# Instructions for Use
# TROLLEY™ Growth Guiding Solution

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
manual is always available online.
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PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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# Instructions for Use

TROLLEY™ Growth Guiding Solution
TROLLEY is a posterior passive growth-guiding implant placed in the thoracolumbar regions of the spine.
TROLLEY implants consist of Gliding Vehicle (GV), Cable Tie, Parallel Spacer and Rod ∅ 5.0 mm/∅ 6.0 mm. Additionally, TROLLEY GV comes with its own preassembled Applicator, a single use polycarbonate component that is disposed of post-procedure.

The implants provide the flexibility to accommodate a range of pathologies and variations in patient anatomy for the immature scoliotic thoracolumbar spine. TROLLEY offers two construct options: two-rod technique and four-rod technique.

These instructions for use contain information about the following products:

| | |
|---|---|
| 04.625.053S | 04.625.645S |
| 04.625.054S | 04.625.650S |
| 04.625.055S | 04.626.415S |
| 04.625.063S | 04.626.420S |
| 04.625.064S | 04.626.425S |
| 04.625.065S | 04.626.430S |
| 04.625.415S | 04.626.435S |
| 04.625.420S | 04.626.440S |
| 04.625.425S | 04.626.520S |
| 04.625.430S | 04.626.525S |
| 04.625.435S | 04.626.530S |
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| 04.625.625S | 04.626.645S |
| 04.625.630S | 04.626.650S |
| 04.625.635S | 08.625.009S |
| 04.625.640S | 08.625.012S |

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

For accompanying information, such as Surgical Techniques, please visit www.jnjmedtech.com/en-EMEA/product/accompanying-information or contact local customer support.

**Materials**
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11
Titanium: TiCP (Commercially pure Titanium) according to ISO 5832-2
PEEK: Polyetheretherketone according to ASTM F 2026
UHMWPE (Ultra-high-molecular-weight- polyethylene) according to ISO 5834-2

**Intended Use**
TROLLEY implants are intended for passive growth-guiding posterior deformity correction in the thoracolumbar spine when used in combination with spinal anchors in patients with the potential for additional spinal growth.

**Indications**
– Progressive scoliosis in patients with the potential for additional spinal growth.

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

**Patient Target Group**
The TROLLEY implants are intended for use in skeletally immature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

**Intended User**
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

**Expected Clinical Benefits**
When the TROLLEY implants are used as intended and according to the instructions for use and labeling, they are expected to provide correction of deformity and maintenance of the alignment achieved.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

**Performance Characteristics of the Device**
The TROLLEY implants are growth-guiding devices, designed to allow for continued spinal growth during deformity correction of the immature scoliotic spine when used in combination with a compatible posterior fixation system.

**Potential Adverse Events, Undesirable Side Effects and Residual Risks**
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; excessive bleeding; neural and vascular injury; death, stroke; swelling, abnormal wound healing or scar formation; heterotopic ossification; functional impairment of the musculoskeletal system; paralysis (temporary or permanent); complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence, implant breakage, loosening or migration; malunion, non-union or delayed union; decrease in bone density due to stress shielding; adjacent segment degeneration; new or ongoing pain or neurological symptoms; damage to adjacent bones, discs, organs, or other soft tissues; osteolysis; lymphatic injury; dural tear or spinal fluid leak; spinal cord compression and/or contusion; device or graft material displacement; vertebral angulation.

Of the potential risks above, EOS patients undergoing this procedure may experience complications including but not limited to rod fracture, screw loosening/pull-out and spontaneous fusion at a rate higher than seen in other posterior fixation procedures.

**Sterile Device**

Sterilized using irradiation

Store sterile devices 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

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

**Single Use Device**

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical 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, re-use 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.

