BEYOND THE EXPECTED

CE 0476

Neo Medical Pedicle Screw System™ - Persuader device (also called Rescue Tool) Instructions for use and processing (cleaning, disinfection, and sterilization)

PURPOSE

The Neo Medical Pedicle Screw System™ is intended to help provide immobilization, correction and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

Persuaders are used to clamp below the screw head and apply force during the connection of the rod and the pedicle screw in cases where appropriate bending of the rods and the rod reduction cannot be achieved using the standard procedure.

This instructions leaflet provides information for use of the persuader device (**Section A**) and for their proper processing before first use and after each subsequent use (**Section B**).

DESCRIPTION

The Neo Medical Pedicle Screw System™ is mainly used with dedicated instruments which are described in the system's instructions for use. The procedure for use is described in the surgical technique.

In adjunction to the standards instruments provided as single use sterile, Neo Medical provides a Persuader device which provides surgeons more intraoperative flexibility in open complex surgery. During specific open complex deformity surgeries, the surgeon might decide to remove the Neo pedicle screw guide in order to achieve specific manoeuvres. In this context, after the targeted manoeuvre is achieved the surgeon could need an instrument to reconnect to the pedicle screw head to ensure the appropriate and controllable positioning of the rod within this screw head.

The persuader device includes several components that need to be assembled before surgery. The persuader device is only compatible with the Neo Pedicle Screw System™.

The persuader device is provided by Neo Medical as non-sterile and is intended to be re-used after appropriate cleaning, disinfection and sterilization procedure.
This Instruction for use applies to the following articles:

REF	Part Number	Description
1/4	100-3611.00	Persuader Handle, NS
2/4	100-3612.00	Persuader Lever, NS
3/4	100-3630.90	Locking ring, NS
4/4	100-3620.90	Rod controller, NS

Please follow these instructions for the preparation of the instruments before surgery and for their reprocessing after surgery (section B of this instruction for use).

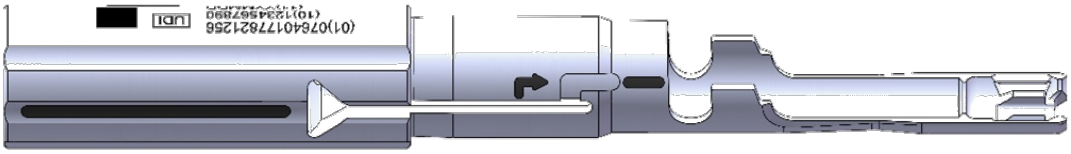
Neo Medical's products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

SECTION A – USE OF THE PERSUADER DEVICE

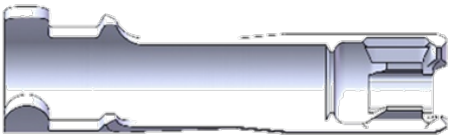
1. Device Description

The persuader is made of four distinct components. The corresponding components are the following:

