SYSTEM APPLICATION

Single-piece implants

MULTI UNIT*

DENTAL IMPLANT SYSTEM

* Pat. pending

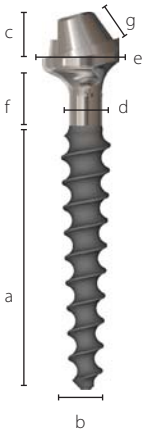
SIMPLADENT®
Switzerland

SIMPLADENT®

Headquarter Switzerland

SINGLE-PIECE MULTIUNIT IMPLANTS

KOC® MU features a pre-angulation of 15 degrees. **KOC® MU** may be bent additionally, using the insertion tool. In conjunction with the clinically possible rotational positions of the head, all possible angulation can thus conceivably be realized. Material Ti6Al4V.



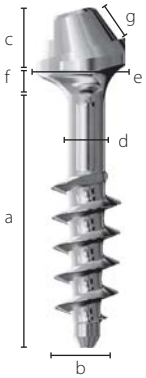
a) endosseous length	10 - 15 mm
b) endosseous Ø	3.0 - 5.0 mm
c) hight abutment	3.7 mm
d) shaft Ø	2 mm
e) platform Ø	4.8 mm
f) trans-mucosal height	3 mm
g) height of connecting part	2 mm
Prosthetic screw	SFK MU

Description	REF
KOC® MU 3.0 15	**13-455830**
KOC® MU 3.2 12	**13-455838**
KOC® MU 3.2 15	**13-455839**
KOC® MU 3.7 10	**13-455840**
KOC® MU 3.7 12	**13-455841**
KOC® MU 3.7 15	**13-455831**
KOC® MU 4.1 12	**13-455832**
KOC® MU 4.1 15	**13-455833**
KOC® MU 5.0 10	**13-455834**
KOC® MU 5.0 12	**13-455835**

FIELD OF APPLICATION endosseous oral (dental) implant.

Strategic Implant®

BECES® MU features a fixed pre-angulation of 15 degrees. **BECES® MU** can also be bent after insertion using the insertion tool. Since the implant head can be positioned during the surgery in any direction, directional changes for the prosthetic screw of between -15 and +15 degrees are possible due to the pre-angulation. In addition, if the neck is bent by max. 15 degrees, angulation of the prosthetic screw of between -30 and +30 degrees relative to the implant axis can be achieved. **BECES® MU** implants may be used by authorized users only. Material **Ti6Al4V**.



a) endosseous length	8 - 32 mm
b) endosseous Ø	3.6 - 9 mm
c) hight abutment	3.7 mm
d) shaft Ø	2 mm
e) platform Ø	4.8 mm
f) neck height	0.8 mm
g) height of connecting part	2 mm
Prosthetic screw	SFK MU
Field of application Endosseous oral (dental) implant	

Description		REF
BECES® MU 3.6 8	***Strategic Implant®***	**13-900397**
BECES® MU 3.6 10	***Strategic Implant®***	**13-900398**
BECES® MU 3.6 12	***Strategic Implant®***	**13-900376**
BECES® MU 3.6 14	***Strategic Implant®***	**13-900330**
BECES® MU 3.6 17	***Strategic Implant®***	**13-900331**
BECES® MU 3.6 20	***Strategic Implant®***	**13-900332**
BECES® MU 3.6 23	***Strategic Implant®***	**13-900333**
BECES® MU 3.6 26	***Strategic Implant®***	**13-900377**
BECES® MU 3.6 29	***Strategic Implant®***	**13-900378**
BECES® MU 5.5 10	***Strategic Implant®***	**13-900334**
BECES® MU 5.5 12	***Strategic Implant®***	**13-900335**
BECES® MU 5.5 14	***Strategic Implant®***	**13-900336**
BECES® MU 7.0 10	***Strategic Implant®***	**13-900337**
BECES® MU 7.0 12	***Strategic Implant®***	**13-900338**

HEATLESS® DRILLS **DOS** FOR IMPLANTS WITH CONICAL CORE

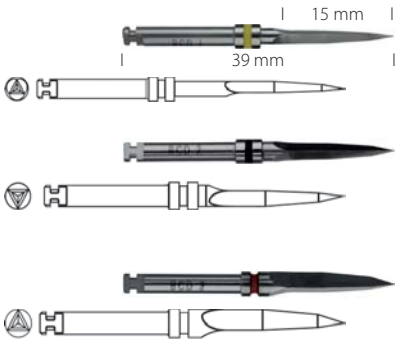
-55% heat

Surgical steel, color-coded, depth-coded and autoclaveable. The drill is marked with laser depth markings. Use between 3,000 and 5,000 rpm with good cooling and intermittent drill technique. Due to the extremely high cutting performance, you can work without pressure.