**Warnings and Precautions**
- It is strongly advised that the TROLLEY implant is implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.
- Implantation is to take place as per 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.
- Warning: Special considerations should be taken with patients with known allergies or hypersensitivities to implant materials.
- The TROLLEY implants are an addition to the indicated pedicle screw systems listed in section "Combination of Medical Devices".
- To reduce the risk of spontaneous fusion, skip a minimum of one level between the TROLLEY GVs and the fixed USS spinal anchors.
- 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 may decrease the risk of deep infections. Patients with a diagnosis of spina bifida need additional surveillance due to their decreased levels of sensation.
- 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.
- It is important to note that EOS patients who receive TROLLEY will need careful ongoing monitoring and may require additional surgery.

Preparation and approach
- Dissection at the area where TROLLEY GVs are to be inserted should be kept at a minimum, using extra-periosteal and muscle sparing techniques to reduce the risk of spontaneous fusion.
- Additionally, the depth of the TROLLEY GV is crucial. If left too superficial, skin breakdown may occur. Conversely, if TROLLEY GVs are inserted too deep, the rods will be resting on the bone or facet joints above and below, increasing the risk of early spontaneous fusion.

Screw insertion
Perforate cortex of pedicle and prepare for screw insertion.
- Do not use the pedicle awl or the pedicle probe for any screws that are smaller or bigger than the corresponding size of screw.
- Screw entry points between levels should deviate as little as possible. This will help to create good alignment of the TROLLEY GV and reduce stresses in the final construct. Keeping the rods parallel to each other is an important factor to allow guided growth.
- Additional care must be taken with EOS patients who may have small pedicles. Therefore, the use of radiographic imaging is crucial to locate pedicles and to reduce the risk of malpositioned screws.

Assemble TROLLEY screwdriver to TROLLEY GV
- The TROLLEY screwdriver can only be used with TROLLEY GVs.

Insert remaining TROLLEY GVs
- To reduce the risk of spontaneous fusion, ensure to skip minimum one level between the TROLLEY GVs.

Align TROLLEY GVs
- Orientation and depth adjustment is crucial to ensure usability of the cable tie closure. If the TROLLEY GV bearing surface is not aligned to the rod then cable tie closure may be difficult and may result in asymmetrical wear of the bearing. This is particularly important when using a TROLLEY GV with double bearing.
- Depth adjustment is particularly important for TROLLEY GVs in adjacent vertebrae as a difference in depth may lead to difficulties in closing the cable tie.
- Ideally, the cable tie lock is placed facing laterally in the final position. A midline position for the lock is not recommended due to potential conflicts with the spinous processes.
- Always check if the cable tie is mobile before insertion of the rod.

Rod insertion
- Insert remaining fixed spinal anchors according to chosen construct type prior to rod insertion.
- Select appropriate rod diameter (∅ 5.0/6.0 mm) depending on chosen pedicle screw system and patient anatomy.
- For larger, neuromuscular patients a ∅ 6.0 mm might be beneficial.
- To reduce the risk of spontaneous fusion, ensure to skip minimum one level between the TROLLEY GVs and the fixed spinal anchors.

Determine rod contour and length
- Make sure to cut the rods appropriately at the flat end to reduce the risk of sharp rod ends (do not cut the rod at the blunt tip end as this is important to ease rod tunneling).
- Rod contouring needs to be done carefully to produce smooth curves and to avoid any notches.

Four-rod technique – Contour and insert rods
- Insert the rod with the blunt tip first to reduce soft tissue or implant damage.
- Check that the rods can slide freely after assembly and are separated from each other.
- Mishandling of the rod causing surface damage, may reduce the gliding potential of the construct.
- Rod bending in the gliding zone (proximity of TROLLEY GVs) may compromise the gliding capabilities of the construct.
- Do not reverse or over-bend the rods. Reverse or repeated bending produces internal stresses, which may become the focal point for early failure of the implant.

Four-rod technique – Parallel spacer
- Parallel spacers are designed to reduce convergence of the two parallel rods. Direct contact of the rods could cause wear debris.
- Therefore, it is recommended to implant parallel spacers at long intersections in four-rod constructs.

Four-rod technique – Insertion of cable tie for parallel spacer
- Do not bend the cable tie at the hole location where you put the holding forceps as this may compromise the closing procedure.

