Epikut

The line of Epikut implants reaches the market in order to optimize the clinical routine, bringing a more cutting macro geometry, making bone installation easier and with a high primary stability.

Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

PRODUCT DESCRIPTION

Epikut implants are manufactured from unalloyed titanium conforming to ASTM F67, Grade 4, and provided with a double acid etched surface treatment.
The macro geometry of the implant is hybrid, with cervical micro threads and prosthetic connection of external hexagon (EH) and morse taper (MT), platform diameter from 3.5 to 5.0mm and length from 7.0 to 24.0mm. Implants with a length of 18.0 to 24.0mm are called long implants.
Provided STERILE. Sterilized by irradiation.

Implant Diameters (mm)	Length (mm)
3.5, 3.8, 4.5, 5.0	7, 8.5, 10, 11.5, 13, 15.

Implant Diameters (mm)	Long Lengths (mm)
3.8, 4.0, 4.5	18, 20, 22, 24.

INDICATIONS OF USE

S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
S.I.N. Dental Implant System implants with lengths of 18, 20, 22, or 24 mm may be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

CONTRAINDICATIONS

S.I.N. Dental Implant System is contraindicated in the following conditions:

- the mandibular or maxillary bone quantity and quality is insufficient to provide initial stability to the implant
- when the site or systemic conditions show inadequate or poor oral hygiene
- acute or chronic periodontal infection
- chemical dependence
- occlusal parafunction
- radiation history to the implant site
- inappropriate patient for prolonged or complicated oral surgery
- inability to build a functional prosthesis
- rehabilitation with dental implants is also contraindicated for children, pregnant women and during breastfeeding.

WARNING

The surgical technique of dental implant installation is highly specialized and the surgical procedure complex, it is recommended that the professionals be technically qualified so that the application of the S.I.N. implants is safe and efficient.

Epikut HE implants are not for use with angled abutments.
Epikut MT Ø 3.5mm implants with angled abutments are recommended for incisors region only. Small diameter implants and angled abutments are not recommended for the posterior region.

Product is for professional use only.

Product is sterilized by gamma radiation. Sterility is ensured except in cases where the package has been violated or damaged. Do not use if the package is damaged or after the expiration date.

Single use only. Do not resterilize.

The reuse or re-sterilization of this product can cause damage to health.

MRI Safety Information

Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. Dental Implant System devices are MR Conditional.
A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	S.I.N. Dental Implant System
Static Magnetic Field Strength (B_0)	≤ 3.0 T
Maximum Spatial Field Gradient	50 T/m (5,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head coil and body coil permitted. Extremity T/R coils permitted.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2.4 W/kg (15 minutes of scanning, Normal Operating Mode)
Maximum Head SAR	2.0 W/kg (15 minutes of scanning, Normal Operating Mode)
Scan Duration	15 minutes
Temperature Rise	Maximum temperature rise of 0.45 °C/(W/kg), after 15 minutes of continuous scanning in a static magnetic field of 3 T with either head type or body type coils
Artifact	when imaged using a gradient-echo sequence and a 3 T MR system, image artifact can extend up to approximately 12 mm with a body coil type, and up to approximately 32 mm with a head coil type

SHIPMENT AND HANDLING

The S.I.N. implants are sent to professionals duly packaged, sealed and sterilized. Therefore, the package must be opened using sterile technique, and must be handled only with sterilized titanium instruments.

ATTENTION

In order to obtain technical support or additional information material about the product, contact: SIN - Sistema de Implante Nacional S.A. Contact details are provided at the end of these instructions.

PRECAUTIONS

Before implant installation, to obtain a predictable long-term outcome, the professional must submit the patient to a detailed and careful medical history, examination, radiographs, laboratory tests, and study models for appropriate planning.

ADVERSE EFFECTS

Loss of the implant and prosthesis is possible due to a number of reasons, including implant contamination, inappropriate surgical technique, poor bone quality, inappropriate oral hygiene, and parafunctional habits (tooth-grinding).

INSTRUCTIONS FOR USE

Epikut Implants HE and MT Lengths 7, 8.5, 10, 11.5, 13, 15 (mm) .

Note: During all drilling to shape the implant site, avoid deflecting the drill sideways, and use continuous, copious irrigation.

Transfer of the implant from the package to insertion in the surgical site shall be carried out using the drivers with counter-angle fitting morse connection (CTUM 20 or CTUM 24) and (CTWD 20 or CTWD 24) for HE connection. Drivers with a fitting for torque wrench for morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE, they do not perform implant capture, and shall only be used for final insertion torque Epikut and

Epikut Plus implants were designed for a maximum torque of 80 Ncm.

Higher torques may cause irreversible damage to the implants as well as surgical complications.

The torque for intermediary fixation (cemented abutment, conic abutment or mini-abutment) on the implant is 20 Ncm.

