Instructions for use
Resorbable Sleeves for ASLS for Intramedullary Tibial Nails

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Resorbable sleeves for ASLS (Angular Stable Locking System) for Intramedullary Tibial Nails (IM Nails)
Please read these instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Important note for medical professionals and OR staff: These instructions for use do not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information (corresponding surgical technique, Important Information and device-specific label). This instruction for use alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

System Description
ASLS consists of Titanium screws, resorbable sleeves, and instruments and is used with cannulated Synthes Titanium IM Tibial Nails instead of standard locking screws to provide angular stability.
Available diameters are ASLS4 (4.0 mm) and ASLS5 (5.0 mm). The indicated diameter is the diameter of the respective standard screw.
Each ASLS screw has a threaded shaft with 3 different diameters:
– the smallest at the tip to hold the unexpanded ASLS sleeve for insertion,
– a medium diameter in the middle on which the expanded ASLS sleeve sits when insertion is completed,
– and the biggest diameter next to the screw head to provide hold in the over-reamed near cortex.

Material(s)

Material(s):	Standard(s):
70:30 poly(L-lactide-co-D,L-lactide)	ASTM F 1925

This material consists of a co-polymer produced only from lactide monomers. It retains stability for 12 weeks, and then it gradually breaks down to lactic acid, which the body metabolizes to H_2O and CO_2.

Properties/Effects
The ASLS sleeve is mounted onto the smallest thread diameter of the ASLS screw. When inserted into the nail locking hole, the sleeve expands while advancing from the smallest screw diameter to the main, medium screw diameter. In its final position, the expanded sleeve fills the gap between ASLS screw and nail locking hole completely and thus prevents the screw from toggling, providing angular stability to the nail-screw construct.

Intended Use
System to achieve angular stable locking for Synthes cannulated titanium intramedullary tibial nails.

Indications
ASLS is used as an alternative to standard locking of cannulated Synthes Titanium IM Nails, for the operative treatment and stabilization of fractures in the tibia, according to the specific indications listed in the labeling of the corresponding nail system. The ASLS construct retains increased stability (compared to standard locking) for 12 weeks.
ASLS is particularly indicated in cases where increased stability is needed, for example in fractures closer to the metaphyseal area or in osteopenic bone.
Full degradation takes about 2 years. The resorption rate varies from patient to patient.

Contraindications
– Contraindications of the respective nail system
– The patient has an established intolerance/allergy to poly-lactides
– Situations in which internal fixation is contraindicated for other reasons, e.g. in patients with acute, potential or chronic infections, with poor bone quality, with reduced blood circulation, with bone disorders or lack of willingness to cooperate (e.g. alcoholism)

Potential adverse events
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, and side effects associated with hardware prominence, malunion, non-union.

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.

Do not use when packaging is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.

Do not resterilize

Implantable devices labeled with "Do not resterilize" symbol must not be resterilized because re-sterilization may compromise the structural integrity of the device and/or may lead to device failure.

Single-use device

Do not re-use

Products intended for single-use must not be re-used.

Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.
Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions
The following complications may occur:
– Fragment displacement as a result of use in inappropriate indications
– Neurovascular injuries caused by surgical trauma

As with all ostesynthesis, a good reduction of the fragments prior to insertion of the implants is crucial for a good clinical outcome.

Warnings
– Only use ASLS Sleeves together with the specially developed Synthes ASLS screws.
– Do not attempt to re-sterilize the unused contents of an opened pack, but dispose of such remnants: this applies to both the inner primary and the outer secondary packaging.
– Re-sterilization of ASLS Sleeves can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.
– Do not use the ASLS Sleeve after the expiry date printed on the packaging.
– Do not use ASLS with solid nails.
– Do not use ASLS with Stainless Steel nails.
– Do not use ASLS with any other than Synthes nails.
– The use of ASLS with antibiotic-coated nails may require increased force for the insertion of the ASLS sleeve.

