

Direct Luxator Instruments IFU

en

Intended use

Luxator® Periotome are used to luxate the tooth before final extraction. To be used by dentist or dental surgeon. To be processed by dental personnel.

Contraindication

Lack of bone or extremely thin bone.

Features

The handle is ergonomically designed for optimal tactility and control.

Precaution



- Clean and sterilize the instrument according to the processing instruction before first use and between uses.
- Luxator® Periotome should NOT be used as an elevator.
- In case of a serious incident from using the instruments, immediately contact Directa AB and the applicable authority in your country.

Warnings



- The tips of all types of Luxator® Periotomes are extremely thin and sharp and can be damaged if exposed to excessive forces.
- These tips are not designed for strong forces.
- Model L1S and DE3 are extremely sharp and delicate, use with caution!
- The thin and sharp tips are not intended for excessive force and should be used with caution.

How to use

1. Place your index finger along the axis of the blade, marking the depth of required penetration. Thus, the index finger serves as an occlusal stop.
2. Place the tip axially in the periodontal space.
3. Proceed with a slight twisting action to gently drive the tip into the socket. The thin and sharp tip cuts ligaments while compressing the bone and raising the tooth gently from the socket.
4. Continue to two-thirds of the depth of root keeping close to the root wall. Avoid snagging of the root. If root remains firm, repeat on the other side.

Sharpening of instrument

To obtain optimal result, sharpen the instrument on a regular basis using a Luxator sharpening stone. Sharpen the instrument after thorough cleaning, before sterilization. Luxator® TiN do NOT sharpen this instrument as it will damage the titanium coating

Examples of use

L1S Apical and/or Interproximal
L2S, S2S Apical and/or Interproximal
L3C, S3C General use/Starter
L3S, S3S, L5S, S5S Interproximal
L3CA, S3CA Lingual and/or Distal – Molars
L3IC General, Lingual and/or Distal
L5C Large molar roots – general use

Dual Edge Periotome

DE3, DE5 Deep fractured and decayed roots

Disposal

The instruments must be disposed in accordance with national healthcare regulations for safe disposal of sharp and contaminated instruments.

Processing instruction

Warnings	The tip of the instrument is sharp, handle with caution. The working part of the instrument is stainless steel, nevertheless take precautions to avoid corrosion which can be caused by delayed reprocessing.
Limitations on reprocessing	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use. Improper use and care of the instrument will decrease the lifetime significantly. Tested for up to 200 reprocessing cycles

Instructions	
Point of use care:	See Preparation of cleaning.
Cleaning: General	It is essential that the instruments are cleaned before sterilization. <ol style="list-style-type: none"> 1. Preparations of cleaning 2. Cleaning/disinfection 3. Sterilization
Containment and transportation:	The instruments should be stored and transported in dedicated instrument trays to protect the personnel and the edge of the instrument.
Preparations before cleaning	Right after the instrument is used it is essential to remove the bioburden by brushing all the surfaces thoroughly with a soft bristle brush and room-tempered water. This is also recommended if the operation exceeds 60 min.
Cleaning: Manual with Ultrasonic bath	Equipment: Soft bristle brushes of various sizes, Ultrasonic bath. Detergent and Ultrasonic solution: Enzymatic or low alkaline, CE approved and suited for medical devices. Method: <ol style="list-style-type: none"> 1. Rinse in cold tap water for minimum 30 sec. 2. Immerse in cleaning solution as per manufacturer's instructions although maximum 40°C and soak for 5 min. 3. Clean mechanically with a brush, working beneath the liquid level, until visibly clean, minimum 30 sec. 4. Rinse with running tap water for at least 15 sec. 5. Clean the instrument with an ultrasonic bath for minimum of 5 min (take caution of wear and use dedicated instrument trays when cleaning multiple objects). 6. Rinse with running DI or PURW water for at least 15 sec. 7. Inspect cleanliness. If necessary, repeat from step 1 or use automated cleaning.

Cleaning: Automated	<p>Equipment: washer-disinfector, deionized (DI) or purified (PURW) water. Cleaning /detergent agent: Low alkaline, CE approved and suited for medical devices. Rinsing agent: CE approved and suited for medical devices. Follow agent manufacturer's instructions regarding concentration and temperature.</p> <ol style="list-style-type: none"> 1. Secure the instruments in dedicated instrument trays. 2. Load the trays in the washer/disinfector. 3. Run program: <ul style="list-style-type: none"> - Pre-wash in cold water, 5 min. - Main wash 65°C, 10 min. - Rinse in warm water, 3 min. - Rinse in warm water and rinsing agent, 10 min. - Final rinse in DI or PURW water 65°C, 5 min. - Drying 90°C, 15 min. 4. When unloading, control that the instruments are clean. If necessary, repeat from step 1 or use manual cleaning.
Disinfection: Automated	<p><u>Washer-disinfector – EN ISO 15883-1.</u> Equipment: washer-disinfector, deionized (DI) or purified (PURW) water. Cleaning /detergent agent: Low alkaline, CE approved and suited for medical devices. Rinsing agent: CE approved and suited for medical devices. Follow agent manufacturer's instructions regarding concentration and temperature.</p> <ol style="list-style-type: none"> 1. Secure the instruments in dedicated instrument trays. 2. Load the trays in the washer/disinfector. 3. Run program: <ul style="list-style-type: none"> - Pre-wash in cold water, 5 min. - Main wash 65°C, 10 min. - Rinse in warm water and rinsing agent, 10 min. - Final rinse in DI or PURW 93°C, 5min. - Drying 90°C, 15 min . 4. When unloading, control that the instruments are clean. If necessary, repeat the cycle or use manual cleaning.
Drying:	When drying is achieved as part of washer disinfector cycle do not exceed 100 °C or 20 minutes.
Maintenance, inspection and function Testing:	Protect the edge, discard damaged instruments. Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge.
Packaging:	Instruments should be loaded into dedicated instrument trays. Ensure that cutting edges are protected. A standard packaging material may be used. Ensure that the pack is large enough to contain the trays without stressing the seals.
Sterilization:	<p><u>Autoclave EN 13060, EN 285, EN ISO 17665-1</u> Equipment: Class-B Autoclave, standard packaging pouch.</p> <p><u>B-process, EN 13060</u> Minimum 134°C. 4 min. Minimum vacuum drying. 3 min</p>
Storage:	The instrument should be stored in a packed tray, free from dust and moisture.
Additional information:	When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded.