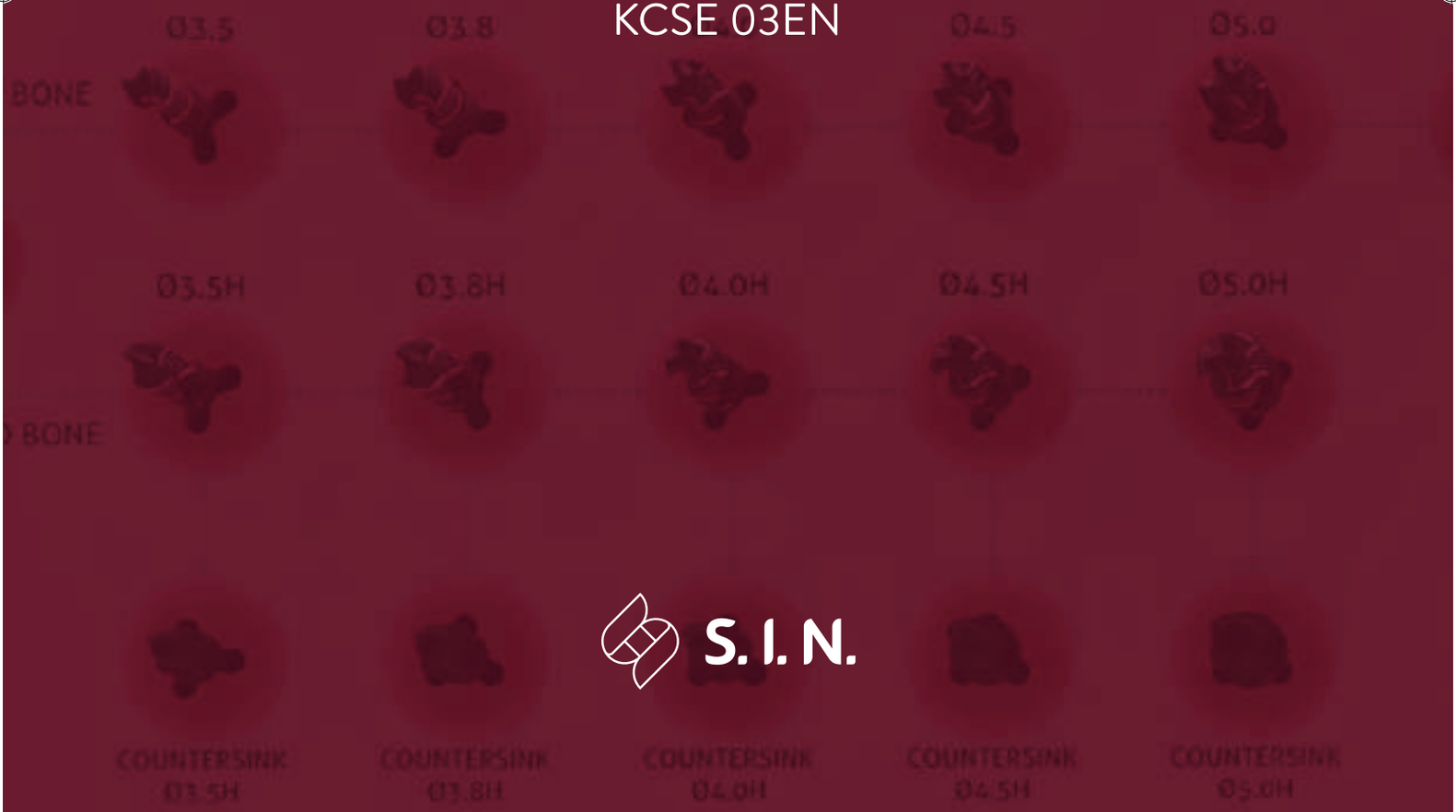
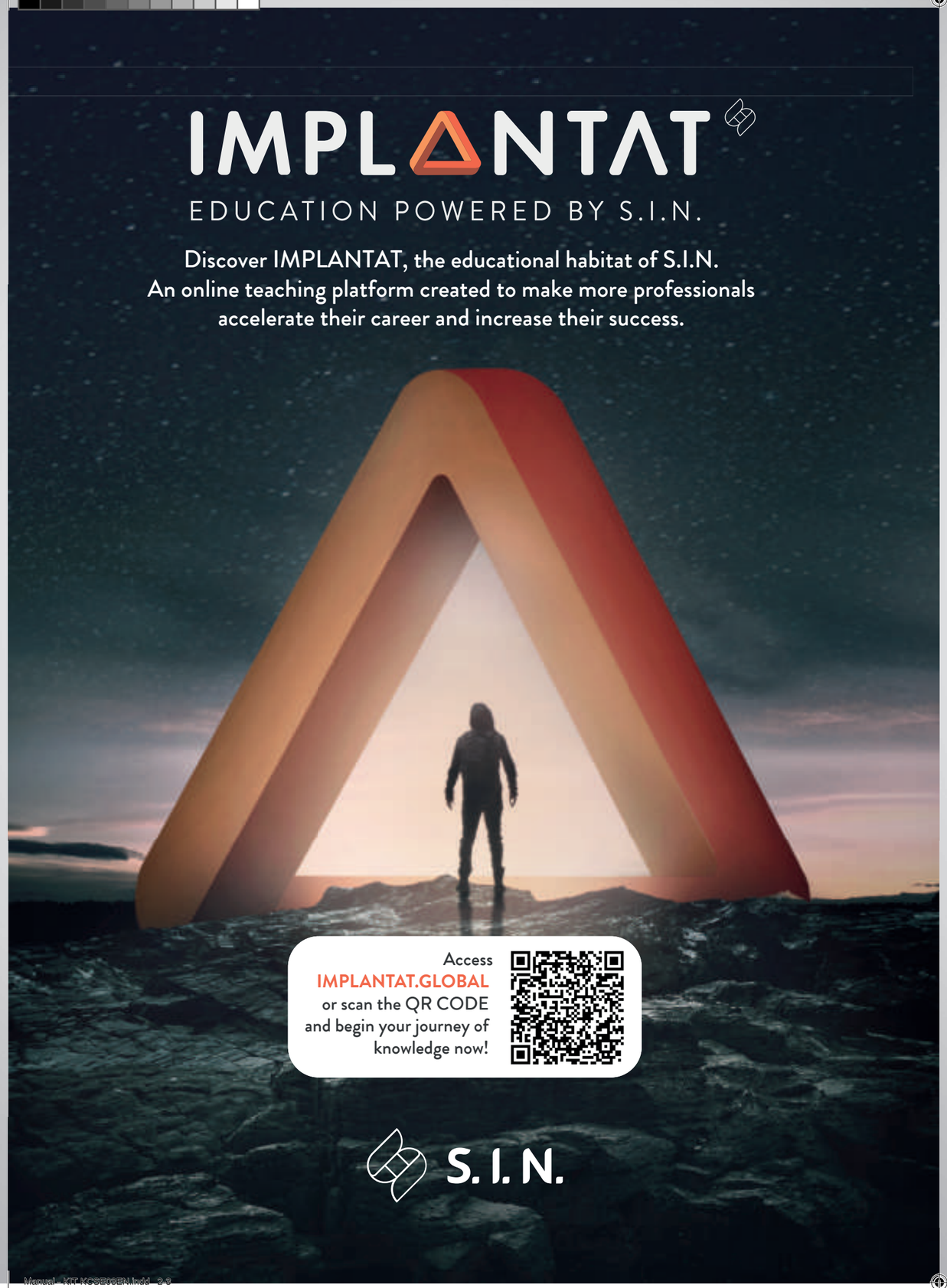
Get to know the

