ErgoDenta

Diagnostic

IFU-00-001
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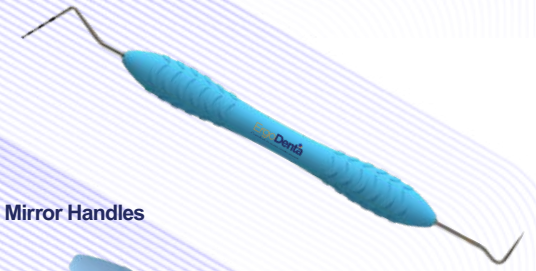
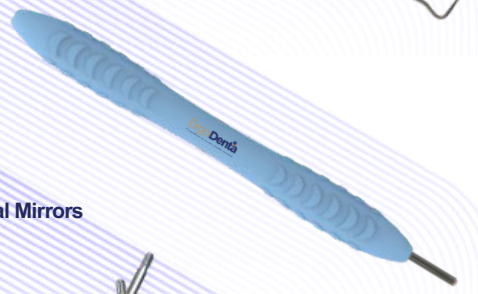
Periodontal Probes

Explorers

Probes & Explorer



Mirror Handles



Dental Mirrors

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Dental Diagnostic Instruments

en-English

Attention

The operator/user must carefully read and understand this manual thoroughly to keep the product performance durable and reliable for defined life expectancy. After opening the packaging, first of all it is necessary to check the component(s) against the standard configuration. Check that these are all present and in perfect condition.

Intended Use:

These diagnostic instruments are intended to be used for the assessment and evaluation of oral health conditions, including caries detection, periodontal pocket measurement, tactile examination of teeth and surrounding structures, and enhanced intraoral visualization. The Instrument Specific Intended Use is given below:

Dental Mirrors & Handles:

Dental Mirrors in combination with Mirror Handles are intended to be used to provide indirect vision, retract soft tissues, and improve visibility in the oral cavity during dental examination and treatment.

Periodontal Probes:

Are intended to be used for measuring depth of periodontal pockets, attachment levels, and for assessing gingival health.

Dental Explorers:

Are intended to be used for the tactile examination of tooth surfaces to detect caries, calculus, and structural irregularities in tooth surface.

Expros:

These are Dual-ended instruments with a periodontal probe on one side and an explorer on the other, intended to achieve multifunctional diagnostic capability in a single tool.

⚠ Our Dental Diagnostic Instruments are intended to be used by qualified dental professionals only in a professional dental facility.

Patient population:

These instruments are intended for use on adult patients, as well as children who can tolerate the procedure as determined by a qualified healthcare professional. The appropriate size and type must be selected based on the patient's anatomy and specific treatment requirements.

For Available Configurations/Models please visit the Diagnostics section in our Catalogue

Features

Dental Mirrors and Handles:

- Front-surface mirrors provide a clear, distortion-free image for precise intraoral visualization.
- Dual-sided variants enhance indirect visualization while effectively retracting the cheek and tongue.
- Available in rhodium-coated and high-definition options for superior reflection, anti-fog properties, and scratch resistance.
- Universal threading (ISO-compliant) handles ensure compatibility with various mirror heads.
- Ergonomically designed handles come in stainless steel or silicone options, ensuring a secure, comfortable grip and easy handling.

Periodontal Probes:

- Designed with calibrated markings to measure periodontal pockets accurately.
- The slender, rounded tip ensures gentle probing with minimal tissue trauma.
- Available with laser-etched or color-coded markings for better readability.
- Made from stainless steel to ensure durability and resistance to sterilization.

Explorers:

- Sharp, slender tips provide high sensitivity for detecting enamel irregularities, caries, and calculus.
- Double-ended designs allow optimal access to different tooth surfaces.
- Fabricated from high-carbon stainless steel to maintain tip sharpness.
- Electropolished working tips provide a corrosion-resistant finish to prevent microbial adhesion.

Expros:

- Combines periodontal probe and explorer functionality in one instrument for convenience.
- Designed with ergonomic balance for efficient switching between probing and exploring.
- Manufactured with long-lasting stainless steel to withstand sterilization and clinical use.
- Markings and tips remain clearly visible and precise for consistent diagnostics.

Operating instructions:

⚠ These instruments are non-sterile and must be cleaned and sterilized before first use.

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⚠ These instruments are non-sterile and must be cleaned and sterilized before first use.

⚠ Always check if the reprocessed instruments are in perfect condition and do not use the instruments if any kind of deterioration, bent or breakage is observed.

⚠ Use a firm but gentle grip to maintain control and precision. Avoid excessive force to prevent unnecessary trauma or instrument damage.

For Dental Mirrors & Handles:

- Select the appropriate size of the dental mirror, keeping in view the application.
- Securely attach the dental mirror to the compatible handle by aligning the threads and twisting until firmly connected and ensure that the mirror is stable in the handle, before use.
- Adjust the mirror angle for optimal viewing

For Periodontal Probes:

- Insert the probe gently into the gingival sulcus, parallel to the root surface.
- Use a light walking motion to measure pocket depth at multiple points.
- Record measurements using the calibrated markings on the probe.

