












SYMBOLS

-  General warning sign
-  Observe instructions for use
-  Note
-  Suitable for thermal disinfection
-  Manufacturer
-  Date of manufacture
-  Autoclavable at 134°C
-  CE 0197 European Conformity mark
-  Catalog number
-  Serial number
-  Authorized representative in the European Community

INTENDED PURPOSE

The contra-angle handpieces are intended for use in dental practices for implantology, prophylaxis, restoration and oral surgery. The intended use is obvious to the trained user.

CONTRA INDICATIONS



Relative or absolute contra indications can arise from the general medical diagnosis, 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.

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	0–50 °C	10–30 °C
Atmospheric pressure	700–1'060 hPa	800–1'060 hPa

SAFETY INFORMATION

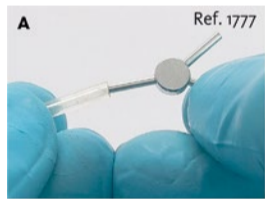







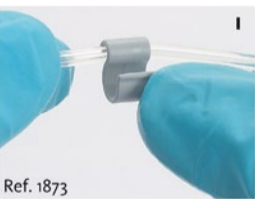




-  We deliver an unsterile contra-angle. Clean, disinfect, and sterilize the contra-angle before the first application and immediately after each use!
Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile and operational.
Improper use or repair of the device, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.
-  The use of the product other than that for which it was designed is not permitted. The responsibility is solely carried by the operator.
Manipulate the instrument only when the motor is at a standstill.
Do not attempt to open the chuck while the motor is running!
The device shall only be operated by qualified and trained personnel.
Do not clean the contra-angle with compressed air!
The contra-angle may be operated up to a maximum of 50'000 rpm.

USE

EXTERNAL COOLING

- A**  Connect the open end of the irrigation tube set with the cooling pipe of the contra-angle.
- B**  Attach the white clip to the tube set. *Ref. 1881*
- C**  Attach white clip with tube set to the contra-angle.
- D**  Connect the electronic motor with the contra-angle.
- E**  Attach grey clip (optional, REF 1873) to the tube set. *Ref. 1873*
- F**  Attach grey clip with tube set to the cable of the motor.
- G**  Ready to use drill unit with attached external cooling system.

INTERNAL/EXTERNAL COOLING


- A**  Attach open end of the tube set (REF 1706) to the single out branch of the Y-connector (optional, REF 1777). *Ref. 1777*
- B**  Connect a 160mm piece of tube (optional, REF 1773) to each of the branching tubes of the Y-connector.
- C**  Connect one of the 160mm pieces of tube, that branch out of the Y-connector, with the internal cooling tube of the contra-angle (delivered together with the contra-angle, REF 39116).
- D**  Connect the second piece of tube that branches out of the Y-connector with the external cooling pipe of the contra-angle (welded on laterally to the contra-angles head).
- E**  Both 160mm pieces of tube are now connected to the cooling system of the contra-angle.
- F**  Secure a white tube clip (included with the contra-angle, REF 1881) to each of the short tube pieces. *Ref. 1881*
- G**  Secure tube clips to the contra-angle.
- H**  Contra-angle with attached tube clips.
- I**  Fix a gray clip (optional, REF 1873) to the tube set leading to the Y-connector. *Ref. 1873*
- J**  Fix tube set with the gray clip to the motor cable.
- K**  Motor cable with ready attached tube set to the motor cable. Secure further gray clips to the motor cable if needed.
- L**  Tube set routing with Y-connector for internal and external cooling of the instrument.
- L**  Ready-mounted cooling on contra-angle handpiece and motor.

REQUIRED EXTENSIONS FOR INTERNAL COOLING

-  **REF 1777**
Y-connector
-  **REF 1873**
Motor cable clips
-  **REF 1773**
160mm connection tubes

REPROCESSING INSTRUCTIONS

- !** In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for re-use of the contra-angle. 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 contra-angle in an ultrasonic bath! This impairs the functionality of the contra-angle.

