Surgical Manual

SL Tapered
Implant System

MCImplants
DENTAL IMPLANT SYSTEM

Contents

Introduction

The components of the MCI implant system are medical devices that always meet the highest standards of safety and comfort. Each individual implant and instrument undergoes rigorous inspection after production. MCI products are manufactured exclusively in Germany. MCI GmbH is CE-certified by MED_CERT according to ISO 13485 and Annex II of Directive 93/42/EEC.

Attention:

Before using the surgical set, training should be provided by the manufac turer. Instruments are delivered non-sterile. Reprocessing before first use is mandatory! The information in the instructions for use for implants must be observed!

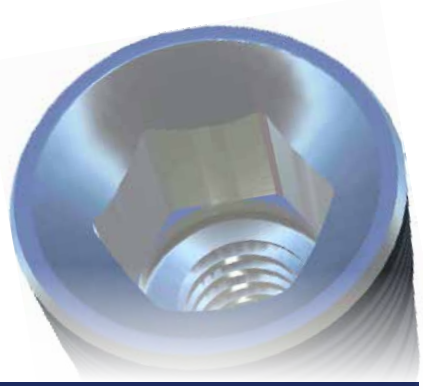
The MCI implant system offers three different implant configurations: the MCI SLS Straight Implant (parallel-walled), the MCI SL Tapered Implant (root-shaped), and the MCI Soft-Bone Implant. Each implant has the same prosthetic connection for each diameter. MCI also offers a reduced-diameter Straight & Tapered Implant and a one-piece mini-ball head implant (see separate instructions).

MCI SLS Straight, SL Tapered, and Soft-Bone implants are available in six diameters. Uniform color coding simplifies diameter identification:

Silver/White	implant diameter 2.7	(mini ball head implant)
Yellow	implant diameter 3.3	(S&T implant)
Black	implant diameter 3.8	
Grey	implant diameter 4.1	
Blue	implant diameter 4.5	
Magenta	implant diameter 5.5	

The hexagon socket connection has proven itself to be extremely effective in over 30 years of clinical experience.

Optimal prosthetic stability and a precise fit facilitate the placement of impression posts and abutments. The beveled neck area ensures even distribution of occlusal forces, prosthetic stability, and bacterial resistance.* The internal connection provides perfect control during the placement of abutments.



Contraindications
The contraindications to surgery must be taken into account.

* Certificate dated 28 October 2008

	S&T Implant **Ø 3.3** Lengths: 10/11.5/13/14.5	The S&T implant is a reduced diameter implant with a conical universal shape and is designed for use in cases of reduced bone availability or confined space.	Proven blasted and etched surface
	**SLS STRAIGHT** **Ø 3.8** Lengths: 8/10/11.5/13/14.5mm **Ø 4.1** Lengths: 8/10/11.5/13/14.5mm **Ø 4.5** Lengths: 8/10/11.5/13/14.5mm **Ø 5.5** Lengths: 8/10/11.5/13mm	The universally applicable SLS Straight implant features a double-threaded fine thread with a raised surface in the neck area. This increases the contact between the bone and the implant.	Proven blasted and etched surface
	**SL Tapered** **Ø 3.8** Lengths: 8/10/11.5/13/14.5mm **Ø 4.1** Lengths: 8/10/11.5/13/14.5mm **Ø 4.5** Lengths: 8/10/11.5/13/14.5mm **Ø 5.5** Lengths: 8/10/11.5/13mm	The conical SL Tapered implant with apical rounding features a double-pitch fine thread in the neck area, which provides improved primary stability with reduced residual bone height. The raised surface increases the contact between bone and implant. The SL Tapered implant is universally applicable.	Proven blasted and etched surface
	**SB Soft-Bone - Implant** **Ø 3.8** Lengths: 8/10/11.5/13/14.5mm **Ø 4.1** Lengths: 8/10/11.5/13/14.5mm **Ø 4.5** Lengths: 8/10/11.5/13/14.5mm	The Soft-Bone implant was specifically developed for use in structurally unfavorable bone conditions, but is also very suitable for universal use. Excellent primary stability is achieved through the newly designed macro-thread design.	Proven blasted and etched surface
	**MINI-Ballhead** **Ø 2.7mm** Lengths:10/11.5/13mm (nach apikal leicht konisch) Durchmesser des Kugelkopfes: 2.25mm	The mini ball head implant is a cost-effective implantological solution for the interforaminal area.	Proven blasted and etched surface