Description	Colour	Max. working length	REF
DOS 1	yellow	17 mm	13-455311
DOS 2	black	17 mm	13-455312
DOS 3	red	17 mm	13-455313

PATHFINDER DRILLS

Conical 3-edge drill as initial drill, ideally suited for all crestal implant systems. The drill finds its path between narrow cortical areas without pressure.



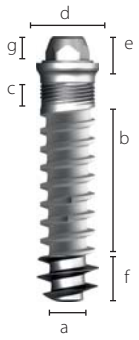
Description	Colour	Max. working length	REF
BCD 1	yellow	15 mm	**13-900240**
BCD 2	black	15 mm	**13-900241**
BCD 3	red	15 mm	**13-900242**

TWIST DRILLS

Description	Ø	Max. working length	REF
Twist Drill 2.0/21	2.0 mm	21 mm	**13-90022**
Twist Drill 2.0/30	2.0 mm	30 mm	**13-90020**
Twist Drill 2.0/40	2.0 mm	40 mm	**13-90019**
Twist Drill 2.5/21	2.5 mm	21 mm	**13-90026**

Description	Max. working length	REF
Twist Drill 2.0 Cylindrical drill 2.0 mm for handgrip, length 110 mm	35 mm	**13-310512**

HEXACONE® PLUS MU 0° IMPLANTS



Maximum insertion torque:
50 Ncm.
Material Ti6Al4V

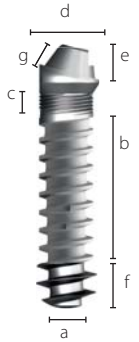
Dimensions
HC Plus MU 0° 4.1 17

a) endosseous maximal Ø	3.3 / 4.1 mm
b) endosseous length	11.5 - 21.5 mm
c) length micro thread	1.5 mm
d) platform Ø	4.8 mm
e) height head	2.6 mm
f) height of the apical thread	3.2
g) connecting part	2 mm

Description	max. nominal Ø / without apical thread	max. nominal Ø / with apical thread	endosseous length	REF
HC Plus MU 3.3 13 0°	3.3 mm	4 mm	13 mm	**13-412250**
HC Plus MU 3.3 15 0°	3.3 mm	4 mm	15 mm	**13-412251**
HC Plus MU 3.3 17 0°	3.3 mm	4 mm	17 mm	**13-412252**
HC Plus MU 3.3 19 0°	3.3 mm	4 mm	19 mm	**13-412253**
HC Plus MU 3.3 21 0°	3.3 mm	4 mm	21 mm	**13-412254**
HC Plus MU 3.3 23 0°	3.3 mm	4 mm	23 mm	**13-412255**
HC Plus MU 4.1 10 0°	4.1 mm	4.7 mm	10 mm	**13-412259**
HC Plus MU 4.1 13 0°	4.1 mm	4.7 mm	13 mm	**13-412260**
HC Plus MU 4.1 15 0°	4.1 mm	4.7 mm	15 mm	**13-412261**
HC Plus MU 4.1 17 0°	4.1 mm	4.7 mm	17 mm	**13-412262**
HC Plus MU 4.1 19 0°	4.1 mm	4.7 mm	19 mm	**13-412263**
HC Plus MU 4.1 21 0°	4.1 mm	4.7 mm	21 mm	**13-412264**
HC Plus MU 4.1 23 0°	4.1 mm	4.7 mm	23 mm	**13-412265**

Description	Code	REF
Insertion tool for KOC MU, BECES MU & Hexacone Plus MU 15°. Use with IT2 BCS, IT2 S BCS, AHB, handgrip. Tool for the screw: HT 1.25	**ITX MU15**	**13-418203**

HEXACONE® PLUS MU 15° IMPLANTS



Maximum insertion torque:
50 Ncm.
Material Ti6Al4V

Dimensions
HC Plus MU 15° 4.1 17

a) endosseous maximal Ø	3.3 / 4.1 mm
b) endosseous length	11.5 - 21.5 mm
c) length micro thread	1.5 mm
d) platform Ø	4.8 mm
e) height head	3.9 mm
f) height of the apical thread	3.2
g) connecting part	2 mm