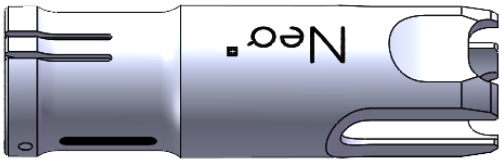
1/4 The Persuader handle



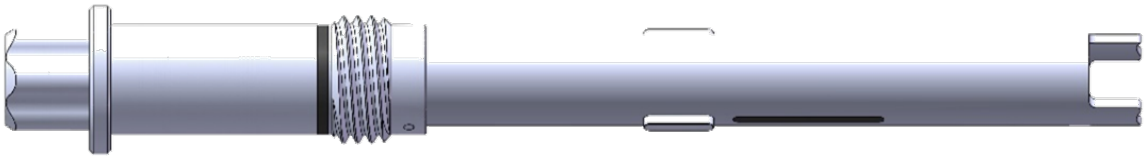
2/4 The Persuader lever



3/4 The Locking ring



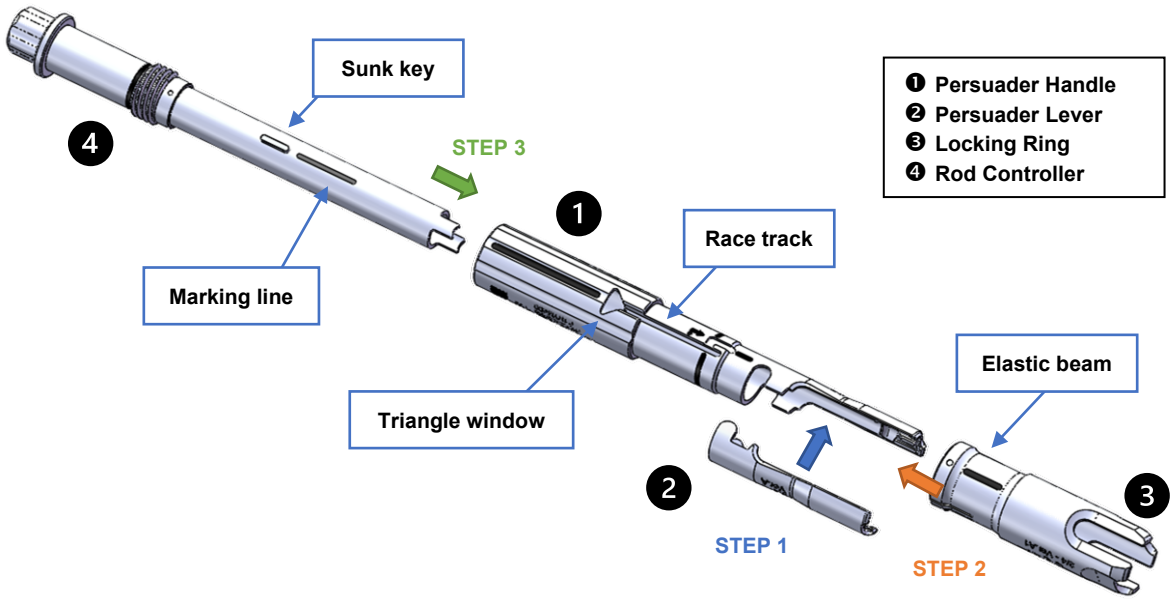
4/4 The Rod controller



2. Assembly and disassembly

The persuader device shall be disassembled and sterilized in a proper sterilization tray. Assembly shall take place within the sterile field before use in surgery.

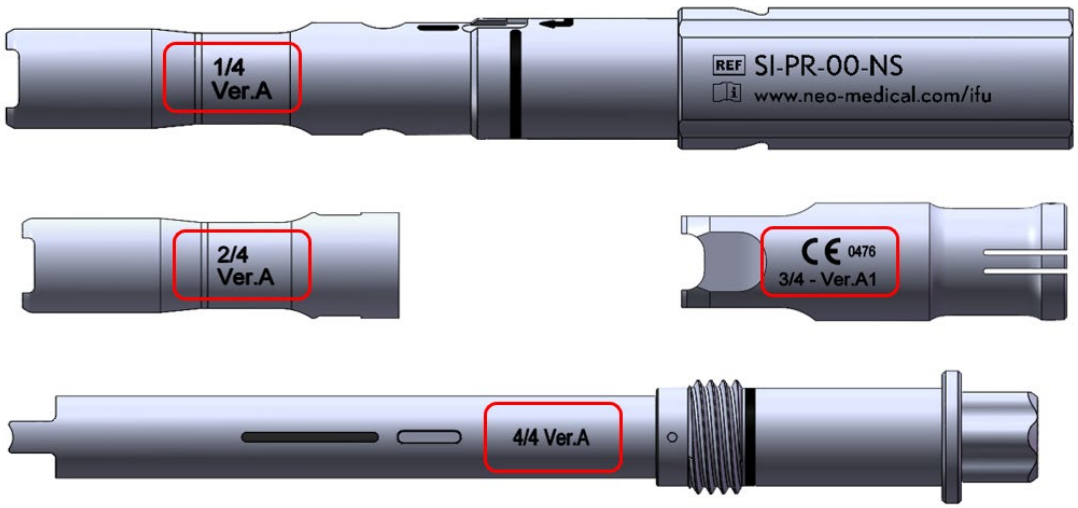
⇨ *Assembly workflow*



⇨ *Assembly description*

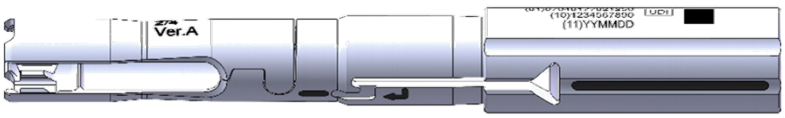
Step 1 – Gather components

⚠ Check that parts belong to the same instruments by verifying the marking of versions on each component (see Ver.# on each component as shown below. Only the letter is determinant). This step is needed only if you have more than one persuader device; thus, the risk of mixups during reprocessing cannot be excluded.



