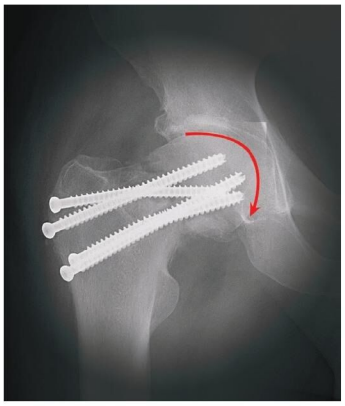
FEMORAL NECK SYSTEM (FNS)

Austeofix Surgical Pvt. Ltd.

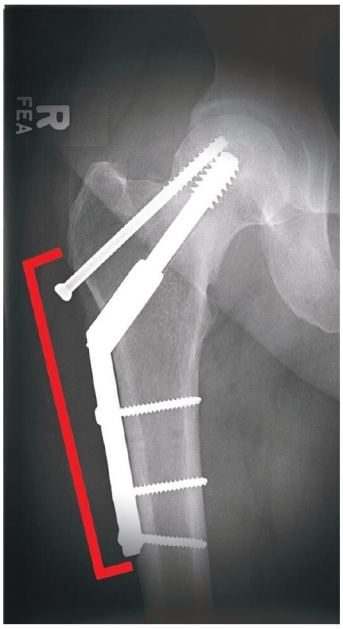
COMMAN CLINICAL COMPLICATIONS



UNSTABLE CONSTRUCT

leading to **VARUS COLLAPSE** resulting in a reoperation rate **UP TO 13%** for cannulated screws

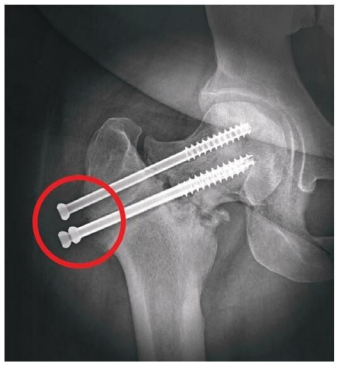
Multiple cannulated screws have been shown to lack the mechanical stability of sliding hip screws, as they do not provide a fixed angle with additional fixation into the femoral shaft. This lack of stability is often associated with higher rates of reoperation, which can be as high as 13% due to mechanical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



SURGICAL APPROACHES

are associated with **INFECTION** in **UP TO 10%** of cases with sliding hip screws

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.



REPORTED THIGH PAIN

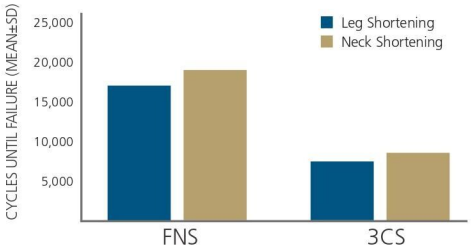
resulting from **LATERAL IMPLANT PROTRUSION** in up to 5.3% of cases

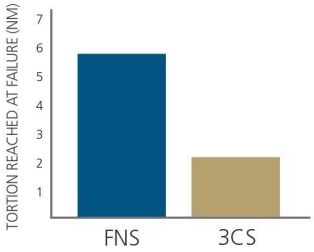
Lateral protrusion can either occur when the implant moves laterally while the femoral neck is shortening during fracture healing, or when the side plate protrudes from the side of the hip. In either case, it often results in lateral thigh pain.[5] Rates of lateral protrusion have been shown to be as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

FEMORAL NECK SYSTEM (FNS)

1 STABILITY

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





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

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

BENEFITS

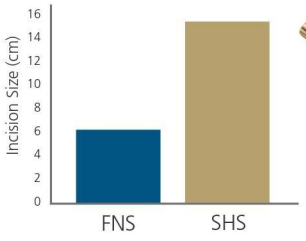
These FNS design features are intended to reduce varus collapse and rotational failures, potentially reducing reoperations due to mechanical instability to a similar level as sliding hip screws.

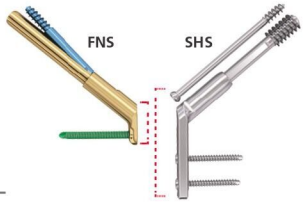
2 MINIMALLY INVASIVE

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

71% REDUCTION **In Footprint Compared to SHS**

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





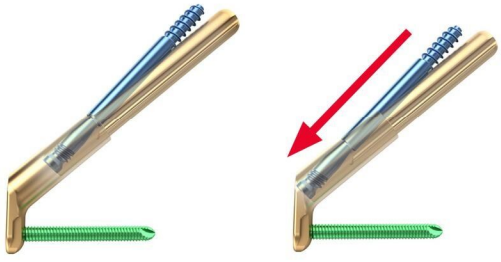
60% REDUCTION **In Incision Size Compared to SHS**

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 20 mm of controlled collapse of the head fragment, with no lateral protrusion for the first 15mm.



BENEFITS

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

PRODUCT OFFERING

IMPLANT FEATURES

1. Antirotation-Screw (ARScrew)

- **Provides rotational stability.**
- **Allows implant placement even in a small femoral neck.**
- **Corresponding size (length) to Bolt.**

2. Bolt

- **Cylindrical design intended to maintain reduction during Insertion.**
- **Provides angular stability.**
- **Dynamic design (Bolt and ARScrew slide together, max 20mm)**
- **Guided collapse designed to reduce lateral protrusion.**

3. Plate

- **Provides angular stability.**
- **Designed to reduce implant footprint.**

IMPLANT SPECIFICATION

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

Austeofix®

QUALITY MANAGEMENT SYSTEM

Certificate of Registration

This is to Certify That The Quality Management System of

AUSTEOFIX SURGICAL PVT. LTD.

PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK, PHASE 1,
DEHMI KALAN, JAIPUR AJMER EXPRESS HIGHWAY,
BAGRU, JAIPUR- 303007, RAJASTHAN, INDIA

has been assessed and found to conform to the requirements of

ISO 9001:2015

for the following scope :

DESIGN, MANUFACTURE AND SUPPLY OF VARIOUS TYPES OF TRAUMA (VARIOUS LOCKING AND NON LOCKING), SPINE, ARTHOPLASTY, ARTHROSCOPIC, MAXILLOFACIAL (DENTAL), CRANIO MAXILLOFACIAL, EXTERNAL FIXATORS AND VARIOUS TYPES OF ORTHOPEDIC SURGICAL INSTRUMENTS

Certificate No : 20DQGUSB
Initial Registration Date : 02/06/2020
Date of Expiry* : 01/06/2021
Date of Re certification : 02/06/2023
Issuance Date : 02/06/2020

DIRECTOR
ROHS Certification Pvt. Ltd.

IAF
eiaCI
035-CB-QMS

CERTIFICATE

CERTIFICATE

This is to Certify that the

Medical Device Quality Management System of

AUSTEOFIX SURGICAL PRIVATE LIMITED

PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK, PHASE 1, DEHMI KALAN, JAIPUR AJMER EXPRESS HIGHWAY, BAGRU, JAIPUR - 303007, RAJASTHAN, INDIA

has been independently assessed and is compliant with the requirements of:

ISO 13485:2016

(Medical devices - Quality management systems - Requirements for regulatory purposes)
This certificate is applicable to the following scope of operations:

DESIGN, MANUFACTURE, EXPORT AND SUPPLY OF ALL TYPES OF TRAUMA (ALL LOCKING AND NON LOCKING), SPINE, ARTHOPLASTY, ARTHROSCOPIC, MAXILLOFACIAL (DENTAL), CRANIO MAXILLOFACIAL, EXTERNAL FIXATORS AND ALL TYPES OF ORTHOPEDIC AND GENERAL SURGICAL INSTRUMENTS

Certificate No.: SPC17M1226

Date of Initial Registration: 29-04-2017
Date of This Certificate: 01-06-2020
Surveillance audit on or before: 28-04-2021
Date of Re-Certification: 29-04-2023

Authorised Signatory

SP Certification Limited
130, Old Street, London,
EC1V9BD, U.K.
Email: info@spcertification.co.uk
www.spcertification.co.uk

AFIST

Accredited by Accreditation Forum of International Standards (AFIST (UK) LTD.)
9, Park View Road, Leeds, LS4 2LG, United Kingdom (UK), Email : info@afist.org, Website : www.afist.org
The approval is subject to the company maintaining its system to the required standards, which will be monitored by SPC.
The Certificate remains the property of SPC and must be returned on request.
To check validity of this certificate please visit **www.spcertification.co.uk** and **www.afist.org**

CERTIFICATE

CERTIFICATE

Of Compliance

This is to certify that the technical documentation has been independently assessed and compliant with the requirements of MDD directive 93/42/EEC

Manufacturer

Name : **AUSTEOFIX SURGICAL PRIVATE LIMITED**

Address : **PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK, PHASE 1, DEHMI KALAN, JAIPUR AJMER EXPRESS HIGHWAY, BAGRU, JAIPUR - 303007, RAJASTHAN, INDIA**

Product Details : **TRAUMA (ALL LOCKING AND NON LOCKING), SPINE, ARTHOPLASTY, ARTHROSCOPIC, MAXILLOFACIAL (DENTAL), CRANIO MAXILLOFACIAL, EXTERNAL FIXATORS AND ALL TYPES OF ORTHOPEDIC AND GENERAL SURGICAL INSTRUMENTS (AS PER ANNEXURE ATTACHED)**

Applicable Standard : **Directive 93/42/EEC as amended 2007/47/EC**

This certificate refers to the information examined and read with manufacturer's declaration of conformity. Further, the product liability rests with the manufacturer or his representative in accordance with the council directive 93/42/EEC as amended 2007/47/EC. The CE Mark as shown below can be used, under the responsibility of manufacturer, after completion of a CE Declaration of conformity and compliance with the relevant CE Directives.

Certificate No.: SPC17C1228

Date of Initial Registration: 29-04-2017
Date of This Certificate: 01-06-2020
Surveillance audit on or before: 28-04-2021
Date of Re-Certification: 29-04-2023

Authorised Signatory

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CE AFIST

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Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare
(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
Fax: 23236973
Dated : 22-APR-2020

File No. : NZ/MD/2019/000033

M/s Austeofix Surgical Pvt. Ltd.,
10-11-12, PLOT NO. 6, Vivekanand Marg,
C-Scheme, Jaipur, Rajasthan, India, 302001
Jaipur , Jaipur, Rajasthan (India) - 302001
Telephone No.: 9314522429 FAX:
9782002006 Email: info@austeofix.com

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

Manufacturing licence No. MFG/MD/2020/000091 in Form MD-9 is hereby forwarded to you. This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

City Office :-

C-6, Pearl Pride, Vivekanand Marg, C-Scheme, Jaipur-302005 (Raj.) India

Ph. : +91-141-4010028, 4010029

Factory Address :-

Plot No.81, Solitaire Industrial Park Phase 1, Dahmi Kalan. Jaipur Ajmer Exp. Highway

RIICO Ind.Area, Bagru, jaipur

Ph. : +91-9511348306

info@austeofix.com, www.austeofix.com