Description	max. nominal Ø / without apical thread	max. nominal Ø / with apical thread	endosseous length	REF
HC Plus MU 3.3 13 15°	3.3 mm	4 mm	13 mm	**13-412225**
HC Plus MU 3.3 15 15°	3.3 mm	4 mm	15 mm	**13-412226**
HC Plus MU 3.3 17 15°	3.3 mm	4 mm	17 mm	**13-412227**
HC Plus MU 3.3 19 15°	3.3 mm	4 mm	19 mm	**13-412228**
HC Plus MU 3.3 21 15°	3.3 mm	4 mm	21 mm	**13-412229**
HC Plus MU 3.3 23 15°	3.3 mm	4 mm	23 mm	**13-412230**
HC Plus MU 4.1 10 15°	4.1 mm	4.7 mm	10 mm	**13-412235**
HC Plus MU 4.1 13 15°	4.1 mm	4.7 mm	13 mm	**13-412236**
HC Plus MU 4.1 15 15°	4.1 mm	4.7 mm	15 mm	**13-412237**
HC Plus MU 4.1 17 15°	4.1 mm	4.7 mm	17 mm	**13-412238**
HC Plus MU 4.1 19 15°	4.1 mm	4.7 mm	19 mm	**13-412239**
HC Plus MU 4.1 21 15°	4.1 mm	4.7 mm	21 mm	**13-412240**
HC Plus MU 4.1 23 15°	4.1 mm	4.7 mm	23 mm	**13-412241**

Description	Code	REF
Insertion tool incl. screw REF 418316. For Hexacone Plus MU.	**IT HCMU**	**13-418315**
Ratchet for all hex instruments and insertion tools	**RAT2**	**13-425051**
Torque wrench 10 - 70 Ncm. **It is recommended to have the torque ratchets recalibrated by us once a year.**	**TW2**	**13-425402**

ACCESSORIES FOR KOC MU, BECES MU AND HEXACONE® PLUS MU

Description		Code	REF
Insertion tool short. Total length 10,8 mm For RAT 2	Use Hex instrument for screw tightening	IT1 MU 15	13-418166
Insertion tool medium. Total length 23,8 mm Use with IT ITV (REF 500854)		IT2 MU15	13-418201
Insertion tool long. Total length 33,8 mm Use with IT ITV (REF 500854)		IT3 MU15	13-418202

Insertion tool for KOC MU, BECES MU & Hexacone Plus MU 15°. Use with IT2 BECES, IT2 S BECES, AHB. Tool: HT 1.25	ITX MU15	13-418203

Insertion tool medium, for large head. Use with RAT2 and TW2. Length 19 mm	IT2 BECES	13-900030

Insertion tool short, for large head. Use with RAT2 and TW2. Length 7 mm	IT2 S BECES	13-900038

Adapter for implants > Ø 5.5 mm, fits the handgrip, REF 13-311430 / 13-311431 / KOC X, KOC XB	AHB	13-900037

Parts for passive connection of the bridge frame

Prosthetic screw for KOC® MU and BECES® MU	SF K MU	13-418164
Castable abutment for use with T-Base and SF K MU	PA2 MU	13-418189
Titanium base Use with SF K MU (REF 418164)	T-Base MU	13-418188

Parts for UCLA technique

Prosthetic screw for KOC® MU and BECES® MU	SF K MU	13-418164
Castable abutment UCLA for direct use on MU-implants. SF K MU sold separately	PA MU	13-418119

Part for UCLA technique & passive connection

Lab analogue for MU-implants	IA K MU	13-418159

Long screw for prosthetic use or as pick-up screw for use with HLT MU (Tool: HT 1.25). Material Ti6Al4V	Works with all MU implants	SFL MU	13-418168
Transfer Coping (Temporary base) SF K MU or SFL MU must be ordered separately		TC MU	13-418161
Transfer for pick-up impressions, straight. Delivery incl. SFL MU		HLT MU	13-418162

Description		Code	REF
Hex-instrument 1.25, length 14 mm	short	HTS 1.25	13-425101
Hex-instrument 1.25, length 21 mm	medium	HT 1.25	13-425100
Hex-instrument, length 45 mm	long	HTX 1.25	13-425102

ACCESSORIES FOR HEXACONE® PLUS MU (**0°**)

Description	Code	REF
Insertion tool incl. screw REF 418316. For Hexacone Plus MU.	**IT HCMU**	**13-418315**
Ratchet for all hex instruments and insertion tools	**RAT2**	**13-425051**
Torque wrench 10 - 70 Ncm.	**TW2**	**13-425402**

It is recommended to have the torque ratchets recalibrated by us once a year.

HEATLESS® DRILLS FOR HEXACONE® PLUS MU IMPLANTS

-55% Heat

Surgical steel, color-coded, depth-coded and autoclavable. The drill is marked with laser depth markings. Drill stops may be used.
Use between 3,000 and 5,000 rpm with good cooling and intermittent drill technique.
Due to the extremely high cutting performance, you can work without pressure. Drill types DFN 3.0 - DFN 4.2-4.5.

