Operating instructions

4:1 Handpiece

Safety measures

- The handpiece is delivered in non sterile condition. Clean, disinfect, and assemble the handpiece before the first application and immediately after each use!
- Operate the handpiece with a maximum speed of < 12,500 rpm.
- Attach the handpiece to the motor only when it’s standing still.
- Perform manipulations on the instrument only when the motor is at a standstill.
- Any guarantees on our part or other claims against us become void in the case of inappropriate use of the handpiece or failure to comply with our instructions!

Intended use / Indication

The 4:1 Handpiece together with the appropriate instrument head is applied in Periostealus Foot and Ankle Surgery especially for the treatment of Hallux Valgus and Hallux Rigidus. Therefore the handpiece with the according milling tool is applied for the removal of tissue masses and cartilages at the Metatarsophalangeal joint and the metatarsal while retaining these bones. In the dental field, the handpiece is used for drilling and grinding the zygomatic bone to insert zygomatic implants.

Contraindication / Limitations

a) An operation is not advisable in the case of arterial occlusive disease with indeterminate foot pulse because of lack of perfusion (Application: percutaneous foot surgery).

b) Severe Scleroses, diseases of the maxillary sinuses and the jaw bone or zygomatic bone (Application: Dental field).

c) Poor physical health of patient.

d) Infections Wounds - The hallux surgery may only be performed after treatment of the infection and the recrusted tissue.

Relation or absolute contraindications may result from the general medical findings or in special cases in which the patient’s risk for motor-driven tools is significantly increased. Cases described in the relevant literature must be taken in account.

Symbols

LOT number
Autoclave at 135°C
Suitable for thermal disinfection
EN
Date of manufacturing
Serial number
Observance instructions for use

Technical data, 4:1 Handpiece

Overview

Cutter runs irregularly
Motor is running but cutter is not turning.
Cutters cutter isn’t correctly coupled.
Adjust cutter correctly in the collet and lock it.

Detachable cooling tube
Quick-release cooling tube
Coupling flange
Motor connection

Possible combinations

4:1 Handpiece, REF 1041450 is exclusively used:
- In combination with the surgical motor systems HighLux = OFA-Drill (REF 9765) and HighLux 30 (REF 9760), which control the 4:1 Handpiece via the upstream electronic motor 21 and enables settings for speed and torque according to the selected tool used.
- In combination with the M2 30 implant motor system (REF 3550), which controls the handpiece via the upstream electronic motor 21 and enables settings for speed and torque according to the tools used.

Wrong combination of products

Damage to the product and injury to the patient, user or third parties are possible.
- Only use the different products together if the purpose and the relevant technical data such as tool lengths, diameters, and so on match.
- Always follow the instructions for use of the products used in combination.

Spare parts

- Footcutters, Quick-release coupling flange
- Motor connection

Troubleshooting

Problem
Motor is running but cutter is not turning.
Cutters cutter isn’t correctly coupled.
Any guarantees on our part or other claims against us become void in the case of inappropriate use of the handpiece or failure to comply with our instructions!

Solution
Handpiece is not correctly coupled.
Press handpiece firmly against the motor. Check for proper seating.
Cutters cutter isn’t correctly coupled.
Adjust cutter correctly in the collet and lock it.

Manufacturer and Service points

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The complete list of all Novug authorized service points worldwide are to be found on our Website, under: www.nouvag.com/en/service/service provider

Operated by
Nouvag AG

Disposal

When disposing of instruments, local legislations must be observed. Do not dispose of instruments with household waste. Observe the national regulations for the disposal of infectious waste.

Ambient conditions

Transport and storage: Operation:

Relative humidity: Max. 90 %
Min. 5 %
Temperature: 0 – 35 °C
Relative humidity: 0 – 70 %
Atmospheric pressure: 700 – 1060 hPa
860 – 1060 hPa

Attach clips to the tubing set
Connect the tubing set with the cooling tube and clamp the clips to the handpiece.
Open the clamping mechanism.
Take out the placeholder pin ...
... and replace it with a fracze bun.
Connect the motor (optional) at the coupling flange.
Attach the cable clip to the motor cable and hook in the tube.