Step 2

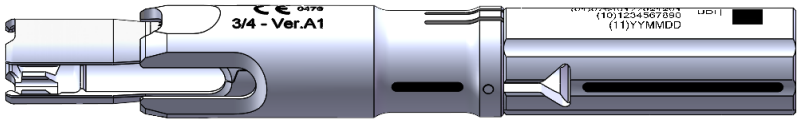
- Position the Persuader lever (2/4) facing the Persuader handle (1/4)



Step 3

- Insert the Locking ring (3/4) over the assembled Persuader handle (1/4) and lever (2/4). Guide the pin to engage to the race track with a 20-30° initial turn clockwise. This will secure the Persuader lever within the assembly.

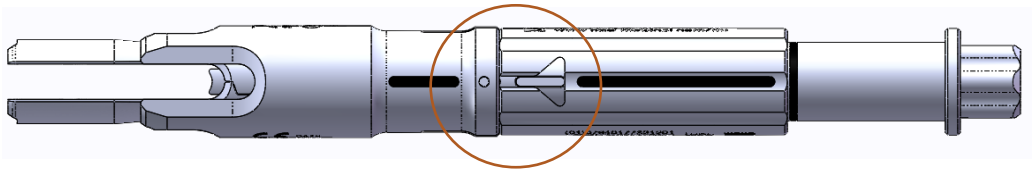
- Check that the Locking ring is in the unlocked upward position.

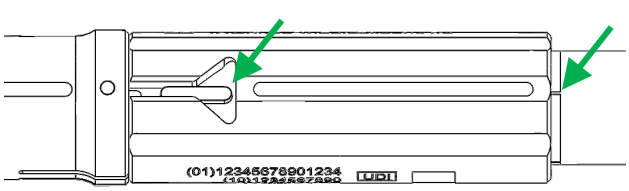


Step 4

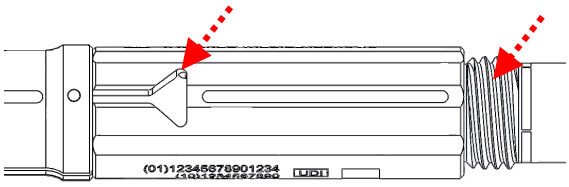
- From the top, insert the Rod Controller (4/4) into the previous assembly.

  Ensure the sunk-key is engaged into the race-track via the triangle window (see OK, NOK pictures below). A marking on the Rod Controller line may help to orient the sunk key.
  Turn the Rod Controller clockwise to engage into the Persuader handle.





Left OK: sunk key engaged in racetrack, marking is flush.



Right NOK: Sunk key not in triangle window, thread still out

⇨ *Disassembly workflow*

Follow the steps according to the assembly description in this chapter in reverse sequence.

3. Surgical technique application

⇨ *Intended purpose*

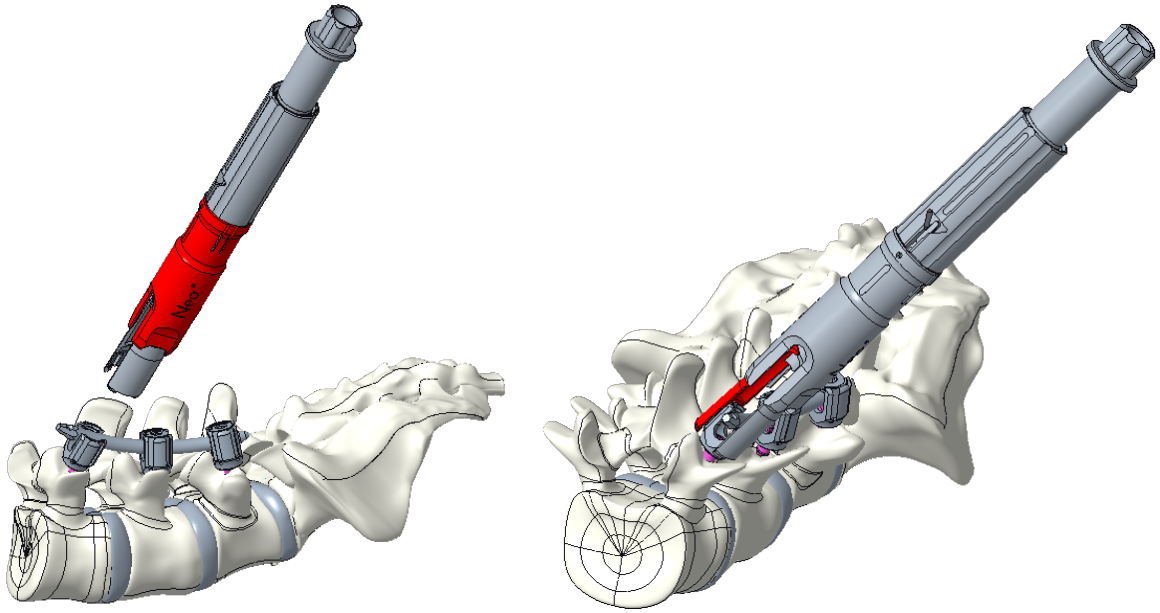
The persuader device is intended to be used together with the Neo Pedicle Screw System™ to allow rod reduction in cases where the screw guide has been removed. The persuader device is intended to be used in open surgeries only.

