A close-up, high-angle photograph of a dental implant. The implant is a cylindrical metal component with a threaded lower section and a smooth upper section. The top of the implant is open, revealing a dark interior. The lighting is dramatic, highlighting the metallic texture and the sharp edges of the threads.

# **SURGICAL** Guidelines

INTERNAL CONNECTION

**YOU**UNIVERSAL IMPLANTOLOGY SYSTEM



BEYOND  
SENSATIONS.



# ► Index.

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## KEEP IN TOUCH

Stay connected: when you find this symbol, scan it with your smartphone or tablet to find constantly updated content on our site.

# ▶ ONE Implants.



**INTERNAL CONNECTION: color code blue with locking hexagone and inner bevel**

IMPLANT CONNECTION	IMPLANT DIAMETER	IMPLANT LENGHT				
		6.0 mm	8.0 mm	10.0 mm	11.5 mm	13.0 mm
INTERNAL	 Ø 3.75 mm		N3808	N3810	N3811	N3813
	 Ø 4.20 mm	N4206	N4208	N4210	N4211	N4213
	 Ø 4.65 mm	N4706	N4708	N4710	N4711	N4713

# ► Indications.






**ONE dental implants** are indicated for oral endosseous placement in the upper and lower jaw and for functional and aesthetic rehabilitation of edentulous and partially dentate patients (provided there are no particular contraindications or limitations, as shown below).

**ONE dental implants** can also be used for immediate or early implantation following extraction or lost of natural teeth. Within the scope of these indications, ONE implants are approved for immediate restoration in cases of single tooth gaps, edentulous or partially dentate jaw. Good primary stability and adequate occlusal load are essential requirements. In case of immediate restoration, two or more adjacent implants

should be prosthetically connected together. In case of immediate restoration in edentulous patients, at least 4 implants must be connected together. Approximate duration of the healing phase for delayed restorations is given below. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).

In the following pages, detailed information is given about the indications, the necessary bone volume and the spacing between implants and adjacent teeth.

IMPLANT CONNECTION	IMPLANT DIAMETER	INDICATIONS	MINIMUM VESTIBULAR-PALATAL	MINIMUM MESIO-DISTAL
INTERNAL	 Ø 3.75 mm	REHABILITATION OF PARTIALLY OR COMPLETELY EDENTULOUS MAXILLA	6,8 mm	7,8 mm
	 Ø 4.20 mm	REHABILITATION OF PARTIALLY OR COMPLETELY EDENTULOUS MOLAR REGIONS OF THE MAXILLA	7,2 mm	8,2 mm
	 Ø 4.65 mm	REHABILITATION OF PARTIALLY OR COMPLETELY EDENTULOUS MOLAR REGIONS OF THE MAXILLA	7,7 mm	8,7 mm

## ► Indications.

### **Specific indications for small diameter implants ONE INTERNAL Ø 3.75 mm**

The ONE INTERNAL implant does not follow the general rule of the traditional implant systems to use the largest possible implant diameter. With the ONE INTERNAL implant system it is possible to use ONE INTERNAL Ø 3.75 mm diameter both in the incisal and the distal regions of the maxilla.

Even the modern approaches to the immediate post-extractive implants suggest to position a small diameter implant in palatine position to preserve the vestibular bundle bone and allow enough volume to it to become thick and stable.

### **Specific indications for short ONE INTERNAL implants of 6.0 mm length**

Thanks to their feature of high biological performance, the short ONE INTERNAL implants of 6.0 mm length have no particular contraindications but should be used as an auxiliary implant, used together with longer ONE implants to support prosthetic rehabilitations on multiple implants. They can also be used to replace a single missing tooth. However, due to the limited available surface their use in post-extraction protocols with immediate or early loading demands great caution because the achieved mechanical primary stability is lower than in implants of higher length.

# ► Contraindications.

Serious internal medical problems, bone metabolism disturbances, uncontrolled bleeding disorders, inadequate wound healing capacity, poor oral hygiene, maxillary and mandibular growth not completed, poor general state of health, uncooperative, unmotivated patient, drug or alcohol abuse, psychoses, prolonged therapy-resistant functional disorders, xerostomia, weakened immune system, illnesses requiring periodic use of steroids, titanium allergy, uncontrollable endocrine disorders.

## **Relative contraindications**

Previously irradiated bone, diabetes mellitus, anti-coagulation drugs/haemorrhagic diathesis, bruxism, parafunctional habits, unfavourable anatomic bone conditions, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disorders, treatable pathologic diseases of the jaw and changes in the oral mucosa, pregnancy, inadequate oral hygiene.

## **Local contraindications**

Inadequate bone volume and/or quality, local root remnants.

# Pre-operative planning.

## Implant Position

The implant is the most important point of the restoration. It provides the basis for planning the surgical procedure. Close communication between patient, dentist, surgeon and dental technician is imperative for achieving the desired prosthetic result. In order to establish the topographical situation, the axial orientation and the choice of implants, we recommend the following procedures::

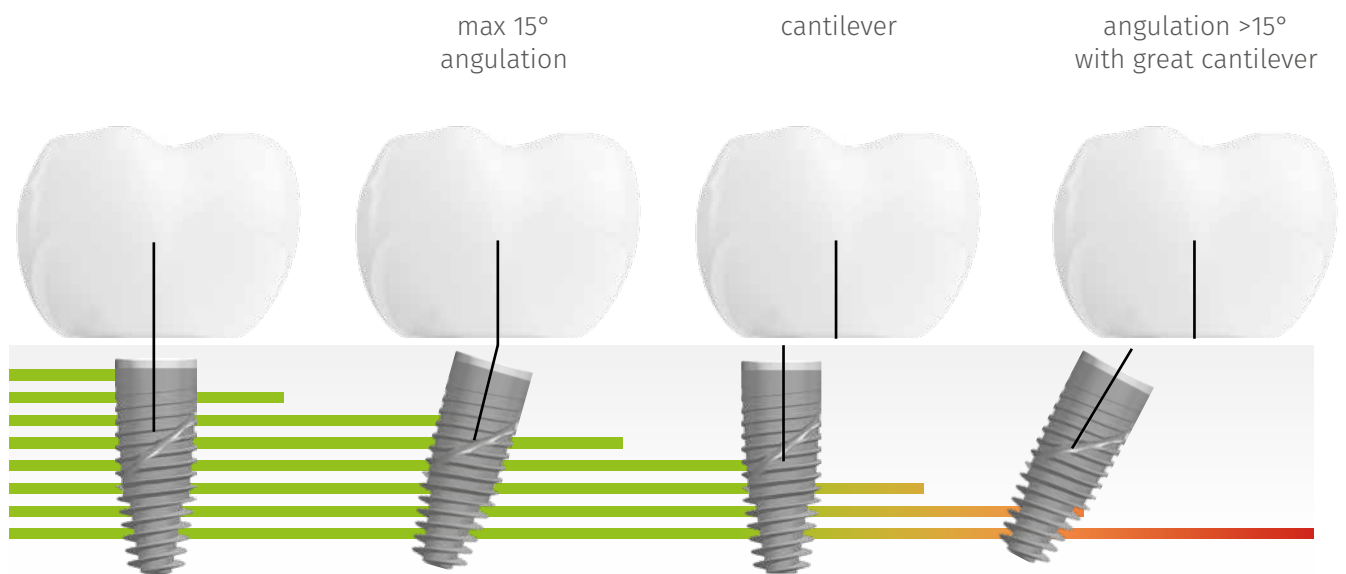
- ▶ **Make a dental wax-up/set-up on the previously prepared study cast.**
- ▶ **Define the type of superstructure.**
- ▶ **The wax-up/set-up can later be used as the basis for a custom-made X-ray or drill template and for a temporary restoration.**

