irritation of surrounding soft tissues.

3.4.3 Hansson End Cap

Hansson End Cap was CE-marked for the first time under the Medical Device Regulation (MDR, 2017/745) in 2022. There are no previous versions of the Hansson End Cap.

3.5 Accessories

There are no accessories to be used with the Swemac FNF System.

3.6 Other devices to be used in combination with the device

The Swemac FNF System is supplied with a separate set of surgical instruments intended to be used for implantation and extraction of the Swemac FNF System implants.

4 Risks and warnings

4.1 Residual risks and side-effects

Risks related to the Swemac FNF System are managed through a continuous and systematic approach according to the SS-EN ISO 14971:2020. All residual risks and side-effects related to the Swemac FNF System are presented in Table 2. Measures have been implemented to, as far as possible, reduce the risks and the occurrence of side-effects and the benefit of the device have been concluded to outweigh the residual risks.

Table 2: Residual risks and side-effects related to the Swemac FNF System and their estimated or observed frequencies.

Residual risks and side-effects, General	Frequency
Risk: Penetration of the hip joint using sharp instruments Sharp instruments (such as guide wires and drills) used during the surgical procedure may penetrate the hip joint space.	Swemac did not receive any reports of malfunctioning devices causing penetration of the hip joint since 2018.
Risk: Damages to nerves and blood vessels during surgery Surgical trauma, fracture reduction and implantation of devices for internal fixation of femoral neck fractures/SCFE may cause pain, nerve damage, soft tissue damage, bone resorption and necrosis of soft tissue or bone.	Damages to critical blood supply is reflected in observed frequencies of avascular necrosis of the femoral head, see below. Swemac did not receive any reports related to nerve damage since 2018.
Risk: Insufficient reduction Insufficient reduction of the fracture or the acute/unstable slip of an SCFE may result in mal-union, delayed union, non-union, leg shortening, pain and reduced walking ability.	The quality of a fracture reduction is the responsibility of the surgeon. However, the frequency of side-effects like mal-union, non-union and leg shortening (see below) may be explained by insufficient fracture reductions.

Residual risks and side-effects, Femoral neck fractures in adults	Frequency
Risk: Incorrect placement or multiple attempts to place the guide wire An incorrect placement or repeated attempts to place the guide wire may lead to a weakening of the lateral cortex and/or an unstable fixation of the fracture.	Weakening of the lateral cortex and unstable fracture fixations are reflected in the frequencies of non-union, cut-out, avascular necrosis and secondary fractures, see below.
Risk: Non-parallel Pins Not using the provided guide-instruments for placement of the Pins in the femoral neck may lead to non-parallel Pins that may result in non-union of the fracture.	The frequency of non-parallel Pins is mainly reflected in the observed frequency of non-unions, see below.
Risk: Unstable fixation Incorrect placement of the device in the femoral neck may lead to an unstable fixation that fails and cause fracture dislocation, mal-union or non-union.	An unstable fixation would be reflected in the frequency of mal-union, non-union and fracture dislocation, see below.
Side-effect: Mal-union Mal-union may occur if the fixation of the fracture fails during healing and may be related to the risk of an unstable fixation or poor fracture reduction.	Currently, no frequency data was established specifically for the mal-union rates using the Swemac FNF System.
Side-effect: Non-union Non-union of the fracture may be related to an unstable fixation, insufficient fracture reduction as well as other patient or fracture specific conditions.	In a clinical study of 535 femoral neck fracture patients, non-unions were observed within 12 months in 5 % and 10% of the undisplaced fractures using Pinloc and Hansson Pin, respectively. In displaced fractures, the frequencies were 22% for both configurations. The non-union rate using comparable implants from other manufacturers have shown to be 0-12% for undisplaced fractures and 2-35% for displaced.
Side-effect: Cut-out The above mentioned risks of unstable fixation, insufficient fracture reduction as well as other patient or fracture specific conditions may lead to a cut-out, i.e. penetration of the implant into the joint in superior direction.	Cut-out has not been specifically evaluated in clinical studies but may have been included in the observed frequencies of non-unions (see above). In approximately 38 500 surgeries world-wide using the Swemac FNF System during the years 2018-2022, six cut-outs were reported from users.
Side-effect: Avascular necrosis Necrosis of the femoral head may occur as a consequence of damaged blood supply related to the femoral neck fracture itself, the fracture reduction procedure or the implantation of the device in the femoral neck.	In a clinical study of 535 femoral neck fracture patients, necrosis was observed within 12 months in 5% and 2% of the undisplaced fractures using Pinloc and Hansson Pin, respectively. In displaced fractures, the frequencies were 8% and 6% for Pinloc and Hansson Pin, respectively.
Side-effect: Secondary fracture Secondary fractures may occur as a consequence of incorrect positioning of Pins, weakening of the lateral cortex of the femur as well as other factors such as patients falling on their fixated hip and the failure to detect additional fractures at the first intervention.	In a clinical study of 535 femoral neck fracture patients, secondary fractures were observed within 12 months in 2% and 1% of the undisplaced fractures using Pinloc and Hansson Pin, respectively. In displaced fractures, the frequencies were <2% for both configurations since no secondary fracture was observed in this subgroup of patients.
Side-effect: Lateral pain Implant migration during fracture healing may cause lateral pain due to irritation of the soft tissue. This may lead to a surgical intervention to remove implants after fracture healing.	In a clinical study of 535 femoral neck fracture patients, implants were removed due to local pain in 9% and 5% of the patients treated with Pinloc and Hansson Pin, respectively. The removal rate is in line with what has been observed for comparable implants from other manufacturers.