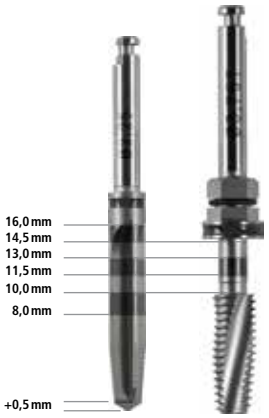
The MCI SL Tapered “Standard Line” Surgery Kit

The MCI SL Tapered "Standard Line" Implant System

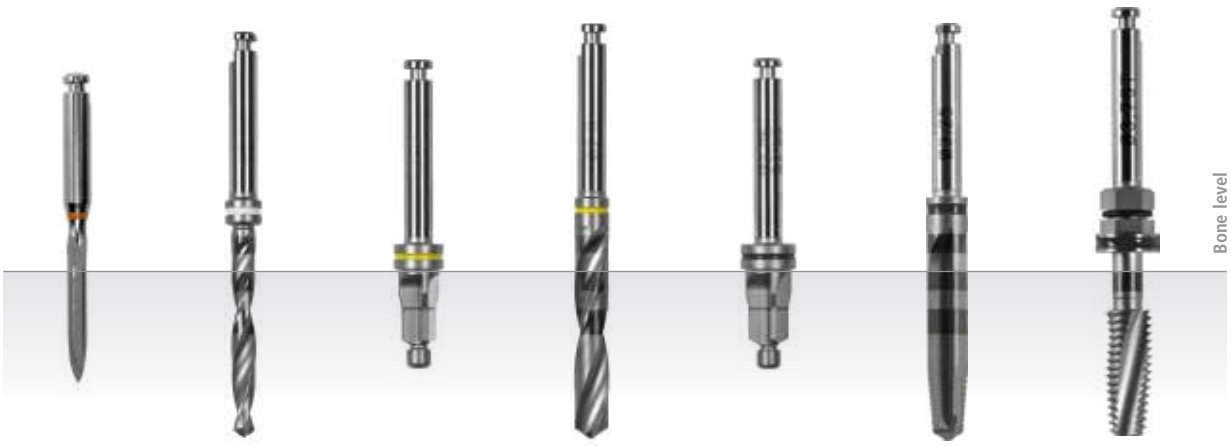
Guidelines for drilling and tapping

- The drilling speed should not exceed 800 rpm.
- For thread cutting, a speed of 20-30 rpm should be maintained.
- Always ensure adequate external cooling during drilling and thread cutting.
- Avoid laterally directed forces during drilling and thread cutting.
- When drilling the implant bed, apply light contact pressure and use forward and backward movements along the longitudinal axis of the implant.

Depth markings, tapered "Standard Line" drill



Drilling sequence for the SL Tapered Implant with depth marking drills example for an implant with a diameter of 3.8 mm and a length of 13 mm.



Step 1 | Step 2 | Step 3 | Step 4 | Step 5 | Step 6 | Step 7 (D1 & D2 bone)

Step 1 – The first drilling (initial drill) is used to pre-punch and determine the position of the implant.

Step 2 – The implant bed is prepared with the 2.0 mm twist drill (white) to the corresponding depth marking. The lasered depth markings correspond to the lengths of the implants (see above). After drilling the 2.0 mm (white) and 3.3 mm (black) holes, the parallel pins can be used for X-ray control or to orient the direction or parallelism.

Step 3 – The countersink (yellow) for 3.3 mm is countersunk to the depth stop. This prepares the seat for the implant shoulder and provides optimal guidance for the subsequent drill.

Step 4 – Using the 3.3mm (Ø2.8mm) twist drill (yellow), the implant bed is prepared to the corresponding depth marking. The lasered depth markings correspond to the lengths of the implants (see above).

Step 5 (Note the additional information for the indication of sinus lift!) – The countersink (black) for 3.8 mm is countersunk completely to the depth stop in hard bone (D1-D3), and only to the laser mark in soft bone (D4) and for sinus lift indications. This prepares the seat for the implant shoulder and provides optimal guidance for the subsequent 3.3 mm drill.

Step 6 – Using the 3.8mm (Ø3.3mm) depth drill (black), the implant bed is prepared to the corresponding depth marking. The lasered depth markings correspond to the lengths of the implants (see above). After drilling the Ø2.0mm (white) and Ø3.3mm (black) holes, the parallel pins can be used for X-ray control or to orient the direction or parallelism.