Epikut S Surgical Kit

KCSE 03EN



S.I.N.



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2. INFORMATION ON SURGICAL PROCEDURES

More than a new smile, a full rehabilitation quickly leads to improved patient satisfaction with regards to: Function, Aesthetics, Sensitivity, Speech and Self Esteem.

Failing dentition is a common condition, and there is a great need for a wider variety of solutions to treat this diverse group of patients. It represents a global health care burden, and will continue to do so in the foreseeable future.

Several concepts may be included on these protocols, namely: palatine implant approach, tilted posterior implants, short implants, angled abutments, graft less solutions and screwed fixed restorations.

More than 36 million Americans do not have any teeth, and 120 million people in the U.S. are missing at least one tooth. These numbers are expected to grow in the next two decades.

In the geriatric population, the ratio of edentulous individuals is 2 to 1. About 23 million are completely edentulous, and about 12 million are edentulous in one arch.

The number of partially edentulous patients will continue to increase in the next 15 years to more than 200 million individuals. Partial edentulism affects the majority of adult Americans.

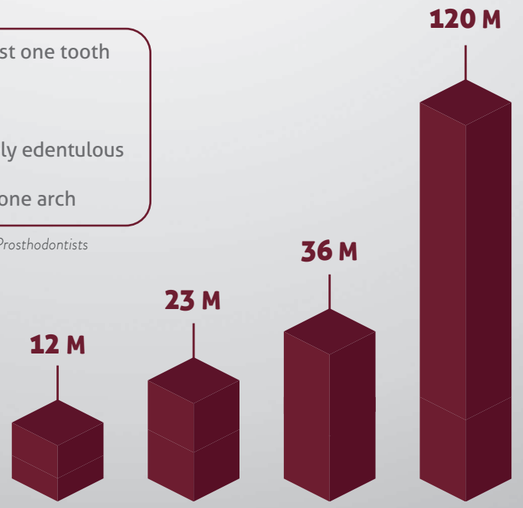
120 Million Americans missing at least one tooth

36 Million completely edentulous

23 Million geriatric patients completely edentulous

12 Million geriatric patients missing one arch

Source: 2020 USA market data. American College of Prosthodontists National Center for Health Statistics.



Epikut S

MORSE TAPER 16°

The **Epikut S** implant line features a 16° Morse Taper Connection, designed to provide greater stability and long-term performance. This advanced connection ensures a precise fit between the component and the implant, minimizing micro-movements and enhancing the durability of prosthetic restorations. One of the key advantages of this connection is that force distribution occurs at the center of the implant, reducing stress on the surrounding bone.

The implant features hybrid macrogeometry for optimized primary stability. Its cutting threads and inverted dual support threads enhance bone compaction and improve insertion control, while exclusive cervical microthreads increase the bone contact area and improve the dissipation of occlusal forces, especially shear forces.

Manufactured from Grade IV Cold Worked Titanium, this implant offers superior mechanical strength and biocompatibility. The Morse Taper Connection with 16° angle ensures a secure fit, minimizing micro-movements and bacterial infiltration.

The macrogeometry of this implant allows smooth installation with excellent torque, irrespective of the bone quality, if the drilling protocols are followed.

INDICATIONS FOR CLINICAL USE:

- 3.5 mm - Central incisors and lateral incisors.
- 3.8 mm - Central incisors, canines and premolars.
- 4.0 mm - Upper central incisors, canines, premolars and molars
- 4.5 mm - Upper central incisors, canines, premolars and molars
- 5.0 mm - Molars

All implants can be inserted using the KCSE 03EN kit, following the recommended drilling protocol. A versatile implant, EPIKUT S can also be used in several clinical situations, with specific drilling guidelines followed.

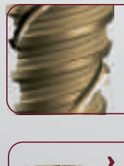
4. IMPLANT DESIGN

The Epikut S Line features a 16° Morse Taper connection (MT 16°) and is available in lengths of 8.5, 10, 11.5, 13, and 15mm, with diameters of 3.5, 3.8, 4.0, 4.5, and 5.0mm, and includes a 2.0mm cover screw for added convenience, as detailed in the table below.

TECHNICAL MEASURES

		A	B	C
CODE DAE	CODE PLUS	PLATFORM DIAMETER (mm)	APICAL DIAMETER (mm)	LENGTH (mm)
ILM 3585	ILM 3585N	3.5	2.0	8.5
ILM 3510	ILM 3510N			10.0
ILM 3511	ILM 3511N			11.5
ILM 3513	ILM 3513N			13.0
ILM 3515	ILM 3515N			15.0
ILM 3885	ILM 3885N	3.8	2.0	8.5
ILM 3810	ILM 3810N			10.0
ILM 3811	ILM 3811N			11.5
ILM 3813	ILM 3813N			13.0
ILM 3815	ILM 3815N			15.0
ILM 4085	ILM 4085N	4.0	2.0	8.5
ILM 4010	ILM 4010N			10.0
ILM 4011	ILM 4011N			11.5
ILM 4013	ILM 4013N			13.0
ILM 4015	ILM 4015N			15.0
ILM 4585	ILM 4585N	4.5	2.95	8.5
ILM 4510	ILM 4510N			10.0
ILM 4511	ILM 4511N			11.5
ILM 4513	ILM 4513N			13.0
ILM 4515	ILM 4515N			15.0
ILM 5085	ILM 5085N	5.0	2.95	8.5
ILM 5010	ILM 5010N			10.0
ILM 5011	ILM 5011N			11.5
ILM 5013	ILM 5013N			13.0
ILM 5015	ILM 5015N			15.0

The exclusive macrogeometry features a progressive cutting screw design, ensuring optimal performance. Its 16° Morse Taper connection simplifies your clinical routine, providing a more efficient workflow. Additionally, the thinner apex, with a 2mm diameter, facilitates bicorticalization for enhanced precision.