Residual risks and side-effects, Slipped capital femoral epiphyses in children	Frequency
Risk: Prevented growth of the femoral neck The choice of a too short Pin may cause the Pin to prevent continued growth of the femoral neck, possibly resulting in pain, leg shortening and reduced walking ability.	The frequency of prevented growth of the femoral neck would mainly be reflected in the observed frequency of unequal bone length, see below.
Side-effect: Unequal bone length Unequal bone length may occur as a consequence of a premature closure of the growth plate that may be related to the choice of a too short Pin or other disturbances of the growth mechanism of the femoral epiphysis.	The frequency of unequal bone length has not been specifically investigated in clinical studies. A clinical study of 54 patients with SCFE demonstrated that Hansson Pin allow continued growth of the femoral neck.
Side-effect: Avascular necrosis Necrosis of the femoral head may occur as a consequence of damaged blood supply related to the implantation of the Pin in the femoral neck.	In a clinical study of 54 patients with Hansson Pin-treated SCFE, no case of avascular necrosis was identified.
Side-effect: Increased displacement of the femoral epiphysis/re-slipping A failure of the Pin to maintain the femoral head in position may lead to an increased displacement of the epiphysis	In a clinical study of 54 patients with Hansson Pin-treated SCFE, no patient showed signs of re-slipping.

4.2 Warnings and pre-cautions

4.2.1 Warnings

- Do not use the device without studying the surgical technique brochure, which has been provided to the user separately.
- The device must only be used by a professional surgeon who is thoroughly familiar with the indications and contraindications, the implant, the methods of application, instruments, and the recommended surgical technique of the device.
- 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 height, body weight, anatomy and functional demands of the patient. Implants which consist of several components must only be used in the described combination (see surgical technique brochure).
- Do not re-use the implants, since previous stresses in implant material may have created imperfections, which can lead to a device failure.
- Do not touch sharp edges of instruments or implants.
- 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 re-use single use guide wires. Single use guide wires may be damaged or bent during surgical procedures. If a single use guide wire is re-used it may become lodged in a drill or reamer and unintentionally advanced into the body.
- Drills and reamers must not be re-sharpened.
- Insufficient quantity or quality of bone/soft tissue may increase the risk of loosening or migration.
- The implant is designed as a load sharing device and cannot withstand immediate weight bearing as a load bearing device.
- Selecting the most appropriate fracture fixation method is extremely important. Failure to do so may initiate clinical failure. Failure to use the correct component to maintain blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or the bone.

- It is important to ensure that neither the guide wire nor the drill penetrate the hip joint.
- Do not use the reamer or drill if the cutting edge has been damaged or shows evidence of wear.
- The Swemac FNF System is not recommended for treatment of pediatric hip fractures.
- Improper implantation and/or positioning of the device can increase the risk of loosening, migration, chondrolysis, non-union, mal-union, femoral head penetration, cut-out or secondary fracture.
- Do not place the distal guide wire (for the inferior Pin) below the lower edge of the lesser trochanter.
- When choosing the Pin length for the treatment of Slipped Capital Femoral Epiphysis in children, ensure that 10-15 mm is added to the measured length to allow for continuous growth of the femoral neck.
- The system is not intended for spinal use.

The implants in the Swemac FNF System have not been evaluated for safety in the MRI environment. They have not been tested for heating or unwanted movement in the MRI environment. The safety of the Swemac FNF System in the MRI environment is unknown. Performing an MRI examination on a person who has this medical device may result in an injury or device malfunction. For details see Swemac MRI Statement.

4.2.2 Precautions

- Ensure that all components needed for the surgery are available in the surgical theatre.
- Inspection is recommended prior to surgery to determine if implants have been contaminated or damaged during transport or storage, discard all damaged or mishandled implants.
- Handle instruments with care. Instruments should be examined for wear or damage prior to surgery. For details see Swemac Inspection Instructions.
- The surgeon must be proficient in fracture reduction.
- Ensure that the guide wires and the Pins are inserted parallel. Pins which are not parallel might lead to improper function and reduced performance of the implant.
- The Swemac FNF System is not compatible with implants from other manufacturer's systems.

4.2.3 Post-operative care instructions

Postoperative care is extremely important. The physician's education, training and professional judgment must be relied upon to choose the most appropriate postoperative regime. 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 she/he 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 behaviour after implantation.
- The implant is designed as a load sharing device and cannot withstand immediate weight bearing as a load bearing device.
- The patient must be informed about 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. Serious incidents shall be reported to Swemac and the Competent Authority.

4.2.4 Field safety of the device

No corrective actions on the market such as field safety notices, re-calls or withdrawals have been necessary for the device since Swemac Innovation AB assumed the role of legal manufacturer in 2018.