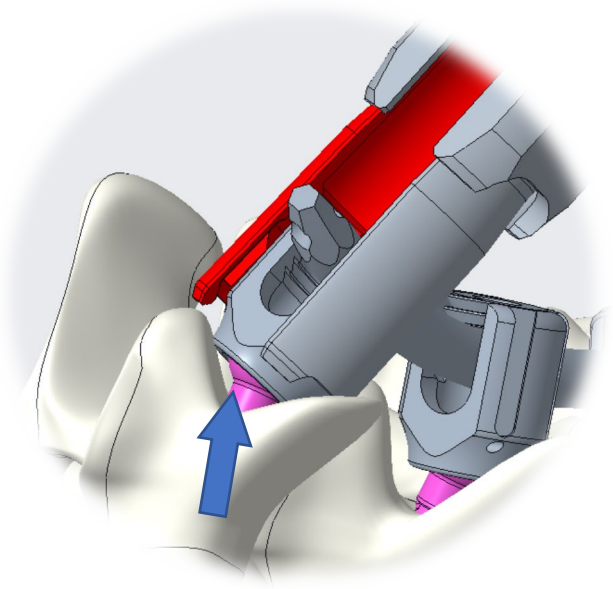
⇨ *Surgical steps*

The Persuader device can be used once the pedicle screws have been inserted following the steps required in the Neo Pedicle Screw System™ surgical technique.

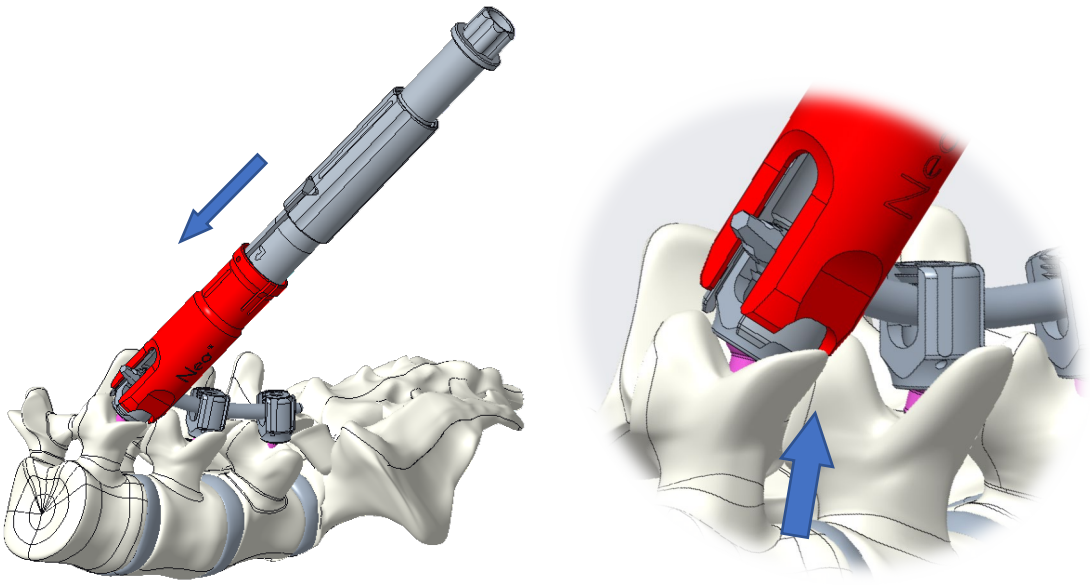
Step 1 – Lock the persuader onto the screw head

Ensure the Locking ring is in the unlocked upwards position.
Bring the persuader on the screw head ensuring the Persuader lever engages at the bottom of the screw head. The rod must be already sitting inside the proper slot.





Slide the Locking ring towards the pedicle screw until it stops to ensure a firm connection. The black line on the persuader handle shall be visible once the locking ring has been fully deployed. Check visually the connection between the persuader and the screw head.