Select the implant diameter, type, position and number of implants individually for each case, considering the singular anatomy and spatial circumstances (e.g. malpositioned or inclined teeth). The measurements indicated here should be regarded as minimum guidelines. The minimum distances must be observed to achieve adequate restoration planning which will also allow the necessary oral hygiene measures to be carried out. The final response of hard and soft tissues is influenced by the position between the implant and the proposed restoration that should therefore be based on the position of the implant-abutment connection.

The following two dimensions determine the implant position:

- ▶ **Mesio-distal**
- ▶ **Vestibulo-palatal & Bucco-lingual**

The prosthetic components should always be loaded axially. Ideally, the long axis of the implant is aligned with the cusps of the opposing tooth. It is recommended to avoid extreme cusp formation since this could lead to unphysiological loading.

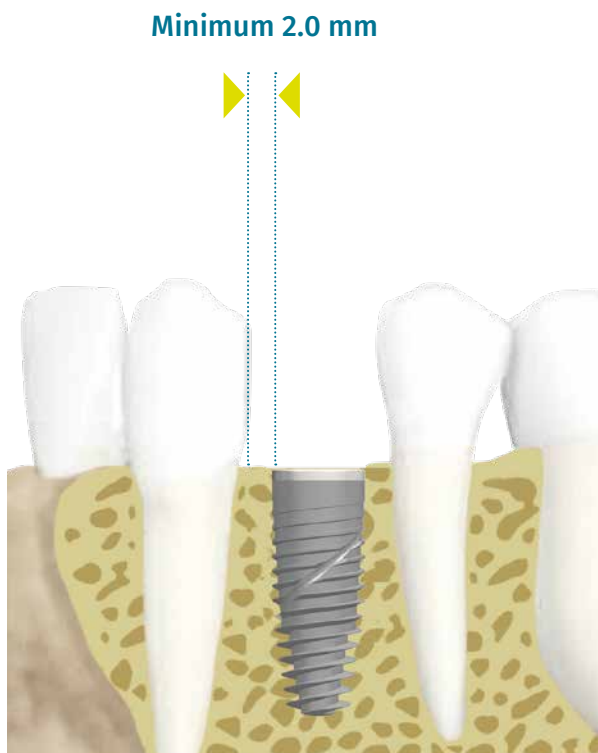


# Mesio-distal positioning.

The mesio-distal bone availability is an important factor for choosing the implant type and diameter as well as the interimplant distance in case of multiple implants.

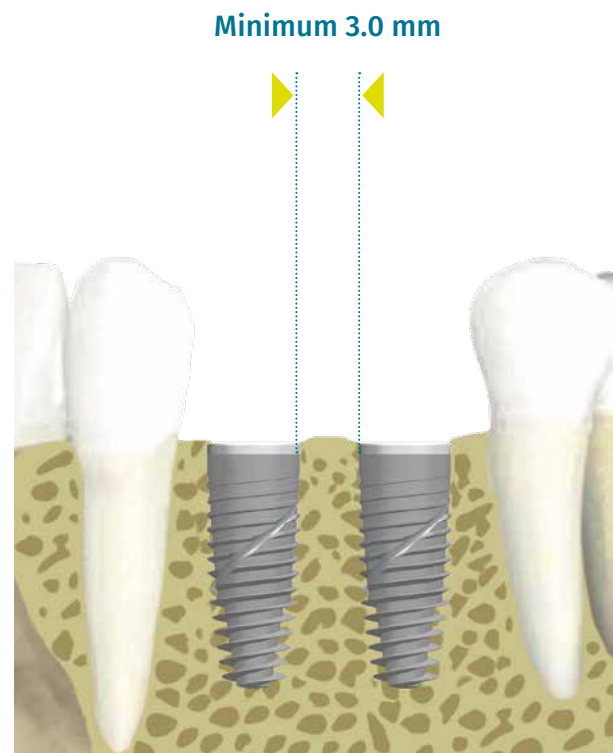
## Rule No. 1

Distance to adjacent tooth at bone level: a minimum distance of 2,0 mm is required between the implant emergence and the adjacent tooth at bone level (both mesial and distal).



## Rule No. 2

Distance to adjacent implants at bone level: a minimum distance of 3,0 mm is required between two adjacent implant emergences (both mesial and distal)