5 Summary of clinical evaluation and post-market clinical follow-up

The conformity of the Swemac FNF System to the Medical Device Regulation (MDR, EU 2017/745) was assessed and endorsed by the Notified Body based on equivalence between Hansson Pin 2 and the previous version of Hansson Pin marketed by Swemac under MDD. For the Hansson Plate used in the Pinloc configuration, assessment and endorsement was based on clinical data on the actual device.

5.1 Clinical data on the stabilisation of femoral neck fractures in adults

The clinical evidence for the safety and performance of the Swemac FNF System for stabilisation of femoral neck fractures in adults are primarily based on a post-market, investigator-initiated clinical study (Kalland 2019). This randomised controlled study compared the safety of Pinloc and the Hansson Pin configurations. Hansson Pins used in the study were of the previous design in stainless steel and the Hansson Plate used for the Pinloc configuration was of the 125° version (see section 3.4 for previous versions of the device). Patients with femoral neck fractures (n=538) were randomized to treatment with Hansson Pin or Pinloc and randomisation was stratified on undisplaced and displaced fractures. The study concluded that the Hansson Pin and Pinloc configurations performed equally well in terms of complication rates in both the undisplaced and displaced fracture types.

Moreover, the collected information about complications in this study allowed verification of the frequencies of side-effects related to the Swemac FNF System: non-unions, necrosis and secondary fractures. The total reoperation rate of undisplaced fractures at 12 months follow-up were 8% and 10% in the Hansson Pin and Pinloc groups, respectively (simple surgery due to extraction of implant was excluded). As expected, displaced fractures had higher reoperation rates with 24% and 20% of Hansson Pin and Pinloc patients having a second surgery within 12 months of follow-up.

Another investigator-initiated retrospective study of 40 patients reported the outcome of Pinloc treatment in undisplaced femoral neck fractures (Yamamoto 2019). This study demonstrated a higher reoperation frequency after a minimum of 6 months follow-up (20%) compared to Kalland *et al*. However, it was also shown that reoperation rates could be explained by poor reduction and > 48 hours interval from injury to surgery in a subset of patients. This study was given a lower level of clinical evidence due to its retrospective nature and a fraction of patients lost to follow-up.

The reported re-operation frequency on similar benchmarking devices used for internal fixation of femoral neck fractures varies between 5-10% for undisplaced fractures and 21-33% for displaced fractures (summarised from the systematic literature review included in the clinical evaluation process of the device). It can be concluded that the Swemac FNF System performs well compared to similar devices. This was also true when comparing frequencies of the individual side-effects of avascular necrosis and non-union of displaced and undisplaced fractures.

There are also biomechanical studies on synthetic or cadaver bones (not presented here) in support of the safety and performance of the Swemac FNF System.

5.2 Clinical data on the treatment of slipped capital femoral epiphysis in children

The treatment of slipped capital femoral epiphysis (SCFE) in children was one of the very first applications of Hansson Pins in the 1970's and the clinical experience using the device for this indication is long. To reflect current clinical practice, the evidence on which the use of Hansson Pin for SCFE is based on emanates from more recent clinical studies.

A post-market retrospective study of 54 children with SCFE demonstrated a continued growth of the femoral neck after fixation of the slip using one Hansson Pin of previous design in stainless steel (Ortegren 2016). The average longitudinal growth was 7.1 mm in the affected hip compared to 10 mm in the contralateral hip. In younger patients, a growth of up to 15-20 mm was allowed in the affected hip.

Moreover, there were no re-slipping, infections, or necrosis observed. One patient had a re-operation to exchange the Pin for a longer size.

The same cohort of 54 patients was further investigated and it was shown that treatment using one Hansson Pin reduce the alpha angle (used for radiologic evaluation of femoroacetabular impingement) and the degree of displacement in moderate and severe slips (Ortegren 2018).

5.3 Overall clinical performance and safety

It can be concluded that the intended clinical benefits, performance, and safety of the Swemac FNF System have support in clinical data. It has been shown that implants in both Hansson Pin and Pinloc configurations can be used for stabilisation of femoral neck fractures with complication frequencies well in line with state-of-the-art treatment.

It was also demonstrated that Hansson Pin used for treatment of SCFE in children achieve the intended clinical benefit of allowing a continued growth of the femoral neck and prevention of further slippage of the femoral epiphyses while maintaining a low rate of complication frequencies well in line with state-of-the-art treatment.

The implants of the Swemac FNF System are intended to be used during a normal fracture healing period and until physeal closure in SCFE. The clinical studies on the device had relevant follow-up time of patients (12 months for fracture patients and until physeal closure for SCFE patients) to allow the conclusion that the intended lifetime of the device has been supported by clinical data.

5.4 Plans for future post-market clinical follow-up

The clinical literature related to the treatment of femoral neck fractures are reviewed annually. This review includes the monitoring of clinical outcomes from benchmarking devices and new technologies in order to ensure that the Swemac FNF System performs better than or equally good as other state-of-the-art treatments for the indicated conditions.

6 Possible diagnostic or therapeutic alternatives

6.1 Femoral neck fractures

Today, femoral neck fracturs are almost exclusively treated with surgery, either with the aim of stabilizing the fracture to heal using various implants (internal fixation) or by replacing the femoral head with an artificial hemi or total hip prosthesis (arthroplasty). Internal fixation is generally preferred in the more stable fracture types but may also be used in complex and unstable fractures in younger patients where the preservation of an anatomical femoral head is beneficial in the long term.