Step 2 – Rod reduction

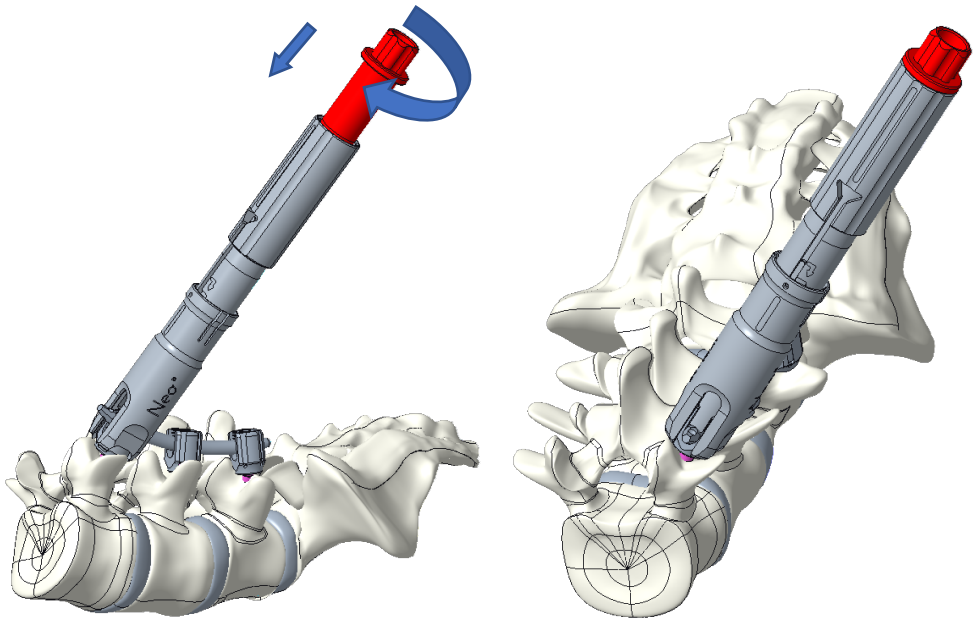
Reduce the rod by turning clockwise the Rod controller until it reaches the end position and gets in contact with the handle. This ensures that the rod is properly seated in the screw head.
Once the Rod controller reaches the rod the torque needed to reduce the rod increases. Use the counter torque handle from the Neo Pedicle Screw System™ instrument kit to help turn the Rod controller.

⚠ The surgeon shall always aim for the best bending of the rod to avoid unnecessary forces being introduced to the spine. The persuader is not intended to force rods and avoid in-situ bending.

⚠ The excess of forces on the construct can lead to screw loosening of the active or adjacent screws.

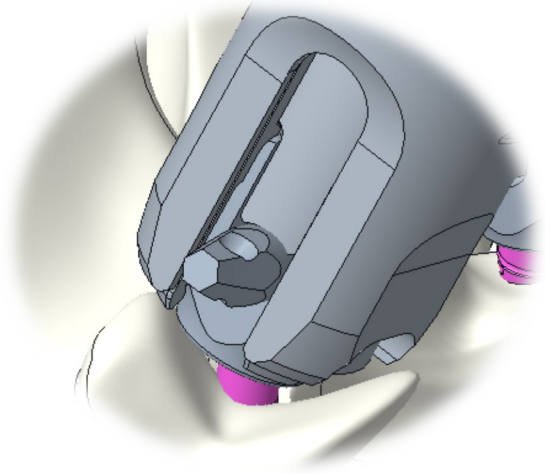
⚠ Patients with osteoporosis or osteopenia have poor bone quality. When using the persuader on poor bone quality patients, caution must be taken during the rod reduction to avoid screw pull out. The surgeon must carefully evaluate the potential effect of forcing down the rod onto the screw head.

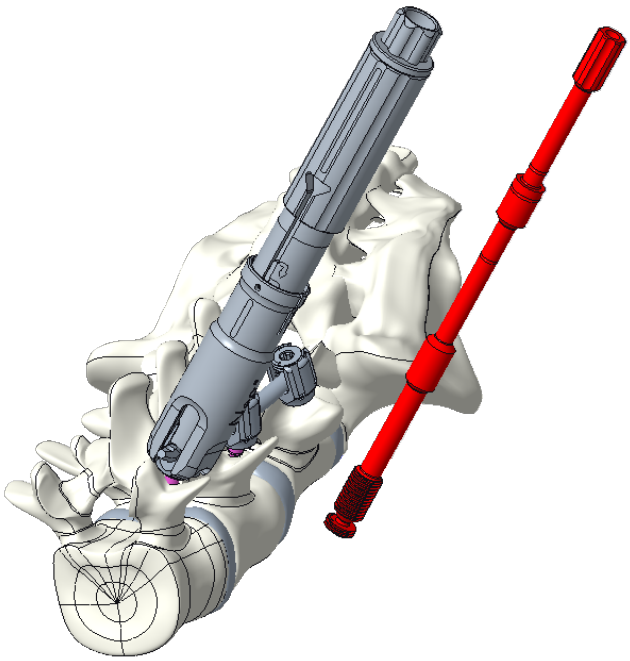
⚠ Make sure that the persuader is perpendicular to the rod during rod reduction. Any angular correction during this step can lead to additional forces and early disconnection of the persuader.