Two-rod technique – Contour and insert rods
- Insert the rod with the blunt tip first to reduce soft tissue or implant damage.
- Check that the rods can slide freely after assembly.
- Mishandling of the rod causing surface damage, may reduce the gliding potential of the construct.
- Rod bending in the gliding zone (proximity of TROLLEY GVs) may compromise the gliding capabilities of the construct.
- Do not reverse or over-bend the rods. Reverse or repeated bending produces internal stresses, which may become the focal point for early failure of the implant.

Final tightening
Final closure of TROLLEY GVs
- Do not use the cable tie for rod reduction. Use the double rod pusher(s) to reduce rods.
- Do not attempt to correct the deformity by simply pulling on the cable tie as the cable tie is not indicated for such a maneuver.
- Avoid scratching the rods with the double rod pusher(s).

Cutting off cable tie ends
- Before cutting the cable tie ends, ensure that the rods are fully seated inside the bearing of the TROLLEY GV. Then, make sure to align the TROLLEY cable cutter for cable tie before cutting to avoid damage to the cable tie.
- Maintain pressure on cable cutter handle when removing to prevent cut-off portion of cable tie from falling into the wound.

Finalize construct
Use TROLLEY with indicated systems only.

Additional implants for stabilization
Use of transverse connectors
- Do not use transverse connectors in the gliding zone as it will negatively affect the construct's ability to support growth.

Components assembly
– Make sure that the bearing of the TROLLEY GV is still intact before inserting a new cable tie. If the bearing is damaged, the TROLLEY GV needs to be replaced completely.
– Do not bend the cable tie at the hole location where you put the holding forceps as this may compromise the closing procedure

For more information, please refer to the Synthes brochure "Important Information".

**Combination of Medical Devices**
TROLLEY GVs need to be used in conjunction with the following pedicle screw and hook systems that are indicated for use in the thoracolumbar spine:

| Indicated Pedicle Screw System | Rod Diameter |
|---|---|
| USS™ Small Stature/Paediatric Spinal System | ∅ 5.0 mm |
| USS™ II Spinal System | ∅ 5.0 mm/∅ 6.0 mm |

The TROLLEY implants are applied using associated TROLLEY Instruments.

| | |
|---|---|
| 03.625.001 | TROLLEY Screwdriver |
| 03.625.004 | TROLLEY Holding Forceps f/Cable Tie |
| 03.625.005 | TROLLEY Alignment Tool |
| 03.625.006 | TROLLEY Cable Tie Pusher |
| 03.625.007 | Double Rod Pusher, f/Rods ∅ 5.0/6.0mm |
| 03.625.009 | TROLLEY Cable Cutter f/Cable Tie |
| 03.641.006 | Holding Forceps f/Rib Hook Cap |
| 391.905 | Cable Cutter, standard |

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.

**Treatment before Device is Used**
Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.
Store sterile devices in their original protective packaging.
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 by visual inspection:
– Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
– Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.
Do not use if the package is damaged or expired.

**Implant Removal**
The TROLLEY implant is intended for permanent implantation and is not intended for removal. Any decision to remove the device must be made by the Surgeon and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Removal of TROLLEY GV
If a TROLLEY implant has to be removed, the following technique is recommended:
– For removal of the cable ties and the TROLLEY GVs, the cable tie has to be cut. It cannot be reused. For cutting of the cable tie use the cable cutter, standard. Alternatively, the cable cutter for cable tie can be used.
– Removal of the cable tie and rod(s) is required for complete removal of the TROLLEY GV. The TROLLEY alignment tool can be used as a screwdriver to remove the TROLLEY GV.
– In case of revision surgeries (e.g. rod needs to be replaced) cut all cable ties with the cable cutter, then replace the implanted rod with a longer one and follow the steps described in the step "Components Assembly" (in section "Special Operating Instructions") to insert new cable ties.

