INSTRUCTIONS FOR USE

United States Federal law restricts this device to sale by or on the order of a physician or licensed practitioner

Guide Wire and Instrumentation Kit

V-STRUT© Guide Wire and Instrumentation Kit are intended for use with V-STRUT© Vertebral Implant.

See also the V-STRUT© Operative technique

Table of content

Standard symbols used for labelling

Single use Guide Wire		Do not reuse – Single use only
Reusable Instruments		Provided non-sterile
		Consult instructions for use
		Indicates medical device manufacturer, as it is defined in European directives 93/42/CEE
		Do not use in case of damaged packaging

Device description

Hyprevention provides non-sterile reusable instruments and single-use guide wire necessary for V-STRUT® procedure.

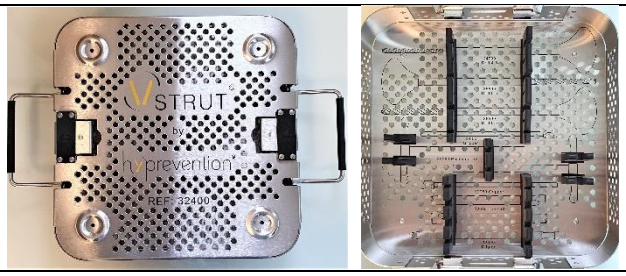
V-STRUT© Guide Wire and V-STRUT© Instrumentation Kit are intended for use with V-STRUT© Vertebral Implant. Refer to the specific V-STRUT© Vertebral Implant Instruction for use.

The instruments and guide wire cannot be used as part of any other procedure.

V-STRUT© Single use Guide Wire (ref 32300)

Ref	Quantity	Name	Material	Picture
32300	2	Guide wire	Stainless steel	

V-STRUT© Reusable Instruments Kit (ref 32500)

Ref	Quantity	Name	Material	Picture
32010	2	Tube	Stainless steel	
32020	1	Dilator	Stainless steel	
34500	1	Drill 4.5	Stainless steel + polypropylene	
35500	1	Drill 5.5	Stainless steel + polypropylene	
36500	1	Drill 6.5	Stainless steel + polypropylene	
32050	2	Gripper	Stainless steel	
32060	2	Positioner	Stainless steel	
32400	1	Container	Stainless steel + silicon + radel + acetal	

Warnings and precautions

Hyprevention declines any responsibility in case of non-compliance with the Instructions For Use. In addition, it is mandatory to refer to V-STRUT© Vertebral Implant Instructions.

Only use instruments and guide wires for its intended purpose.

Always treat instruments and guide wires carefully to avoid superficial damage or alterations to the geometry and function. Ensure that the drills are sharp.

V-STRUT© Instruments are reusable and provided non-sterile. V-STRUT© Guide wire is a single use device and must not be re-sterilized or re-used after one surgery under any circumstances.

Inspection, pre-treatment, cleaning and sterilization requirements must be strictly followed, as described below, prior to instruments use.

Ensure the V-STRUT© Instrumentation Kit and V-STRUT© Guide wires are cleaned and sterilized following the instructions in chapter “Instruments and Guide wires cleaning and sterilization”.

Before starting an operation, it is necessary to check the presence and the good operational state of all instruments in the container.

Strictly follow the V-STRUT© Operative technique.

Hyprevention is not responsible for complications arising from incorrect diagnosis, choice of incorrect implant, incorrect combination of implants and/or operative technique nor inadequate asepsis.

V-STRUT© Instruments and V-STRUT© Guide Wire must not be used with components of any other system or manufacturer (except the systems described in section Additional necessary equipment of V-STRUT© Vertebral Implant Instructions) to avoid failure of the procedure.

Instruments and guide wire packaging

Instruments

Hyprevention provides a container to protect and maintain instruments during transportation, cleaning and sterilization. Each instrument must be placed individually (disassembled) in the container’s base as indicated by marked templates at the bottom. The container is not intended to maintain a sterile barrier. Sterilization of container or any other appropriate packaging able to maintain a sterile barrier is not provided by Hyprevention.

Replacement instruments can be provided, in case of damaged instruments. They are individually packed in a plastic pouch. The sharp and/or fragile instruments could be packed with a protection which must be removed before use. Replacement instruments are provided non-sterile and must be cleaned and sterilized before use according to the same process as the Instrumentation Kit.

Guide wire

The guide wire is wrapped in a plastic packaging with tip protection for transportation. The packaging and tip protection must be removed prior to cleaning and sterilization. The guide wire must be cleaned and sterilized before use. Packaging for steam sterilization is not provided by Hyprevention.

