

Intended Use

All instruments are intended for use by trained dental professionals in diagnostic, hygiene, restorative, laboratory, or surgical dental procedures.

Amalgam Carriers are instruments with hollow barrel-shaped tips that are used to deliver filling material to a restoration. Amalgam Carrier tips have a plunger inside the hollow barrel that is attached to a lever protruding from the handle. When the lever is depressed, the plunger moves through the barrel to expel the filling material into the restoration.

Amalgam Carvers are instruments with sharp blades that are used to carve set filling material in restorations into the appropriate anatomical shape.

Amalgam Wells are smooth stainless steel receptacles that are placed on the patient tray to hold mixed amalgam, before it is delivered to the restoration.

Articulating Paper Forceps are hinged instruments that are used to hold articulating paper, when the dentist is checking the occlusal fit of a restoration.

Aspirator Suction Tips are used to evacuate fluid and debris from surgical sites. Suction is controlled with a small hole in the handle.

Bone Condensers have cylindrical shaped working ends with fine serrations and are used to compact bone graft material.

Bone Files are used to remove or smooth rough edges of alveolar bone during surgical procedures. Straight-cut Bone Files are used with a pull stroke, while Cross-cut Bone Files can be used with a push-pull motion.

Burnishers are blunt instruments that are used to smooth sharp edges left from carving filling material in restorations.

Calcium Hydroxide Placement Instruments are blunt instruments that are used to place cavity liners in an amalgam restoration. Some Calcium Hydroxide Placement Instruments have a spatula for one tip that may be used to mix the cavity liner prior to placement.

Dental/Lab Carvers are designed to shape or cut dental wax. They are frequently heated to soften the wax while creating the pattern. Dental wax carvers are used in a variety of dental procedures, including formation of bite patterns for casting custom dental prostheses, construction of nonmetallic denture bases, and registration of jaw relations.

Cavity Preparation Instruments consist of Margin Trimmers, Chisels, and Hatchets. They are used to remove decay and healthy dentin and enamel, in order to form the cavity box.

Composite/Plastic Filling Instruments are used to place and shape filling material into a cavity preparation.

Condensers are blunt instruments that are used to compact filling material into a cavity preparation.

Crown Adaptor Pliers are hinged instruments that have ribbed, silicon inserts in the beaks. They are used to grasp and remove a temporary crown and to grasp and seat a permanent crown.

Crown Removers have thin, flat blades and are used to remove old, permanent crowns. After dissecting the old crown with a bur, the dentist will insert the blade of the crown remover into the slot in the crown. By twisting the instrument, they will leverage the blade against the sides of the slot to pry open the old crown and remove it.

Diamond Periodontal Files have thin tips and blades that feature a fine diamond coating on one side of the blade. They are designed to remove smaller calculus deposits, sheet and burnished calculus from subgingival tooth surfaces. The fine diamond coating allows the clinician to use a multi-directional stroke when removing the calculus.

Dressing Pliers are hinged instruments that are used to pick up and hold small objects during dental procedures.

Endodontic Condensers are instruments with long, thin, blunt tips that are used to condense filling material vertically into root canals.

Endodontic Spreaders are instruments with thin sharp tips that are used to condense gutta percha laterally into irregularities in the sides of root canals.

Excavators are instruments with sharp blades that are used to remove decayed dentin that is close to the pulp or soft, gummy, decayed dentin that cannot be removed with a bur.

Explorers are instruments with thin pointed tips that are used to detect decayed enamel and dentin or to detect calculus on root surfaces.

Expros are double end instruments that have an explorer tip on one end and a probe tip on the other. The explorer tip ends in a sharp point, which is pressed against dark spots on natural tooth surfaces to determine the presence of carious lesions. The probe tip is thin and blunt with millimeter markings. It is used to measure the depth of gingival pockets to assess periodontal health.

Extraction Forceps are hinged instruments that are used to grasp teeth with the purpose of extraction.

Gingival Cord Packers are double end instruments with thin, dull blades that are used to place gingival retraction cord into the gingival pocket.

Hemostats are used in a dental surgical setting to hold and place small objects. Hemostats are hinged instruments that have handles with a locking mechanism. The locking mechanism is typically a series of interlocking teeth on each handle that allow the clinician to adjust the clamping force being applied.

Luxation Blades have very thin, sharp blades that are designed to cut the periodontal ligament. Notably, the blades are not designed to withstand any lateral pressure or to be used for any type of tooth elevation.