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- Insert the probe gently into the gingival sulcus, parallel to the root surface.
- Use a light walking motion to measure pocket depth at multiple points.
- Record measurements using the calibrated markings on the probe.

For Explorers:

- Move the tip along the enamel surface to detect caries, plaque, and calculus.
- Use a light touch to prevent damage to enamel and soft tissues.

For Expros:

- Use the probe end to assess periodontal pockets and the explorer end for tactile examination.
- Follow best practices for both functionalities in one instrument.

Adverse Event

Any serious inwcident that has occurred concerning the device should be reported to the manufacturer and to the respective competent authority of the Member State in which the incident has occurred.

Cleaning & Sterilization

Cleaning:

⚠ Always clean the Mirror and Handle in disassembled form i.e. separated from each other. Clean the device with care after each application to avoid the drying of contaminants.

Initial Cleaning:

1. Remove any visible debris from the instruments using moisten a cotton swab or cloth with isopropyl or ethyl alcohol and gently wiping the surface of the product.
2. Always wipe the mirror surface from side to side rather than in a circular motion.
3. Use a soft brush for cleaning the instrument if required. Avoid using brush for cleaning the mirrors.

Manual Cleaning

4. Prepare a solution of neutral pH enzymatic detergent according to the manufacturer's instructions.
5. Immerse in a pre-soak enzymatic cleaner solution
   Thoroughly clean all surfaces of the Instrument using a soft brush or cloth.
6. Pay close attention to any crevices or hard-to-reach areas.

⚠ Do not use brush on the front surface of the mirror as it may cause scratches

7. Rinse thoroughly under lukewarm running tap water for a minimum of 30-60 seconds to remove all traces of detergent.

Automated Cleaning:

1. To avoid scratches on the mirror surface, clean in an appropriate accessory box or cassette separately from other pointed instruments and ensure that they are properly positioned within the unit.
2. Always follow the equipment manufacturer's instructions and ensure the instruments are compatible with the cleaning system.
3. Visually inspect for cleanliness, If any contamination is visible, repeat the cleaning steps until required cleanliness is achieved.
4. Dry with clean, lint free cloth or filtered compressed air until there is no visible moisture. Follow STEAM STERLIZATION PROCEDURE.

⚠ Ultrasonic cleaning may be performed in accordance with hospital or facility protocols. Ensure proper rinsing and drying after the process to prevent residue buildup.

Sterilization

Note: Ensure that the instruments are completely dry before sterilization.

Steam Autoclaving:

1. Place the instrument in an approved sterilization pouch or wrap.
2. Sterilize using a steam autoclave following a validated sterilization cycle according to ISO 17665-1 and your facility's protocols. A typical recommended cycle is 132-134°C (270-273°F) for 4 minutes.
3. Allow the instruments to cool completely before handling. Store in a clean, dry, and controlled environment until ready for use.
4. Follow the pouch/wrap manufacturer instructions for storge conditions and maximum storage time

Important Notes:

- Always Inspect the instruments for any signs of deterioration, breakage and bent etc. after each sterilization cycle. Discard if damage is observed.
- Always follow your facility's infection control protocols.
- Refer to your autoclave manufacturer's instructions for proper operation and maintenance. The Sterilization equipment must be validated by the hospital and or sterilization equipment manufacturers.
- The above-mentioned cleaning and sterilization guidelines, provided by us are intended as procedures compatible with specific materials. Sterilization must be performed according to the Hospital/Clinic approved protocol.
- The responsibility for ensuring proper sterilization of instruments lies with the user. The effectiveness of sterilization depends on validated cleaning, packaging, and sterilization procedures carried out at the facility.

Disposal:

The Dental Mirrors & Handles, Periodontal Probes, Explorers and Expros contain no hazardous materials. However, these must be cleaned/sterilized as per defined procedures before disposition. Please follow the local and national regulations or healthcare facilities' defined disposal and waste management policies.

Disclaimer:

The product must be used, reprocessed, and maintained strictly in accordance with the instructions provided above. Any deviation from these guidelines by the dental professional or user is undertaken at the user's sole risk. The Manufacturer will not accept any requests for refunds or exchanges under warranty for products that have not been handled and reprocessed in compliance with these instructions.

Explanation of utilized symbols:

CE	Medical Device Compliant with Regulation (EU) 2017/745
	Consult instructions for use
MD	Medical Device
REF	Product Code/Catalogue Number
#	Model/Variant
LOT	Lot Number
	The Device is supplied non-sterile.
134 °C	Sterilizable in a steam sterilizer (autoclave) at 132-134°C (270-273°F)
	Manufacturing Date
	Manufacturer
	Keep in a cool, dry place
⚠	Caution, read instructions