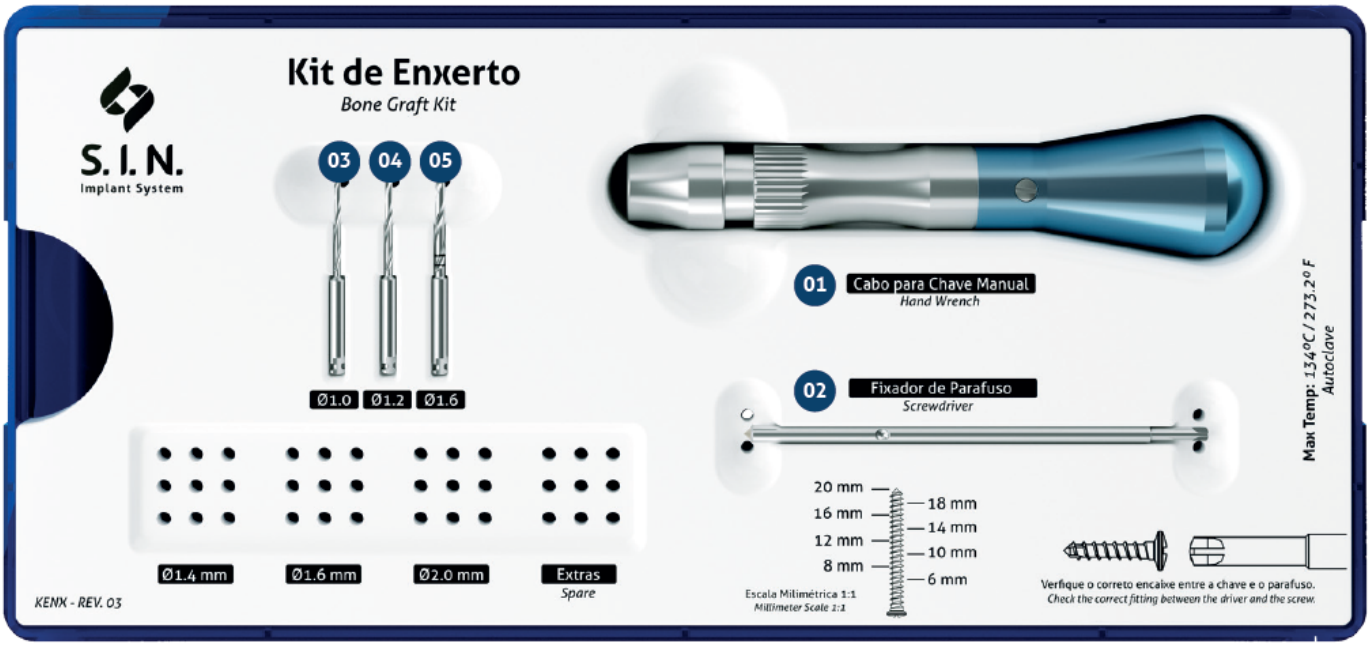
IMAGE 1 – BONE GRAFT KIT

CDM 02	DRIVE HANDPIECE ORTHODONTIC
CPEX	BONE GRAFT SCREW FIXER
FH 1015	DRILL HELICAL Ø1.0X15
FH 1215	DRILL HELICAL Ø1.2X15
FH 1615	DRILL HELICAL Ø1.6X15

CAIXA ORGANIZADORA KIT ENXERTO ÓSSEO
ORGANIZING BOX BONE GRAFT KIT



Caixa organizadora (COENX)
Organizing Box (COENX)

01 **Cabo para Chave Manual (CDM 02)**
HAND WRENCH

02 **Fixador de Parafuso (CPEX)**
SCREWDRIVER

03 **Fresa Helicoidal Ø 1.0 X 15 (FH 1015)**
CILINDRIC DRILL

04 **Fresa Helicoidal Ø 1.2 X 15 (FH 1215)**
CILINDRIC DRILL

05 **Fresa Helicoidal Ø 1.6 X 15 (FH 1615)**
CILINDRIC DRILL

1. DESCRIPTION

Bone Graft Kit are reusable rigid containers, comprising a case bottom (or base), a removable inner tray base (tray), and tray lid (lid). The Bone Graft Kit s 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 Bone Graft Kit s 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 Bone Graft Kit and the associated instruments is 430 grams.
The weight of the empty Bone Graft Kit is 310 grams.

3. APPLICATIONS

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

4. CONTRAINDICATIONS

The Bone Graft 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 CASE 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 430 grams, based on the maximum load configuration shown in Table 1. The weight of the empty Kit Case is 310 grams.

7. SANITATION

Clean the Kit Case 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 Point-of-Use Processing

1. Thoroughly clean instruments as soon as possible after use. Remove all visual soil with a disposable wipe.
2. If the complete cleaning process (Steps 7.2-7.3) must be delayed, immerse instruments in a compatible detergent solution or water to prevent drying of soil and contaminants in and on the Kit Case and instruments. See Section 7.2.4 for the recommended detergent.
3. The Kit Case and instruments should be thoroughly cleaned after the point-of-use processing by following Steps 7.2 – 7.5 as soon as possible.

7.2 Cleaning the Kit Case

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. Thoroughly clean the Kit Case.
5. Remove trays from detergent solution and rinse with critical water (per AAMI TIR34) for 1 minute, repeat the rinse with critical water (per AAMI TIR34) for two more times, a total of three rinses of 1 minute each.
6. Visually inspect of each part of the Kit Case for cleaning process residue or organic waste from product use.
7. If residue is detected in the product, repeat the cleaning process until the residue is completely removed and no visible residue remains.
8. Dry with a soft, clean, dry cloth or disposable paper.

7.3 Cleaning the surgical instruments

1. Prepare Prolystica® (STERIS Healthcare) according to the manufacturer's recommendation.
2. 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.
3. Thoroughly clean all parts of each instrument.
4. Remove the instruments from detergent solution and rinse with critical water (per AAMI TIR34) for 1 minute, repeat the rinse with critical water (per AAMI TIR34) for two more times, a total of three rinses of 1 minute each.
5. Visually inspect each instrument 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 and no visible residue remains.
7. Dry with a soft, clean, dry cloth or disposable paper.

7.4 Placing the instruments into the Kit Case

Place cleaned instruments into the Kit Case, 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 ºC 1 ATM
Drying Time	30 minutes

1. Please store the Kit Case 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

Bone Graft 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

Bone Graft 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 Case 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.
REF	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
Rx Only	Prescription only (21 CFR 801.109(b)(1)	Requires prescription in the United States

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

DEVELOPED AND MANUFACTURED BY:

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