VALUE ANALYSIS BRIEF

FEMORAL NECK SYSTEM (FNS)

DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CLINICAL & ECONOMIC BURDEN

Epidemiology of Femoral Neck Fractures

Increasing Incidence of Hip Fractures[1]

Proximal Femur Fractures Costing

12 BILLION

Annually[1]

- The incidence of femoral neck fractures, one of the most common traumatic injuries in the elderly, increases continuously due to the aging population and urbanization.[1]
- North America has the highest incidence of femoral neck fractures in the world at 201 (per 100,000) per year in men and 511 (per 100,000) in women.[1]
- Currently, hip fractures represent a major economic burden on health care systems. Increasingly, more funds will have to be paid by health systems for the treatment of these fractures.[1]
- In 2005, the United States registered 2 million fractures in patients >50 years of age, costing a total of $17 billion for medical care. From all registered fractures, 14% were fractures of the proximal femur, but they took up 72% of the total value for the treatment of fractures.[1]

The Need for an Improved Solution

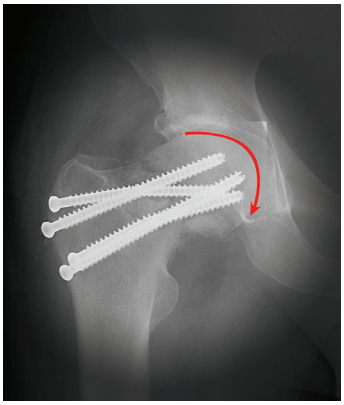
- Surgical treatment for femoral neck fractures comprise of internal fixation, hemiarthroplasty (HA) and total hip arthroplasty (THA).
- Internal fixation, which includes multiple cannulated screws (MCS) or sliding hip screws (SHS), is often a method of choice for patients with non-displaced fractures.[2] Unfortunately, each of these methods have their drawbacks;

	MULTIPLE CANNULATED SCREWS‡	SLIDING HIP SCREW‡
Overall Rates of Reoperation	**Up to 33%[4]**	**Up to 22%[4]**
Mechanical Failure Rate	**Up to 13%[3,4]** Many surgeons agree this can be attributed to lack of stability, which can lead to shortening and varus collapse.[8]	**Up to 5%[4]**
Invasiveness	**1.5% Rate of Infection[6]** and less invasive approach compared to SHS. Smaller incision size and less blood loss (106 ml)[2]	**10% Rate of Infection[7]** and more invasive approach compared to MCS. Longer incision size, larger implant footprint and greater blood loss (267 ml)[2]
Rates of Lateral Implant Protrusion	**Up to 5.3%** which may lead to thigh pain[6]	**Up to 3.6%** which may lead to thigh pain[5]
Procedural and Placement Complexity	May be **challenging to place** multiple parallel screws[9,10]	Described as **technically difficult[9]**
Operating Time	**47 Min** on average[2]	**66 Min** on average[2]
Length of Stay	**6.65 Days** on average[2]	**9.55 Days** on average[2] This can be related to greater blood loss and larger incision size[2]

‡ Percentages are quoted directly from the cited literature. Other publications may report different results.

A summary of the most common clinical complications are shown in the next page.

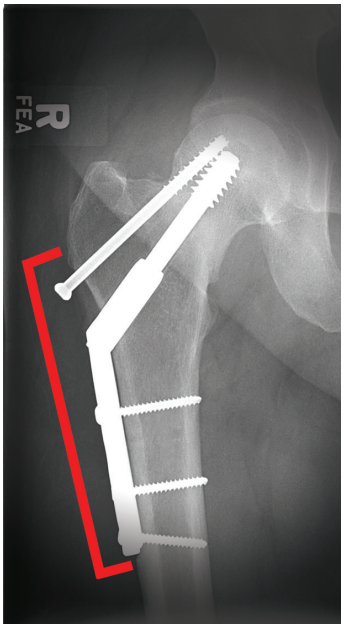
COMMON CLINICAL COMPLICATIONS‡



UNSTABLE CONSTRUCT

leading to **VARUS COLLAPSE** resulting in a reoperation rate **UP TO 13%** for cannulated screws[3,4]

