Saftey measures

- These operating instructions generally apply to the ENT handpieces and accessories.
- We deliver a non sterile Instrument. Clean, disinfect, and sterilize the Instrument and accessories before the first application and immediately after each use.
- Do not clean handpiece with compressed air.
- The handpiece may be applied with max. 50,000 rpm!
- Handpieces may only be connected to the electrical motor when it's at a standstill!
- Never operate the clamping mechanism during operation, or without a clamped tool or placeholder pin.
- Operation of instrument by qualified and trained personnel only!
- Improper use or repair, or failure to observe these instructions, relieve us from any obligation arising from warranty provisions or other claims.

Intended use and operation

The handpieces in conjunction with a drive system and corresponding rotating instruments serve for milling, grinding and drilling in the area of ENT surgery. Handpieces may only be operated by qualified and trained personnel. Improper operation can lead to malfunctions. The intended use is obvious to the trained user.

Contraindications/Limitations

Relative or absolute contraindications 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 systems. Relevant cases in the literature must be taken into consideration.

Symboles

Conform to EU standards
certificated to RoHS
certificated to WEEE
Autoclave with 135°C
Suitable for thermal disinfection
Note
Date of expiry
Order number
Lot number
Serial number
Date of manufacturing

Technical data

Described parts

Straight handpieces

- Tool
- Cooling pin
- Placeholder pin
- Tightening sleeve
- Handpiece

Angled handpieces

- Tool
- Cooling pin
- Placeholder pin
- Tightening sleeve
- Handpiece

Inserting and exchanging the tool:

1. Hold handpiece with one hand at the lower part and open and clamp it to the handpiece.
2. Extricate placeholder pin or previously used tool.
3. Attach tube fixing clip (REF 1881) to the irrigation tube and clamp by turning the tightening sleeve with the other hand with a countermotion until it clicks.
4. Lock tightening sleeve by twisting in the opposite direction.
5. Check seating of the tool by gently pulling it.

Contraindications/Limitations

Relative or absolute contraindications 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 systems. Relevant cases in the literature must be taken into consideration.

Preparation instructions

Restrictions

- Frequent reprocessing hardly affects the Instrument. The products life end usually is determined by damage, wear and tear caused by usage. The handpiece is designed for 250 sterilization cycles.

General procedure

1. Every handpiece and accessories must be cleaned, disinfected and sterilised according to the instructions before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected handpiece permits a proper sterilisation!
2. The handpiece should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored.
3. Adhere exactly to the applicable regulations in your country for reprocessing medical devices.
4. Only the cooling clip may be cleaned with ultrasound, the handpiece must never be subjected to ultrasonic cleaning! It would impair the functionality.
5. Follow the applicable instructions of the devices and chemicals etc. used during preparation.
6. Adhere exactly to the chemical dosages, action times and suitability of disinfection and cleaning substances.
7. In case of excessive wear and damage due to use, the product life can be reached even before the maximum of 250 sterilization cycles.
8. Do not overload dishwashers. Avoid dead zones. 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 with ultrasound, the handpiece must never be subjected to ultrasonic cleaning! It would impair the functionality.

Advisory

In relation to patients with Creutzfeldt Jakob disease or its variant (vCJD) 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.

Preliminary 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.
**Troubleshooting**

### Cleaning

**Mechanical cleaning**

1. Place the handpiece after pre-cleaning on a suitable attachment.
2. Placing the parts (drill, tube, clip, and cooling clip) in a strainer basket and close it.

**Automatic cleaning process (Vario TD programme)**

1. Pre-clean for 4 minutes with cold water.
2. Clean for 10 minutes at 95°C with a 0.5 % alkaline cleaner.
3. Alternatively: at 20°C with 0.5 % enzymatic cleaner.

**Disposal of device, components and accessories**

- **Cleaning**
  - Set the handpiece up in an upright position with the cooling clip separately, in order to abet the outflow of water. Dry the clean handpiece for at least 30 minutes.

**Drying**

- Dry the handpiece using the disinfection unit's (CDU) drying cycle. If required, manual drying can also be achieved by using a lint-free cloth. When drying manually, take particular care with the grooves and gaps of the handpiece.

**Sterilisation**

- Sterilised product must be stored away from dust, humidity and contamination.

**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 procedure.

**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; Dental.
2. **Enzymatic cleaner**: Neodisher® MediZyme; Dental. When using an enzymatic cleaner neutralise it by a 5 min. water rinse.
3. **Cleaning and disinfection unit**: Miele G 7835 CD
4. **Chemical storage and care**

### Disinfection

- **Mechanical disinfection**

  - The cleaning/disinfection unit has a thermal disinfection programme which facilitates the transportation of the device to the sterilising plant. The cleaning process can also be induced by the use of hot water.

- **Mechanical cleaning**

  - Set up the handpiece vertically, separated from the cooling clip, to make sure the outflow of water is favored. Dry products with a lint-free paper towel. Then dry with suitable compressed air in accordance with the RKI recommendation. Pay particular attention to the drying of hard to reach areas.

- **Manual cleaning and drying**

  - Set up the handpiece in an upright position with the cooling clip separately, in order to abet the outflow of water. Dry the clean handpiece for at least 30 minutes.

- **Inspection and care**

  - Check for visual damage, corrosion, and wear.

  - After the disinfection spray the handpiece with mounted spray adapter REF 1958 with a cooling dosage of 15 ml. Repeat if necessary.

### Information on disposal

Disposal of device, components and accessories must strictly conform to local laws and regulations as set out by the relevant authorities.