› Double inverted support curls
They ensure greater primary stability and insertion torque.

› More portfolio options
16° Morse Taper connection to facilitate daily clinical practice.

› Exclusive cervical microthreads
Larger bone contact area and improves the dissipation of occlusal forces.

› Apex
Stability and support for cases with low bone density.

5. HANANO SURFACE

In vitro studies using pre-osteoblast cells, evaluating the HAnano coating by assessment of cell signaling dynamics, have demonstrated a greater transition from adhesion/proliferative-related signaling to differentiation-related signaling compared to uncoated titanium, thus culminating in changes in osteogenic gene marker expression, which is important in bone regeneration processes.* (Bezerra, et al., 2017). Cells grown on HAnano surfaces demonstrated a spreading morphology different than that of cells grown on machined surfaces.* (Bezerra, et al.,2017)

The HAnano Surface promotes osteoblast differentiation by significantly upregulating RUNX2 and ALP activity when pre-osteoblasts were grown directly on titanium discs.* (Bezerra, et al., 2017)

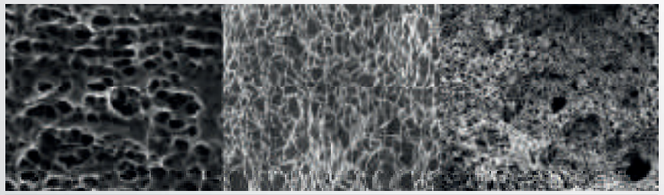
Osteoblasts were observed to have a morphology that spread across the HAnano surface differently than over a hydrophilic dual acid-etched surface (SLActive) in in vitro experiments.* (da Silva, et al., 2020)

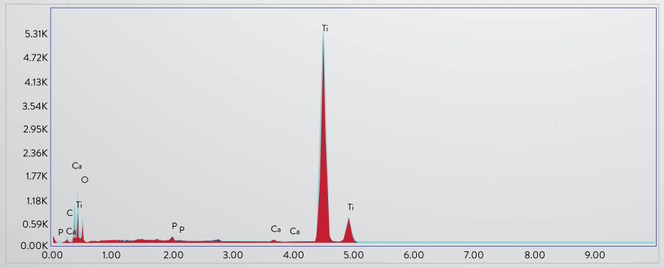
*Results of in vitro testing are not necessarily predictive of human clinical performance

** References

Bezerra F, Ferreira MR, Fontes GN, da Costa Fernandes CJ, Andia DC, Cruz NC, da Silva RA, Zambuzzi WF. Nano hydroxyapatite-blasted titanium surface affects pre-osteoblast morphology by modulating critical intracellular pathways. Biotechnol Bioeng. 2017 Aug;114(8):1888-1898. da Silva RA, a Silva Feltran G, Ferreira MR, Wood PF, Bezerra F, Zambuzzi WF. The Impact of Bioactive Surfaces in the Early Stages of Osseointegration: An In Vitro Comparative Study Evaluating the HAnano® and SLActive® Super Hydrophilic Surfaces. Biomed Res Int. 2020 Sep 13.

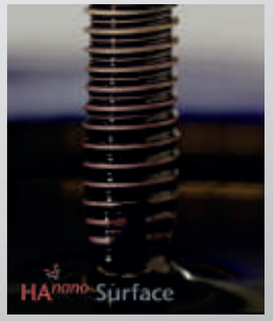
The image below shows the surface of EPIKUT PLUS at 5,000x / 10,000x / 100,000x magnification respectively. The moderately rough Ti surface with the PLUS of a nanolayer of Hydroxyapatite.





Element	Weight %	Atomic %	Net Int.	Error %	Kratio	Z	A	F
C K	2.38	6.12	17.55	14.07	0.0109	1.2237	0.3738	1.0000
O K	23.65	45.76	86.13	12.54	0.0225	1.1758	0.0809	1.0000
P K	0.62	0.62	27.83	21.11	0.0049	1.0352	0.7510	1.0095
CaK	0.74	0.57	28.30	17.15	0.0080	1.0212	0.9855	1.0730
TiK	72.61	46.92	2177.66	1.66	0.6760	0.9268	1.0034	1.0014

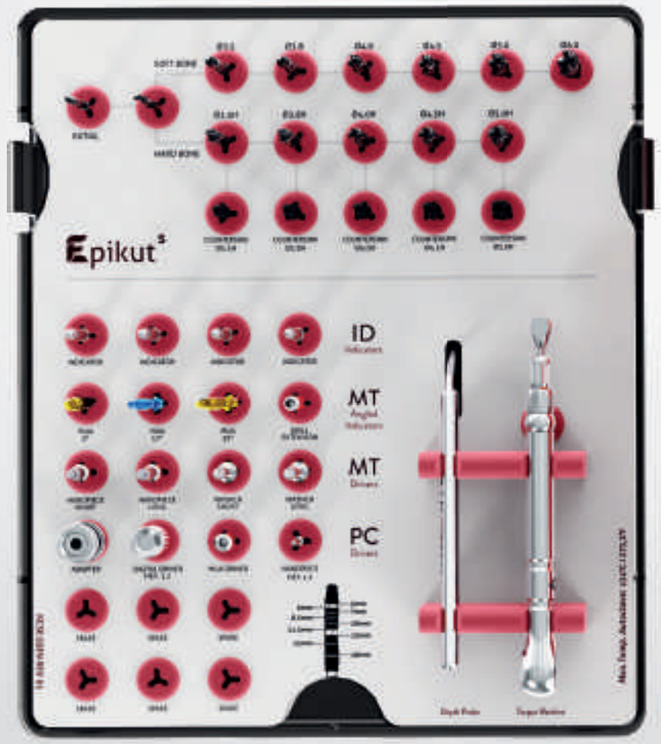
The graph and table above correspond to an EDS analysis on the surface of EPIKUT PLUS, approximating the purity and stability of the implant surface.