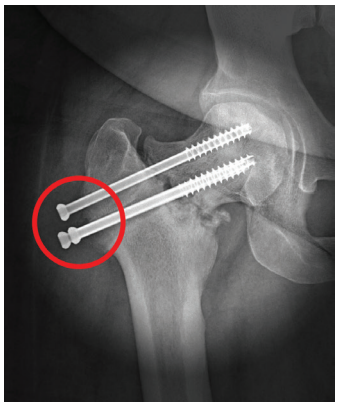
Multiple cannulated screws have been shown to lack the mechanical stability of sliding hip screws, as they do not provide a fixed angle with additional fixation into the femoral shaft.[3,4] This lack of stability is often associated with higher rates of reoperation, which can be as high as 13% due to mechanical failure.[3,4]



SURGICAL APPROACHES

are associated with **INFECTION** in **UP TO 10%** of cases with sliding hip screws[2,6,7]

While sliding hip screws offer greater stability when compared to multiple cannulated screws, it requires a more invasive approach for implant insertion due to the size of the implant and surgical technique. This may ultimately result in a larger drop in hemoglobin levels, longer hospital stays, and may increase postoperative infection rates.[2,6,7]



REPORTED THIGH PAIN

resulting from **LATERAL IMPLANT PROTRUSION** in up to 5.3% of cases[5,6]

Lateral protrusion can either occur when the implant moves laterally while the femoral neck is shortening during fracture healing, or when the side plate protrudes from the side of the hip. In either case, it often results in lateral thigh pain.[5] Rates of lateral protrusion have been shown to be as high as 5.3% and 3.6% for multiple cannulated screws and sliding hip screws respectively.[5,6]

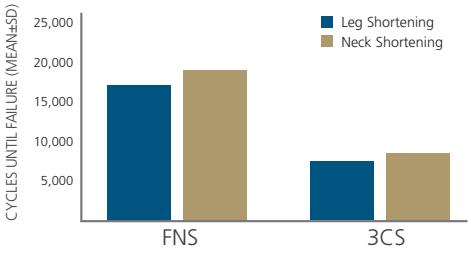
Current evidence suggests[2-7] that a solution is necessary which **combines the angular stability of sliding hip screws** with the **minimal invasiveness of multiple cannulated screws** while **reducing lateral thigh pain and procedural complexity.**

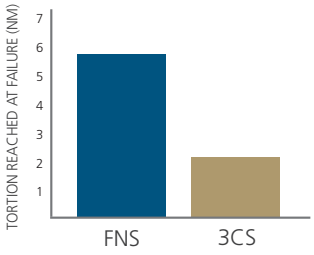
‡ Percentages are quoted directly from the cited literature. Other publications may report different results.

THE FEMORAL NECK SYSTEM SOLUTION

1 STABILITY

The FNS was designed to provide higher mechanical stability then multiple cannulated screws.





A Minimum Of 100% MORE **Resistance to Varus Collapse** due to leg and neck shortening when compared to Multiple Cannulated Screws[11]

A Minimum Of 150% MORE **Rotational Stability** when compared to Multiple Cannulated Screws[12]

BENEFITS

These FNS design features are intended to reduce varus collapse and rotational failures, potentially reducing reoperations due to mechanical instability to a similar level as sliding hip screws.

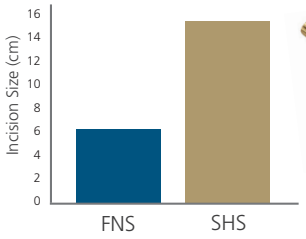
2 MINIMALLY INVASIVE

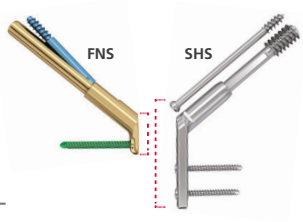
The FNS was designed to minimize implant footprint on the bone with its compact design.[13]

FNS SHS

71% REDUCTION **In Footprint Compared to SHS[13]**

Furthermore, the FNS was designed to reduce the length of incision necessary for implant insertion when compared to a sliding hip screw system.[13]