Instruments and guide wire visual inspection

The instruments are reusable. Integrity of each instrument must be checked before use or reuse.

The guide wire is single use and must be checked before use.

Integrity of instruments must be checked. Discard any instrument which seems damaged.

Integrity of the guide wire must be checked prior to use. Discard any guide wire which seems damaged.

The guide wire is non-reusable and must be discarded after each use.

If visual inspection highlights a suspicion of damage that is not listed in the specification table below, discard the instrument or guide wire which seems damaged.

Visual inspection must be done by a qualified person.

Ref	Picture	Specifications for visual inspection
32300		- Guide wire must be straight with no damage
32020		- Canula is empty with no residue - Laser marking is visible - Conical tip is not damaged
32010		- Canula is empty with no residue - Laser marking is visible - Distal extremity is not damaged
34500 35500 36500		- Canula is empty with no residue - Laser marking is visible - Cutting part is sharp and not damaged
32050		- Canula is empty with no residue - Laser marking is visible - Thread is not damaged and with no residue - Shaft is straight
32060		- Canula is empty with no residue - Laser marking is visible - Inner tip is not damaged with no residue

Instruments and guide wire cleaning and sterilization

Instruments and Guide wires pre-treatment, cleaning and sterilization must be performed by a qualified person.

Equipment used for cleaning and sterilization must be appropriate and qualified.

INSTRUMENTS

Instruments are provided non-sterile. They are usable and reusable after cleaning and sterilization.

All instruments must be present in the container before starting the cleaning and sterilization process.

Instruments must be pre-treated, cleaned and sterilized before their first use and after each use.

Pre-treatment

	First use of V-STRUT© Instrumentation Kit (ref 32500)	Reuse of V-STRUT© Instrumentation Kit (ref 32500)	New replacement instruments before first use	
Unpacking and/or disassembly	**1**. Remove instruments from the container	**1**. Disassemble the instruments (positioners and grippers) Remove instruments from the container	**1**. Unpack instruments and remove any protections, if necessary	Do not allow dirty instruments to dry after use
Soak	**2.** Totally immerse the instruments in a solution of enzymatic detergent/disinfectant (neutral pH). Aniosyme X3 at 0.5% in tap water. **Time: 5 minutes**			
Rinse 1	**3.** Remove the instruments from the soaking solution and rinse them abundantly with tap water between **15 and 20°C**. **Time: 1 minute**			
Manual cleaning	**4**. Brush the immersed instruments in a solution of detergent /disinfectant Aniosyme X3 at 0.5% in tap water. Use a soft brush and a swab adapted for long hollow instruments Clear all visible dirt. **Time:** Soft brush: **5 minutes** Swab: **2 minutes**			

Rinse 2	**5.** Rinse abundantly and carefully the inside / outside of the instruments with tap water between **15 and 20°C** **Time: 1 minute**
Visual Inspection	**6.** Check for instruments integrity: Cannula is empty with no residue, laser marking is visible on the instruments, cutting part is sharp and not damaged.

Automatic cleaning/disinfection

Instruments positioning	**7.** Immediately after the pre-treatment Place instruments in the container's base. The lid must be separately washed. A basket of an adapted washer-disinfector can also be used to favor the flow of liquids along and through instruments (in this case, the container is cleaned separately).
Cycle	**8. Recommended cleaning cycle** a) **Pre-cleaning:** Cold freshwater ➔ **t ≥ 2 minutes** b) **Cleaning:** Freshwater, 40°C<T<60°C ➔ **t ≥ 5 minutes** Use an alkaline detergent: Aniosyme DLM between 0.1 and 0.5% c) **Intermediary rinse:** Freshwater, 40°C<T<60°C ➔ **t ≥ 2 minutes** Use a neutralizer and drying: Anios RDA at 0.1% d) **Final rinse:** Freshwater, 40°C<T<60°C ➔ **t ≥ 1 minute** e) **Disinfection:** Osmosis water, t ≥ 1 min, T ≥ 90°C ➔ **t ≥ 1 minute** f) **Drying:** T ≥ 60°C **t ≥ 20 minute** g) **Cooling down:** T ≈ 30°C **t ≥ 2 minute**
Visual Inspection	**9.** Check instruments integrity
Packaging	**10.** Place each instrument in its dedicated location in V-STRUT© Container and close the lid.

