

Asnis[®] Micro

Cannulated screw system

Xpress operative technique



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This publication sets forth detailed recommended procedures for using Stryker devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to first surgery. All non-sterile devices must be cleaned and sterilized before use.

Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

For additional information please refer to the instructions for use (IFU), Ref.-No. 90-01971 delivered with each implant and IFU, Ref. No. 90-01972 and 600001-010 delivered with each instrument. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Warning: fixation screws:

Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Indications, precautions & contraindications

Intended use

The Asnis®III cannulated screw system is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Warnings & precautions

Implant selection and sizing:

The correct selection of the fracture fixation appliance is extremely important. Failure to use the appropriate appliance for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

Fixation Screws:

Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Asnis Micro Xpress has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Asnis Micro Xpress in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Indications

The indications for use of these internal fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

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 failure include:

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

Note: For additional information please refer to the Instructions For Use (IFU), Ref.-No. 90-01971 delivered with each implant and IFU, 90-91972 and 600001-010 delivered with each instrument

Operative
technique

Sterile packaging

The 2.0 and 3.0 Sterile Instrument Kits are packaged using a double blister. Sterile field transfer should be done in accordance with normal procedures.



Figure 1

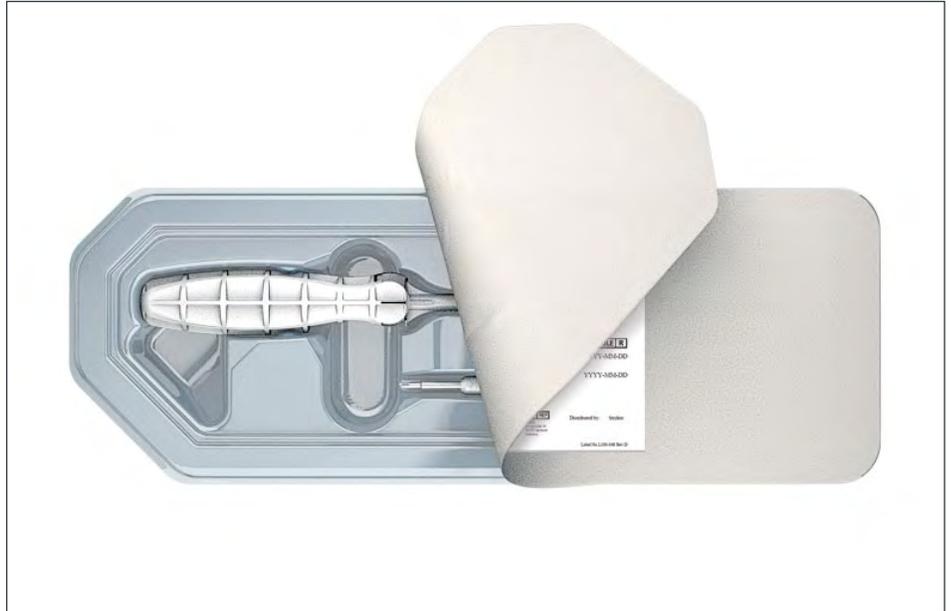


Figure 2

Asnis Micro general considerations

Guide wire insertion

Insert the K-wire at the entry point to depth of intended screw placement.



Figure 3

Countersinking of the screw head (optional step)

Where soft tissue coverage is minimal, the option for countersinking the screw head for further recess of the low profile screw head may be used.

Apply the countersink/depth gauge over the K-wire and prepare the bone for countersinking by turning the instrument clockwise.

Note: Countersinking should be applied before screw length measurement since it influences the measurement of the overall screw length.



Figure 4

Washers

Washers may be placed under the screw head in order to spread the load over a bigger area. After countersinking washers cannot be used.



Figure 5

Asnis Micro general considerations

Measurement of the screw length

All screw measurements need to be taken prior to drilling and/ or countersinking over the K-wire.

In order to achieve the correct screw length measurement, prior to measuring, ensure that the final position of the K-wire is accurate via visual confirmation or by using an image intensifier.