**Special Operating Instructions**

Preparation and approach
Preparation
– The standard TROLLEY set in combination with one of the pedicle screw systems contains the required implants and instruments to perform the procedure.
– Have the required sets readily available prior to the surgery. Have all necessary imaging readily available to plan construct type, implant placement, incision approach and to identify individual patient anatomy.

Approach
– Make a midline incision spanning segments of spine to be instrumented. Three smaller midline incisions may also be used.
– For fixed spinal anchors, insert spinal fixation through classic subperiosteal dissection as these segments will be fused. Please refer to the instruction for use of the corresponding pedicle screw systems.
– For the insertion of TROLLEY GVs use a transmuscular approach, sparing joints and minimizing bony exposure to reduce the risk of spontaneous fusion. At the thoracic levels, use a lateral to midline erector spinae insertion technique, dissecting directly onto the transverse process, avoiding exposure of the lamina.
– Use of fluoroscopic guidance to confirm pedicle entry point is crucial.

Screw insertion
Perforate cortex of pedicle and prepare for screw insertion.
– Locate pedicles and use the awl of the corresponding screw diameter from the chosen pedicle screw system to perforate the cortex. Use the probe of the corresponding screw diameter to open the pedicle canal. Alternatively, taps can be used to open the pedicle canal.
– Using radiographic imaging, confirm the pedicle location, orientation and depth. When selecting the appropriate length of the TROLLEY GV, use the markings on the probe to determine the pedicle depth. Use the feeler to check pedicle canal integrity prior to insertion of the TROLLEY GV.

TROLLEY GV selection
– TROLLEY GVs are placed at strategic points across the deformity based on curve patterns and construct type used.
– Choose the proper approach according to the region of the spine for TROLLEY GV placement.

Assemble TROLLEY screwdriver to TROLLEY GV
– Make sure the TROLLEY screwdriver is in the "OPEN" position prior to the TROLLEY GV insertion.
– All TROLLEY GVs will be delivered in sterile packaging. Assemble the TROLLEY screwdriver with the unpacked TROLLEY GVs with applicator. The correct orientation of the screw portion is ensured by the driver geometry. The TROLLEY GV with applicator is introduced into the screwdriver by pushing it into the guide. Push the applicator into the screwdriver until it is completely inserted.
– Once the TROLLEY GV with applicator is fully inserted, lock it into place by turning the wheel on the screwdriver clockwise into the "CLOSE" position.

Insert TROLLEY GVs
– The TROLLEY GV can now be inserted into the prepared pedicle under fluoroscopic control. Advance the TROLLEY GV until it is just slightly above the bony surface. The depth of screw insertion can be determined by looking at the skin level.
– The orientation of the cable tie lock is given by the engraved pictogram on top of the TROLLEY GV applicator. The lock on the engraved pictogram should look towards the midline to ensure that in the closed position the lock is placed lateral.
– Visibility in the wound and of the implant can be increased by slightly pulling up the screwdriver. For backing up the screwdriver, make sure you do not completely release the cable tie from the applicator.
– The TROLLEY GVs are self-tapping pedicle screws however, if tapping is preferred, use the appropriate tap and tap handle of indicated pedicle screw systems.
– Make sure to keep the operation site free of disturbing soft tissues.

Remove TROLLEY screwdriver
– The TROLLEY screwdriver can be removed by simply pulling on the instrument. The applicator of the TROLLEY GV will be removed within the same step. To remove the applicator from the TROLLEY screwdriver, turn the wheel on the

screwdriver counterclockwise to the "OPEN" position and pull out the applicator. The single use applicator can then be discarded.

Insert remaining TROLLEY GVs
- Continue inserting the remaining TROLLEY GVs by repeating the previous steps accordingly.
- Make sure to insert the remaining TROLLEY GVs appropriately to allow rod insertion.

Align TROLLEY GVs
- For orientation and depth adjustment of the TROLLEY GV pedicle screw, the TROLLEY alignment tool is placed over the cable tie and rod bearing onto the screw portion of the TROLLEY GV.