	Ø working range	max. working depth	total length	color code	Code	REF
	0.1 - 1.5 mm	15 mm	31.7 mm	yellow	**BCD 1**	**13-900240**
	0.1 - 1.5 mm	15 mm	42 mm	yellow	**BCDX 1**	**13-900243**
	2.0 mm	17 mm	36.5 mm		**DS 2**	**13-425001**
	2.8 mm	17 mm	36.5 mm		**DS 2.8**	**13-425005**
	2.7 mm	18 mm	36 mm		**DFN 3.0**	**13-425030**
	3.0 mm	18 mm	36 mm		**DFN 3.4**	**13-425031**
	3.4 mm	18 mm	36 mm		**DFN 3.7**	**13-425032**
	3.5 mm	18 mm	36 mm		**DFN 4.1**	**13-425049**
	2.7 mm	18 mm	39 mm		**DFLN 3.0**	**13-425035**
	3.0 mm	18 mm	39 mm		**DFLN 3.4**	**13-425036**
	3.4 mm	18 mm	39 mm		**DFLN 3.7**	**13-425037**
	max. 3.7 mm	2.5 mm	27 mm		**C Drill 3.7**	**13-425043**
	max. 4.1 mm	2.5 mm	27 mm		**C Drill 4.1**	**13-425050**

IT HAS BEEN SCIENTIFICALLY PROVEN

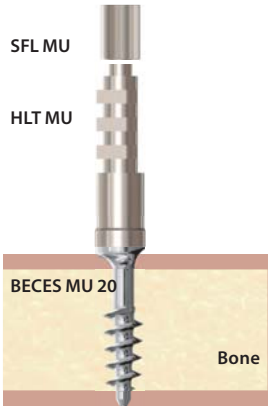
that **Heatless® Drills generate 55% less heat** compared to traditional bone drills ofother manufacturers. This enables higher rotational speeds:
We recommend between 3.000 and 5.000 RPM with good external cooling and intermittent drill technique.

APPLICATION OF SINGLE-PIECE MULTIUNIT IMPLANTS

1.

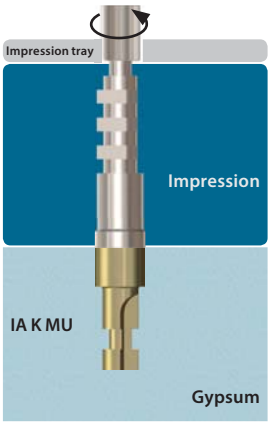
Tighten screw SFL MU with the tool HT 1.25.

Fix the transfer with the long screw, then take pick-up-impression.



2.

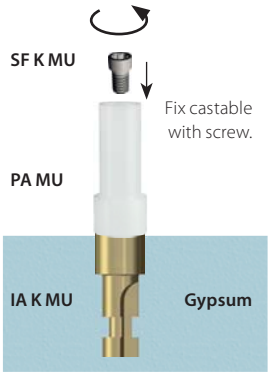
Connect the transfer to the implant analogue (IA K MU) and pour the impression with gypsum.



3. a

Connect PA MU with SF K MU on the analogue IA K MU. Tighten screw SFL MU with the tool HT 1.25.

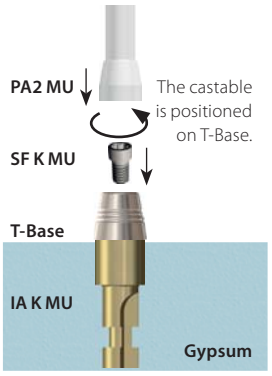
Now the modulation can be created and the frame is veneered. Veneering is possible with acryl, composite and ceramics.



3. b

T-Base is positioned over the analogue and screwed on with SF K MU. The castable PA2 MU is then fitted on top of the T-Base.

Now the modulation is made. Veneering is possible with acryl, composite and ceramics.



4.

T-Base is sandblasted **from the outside** and cleaned.

The bridge frame is sandblasted **from below in the area of the implants**.

5.

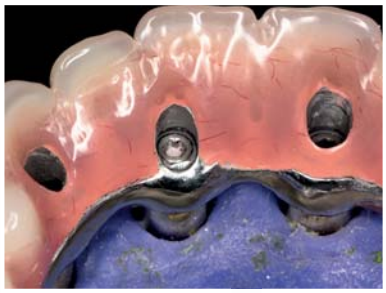
All T-Bases are fixed to the implants with SF K MU or the long screw SFL MU. Then all T-Base are glued with adhesive cement for passive fit.

Composite excess is removed and the site is polished.

6.

