SURGICAL INSTRUMENTS
Safe Drill Unitite Kit

Image 1 – Safe Drill Unitite Kit

LSDD 2005	STOPPER SAFEDRILL Ø2,00/Ø2,70X5,0MM
LSDD 2006	STOPPER SAFEDRILL Ø2,00/Ø2,70X6,0MM
LSDD 2007	STOPPER SAFEDRILL Ø2,00/Ø2,70X7,0MM
LSDD 2085	STOPPER SAFEDRILL Ø2,00/Ø2,70X10,0MM
LSDD 2010	STOPPER SAFEDRILL Ø2,00/Ø2,70X11,5MM
LSDD 2011	STOPPER SAFEDRILL Ø2,00/Ø2,70X13,0MM
LSDD 2013	STOPPER SAFEDRILL Ø2,00/Ø2,70X15,0MM
LSDD 2015	STOPPER SAFEDRILL Ø2,00/Ø2,70X8,5MM
LSDD 3005	STOPPER SAFEDRILL Ø2,00/Ø2,70X8,5MM
LSDD 3006	STOPPER SAFEDRILL Ø3,00/Ø3,30X6,0MM
LSDD 3007	STOPPER SAFEDRILL Ø3,00/Ø3,30X7MM
LSDD 3085	STOPPER SAFEDRILL Ø3,00/Ø3,30X10MM
LSDD 3010	STOP. SAFEDRILLØ3,00/Ø3,30X11,5MM
LSDD 3011	STOPPER SAFEDRILL Ø3,00/Ø3,30X13MM
LSDD 3013	STOPPER SAFEDRILL Ø3,00/Ø3,30X15MM
LSDD 3015	STOPPER SAFEDRILL Ø3,00/Ø3,30X8,5MM
LSDD 3805C	STOPPER SAFEDRILL Ø3,80/Ø4,25X5MM
LSDD 3806C	STOPPER SAFEDRILL Ø3,80/Ø4,25X6MM
LSDD 3807C	STOPPER SAFEDRILL Ø3,80/Ø4,25X7MM
LSDD 3885	STOPPER SAFEDRILL Ø3,80/Ø4,25X7MM
LSDD 3810	STOPPER SAFEDRILL Ø3,80/Ø4,25X10MM
LSDD 3811	STOP. SAFEDRILL Ø3,80/Ø4,25X11,5MM
LSDD 3813	STOPPER SAFEDRILL Ø3,80/Ø4,25X13MM
LSDD 3815	STOPPER SAFEDRILL Ø3,80/Ø4,25X15MM
LSDD 4505C	STOP. SAFEDRILL Ø3,80/Ø4,25X8,5MM
LSDD 4506C	STOPPER SAFEDRILL Ø4,50/Ø5,80X5MM
LSDD 4507C	STOPPER SAFEDRILL Ø4,50/Ø5,80X6MM
LSDD 4585	STOPPER SAFEDRILL Ø4,50/Ø5,80X7MM
LSDD 4510	STOPPER SAFEDRILL Ø4,50/Ø5,80X10MM
LSDD 4511	STOPPER SAFEDRILL Ø4,50/Ø5,80X11,5MM
LSDD 4513	STOPPER SAFEDRILL Ø4,50/Ø5,80X13MM
LSDD 4515	STOPPER SAFEDRILL Ø4,50/Ø5,80X15MM

Image 2 – Safe Drill Unitite Kit with items position

1. DESCRIPTION

Safe Drill Unitite Kit are reusable rigid containers, comprising a case bottom (or base), a removable inner tray base (tray), and tray lid (lid). The Safe Drill Unitite Kit are to be used to organize and protect instruments and accessories that are to be sterilized by the healthcare provider. The lids are manufactured from injection molded Udel® P-1700 polysulfone, the tray base and case bottoms are manufactured from injection-molded polysulfone, and holders of various geometries to position items in the trays are manufactured from molded silicone. The Safe Drill Unitite Kit are provided nonsterile to the end-user.

2. INDICATIONS FOR USE STATEMENT

S.I.N. Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. S.I.N. Instrument Kits are intended to allow sterilization of the enclosed medical devices. S.I.N. Instrument Kits require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle:
Gravity displacement – Exposure at 121 °C for 30 minutes and 30 minutes dry time.
S.I.N. Instrument Kits are intended for sterilization of non-porous loads.
S.I.N. Instrument Kits are recommended not to be stacked during sterilization.
The combined weight of the Safe Drill Unitite Kit and the associated instruments is 304 grams.
The weight of the empty Safe Drill Unitite Kit is 150 grams.

3. APPLICATIONS

The Safe Drill Unitite Kit is exclusively indicated to assist in the installation of S.I.N implants and is not compatible with other lines and systems of other manufacturers.