Mirror Handles have a threaded opening that is used to hold replaceable mirror heads. Mirror Handles are available in either cone socket or simple stem versions. Cone Socket Mirror Heads may only be used with Cone

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Socket Mirror Handles and the same is true of Simple Stem Mirror Heads and Handles.

Mirror Heads are used in combination with Mirror Handles to provide the clinician with indirect vision. Mirror Heads are available in either cone socket or simple stem versions. Cone Socket Mirror Heads may only be used with Cone Socket Mirror Handles and the same is true of Simple Stem Mirror Heads and Handles.

Needle Holders are used to hold and push a suturing needle during wound closure. Needle Holders are hinged instruments that have handles with a locking mechanism. The locking mechanism is typically a series of interlocking teeth on each handle that allow the clinician to adjust the clamping force being applied.

Orthodontic Band Pushers and Ligature Directors are used to position components of orthodontic appliances and remove hardened cement during orthodontic treatment.

Orthodontic Cutters are used to neatly trim hard orthodontic wires to the proper length for use in creating orthodontic appliances.

Orthodontic Pliers are used to guide and move orthodontic arch wire in and out of orthodontic brackets and to bend the ends of the arch wire.

Periodontal Chisels have sharp blades and are used to reshape and remove bone.

Periodontal Files have blades with triangular teeth that are sharp at the apex. They are used to break up large deposits of tenacious calculus. The clinician will press the blade of the periodontal file onto the calculus deposit to crush it, making the remaining calculus more easily removed with a curette.

Periodontal Knives are single-end or double-end instruments with thin, sharp blades that are used to cut soft tissue.

Periosteal Elevators are typically double-ended instruments that are used for a variety of purposes in the dental setting. They are available with tips sharpened or not and may be used to shield gingiva when drilling near the gumline, loosen gingiva prior to extraction, retract tissue, sever ligament, and scrape small amounts of tissue and ligament from bone.

Periotomes are instruments with thin, sharp blades that are used to sever the periodontal ligament prior to extracting a tooth.

Dental Probes are instruments with very thin, blunt tips that have millimeter markings. They are used to measure the depth of gingival pockets in order to assess the patient's periodontal health.

Dental Retractors are dull instruments that are used to move the patient's cheek or gum in order to provide the clinician with better access to a particular site.

Rongeurs are hinged instruments with sharp beaks that are used to cut or reduce bone.

Root Tip Picks are thin extraction elevators that are only used to extract residual root fragments of fractured teeth, during an extraction.

Scalers and Curettes are instruments with sharp blades that are used to remove stain and calculus from tooth surfaces.

Scalpel Blade Handles are reusable instruments that are used to securely hold disposable scalpel blades during surgical procedures.

Scissors are used to cut many things in a dental office, including but not limited to tissue, retraction cord, gauze, cotton rolls, sutures, and temporary crowns.

Sinus Lift Curettes have spoon shaped working ends with smooth, non-cutting edges that are used to detach the delicate sinus membrane from lateral walls.

Spatulas are used to mix different materials, usually consisting of a powder and a liquid. These materials include, but are not limited to, cavity liners, impression materials, and cements.

Surgical Curettes have sharp, spoon-shaped working ends and are used for debridement and curettage during surgical procedures.

Surgical Elevators are single end instruments with thick, sharp tips that are inserted interproximally to loosen teeth prior to extraction.

Tissue Forceps are hinged instruments that are used to grasp and retract tissue after a flap has been cut.

Contraindications

Do not use on patients with hypersensitivity to nickel or stainless steel.

Reusability

The instruments are reusable medical devices. The lifetime of the instruments depends on the frequency of use, the care of the user, and proper reprocessing methods. The user is responsible for inspecting instruments prior to each use.

Instruments with sharp blades should be resharpener regularly. Repeatedly using dull instruments may cause the end user to apply inordinate pressure to a blade that is designed to be sharp. Completely remove any residues from the sharpening process, such as metal residue or sharpening oil. After sharpening, clean and sterilize the instrument.

Inspection

Care must be taken to clean, sterilize, and inspect instruments prior to each use. Be sure to inspect the instruments for fissures, cracks, chips, surface damage, corrosion, bent tips, dull or weakened blades, misalignment, or other defects/damage prior to each use. Any instrument that shows one of these or any other sign of damage must be taken out of service immediately.