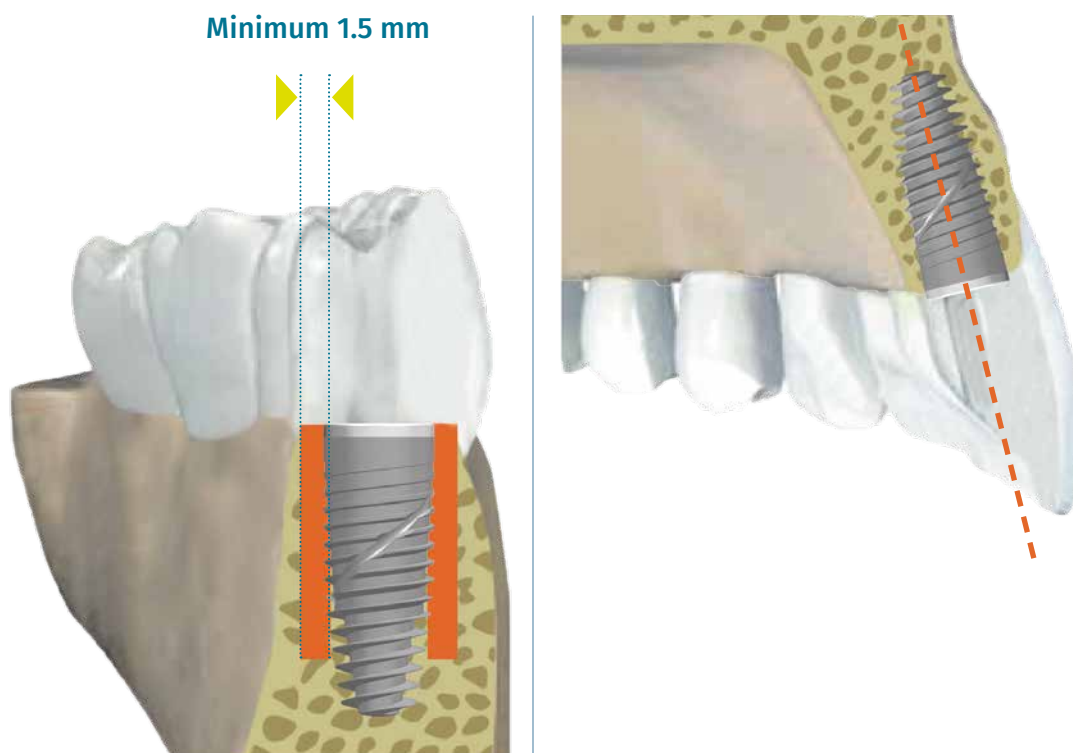


# Vestibulo-palatal positioning.

The palatal bone must be at least 1,5 mm thick in order to ensure stable conditions of hard and soft tissues. The minimum width of oro-facial ridges is given in the ONE implant system indication table. Choose the implant position and its oro-facial axis in such a way that the retaining screw channel of prosthetic abutment is situated behind the incisal edge.

## **WARNING:**

Bone augmentation procedure is indicated when oro-facial bone wall is less than 1,0 mm thick or a bone layer is missing on one, or more, sides. Only dentists who have adequate experience in performing bone augmentation procedures should use this technique.



# Surgical tray description.



**1** Starting drills

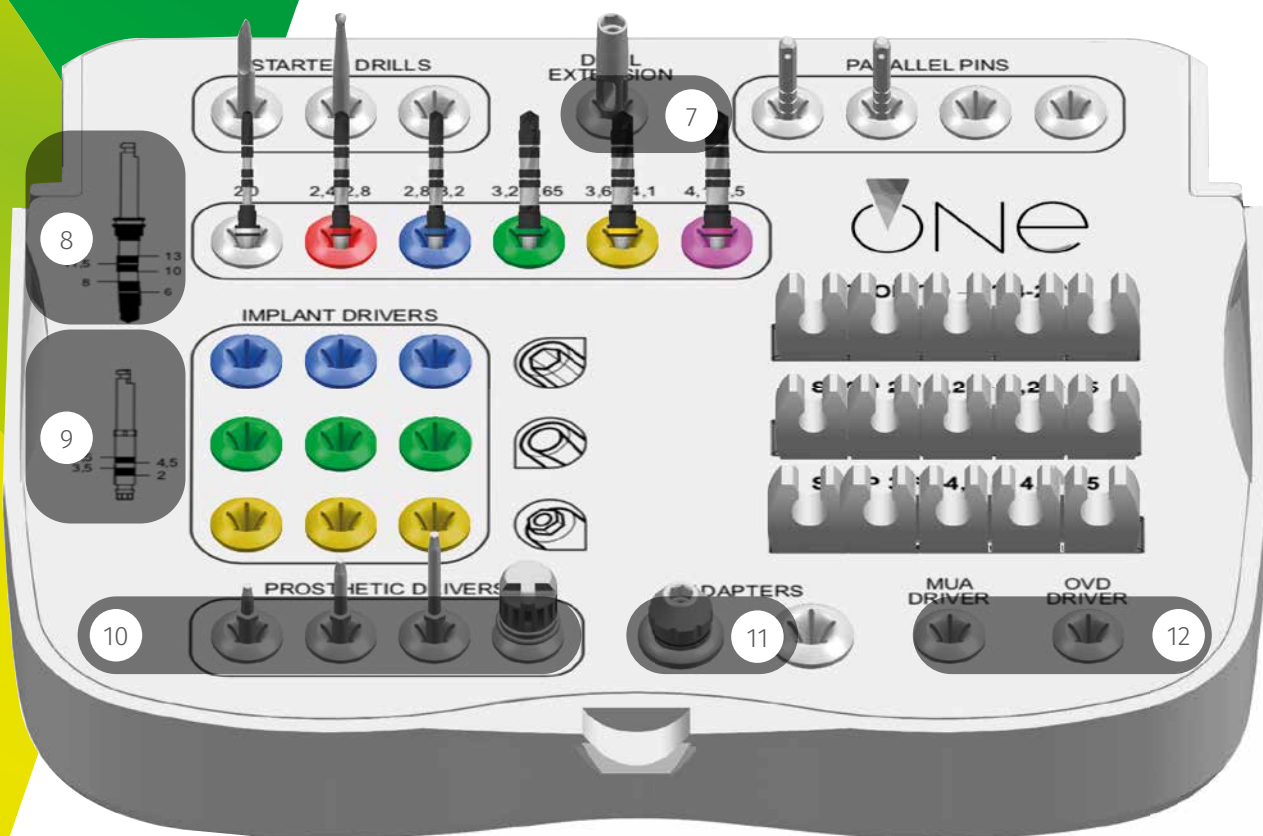
**2** Parallel pins

**3** Alveolar step drills

**4** One Internal implant driver

**5** One Conical implant driver

**6** Alveolar step Drill stop tray



**7** Drill extension

**8** 1:1 scale step  
Drills depth marks

**9** 1:1 scale implant  
Drivers depth marks

**10** Prosthetic drivers

**11** Torque wrench adapter

**12** MUA & Overdenture  
drivers

# Milling tools description.

The final drill diameter has to be selected based on the bone quality and, of course, based on the ONE Internal implant diameter. The drill body is covered with DLC finish to enhance resistance to corrosion and wearing.

**Drilling speed: below 300 rpm (MAX. TORQUE 45 Ncm)**

**Indicative duration<sup>1</sup>: 50 work cycles**

#### **<sup>1</sup> INDICATIVE DURATION OF CUTTING INSTRUMENTS:**

The number of work cycles for each cutting instrument is only an indication and is referred to the use in medium density bone. In case of drilling thick and compact cortical bones, it is advisable not to exceed 10 working cycles with a single instrument since impaired cutting performance can lead to bone overheating.

This is particularly important for the first three drill diameters used usually and for the finishing instruments used in cortical bone, such as conical reamers.





