INSTRUCTIONS FOR USE – Instruments

This IFU is applicable to all current and previous generations of this product.

1. IDENTIFICATION OF THE COMPANY

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CE	www.americanortho.com/resources/instructions-for-use/	

2. IDENTIFICATION OF THE PRODUCT

Product Name: Orthodontic Instruments: Luno, Masterline, General Instruments
Product Description: REF Various Descriptions
Product Part Number: REF Various Part Numbers

3. INDICATIONS FOR USE, DOMAIN OF USAGE

Instruments are used by trained dental professionals and/or orthodontists in the clinical setting for orthodontic treatment. They are used as diagnosed by a trained dental professional and/or orthodontist. The patient population includes the general public of any age group seeking orthodontic treatment.

4. CONTRAINDICATIONS

Instruments should only be used by trained dental professionals and/or orthodontists for orthodontic treatment.

5. SIDE EFFECTS

It is the primary responsibility of the dental professional and/or orthodontist to identify any possible risk of injury that may arise during treatment, relay any possible unwanted side effects to the patient and to individualize treatment accordingly.

6. WARNINGS & PRECAUTIONS

- All instruments are to be used only by trained dental professionals and/or orthodontists and are to be used only for their intended purpose.
- All instruments are shipped in the non-sterile condition and must be cleaned and sterilized prior to first use.
- All instruments must be cleaned and sterilized before each use.
- The instructions provided have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that reprocessing - as actually performed using equipment, materials and personnel in the processing facility - achieves the desired result. Use only validated methods for cleaning and sterilization.
- Single use instruments are intended and manufactured for one use only. They must not be reprocessed.
- Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool.
- Do not expose any instruments, cassettes, trays or sterilization containers to temperatures higher than 134°C (273°F). Exposure to higher temperatures is the responsibility of the user.
- Chemically dissimilar metals should not be cleaned or sterilized together, as this could result in corrosion or other adverse effects.
- All used and contaminated instruments should be handled with puncture- and chemical-resistant protective gloves.
- Any repairs made by the user may void the warranty.
- Do not use damaged instruments.
- Instruments may contain nickel; use with caution on patients with a nickel allergy.

- For PowerScope Hex Driver magnets:
  - The hex driver is reusable. The magnets are single use only and should not be reprocessed.

- Do not ingest or inhale magnets. Ingestion or inhalation of magnets may result in serious injury. If ingestion or inhalation of one or more magnets occurs, contact a physician IMMEDIATELY.
- Loose magnets should be kept away from children since they pose of choking hazard and a risk of intestinal damage if multiple magnets are swallowed.
- Magnets should be kept away from pacemakers, ICDs, and other electronic implanted medical devices since their magnetic fields can affect the function of these devices.
- Secure magnets when unattended. Safety glasses are recommended when handling loose magnets.
- Any serious incidents should be reported to the manufacturer and competent authority.

7. PRE-STARTING PROCEDURES

A. Limitations on Processing

Frequent re-treating has little deleterious effect on the service life of the instrument. The end of the instrument lifetime is determined by wear and damage from use. The user is responsible for inspecting instruments prior to each use. Instruments shall be disposed of in compliance with local, state, and federal laws. Do not use any damaged instruments.

B. Selection of Detergents

Consider the following during selection of cleaning detergents:

- suitability for the cleaning of dental instruments
- compatibility of the detergents used with the instruments

Observe the instructions of the detergent manufacturer with respect to the concentration and temperature of the cleaning solution. Use detergent manufacturer exposure time if it exceeds recommendations in this guideline.

If using a cassette system, follow cassette manufacturer's instructions for loading, exposure time, and other parameters unless a longer exposure time is required by the detergent manufacturer.

Powdered cleaners must be dissolved completely in water before immersing the instruments into the solution.

Detergents containing the following substances must not be used:

- strong alkalines (> pH 9)
- strong acids (< pH 4)
- chloride solutions or bleach
- phenols
- interhalogenic agents/halogenic hydrocarbons/iodophors
- strong oxidizing agents/peroxides
- organic solvents

C. Water Quality

Water quality may influence the result of the cleaning and sterilization of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in your area. The use of completely deionized or distilled water will help to avoid most problems related to water quality.

Use only ultra-pure and deionized water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), i.e. aqua purificata for rinsing. Follow the sterilizer equipment manufacturer recommendations for water quality requirements.

Instruments must be thoroughly dried immediately after any exposure to water; water droplets remaining on stainless steel can result in surface oxidation (dark or rust-colored spots). If drying with air, use only filtered air.

Any local, regional, national, and international standards or regulations pertaining to water quality supersede those described in this guideline.

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8. STEP-BY-STEP INSTRUCTIONS

Instructions for two different instrument cleaning methods are provided in this guideline

A) Manual Cleaning using ultrasonics
B) Automated Cleaning

Pre-treatment steps (which can include initial treatment at the point of use and other preparations before cleaning) should be performed for both cleaning methods. The user is responsible for selecting one of the two cleaning methods to perform. Selection should be guided by relevant local, regional, national, and international standards or regulations pertaining to these activities.

Initial Treatment at the Point of Use
Remove coarse impurities on the instruments immediately after use. Instruments with visible impurities should be pre-treated within two hours of use. Always process hinged instruments in the open position.

Use an enzymatic cleaner or a precleaning product. Observe the instructions of the manufacturer with respect to the concentration and temperature of the cleaning solution.

Remove coarse impurities using a soft bristled brush. NEVER use metal brushes or steel wool.