Magnetic resonance environment
Due to the nature of the polymer material, i.e. intrinsically non-metallic, non-conductive and non-magnetic, no influence in a magnetic field must be expected.
For details on MRI information for the used nails and locking bolts/screws please refer to the specific labeling of these devices.

Special operating instructions
The system may only be used with the specially developed instruments for ASLS and the respective IM Tibial Nail system. The manufacturer does not accept any liability for complications that may arise from the use of other instruments.
ASLS sleeves must only be used together with ASLS screws of the same size.
The right choice of implant (size, shape and adaptation) and correct positioning and fixation are crucially important to the success of osteosynthesis.
It is highly recommended that the operating surgeon is thoroughly familiar with the implants, instruments and relevant surgical techniques.

The implantation should be performed according to the standard surgical procedures employed for metallic implants (please refer to the relevant details in the handling techniques for the IM Tibial Nails and the current «AO Principles of Fracture Management».). The choice of sleeve size is determined by the diameter of the screws (ASLS4 or ASLS5), which again depends on the diameter of the used nail. For easier determination of screw diameter, the nails, instruments and screws are color coded. The surgery is performed according to the standard surgical technique for the respective nail system. For locking of the nails, a modified technique has to be used. The following technique describes the steps for aiming arm guided locking and freehand locking using the Synthes Radiolucent Drive:

Drill through both cortices
- Use the special ASLS drill bit for the respective screw diameter (ASLS4 or ASLS5).
- Precisely align the drill bit with the locking hole axis.
- Drill through both cortices.

Measure screw length
- Use the special ASLS depth gauge to measure the screw length or use the calibration on the ASLS drill bit.
- Make sure the hook of the depth gauge catches at the far cortex for measuring. Check with image.

Ream cis-cortex
- In order to being able to insert the sleeve, the cis-cortex needs to be overreamed. Use the special ASLS reamer for the respective screw diameter (ASLS4 or ASLS5) to ream the cis-cortex.
- Precisely align the reamer with the locking hole axis.
- Be careful not to damage the nail with the reamer, but make sure the cis-cortex is completely reamed and cleaned.

Insert screw and sleeve
- Mount the chosen ASLS sleeve onto the ASLS screw until approx. 2 mm of the screw's tip protrude on the far end of the sleeve. The sleeve must not be expanded yet, the sleeve's bridges should not break.
- Use screw driver to push the screw-sleeve-assembly through the protection sleeve into the nail locking hole. Do not use any rotational movements until the sleeve is completely seated in the nail locking hole.
- Use only very slight hammering.
- When the sleeve is in its correct position in the nail locking hole, start rotational movements with the screw driver to advance the screw through the nail into the far cortex. At the same time keep pushing the sleeve into the nail to prevent the sleeve from rotating with the screw.
- A ring marking on the screw driver indicates, when the screw is completely inserted. Check with image. Do not overinsert the screw.

Freehand locking without radiolucent drive
The above described steps are performed in this order:
- Ream cis-cortex.
- Drill through both cortices (a special drill sleeve is used for more accuracy).
- Measure screw length.
- Insert screw and sleeve.

Screw exchange
If the screw needs to be replaced intra-operatively, it can simply be removed like any other standard screw and a new ASLS screw is inserted. The sleeve remains in the nail locking hole.

Implant removal
First the screws, then the nail are removed as any standard implant. The ASLS sleeve normally already is resorbed and does not need to be removed. If explantation is necessary before the sleeve is resorbed, it remains in the nail locking hole and is removed together with the nail without further steps.

Implantation period
The implantation period of ASLS is identical to that of standard implants. In this context, please refer to the relevant details in the current "AO Principles of Fracture Management".

Restricted or invalid usability
Sleeves removed during operation are already deformed and must not be re-implanted.

Device-related storage and handling information

Upper limit of temperature: 25°C

Store the ASLS sleeve under 25° Celsius. If the temperature limit was exceeded this may compromise the structural integrity of the device and/or may lead to device failure.


Keep away from sunlight


Keep dry

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

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