EN

Instructions for use

Kirschner Handpiece for Surgical Wires

NOUVAG+

SYMBOLS

General warning sign	Observe instructions for use	Note	Suitable for thermal disinfection
Manufacturer	Date of manufacture	Autoclavable at 134 °C	Not for reuse
REF Catalog number	SN Serial number	LOT Batch code	EC REP Authorized representative in the European Community
Non-sterile	Pieces per packaging unit (PU)	Importer	CE 0197 CE symbol with notified body

INTENDED PURPOSE

Repositioning and fixation of metaphyseal fractures, diaphyseal fractures and luxations of the hand and foot bones, temporary arthrodesis of small joints, temporary intraoperative fixation of fracture fragments.

CONTRA INDICATIONS

Relative or absolute contra indications can arise from the general medical diagnose, or in special cases by a significantly increased risk to the patient through the use of motor-driven devices. Relevant cases in the literature must be taken into consideration. In case of stated allergy to implant steel do not use Kirschner wires of this material. For these cases choose titanium and/or titanium alloys. In particular, the surgeon must determine the extent of the injuries or changes that require surgical treatment and determine the appropriate surgical therapeutic procedure and the correct Kirschner wires. This is particularly important if the patient suffers from comorbidities, osteoporosis, infections, alcohol and/or drug abuse, epilepsy, cognitive decline and/or obesity. In the case of complex multiple injuries, both the timing and the choice of osteosynthesis procedure are of the utmost importance.

The Kirschner wires can never fully bear the load of the treated bone segment. The surgeon must therefore inform the patient about the load limits and prescribe appropriate post-operative care. In general, the surgeon must inform the patient about indications, contraindications, potential side effects, and postoperative treatment. Regular medical follow-ups are required after implantation.

INTENDED USERS

Intended users are trained and qualified personnel, in professional settings (e.g. hospital, ambulatory).

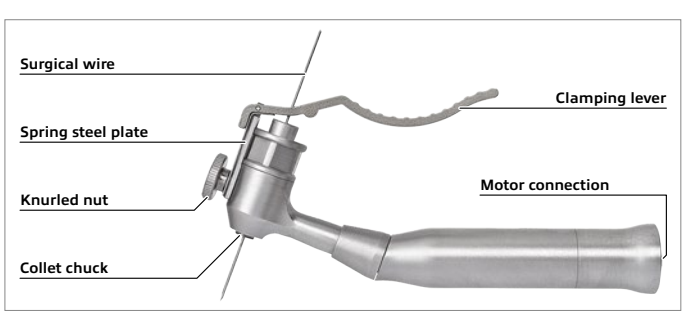
AMBIENT CONDITIONS	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90%	max. 80%
Temperature	0 °C – 50 °C	10 °C – 30 °C
Atmospheric pressure	700 hPa – 1'060 hPa	800 hPa – 1'060 hPa

SAFETY INFORMATION

- The handpiece and accessories are supplied by us non-sterile. The handpiece and accessories must be cleaned, disinfected and sterilised before first use and immediately after each use!
- Prior to using the product, before startup, and before operation, the user must always ensure that the product and accessories are in good working order and are clean, sterile and operational.
- Improper use or repair of the product, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.
- When using partially and fully tapped wires with small diameters, they can easily break if used incorrectly. NOUVAG cannot accept any liability for this.
- The use of the product other than that for which it was designed is not permitted. The responsibility is solely carried by the operator.

- Only manipulate the handpiece or surgical wire when the motor is at a standstill.
- Never operate the clamping mechanism during operation or without a clamped tool or spacer pin.
- Handpiece and surgical wires may only be used by qualified and trained personnel.
- Do not clean the handpiece with compressed air!
- The handpiece may be operated up to a maximum of 2'800 rpm.
- The handpiece may only be operated in clockwise rotation. The control unit displays an arrow pointing clockwise.
- To ensure complete traceability, the article and lot number of the Kirschner wires used must be attached to the surgical report.

OVERVIEW



POSSIBLE COMBINATIONS

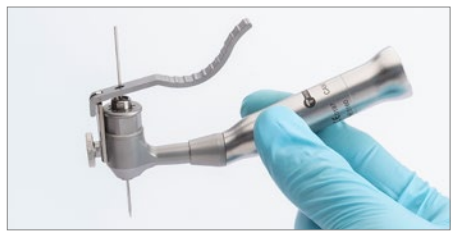
REF	CONTROL UNIT	INTENDED USE
3390	HighSurg 30	Hand and foot surgery

USE

CHANGING THE TOOL

Remove the placeholder pin from the collet chuck by pressing the clamping lever.