(A) Cleaning: Manual

If using a cassette system, follow cassette manufacturer's instructions for loading and exposure time unless a longer exposure time is recommended by either the detergent manufacturer or this guideline. Always process hinged instruments in the open position.

1. Soak instruments in the cleaning solution for 5 minutes. Ensure that all instruments are sufficiently immersed with no contact between the instruments.
2. Sonicate for 15 minutes.
3. Remove the instruments from the cleaning solution and rinse them intensively.

Inspect the instruments. If visible debris remains, repeat steps 1 through 3.

(B) Cleaning: Automated

1. Place instruments into cassettes or other suitable tray systems compatible with the washer unit. Ensure no contact between the instruments.
2. Start the cycle.

Suggested Parameters

1	2 min pre-wash
2	2 min wash with enzymatic detergent
3	5 min wash with neutral detergent, minimum 40°C
4	2 min rinse, minimum 40°C
5	30 min dry

- Use only cleaning agents recommended for the type of automated washer/disinfector.
- Use only washer/disinfectors with approved efficacy (e.g. CE mark, validation according to ISO 15883).
- Follow washer/disinfector manufacturer's instructions if longer exposure time and/or higher temperatures are recommended.
- Follow detergent manufacturer's instructions if longer exposure time and/or higher temperatures are recommended.

3. Remove the instruments from the automated washer unit after end of the cycle.

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Disinfection
Required only if specified by local, regional, and/or national regulations.

Directly after use, instruments may be disinfected by hand in order to reduce the risk of infection for the user. The instruments can be placed in a disinfection solution. Make sure that the instruments are fully immersed in the disinfection solution and that no air bubbles are formed. Follow the instructions of the manufacturer of the disinfection solution.

The disinfectant should:
- be aldehyde-free (otherwise fixation or stabilization of blood contamination can occur),
- have a certified proof of efficacy
- be suitable for instrument disinfection

Drying
After cleaning, all instruments must be completely dry before packaging for sterilization. Always process hinged instruments in the open position.

Maintenance / Inspection / Testing
Inspect all instruments after cleaning for corrosion, damaged surfaces, and impurities. Check for misalignment of instrument tips, loose joints, and other functional issues. Remove damaged instruments from use!

If visible debris remains on instruments, repeat the cleaning process.

Re-sharpen instruments if necessary. Service and repairs must be done by properly trained personnel only. Repeat the cleaning process prior to sterilization of re-sharpened instruments.

Hinged instruments must be lubricated with a lubricant suitable for steam sterilization. Only use lubricants specifically formulated for dental and/or surgical instruments, and follow manufacturers' instructions for application. Ensure any excess lubricant is wiped off prior to sterilization.

Packaging
Ensure all instruments are completely dry before packaging for sterilization. Use of a cassette system, sterilization pouches/wrap, or other suitable sterilization containers is recommended according to ISO 11607-1 (EN 686-2). Always process hinged instruments in the open position.

Appropriate sterilization packaging should be:
- suitable for steam sterilization (temperature resistance up to at least 141 °C (286 °F), sufficient steam permeability)
- sufficiently protective of the instruments and the sterilization packaging against mechanical damage
- maintained regularly according to the manufacturers' instructions
- in conformance with FDA regulations (for US applications)

If using a cassette system, follow cassette manufacturer's instructions for loading and wrapping of the cassette.

Sterilization
Any deviations from the recommended sterilization procedure are the responsibility of the user. A 30 minute (minimum) dry time is recommended; however, use equipment manufacturer's instructions if they exceed the recommendations in this guideline. Flash sterilization procedures must not be used. The application of dry heat sterilization is the responsibility of the user. Always process hinged instruments in the open position.

- Use a steam sterilizer according to local, regional, national, or international standards as applicable.
- Ensure equipment/process is validated regularly according to local, regional, national, or international standards.
- Follow sterilizer manufacturers' instructions with respect to routine inspection and regular maintenance.
- Follow sterilizer manufacturers' instructions for load limits.
- Abide by any special instructions provided by the sterilizer equipment manufacturer.

- Sterilizers with an automatic drying program are recommended, as the sterilized items must be completely dried after sterilization and before handling.

Minimum cycle times for gravity-displacement steam sterilization cycles

Item	Exposure time at 121°C (250°F)	Drying times
Wrapped instruments	30 minutes	Minimum 30 minutes

Minimum cycle times for dynamic-air-removal steam sterilization cycles

Item	Exposure time at 134°C (273°F)	Drying times
Wrapped instruments	5 minutes	Minimum 30 minutes

Storage
Store instruments in a dry and dust free place in the clean section of the instrument processing area after sterilization. Sterilization can only be maintained if the instruments remain packaged or wrapped - impermeable to micro-organisms - following validated instructions developed by the packaging manufacturer.

9. STORAGE AND TRANSPORT CONDITIONS
PowerScope Hex Driver magnets must be stored and transported in original packaging, out of reach of children, and away from pacemakers.

10. DISPOSAL
Instruments and magnets should be disposed of in compliance with local, state, and federal law.

11. REGULATORY INFORMATION

All instruments include the following information on the label:

	MANUFACTURER
	EC REP
	RX ONLY
	MEDICAL DEVICE
	REF NUMBER
	LOT NUMBER
	NOT STERILIZED
	MANUFACTURE DATE
	CONSULT INSTRUCTIONS FOR USE

Instruments may also include one or more of the following symbols on the label:

	Intended for single use only; do not reuse
	Caution is necessary when operating the device

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	Warning: Product contains chromium-nickel; keep away from patients with a nickel allergy
	Warning: Magnetic Field
	Warning: Not to be used by people with implanted cardiac devices
	CE MARK

Refer to the product label for product-specific information.