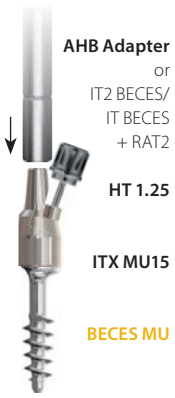
Now the bridge may be screwed on passively with SF K MU.

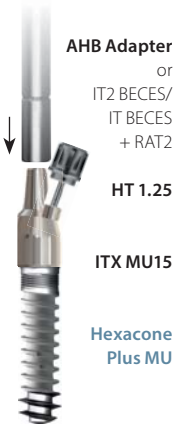
Screw canals are closed with temporary filling material or composite, taking into consideration that later access must be possible.



Application
of the insertion tool MU

Example for insertion tool ITX MU15 on the implant BECES® MU / KOC® MU and Hexacone Plus MU.





SIMPLADENT®

MANUFACTURER'S INFORMATION regarding the preparation of resterilisable medical devices complies with EN ISO 17664

Please read carefully!

SIMPLADENT GmbH resterilisable medical products are:
- Instruments for operating abutments and screws
- Instruments for determining the insertion torque (torque control) and ratchets
- Instruments for preparing endosseous bone cavities (drills, cutters)
- Bone expansion screws and distractors
- Drill guide sleeves
- Abutments and screws, provided they do not remain in / with the patient between individual treatment appointments and are not used on other patients. They should be stored by the operator between the treatment appointments, e.g. together with the patient's file.
- Manual instruments for the placement of implants and bone preparation.

Reusability
Frequent reconditioning has no effect or restriction on the products mentioned above, as the end of the product service life is determined by wear and damage due to use. The operator is responsible for the use of damaged and contaminated instruments. Liability is excluded if disregarded.

Legal bases
The following legal bases, regulations and recommendations are applied with regard to the products mentioned above: (Germany)
- Medizinprodukt gesetz MPG (Medical Devices Act)
- Medizinprodukt – Betreiberverordnung (Medical Device – Operator Ordinance)
- Bundesgesundheitsblatt (Federal Health Gazette) 2001 : 44: 1115-1126

Hygiene requirements for the processing of medical devices (Recommendation of the Commission for Hospital Hygiene [Kommission für Krankenhaushygiene] at the Robert-Koch Institute and the Federal Ministry for Drugs and Medical Devices [Bundesministeriums für Arzneimittel und Medizinprodukte]).

Legal information:
Implants and components of the COI/Diskos system should only be used and operated by users with valid authorisation pursuant to § 2 Medizinprodukte- BetreibV (Medical Devices Operator Ordinance). This also applies to the consultation of patients who have had implants placed or patients who are to have implants placed.

General principles
All reusable products must be cleaned, disinfected and sterilised before each use; this also applies to the initial use of products that are supplied nonsterile. Efficient cleaning and disinfection is essential for effective sterilisation. Special cleaning / sterilisation instructions should be obtained from the instructions for use. The operating instructions of the practice units must also be observed. As the operator is responsible for the sterility of instruments during use, please ensure that only adequate, validated parameters specific to the unit and product are constantly maintained during each cycle. Please also observe all valid legal and hygiene regulations of the dental practice and dental hospital.
This applies in particular to the different guidelines regarding effective prion inactivation. Important: Always wear protective gloves for your own safety when handling contaminated instruments!
- Instruments made from different materials should never be disinfected, cleaned or sterilised together. This also applies when using an ultrasonic cleaner.
- During mechanical cleaning, instruments should be arranged so that they cannot come into contact, as otherwise there is the risk of damage.
- Multi-part instruments such as ratchets, trephine drills, screw-drivers etc. should be disassembled into their component parts and these should be individually disinfected, cleaned or sterilised.
- These instruments should also be stored disassembled until the next use.

Care instructions of surgical steel instruments
Surgical steel instruments can quickly become damaged with inadequate or incorrect care. Only commercially available solvents should be used for surgical steel; if in doubt contact **SIMPLADENT GmbH**.
The following are not recommended:
- Disinfection/cleaning agent with a high chlorine content
- Disinfection/cleaning agent with a high oxalic acid content

The following are not recommended for instruments with colour coding
- Too high solvent concentrations, disinfection / cleaning agent with the ingredients mentioned above
- Too high temperatures with mechanical cleaning and sterilisation; never higher than 135 °C