Step 7 – The implant threads are self-tapping. The following procedure for using the 3.8 mm thread tap is recommended for each bone quality:

D1 & D2:	Tapping!
D3:	Tapping is at the surgeon's discretion!
D4:	Tapping is not recommended!

Machine application:
Insert the tap into the prepared implant bed and initially apply light pressure (20-30 rpm) using a geared contra-angle handpiece with high torque (do not exceed 45 Ncm in the contra-angle handpiece; higher torque is also possible with the ratchet). Once the cutting edges engage, the tap should be allowed to retract automatically into the implant bed without additional pressure. The tap should be sunk exactly to the corresponding depth mark. The tap is rotated out of the bone at the same speed. The depth marks correspond to the lengths of the implants (see above).

The following instruments are available for manual application of the tap, although the use of the contra-angle handpiece is recommended for precise torque control:

Handwheel
torque wrench
Ratchet adapter for the torque wrench

The detailed drilling sequence for implant diameters 3.3 / 3.8 / 4.1 / 4.5 / 5.5 can be found in Appendix 1 of the surgical instructions on pages 14/15.

The MCI SL Tapered “Safety Stop Line” Surgery Kit

The MCI SL Tapered "Safety Stop Line" Implant System

Guidelines for drilling and tapping

- The drilling speed should not exceed 800 rpm.
- For threading, the speed should be set to 20-30 rpm.
- Always ensure adequate external cooling when drilling and threading.
- Avoid laterally directed forces when drilling and threading.
- When drilling the implant bed, apply light contact pressure and use forward and backward movements along the longitudinal axis of the implant.

Depth markings SL Tapered "Safety Stop Line" drills and taps

Removing the depth stop

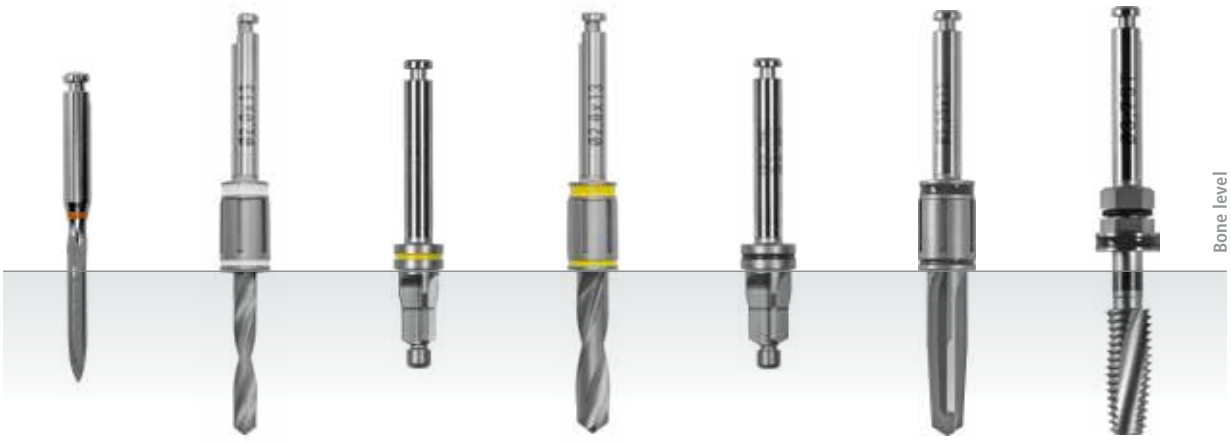
Reasons:

A) If the bone level varies, it is recommended to pull the depth stop towards the drill tip and to orient yourself using the laser-etched depth marking.

B) Every time you clean the drill (see Appendix 3 for cleaning details).

Pull the depth stop towards the drill tip

Drilling sequence for the SL Tapered Implant with „Safety Stop" drills using an implant with a diameter of 3.8 mm and a length of 13 mm.



Step 1 | Step 2 | Step 3 | Step 4 | Step 5 | Step 6 | Step 7 (D1 & D2 bone)

Step 1 – The first drilling (initial drill) is used to pre-punch and determine the position of the implant.

Step 2 – Using the Ø2.0mm twist drill (white) of the planned implant length, the implant bed is prepared until the depth stop is reached. If the bone level varies, it is recommended to pull the depth stop toward the drill tip and use the lasered depth marking as a guide. (See „Removing the Depth Stop" on page 9.) After drilling the Ø2.0mm (white) and Ø3.3mm (black) holes, the parallel pins can be used for X-ray control or to orient the drill direction or parallelism.