4. CONTRAINDICATIONS

The Safe Drill Unitite Kit does not present contraindications since its recommendations are followed correctly, as directed in this Instructions for Use and used by a specialized professional, who will be responsible for the adequate planning of the surgical procedure in which the Kit will be used.

5. HANDLING

Once sterilized, instruments should be handled only in a sterile environment by properly trained professionals and wearing appropriate gowning at the time of surgery to install dental implants. Scratches, creases or notches from surgical instruments should be avoided as these factors may increase the possibility of corrosion of the products.

6. KIT ASSEMBLY

To set up this Kit, each reserved space is related to a number from the instrument table; see the image on page 2.
The maximum load configuration is shown in Image 2. The maximum load (weight) configuration is 154 grams, based on the maximum load configuration shown in Table 1. The weight of the empty Kit is 150 grams.

7. SANITATION

Clean the Kit and all instruments right after of each use.
Use the following manual cleaning process only. Automated cleaning has not been validated. Do not use automated cleaning

7.1 Cleaning the Kit

1. Remove manually all surgical instruments from the kit. Remove the kit box parts (lid, tray and bottom).
2. Prepare Prolystica® (STERIS Healthcare) according to the manufacturer's recommendation.
3. Immerse the trays into the prepared detergent solution and keep in contact for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove trays from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
5. Visual inspection of each part for cleaning process residue or organic waste from product use.
6. If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
7. Dry with a soft, clean, dry cloth or disposable paper.

7.2 Cleaning the surgical instruments

1. Disassemble the product, if applicable.
2. Prepare Prolystica® (STERIS Healthcare) according to the manufacturer's recommendation.
3. Immerse all parts of the product into the prepared detergent solution and keep in contact for at least 5 minutes, then using soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove parts from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
5. Visual inspection of each part for cleaning process residue or organic waste from product use.
6. If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
7. Dry with a soft, clean, dry cloth or disposable paper.

7.3 Placing the instruments into the Kit

Place cleaned instruments into the Kit, according to the tray layout illustration and instruments table. Proceed to sterilization instructions (Section 8).

8. STERILIZATION

The Kit is to be enclosed in a sterilizable wrap that is FDA cleared for the indicated cycles.

Please use for sterilization only the steam sterilization according to the following parameters:

	Cycle (gravity)
Sterilization Time	30 minutes
Sterilization Temperature	121°C
Drying Time	30 minutes

1. Please store the Kit after sterilization in the sterilization packaging at a dry and dust-free place.
2. The flash/ immediate use sterilization procedure must not be used.
3. Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

9. PRECAUTIONS

The Safe Drill Unitite Kit requires specialized surgical procedures, only to be used by qualified dental surgeons, including: diagnosis, preoperative planning and surgical protocol. The use of the product without knowledge of the proper techniques and/ or inadequate procedures and conditions may harm the patient leading to unsatisfactory results.

For drills cutters, it is recommended to use up to 20 to 30 perforations, which are:

- 20 high-density bone perforations;
- 30 perforations in low-density bones.

Do not stick labels, tapes, as well as write, or mark the surface of the product.

It is recommended to immediately wash and sterilize the kit and its components after use.

10. ADVERSE EFFECTS

The Safe Drill Unitite Kit is used to aid in the installation of dental implants, so adverse effects will occur only if the choice of instruments is inadequate.

11. STORAGE CONDITIONS

This product should be stored, in its original packaging, in a clean and dry location, in a maximum temperature of 35°C and protected from direct sunlight.

12. LIFE CYCLE

This product is recommended for up to 250 uses, provided that the recommended conditions of use are followed.

Regardless of the number of times the instrument has been used, the professional must always evaluate its condition after each use. Visually inspect the lid, tray, and case bottom to ensure there is no cracking, deformation, or other damage.

Visually inspect that all labeling printed on the lid and tray is clear and legible.

Verify that the lid, tray, and case bottom can be assembled and that the Lid latches securely to the case bottom.

Do not use the Kit if any of the above or any other damage is observed, regardless of the number of cycles of use.

Symbols Glossary

ANSI/AAMI/ ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Title of Symbol (Reference Number)	Meaning of Symbol
	Caution (5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Keep away from sunlight (5.3.2)	Indicates a medical device that needs protection from light sources.
	Upper limit of temperature (5.3.6)	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	Keep dry (5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Do not use if package damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Date of manufacture (5.1.3)	Indicates the date when the medical device was manufactured
	Manufacturer (5.1.1)	Indicates the medical device manufacturer.
	Non-sterile (5.2.7)	Indicates a medical device that has not been subjected to a sterilization process.
	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed dentist or physician.vc

DEVELOPED AND MANUFACTURED BY:

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