There are several implant types available for internal fixation of femoral neck fractures. The most used are multiple cannulated screws or pins, screw or pin with different side-plate constructs as well as a sliding hip screw with a plate. There is no consensus regarding the optimal device for internal fixation of femoral neck fractures today. The choice of device is based on the stability and orientation of the fracture, the physiological status of the patient and the surgeons experience and preferences.

6.2 Slipped capital femoral epiphysis

The standard treatment of slipped capital femoral epiphysis is a surgical procedure of *in situ* pinning, aiming for the prevention of additional slipping of the femoral head until the growth plate closes. The more severe slips are sometimes treated with reduction of the femoral head or osteotomies to achieve an anatomically correct position before stabilization. In situ pinning of the femoral head can be achieved using K-wires or a single pin or screw. It has been concluded that devices that allow continued growth of the femoral neck are beneficial in terms of avoiding a premature closure of the growth plate and subsequent complications related to anatomical deformity.

7 Suggested profile and training for users

The intended users of the Swemac FNF System are orthopaedic surgeons and assistant surgical staff. Swemac requires all surgeons to complete training held by Swemac or its partners prior to use of the devices.

8 Reference to harmonised standards and common specification applied

See Annex A for a full list of harmonised standards applied to the Swemac FNF System. No common specifications were identified as applicable to the device.

9 Revision history

Doc. ID	Revision date	PSUR and CER versions from which the SSCP info is sourced	Description of main changes	Date submitted to Notified Body	Revision validated by the Notified Body
SSCP-P205-EN	20230504	PSUR 2022 – Swemac FNF System, P205_TF_10.3, Rev02 Clinical evaluation report, P205-TF-8.1, Rev04	First version	03 May 2023	x Yes, validation of version SSCP-P205-EN-20230502 DRAFT was confirmed 20230504. Validation language: English □ No (only administrative corrections of the SSCP)
SSCP-P205-EN	20231027	PSUR 2022 – Swemac FNF System, P205_TF_10.3, Rev02 Clinical evaluation report, P205-TF-8.1, Rev04	Administrative corrections.	NA	□ Yes. Validation language: English x No (only administrative corrections of the SSCP)
SSCP-P205-EN	20250305	PSUR 2023 – Swemac FNF System, P205_TF_10.3, Rev01 PSUR 2024 – Swemac FNF System, P205_TF_10.3, Rev02 Clinical evaluation report, P205-TF-8.1, Rev07	Added the side-effect “Lateral Pain” to the table of residual risks and side-effects. Change of plans for future post-market clinical follow-up. Administrative corrections.	15 Mar 2024	x Yes, validation of version SSCP-P205-EN-20250305 was confirmed 20250305. Validation language: English □ No (only administrative corrections of the SSCP)

10 References

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4. Ortegren J, Bjorklund-Sand L, Engbom M, Tiderius CJ. Continued Growth of the Femoral Neck Leads to Improved Remodeling After In Situ Fixation of Slipped Capital Femoral Epiphysis. J Pediatr Orthop. 2018;38(3):170-5.

Annex A – Applied harmonised standards

Quality Management		
Number	**Document name**	**Version / published**
SS-EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)	Edition 4 2016-03-07
SS-EN ISO 13485:2016/A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)	Edition 1 2021-09-13
SS-EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011) EN ISO 14155:2011/AC:2011	Edition 2 2011-11-03
SS-EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)	Edition 3 2020-08-25
ISO 14971:2012	Medical devices - Application of risk management to medical devices	Edition 4 2012-08-14
SS-EN ISO 14971:2020	Medical devices — Application of risk management to medical devices (ISO 14971:2019)	Edition 5 2020-01-02
SS-EN ISO 14971:2020/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	Edition 1 2021-12-19
SS-EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	Edition 1 2016-01-13
SS-EN 62366-1 A 1	Medical devices - Part 1: Application of usability engineering to medical devices	Edition 2020 2020-11-11
Markings and Symbols		
Number	**Document name**	**Version / published**
ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer	Edition 1 2021-04-13
SS-EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)	Edition 2 2016-12-08
ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	Edition 4 2021-07-06
Biological Evaluation		
Number	**Document name**	**Version / published**
SS-EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)	Edition 4 2009-10-26
SS-EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Technical Corrigendum 1 (ISO 10993-1:2009/Cor 1:2010)	Edition 1 2010-06-21
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Edition 5 2018-08-17
ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Edition 3 2014-09-24
SS-EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	Edition 2 2009-06-15
ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	Edition 3 2016-11-28

