

SURGICAL INSTRUMENTS

Zygomatic Surgical Kit – KZ 01



Image 1 – Zygomatic Surgical Kit

FHZ 2030	HELICAL DRILL Ø2.0XØ2.6XØ3.0XØ4.0MM
FHZ 2932	HELICAL DRILL Ø2.9XØ3.2XØ4.0MM
FHZ 3234	HELICAL DRILL Ø3.2XØ3.45Ø4.0MM
FRLZ 27	ZIGO LANCE DRILL Ø2.7MM
FL 20M	MEDIUM LANCE DRILL Ø2.0MM
SOPZ	ZIGO DEPTH PROBE
FBD 40E	SPHERICAL DIAMOND DRILL Ø4.0MM
FBD 40	DIAMOND DRILL Ø4.0X30MM
CCM 01L	LONG CM RATCHET WRENCH
CCM 01M	MEDIUM CM RATCHET WRENCH
CDH 1224	DRIVER HAND HEX 1.2X24
CTHA 1224	ACCESS IMPL FIXER TOR HEX MINI ABUT ANG
CQCA 27	DRIVE HANDPIECE
CMZ	DRIVER HANDS IMPLANT ZYGOMATIC

1. DESCRIPTION

Zygomatic Surgical Kit are reusable rigid containers, comprising a case bottom (or base), a removable inner tray base (tray), and tray lid (lid). The Zygomatic Surgical 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 Zygomatic Surgical Surgical 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 Zygomatic Surgical Kit and the associated instruments is 686 grams.

The weight of the empty Zygomatic Surgical Kit is 464 grams.

3. APPLICATIONS

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

4. CONTRAINDICATIONS

The Zygomatic Surgical 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 686 grams, based on the maximum load configuration shown in Table 1. The weight of the empty Kit is 464 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 any excess soil with a disposable wipe.
2. If the complete cleaning process (Steps 7.2-7.5) 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 Disassemble the Torque Wrench

Note: no other instrument requires disassembly.

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.

7.4 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.

7.5 Reassemble the Torque Wrench

1. Replace the stem and apply torque to tighten.
2. Replace the central axis of the torque wrench.
3. Rotate the torque wrench drum clockwise until it is fully tightened.
4. Replace the ratchet fitting head.
5. Push the drive rod in a forward direction.

7.6 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°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 Zygomatic Surgical 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 Zygomatic Surgical 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.
	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:

S.I.N. Sistema de Implante Nacional S/A

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
 Rua Soldado Ocimar Guimarães da Silva, 421 –
 Vila Rio Branco CEP: 03348-060 - São Paulo - SP - Brazil
 Phone/Fax: +55 (11) 2169-3000

SERVICE TO PROFESSIONALS

0800 770 8290 +55 (11) 2169-3000
www.sinimplante.com.br
 e-mail: sin@sinimplante.com.br