Step 3 – The 3.3mm countersink (yellow) is countersunk to the depth stop. This prepares the seat for the implant shoulder and provides optimal guidance for the subsequent 2.8mm drill (yellow).

Step 4 – Using the twist drill (yellow) for 3.3 mm (Ø2.8 mm) of the planned implant length, the implant bed is prepared until the depth stop is reached. If the bone level varies, it is recommended to pull the depth stop toward the drill tip and use the lasered depth marking as a guide. (See „Removing the Depth Stop" on page 9.)

Step 5 (Note the additional information for the indication of sinus lift!) – The 3.8 mm countersink (black) is countersunk completely to the depth stop in hard bone (D1-D3), and only to the laser mark in soft bone (D4) and for sinus lift indications.
This prepares the seat for the implant shoulder and widens the guide for the subsequent 3.3 mm drill (black).

Step 6 – Using the depth drill (black) for 3.8 mm (Ø3.3 mm) of the appropriate implant length, the implant bed is prepared until the depth stop is reached. If the bone level varies, it is recommended to pull the depth stop toward the drill tip and use the lasered depth marking as a guide. (See „Removing the Depth Stop" on page 9.) After drilling the Ø2.0 mm (yellow) and Ø3.3 mm (black) holes, the parallel pins can be used for X-ray control or to orient the implant to the direction or parallelism.

Step 7 – The implant threads are self-tapping. The following procedure for using the 3.8 mm tap (black) is recommended for each bone quality:

D1 & D2:	Tapping!
D2 & D3:	Tapping is at the surgeon's discretion!
D4:	Tapping is not recommended!

Application mechanically:
Insert the tap into the prepared implant bed and initially apply light pressure (20-30 rpm) using a geared contra-angle handpiece with high torque (do not exceed 45 Ncm in the contra-angle handpiece; higher torque is also possible with the ratchet). Once the cutting edges engage, the tap should be allowed to retract automatically into the implant bed without additional pressure. The tap should be sunk exactly to the corresponding depth mark. The tap is rotated out of the bone at the same speed. The depth marks correspond to the lengths of the implants (see above).

The following instruments are available for manual application of the tap, although the use of the contra-angle handpiece is recommended for precise torque control:

Handwheel
torque wrench
Ratchet adapter for the torque wrench

The detailed drilling sequence for diameters 3.3 / 3.8 / 4.5 / 5.5 can be found in Appendix 2 of the surgical instructions on pages 16/17.

Implant insertion

Preparation:

1) Non-sterile assistance
Remove the double blister (plastic packaging with implant) from the color-coded outer packaging.

(Unsterile assistance)

(Unsterile assistance)

2) Unsterile assistance
Open the outer blister and drop the sterile inner blister containing the implant onto the sterile tray. The sterile inner blister must not be touched by the non-sterile assistant under any circumstances!

(Unsterile assistance)

3) Sterile assistant / surgeon
Opening of the inner packaging by the sterile assistant or the surgeon

(Sterile assistance / Surgeon)

4) Surgeon
Remove the implant from the inner blister using the handle. Do not touch the implant or allow it to come into contact with other objects.

(Surgeon)

5) Surgeon
Insert the implant into the implant bed using the handle. Once initial primary stability is achieved in the bone (Caution: Do not twist the handle while it is in the implant), pull the handle upward and remove it. Note the cover screw located on the back of the handle (see page 16).

(Surgeon)

6) Surgeon
The implant can be inserted with the implant driver that matches the diameter (short for the posterior area or long for the anterior area) and:

A) The angle piece (Recommended for torque control!)
The angled handpiece must have a gear ratio (e.g., 20:1) and must not exceed a speed of 20-30 rpm!
B) The ratchet
With or without attached ratchet adapter
C) The attached handwheel

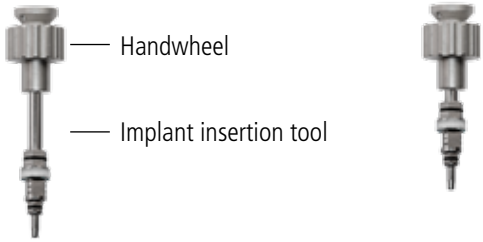
The implant is countersunk flush with the bone following the described drilling sequence.