Insert the surgical wire intended for use through the collet with the clamping lever depressed. As soon as the surgical wire has reached the required position, release the clamping lever.



If the surgical wire is to be moved, stop the electronic motor, hold the surgical wire with two fingers, press the clamping lever and move the surgical wire to the desired position. Release the clamping lever.

REPROCESSING INSTRUCTIONS

- In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for re-use of the handpiece. The Robert-Koch Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.
- Never clean the handpiece in an ultrasonic bath! This impairs the functionality of the handpiece.

Reprocessing restrictions	Frequent reprocessing has only a limited impact on the handpiece. The end of the products service life is normally determined by wear and damage through use. The handpiece is designed for 250 sterilization cycles.
General handling	**1.** The handpiece and accessories must be thoroughly cleaned, disinfected and sterilised before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected handpiece enables correct sterilisation! **2.** The handpiece and accessories should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. **3.** We recommend the use of mildly alkaline and enzymatic cleaners with as low a silicate content as possible to avoid staining (silicatization) on the handpiece and accessories. **4.** Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturers' specifications for the method of use, action time and suitability of disinfection and cleaning substances. **5.** Operating instructions for the equipment and chemicals etc. used during reprocessing must be strictly followed. **6.** Dosage of chemicals, exposure times and exposure temperatures for cleaning and disinfection must be strictly followed. **7.** The end of product life may be reached before the 250 sterilization cycles in case of excessive wear and damage from use. **8.** Do not overload the washer. Avoid rinsing blind spots. Ensure secure storage in the machine. **9.** Observe the regulations valid in your country for the reprocessing of medical devices. **10.** NOUVAG recommends the use of a screen basket with rinsing bar from 3mach (NOUVAG REF 51401), a reusable container for convenient preparation and storage (including transport) of the products. The screen basket can be used for safe storage of the products during the rinsing process as well as during and after sterilization until the products are used. The screen basket is suitable for use with sterilization paper or a rigid sterilization container. It does not have a barrier effect on its own to protect sterility.
Preparation at the point of use	After surgery immediately remove blood, secretion, tissue and bone residue with a disposable cloth/paper towel, do not allow to dry! Dried residues cause corrosion.
Safe-keeping and transport	Contaminated products must be stored and transported to the preparation site in a closed container to avoid damaging the products and the contamination of the environment.
Cleaning and disinfection, pre-cleaning	**Remove the surgical wire from the handpiece and dispose of it properly. Wash off any visible soiling with water.** **1.** Wipe the handpiece and accessories with a damp disposable cloth/paper towel, removing all visible dirt. **2.** Brush the handpiece and accessories under running tap water using a soft brush (e.g. Insitumend GmbH, REF MED100.33). **3.** Rinse the outer surface of the handpiece and accessories for 10 seconds with a water pressure gun at a pressure of at least 2.0 bar (e.g. HEGA Medical, REF 6010 or REF 7060). Local tap water is sufficient for this purpose, since the last step is always a machine cleaning with deionized water, so possibly hard water with lime traces from the pre-cleaning cannot remain on the handpiece.