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Troubleshooting

Manufacturer and Service points

Problem
Motor is running but cutter is not turning.
Cutters cutter isn’t correctly coupled.

Solution
Handpiece is not correctly coupled.
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Cutters cutter isn’t correctly coupled.
Adjust cutter correctly in the collet and lock it.

WARNING
• Always follow the instructions for use of the products used in combination.
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Possible combinations

4:1 Handpiece, REF 1041450 is exclusively used:
- In combination with the surgical motor systems HighLux = OFA-Drill (REF 9765) and HighLux 30 (REF 9760), which control the 4:1 Handpiece via the upstream electronic motor 21 and enables settings for speed and torque according to the selected tool used.
- In combination with the M2 30 implant motor system (REF 3550), which controls the handpiece via the upstream electronic motor 21 and enables settings for speed and torque according to the tools used.

Wrong combination of products

Damage to the product and injury to the patient, user or third parties are possible.
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- Always follow the instructions for use of the products used in combination.

Spare parts

Footcutters, Quick-release coupling flange
Motor connection

Troubleshooting

Problem
Motor is running but cutter is not turning.
Cutters cutter isn’t correctly coupled.

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Possible combinations

4:1 Handpiece, REF 1041450 is exclusively used:
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- In combination with the M2 30 implant motor system (REF 3550), which controls the handpiece via the upstream electronic motor 21 and enables settings for speed and torque according to the tools used.

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- Only use the different products together if the purpose and the relevant technical data such as tool lengths, diameters, and so on match.
- Always follow the instructions for use of the products used in combination.

Spare parts

Footcutters, Quick-release coupling flange
Motor connection

Troubleshooting

Problem
Motor is running but cutter is not turning.
Cutters cutter isn’t correctly coupled.

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Handpiece is not correctly coupled.
Press handpiece firmly against the motor. Check for proper seating.
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Possible combinations

4:1 Handpiece, REF 1041450 is exclusively used:
- In combination with the surgical motor systems HighLux = OFA-Drill (REF 9765) and HighLux 30 (REF 9760), which control the 4:1 Handpiece via the upstream electronic motor 21 and enables settings for speed and torque according to the selected tool used.
- In combination with the M2 30 implant motor system (REF 3550), which controls the handpiece via the upstream electronic motor 21 and enables settings for speed and torque according to the tools used.

Wrong combination of products

Damage to the product and injury to the patient, user or third parties are possible.
- Only use the different products together if the purpose and the relevant technical data such as tool lengths, diameters, and so on match.
- Always follow the instructions for use of the products used in combination.

Spare parts

Footcutters, Quick-release coupling flange
Motor connection

Troubleshooting

Problem
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Cutters cutter isn’t correctly coupled.
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Troubleshooting

Problem
Motor is running but cutter is not turning.
Cutters cutter isn’t correctly coupled.

Solution
Handpiece is not correctly coupled.
Press handpiece firmly against the motor. Check for proper seating.
Cutters cutter isn’t correctly coupled.
Adjust cutter correctly in the collet and lock it.
Reprocessing instructions

Frequent reprocessing has only a limited impact on the handpiece. The end of the products service life is normally determined by wear and dam-
age through use. The instrument is designed for 250 sterilization cycles.

General handling
1. The handpiece must be thoroughly cleaned, disinfected and sterilized before initial operation (products straight from the factory) and also after repair or cleaning use. Only a cleaned and disinfected instrument permits proper sterilization.
2. The handpiece should always be treated with utmost care when being transported, cleaned, serviced, sterilized and stored.
3. We recommend the use of mild alkaline and enzymatic cleaners with a low content of silicate as possible in order to avoid staining (lack-
a of soaps or detergents).
4. Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturer's specifica-
tions for the method of use, action time and suitable disinfection and cleaning substances.
5. Follow precisely the operating instructions of the devices and chemicals etc., used during preparation. A drying cycle must be added in case of autoclaves without a post-vacuum function. After sterilisation an immaculate sterilisation result must be achieved.
6. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection.
7. The end of the products service life is determined by wear and damage through use. For the handpiece it can be reached even before the 250 sterilisation cycles, that's why it's designed for, due to wear and damage.
8. Do not overload washer. Avoid blind spots while rinsing. Pay attention to secure storage in the machine.
9. Follow the applicable regulations in your country for reprocessing medical devices.
10. Only the cooling clip may be cleaned in an ultrasonic bath. The handpiece must never be subjected to ultrasonic cleaning! This will impair the functionality.
11. NouzG AG recommends removing unused products from circulation and all other processing (e.g. cleaning, disinfection) before sterilization.