The insertion torque of the implant into the bone must not exceed 50 Ncm, regardless of the instrumentation selected! The implant should be inserted at a speed of 20-30 rpm.

6A

6B

6C



Implant insertion tool

The cover screw is located in the plastic handle of the implant. Insert the hand screwdriver (short or long) into the hexagon of the cover screw and unscrew it to the left. Screw the cover screw into the implant to the right. (Fig. 1)

Healing phase
A non-loading healing period of at least 3 months in the lower jaw and 5-6 months in the upper jaw is recommended. The duration depends on bone quality, the indication, and the healing process and is the responsibility of the surgeon/treatment provider.

Implant exposure (second procedure)
During exposure, after opening the gingiva, the cover screw is unscrewed to the left. The manual screwdriver is inserted into the hexagon of the gingiva former and screwed to the right into the implant.

The displayed gingiva formers are recommended (see Fig. 2)!

(Fig. 1)

(Fig. 2)

Drilling sequence for the “Standard Line” implant system

SL Tapered Implants:

3.3

1) Initial drill (pre-punching of the implant position)

2) Twist drill (white) 2.0mm to the desired depth mark

3) Countersink (yellow) for 3.3mm :
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

4) Twist drill (yellow) for 3.3mm (Ø2.8mm) to the desired depth mark

5) Tap (yellow) for 3.3mm
(use for D1 bone quality!)
(not recommended for D4 bone quality!)

3.8

1) Initial drill (pre-punching of the implant position)

2) Twist drill (white) 2.0mm to the desired depth mark

3) Countersink (yellow) for 3.3mm (sink completely to depth stop)

4) Twist drill (yellow) for 3.3mm (Ø2.8mm) to the desired depth mark

5) Countersink (black) for 3.8mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

ATTENTION: If sinus lift is indicated, only lower up to the laser marking!

6) Depth drill (black) for 3.8mm (Ø3.3mm) to the desired depth mark

7) Tap (black) for 3.8mm
(**apply** for **D1** and **D2** bone quality!)
(**not recommended** for **D4** bone quality!)

4.1

1) Initial drill (pre-punching of the implant position)

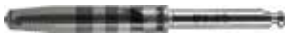
2) Twist drill (white) 2.0mm to the desired depth mark

3) Countersink (yellow) for 3.3mm (sink completely to depth stop)

4) Twist drill (yellow) for 3.3mm (Ø2.8mm) to the desired depth mark

5) Countersink (black) for 3.8mm (sink completely to depth stop)

6) Depth drill (black) for 3.8mm (Ø3.3mm) to the desired depth mark



7) Countersink (Gray) for 4.1mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

ATTENTION: If sinus lift is indicated, only lower up to the laser marking!

8) Depth drill (grey) for 4.1mm (Ø3.7mm) to the desired depth mark

9) Tap (grey) for 4.1mm
(**apply** for **D1** and **D2** bone quality!)
(**not recommended** for **D4** bone quality!)

4.5

1) Initial drill (pre-punching of the implant position)

2) Twist drill (white) 2.0mm to the desired depth mark

3) Countersink (yellow) for 3.3mm (sink completely to depth stop)

4) Twist drill (yellow) for 3.3mm (Ø2.8mm) to the desired depth mark

5) Countersink (black) for 3.8mm (sink completely to depth stop)

6) Depth drill (black) for 3.8mm (Ø3.3mm) to the desired depth mark

7) Countersink (grey) for 4.1mm (sink completely to depth stop)

8) Depth drill (grey) for 4.1mm (Ø3.7mm) to the desired depth mark

9) Countersink (Blue) for 4.5mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

ATTENTION: If sinus lift is indicated, only lower up to the laser marking!

10) Depth drill (blue) for 4.5mm (Ø4.2mm) to the desired depth mark

11) Tap (blue) for 4.5mm
(**apply** for **D1** and **D2** bone quality!)
(**not recommended** for **D4** bone quality!)

5.5

1) Initial drill (pre-punching of the implant position)

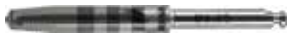
2) Twist drill (white) 2.0mm to the desired depth mark

3) Countersink (yellow) for 3.3mm (sink completely to depth stop)

4) Twist drill (yellow) for 3.3mm (Ø2.8mm) to the desired depth mark

5) Countersink (black) for 3.8mm (sink completely to depth stop)

6) Depth drill (black) for 3.8mm (Ø3.3mm) to the desired depth mark



7) Countersink (grey) for 4.1mm (sink completely to depth stop)

8) Depth drill (grey) for 4.1mm (Ø3.7mm) to the desired depth mark

9) Countersink (blue) for 4.5mm (sink completely to depth stop)

10) Depth drill (blue) for 4.5mm (Ø4.2mm) to the desired depth mark

11) Countersink (purple) for 5.5mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

ATTENTION: If sinus lift is indicated, only lower up to the laser marking!