SS-EN ISO 10993-6: 2009	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	Edition 2 2009-05-28
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization	Edition 4 2021-11-16
ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Edition 3 2017-09-14
SS-EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)	Edition 5 2012-07-16
ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Edition 5 2021-01-20
SS-EN ISO 10993-13:2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)	Edition 3 2010-06-29
SS-EN ISO 10993-14:2009	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)	Edition 2 2009-05-08
SS-EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)	Edition 2 2009-06-22
ISO 10993-15:2019	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys.	Edition 2 2019-11-26
SS-EN ISO 10993-16:2017	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2017)	Edition 4 2017-12-13
SS-EN ISO 10993-16:2010	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)	Edition 3 2010-03-01
ISO 10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	Edition 1 2002-07-24
SS-EN ISO 10993-18:2009	Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)	Edition 2 2009-05-08
SS-EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2020)	Edition 3 2020-06-02
ISO/TS 10993-19:2020	Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials	Edition 2 2020-03-12
ISO/TS 10993-20:2006	Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices	Edition 1 2006-08-03
ISO/TR 10993-22:2017	Biological evaluation of medical devices — Part 22: Guidance on nanomaterials	Edition 1 2017-07-14
Packaging, washing and sterilisation		
Number	**Document name**	**Version / published**
SS-EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)	Edition 1 2014-07-24
SS-EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/Amd 1:2018)	Edition 1 2019-11-28
SS-EN ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the application of ISO 11135-1	Edition 1 2007-05-16

SS-EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)	Edition 2 2015-07-06
SS-EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/Amd 2:2018)	Edition 1 2019-11-28
ISO 11137-2:2013	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose	Edition 3 2013-05-21
ISO 11137-2:2013/AMD 1:2022	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose — Amendment 1	Edition 3 2022-06-13
SS-EN ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)	Edition 2 2017-08-14
SS-EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	Edition 4 2020-01-20
SS-EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems – Amendment 1 (ISO 11607-1:2019)	Edition 1 2022-06-21
SS-EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	Edition 2 2009-06-15
SS-EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	Edition 3 2020-01-20
SS-EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes – Amendment (ISO 11607-2:2019)	Edition 1 2022-06-21
SS-EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	Edition 1 2006-04-27
SS-EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	Edition 2 2018-02-12
SS-EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1 (ISO 11737-1:2018/Amd 1:2021)	Edition 1 2021-06-22
SS-EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006/Cor 1:2007)	Edition 1 2009-05-08
ISO 11737-2:2019	Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Edition 3 2019-12-02
SS-EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)	Edition 2 2009-11-30
SS-EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)	Edition 3 2017-04-05
SS-EN ISO 11138-2:2009	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)	Edition 2 2009-05-18

SS-EN ISO 14644-1:2016	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)	Edition 2 2016-01-12
SS-EN ISO 15883-2:2009	Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaestetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)	Edition 2 2009-06-15
ISO 17664-1:2021	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices	Edition 1 2021-07-06
SS-EN ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664:2017)	Edition 2 2017-12-14
SS-EN ISO 17665-1:2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development,validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006, IDT)	Edition 1 2006-08-17
SS-EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	Edition 1 2001-11-23
SS-EN 556-1/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "sterile" - Part: 1 Reqiurements for terminally sterilized medical devices	Edition 1 2006-10-16
ISO 19227:2018	Implants for surgery -- Cleanliness of orthopedic implants -- General requirements	Edition 1 2018-03-21
SIS-CEN ISO/TS 17665-2:2009	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1 (ISO/TS 17665-2:2009)	Edition 1 2009-01-15
SS-EN ISO 14937:2009	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)	Edition 2 2009-10-26
SS-EN ISO 15883-1:2009	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)	Edition 2 2009-06-15
SS-EN ISO 15883-1:2009/A1:2014	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006/Amd 1:2014)	Edition 1 2014-07-24
Implants and Instruments		
Number	**Document name**	**Version / published**
SS-EN ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular requirements (ISO 14602:2010)	Edition 4 2011-11-15
SS-EN ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2012)	Edition 5 2012-12-11
EN ISO 14630:2009	Non-active surgical implants - General requirements (ISO 14630:2008)	Edition 4 2009-05-25
ISO 16061:2021	Instruments for use in association with non-active surgical implants – General requirements	Edition 4 2021-03-15
SS-EN ISO 16061:2009	Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2008 Corrected version 2009-03-15)	Edition 2 2009-08-17
SS-EN ISO 21534:2009	Non-active surgical implants - Joint replacement implants - Particular requirements (ISO 21534:2007)	Edition 2 2009-05-25

Materials, tolerances and other technical standards		
Number	**Document name**	**Version / published**
SS-ISO 2768-1	General tolerances - Part 1: Tolerances for linear and angular dimensions without individual tolerance indications	Edition 1 1990-10-17
ISO 5832-1:2016	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel	Edition 5 2016-07-11
ISO 5832-3:2021	Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminum 4-vanadium alloy	Edition 5 2021-11-18
ISO 5835	Implants for surgery – Metal bone screws with hexagonal drive connection, spherical under-surface of head, assymetrical thread – Dimensions	Edition 1 1991-01-17
ISO 5836	Implants for surgery - Metal bone plates - Holes corresponding to screws with asymmetrical thread and spherical under-surface	Edition 1 1988-12-01
ISO 13715:2017	Technical product documentation – Edges of undefined shape – Indication and dimensioning	Edition 3 2017-03-17

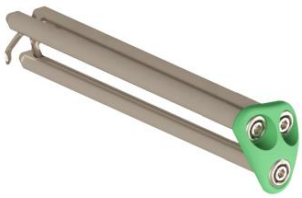
Annex B - Information for patients
Summary of Safety and Clinical Performance

Revision date: 05 March 2025

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information provided below is intended for patients or lay persons. A more extensive summary prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare provider in case you have questions about your medical condition or about having a device implanted in your particular situation. This SSCP is not intended to replace the information in your implant card or the advice and instructions you have received from healthcare providers.