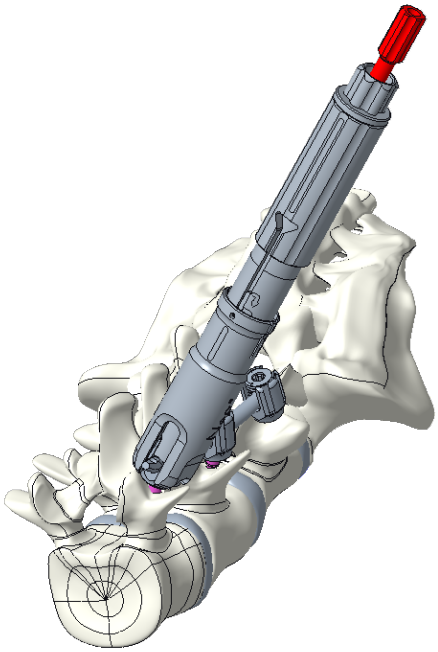


Step 3 – Set screw pre-tightening

Check visually the position of the rod and make sure is sits on the bottom of the screw head.
Insert the set-screwdriver into the persuader and pre-tighten the set-screw manually by following the steps described in the Neo Pedicle Screw System™ surgical technique.

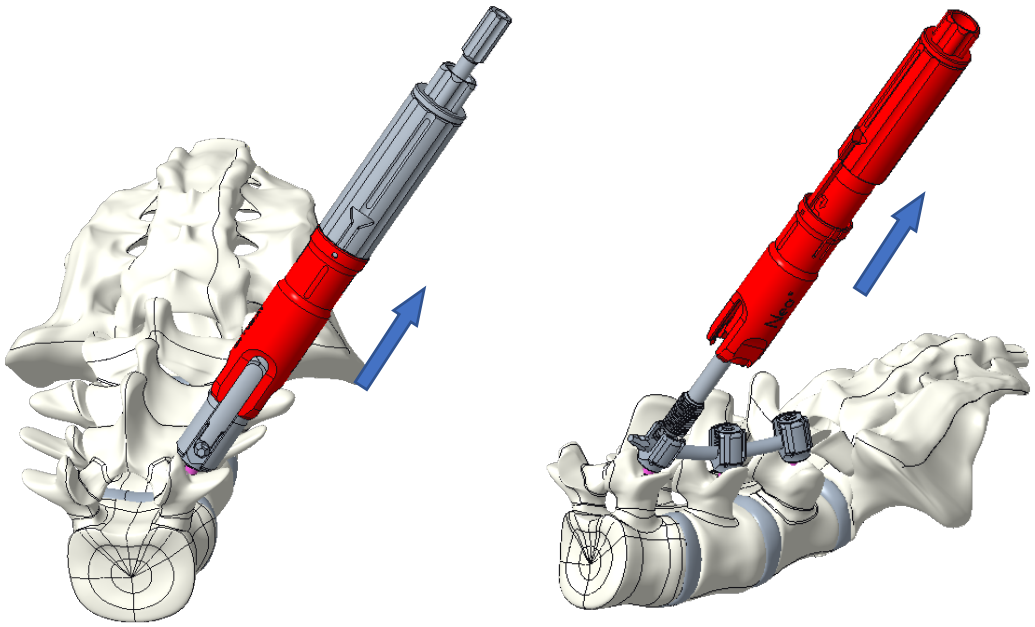






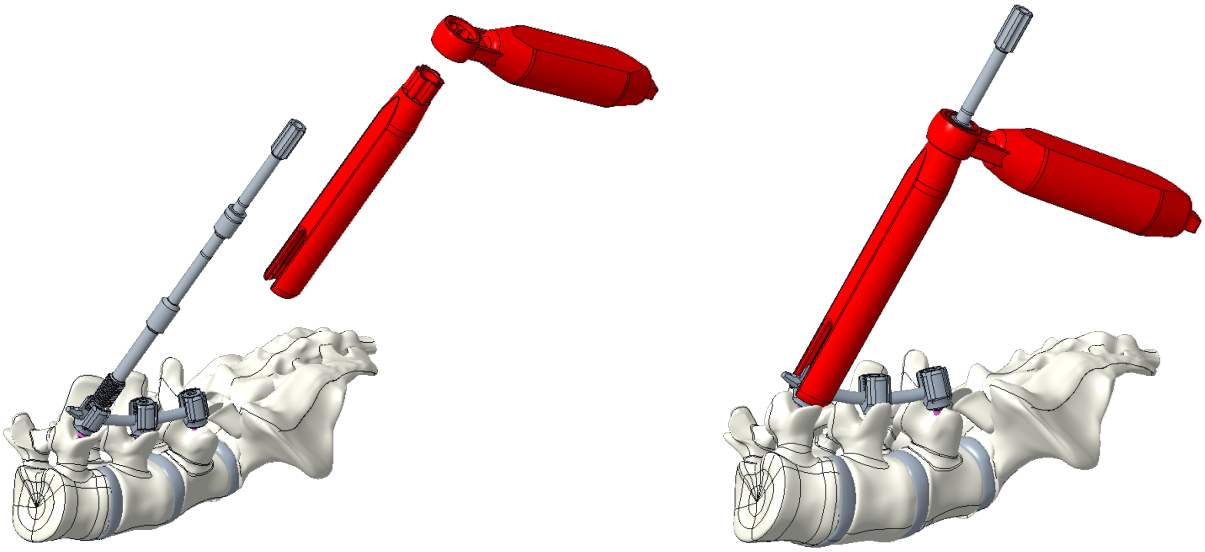
Once the set-screw is pre-tightened the persuader can be removed by pulling back the Locking ring in the unlocked position.

Leave the set screwdriver in position and pull back the persuader device.



Step 4 – Final tightening

To final tighten the set screw, insert the Revision guide (SI-RE-SE-00) until it catches on the screw head.
Connect the counter torque handle on the revision guide and the T-handle to the set-screwdriver and proceed with the final tightening as described in the Neo Pedicle Screw System™ surgical technique.



SECTION B – PROCESSING (CLEANING, DISINFECTION, AND STERILIZATION)

FUNDAMENTAL POINTS

All instruments labelled as non-sterile are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

The sterility of the instruments falls under your responsibility. Please ensure that only product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD, sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your Country as well as to the hygienic instructions of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions (not relevant for USA), which can require the application of cleaning detergents with proven prion efficiency as well as a sterilization with more intensive parameters.

Caution: Non-sterile instruments are provided in a protective packaging designed for maintaining the integrity and cleanliness of the product. However, in no case the product shall be sterilized within this packaging but needs to be removed from the package and be treated as follows.

CLEANING AND DISINFECTION

Basics

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered[1].

The pre-treatment step is to be performed in both cases.

Please ensure already during use that you collect contaminated instruments separately and do not place them back in the instrument tray to avoid greater contamination of the loaded instrument tray.

[1] In case of application of a manual cleaning and disinfection procedure a product and procedure specific development and validation of the specific manual procedure under sole responsibility of the user is required.

Disassembly

Disassemble the Persuader device following the instruction provided in Section A – Disassembly workflow.

Pre-treatment

Please remove coarse impurities of the instruments directly after application (within a maximum of 2 h).

Procedure:

1. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F).