12) Depth drill (purple) for 5.5mm (Ø5.2mm) to the desired depth mark

13) Tap (purple) for 5.5mm
(**apply** for **D1** and **D2** bone quality!)
(**not recommended** for **D4** bone quality!)

Drilling sequence for the “Safety Stop Line” implant system

SL Tapered Implants:

3.3

1) Initial drill (pre-punching of the implant position)

2) Twist drill (white) 2.0mm, sink to depth stop

3) Countersink (yellow) for 3.3mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

4) Sink the 3.3mm (Ø 2.8mm) twist drill to the depth stop

5) Tap (yellow) for 3.3mm
(**apply** for **D1** bone quality!)
(**not recommended** for **D4** bone quality!)

3.8

1) Initial drill (pre-punching of the implant position)

2) Sink twist drill (white) 2.0mm to depth stop

3) Countersink (yellow) for 3.3mm (sink completely to depth stop)

4) Sink the 3.3mm (Ø 2.8mm) twist drill to the depth stop

5) Countersink (black) for 3.8mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

ATTENTION: If sinus lift is indicated, only lower up to the laser marking!

6) Depth drill (black) for 3.8mm (Ø 3.3mm) sink to depth stop

7) Tap (black) for 3.8mm
(**apply** for **D1** and **D2** bone quality!)
(**not recommended** for **D4** bone quality!)

4.1

1) Initial drill (pre-punching of the implant position)

2) Countersink twist drill (white) 2.0mm to depth stop

3) Countersink (yellow) for 3.3mm (sink completely to depth stop)

4) Sink the 3.3mm (Ø 2.8mm) twist drill to the depth stop

5) Countersink (black) for 3.8mm (sink completely to depth stop)

6) Depth drill (black) for 3.8mm (Ø 3.3mm) sink to depth stop

7) Tap (grey) for 4.1mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

ATTENTION: If sinus lift is indicated, only lower up to the laser marking!

8) Depth drill (grey) for 4.1mm (Ø 3.7mm) sink to depth stop

9) Tap (grey) for 4.1mm
(**apply** for **D1** and **D2** bone quality!)
(**not recommended** for **D4** bone quality!)

4.5

1) Initial drill (pre-punching of the implant position)

2) Countersink twist drill (white) 2.0mm to depth stop

3) Countersink (yellow) for 3.3mm (sink completely to depth stop)

4) Sink the 3.3mm (Ø 2.8mm) twist drill to the depth stop

5) Sink (black) for 3.8mm (sink completely to depth stop)

6) Depth drill (black) for 3.8mm (Ø 3.3mm) sink to depth stop

7) Countersink (grey) for 4.1mm (sink completely to depth stop)

8) Depth drill (grey) for 4.1mm (Ø 3.7mm) sink to depth stop

9) Countersink (Blue) for 4.5mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

ATTENTION: If sinus lift is indicated, only lower up to the laser marking!

10) Depth drill (blue) for 4.5mm (Ø4.2mm) countersink to depth stop

11) Tap (blue) for 4.5mm
(**apply** for **D1** and **D2** bone quality!)
(**not recommended** for **D4** bone quality!)

Ø 5,5mm:

1) Initial drill (pre-punching of the implant position)

2) Countersink twist drill (white) 2.0mm to depth stop

3) Versenker (Gelb) für 3.3mm (komplett bis Tiefenstopp versenken)

4) Sink the 3.3mm (Ø 2.8mm) twist drill to the depth stop

5) Sink (black) for 3.8mm (sink completely to depth stop)

6) Depth drill (black) for 3.8mm (Ø 3.3mm) sink to depth stop

7) Countersink (grey) for 4.1mm (sink completely to depth stop)

8) Depth drill (grey) for 4.1mm (Ø 3.7mm) sink to depth stop

9) Countersink (blue) for 4.5mm (sink completely to depth stop)

10)Depth drill (blue) for 4.5mm (Ø4.2mm) countersink to depth stop

11) Countersink (purple) for 5.5mm:
Hard bone (D1-D3): Submerge completely to the depth stop!!
Soft bone (D4): Only sink up to the laser mark!!

