LEONE s.p.a.

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General Indications

Purposes and Direction for use. All Leone devices, as orthodontic and dental medical devices, instruments, and accessories are intended exclusively for orthodontic and dental use and must be used by specialized and legally qualified personnel, such as laboratory technicians and dentists. For their proper functioning, it is recommended the usage in conjunction with other Leone original products, accessories, and instruments.
Except the instruments, all Leone products are designed and manufactured for single use. Leone assumes no responsibility for possible damage, injury or otherwise caused by reuse of products claimed to be for single use. Decontaminate and sterilize before use reusable products that have come in contact with a different patient.
The above-mentioned professional users should use the products according to the intended use as defined by the manufacturer (according to EU directive 93/42CEE, art.1 g. *'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;* according to the new EU Regulation 2017/745 art.2, 12 *'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation*). If the product is used differently than the intended use as defined by the manufacturer, it is qualified as illegitimate: any liability for damages resulting from such use cannot be attributed, in part or in whole, to the manufacturer but to the end user and even to the distributor for neglecting, modifying, or omitting the manufacturer's warnings or instructions while marketing the product.
Each Leone product comes with all the necessary information for a safe usage. This information is specified on the label, sometimes through symbols according to International Standards. Moreover, in order to ensure a safe usage of the products, in addition to the information described in the label, some products are provided with instructions for use included in the packaging.
It should be noted that the instructions for use are not intended to replace the knowledge of the legally licensed professional, who will remain the sole responsible for the construction of the custom-made device, whether of individual manufacture or in combination with other products, and for the use of the instruments and accessory devices.
Considering the use and the intended use of the product, not all Leone products are supplied with additional instructions for use in the packaging as allowed by the provisions of law (in Europe, according to EU Directive 93/42 CEE, Annex I, 13.1, *Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions*; according to EU Regulation 2017/745, Annex I 23.1.d, *Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section*).
Contraindications. Where not specifically stated in the instructions for use included in the package, for the above-mentioned devices, Leone S.p.a. reminds that all pathological conditions, both local and systemic, that contraindicate orthodontic and dental appliances should be considered valid contraindications for the application of the above products. In the clinical evaluation of the patient and in the usage of the product, dentists should contemplate the contraindications, side effects, complications, and interactions that may be generally applicable with orthodontic or dental treatment and should inform patients about the benefits and any side effects or complications.
The effects of orthodontic and dental metal devices should be carefully monitored during the MRI (Magnetic Resonance Imaging) examination. It is recommended to instruct the patient to report in advance to the radiologist in charge of the MRI examination, the presence of any type of device and dental material in the mouth. Ceramic and polymeric products (with the exception of certain items containing medical barium) are

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not radiopaque. For more information see the Reference Documentation: Interactions between Leone orthodontic and implantology devices and medical imaging techniques.

Storage. No special storage conditions are generally indicated. Special storage conditions apply to some devices; these conditions are indicated on the label. For more details, see section 7 of the applicable MSDS on the website: https://www.leone.it/english/services/quality/safety-data-sheet.php. Some devices are subject to expiration; the expiration date is indicated on the label.

Disposal. Depending on the material composition of Leone orthodontic and dental products, the wastes, whether generated after or before end use, require simple or special management to minimize their effect on the environment. Below some usual ways of disposal for orthodontic and dental devices:

- Normal commercial waste, usually landfilled or, where possible, recyclable, or composted, such as plastic, paper, and glass packaging waste, and plastic or metal waste from laboratory products
- Controlled waste, usually disposed of in landfills or, where possible, that can be recycled or composted, at the end of therapy after a decontamination procedure, such as disposable devices or worn reusable devices
- special wastes, usually incinerated through specialized waste management or disposed of in a hazardous waste landfill after specialized, pretreated management, or partially disposed of in a landfill after a specialized recycling procedure, such as devices with integrated human biological residues or infected clinical waste, or expired hazardous devices that must be discharged according to the relevant Material Safety Data Sheet.

For more information on hazard identification, ecological information, accidental release measures and disposal considerations, see the material safety data sheets on the website
https://www.leone.it/english/services/quality/safety-data-sheet.php

The end user is responsible for verifying the application and completeness of the information herein in relation to the specific use and the reliability of applicable local regulations and provisions.

User and/or patient warning: in the event of a serious accident occurring in connection with the device, immediately inform the manufacturer and the competent authority in your state.
Leone S.p.a. point of contact: help.products@leone.it
Contact points of European Competent Authorities: https://ec.europa.eu/health/md_sector/contact_en

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