SURGICAL INSTRUMENTS
Epikut Surgical Guided Kit

Image 1 – Epikut Surgical Guided Kit

EM 35E	EXTRACTING DRILL Ø3,5 MM EPIKUT
EM 45	EXTRACTING DRILL Ø4,5 MM
FPG 35E	DRILL PILOT Ø3,5 MM GUIDED EPIKUT
FPG 45E	DRILL PILOT Ø4,5 MM GUIDED EPIKUT
FHG 20	DRILL HELICAL GUIDED Ø2,0 MM
FHG 20C	DRILL HELICAL GUIDED Ø2,0 MM SHORT
FHIG 27	DRILL GUIDED Ø2,7 MM
FHIG 27C	SHORT DRILL Ø2,7 MM GUIDED
FHIG 30	DRILL Ø3,0 MM GUIDED
FHIG 30C	SHORT DRILL Ø3,0 MM GUIDED
FHIG 33	DRILL Ø3,3MM GUIDED
FHIG 33C	SHORT DRILL Ø3,3MM GUIDED
FHIG 36	DRILL Ø3,6MM GUIDED
FHIG 36C	SHORT DRILL Ø3,6MM GUIDED
FHIG 40	DRILL Ø4,0MM GUIDED
FHIG 40C	SHORT DRILL Ø4,0MM GUIDED
FHIG 43	DRILL Ø4,3MM GUIDED
FHIG 43C	SHORT DRILL Ø4,3MM GUIDED
FGC 14	FIXER SURGICAL GUIDE Ø1,4X20MM
FHDG 13	TWIST DRILL Ø1.3MM
CTWCM 50	MORSE HANDPIECE H5,0
CTWCM 65	MORSE HANDPIECE H6,5
CTWCM 504E	MORSE HANDPIECE H5,0 XØ 4,0MM NARROW
CTWCM 654E	MORSE HANDPIECE H6,5 X Ø4,0MM NARROW
CTWHE 50	DRIVE HANDPIECE H6,5
CTWHE 65	DRIVE HANDPIECE H6,5
CTWHE 504E	DRIVE HANDPIECE H5,0 X Ø4,0MM NARROW
CTWHE 654E	DRIVE HANDPIECE H6,5 X Ø4,0MM NARROW
CAT	KEY CONNECTOR
CATL	CONNECTOR FOR LONG KEY
CAT E	NARROW CONNECTOR FOR KEY

CATL E	NARROW CONNECTOR FOR LONG KEY
CDH 1224	DRIVER HAND HEX 1.2X24
GFE 2027	GUIDE DRILL Ø2,00 / Ø2,70MM
GFE 2027E	GUIDE DRILL Ø2,00 / Ø2,70MM NARROW
GFE 3033	GUIDE DRILL Ø3,00 / Ø3,30MM
GFE 3033E	GUIDE DRILL Ø3,00 / Ø3,30MM NARROW
GFE 3640	GUIDE DRILL Ø3,60 / Ø4,00MM
GFE 4345	GUIDE DRILL Ø4,30 / Ø4,50MM
SPG 01	GUIDED DEPTH PROBE
TMECC 02	SURGICAL TORQUE RATCHET
LSDGD 2005	LIMIT SAFE DRILL GUIDE Ø2,0/Ø2,7x5,0MM
LSDGD 2006	LIMIT SAFE DRILL GUIDE Ø2,0/Ø2,7x6MM
LSDGD 2007	LIMIT SAFE DRILL GUIDE Ø2,0/Ø2,7x7MM
LSDGD 2085	LIMIT SAFE DRILL GUIDE Ø2,0/Ø2,7x8,5MM
LSDGD 2010	LIMIT SAFE DRILL GUIDE Ø2,0/Ø2,7x10MM
LSDGD 2011	LIMIT SAFE DRILL GUIDE Ø2,0/Ø2,7x11,5MM
LSDGD 2013	LIMIT SAFE DRILL GUIDE Ø2,0/Ø2,7x13MM
LSDGD 3005	LIMIT SAFE DRILL GUIDE Ø3,0/Ø3,3x5MM
LSDGD 3006	LIMIT SAFE DRILL GUIDE Ø3,0/Ø3,3x6MM
LSDGD 3007	LIMIT SAFE DRILL GUIDE Ø3,0/Ø3,3x7MM
LSDGD 3085	LIMIT SAFE DRILL GUIDE Ø3,0/Ø3,3x8,5MM
LSDGD 3010	LIMIT SAFE DRILL GUIDE Ø3,0/Ø3,3x10MM
LSDGD 3011	LIMIT SAFE DRILL GUIDE Ø3,0/Ø3,3x11,5MM
LSDGD 3013	LIMIT SAFE DRILL GUIDE Ø3,0/Ø3,3x13MM
LSDGD 3805	LIMIT SAFE DRILL GUIDE Ø3,8/Ø4,25x5,0MM
LSDGD 3806	LIMIT SAFE DRILL GUIDE Ø3,8/Ø4,25x6,0MM
LSDGD 3807	LIMIT SAFE DRILL GUIDE Ø3,8/Ø4,25x7,0MM
LSDGD 3885	LIMIT SAFE DRILL GUIDE Ø3,8/Ø4,25x8,5MM
LSDGD 3810	LIMIT SAFE DRILL GUIDE Ø3,8/Ø4,25x10,0MM
LSDGD 3811	LIMIT SAFE DRILL GUIDE Ø3,8/Ø4,25x11,5MM
LSDGD 3813	LIMIT SAFE DRILL GUIDE Ø3,8/Ø4,25x13,0MM