ACHTUNG: Bei Indikation Sinus-Lift nur bis zur Laser-markierung versenken!

12) Depth drill (purple) for 5.5mm (Ø5.3mm) countersink to depth stop

13) Tap (purple) for 5.5mm
(**apply** for **D1** and **D2** bone quality!)
(**not recommended** for **D4** bone quality!)

Manufacturer information for the reprocessing of MCI instruments

Validated machine processing

Products:
This manufacturer's information applies to all dental instruments supplied by MCI GmbH. These include rotary drills, drill stops, drill extenders, implant inserters, parallel pins, adapters, and screwdrivers.
Special care is required when cleaning products with internal holes and cavities.

Exclusions:
These reconditioning instructions do not apply to the torque ratchet.
A separate reconditioning instruction is available from Ganter for the torque ratchet.

Warnings:

- MCI instruments are delivered NON-STERILE!
- All non-sterile packaged products must not be sterilized in their original packaging!
- Do not use damaged and/or contaminated instruments.
- Brittle or cracked holders or retaining rings must be replaced immediately.
- Hazardous waste from contaminated products or sharp objects should be disposed of in suitable containers that meet specific technical requirements.
- Instruments may only be reprocessed by personnel with the necessary expertise and training who can assess the risks involved and their corresponding effects.

Restriction on reprocessing:

- Repeated reprocessing has little impact on the instruments. The end of a product's life is usually determined by wear and tear caused by use. Therefore, with proper care and provided they are not damaged or contaminated, instruments can be used multiple times.
- Instruments should be disposed of in an environmentally sound manner and in accordance with local laws and regulations.

Place of use:

- Observe country-specific regulations and only perform reprocessing in designated rooms/areas.
- It is recommended that instruments be removed from their packaging and reprocessed immediately upon receipt.
- Manual disinfection should be performed immediately after use to reduce the risk of infection for users. The instruments are placed in a disinfectant solution. Ensure that the instruments are fully immersed in the disinfectant solution without bubbles forming.

Storage and transport:

It is recommended that instruments be reprocessed no later than one hour after use. The instruments should be transported to the reprocessing site in a milling machine.

Preparation:

Wear personal protective equipment (stiff gloves, water-repellent protective gown, face mask or safety goggles and mask).

Pre-cleaning and disinfection: manual:

- Equipment: non-protein-fixing virucidal disinfectant with cleaning action based on alkylamine derivatives of quaternary compounds (e.g., DC1, Komet Dental #9829), plastic brush (e.g., Interlock #09050), tap water (20± 2°C) (at least drinking water quality), tub for cleaning and disinfection agents

1) Prepare the cleaning and disinfection solution according to the manufacturer's instructions (DC1, 1%) has been validated.
2) Immerse the medical devices completely in the cleaning and disinfection solution.
3) During the contact time, brush the hard-to-reach areas of the immersed medical devices with a soft brush. Pay attention to critical, hard-to-reach areas and cavities where it is not possible to visually assess the cleaning effect.
4) Contact time in the cleaning and disinfection solution according to the manufacturer's instructions (validated as 30 minutes).
5) Remove medical devices from the cleaning and disinfection solution and rinse each one thoroughly (validated for 30 seconds) under running water.
6) Check for cleanliness; if dirt is still visible, repeat the above steps.

Cleaning and disinfection: Mechanical:

- Equipment: Cleaning and disinfection device according to DIN EN ISO 15883-1 and 2 with thermal program (temperature 90°C to 95°C).
Cleaner: mildly alkaline cleaner (validated with neodisher Mediclean forte, Dr. Weigert).

1) Sort the individual parts into the insert of the reprocessing box and place them on the load carrier of the RDG so that all internal and external surfaces of the instruments are cleaned and disinfected.

Prog.-Step	Water	Dosage	Time	Temperature
Pre-rinse	TW		5 min	
Dosing Cleaner		According to the manufacturer's information (validated, 0.2%)		According to the manufacturer's information
Clean			10 min	55 °C
Wash			2 min	
Disinfect			5 min	Ao value > 30001 (validated at 90 °C, 5 min)
Dry			15 min	Up to 120 °C (validated at 90 °C)
[1] Authorities may issue other implementing regulations (parameters for disinfection performance) within their area of responsibility.				