Conditioning
Coarse impurities must be removed from the products immediately after use (within 1-2 hrs maximum). Surgical residue (blood, secretions, tissue residue) should not be allowed to dry on the products. Instruments should be placed in a disinfectant solution immediately after surgery. For temporary storage and pre-disinfection/ cleaning immediately after use on patients the instruments can be placed in an interim stand filled with a suitable cleaning / disinfection agent. Contamination should then be cleaned from the instru-ments under running water or in a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood and contamination), have proven efficacy (e.g. DGHM [German Society for Hygiene and Microbiology] / FDA approved and CE Mark), be suitable for instrument disinfection and compatible with the instruments (see Section "Material compatibility"). Follow the disinfectant instructions for use. For manual removal of contamination use only a clean, soft brush or a clean soft cloth which is used specifically for this purpose. Never use metal brushes or steel wool.
- Please note that the disinfectant used for conditioning is only for personal protection and cannot replace the subsequent disinfection step to be performed after cleaning.
- Never allow instruments to remain wet or moist for a longer period of time.
- Corroded, rusty instruments must be cleaned in an ultrasonic cleaner.
If the corrosion cannot be removed, the instrument should be discarded and may no longer be used.

- Encrustations must be thoroughly removed using nylon brushes.
- Encrusted blood can also be dissolved using hydrogen peroxide 3%
- Instrument disinfectant residues can be removed by rinsing several times with water.

Cleaning / Disinfection
Ensure when using products for cleaning and disinfection

- that the products are basically suitable for the cleaning and disinfection of instruments
- that the cleaning and disinfection agent – if applicable – is suitable for ultrasonic cleaning (no foaming)
- that a cleaning and disinfection agent with proven efficacy (e.g. DGHM or FDA approved and CE Mark) is used
- that the chemicals used are compatible with the instruments; alkaline cleaning solutions should be preferred. A prerequisite for the use of a combined cleaning / disinfection agent is very low bacterial preloading (no visible contamination) due to effective pre-cleaning of the instruments. The concentrations and reaction times given by the manufacturer of the cleaning-disinfection agent must be strictly adhered to.

Use only freshly mixed solutions, sterile or low-bacteria (max. 10 germs / ml) and low-endotoxin (max. 0.25 endotoxin units / ml) water (e.g. aqua valde purificata) and only filtered air for drying. Instruments that cannot be autoclaved must be disinfected before each use.

Process: Cleaning and disinfection

Automatic cleaning in a cleaning and disinfection unit in combination with the cleaning agent recommended by the unit manufacturer.

Procedure:
Insert the instruments so that the liquid can flow out of the drain tubes and blind holes. Set the cycle and adhere to the unit manufacturer's wash and rinse times. The cleaned components should be examined for visible dirt when removing the instruments. If necessary, repeat the cycle or clean manually.

Manual cleaning
1. Thoroughly clean disinfection / cleaning agent from the instruments by rinsing them with water and, if required, with the aid of a soft nylon brush.
Ultrasonic cleaner: Place the components in a basket, avoid acoustic shadows. Add an enzymatic cleaning agent to the water and clean the components at a temperature of 40 - 50 °C in the ultrasonic cleaner (35-40 kHz) for 3 minutes.
Ensure that the components are immersed completely in the water without bubbles.
2. Then remove the instruments from the cleaning solution and rinse them thoroughly (minimum 1 min.) under running water. Use fully desalinated water for this stage, if possible.
3. Then dry the instruments with compressed air
4. Check the instruments visually and repeat the cleaning stage, if necessary.
5. Pack the instrument as soon as possible after removal (see Section "Packaging", if necessary after drying again at a clean location).
6. Document the approval.

Mechanical cleaning
Cleaning, disinfection and drying in accordance with DIN EN ISO 15883-1 2006 and DIN EN 15883:2006
Pre-cleaning: Place the disassembled instruments in cold water for 5 minutes. Then brush the disassembled instruments with a soft nylon brush under water to remove coarse impurities.
Mechanical cleaning: e.g. using the Miele 8535 CD unit at 55 °C for 5 minutes (programme Vario TD) with an enzymatic cleaner.

Important points
- All instruments must be sterilised after cleaning.
- When sterilising multi-part instruments in an autoclave without a drying programme, it is essential that the instruments are always sterilised in a disassembled state!
- The instruments should always be checked for corrosion after sterilisation.
- The scaling of the instruments must still be visible after sterilisation; otherwise the instruments should be replaced.
- New instruments must be cleaned and sterilised without packaging before using for the first time.
- Preparation of all instruments with cavities is particularly critical. This applies especially to internally cooled drills, placement aids and instruments with blind holes. As the water supply cavity cannot be checked with internally cooled drills and bone chips and debris could be carried from patient to patient, we recommend using these instruments as single-use products only or using them exclusively on one patient. With all other instruments it must be ensured that the cavities are completely clean. Multi-part placement aids should be disassembled for cleaning, if possible.