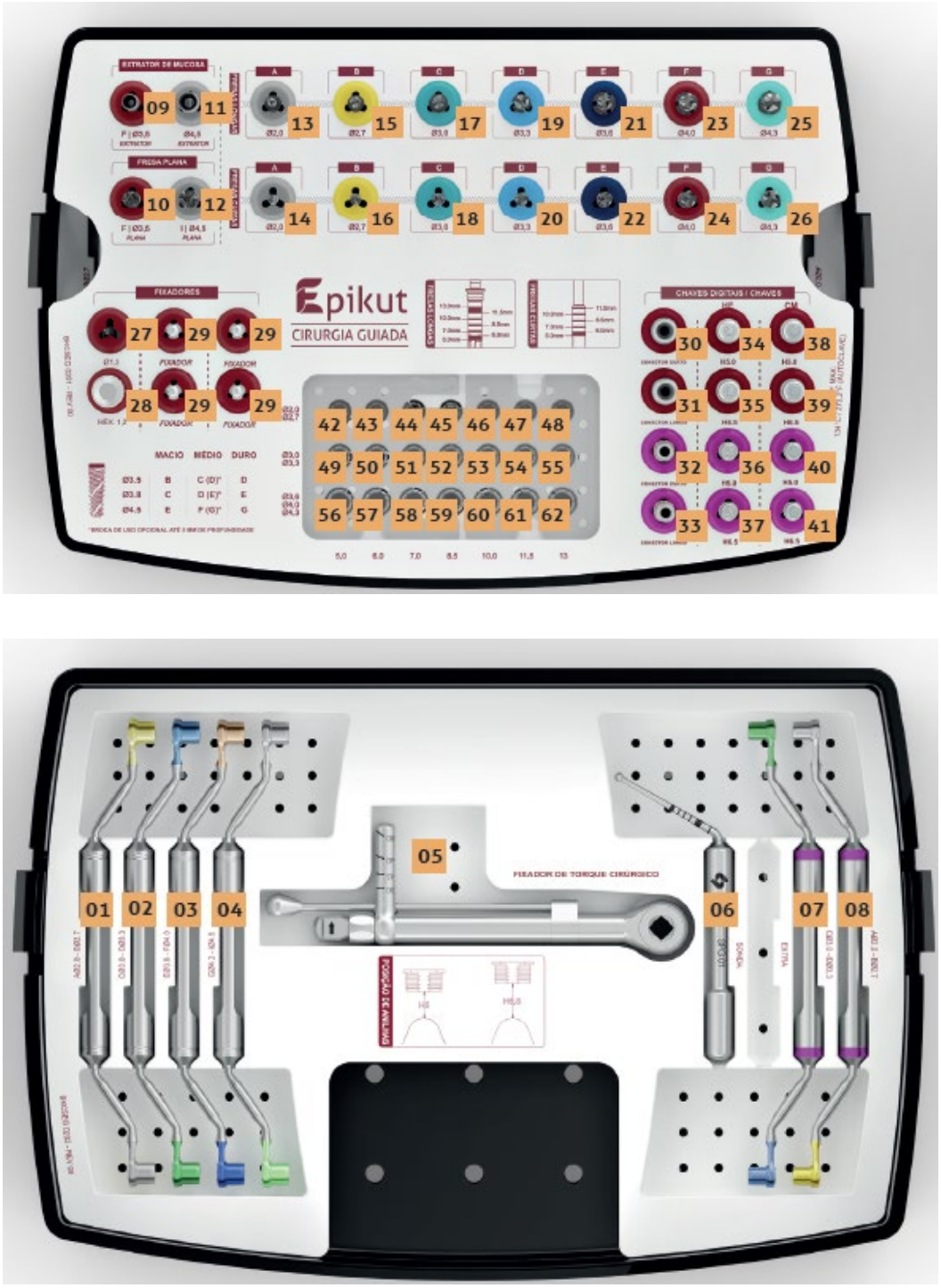

Image 2 – Epikut Surgical Guided Kit with items position

1. DESCRIPTION

Epikut Surgical Guided Kits are reusable rigid containers, comprising a case bottom (or base), a removable inner tray base (tray), and tray lid (lid). The Epikut Surgical Guided Kits 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 Epikut Surgical Guided Kits 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 Epikut Surgical Guided Kit and the associated instruments is 808 grams.
The weight of the empty Epikut Surgical Guided Kit is 650 grams.

3. APPLICATIONS

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

4. CONTRAINDICATIONS

The Epikut Surgical Guided 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 808 grams, based on the maximum load configuration shown in Table 1. The weight of the empty Kit Case is 752 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 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. 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 Dismantling the Torque Wrench

1. Pull the drive rod backward direction.
2. Remove the ratchet fitting head.
3. Rotate the torque wrench drum counterclockwise until it is fully loosened.
4. Remove the central axis of the torque wrench.
5. Remove the stem with torque.
6. Start the following washing procedure.

7.3 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.
8. Follow to sterilization process.

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

The Epikut Surgical Guided 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 Epikut Surgical Guided 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.

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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