The standard twist drill present a parallel design and a double diameter with a reduced apex (the first 3.0 mm of the drill) that allows to obtain a better implant grip with soft trabecular bone, makes easier to center the larger drills and limits the overheating effect of bone during milling phases:

**COLOR CODE RED: Ø2.80 → APEX Ø2.40**

**COLOR CODE BLUE: Ø3.20 → APEX Ø2.80**

**COLOR CODE GREEN: Ø3.65 → APEX Ø3.20**

**COLOR CODE YELLOW: Ø4.10 → APEX Ø3.65**

**COLOR CODE PURPLE: Ø4.50 → APEX Ø4.10**

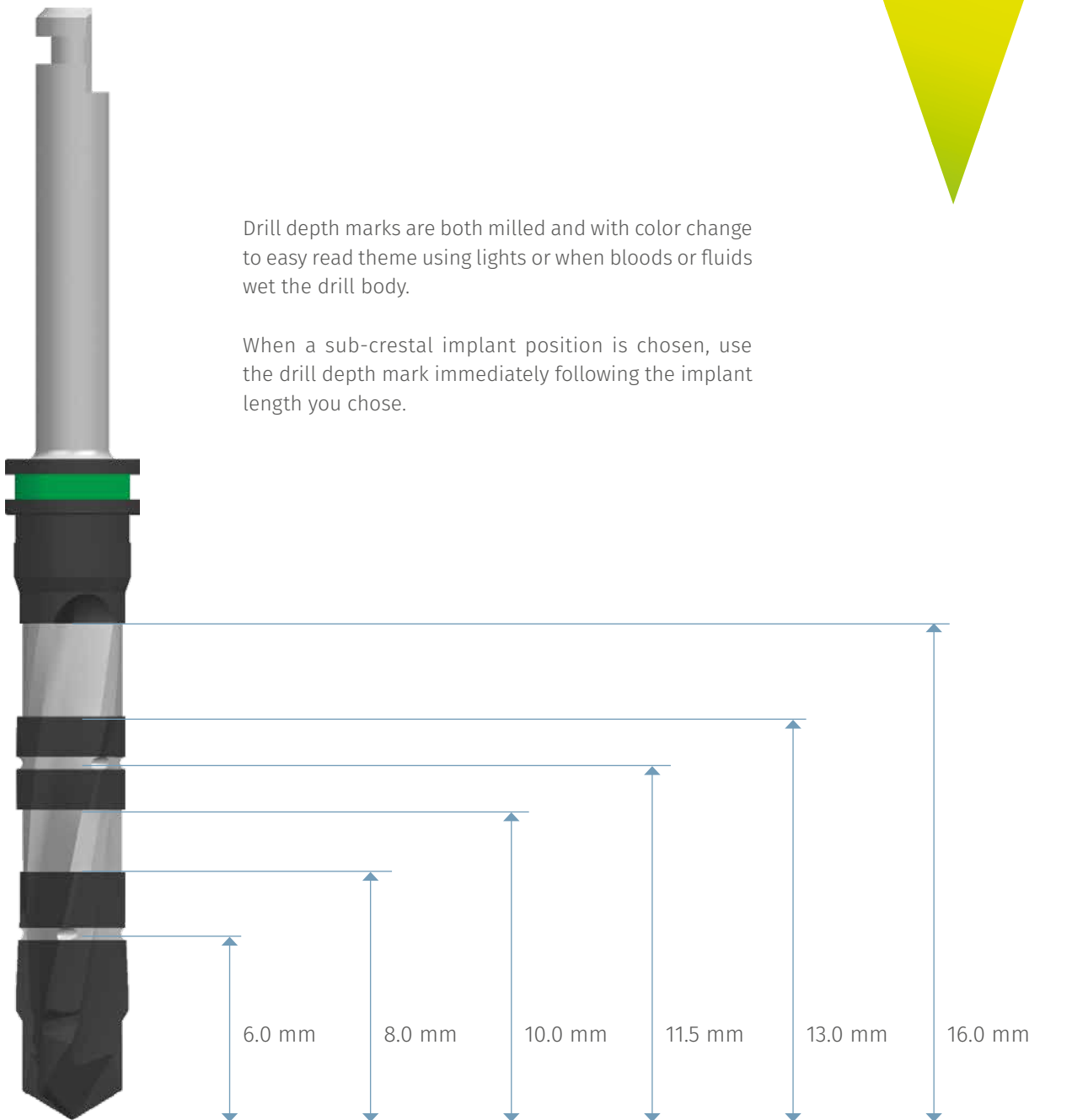
The initial twist drill present a parallel design with single diameter:

**COLOR CODE WHITE: Ø2.00**

► Milling tools description.

Drill depth marks are both milled and with color change to easy read them using lights or when bloods or fluids wet the drill body.

When a sub-crestal implant position is chosen, use the drill depth mark immediately following the implant length you chose.



# Drill stops description.

The twist drill stop ensures accurate control of the drilling depth during the implant bed preparation for ONE implant positioning. The drilling depth indicated on the stop does not include the 0.4 mm difference, which is the result of the drill's conical tip. Always keep this feature in mind when planning the procedure.

In this way, the mesio-distal overall measure of the smallest diameter drills is not increased excessively and allows easy preparation of the implant bed with stop mounted even when small implants are being positioned or when the gap is not wider than 4,5 mm. The stops are mounted on the drill with the help of mounting collars. Check the stop tightness regularly and replace the worn out stops.

The drill stops are available in 3 different series:

- ▶ Drills with diameter of 2,0 mm and 2,4-2,8 mm
- ▶ Drills with diameter of 2,8-3,2 mm and 3,2-3,65 mm
- ▶ Drills with diameter of 3,65-4,1 mm and 4,1-4,5 mm

## DRILL STOP 28STO series

Made of surgical grade stainless steel and used for stopping the drill at a precise depth.

Available for the following drilling depths:

6.0 - 8.0 - 10.0 - 11.5 - 13.0 mm.

Adaptable to twist drills of following diameters:

2.0 - 2.4/2.8 mm.

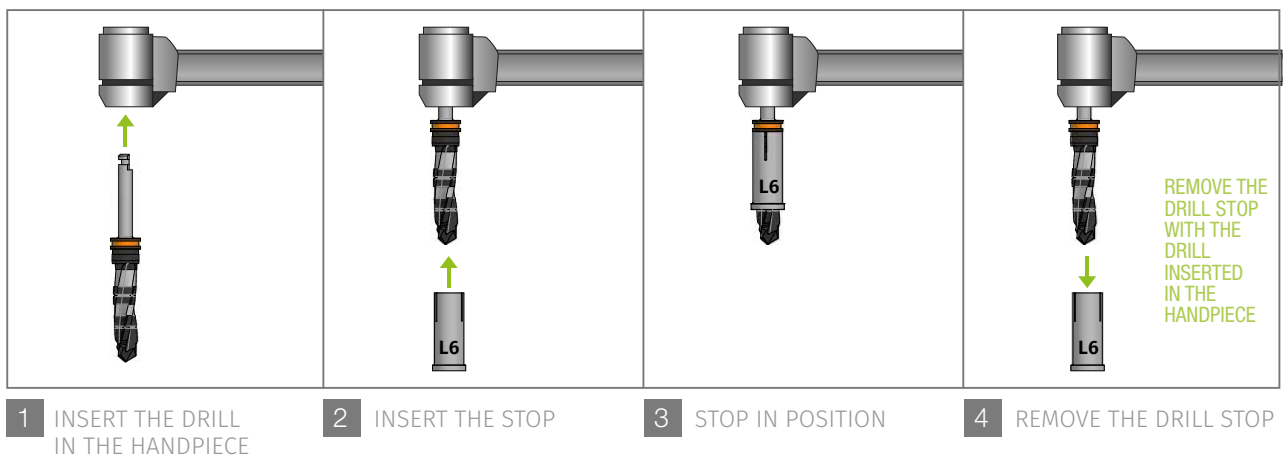


### Attention

Position and remove the stop with the drill correctly inserted in the contra-angle handpiece.