The torque for component fixation on the intermediaries is 10 Ncm.

Do not install the protection screw (cover screw) with the ratchet wrench or torque meter since this may damage the implant; tighten it manually with a digital driver.

For all Epikut MT implants (Morse taper) it is recommended to place the implant 1.5 mm intra-bony (sub-crestal), and for HE (external hexagon) it is recommended to place the implant at bone level.

All Epikut dental implants (MT and HE) are intended for placement in all bone types (I, II, III, and IV; Lekholm and Zarb classification).

Epikut Implants (HE and MT) – Body Ø 3.5 mm

For Type IV bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM). Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).

For Type II and Type III bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM).

Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).

Follow for the helical drill Ø 3.0 mm (FHI 30) and optionally the countersink drill Ø 3.3 mm (FHI 33) (1500 RPM).

For Type I Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM). Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).

Follow for the helical drill Ø 3.0 mm (FHI 30) and the countersink drill Ø 3.3 mm (FHI 33) (1500 RPM).

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTUM 20 or CTUM 24) and for hexagon external connection (CTWD 20 or CTWD 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive Morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE.
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

For single-stage or immediate loading, install the selected prosthetic components.

Epikut Implants (MT) – Body Ø 3.8 mm

For Type IV Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).

Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant, follow for the helical drill Ø 3.0 mm (FHI 30) (1500 RPM).

For Type II and III Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).

Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant.

Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), optionally use the drill Ø 3.6 mm (FHI 36) (1500 RPM).

For Type I Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM).

Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).
Follow for the helical drill Ø 3.0 mm (FHI 30) and the countersink drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36) (1500 RPM).

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTUM 20 or CTUM 24) and for hexagon external connection (CTWD 20 or CTWD 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive Morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE.
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

For single-stage or immediate loading, install the selected prosthetic components.

Epikut Implants (HE and MT) – Body Ø 4.5 mm
For Type IV Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant, follow for the helical drill Ø 3.0 mm (FHI 30), use the drill Ø 3.6 mm (FHI 36) (1500 RPM)

For Type II and Type III Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant.
Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36), follow to drill Ø 4.0 mm (FHI 40), optionally use the drill Ø 4.3 mm (FHI 43) (1500 RPM).

For Type I Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).
Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36), follow to drill Ø 4.0 mm (FHI 40), use the drill Ø 4.3 mm (FHI 43) (1500 RPM).

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTUM 20 or CTUM 24) and for hexagon external connection (CTWD 20 or CTWD 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive Morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE.
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

For single-stage or immediate loading, install the selected prosthetic components.

Epikut Implants (HE and MT) – Body Ø 5.0 mm
For Type IV Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant, follow for the helical drill Ø 3.0 mm (FHI 30), use the drill Ø 3.6 mm (FHI 36) and the drill Ø 4.0 mm (FHI 40) (1500 RPM).

For Type II and Type III Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20). Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant.

Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36), follow to drill Ø 4.0 mm (FHI 40) and the drill Ø 4.3 mm (FHI 43), optionally use the drill Ø 4.8 mm (FHI 48) (1500 RPM).

For Type I Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM). Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).

Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36), follow to drill Ø 4.0 mm (FHI 40), use the drill Ø 4.3 mm (FHI 43) (1500 RPM), follow to use the drill Ø 4.8 mm (FHI 48) (1500 RPM).

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTUM 20 or CTUM 24) and for hexagon external connection (CTWD 20 or CTWD 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive Morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE.
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

For single-stage or immediate loading, install the selected prosthetic components.

Lekholm UR and Zarb GA, Patient selection and preparation, in Brånemark P-I, Zarb GA, Albrektsson T (eds): Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chicago IL, Quintessence, 1985, 199-209.

Epikut Implants MT Long Lengths 18, 20, 22, 24 mm

Note: During all drilling to shape the implant site, avoid deflecting the drill sideways, and use continuous, copious irrigation.

To transfer the implant from the package to the surgical site, use drives with contra-angle fitting (CTMD 20 or CTMD 24). Drives with fittings for torque meter cannot be used to transfer the implant, and should only be use for the final insertion torque (CCM 20 or CCM 24).

S.I.N. implants were design for a maximum torque of 80 N.cm. Higher torques might cause irreversible damages to the implants as well as surgical complications.

The torque for intermediate fixation for the multifunction abutment is 32 N.cm, and for the cemented abutment, conical abutment or mini abutment is 20 N.cm on the implant.

For Angled Mini Abutment 17° and 30°, the torque for intermediate fixation is 20 N.cm on the implant.

The torque for component fixation on the intermediaries is 10 N.cm.

Do not install the protection screw (cover screw) with the ratchet wrench or torque meter since this may damage the implant; tighten it manually with a digital driver.