6. KCSE 03EN KIT

For surgical efficiency, the drilling protocol includes an initial drill speed of 1200 rpm and a drill speed of 800 rpm, the conical and countersink drills. The insertion speed ranges from 20 to 40 rpm, with a maximum insertion torque of 80 N.cm.

The recommended infra-bone installation is 1.5mm, ensuring optimal performance.

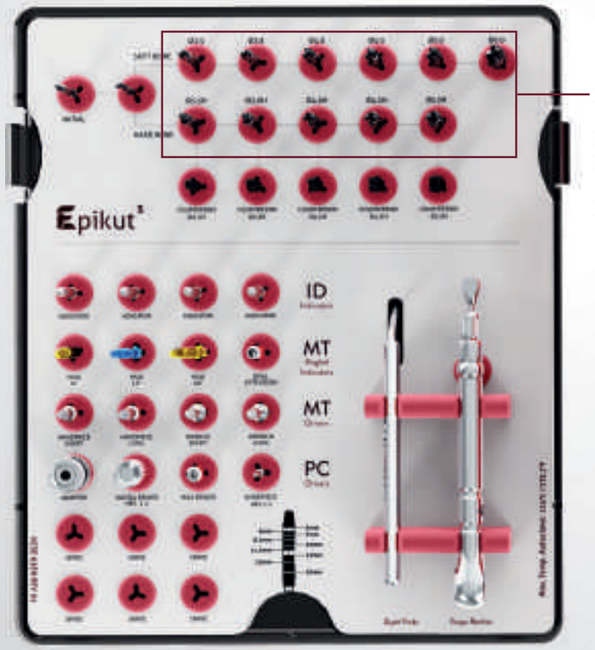


7. INSTALLATION

The placement of conventional-sized implants from the Epikut S line follows a technical approach that prioritizes stability and bone integration. These implants are designed with dimensions that enhance anchorage in native bone, reducing the need for grafting and facilitating installation in areas with high bone quality.

KIT

To install Epikut S implants, it is essential to use the specific kit designed for this line. A complete and compact kit with a linear and intuitive sequence ensures precision and ease of use.

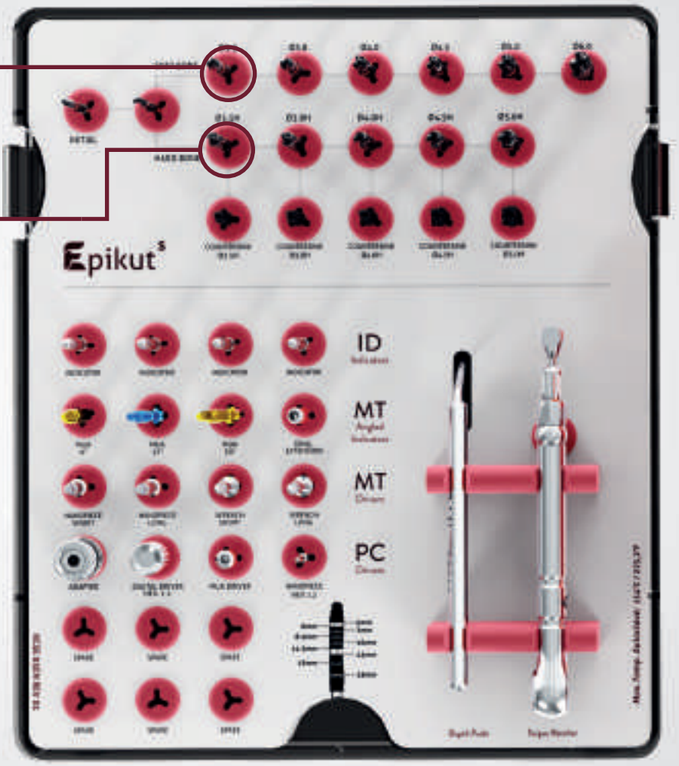


- Drills are named according to the implant diameter.
- **They are not true size**
- Soft bone drills are Extremely-undersized (upper row) and named øXX.
- Hard bone drills are undersized (middle row) and named øXXH.

8. DRILLING

Drilling 3.5mm

- **For soft bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20) and followed by the ø3.5 drill (FRC 35S) - optional.
- **For hard bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20) and followed by the ø3.5 drill and followed by the 3.5 Countersink (FRCT 35)(countersink). Countersink is optional, in case of need.

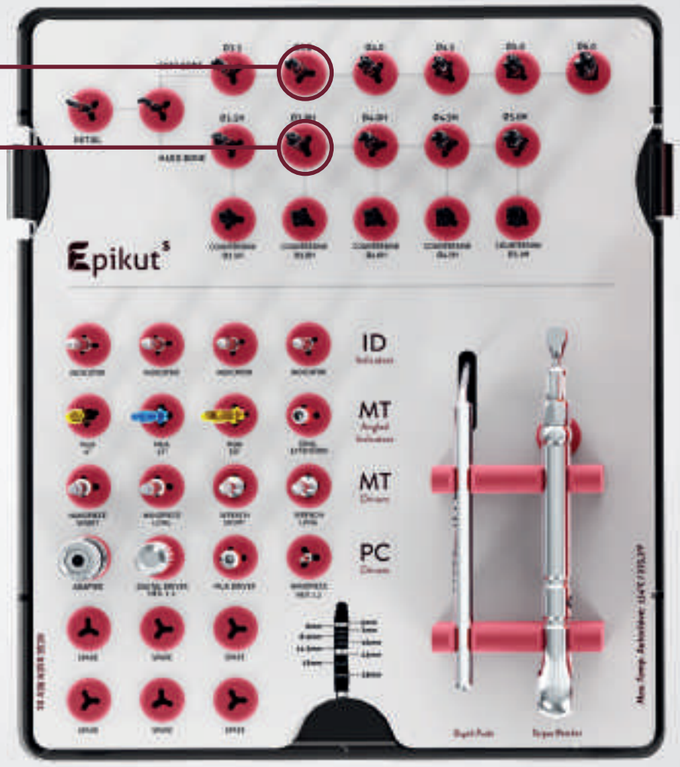


Below, we can see a more detailed view of the measurements of each part of the drills mentioned for the insertion of the 3.5mm diameter implant.

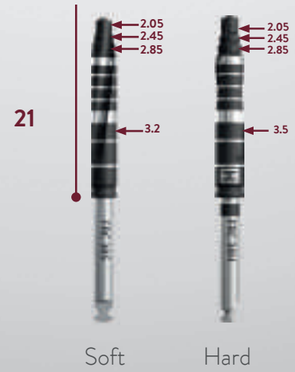
9. DRILLING

Drilling 3.8mm

- **For soft bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20), followed by the ø3.5 drill (FRC 35S) and followed by 3.8 drill (FRC 38S) - optional.
- **For hard bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20), followed by the ø3.5 drill (FRC 35H), followed by the ø3.8 drill (FRC 38H) and followed by the 3.8 Countersink (FRCT 38). Countersink is optional, in case of need.



Below, we can see a more detailed view of the measurements of each part of the drills mentioned for the insertion of the 3.8mm diameter implant.

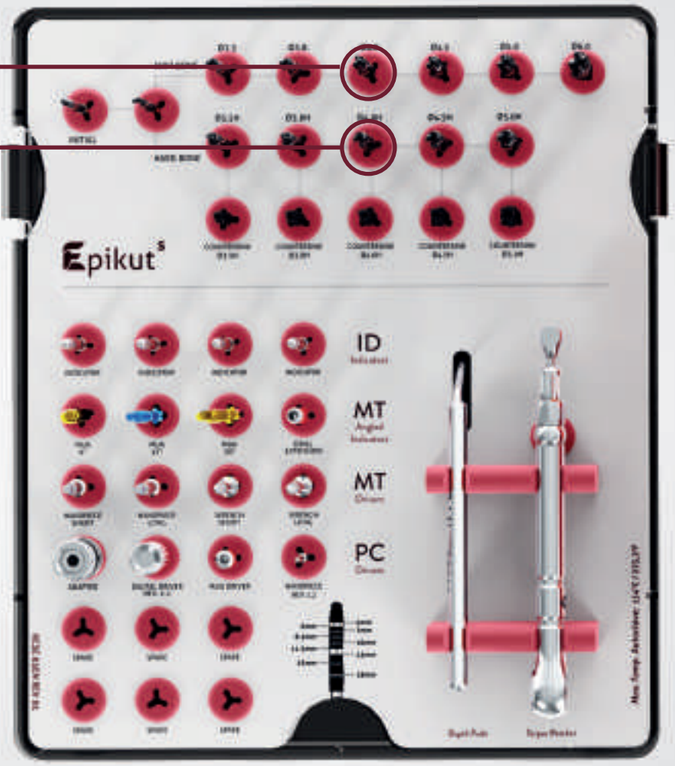


10. DRILLING

Drilling 4.0mm

› **For soft bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20), followed by the ø3.5 drill (FRC 35S) and the ø4.0 drill (FRC 40S). For soft bone cases, the 3.8mm drill is not required before using the 4.0mm drill.

› **For hard bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20), followed by the ø3.5 drill (FRC 35H), followed by the ø3.8 drill and followed by the 4.0 countersink (FRCT 40). Countersink is optional, in case of need.



Below, we can see a more detailed view of the measurements of each part of the drills mentioned for the insertion of the 4.0mm diameter implant.

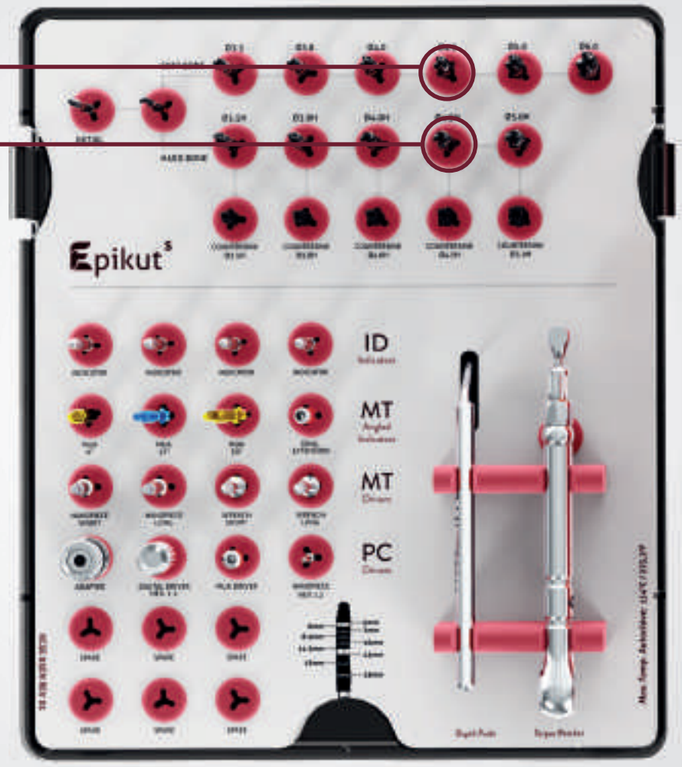
11. DRILLING

Drilling 4.5mm

› **For soft bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20), followed by the ø3.5 drill (FRC 35S), followed by the the ø4.0 drill (FRC 40S) and the ø4.5 drill (FRC 45S) - optional.

For soft bone cases, the 3.8mm drill is not required before using the 4.0mm drill.