2. Soak the instruments for the given soaking time in the pre-cleaning solution[2], e.g. 0.5-2% neodisher® Mediclean forte for 10-30 min (with activated ultrasound) so that the instruments are completely covered. Pay attention that there is no contact between the instruments.
3. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water (temperature <35°C/95 °F).

⚠ The Persuader device is cannulated, make sure the hole is cleaned and no impurities remain before proceeding with the automated cleaning. To obtain a clean cannula use a soft brush to wipe the hole and then proceed with a water jet to flush the hole.

Pay attention to following points during selection of the cleaning detergent[2]:
- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (see chapter „material resistance„)

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

[2] In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel´s safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (see chapter „material resistance„).
Please consider, that a disinfectant used in the pre-treatment step serves only the personnel`s safety, but cannot replace the disinfection step later to be performed after cleaning.

Automated cleaning/disinfection (WD (Washer-Disinfector))

Pay attention to following points during selection of the WD:
- WD according to EN ISO/ANSI AAMI ST15883 and with fundamentally approved efficiency (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- if possible selection of an approved program for thermal disinfection (A_0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments
- program with a sufficient number of rinsing steps (at least three degrading steps after cleaning (respectively neutralization, if applied) or conductance based rinsing control recommended in order to prevent effectively remnants of the detergents)
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to following points during selection of the cleaning detergent:
- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter „material resistance„)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

Procedure:

1. Transfer the disassembled instruments in the WD (pay attention, that the instruments are located with the big opening downwards and that instruments have no contact).
2. Start the program, e.g.:
   - pre-rinse 1 min with cold water <40°C
   - wash at 55°C with 0.5% neodisher® Mediclean forte for 10 min
   - rinse for 1 min with cold water <40°C
   - rinse for 2 min with deionized water <40°C
   - thermal disinfection for 5 min at >90°C with deionized water
   - drying for 30 min at 100°C
3. Remove the instruments of the WD after end of the program.
4. Check and pack the instruments immediately after the removal (see chapters „check„, „maintenance„, and “packaging„, if necessary after additional post-drying at a clean place).