Length indication on the stop refers to the marking depth

at which the drill will be stopped. The working depth must always be increased by 0.4 mm corresponding to the drill's conical apex.



## ► Drill stops description.

### DRILL STOP 36STO series

Made of surgical grade stainless steel and used for stopping the drill at a precise depth.

**Available for the following drilling depths:**  
6.0 - 8.0 - 10.0 - 11.5 - 13.0 mm.

**Adaptable to twist drills of following diameters:**  
2.8/3.2 - 3.2/3.65 mm.

#### Attention

Position and remove the stop with the drill correctly inserted in the contra-angle handpiece. Length indication on the stop refers to the



marking depth at which the drill will be stopped. The working depth must always be increased by 0.4 mm corresponding to the drill's conical apex.

### DRILL STOP 45STO series

Made of surgical grade stainless steel and used for stopping the drill at a precise depth.

**Available for the following drilling depths:**  
6.0 - 8.0 - 10.0 - 11.5 - 13.0 mm.

**Adaptable to twist drills of following diameters:**  
3.65/4.1 - 4.1/4.5 mm.

#### Attention

Position and remove the stop with the drill correctly inserted in the contra-angle handpiece. Length indication on the stop refers to the



marking depth at which the drill will be stopped. The working depth must always be increased by 0.4 mm corresponding to the drill's conical apex.

# Drivers description.

**The IMPLANT DRIVERS engage the implant directly and make it possible to pick up, carry and position the ONE INTERNAL implant. This allows to insert the implant with a greater torque in comparison to what is achievable with a mounting device, and it also simplifies the surgical procedure since there is no mounting device to be removed after finalizing the placement. IMPLANT DRIVERS are available in manual version and mechanical version suitable for contraangle, provided in different length option.**

All prosthetic components are screwed on the implant with the help of PROSTHETIC DRIVERS available in manual version and in mechanical version (for contra-angle), provided in different length option.

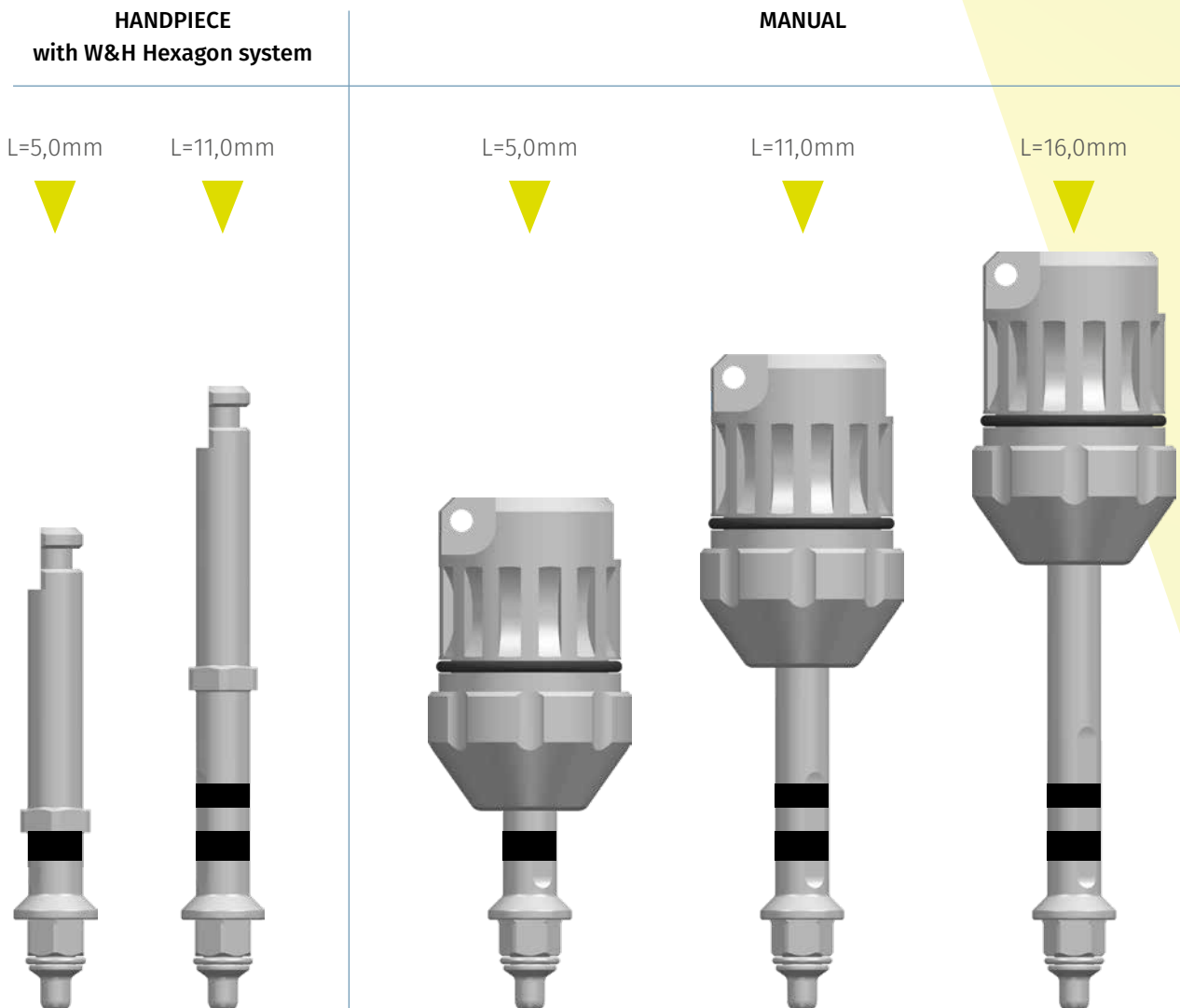
For further information, refer to the implant's instructions for use included in the packaging. All the manual instruments have a hole for attaching a safety thread.