Rod insertion
Determine rod contour and length
- Determine required length and cut the rod to length according to expected growth and patient anatomy with a universal 5.0/6.0 mm rod cutter.
- Choose appropriate rod length to allow for growth of the spine without significant soft tissue disturbance.
- Bend the rods to match the spinal anchor locations.
- Bend the rods in respect to the expected growth potential (for TROLLEY GVs).

Four-rod technique – Contour and insert rods
- Contour the polished rods according to your preferred sagittal profile (planned curve correction) and cut the rods (attached at proximally fixed anchors) to travel the length of the spine till they just reach the distally fixed anchors. Similarly, the rods (attached at the distally fixed anchors) should travel just proximal to the proximal fixed anchors.
- Insertion of the rods can be done either from the proximal or distal incision, tunneling the blunt tip towards the middle incision and engaging the TROLLEY GV bearing. Using the sagittal curve of the rods, they can be rotated partially facilitating the insertion of the rods and capturing the spinal implants.
- The rods should be passed subfascially, without touching any bony surface.
- Ensure that overlapping rods are aligned to each other as parallel as possible in the gliding section. This allows for controlled and guided spinal growth.
- Leave sufficient overlap at the gliding free ends. The overlap dictates the growth potential created in the construct.
- Bend rods appropriately to allow insertion into the TROLLEY GVs as well as fixed spinal anchors and use parallel spacers to separate the rods.
- Minimize muscle contusion during rod insertion.

Four-rod technique – Parallel spacer (intended to be used in four-rod constructs only)
- Parallel spacers can be used to guide and separate the rods from each other to prevent rod impingement.
- Begin placement by clipping the parallel spacer onto one of the rods using the holding forceps and in a second step the parallel spacer will be pushed over the second rod. Use a TROLLEY cable tie to secure the parallel spacer. The cable tie pusher in combination with the holding forceps for cable tie is used to close the cable tie and the cable cutter to cut the cable tie.
- Be aware that parallel spacers might migrate during spinal growth. This does not affect functionality.
- The use of parallel spacers is appropriate for four-rod constructs only where two parallel rods are placed in the same run of pedicle screws and interconnected to each other.

Four-rod technique - Insertion of cable tie for parallel spacer
- To secure the parallel spacer to the rods, an additional cable tie will be used.
- It is recommended to bend the tip of the cable tie by hand and thread it mediolateral through the TROLLEY GV bearing.
- Grip the cable tie with the TROLLEY holding forceps for cable tie and pull.

Two-rod technique – Contour and insert rods
- Contour the polished rods according to your planned sagittal profile.
- Insertion of the rods can be done either from the proximal or distal incision, tunneling the blunt tip towards the middle incision and engaging the TROLLEY GV bearing. Using the sagittal curve of the rods, they can be rotated partially facilitating the insertion of the rods and capturing the spinal implants.
- The rods should be passed subfascially, without touching any bony surface.
- Leave sufficient overlap at the gliding free ends. The overlap dictates the growth potential created in the construct.
- Bend rods appropriately to allow insertion into the TROLLEY GVs as well as fixed spinal anchors.
- Minimize muscle contusion during rod insertion.

Final tightening
Close cable ties by hand
- Close the TROLLEY cable ties over the rods by inserting the tip of the TROLLEY cable tie into the closure until the first teeth are engaged, approximately after ~30 mm. Continue pulling by hand in one swift motion making sure that the cable does not bind or kink.
- Cable ties cannot be reopened again. If required, the cable tie needs to be cut and replaced.