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-handling and transport
Contacted surface of handpiece 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

Cleaning and pre-cleaning
Remove cooling tube, clips for the cooling tube attachment and cooling clip from the micro cooler. Avoid damaging the rubber components.
1. Visually inspect the end of the product to ensure no chips, debris or other foreign materials are present.
2. Brush the handpiece and accessories under running tap water using a soft brush (manufacturer Insutmed GmbH, Rif. MID D553).
3. The outer shell of the handpiece is to be rinsed under running water (at a velocity of at least 1 m/s), preferably with an ultrasonic cleaning device (e.g. Hega Medical, Rif. 6000 or 7000).

Disinfection

Mechanical disinfection
The cleaning/disinfection unit has a thermal disinfection programme which follows after the cleaning programme. Other than performing mechanical thermal disinfection, great due consider-
4. After completing the cleaning process (including Thermal disinfection) check the handpiece and the cooling clip for visible contamination in grooves and gaps. Gaps may need to be cleaned to reach areas.
5. After spraying the handpiece, re-install the cooling clip on the handpiece.
6. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection.
7. Inter-rinse for 2 minutes with cold water.
8. Perform a complete post-clean of the product under running drinking water, using a soft brush. Insufficient rinse, if there is any corrosion and/or lumen existing, with a water pressure gun (or similar) for at least 30 seconds.
9. After disinfection thoroughly rinse all products with deionised water to remove the disinfectant (> 1 min.).
10. Only the cooling clip may be cleaned in an ultrasonic bath. The handpiece must never be subjected to ultrasonic cleaning! This will impair the functionality.
11. Follow precisely the operating instructions of the devices and chemicals etc., used during preparation.

Drying

Mechanical drying

Manual drying

Sterilisation

Sterilisation of the handpiece is performed with a fractionated pre-vacuum steam sterilisation technique (in accordance with DIN EN 13086-2 and DIN EN ISO 16750-2) giving due consideration to the respective national requirements.

Minimal requirements:
1. Pre-vacuum phases: 3
2. Holding time: At least 5 minutes (full cycle).
3. Sterilisation: At least 157°C. From the cooling clip to the handpiece (example: without insulating sleeve).
4. Stoppage: After sterilising several products during one sterilisation cycle, do not exceed the maximum steriliser load. (see manufacturer's details).
5. A drying cycle must be added in case of autoclaves without a post-vacuum function. After sterilisation an immaculate sterilisation result must be achieved. (Please refer to the equipment manufacturer's operating manual for the dry heat steriliser).

Storage

Storing the sterile packaging
The used product is stored away from dust, humidity and contamination. During storage, direct sunlight must be safely avoided. After the expiry date has passed, do not use the product any longer. Only a cleaned and disinfected instrument permits proper sterilization!

Handling the sterile packaging
Before reprocessing, inspect the packaging to be intact. When taking out the product, follow the respective application procedures.

Information for facilitating the preparation
The above preparation process has been verified by a validated procedure. The following materials and machines were used:
1. Alkaline cleaner: Neodisher® Medical; Chemicke Fabrik Dr. Wegert GmbH & Co. KG
2. Enzymatic cleaner: Neodisher® MD24; Chemicke Fabrik Dr. Wegert GmbH & Co. KG
3. Washing machine: Miele G 7800 CD
4. Rock trolley: Miele E429
5. Sterilisation basket/flush socket bar: 3/4" (NOUVA/G Rif 19500)
6. Autoclave: Selectomat 666-HP (MMM)
7. Sterilisation: Steam steriliser (e.g. Stoeckelhorn, Bronmeco Amorflex GmbH & Co.
8. Chemicals and machines other than those mentioned can also be used. In such a case consult the manufacturers or suppliers to find out wheth-
er their products confirm the same performance as the products that the procedure was validated with.

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

Attention!
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.