# ▶ Implant driver description.



**INTERNAL CONNECTION: color code blue with locking hexagone and inner bevel**

Used for picking up, carrying and positioning of the implant.  
The shaft present a notch to quickly adjust the hexagon position during implant positioning.



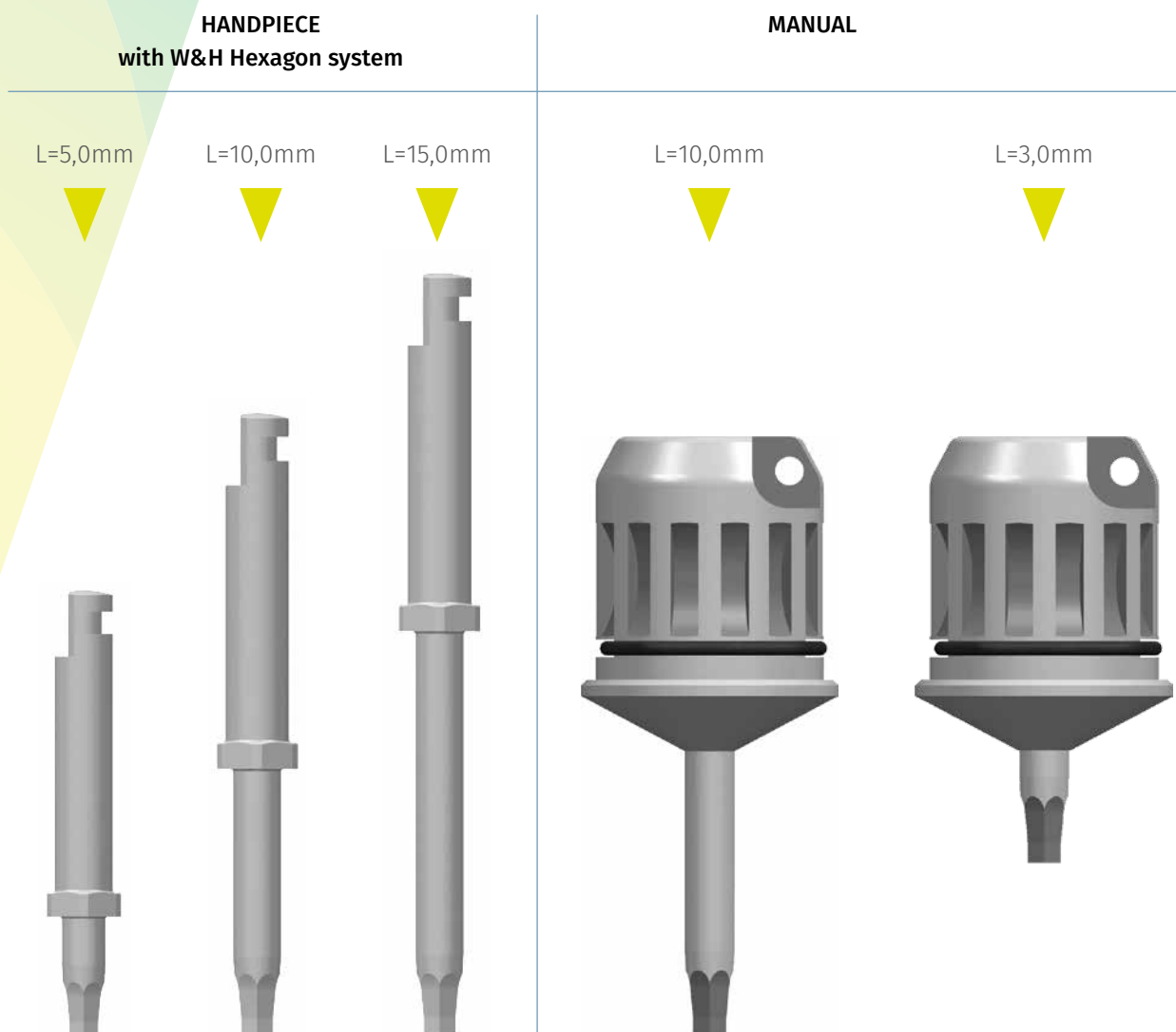
# ▶ Prosthetic driver description.

Designed to engage and tighten all of the prosthetic components of ONE implant system, including the surgical cover screw placed inside the cap of the sterile vial.

**The tightening torque for surgical cover screws must not exceed 10 Ncm.**

**The tightening torque for healing abutments, impression post and scan abutment is 20 Ncm.**

**The tightening torque for prosthodontics components is 30 Ncm.**



# ▶ Torque wrench description.



## **Surgical and prosthetic ratchet with adjustable torque control**

Check periodically the condition of the torque wrench and verify the correct functioning of all mobile parts.

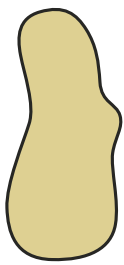
All the components of the torque wrench must be disassembled prior to cleaning and reassembled only before sterilization. The above-mentioned operations are described in detail in the use and maintenance instructions of the torque wrench.

▶ **Adjustable torque range from 10 Ncm to 70 Ncm.**

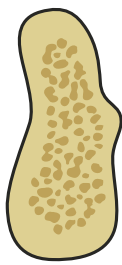
## ▶ General indications.

1. ▶ Check that all necessary instruments are available and in perfect working condition. It is advisable to keep an adequate stock of implants and sterile spare instruments available.
2. ▶ Do not use cutting instruments more than 10 times on compact bones and always change drills after 50 uses.
3. ▶ Ensure proper cooling of drills with pre-cooled (5°c/41°f) physiological sterile saline solution (nacl) or ringer's solution.
4. ▶ Do not exceed the speed indications for drills of 200-300 rpm.
5. ▶ Use drills in ascending order of their diameter and avoid considerable diameter changes when drilling compact bone (always use drills of intermediate diameter in compact bone).
6. ▶ Always apply only light pressure and an intermittent drilling technique (alternate up and down movements).

# ▶ Bone quality classification.



▶ **D1**  
Maxillary bone composed almost exclusively of dense cortical bone



▶ **D2**  
Thick and dense cortical bone surrounding spongy bone



▶ **D3**  
Thin layer of cortical bone surrounding spongy bone with dense trabecular structure



▶ **D4**  
Very thin layer of cortical bone surrounding spongy bone with trabecular structure

Typical anatomical distribution based on bone density (Misch, 1990)

BONE QUALITY	D1	D2	D3	D4
Anterior maxilla	0	25	65	10
Posterior maxilla	0	10	50	40
Anterior mandible	6	66	25	3
Posterior mandible	3	50	46	1

Compact bone	Medium bone	Soft bone
D1 and D2 verging to D1	D2 and D3	D4 and D3 verging to D4

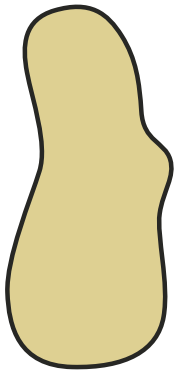
# ▶ Compact bone

D1 and D2 verging to D1.