Functional Testing

After processing and before each use, assess the functionality of each instrument. When assessing hinged instruments, ensure that they can be opened and closed and that their tips or jaws are aligned and seat together correctly. Confirm that forceps can be opened and closed and that their tips

are aligned and seat together correctly. Ensure that all sharp instruments do not have dull or weakened blades. Verify that instruments are clear of any debris, paying special attention to instruments with internal and difficult-to-access areas such as amalgam carriers.

Processing

The instruments are delivered non-sterile.

Brand-new instruments, as well as instruments returned from repair, must be removed from their transportation packaging before including them in the sterile processing and supply cycle. This also requires removal of all protective devices (such as foils, caps, etc.).

Prior to sterilizing instruments for the first time, they must be thoroughly cleaned. In particular, all oil residues must be carefully removed. If cleaning is done manually, hot water must be used for this purpose, adding a suitable, commonly available washing-up liquid.

Before processing an instrument, check the following section "Special Considerations for Specific Nordent Instruments" for any special instructions for that instrument type.

Instruments should always be stored in a dry room to prevent condensation and consequential corrosion damage. Prior to initial use, instruments must be sent through the entire processing cycle. This may only be done by trained personnel and in compliance with the current regulations.

Process instruments immediately after use (do not store them dirty). Ensure that all residues (blood, tissue particles, medicines) are carefully removed from the instruments immediately after surgical intervention. Take special care to ensure that all amalgam has been removed from amalgam carriers before sterilization processing.

Medical devices should not be distorted, bent, or overloaded as this can cause loss of function, fracture, or destruction of the devices. Avoid overloading instruments and washing trays during cleaning and sterilization.

During transportation, instruments should never be "dropped". Instead, put them down carefully to avoid damage.

Do not immerse instruments in NaCl solutions because this may cause pitting or stress corrosion cracking. Use only an approved detergent-disinfectant solution that has no protein-fixing effect (as regards the mix, be sure to follow the product manufacturer's instructions for use).

Water quality may influence the result of the cleaning and disinfection 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. By using completely deionized or distilled water most water quality problems can be avoided beforehand.

Special Considerations for Specific Nordent Instruments

This section details any special maintenance, processing, or usage

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instructions for relevant Nordent instrument types.

Amalgam Carriers

Maintenance: After use, expel any unused amalgam. Fully submerge the barrel in isopropyl rubbing alcohol for 30 seconds and depress the lever several times. All residual amalgam must be removed.

Special instructions if Amalgam is hardened in the Amalgam Carrier: If amalgam hardens in the Amalgam Carrier, gently lay the barrel on a running felt wheel. When the barrel begins to spin, submerge the barrel in isopropyl alcohol and depress the lever several times. Never apply any part of the carrier into a flame as this distorts the alignment of the instrument.

Cleaning: Automated cleaning in an automated washer disinfectant is recommended. Do not use chemical disinfection (cold sterilization); these chemicals may damage the Amalgam Carrier. After the cleaning apply a lubricant.

Sterilization: For sterilization use steam sterilization (gravity or fractionated vacuum procedure) only.

Anodized Aluminum Composite Placement Instruments

Processing: Anodized Aluminum composite placement (black colored) instruments such as the Felt Instruments should be kept separate during the cleaning and sterilization process. These instruments should be cleaned with a mild detergent under running water. They should never be ultrasonically cleaned. After cleaning they may be sterilized in a Steam Autoclave or Dry Heat sterilizer according to the manufacturer's instructions for aluminum instruments.

Composite Placement Instruments

Maintenance: Proper care should be taken to remove any residual composite materials from the blade within 5 minutes after use by wiping the blade with alcohol on a 2x2 gauze. Composite materials or residue can harden on the blade and affect the quality of future restorations. Composite residue left to harden on the blade cannot be removed without damaging the surface finish of the composite placement instrument.

Composite/Plastic Filling Instruments

Processing: Process in cassettes or trays with instrument rails to avoid scratches on the surface from other pointed instruments.

Maintenance: Residues of Filling Materials and Etching products must be removed immediately. Plastic Filling Instruments are designed with an extra smooth surface, in order to provide a better handling with composite materials. Scratches that are not visible might cause composite materials to stick to the rougher surface.

Hartzell Cone Socket Instruments

Processing: Before processing, fully disassemble every Hartzell Cone Socket Instrument by unscrewing and separating the tips from the handle.