Cleaning	**Mechanical cleaning** 1. After pre-cleaning, place the handpiece on a suitable attachment. Place the small parts in the strainer basket. 2. Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! 3. Cleaning is done using the Vario TD programme in the cleaning and disinfection unit (CDU). For the cleaning process it is advisable to use DI water (fully desalinated water). 4. After completing the cleaning program (incl. thermal disinfection) check the handpiece and accessories for visible contamination in the grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario TD programme)** 1. Pre-clean with cold water for 4 minutes. 2. Empty 3. Clean for 5 minutes at 55°C with 0.5% alkaline or at 40°C with 0.5% enzymatic cleaner. 4. Empty 5. Neutralise with cold water for 3 minutes. 6. Empty 7. Inter-rinse for 2 minutes with cold water. 8. Empty
Disinfection	**Mechanical disinfection** The cleaning/disinfection unit has a thermal disinfection programme which follows after the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating to the A0 value (see DIN EN ISO 15883-1). We recommend an A0 value of 3.000 for the handpiece and accessories. Disinfection must be carried out with DI water.	**⚠ Warning** When inadequately rinsed or exposed to the disinfectant or detergent for too long, the handpiece and accessories can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	**Mechanical drying** Drying of the handpiece and accessories through the drying cycle of the cleaning/disinfection unit's (CDU). If required, manual drying can also be achieved by using a lint-free cloth. Pay particular attention to the grooves and spaces between the handpiece and accessories. Then spray the handpiece and accessories again with lubricant. Every CDU must provide a corresponding drying procedure through the manufacturer (see ISO 15883-1). Please follow the corresponding CDU-manufacturer's directions and operating instructions.	**Manual drying** Set up the handpiece vertically so that water can run out more easily. Allow the handpiece and accessories to dry for at least 30 minutes. Then spray the handpiece and accessories again with lubricant.
Manual cleaning	1. After pre-cleaning, place the handpiece in an immersion bath with enzymatic cleaner for 15 minutes. Clean the accessories in an ultrasonic bath for 15 minutes. Follow the instructions of the cleaning agent manufacturer. 2. Clean products completely with a soft brush under running drinking water. Rinse cavities and lumens, if any, intensively (>30 sec.) with a water pressure gun (or similar). 3. To remove the cleaning agent, rinse products under running tap water (drinking quality) (>30 sec.).	**⚠ Warning** Do not clean the handpiece in an ultrasonic bath!
Manual disinfection	After cleaning, immerse the products in a bath of suitable disinfectant for 5 minutes. Make sure that all surfaces are covered with the disinfectant. Follow the instructions of the disinfectant manufacturer. After disinfection, rinse all products thoroughly with deionised water (>1 min.) to remove the disinfectant.	
Inspection and care	Carry out a visual inspection for damage, corrosion and wear. After cleaning and disinfecting, spray the handpiece with lubricant and wipe with a lint-free cloth moistened with DI water (see instructions on spray can).	
Sterilisation	Sterilisation of the products is performed with a fractionated pre-vacuum steam sterilisation process (in accordance with DIN EN 13060 / DIN EN 285) giving due consideration to the respective national requirements. **Minimum requirements:** 1. Pre-vacuum phases: 3 2. Sterilisation temperature: minimum 132°C – maximum 137°C (within the sterile band) 3. Holding time: At least 5 minutes (full cycle) 4. Drying time: At least 10 minutes When sterilising several products during one sterilisation cycle, do not exceed the maximum steriliser load (see manufacturer's details). A drying cycle must be added in the case of autoclaves without a vacuum function. After sterilisation an immaculate sterilisation result must be detected by examining the appropriate indications. According to the Robert-Koch Institute preparation ends with the documented release for use of the medical device. If the sterilised handpiece is not used immediately after sterilisation, it must be labelled with the sterilisation date on the packaging.	
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. During storage, direct sunlight should be safely avoided. After the expiry date has passed, do not use the product any longer.	**Handling the sterile packaging** Before taking out the product, check for the packaging to be intact. When taking out the product, follow the respective aseptic procedures.
Information for validating the preparation	The above preparation process has been verified by a validated procedure. The following materials and machines were used: 1. Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG 2. Enzymatic cleaner: Neodisher® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG 3. Cleaning and disinfection unit: Miele G 7836 CD 4. Rack trolley: Miele E429 5. Strainer basket/flush socket bar: 3mach (NOUVAG REF 51401) 6. Autoclave: Selectomat 666-HP (MMM) 7. Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH Chemicals and machines other than those mentioned can also be used. In such a case consult the manufacturers or suppliers to find out whether their products confer the same performance as the products that the procedure was validated with. If you should opt for a different procedure for reprocessing to the one given above, you are required to correspondingly establish the suitability.	

There is no experience available from conducting other sterilisation procedures such as plasma sterilisation, low temperature sterilisation procedure, etc. Users bear full responsibility if they use a procedure which differs from the validated sterilisation procedure described!

Please also comply with the applicable legislation in your country and the medical practice or hospital's hygiene rules. This especially applies to the varying requirements for an effective inactivation of prions.

MALFUNCTIONS AND TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
Motor runs, but surgical wire does not move.	Handpiece not optimally coupled to motor.	Press the handpiece onto the motor until it snaps into place. Check the seat with a counter movement.
Surgical wire does not run smoothly.	Surgical wire not optimally clamped.	Align the surgical wire better.
Handpiece is loud.	Ball bearings not oiled or dirty.	Spray the handpiece with lubricant.

TECHNICAL DATA

KIRSCHNER HANDPIECE	REF 5160nou
Speed range at the clamped tool	500 – 2'800 rpm
Torque on the surgical wire	48 Ncm
Diameter range for surgical wires	0.6 – 1.5 mm
Transmission ratio	16 : 1
Coupling	ISO 3964
Weight (without surgical wire)	115 g

ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION	QTY.
1969	Hook spanner	1

POST MARKET SURVEILLANCE

If you have any complaints in relation to the use of the medical device, please contact the manufacturer immediately by e-mail complaint@nouvag.com or by phone.

In order to provide adequate information, please complete the complaint form:
https://nouvag.com/en/service/complaint-form/

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