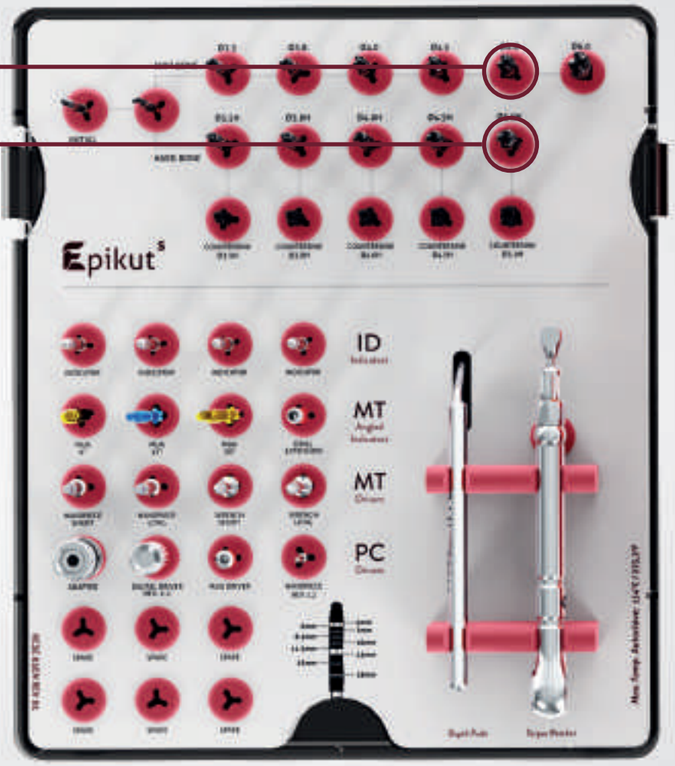
› **For hard bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20), followed by the ø3.5 drill (FRC 35H), followed by the ø3.8 drill, followed by the ø4.0 drill (FRC 40H), followed by the ø4.5 drill (FRC 45H), and followed by 4.5 countersink (FRCT 45). Countersink is optional, in case of need.



Below, we can see a more detailed view of the measurements of each part of the drills mentioned for the insertion of the 4.5mm diameter implant.

12. DRILLING

Drilling 5.0mm



› **For soft bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20), followed by the ø3.5 drill (FRC 35S), followed by the ø4.0 drill (FRC 40S), followed by the ø4.5 drill (FRC 45S) and the ø5.0 drill (FRC 50S) - optional.

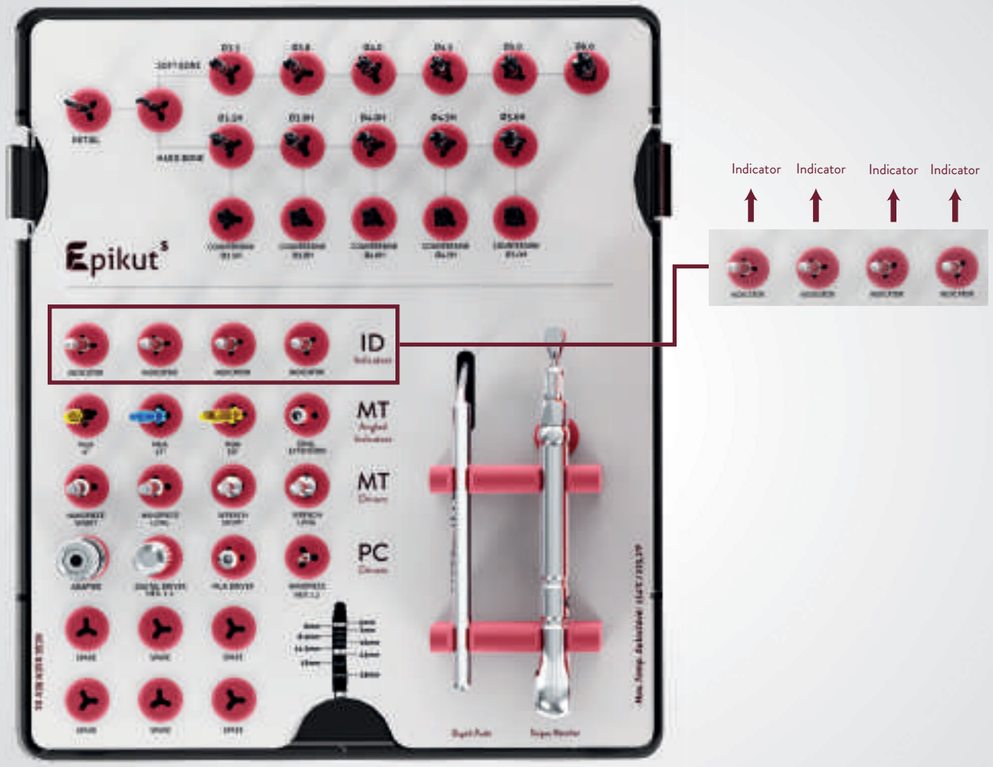
For soft bone cases, the 3.8mm drill is not required before using the 4.0mm drill.

› **For hard bone:** Start with the **Initial** drill (FRL 20), followed by the Helical (FRH 20), followed by the ø3.5 drill (FRC 35H), followed by the ø3.8 drill, followed by ø4.0 drill (FRC 40H), followed by the ø4.5 drill (FRC 45H), followed by the ø5.0 drill (FRC 50H) and the 5.0 countersink (FRCT 50). Countersink is optional, in case of need.

Below, we can see a more detailed view of the measurements of each part of the drills mentioned for the insertion of the 5.0mm diameter implant.

13. DIRECTION INDICATORS

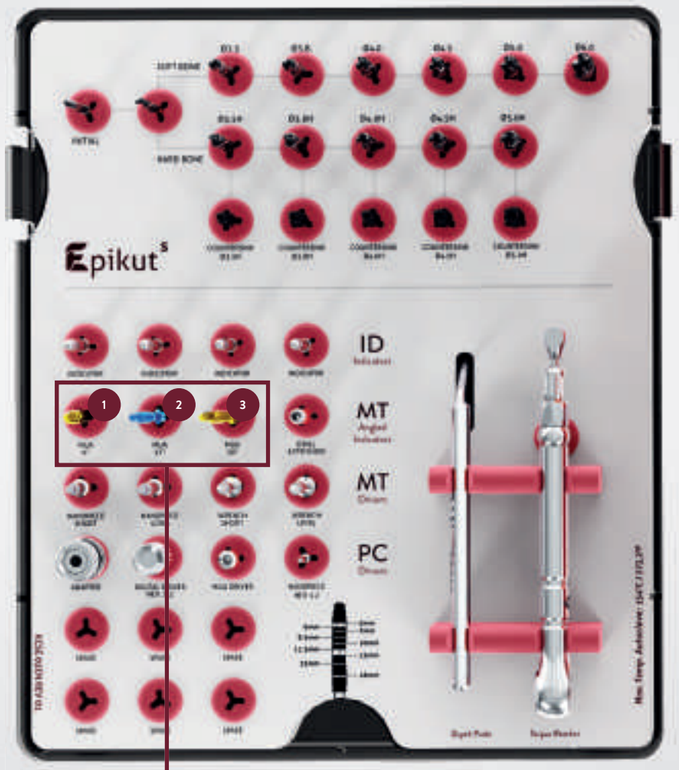
Our kit includes four direction indicators

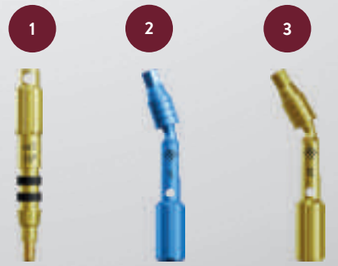


Thicker side compatible with ø3.5 drill (FRC 35S).