Reprocessing restrictions	Frequent reprocessing has only a limited impact on the contra-angle. The end of the products service life is normally determined by wear and damage through use. The instrument is designed for 250 sterilization cycles.
General handling	<ol style="list-style-type: none"> The contra-angle 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 contra-angle enables correct sterilisation! The contra-angle should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. We recommend the use of mildly alkaline and enzymatic cleaners with as low a silicate content as possible to avoid staining (silicization) on the electronic motor. 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. Operating instructions for the equipment and chemicals etc. used during reprocessing must be strictly followed. Dosage of chemicals, exposure times and exposure temperatures for cleaning and disinfection must be strictly followed. The end of product life may be reached before the 250 sterilization cycles in case of excessive wear and damage from use. Do not overload the washer. Avoid rinsing blind spots. Ensure secure storage in the machine. Observe the regulations valid in your country for the reprocessing of medical devices. Never clean the motor in an ultrasonic bath. This will impair the functionality of the motor. 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.
Automatic cleaning and disinfection	<p>Equipment: Cleaning/disinfection device with a special loading carrier, which ensures Handpiece connection to the cleaning/disinfection device and channel irrigation. A fine-meshed basket shall be used for the small parts. Rinse the contra-angle from the rear. Use a neutral or alkaline cleaning agent in the recommended concentration.</p> <ol style="list-style-type: none"> Load contra-angle in the load carrier (irrigation of the channels must be ensured). Place small parts into fine-meshed basket and close it. Set cleaning cycle with effectual rinsing and cleaning. Carry out a rinse cycle with demineralized water. For thermal disinfection rinse with demineralized water at 93°C for 10 minutes. By taking the contra-angle out check whether there's still visible dirt in gaps. If necessary, repeat cycle or clean manually.
Manual cleaning	<p>Equipment: Neutral cleaning agent, soft brush, running cold water</p> <p>Procedure:</p> <ol style="list-style-type: none"> Rinse surface dirt off the contra-angle and small parts under running water. Apply cleaning agent with the soft brush on all surfaces and gaps. Thoroughly rinse the contra-angle under running water. Spray the inside of the contra-angle handpiece with cleaning spray to remove residue of water immediately. This prevents damage and blockages of internal components. If necessary, wipe with a sterile non-woven cloth.
Manual disinfection	For manual disinfection, wipe the contra-angle and small parts with a cloth soaked in disinfectant solution on an ethyl alcohol basis.
Drying	If the drying/disinfection equipment does not provide any drying program dry contra-angle and small parts manually or in a drying chamber.
Inspection and care	<p>Check for visual damage, corrosion, and wear. After the disinfection spray the contra-angle thoroughly and briefly with lubricant spray and wipe with a DI water moistened cloth (see instructions on the spray can). Check the cooling clips for blockage. If necessary, repeat the cleaning cycle. Afterwards, attach cooling clips back onto the handpiece.</p> 
Packaging	<p>Single: Pack the contra-angle in an individual sterile supply package. The bag must be large enough that the seal is not under tension.</p> <p>Sets: Arrange the contra-angles into the foreseen trays or put onto an all-purpose sterilization tray.</p>
Sterilisation	<p>Sterilisation of the contra-angle 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.</p> <p>Minimum requirements:</p> <ol style="list-style-type: none"> Pre-vacuum phases: 3 Sterilisation temperature: minimum 132°C – maximum 137°C (within the sterile band) Holding time: At least 5 minutes (full cycle) Drying time: At least 10 minutes <p>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 contra-angle is not used immediately after sterilisation, it must be labelled with the sterilisation date on the packaging.</p>
Storage	No special requirements. If the sterilized contra-angle is not used immediately after sterilization, the packaging must be labeled with the sterilization date. NOUVAG recommends including a sterility indicator with the packaging.

MALFUNCTIONS AND TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
Motor runs, but tool does not move.	Contra-angle not optimally coupled to motor.	Press the contra-angle onto the motor until it snaps into place. Check the seat with a counter movement.
Tool does not run smoothly.	Tool not optimally clamped.	Align tool.
Contra-angle is loud.	Ball bearings not oiled or dirty.	Spray the contra-angle with lubricant spray.

TECHNICAL DATA

REF	5200nou	5053nou	5201nou
Transmission ratio	16:1	20:1	32:1
Torque max.	27 Ncm	70 Ncm	55 Ncm
Speed range	20–2800 rpm	15–2100 rpm	10–1200 rpm
Weight	88 g	88 g	92 g
Cooling internal/external	●/●	●/●	●/●
Coupling	ISO 3964	ISO 3964	ISO 3964
Shank-Ø	2.35 mm Type 1, ISO 1797	2.35 mm Type 1, ISO 1797	2.35 mm Type 1, ISO 1797
Clamping length min.	to stop	to stop	to stop
Permissible minimum length of the rotating instruments	34 mm	34 mm	34 mm
Maximum working diameter of the rotating instruments	According to the manufacturer of the rotating instruments in connection with the working speed		

POST MARKET SURVEILLANCE

- i** In the event of incidents related to the use of the medical device, please contact immediately the manufacturer by email complaint@nouvag.com or by phone.
- To provide adequate information, please compile the incident questionnaire at the web address Nouvag.com > [Contact us](#) > [Incident questionnaire](#).

ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION	QUANTITY
1777	Y-connector	1
1773	Tubing for Y-connector, 160 mm	20
1881	Clip-set, PU 3 pcs.	1
1969	Hook spanner	1
1940nou	Cleaning pin	1

INFORMATION ON DISPOSAL



When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed. Used electrical and electronic equipment is hazardous waste and must not be disposed of with household waste.



Internal irrigation tube

MANUFACTURER AND SERVICE POINTS

Switzerland
NOUVAG AG
St. Gallerstrasse 25
9403 Goldach



Germany
NOUVAG GmbH
Schultheissstrasse 15
78462 Konstanz



Phone +41 71 846 66 00
info@nouvag.com
www.nouvag.com

Phone +49 7531 1290-0
info-de@nouvag.com
www.nouvag.com