Hinged Instruments

Maintenance: Care should be taken to keep hinges and joints of forceps, rongeurs, scissors, pliers, hemostats, crown placement pliers, etc. well lubricated. Only use lubricants specifically formulated for dental and surgical instruments and follow manufacturer's instructions for applications. Household lubricants, hand-piece lubricants and other lubricants not

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specifically formulated for dental and surgical hand instruments should never be used.

Processing: Jointed and/or hinged instruments must always be processed in an open condition. Hinged Instruments should be allowed to thoroughly dry in an open position after cleaning procedures. Always apply lubricant prior to sterilization.

Luxation Blades

Use: Luxation blades have very thin sharp blades that are only designed to cut the periodontal ligament, and they may only be used with directly downward pressure. They are not designed to withstand any lateral pressure or to be used for any type of elevation. If teeth roots are distinctly curved or if the clinical application requires any amount of lateral pressure, these instruments should not be used.

Mouth Mirrors

Processing: To avoid scratches on the mirror surface from other pointed instruments, reprocess in an appropriate accessory such as a parts box or clip inside a cassette. Clean and sterilize in a completely disassembled state. Disassemble mouth mirrors by unscrewing the mirror head and separating it from the handle.

Ortho-Instruments

Cleaning: Do not clean using an automated washer.

Resin Instruments and Components

Cleaning: For resin or silicone products, do not use detergents or disinfectants containing phenols or iodophors.

Sterilization: Dry heat is not compatible with instruments with resin handles (OnPoint Resin), with resin or Silicone components such as cassette rails, instrument rings or grips, inserts on any instruments, or with resin cassettes. The sterilizer equipment manufacturer's compatibility with specific materials must be observed.

Stainless Steel Instruments

Processing: Never expose stainless steel instruments to products that are not specifically formulated for use with dental instruments or for the purpose of cleaning and sterilizing dental instruments. Do not expose stainless steel dental instruments to the following chemicals. These chemicals will cause an adverse reaction and may destroy your instruments: Chlorine or Chlorinated products, Household Bleach, Tarter and Stain Remover, Aluminum Chloride, Aqua Regia, Barium Chloride, Bichloride of Mercury, Calcium Chloride, Carbolic Acid, Chlorinated Lime, Citric Acid, Dakin's Solution, Ferric Chloride, Ferrous Chloride, Hydrochloric Acid, Iodine, Lysol®, Mercury Chloride, Mercury Salts, Phenol, Potassium Permanganate, Potassium Thiocyanate, Sodium Hypochlorite (bleach), Stannous Chloride, Sulfuric Acid and Tartaric Acid (Tarter & Stain Remover)

Syringes

Processing: Completely disassemble the syringe before processing. Unscrew and remove the cylinder.

Titanium Nitride Coated (gold colored) Instruments

Titanium coatings are used to increase the surface hardness of instrument tips and reduce "pullback" when manipulating composite materials. Nordent produces a selection of the following instruments with titanium

nitride coating:

- Restorative Composite Placement Instruments (increases surface hardness for smoother restorations)
- Surgical Elevators (to maintain longer lasting sharpness)
- Surgical Periotomes (to maintain longer lasting sharpness)
- Surgical Luxation Blades (to maintain longer lasting sharpness)

Processing: Never use abrasives to clean the surface of any titanium coated composite placement instruments, elevators, periotomes, or luxation blades. Titanium Nitride Coated instruments can be cleaned and sterilized using the same recognized acceptable methods as stainless-steel instruments (see stainless steel instruments portion of this document).

Automated/Machine Cleaning

Use an automated washer that is compliant with ISO 15883-1.

1. Completely disassemble the instruments, if applicable.
2. Rinse the instruments under running tap water for 30 seconds.
3. Transfer the instruments to the automated washer.
4. The following cycle settings have been validated for use. Follow the detergent manufacturer's instructions:

Stage	Recirculation Time	Temperature	Detergent Type
Pre-wash	15 sec.	Cold tap water	N/A
Enzyme Wash	1 min.	Hot tap water	Enzol Enzymatic Cleaner (or similar)
Wash 1	2 min.	43° C tap water	Valsure Neutral Detergent (or similar)
Rinse 1	15 sec.	Hot tap water	N/A
Dry Time	6 min.	98.8° C	N/A

5. Inspect the instruments to make certain that all residue, debris, and residual cleaning solution are removed from the instruments and that the instruments are free of defects and are safe to use. Inspect instruments to confirm they are still functional (see "Inspection" section).