1 Device identification and general information

Device family:	Swemac Femoral Neck Fracture System (FNF)		
Included configurations of devices:	**Hansson Pinloc 2 for treatment of femoral neck fractures in adults** 3 pcs Hansson Pin 2 1 pc Hansson Plate	**Hansson Pin 2 for treatment of femoral neck fractures in adults** 2 pcs Hansson Pin 2 2 pcs Hansson End Cap	**Hansson Pin 2 for treatment of slipped capital femoral epiphysis (SCFE) in children** 1 pc Hansson Pin 2 1 pc Hansson End Cap
			
Basic UDI-DI:	Hansson Pin 2: 7340111700001Q3 Hansson Plate: 7340111700008QH Hansson End Cap: 7340111700003Q7		
Manufacturer:	Swemac Innovation AB Cobolgatan 1, SE-583 30 Linköping, Sverige SRN: SE-MF-000000727		
Year for first CE-marking of the device:	Hansson Plate: 2012 Hansson Pin 2: 2012 (previous designs of Hansson Pin have been on the market since the 1970's) Hansson End Cap: 2022		

2 Intended use of the device

2.1 Intended purpose

The Swemac Femoral Neck Fracture (FNF) System consists of surgical implants intended to be used for:

- fixation of femoral neck fractures in adults until such fractures have healed
- stabilisation of the femoral head in children with slipped capital femoral epiphysis (SCFE) until the femoral head is fully grown

2.2 Contraindications

- Suspected or actual infection or local inflammation in the area requiring surgery.
- Sensitivity to the material in the implant.
- Interactions with other devices already implanted in the same area.
- Reduced blood supply, damaged skin or nerve function in the area requiring surgery.
- Weakened bone that cannot provide adequate support for the implant.
- The patient is unwilling or unable to follow healthcare provider advice on post-operative care and safe activities.
- Prior implants in the femoral neck increase the risk of a secondary fracture after surgery.
- Overweight or obesity place strain on the implant, which may result in failed treatment/bone healing.
- The implant must not be used for fractures of the lower part of the femoral neck.
- The implant must not be used if the patient has other physical, mental, medical or surgical conditions that would rule out the potential benefit of surgery.

3 Device description

The surgical implants in the Swemac FNF System consist of pins and plates combined in various ways to stabilise femoral neck fractures in adults and SCFE in children. The surgeon responsible for the operation decides how the devices are to be combined to achieve the best treatment outcome. All the main components of the Swemac FNF System are for single use, made from a titanium alloy and are supplied sterile.

3.1 Treatment principles

The implants are placed by a surgical procedure while the patient is fully sedated (patient is asleep throughout the procedure).

For a femoral neck fracture procedure, the fracture may need to be corrected first, before the implant procedure. A hole is then drilled in the femoral neck for the implant, which is then placed in the best combination for each individual patient. The implants consist of either 2 pins with no connector between them, or 3 pins held together by a plate positioned towards the outside of the thighbone (Illustrations 1A and 1B). Once these implants are in place, a hook slides out of each pin to secure the implants inside the femoral head. Once secured, the implants stabilise the fracture so it can heal.

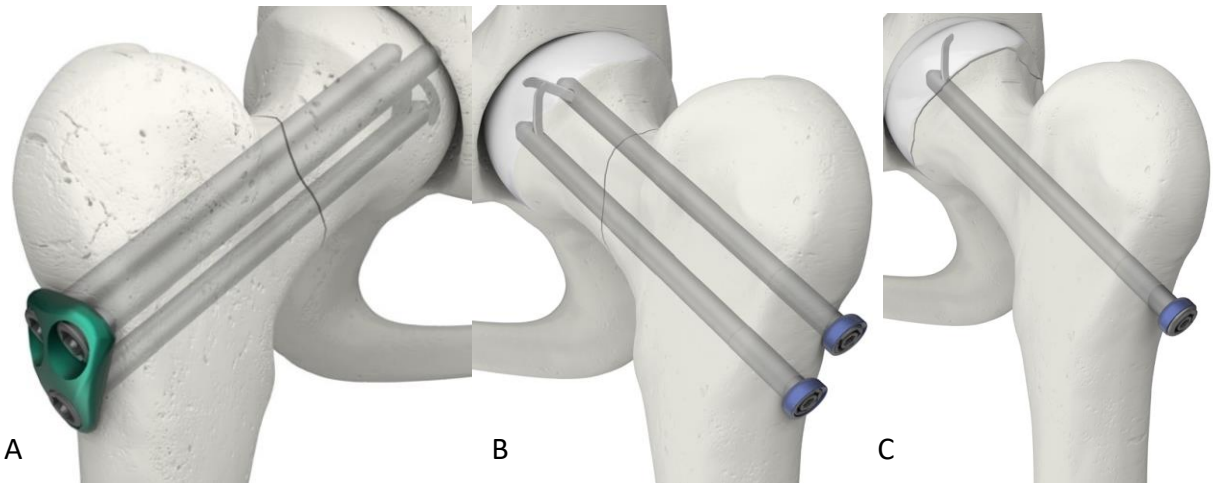


Illustration 1: Stabilisation of a femoral neck fracture using 3 pins and 1 plate (A) or 2 unconnected pins (B). Stabilisation of SCFE in children using a single pin (C).

