LiteSet™ Trays

Important – Disclaimer of Liability

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Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description

LiteSet™ Trays

LiteSet™ Trays are reusable trays to be used in combination with Nobel Biocare surgical/prosthetic instruments and components. The LiteSet™ Trays are used to organize, store, and sterilize instrumentation or components used for dental implant surgical and prosthetic procedures.

The LiteSet™ Tray consists of three parts

1) a base, 2) a removable LiteSet™ Plate to indicate the surgical workflow (in case of the surgical tray) and the position of the instruments and components within the tray, and 3) a lid to securely contain the instruments during reprocessing.

There are different versions of the LiteSet™ Tray available for the different Nobel Biocare surgical and prosthetic procedures. The instruments and components which are compatible with the various trays are specified in the respective wall charts.

Please contact the local Nobel Biocare sales office for information regarding the wall charts.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Intended Use/Intended Purpose

LiteSet™ Trays

Intended for use to organize, store, and sterilize instrumentation or components used for dental implant surgical and prosthetic procedures.

Indications

LiteSet™ Trays

Intended for use to organize, store, and sterilize instrumentation or components used for dental implant surgical and prosthetic procedures.

Contraindications

None identified.

Materials

LiteSet™ Trays

- LiteSet™ Base: PPSU (Polyphenylsulfone)
- LiteSet™ Plate: PPSU (Polyphenylsulfone)
- LiteSet™ Lid: PPSU (Polyphenylsulfone)
- LiteSet™ Holders: Silicone SE-PX
- None removable grommets: Silicone (acc. USP Class VI and ISO 10993 (6-10-11))

Cautions

General

Nobel Biocare LiteSet™ Trays must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Nobel Biocare LiteSet™ Trays can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery

All components, instruments and tooling used during the clinical and/or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Do not to apply force, twist or move around the drill and take necessary care while using the drill gauge while evaluating the length of the depth marking, to avoid scratching the base.

Intended Users and Patient Groups

LiteSet™ Trays are to be used by dental health care professionals such as dental nurses, general dentists, oral surgeons, periodontists, prosthodontist, endodontists, lab technicians who either prepare the sterile field and the devices used to perform surgical procedures or used the tray during the surgical procedure.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

LiteSet™ Trays are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with LiteSet™ Trays

None known.

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Sterility and Reusability Information

LiteSet™ Trays are delivered non-sterile and are intended for reuse. Prior to first use and reuse clean and sterilize the products following the manual or automated procedure in the Cleaning and Sterilization Instructions.

Warning Use of non-sterile devices may lead to infection of tissues or infectious diseases.

LiteSet™ Trays and any reusable surgical/prosthetic instruments shall be inspected prior to each use to ensure the integrity of the device is maintained. Any device with signs of corrosion and/or damage must be discarded and replaced.

The LiteSet™ Tray should be replaced if the tray is discolored or if the legibility of the pictograms or the text is compromised.

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with the devices, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

Manufacturer 	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
UK Responsible Person 	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
CE Mark for Class I Devices	CE

Note Refer to the product label to determine the applicable conformity marking for each device.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
LiteSet™ Trays	733274700000022472

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.