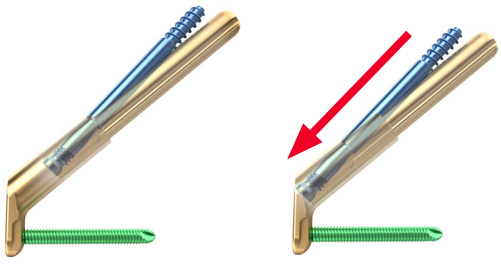
60% REDUCTION **In Incision Size Compared to SHS[13]**

BENEFITS

FNS may help reduce blood loss and length of stay, potentially reducing reoperations due to invasiveness to a similar level as multiple cannulated screws.

3 REDUCED PROTRUSION

The bolt design allows the FNS to freely glide within the barrel of the base plate. This allows for 20mm of controlled collapse of the head fragment, with no lateral protrusion for the first 15mm.[13]



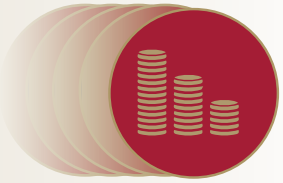
BENEFITS

This FNS design feature is intended to reduce incidences of lateral thigh pain.

ECONOMIC VALUE

Revision procedures resulting from the failed fixation of the hip can be extremely detrimental to the patient, increasing the risk of mortality, decreasing the ability for patients to return to their original state, and resulting in a two to threefold rise in average cost of treatment.[14,15]

An Average Midsized Hospital May Spend Up To



$1,280,867

Annually on Reoperations Related to Femoral Neck Fractures

INPUT PARAMETERS	CANNULATED SCREWS	SLIDING HIP SCREWS
Annual Volume	50	50
Average Cost of Reoperation	$46,577.00[16]	$46,577.00[16]
Reoperation Rate	Up to 33%[4]	Up to 22%[4]
Cost to Hospital	Up to $768,520.50	Up to $512,347.00
Total Cost to Hospital	$1,280,867.50	

The Femoral Neck System was designed with the aim of reducing the incidence of costly reoperations and complications by increasing stability, reducing invasiveness, and reducing the risk of lateral implant protrusion. This may provide the opportunity for significant cost savings for the health care system through the reduction in reoperations.

PROCEDURAL EFFICIENCY

The Femoral Neck System was designed to enhance procedural and operational efficiency to increase ease of use and reduce the number of instruments required for the procedure.

The surgical technique was designed to be used with:[13]

- One guidewire in a center position for implant insertion
- One measurement for main implant selection
- One instrument assembly for main implant insertion

The design of the insertion handle allows a targeted and therefore repeatable insertion of all components.[13]

52% FEWER

Steps When Compared with Sliding Hip Screws[13]

BENEFITS

Reducing surgical treatment complexity may ultimately reduce operation time and variability in the OR

PRODUCT OFFERING

IMPLANT FEATURES

1. Antirotation-Screw (ARScrew)
   - Provides rotational stability[12]
   - Allows implant placement even in a small femoral neck
   - Corresponding size (length) to Bolt
2. Bolt
   - Cylindrical design intended to maintain reduction during insertion[13]
   - Provides angular stability[11]
   - Dynamic design (Bolt and ARScrew slide together, max 20mm)
   - Guided collapse designed to reduce lateral protrusion[13]
3. Plate
   - Provides angular stability[11]
   - Designed to reduce implant footprint[13]

IMPLANT SPECIFICATIONS	
MATERIAL	Ti-6Al-7Nb (TAN)
CONSTRUCT LENGTHS (BOLT + ARSCREW)	75-130mm (5mm increments)
BOLT DIAMETER	10mm
ARSCREW DIAMETER	6.4mm
CCD ANGLE (PLATE TO BOLT)	130° (+7.5° for ARScrew)
PLATE OPTIONS	1 Hole: 12.7mm (width) x 26mm (length) 2 Hole: 12.7mm (width) x 36mm (length)
SCREW COMPATIBILITY	5.0mm Locking Screws

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* Benchtop testing may not be indicative of clinical performance

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