Instructions for Use
LUMBAR PLATES

This instruction for use is not intended for distribution in the USA.

DePuy Synthes
SPINE
COMPANIES OF Johnson&Johnson

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Instructions for Use

LUMBAR PLATES:
– ATB™ Anterior Tension Band Plate
– ArcoFix
– TELEFIX™
– TSLP™ Thoracolumbar Spine Locking Plate
– VENTROFIX™
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material

Material:	Standard:
TAN	ISO 5832-11
CPTI	ISO 5832-2

Intended use
ATB Anterior Tension Band Plate
The Anterior Tension Band (ATB) System is a comprehensive set of implants and instruments designed for anterior stabilization of the lumbar spine.

ArcoFix
ArcoFix is an implant and instrument system for the anterior stabilization of the thoracolumbar spine (T8–L4), e.g. after discectomies and partial or complete corpectomies. It can be used in combination with a bone graft or a vertebral body replacement such as Synex.

TELEFIX
TELEFIX is an implant system for the anterior stabilization of the thoracolumbar spine, e. g. after discectomies and partial or complete vertebrectomies. The system can be used in combination with a bone graft or vertebral body replacement implants such as synex. The TELEFIX instruments are equally suitable for open, minimally invasive or endoscopically assisted approaches.

TSLP Thoracolumbar Spine Locking Plate
TSLP is a low-profile plating system, that can be used for fixation of the thoracolumbar spine (T3 to L5) through an anterolateral or lateral approach. The system is intended to be used in combination with intervertebral fusion devices as well as with partial or complete vertebral replacement devices.

VENTROFIX
VENTROFIX is a modular, stable rod system developed for the fixation of the anterior thoracic and lumbar spine.
Four different clamp types made of a titanium alloy (TAN) can be combined in various ways. This enables the surgeon to choose implant configurations suited to the individual pathology and anatomical conditions.
Locking screws are used to secure the clamps to the vertebral bodies.
These locking screws have a self-tapping cancellous thread and a short machine thread which keeps them firmly locked to the clamp.
The implant may be compressed or distracted when instrumentation has been completed.

Indications
ATB Anterior Tension Band Plate
– Degenerative intervertebral disc diseases,
– Spinal fractures (L1-S1),
– Spinal tumours (L1-S1),
– Pseudoarthrosis and
– Revisions after failed decompression surgery that have sufficient, biomechanically stable, ventral support.

ArcoFix
– A-type fractures with canal clearance
– Pathological fractures with intact posterior ligamentous complex
– Tumor-related surgeries
– Traumatic kyphosis that can be adequately reduced and secured from anterior
– Additional anterior fixation in cases where anterior stabilization and/or correction is important
– Osteoporosis is only indicated when used concurrently with PMMA-Cement indicated for internal spinal fixation supplementation

TELEFIX
TELEFIX can be used from T8 to L5 in:
– Fractures that can be adequately reduced and secured from anterior
– Tumours and infections
– Posttraumatic kyphoses that can be adequately reduced and secured from anterior
– Posterior fixation requiring additional anterior stabilization

TSLP Thoracolumbar Spine Locking Plate
The TSLP plates can be used through an anterolateral or lateral approach in the area of T3 to L5 for:
Instability of the spinal column from
– Fractures
– Tumors, and
– Degenerative intervertebral disc diseases that are suitable for ventral treatment, and where sufficient ventral support is ensured.

VENTROFIX
VENTROFIX is implanted using an anterior approach and is used to stabilize the spine in
– Fractures
– Tumours and infections
– Degenerative diseases
– Posttraumatic kyphoses

Contraindications
ATB Anterior Tension Band Plate
– Scoliosis,
– Serious osteoporosis, especially in the case of osteoporotic fractures and
– Spondylolisthesis.

ArcoFix
– General contraindications against anterior surgery (e.g. patient condition, advanced age)
– Severe osteoporosis
– Correction of scoliotic deformities
– Fractures with severe injury of the posterior structures
– Degenerative disease

TELEFIX
– Severe osteoporosis
– Scolioses

TSLP Thoracolumbar Spine Locking Plate
– Scoliosis
– Severe osteoporosis, especially osteoporotic fractures
– Spondylolisthesis

VENTROFIX
– Severe osteoporosis
– Scolioses

Side effects
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 may 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, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones, discs, or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, partial displacement of the graft, vertebral angulation.

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

Do not resterilize

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 general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".

Warnings
It is strongly advised that ATB Anterior Tension Band Plate, ArcoFix, TELEFIX, TSLP Thoracolumbar Spine Locking Plate, and VENTROFIX implants are implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

The ArcoFix screws, however, are to be combined with bone cement indicated for internal spinal fixation supplementation. Please refer to the associated product information for details on its use, precautions, warnings and side effects.

Magnetic Resonance environment
MR Conditional:

ATB Tension Band Plate
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the ATB Tension Band Plate system are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg for 15 minutes of scanning.
Based on non-clinical testing, the ATB Tension Band Plate implant will produce a temperature rise not greater than 5.6°C at a maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.
MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the ATB Tension Band Plate device.

ArcoFix
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the ArcoFix system are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg for 15 minutes of scanning.
Based on non-clinical testing, the ArcoFix implant will produce a temperature rise not greater than 5.6°C at a maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.
MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the ArcoFix device.

TELEFIX
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the TELEFIX system are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg for 15 minutes of scanning.
Based on non-clinical testing, the TELEFIX implant will produce a temperature rise not greater than 5.6°C at a maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.
MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the TELEFIX device.

TSLP Thoracolumbar Spine Locking Plate
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the TSLP system are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg for 15 minutes of scanning.
Based on non-clinical testing, the TSLP implant will produce a temperature rise not greater than 5.6°C at a maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.
MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the TSLP device.

VENTROFIX
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the VENTROFIX system are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 15 minutes of scanning.
Based on non-clinical testing, the VENTROFIX implant will produce a temperature rise not greater than 5.7°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.
MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the VENTROFIX device.

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling Multipart Instruments" can be downloaded from: http://www.synthes.com/reprocessing

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