Instructions for Use
TROLLEY

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

TROLLEY
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(s)

Material(s):	Standard(s):
TAN	ISO 5832-11
CPTI	ISO 5832-2
PEEK	ASTM F 2026
UHMWPE	ISO 5834-1

Intended use
TROLLEY is a posterior passive growth-guiding solution placed in the thoracolumbar spine. It is used in combination with spinal anchors and helps to provide deformity correction of the scoliotic immature spine while allowing for continued spinal growth.

Indications
Progressive scoliosis with remaining growth of the spine

Contraindications
– Rigid, non-flexible spine
– Pedicles too small for pedicle screw implantation
– Skeletally mature
– Insufficient soft tissue to allow for proper skin coverage of implant
– Poor nutrition status

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.

In addition to the general risks associated with spinal surgery, Early Onset Scoliosis (EOS) patients undergoing this procedure have the potential to experience a high rate of complications including but not limited to rod fracture, screw loosening/pull-out or spontaneous fusion.

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".
The TROLLEY implants are an addition to the indicated pedicle screw systems below. TROLLEY Gliding Vehicles (TROLLEY GVs) need to be used in conjunction with indicated pedicle screws and hooks within the thoracolumbar spine.

Indicated Pedicle Screw Systems	Rod Diameter
– USS Small Stature/Pediatric and USS II	∅ 5.0/∅ 6.0 mm
– Pangea	∅ 6.0 mm
– URS	∅ 6.0 mm

To reduce the risk of spontaneous fusion, ensure to skip minimum one level between:
– the TROLLEY GVs
  and
– the TROLLEY GVs and the fixed spinal anchors

Warnings
Despite TROLLEY GVs having a low profile, patients may require additional wound or skin protection to prevent inadvertent rubbing or bumping of prominent implants. Overlying skin protection is recommended, so patients should initially wear a protective dressing, padding or brace on the skin overlying the implants in order to prevent rubbing or bumping of the skin, which may lead to skin breakdown. Monitoring for skin breakdown decreases the risk of deep infections. Patients with a diagnosis of spina bifida need additional surveillance due to their decreased levels of sensation.

It is important to note that EOS patients who receive TROLLEY will need careful ongoing monitoring and may require additional surgery.

It is strongly advised that TROLLEY is 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.

Magnetic Resonance environment
MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the TROLLEY 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 TROLLEY implants 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 TROLLEY device.

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