BONE TYPE D1

## HOMOGENEOUS COMPACT CORTICAL BONE

FRONT REGION OF AN ATROPHIC EDENTULOUS MANDIBLE



### Advantages

- Good primary implant stability
- High bone-implant contact surface

### Disadvantages

- Poor vascularisation
- Risk of overheating

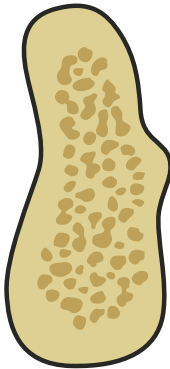
# ▶ Medium bone

D2 and D3.

BONE TYPE D2

## THICK POROUS COMPACT CORTICAL BONE, DENSE TRABECULAR BONE

MANDIBULAR ARCH, CENTRAL AND LATERAL REGIONS CENTRAL MAXILLARY ARCH (INCISAL REGION)



### Advantages

- Good primary stability
- Excellent vascularisation
- Simple implant site preparation

### Disadvantages

- None

BONE TYPE D3

## THIN POROUS COMPACT CORTICAL BONE, LOW-DENSITY TRABECULAR BONE

CENTRAL REGION (LATERO-CANINE) OF THE MAXILLA LATERAL REGION (MOLAR) OF THE MANDIBLE



### Advantages

- Good vascularisation

### Disadvantages

- Risk of over-preparation of the implant site
- Reduced surface of bone-implant contact

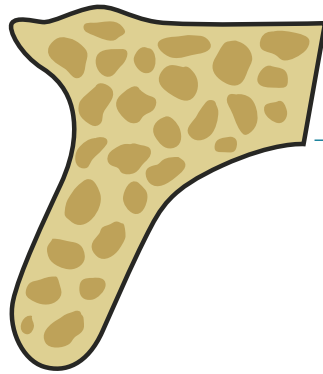
# ▶ Soft bone

D3 and D4 verging to D4.

BONE TYPE D4

## LOW-DENSITY TRABECULAR BONE

REGION OF TUBER MAXILLARE



### Advantages

- None

### Disadvantages

- Risk of implant site over-preparation
- Reduced bone-implant contact surface
- Scarce primary implant stability



# ▶ Drills sequence.

IMPLANT DIAMETER	COMPACT BONE	MEDIUM BONE	SOFT BONE
3,75	2.0 2.4/2.8 2.8/3.2 3.2/3.65	2.0 2.4/2.8 2.8/3.2 3.2/3.65 (CORTICAL USE)	2.0 2.4/2.8
4,20	2.0 2.4/2.8 2.8/3.2 3.2/3.65 3.65/4.1	2.0 2.4/2.8 2.8/3.2 3.2/3.65 3.65/4.1 (CORTICAL USE)	2.0 2.4/2.8 2.8/3.2
4,65	2.0 2.4/2.8 2.8/3.2 3.2/3.65 3.65/4.1 4.1/4.5	2.0 2.4/2.8 2.8/3.2 (OPTIONAL) 3.2/3.65 3.65/4.1 4.1/4.5 (CORTICAL USE)	2.0 2.4/2.8 3.2/3.65

CORTICAL USE: sink the drill up to the 6.0 mm depth mark.

# ▶ Packaging description.

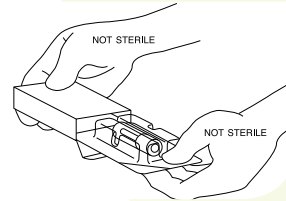
The implant screws are processed, cleaned and treated accordingly to the certified procedures. The final decontamination is performed by cold plasma of argon and they are immediately stored. The implant screws are removed from storage only inside the Clean Room of the production factory. In this way, the superficial oxide layer will be formed in a controlled atmosphere, not allowing the slightest contamination of the implant surface. After packaging in the Clean Room, the implant screws are sent to the sterilization process by  $\beta$  rays.

## **The packaging is characterized by:**

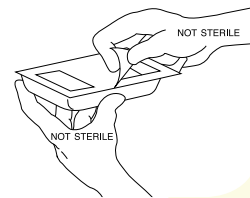
- ▶ **Decontamination by cold plasma of argon**
- ▶ **Sterilization by  $\beta$  rays.**
- ▶ **Double sterility: outer barrier provided by blister PET-G with sheet in TYVEK®; internal barrier provided by the vial in polycarbonate**
- ▶ **Cover screw positioned in the vial cap under a seal in TYVEK®**
- ▶ **Shaped blister to avoid impacts to the vial**
- ▶ **Implant screws in contact only with elements in titanium, to avoid phenomena of bimetalism or contamination from contact with plastic material**

## ► Packaging description.

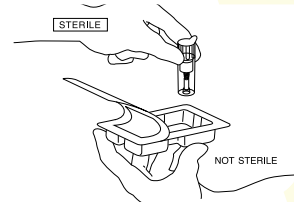
- Choose the implant type, length and diameter and take the blister out of the cardboard box.



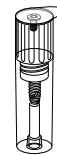
- The vial containing the implant is sterile and lodged in the blister. The product description and the lot number are indicated on the label. Open the blister.



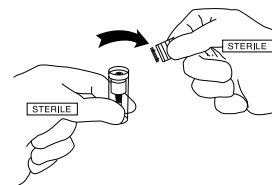
- Take out the vial with the implant.



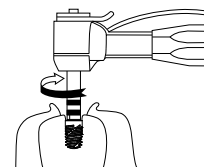
- Surgical cover screw is placed in the vial cap and sealed with a Tyvek film.



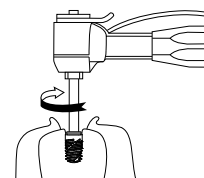
- Gently open the vial cap (do not pull up with force).



- Connect the correct Implant Driver (due to the implant connection) and screw at low speed (10-15 rpm).



- Pick the cover screw from the vial cap and screw it onto the implant with the Prosthetic Driver.