Control
Check all instruments after cleaning and cleaning / disinfection for corrosion, damaged surfaces, chipping, damage to the shape (e.g. bent and non-concentric running instruments, damaged or blunt blades) as well as contamination and discard any damaged instruments. Instruments that are still contaminated must be cleaned and disinfected again. Then check the function and integrity of the instruments. It is not necessary to apply care products (e.g. oil) to instruments and abutments or screws.

Special aspects to observe with drills and cutters
Use cutting instruments for a maximum of 10 times.
Thoroughly check these instruments after each use for cleanliness (including the internal cooling sections in particular) and the sharpness of the blades. The wear of bone drills depends on the hardness of the bone at the site. If in doubt, drills should only be used once. There is a considerable loss of cutting performance if the tip is damaged. To ensure care of the drills it is therefore essential to observe the following points:
- During the operation drills should be placed gently in the storage tray, which can be filled with physiological saline solution. Drills should not be kept in the physiological saline solution for longer than 1 hour to avoid corrosion.
- Never drop the drills directly on the tip
- The drills should not come into contact during ultrasonic cleaning

Packaging
Sort out the instruments in the sterilisation tray and then pack them in single-use sterilisation packaging (single or double packaging) and / or sterilisation container, which
- complies with DIN EN 868-2ff/DIN EN ISO/ANSI AAMI ISO 11607
- is suitable for steam sterilisation (temperature resistant up to min. 137 °C (279 °F), adequate steam permeability)
- provides adequate protection of the instruments and sterilisation packaging against mechanical damage
- is regularly serviced according to the manufacturer's instructions
- (sterilisation container)

Sterilisation

Method:	Fractional pre-vacuum procedure (according to ISO 17665 or ISO 13060), in a unit that complies with EN 285
Temperature:	Heat to 132 °C; max. 137 °C
Pressure:	3 pre-vacuum stages with min. 60 millibar pressure
Hold time:	minimum 3 min. at 132 °C
Drying time:	minimum 10 min.

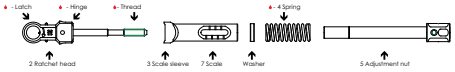
Check the sterile instrument packaging for damage after sterilisation, check the sterilisation indicators.
To avoid staining and corrosion the steam must not contain any ingredients.
The disinfectant therefore has to have been thoroughly removed. The recommended threshold limits of the ingredients for drinking water and steam condensate are specified in EN 285.
Sterilisation using hot-air sterilizers and / or glass bead sterilizers is not advised, as the high temperatures blunt the cutting surfaces of the drills.
Instruments should be sterilised in the trays recommended by the autoclave manufacturers if there is not a system-specific instrument tray available.

Storage
After sterilisation, the instruments must be stored dry and dust-free in the sterilisation packaging. The instruments should also be protected against sunlight and heat. The maximum storage period (expiry date) depends on several factors and must be determined and validated by the user.

Information on handling multi-part instruments:
Multi-part instruments must be disassembled before sterilisation. Please note the schematic diagram below.
RAT2: Unscrew the cover screw and remove the push-rod. The push-rod and ratchet housing (inner and outer) must be thoroughly cleaned and then dried. The individual components of the ratchet are shrink-wrapped together in a sterilisation bag and sterilised. Ensure that the paper side of the sterilisation bag is placed so that the water vapour can escape and that the ratchet or its parts are not lying in water. After sterilisation, - generally just before the beginning of implant placement, the ratchet should be thinly lubricated using a silicone oil and reassembled. The function of the ratchet should then be checked before beginning surgery.

Schematic diagram of the TW/TW2 torque wrench

- After use the instrument should be disassembled into its individual parts – no tool is required for disassembly.



- Pre-clean the individual parts under running cold water using a soft brush. Do not allow blood residue and other adhering deposits to dry on the components.

Schematic diagram of the RAT2 ratchet

- After use the instrument should be disassembled into its individual parts – no tool is required for disassembly.

- Pre-clean the individual parts under running cold water using a soft brush. Do not allow blood residue and other adhering depositsto to dry on the components. The ratchet should be autoclaved in the disassembled state and reassembled immediately before use.

Schematic diagram of the handle REF 13-311430 (can be disassembled)

- After use the instrument should be disassembled into its individual parts – no tool is required for disassembly.

- Pre-clean the individual parts under running cold water using a soft brush. Do not allow blood residue and other adhering deposits to dry on the components. The handle should be autoclaved in the disassembled state and reassembled immediately before use.