The fundamental suitability of the instruments for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of an ultrasonic bath of the SONOREX series with 35 kHz (BANDELIN electronic, Berlin) for pre-cleaning, the WD PG 8535, Miele & Cie. GmbH & Co., Gütersloh (thermal disinfection) and the pre-cleaning and cleaning detergent neodisher® Mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

Check

Check all instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, still readable marking. and impurities. Do not further use damaged instruments (for limitation of the numbers of re-use cycles see chapter „reusability„). Still dirty instruments are to be cleaned and disinfected again.

Maintenance

To ensure the best performance it is recommended to lubricate the thread on the Rod Controller (4/4) approved instrument lubricants (e.g. Hinge Free™ by Steris). Follow the instrument lubricant instructions for use.

Packaging

Please insert the cleaned and disinfected disassembled instruments in a standard sterilization tray and pack them in sterilization containers, which fulfill the following requirements (material/process):
- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

A maximum weight of 8 kg per content of the sterilization tray must not be exceeded.

If you have more than one persuader device make sure to keep separate the components of each device to avoid the risk of mixups during reprocessing.

Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization
- fractionated vacuum/dynamic air removal procedure[3,4] (with sufficient product drying[5])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 137°C (278,6 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

Area	fractionated vacuum/dynamic air removal	gravity displacement
USA	4 min at 132 °C (270 °F), drying time at least 20 min[5]	not recommended
Germany	5 min[6] at 134 °C (273 °F), drying time at least 20 min[5]	not recommended
other countries	at least 4 min[6] at 132 °C (270 °F) / 134 °C (273 °F), drying time at least 20 min[5]	not recommended

[3] at least three vacuum steps
[4] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, requires significantly longer sterilization times as well as a sterilizer, procedure, parameter, and product specific process development and validation under sole responsibility of the user.
[5] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.
[6] respectively 18 min (inactivation of prions, not relevant for USA)

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer Tuttnauer EHS 3870 and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic as well as the specified procedure were considered.

The flash/immediate use sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

Storage

Please store the instruments after sterilization in the sterilization packaging at a dry and dust-free place.

NOTE: upon customer requests Neo Medical can provide a transport tray where to keep the persuader components. Do not use the tray for sterilization of the persuader device.

Material resistance

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:
- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value 11, neutral/enzymatic, weak alkaline, or alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.
Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments by use of metal brushes or steel wool.

Please do not expose any instruments to temperatures higher than 142 °C (288 °F)!

Reusability

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Neo Medical reusable surgical instruments.
End of life of a reusable surgical instrument is normally determined by wear and damage due to use. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used and must be absolutely replaced by a new one. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

ADDITIONAL INFORMATION

It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the Central Sterile Supply Department (CSSD), and achieves the desired result. This requires verification/validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

All users shall be qualified personnel with documented expertise, competency and training. Users shall be trained on hospital policies and procedures along with current applicable guidelines and standards.

Users shall wear appropriate personal protective equipment (PPE) when processing devices in accordance with the Department of Environmental and Occupational Health and Safety's (OSHA) bloodborne pathogen guidelines.

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the official distributor of NEO MEDICAL S.A. and, where applicable, the local competent authority. Further, if any of the implanted spinal system component(s) ever "malfunctions" (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any NEO MEDICAL S.A. product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

Before return of products which were used in hospital environment, perform a complete processing according to these instructions. Confirmation of processing including parameters used shall be provided in the delivery note.

FURTHER INFORMATION

For further information refer also to the Neo Pedicle Screw System Instruction for Use. Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact NEO MEDICAL S.A.

Please ensure that any waste that is generated from reprocessing of reusable instruments is disposed according to local laws and regulations.

EXPLANATION OF SYMBOLS

CE 0476	The device complies with Medical Device Regulation 2017/745		Manufacturer
EC REP	European Authorized Representative		Importer in the EU
REF	Catalogue number	LOT	Batch Code
	Consult the Instructions for use		Caution / Warning
NON STERILE	Non-sterile		Do not re-use
UDI	Unique Device Identification	MD	Medical Device
	Date of manufacture		

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