Note: After using any cannulated instrument over a K-wire, make certain that the K-wire did not shift or dislocate.

Slide the countersink/depth gauge over the K-wire and position it in direct contact with the bone.

Caution: Do not place downward pressure when performing initial measurement with the countersink/depth gauge. Downward pressure may influence final measurement.

The countersink/depth gauge measures directly to the tip of the K-wire, thus ensuring that the final screw position corresponds with the initial tip position of the K-wire.

The end of the K-wire, when placed against the countersink depth gauge, allows for a direct reading of the screw length to be used. This measurement includes the screw head.

Subtract appropriately for any anticipated fracture reduction or inter-fragmentary reduction due to compression of the screw during insertion.



Figure 6

Note: The following can influence the result of your screw length measurement:

- If the measuring gauge is not placed perpendicular to the bone surface, the measurement can be influenced by up to 1–2mm

Caution: If screw head sinks into the bone, this may result in an unanticipated countersinking of approximately 1-2mm

Also note, when washers are used, the height of the implanted washer (0.5mm for the 2.0mm Asnis Micro sterile washer or 0.7mm for 3.0mm Asnis Micro sterile washer) needs to be considered for the overall screw length.

After screw insertion, always confirm proper screw length by using an image intensifier or through direct visual verification.

Pre-drilling (optional step)

Pre-drilling is generally recommended, particularly in hard cortical bone. Insert the cannulated drill bit by power, using a Pin Collet or Jacobs Chuck. Drill through the near cortex up to the osteotomy site.

Note: Avoid drilling too deeply into the far segment. In the case of inadvertent back out of the K-wire, it should be manually repositioned. Verify the correct position of the K-wire by fluoroscopy.

Note: In order to avoid damaging the K-wire, use low speed

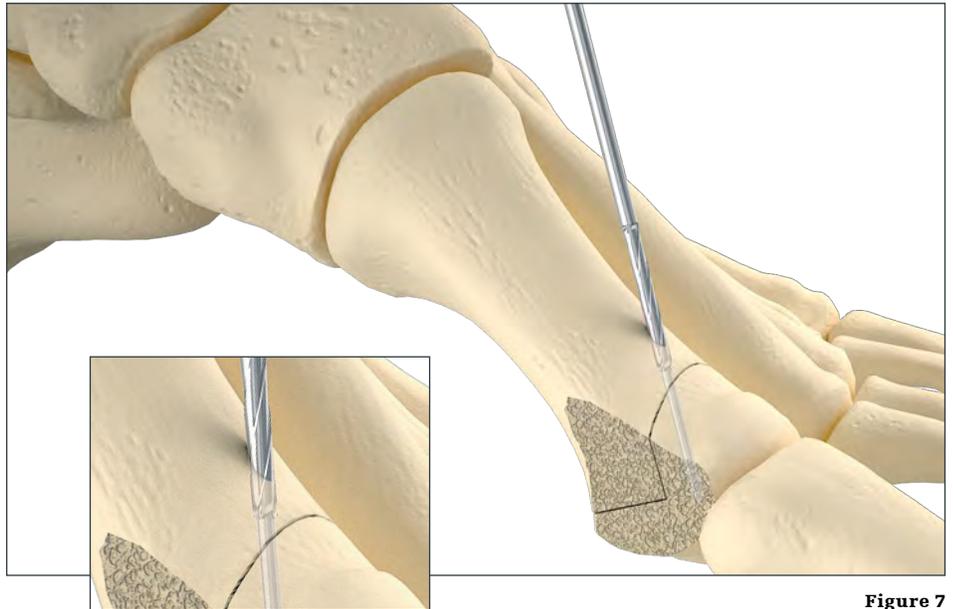


Figure 7

Screw insertion

To prepare for insertion place the screw over the K-wire onto the bone.

Insert the screw over the K-wire by turning the screwdriver clockwise.

After final insertion remove the screwdriver from the screw and verify the K-wire and screw position with the image intensifier.

After the positions have been verified remove and discard the K-wire.



Figure 8



Figure 9

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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