Manual and Ultrasonic Cleaning

Use only cleaners and disinfectants suitable (approved) for stainless steel instruments. When manually cleaning or handling contaminated instruments, personnel should wear heavy duty, puncture resistant utility gloves to avoid injury or cross contamination. They should also wear a face mask, eye protection or face shield and a gown or jacket because splashing will likely occur.

1. Completely disassemble the instruments, if applicable.
2. Pre-Treat all contaminated instruments by soaking in an enzymatic cleaning solution for at least 5 minutes. Contaminated instruments should be pre-treated within one hour of use, and it is necessary that

all instrument surfaces are completely submerged.

3. Remove the instruments from the cleaning solution and remove any remaining debris or deposits using a soft brush. Do not use any brush with metal bristles or steel wool.
4. Rinse instruments completely with low contaminated and deionized water for at least 30 seconds, making certain that there is no remaining residue, debris or residual cleaner left on the instruments.
5. Prepare a detergent bath in an ultrasonic unit using an enzymatic cleaning solution such as Enzol Enzymatic Cleaner. Follow the detergent manufacturer's instructions.
6. Soak the disassembled instruments for the recommended soaking time in the cleaning solution, and make sure that the instruments are sufficiently immersed. Sonicate the instruments for at least 6 minutes. If utilizing a cassette system, use the processing time recommended by the manufacturer of the cassette system.
7. Do not overload the Ultrasonic Cleaning unit. Use "Sweep mode" if available.
8. Remove the instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water for at least 30 seconds.
9. Before reassembly and before packaging for sterilization, thoroughly dry all instruments using lint-free cloths and/or filtered compressed air.
10. Inspect the instruments to make certain that all residue, debris, and residual cleaning solution are removed from the instruments and that the instruments are free of defects and are safe to use. Inspect instruments to confirm they are still functional (see "Processing" section).

Sterilization

Only use steam sterilizers that are in compliance with AAMI/ANSI ST55 or AAMI/ANSI ST8 and have been validated according to ANSI/AAMI ST 79.

Minimum cycle times for gravity-displacement steam sterilization cycles

Item	Exposure Time at 121°C (250°F)	Drying Time
Pouched Instruments	30 Minutes	Minimum 30 Minutes

- NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

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

Item	Exposure Time at 132°C (270°F) or 134°C (273.2°F)	Drying Time
Pouched Instruments	4 Minutes	Minimum 30 Minutes

- NOTE—These tables represent the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

After processing, inspect the instruments to ensure they are free of defects and are safe to use. Inspect instruments to confirm they are still functional (see "Processing" section).

Be sure to use only solutions and chemicals that are compatible with stainless steel hand instruments.

Never exceed temperatures 350° F / 177° C as this will have an adverse effect on the temper of the steel.

Notice : No liability is accepted for reuse instruments which have been applied to patients with Creutzfeldt-Jacob disease or HIV-positive patients.












Storage

Products must be stored in a dry and dust-protected place, avoid humidity and consequential corrosion. Some medical devices are very delicate, should be individually packed or stored in protective containers. Please ensure that instruments are not in contact with chemical substances.

Warranty

Our products are manufactured to the highest quality standards. Please do not hesitate to contact us if there are any problems regarding our products. The user takes full responsibility for proper use and care of these instruments. Damage caused by misuse, neglect, modification, or accidents are not covered by warranty. Nordent Manufacturing, Inc. does not accept liability to results caused by unauthorized repairs or by proven non-compliance of this instruction for use.

Symbols Glossary

	Manufacturer/Legal Manufacturer	ISO 15223-1 Reference no. 5.1.1
	Unique Device Identifier	ISO 15223-1 Reference no. 5.7.10
	Catalog Number	ISO 15223-1 Reference no. 5.1.6
	Lot Number	ISO 15223-1 Reference no. 5.1.5
	Caution	ISO 7000-0434A ISO 7000-0434B
	Caution: Federal law restricts this device to sale by or on the order of a "dentist/physician" licensed by the law of the State in which he/she practices to use or order the use of the device	FDA 21 CFR Part 801.109 (b)(1)
	Non-Sterile	ISO 15223-1 Reference 5.2.7
	Country of Origin Indicates the country of manufacture of products	ISO 15223-1 Reference 5.1.11
	Quantity	N/A
	Do not use if package is damaged	ISO 15223-1 Reference no. 5.2.8
	Consult instructions for use or consult electronic instructions for use.	ISO 15223-1 Reference no. 5.4.3



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