Schematic diagram of the handle REF 13-311431 (cannot be disassembled)

- Pre-clean the instrument under running cold water using a soft brush. Do not allow blood residue and other adhering deposits to dry on the handle. The handle should be thoroughly cleaned manually using an ultrasonic cleaner before mechanical cleaning.
- Manual cleaning including ultrasonic cleaner (see above) and mechanical cleaning should be performed in sequence.

Warnings
We do not know of any warnings, provided the instructions for use are followed for the products to be used as well as the corresponding disinfection and cleaning agent.

SIMPLADENT GmbH reserves the right to change the design of the products and components or their packaging, adapt instructions for use as well as renegotiate prices and delivery conditions. Liability is limited to the use of defective products. Any further claims are excluded.

Further information about the preparation of medical products is available in the Internet at www.rki.de or www.a-k-i.org.

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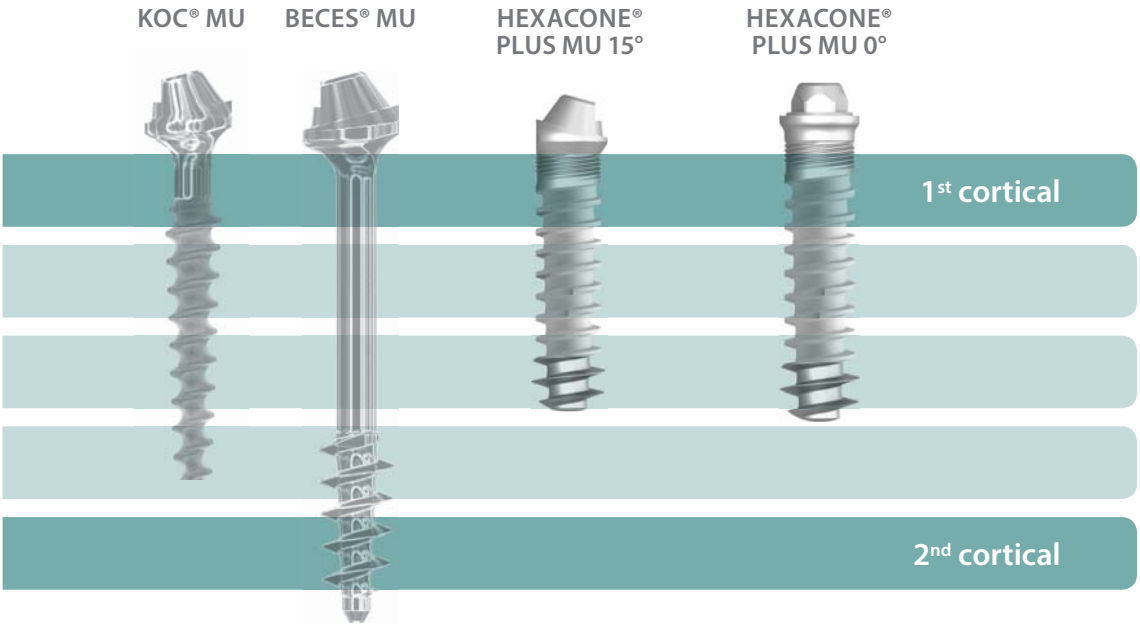
Legend

	Read instructions
	Expiration date
STERILE R γ	Gamma-sterilized
2	Only use once
2 STERILIZE	Do not resterilize
NON STERILE	Non sterile
REF	Catalogue number
LOT	LOT Charge number
	Keep in a dry place
	Store tightly keep closed
-5 °C 25 °C	Temperature range from -5 °C to 25 °C
	Do not use if packing is damaged
	Manufacturer

13-0001-03_V002



4 IMPLANTS - 1 PLATFORM

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SIMPLADENT®

Strategic Implant® may be inserted and serviced only by qualified personnel with valid authorization by the manufacturer (pursuant to legislation on the installation, use and maintenance of medical devices). See http://implantfoundation.org/en/consensus-papers
We are certified DIN EN ISO 13485.
The product dimensions shown in this catalogue differs from the reality. Changes may also occur because and the product has been further developed.
In case that used or non-sterile implants would be reprocessed (cleaned, resterilized) infections could occur, because no validated procedures for reprocessing implants are available in the dental office.

CE 1936

Symbols on the pack:

REF	LOT	STERILE R	STERILE	Rx ONLY	2	
Catalogue No.	Production No.	Sterilized by gamma radiation	Non-sterile	Intended for use by dentists or surgeons only	Single use product	Instruction for use
		25° C / -5° C			2 STERILIZE		
Expiry date	Store in a dry place	Temperature range from -5° C to 25° C	Store tightly keep closed	Do not use if packing is damaged	Do not resterilize	Manufacturer	Production date

REF Single_piece_MU_SAP_EN_V0022-04/17

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