2) Remove all medical devices after the end of the program.
3) Check that the load is dry and, if necessary, dry with medical compressed air according to European Pharmacopoeia or a lint-free cloth.
4) After removal from the WD, a visual inspection for cleanliness is performed. If visibly dirty, medical devices must be recleaned manually. The recleaned medical devices must then be reprocessed mechanically..

Maintenance, inspection and testing:
All instruments must be visually inspected for cleanliness, integrity, and functionality, if necessary using an illuminated magnifying glass (3-6 D).
All medical devices must be inspected for damage and wear, e.g., missing diamond coating (bare spots), blunt and broken cutting edges, and deformed parts (e.g., bent instruments, twisted or fractured working parts, corroded surfaces).
Damaged products must no longer be used and must be discarded.

Packaging:

- **Equipment:** Film-paper packaging (e.g., steriCLIN, Art. No. 3FKFS23016), sealing device (e.g., HAWO, Type 880 DC-V)
A suitable process (sterile barrier system) must be used to package medical devices. Packaging in accordance with DIN EN ISO 11607 (individuals) or DIN 58953-9 (sets).

Single: A sterile barrier system (e.g., foil-paper packaging) in accordance with DIN EN ISO 11607, which is intended by the manufacturer for steam sterilization, must be used. The packaging must be large enough so that the seal is not under tension. (For validation purposes, the reprocessing box was double-wrapped in foil-paper packaging.).

- **Notice:** After the heat-sealing process, the seal must be visually inspected for any defects. If defects are found, the package must be opened, and the instrument must be repackaged and resealed.

Sterilization:

- **Device:** Sterilizer according to DIN EN 285 or small steam sterilizer according to DIN EN 13060, type B process.

- **Proceedings:** Steam sterilization with fractionated pre-vacuum, 134°C, holding time at least 3 minutes or 132°C, holding time at least 4 minutes (validation parameter: 134°C, 1.5 minutes). Longer holding times are possible. In Germany, a holding time of at least 5 minutes is recommended based on the KRINKO/BfArM recommendation.

1) Place the packaged medical devices into the sterilization chamber.
2) Start the program.
3) After the program has ended, remove the products and let them cool down.

Afterwards, check the packaging for any damage or moisture penetration. Any packaging found to be unsterile should be considered unsterile. The instruments must be repackaged and sterilized.

Storage:
Storage (at least protected from dust and moisture) and storage duration according to the user's specifications.

Additional Information:
Only validated processes may be used for the reprocessing of medical devices.

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Checklist for preparing for implant surgery

1. Drapes:
- ☐ Floating table / operating table
- ☐ patient
- ☐ filing
- ☐ 1 cover for extractor
- ☐ 1 sterile suction tube
- ☐ We recommend our sterile cover set

2. Clothing:
- ☐ Sterile gloves for the surgical team (1 each for the surgeon and sterile assistant; non-sterile assistant = non-sterile gloves)
- ☐ Face mask (for all persons in the operating room)
- ☐ Surgical caps (for all persons in the operating room, including the patient)
- ☐ Possibly sterile gowns

3. Prepare the machine (use a machine with adjustable torque)
- ☐ Sterilize motor cable according to manufacturer's instructions
- ☐ Sterilize the contra-angle handpiece and handpiece including the holder according to the manufacturer's instructions
- ☐ Prepare sterile cooling tube
- ☐ Prepare a sterile NaCl bottle 250 - 1000 ml

4. Provide sterile implant, surgical kit and implants

5. Instruments (all sterilized):
- ☐ Hook (Langenbeck possibly cheek holder)
- ☐ Mirror, dental tweezers, probe
- ☐ scalpel
- ☐ Raspatorium (large and small)
- ☐ Surgical forceps
- ☐ Rose drill / bone milling cutter for smoothing the bone

6. Preparation:
- ☐ Sterile plastic disposable teat
- ☐ Sterile syringe and cartridges for anesthesia
- ☐ Sterile swabs
- ☐ Suture material
- ☐ Provide cups of mouthwash for patients
- ☐ Store cooling pads for patients in the refrigerator
- ☐ If necessary, sterilize bone collectors, e.g. Aspeo and prepare sterile filters
- ☐ Possibly bone substitute material and membranes
- ☐ If necessary, sterilize the vessel for collecting bone and/or preparing bone substitute material
- ☐ Place any existing drilling template in alcohol
- ☐ If necessary, sterilize dental floss to protect instruments, e.g., when using the extra-short hand screwdriver

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Signature of the responsible assistant