ErgoDenta

Extraction

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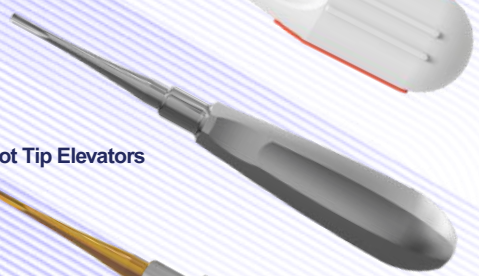
Tooth Extraction Forceps

ErgoLite Elevators

Dental Tooth Elevators



Root Tip Elevators

Periosteal Elevators

X-Tool Elevators

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Dental Extraction Instrument

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:

Our Extraction instruments are intended to assist in tooth extraction by loosening, mobilizing, and removing teeth, roots, or root fragments from the alveolar socket. They aid in controlled tooth removal while minimizing trauma to surrounding tissues.

The Instrument Specific Intended Use is given below:

Tooth Extraction Forceps:

Intended to be used for grasping and removing teeth from the alveolar socket during dental extractions. They provide a secure grip on the tooth structure for controlled removal.

Dental Tooth Elevators:

Intended to be Used for loosening teeth, roots, or root fragments from the surrounding periodontal ligament and alveolar socket, aiding in controlled tooth mobilization.

Root Tip Elevators:

Intended to be Used for the precise removal of fractured or retained root tips from the alveolar socket.

Periosteal Elevators:

Intended to be used for the retraction and separation of soft tissue, including periosteum, from the underlying bone to facilitate surgical access.

X-Tool Elevators:

Intended to be Used for controlled elevation of teeth or root fragments, minimizing trauma to surrounding tissues during extractions.

⚠ Our Dental 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 and child patients undergoing tooth extraction procedures. The appropriate instrument type and size must be selected based on the patient's dental anatomy, tooth condition, and the specific clinical requirements of the extraction.

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

Features

Tooth Extraction Forceps:

- Anatomically shaped beaks conform to the tooth's crown and root morphology, ensuring a secure grip and reducing slippage.
- Designed with specific angulations to enhance access to different quadrants, including posterior and impacted teeth.
- Serrated or diamond-coated beaks provide superior grip, minimizing the risk of tooth fractures during extraction.

Dental Tooth Elevators, Root Tip Elevators, Periosteal Elevators:

- Specialized tip geometries allow for precise engagement, whether for tooth luxation, root retrieval, or periosteal dissection.
- Engineered with specific shank angles to enhance access to deep sockets, posterior teeth, and subperiosteal planes.
- Reinforced blades ensure durability under high-pressure applications without risk of deformation or breakage.

X-Tool Elevators:

- Designed for controlled and efficient elevation of teeth or roots, minimizing trauma to surrounding tissues.
- Ergonomic non-slip grip provides maximum control and reduces hand fatigue during prolonged use.
- Sharp, tapered tips allow for precise insertion into the periodontal ligament space to facilitate tooth loosening.
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Operating instructions

- Designed for controlled and efficient elevation of teeth or roots, minimizing trauma to surrounding tissues.
- Ergonomic non-slip grip provides maximum control and reduces hand fatigue during prolonged use.
- Sharp, tapered tips allow for precise insertion into the periodontal ligament space to facilitate tooth loosening.

⚠ 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, damage or deformation is observed.

⚠ Use a firm but controlled grip to maintain precision and stability. Avoid excessive force to prevent unnecessary trauma to bone, soft tissues, or adjacent teeth. Ensure proper angulation and controlled pressure to facilitate efficient extraction while minimizing complications.

For Tooth Extraction Forceps:

- Select the appropriate forceps based on the tooth type and location.
- Position the beaks around the tooth structure, ensuring a firm grip before applying controlled pressure.
- Apply slow, steady force with a slight rocking motion to loosen the tooth from the socket before removal.

⚠ In Forceps always check the hinge mechanism for smooth operation before use. Any stiffness or looseness may affect performance and should be addressed before the procedure.

For Dental Tooth Elevators & Root Tip Elevators:

- Choose the correct elevator type for the procedure (luxating, root tip, or periosteal elevation).
- Insert the working tip into the periodontal ligament space and apply controlled apical or rotational force.
- Use gentle but firm pressure to avoid excessive trauma to the surrounding bone and soft tissues.

Periosteal Elevators:

- Select the appropriate periosteal elevator based on the surgical requirements.
- Position the tip at the gingival margin and carefully slide it beneath the periosteum.
- Use controlled lateral movements to separate the soft tissue from the underlying bone.

X-Tool Elevators:

- Insert the sharp, tapered tip into the periodontal ligament space.
- Apply controlled force to loosen the tooth while minimizing damage to adjacent structures.
- Maintain a firm yet comfortable grip to ensure precision during the extraction process.

Adverse Event

- Any serious incident 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:

⚠ Clean the device with care after each application to avoid the drying of contaminants.

Initial Cleaning:

1. Remove any visible debris from the instrument using moisten a cotton swab or cloth with isopropyl or ethyl alcohol and gently wiping the surface of the product.
2. Use a soft brush for cleaning the instrument if required

Manual Cleaning:

3. Prepare a solution of neutral pH enzymatic detergent according to the manufacturer's instructions.
4. Immerse in a pre-soak enzymatic cleaner solution
5. Thoroughly clean all surfaces of the Instrument using a soft brush or cloth. Pay close attention to any crevices or hard-to-reach areas.
6. Rinse thoroughly under lukewarm running tap water for a minimum of 30 seconds to remove all traces of detergent.

Automated Cleaning:

1. Always clean in an appropriate box or cassette 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.

⚠ For forceps, ensure that the hinge mechanism is fully cleaned to prevent residue buildup that could affect movement.

⚠ 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 products 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. Verify no residual moisture remains after sterilization to prevent corrosion and ensure longevity.
4. Ensure that forceps hinges are lubricated with an appropriate medical-grade lubricant after sterilization to maintain smooth operation.
5. Allow the instruments to cool and dry completely before handling. Store in a clean, dry, and controlled environment until ready for use.
6. Follow the pouch/wrap manufacturer instructions for storge conditions and maximum storage time.
7. For forceps, periodically check the hinge movement to ensure continued smooth function.

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 manufacturer 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:

Our Dental Extraction instruments: Tooth Extraction Forceps, Dental Tooth Elevators, Root Tip Elevators, Periosteal Elevators, X-Tool Elevators 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 products 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
NON STERILE	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
	Importer
EC REP	Authorized representative in the European Community