If the implant is used to treat SCFE in a child, only a single pin is implanted, and this is secured inside the femoral head by means of a sliding hook, in the same way as for an adult fracture (Illustration 1C). The aim of this is to stabilise the femoral head to prevent it from slipping further out of position, which is what happens in SCFE.

For devices implanted without a plate, a protective ring called a Hansson End Cap is placed over the end of the pin. This protects surrounding tissue against any damage from the screw threads at the end of the pin.

Any implant that needs to be removed after a fracture has healed or, in the case of SCFE, once the femoral neck is fully grown, the pin hooks can be pulled back inside the pin again so the pin can be removed from the bone.

4 Risks and warnings

Please contact your healthcare provider if you think you may be experiencing unwanted side effects from the devices, or if you are worried about risks. This information is not intended to replace any consultation with your healthcare professional.

The implants are continuously assessed regarding risks and reported side effects. Every means of preventing risks and side effects has been considered and applied as far as possible. However, implants can still have unwanted side effects; see Table 1.

Table 1: Side effects from treatment with Swemac FNF System implants

Potential side effects of femoral neck fracture treatment in adults	Frequency
Damage to nerves and blood vessels Femoral head fracture surgery and device implantation in the femoral head may potentially damage nerves, blood vessels and surrounding soft tissue.	See the frequency for avascular necrosis (AVN) below for the side effects of reduced blood flow. No nerve damage side effects have been reported.
Failed or incorrect bone healing There is a risk that the fractured bone fails to heal or heals in an incorrect position. This can happen because the fracture was not correctly aligned during surgery, or because a device was implanted incorrectly, or because the implanted device fails to stabilise the fractured bone as it heals.	The risk of failed bone healing is higher if the fracture is unstable, and if the fracture has caused severe misalignment of the femoral head. Studies have shown that bone healing fails in 5-10% of stable fractures and in 22% of unstable fractures. The frequency of incorrectly healed fractures is not currently known.
Avascular necrosis (AVN) Reduced blood flow to the femoral head can cause avascular necrosis (AVN). AVN causes the bone to die from the inside out. The most	Studies have shown that 2–8% of patients with a femoral neck fracture have necrosis of the femoral head 12 months after surgery.

common cause is damage to the blood vessels when the fracture happened or during surgery when the fracture was corrected. There is also a small risk of blood vessel damage when the device is implanted in the femoral neck.	
Secondary fracture A secondary fracture can occur in the area around the implant following surgery. Falls involving the operated hip increase the risk of a secondary fracture.	Studies have shown that 1–2% of patients with a femoral neck fracture have a secondary fracture within 12 months of surgery.
Pain from protruding device After fracture healing, the implant may sometimes protrude into the surrounding soft tissue of the thigh where it can cause irritation or pain. This may lead to the need for an operation to remove the implants.	Studies have shown that 5-9% of the patients treated with Pinloc and Hansson Pin had their implant removed after fracture healing due to pain.
Potential side effects of SCFE treatment in children	**Frequency**
Leg shortening Leg shortening may happen if the femoral neck stops growing too early because the growth zone in the femoral head has been disturbed by the implant or if the implant has been positioned incorrectly or if an incorrectly sized pin has been implanted.	The frequency of leg shortening is not currently known. A study of 54 children showed that the implants allow continued growth of the femoral neck.
Avascular necrosis (AVN) Reduced blood flow to the femoral head can cause avascular necrosis (AVN). AVN causes the bone to die from the inside out. There is also a small risk of blood vessel damage when a device is implanted in the femoral neck.	A study of 54 children found no cases of AVN.
Displacement of the femoral head The femoral head may become displaced again if the implant detaches from its fixation in the femoral head or fails to keep the femoral head in the corrected position.	A study of 54 children found no cases of re-displacement of the femoral head.

4.1 Warnings and precautions

Warnings

The implants have not been tested for magnetic resonance imaging (MRI) scanning safety. To avoid the risk of injury or implant malfunction, patients with any Swemac FNF System implant must inform their healthcare provider of this and show them their implant card before having any MRI scan.

Post-operative care

Patients must be given individualised instructions from their healthcare provider concerning rehabilitation, care and follow-up. It is important for patients to follow the instructions provided.

Precautions concerning devices on the market

Swemac Innovation AB has been the legal manufacturer of Swemac FNF System devices since 2018. Since then, no corrective actions relating to Swemac FNF System devices on the market, such as safety notices, re-calls or withdrawals, have been necessary for any device.

5 Summary of device clinical evaluation and follow-up

Hansson Pins are tried-and-tested medical devices that have been used since the 1980s for treating femoral neck fractures in adults. In 2022 alone, approximately 3,300 surgical procedures were performed to implant Hansson Pins. The plate that connects three Hansson Pins was introduced back in 2015. This means that experience in implanting this device is extensive, with approximately 3,000 surgeries performed annually since 2018. A new device component was launched in 2021: the Hansson End Caps for use on Hansson Pins. Hansson End Caps have not yet been tested in clinical studies, but have already been used in approximately 1,800 surgical procedures.