Final closure of TROLLEY GVs
- When using the double rod pusher(s), apply forces perpendicular to the rod only to avoid slippage of the double rod pusher(s).
- Always use the double rod pusher(s) as it establishes the recommended space between the two rods.
- The cable ties have to be sequentially closed, gradually capturing the rods. Deformity correction must be achieved by cantilevering the rods into parallel constructs and or undertaking rod derotation maneuvers with partially captured rods at three points of spinal fixation.
- Once the correction has been achieved, position the double rod pusher(s) next to the TROLLEY GVs to push the rod into the bearing of the TROLLEY GVs. To close the cable ties use the cable tie pusher and the holding forceps.
- By levering the holding forceps on the cable tie pusher and pulling on the cable tie, the cable tie can be closed. Proceed in a sequential fashion, final tightening all cable ties.
- To prevent overtightening a fail-safe feature is incorporated in the design of the cable tie. When high tightening forces are applied, the tip will break off to limit forces on the lock. The broken off part will be secured in the forceps.
- Make sure that the rod(s) is (are) fully seated inside the TROLLEY GV bearing and that the bearing is firmly wrapped around the rod(s).

Cutting off cable tie ends
- Before cutting the end of the cable tie, ensure that all cable ties and bearings are firmly wrapped around the rods.
- Use the TROLLEY cable cutter for cable tie to cut off the overhanging ends of the cable tie. Make sure that the head of the cable cutter is flush with the closure to minimize protrusion sharp edges.

Finalize construct
- Finalize the TROLLEY construct using fixed spinal anchors and TROLLEY GVs on the contra-lateral side. Final tighten fixed spinal anchors according to instruction for use of indicated systems.
- Fluoroscopic imaging (anteroposterior [AP] and lateral X-rays) may be crucial to control final construct positioning and achieved correction.
- The cable tie includes a radiopaque marker pin for enhanced visualization indicating the position of the lock.

Continuum of care
Replacement of rod
- Patients who have outgrown their TROLLEY constructs, (equals less than 2 TROLLEY GVs are connected per rod end) need a replacement of their rod(s) with longer one(s) to support further growth of the spine. Please perform the following steps below:
  - Cut open all cable ties by following the steps described in "Removal of TROLLEY GV".
  - Follow the steps described in "Components assembly" to insert new cable ties into the TROLLEY GVs
  - For the rod insertion procedure please perform the steps described in "Rod insertion".
  - Perform the final tightening procedure described in "Final tightening".
  - Finalize the construct by following the steps described in "Finalize construct".

Additional implants for stabilization
Use of transverse connectors
- For additional rotational stability transverse connectors can be mounted depending on the construct type chosen, either cranially and/or caudally or in the apex. The transverse connectors need to be placed between a pair of fixed spinal anchors. Choose the appropriate transverse connector with respect to the implanted rod diameter.
- For ∅ 5.0 mm rods, transverse connectors from the USS Small Stature/Pediatric sets can be used. For ∅ 6.0 mm rods, transverse connectors from USS II sets can be used.
- For instructions of use for the selected transverse connector please refer to the IFU of the corresponding system.
- Transverse connectors are to be taken from the fixed pedicle screw system used to anchor the construct. There are no specific transverse connectors provided with the TROLLEY set.

Component assembly
Insertion of cable tie
- In cases where the cable tie is accidentally removed from the TROLLEY GV or in case of revision surgery, the cable tie can be inserted manually.
- It is recommended to bend the tip of the cable tie by hand and push it through the TROLLEY GV bearing.
- Then, the cable tie can be pulled up – either by hand or with the TROLLEY holding forceps for cable tie.

Reassemble of TROLLEY GV to TROLLEY applicator
- In cases where the TROLLEY GV has been separated from the screwdriver before the screw portion is inserted, the TROLLEY GV can be manually reassembled.
- Match the cable tie head to the notch on the applicator and push the applicator into the TROLLEY GV.
- Hold the cable tie ends toward the applicator and slide the first ring on the holder down to the end of the applicator.
- Slide the second ring over the lock of the cable tie.
- The TROLLEY GV construct can now be reinserted into the TROLLEY screwdriver.

**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.
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

**Implant Card & Patient Information Leaflet**
If supplied with the original packaging, provide the implant card as well as the relevant information according to the patient information leaflet to the patient. The electronic file containing the patient information can be found at the following link: ic.jnjmedicaldevices.com

CE
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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedtech.com

Instructions for Use:
www.e-ifu.com