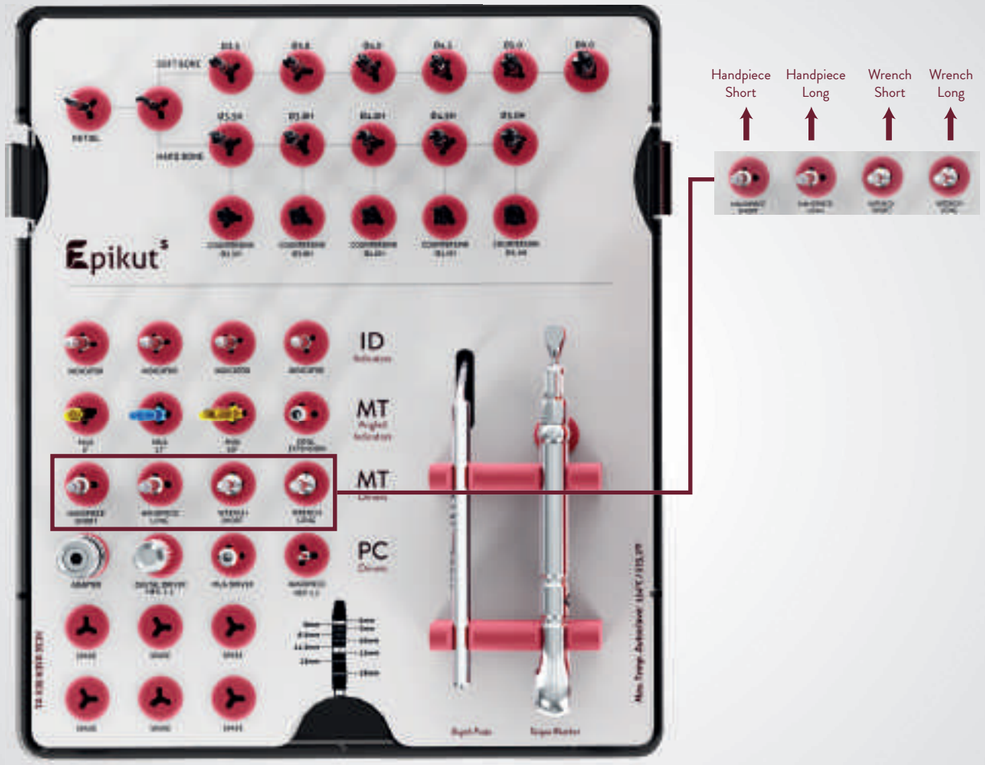
Thinner side compatible with initial drill (FRH20).

The kit includes both angled and straight MUA options, designed to indicate the angle and gingival height for precise implant placement.





The implant drivers are designed for the secure and precise placement of implants. We offer them in short and long options for both handpieces and torque wrenches to suit different clinical needs.



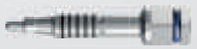
Short and long handpiece:

CTMD 20

CTMD 24

Indicates the indexing of the implant: Ball should always face buccal

CCM 20

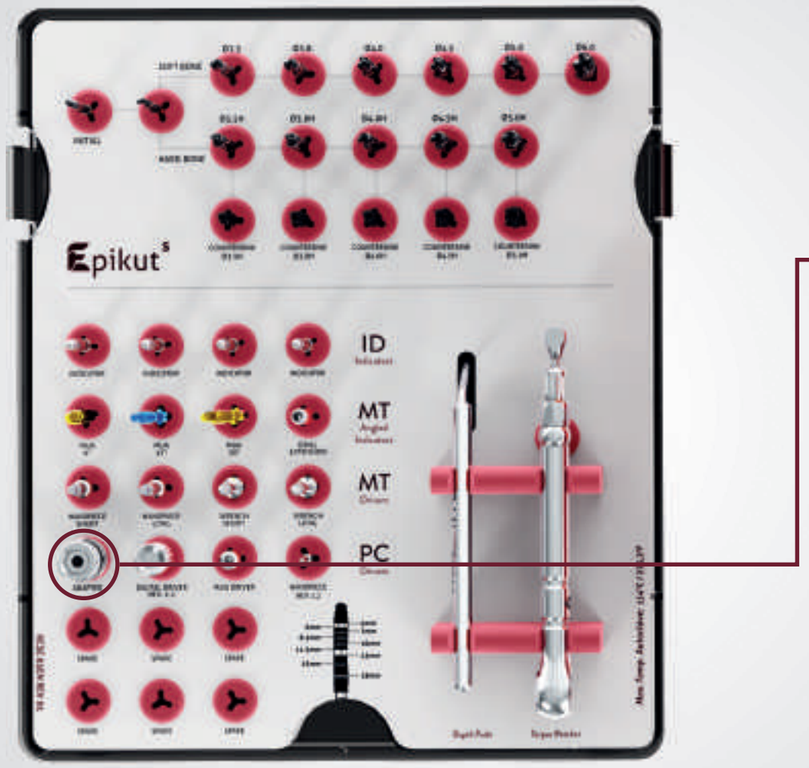


CTMD 24

Short and long torque wrench:

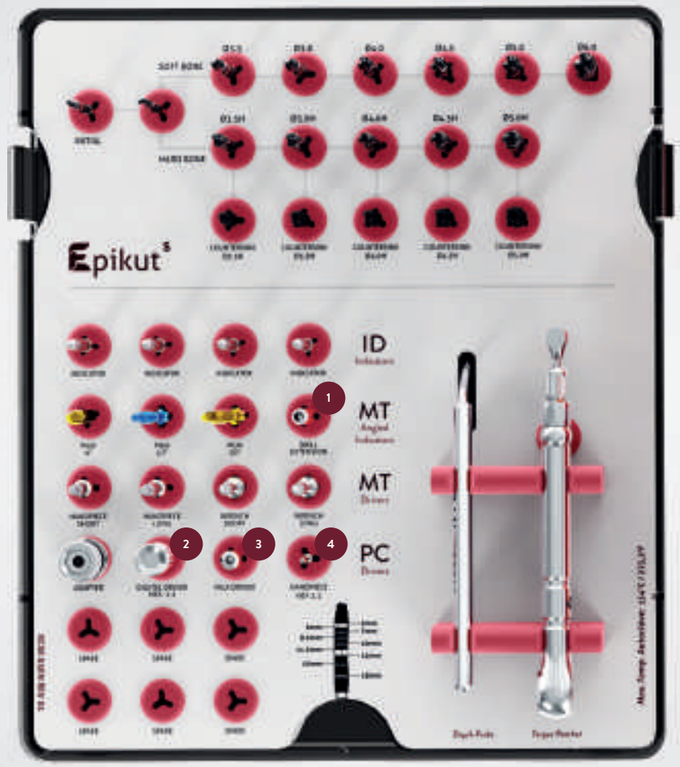
Millimetric markings

The adapter allows the handpiece driver to be used with a torque wrench and digital systems, providing versatility and precision during implant placement.



CBD 01

Our kit includes extra tooling to enhance versatility and efficiency during procedures. These additional tools support various clinical situations, ensuring precision and ease of use.



1

DRIVER EXTENSION
Code: EXFN

2

DRIVER DIGITAL
HEX.1.2 MEDIUM
Code: CDH 1224

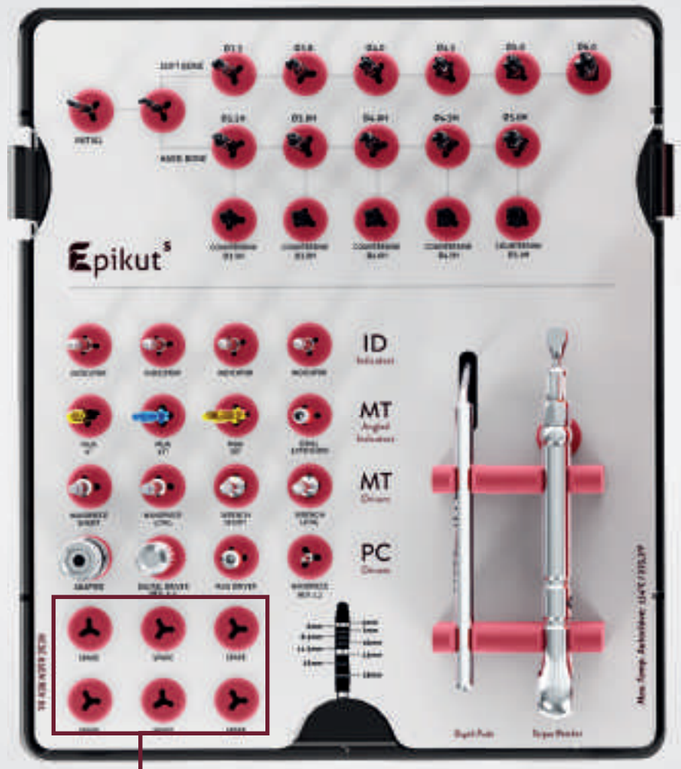
3

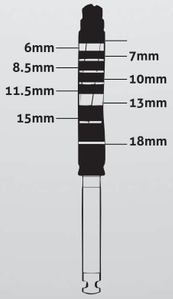
ABUTMENT TORQUE
SCREWDRIVER 24.0MM
Code: CTA 1224

4

DRIVER HANDPIECE
HEX.1.2MM MEDIUM
Code: CTH 1224

Six extra spaces to place any extra tooling you might need





The millimeter markings indicate the true size drill rule, ensuring accuracy and precision during drilling.

The ratchet torque wrench is used for the final insertion of the implant and features a torque measuring shaft with markings up to 80 N.cm. It is extremely important to take care of the internal cleaning of this instrument to ensure its longevity and accuracy over the time. The kit also includes a depth probe with engraved markings to easily measure the milling depth.

GENERAL INSTRUCTIONS

Special care and clarification on surgical instruments.

CLEANING KIT CASE

- Manually remove all surgical instruments from the kit. Wash the kit trays separately.
- Prepare the enzymatic detergent, according to manufacturer's recommendation.
- 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.
- Remove the parts from the detergent solution and rinse with tap water for 1 minute until the residue is completely removed. Repeat the rinse two more times
- Visual inspection of each part for cleaning process residue or organic waste from product use.
- If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
- Dry with a soft, clean, dry cloth or disposable paper.

CLEANING SURGICAL INSTRUMENTS

- Disassemble the product (if applicable). For the torque wrench, disassembly it completely, remove all the internal organic matter using tap water and follow to the next step only after performing such procedures.
- Prepare the enzymatic detergent according to the manufacturer's recommendation.
- 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.
- 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.
- Visual inspection of each part for cleaning process residue or organic waste from product use.
- If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
- Dry with a soft, clean, dry cloth or disposable paper.
- Follow to sterilization process.

STERILIZATION

- Reusable Product and provided non-sterile.
- It must be clean and sterilized in autoclave before use.
- Dry all instruments before the steam sterilization cycle.
- The product must be enclosed in a steam sterilizable wrap.
- Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
- Always accommodate the case in autoclave over a plane surface and away of device walls.
- Never stack objects or other cases.

CLEANING RECOMMENDATION

- Use the proper PPEs (gloves, masks, goggles, caps, etc.).
- Start the cleaning right after the surgical use.
- Never let the instruments dry with organic waste after the surgical use.
- Never let the instrument dry naturally after cleaning.
- Never use saline solutions, including sodium hypochlorite, disinfectant, hydrogen peroxide or alcohol for cleaning or rinsing the surgical instruments and Kits.
- Never use steel wool and abrasive products, so that the instruments are not damaged.
- Do not stack the instruments in lots to avoid the deformation of smaller and delicate pieces.

STERILIZATION RECOMMENDATIONS

- Sterilize the products in the same day or one day earlier the procedure.
- The chemical sterilization is not recommended, once some products may cause the discoloration and damage to the case.
- Do not use temperature higher than 60°C to drying process.
- Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N.

WHERE WE ARE

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