Full Arch Restorations

Ideally, a full arch procedure should optimize an immediate loading with a minimum torque implant placement and a well stablished fixed rehabilitation. Once a full treatment planning is done and approved, the surgery and the full arch concept can be executed.

Lower Arch

When distributing implants, the position and size of the inferior alveolar and mental nerves must be taken into account.

Make an incision that allows full access to the alveolar ridge followed by full-thickness flap. In the case of dental extractions, a careful curettage of the alveolus is necessary, as well as the creation of a bone platform for implants placement. Smile line transition and lip support must be taken in consideration.

Two (2) to four (4) anterior implants in a palatal position should be placed axially, and two (2) posterior implants should be placed tilted up to 30º.

When used in the mandible with implants with lengths of 18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted.
By tilting the two posterior implants, the bone-to-bone implant contact is enhanced, providing optimized bone support even with minimum bone volume. Additionally, tilting of implants in the mandible allows for improved anchorage in better quality anterior bone.
Extensions over one tooth and severe parafunction must be avoided.
For immediate loading primary implant stability of at least 45 N.cm is indicated. In cases with extraction sites, the implant placement should be between the extraction sites.

Epikut MT Long – Implant Body Ø 3.8 mm
For bones type IV

At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant, follow for the conical drill Ø 3.0 mm (FHI 3024) (800 RPM).

For bones type II and III

At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant (800 RPM).
Follow for the conical drill Ø 3.0 mm (FHI 3024) and the drill Ø 3.3 mm (FHI 3324), optionally use the drill Ø 3.6 mm (FHI 3624) (800 RPM).

For bones type I

At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant (800 RPM).
Follow for the conical drill Ø 3.0 mm (FHI 3024) and the drill Ø 3.3 mm (FHI 3324), use the drill Ø 3.6 mm (FHI 3624) (800 RPM).

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTMD 20 or CTMD 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive Morse connection (CCU 20 or CCM 24).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220), and suture the gingiva.
8. For single-stage or immediate loading, install the selected prosthetic components.

Epikut MT Long – Implant Body Ø 4.0

For bones type IV

At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant, follow for the conical drill Ø 3.0 mm (FHI 3024), follow to drill Ø 3.3 mm (FHI 3324) (800 RPM).

For bones type II and III

At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant (800 RPM).
Follow for the conical drill Ø 3.0 mm (FHI 3024) and the drill Ø 3.3 mm (FHI 3324), use the drill Ø 3.6 mm (FHI 3624). optionally use the drill Ø 3.8 mm (FHI 3824) (800 RPM).

For bones type I

At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant (800 RPM).

Follow for the conical drill Ø 3.0 mm (FHI 3024) and the drill Ø 3.3 mm (FHI 3324), use the drill Ø 3.6 mm (FHI 3624), follow to drill Ø 3.8 mm (FHI 3824) (800 RPM).

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTMD 20 or CTMD 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive Morse connection (CCM 20 or CCM 24).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220), and suture the gingiva.
8. For single-stage or immediate loading, install the selected prosthetic components

Epikut MT Long – Implant Body Ø 4.5

For bones type IV

1. At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant, follow for the conical drill Ø 3.0 mm (FHI 3024), use the drill Ø 3.3 mm (FHI 3324), follow to drill Ø 3.6 mm (FHI 3624) (800 RPM).

For bones type II and III

1. At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant (800 RPM).
Follow for the conical drill Ø 3.0 mm (FHI 3024) and the drill Ø 3.3 mm (FHI 3324), use the drill Ø 3.6 mm (FHI 3624), follow to drill Ø 4.0 mm (FHI 4024), optionally use the drill Ø 4.3 mm (FHI 4324) (800 RPM).

For bones type I

1. At the surgical site penetrate the cortical bone with the spear drill (FLI 2024) (1200 RPM).
Prepare the surgical site with the Ø 2.7 mm conical drill (FHI 2724) to the depth of the mark on the previously selected implant (800 RPM).
Follow for the conical drill Ø 3.0 mm (FHI 3024) and the drill Ø 3.3 mm (FHI 3324), use the drill Ø 3.6 mm (FHI 3624), follow to drill Ø 4.0 mm (FHI 4024), use the drill Ø 4.3 mm (FHI 4324) (800 RPM).

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTMD 20 or CTMD 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive Morse connection (CCM 20 or CCM 24).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220), and suture the gingiva.
8. For single-stage or immediate loading, install the selected prosthetic components.

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 (References 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.
	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	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.
	Do not re-use (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Date of manufacture (5.1.3)	Indicates the date when the medical device was manufactured
	Manufacturer (5.1.1)	Indicates the medical device manufacturer.
	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.
	MR Conditional (n/a)	Conditions under which a medical device can safely enter the MR environment

DEVELOPED AND MANUFACTURED BY:
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PRODUCT:
Epikut dental implants

510 (k) FDA-USA:
K211921
K222514
K222453