Sterilization

V-STRUT© Container does not maintain the sterile barrier. Before sterilization, V-STRUT© Instrumentation Kit must be packed in a sterilization container or any other appropriate packaging able to maintain the sterile barrier.
Sterilization must be performed in a qualified autoclave. Sterilization cycle must correspond to the following parameters:

For USA	**11. Steam sterilization** Cycle: Pre-vacuum Temperature: 132°C (270°F) < T < 135°C (275°F) Exposure time: 4 minutes Drying time: 30 minutes

GUIDE WIRE

The guide wire is not provided sterile. It must be pre-treated, cleaned and sterilized before its first use. The guide wire must be discarded after each surgery.

Two guide wires are needed to perform a procedure.

Pre-treatment	
Unpacking	1. Unpack the Guide wires and remove any tip protections
Soak	**2.** Totally immerse the instruments and guide wires in a solution of enzymatic detergent/disinfectant (neutral pH). Aniosyme X3 at 0.5% in tap water. **Time: 5 minutes**
Rinse 1	**3.** Remove guide wires from the soaking solution and rinse them abundantly with tap water between **15 and 20°C**. **Time: 1 minute**
Manual cleaning	**4**. Brush the guide wires in a solution of detergent /disinfectant Aniosyme X3 at 0.5% in tap water. Use a soft brush Clear all visible dirt. **Time:** Soft brush: **5 minutes**

Rinse 2	**5.** Rinse abundantly and carefully the inside / outside of the instruments with tap water between **15 and 20°C** **Time: 1 minute**
Visual Inspection	**6.** Check for guide wires integrity: Not broken or bent

Automatic cleaning/disinfection

Guide wire positioning	**7.** Immediately after the pre-treatment Place the guide wires in an appropriate basket for washer-disinfector in order to favor the flow of liquids along the guide wires
Cycle	**8.** **Recommended cleaning cycle** **a)** **Pre-cleaning:** Cold freshwater ➔ **t ≥ 2 minutes** **b)** **Cleaning:** Freshwater, 40°C<T<60°C ➔ **t ≥ 5 minutes** Use an alkaline detergent: Aniosyme DLM between 0.1 and 0.5% **c)** **Intermediary rinse:** Freshwater, 40°C<T<60°C ➔ **t ≥ 2 minutes** Use a neutralizer and drying: Anios RDA at 0.1% **d)** **Final rinse:** Freshwater, 40°C<T<60°C ➔ **t ≥ 1 minute** **e)** **Disinfection:** Osmosis water, t ≥ 1 min, T ≥ 90°C ➔ **t ≥ 1 minute** **f)** **Drying:** T ≥ 60°C **t ≥ 20 minute** **g)** **Cooling down:** T ≈ 30°C **t ≥ 2 minute**
Visual Inspection	**9.** Check the guide wires integrity
Packaging	**10.** Place the guide wires in an adequate packaging for steam sterilization

Sterilization

Before sterilization, the guide wires must be packed in appropriate packaging able to maintain the sterile barrier.
Sterilization should be performed according to the following parameters:

	11. Steam sterilization
For USA	Cycle: Pre-vacuum Temperature: 132°C (270°F) < T < 135°C (275°F) Exposure time: 4 minutes Drying time: 30 minutes

Storage / Shelf-life

V-STRUT© Instrumentation Kit and V-STRUT© Guide Wire do not require any specific storage conditions. The instruments must be exclusively stored in the dedicated container and handled with care particularly during pre-treatment and cleaning processes.

The instruments are validated for repeated use. Hyprevention does not define a maximum number of uses. The instrument's life depends on several factors, such as conditions of use, handling and maintenance.

Contact Hyprevention for instrument replacement if damage is detected during visual inspection.

Disposal

V-STRUT© Instrumentation Kit and V-STRUT© Guide Wire do not require any special handling or unique requirements for disposal. Disposal of the device should be according to standard waste disposal requirements.

Request for additional information

For service, technical support, requests for information, please contact Hyprevention at contact@hyprevention.com or at the contact details described in section Manufacturer, or your distributor.

Complaint handling

Any device-related-incident which is believed to represent a safety issue should be immediately reported to Hyprevention at vigilance@hyprevention.com or at the contact details given in section Manufacturer.

Manufacturer

Hyprevention SAS
Plateforme Technologique d'Innovation Biomédicale (PTIB) – Hôpital Xavier Arnozan
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Distributor

Name and address

Revision

The revision in force is available on the website instructions.hyprevention.com . Should the user use a copy of this electronic revision he/she is responsible for verifying that he/she uses the version in force.

Copies are available on request at contact@hyprevention.com

Date of the latest revision of the instructions for use: November 28, 2022