The clinical evidence for the safety and reliability of the implant in the treatment of femoral neck fractures is based mainly on a study conducted in 2014–2017. 538 patients with a femoral neck fracture took part in the study and were treated with either 2 Hansson Pins (Illustration 1B) or 3 Hansson Pins with a plate (Illustration 1A). The patients were followed for 12 months after surgery to monitor them for complications and the need for re-operation. The findings of this study were that 2 Hansson Pins versus 3 Hansson Pins with a plate had the same benefits for patients. The study also showed that the frequency of complications and of re-operations was equal to that of other implants available on the market for treating femoral neck fractures.

Hansson Pin has been used for decades to treat SCFE in children, and its effectiveness has been proven by numerous studies. The latest research also demonstrates that the devices have the intended benefits. A study from 2016 of 54 children with SCFE showed that treatment using Hansson Pins prevented the femoral head from continuing to slip out of position while allowing continued growth of the femoral neck.

In sum, the benefits of implants for treating femoral neck fracture in adults and SCFE in children outweigh any risks. Swemac continuously ensures that a positive balance exists between the benefits and any risks of implanting these devices.

6 Possible therapeutic alternatives

When considering alternative treatments, you are recommended to contact your healthcare provider, who will be able to take your particular situation into account in giving you the best advice.

6.1 Treatment of femoral neck fracture

Fractures of the femoral neck are almost only treated by surgery. The aim of surgery is to either stabilise the fracture so the bone heals properly or to replace the femoral head and neck with an artificial prosthesis. For stable, less complex fractures, *in situ* fixation is typically used, which means various types of stabilising implants placed in the femoral neck to aid healing of the broken bone. This procedure may also be used for more complex fractures, especially in young patients, who benefit long term from keeping their own natural bone. Hip replacement is generally the best option for more complex fractures that are unlikely to heal properly and for older patients where the new hip is likely to last the rest of their life.

6.2 Treatment of SCFE

The standard treatment for SCFE involves fixation of the femoral head to prevent it from slipping further out of its position by surgical implantation of a pin, wire or screw. If the femoral head has already slipped far out of position at the time of diagnosis, surgery may be needed to first reposition the femoral head and then to secure it in place by means of an implant. Studies have shown the benefit of using an implant that allows the continued growth of the femoral neck while keeping the femoral head properly positioned. If continued growth of the femoral neck is prevented in the growing child, this may cause shortening of the leg or other deformity and future complications.

Annex C – Devices included in the Swemac FNF System, CE-marked under the Medical Device Regulation (EU 2017/745)

Device name	Article number	Basic UDI-DI	EMDN
Hansson Pin 2, Length 70 mm	62-1070S	7340111700001Q3	P091299
Hansson Pin 2, Length 72.5 mm	62-1072S	7340111700001Q3	P091299
Hansson Pin 2, Length 75 mm	62-1075S	7340111700001Q3	P091299
Hansson Pin 2, Length 77.5 mm	62-1077S	7340111700001Q3	P091299
Hansson Pin 2, Length 80 mm	62-1080S	7340111700001Q3	P091299
Hansson Pin 2, Length 82.5 mm	62-1082S	7340111700001Q3	P091299
Hansson Pin 2, Length 85 mm	62-1085S	7340111700001Q3	P091299
Hansson Pin 2, Length 87.5 mm	62-1087S	7340111700001Q3	P091299
Hansson Pin 2, Length 90 mm	62-1090S	7340111700001Q3	P091299
Hansson Pin 2, Length 92.5 mm	62-1092S	7340111700001Q3	P091299
Hansson Pin 2, Length 95 mm	62-1095S	7340111700001Q3	P091299
Hansson Pin 2, Length 97.5 mm	62-1097S	7340111700001Q3	P091299
Hansson Pin 2, Length 100 mm	62-1100S	7340111700001Q3	P091299
Hansson Pin 2, Length 102.5 mm	62-1102S	7340111700001Q3	P091299
Hansson Pin 2, Length 105 mm	62-1105S	7340111700001Q3	P091299
Hansson Pin 2, Length 107.5 mm	62-1107S	7340111700001Q3	P091299
Hansson Pin 2, Length 110 mm	62-1110S	7340111700001Q3	P091299
Hansson Pin 2, Length 112.5 mm	62-1112S	7340111700001Q3	P091299
Hansson Pin 2, Length 115 mm	62-1115S	7340111700001Q3	P091299
Hansson Pin 2, Length 117.5 mm	62-1117S	7340111700001Q3	P091299
Hansson Pin 2, Length 120 mm	62-1120S	7340111700001Q3	P091299
Hansson Pin 2, Length 122.5 mm	62-1122S	7340111700001Q3	P091299
Hansson Pin 2, Length 125 mm	62-1125S	7340111700001Q3	P091299
Hansson Pin 2, Length 127.5 mm	62-1127S	7340111700001Q3	P091299
Hansson Pin 2, Length 130 mm	62-1130S	7340111700001Q3	P091299
Hansson Plate 120° 6 mm	62-2106S	7340111700008QH	P09120501
Hansson Plate 120° 8 mm	62-2108S	7340111700008QH	P09120501
Hansson Plate 120° 10 mm	62-2110S	7340111700008QH	P09120501
Hansson End Cap	62-0050S	7340111700003Q7	P0120502