# ▶ Healing phase description.

IMPLANT RECOVERY TIME TABLE

CLINICAL CONDITION	HEALING PHASE PERIOD
<ul style="list-style-type: none"> <li>▶ GOOD BONE QUALITY AND ADEQUATE BONE QUANTITY</li> <li>▶ IMPLANTS WITH A DIAMETER OF 3.75 mm OR 4.20 mm</li> <li>▶ IMPLANTS WITH LENGTH OF 10.0 mm OR MORE</li> </ul>	4-6 WEEKS
<ul style="list-style-type: none"> <li>▶ POOR BONE QUALITY OR EXCESSIVELY COMPACT BONE WITH POOR VASCULARISATION</li> <li>▶ IMPLANTS WITH LENGTH OF 6.0 mm OR 8.0 mm</li> </ul>	8-12 WEEKS
<ul style="list-style-type: none"> <li>▶ IMPLANT POSITIONED WITHOUT ADEQUATE PRIMARY STABILITY</li> <li>▶ IMPLANT POSITIONED SIMULTANEOUSLY TO BONE REGENERATION PROCEDURE</li> <li>▶ IMPLANT POSITIONED SIMULTANEOUSLY TO CONSIDERABLE SINUS ELEVATION</li> </ul>	24-32 WEEKS

## ► Healing phase description.

### **IMMEDIATE PROSTHESIS OF IMPLANTS**

Unless there are contraindications to consider, all ONE implants are suitable for immediate restoration of a single missing tooth, as well as for restoration of edentulous or partially edentulous mandible.

The essential conditions that must be met: good primary stability (final tightening torque at least 40-45 Ncm), adequate bone quality and appropriate occlusal load.

In case of multiple teeth rehabilitation, the implants should be rigidly connected. In case of overdenture, a minimum of 4 implants with at least 3.75 mm diameter are connected together by means of a bar.

Restoration or immediate loading of a single implant has not been studied and is not recommended in the following indications:

- **Last molar in the mandible and/or the maxilla.**
- **Making a cantilevered extension on a single implant.**

### **PROSTHESIS OF IMMEDIATE POST-EXTRACTIVE IMPLANTS**

Appropriate timing for functional loading of immediate post-extractive implants must abide by the same guidelines given above. If the conditions for immediate loading are met and the post-extraction implant is in contact with the 4 walls of the implant bed, it is possible to consider the option of immediate loading. If this is not the case, either because there are just 3 walls present or because the implant is positioned very palatally, it is recommended to observe approximately 8-12 weeks recovery time. Using the ONE implants, a palatized position of the implant is advised.

In case of immediate loading, it is recommended to make a temporary crown out of occlusion, without distalizing or centric contacts, and without contacts in eccentric movements.

## IMMEDIATE PROSTHESIS OF IMPLANTS





In case of single tooth missing or partially edentulous jaw, immediate loading is recommended in anterior region of maxilla avoiding the canine pillar, using a temporary crown not in occlusion, without distalizing and centric contacts and without contacts in eccentric movements.

**In case of edentulous jaws, the following recommendations apply:**

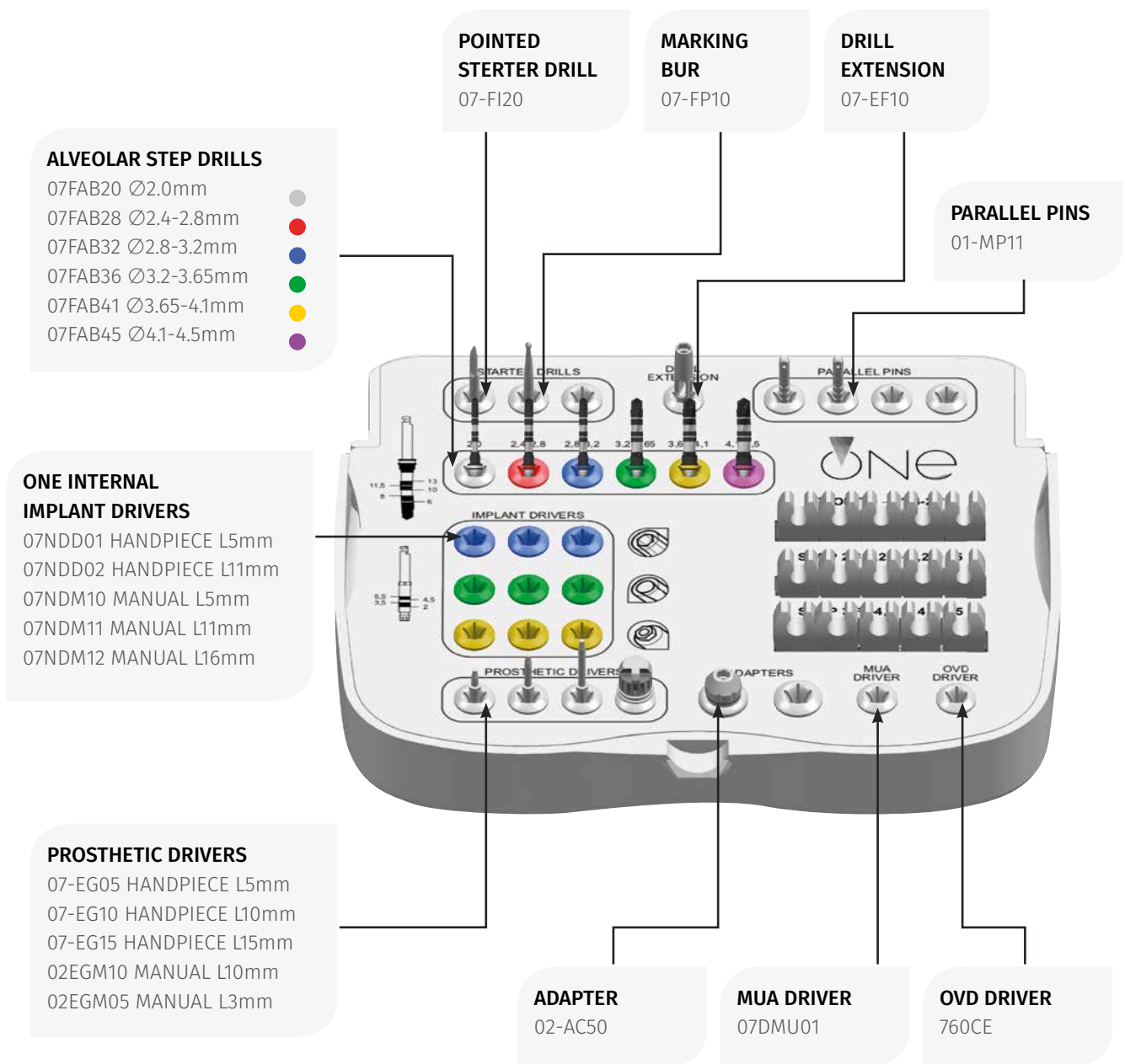
- ▶ **Minimum 4 implant in mandible**
- ▶ **Minimum 6 implant in maxilla**
- ▶ **No particular inclination in mesiodistal and vestibular-lingual directions are required for the implants since the internal vertical conical connection provides optimal support to the prosthetic elements (valid for ONE CONICAL)**
- ▶ **It is possible to place short implants of reduced diameter in the extraforaminal position**
- ▶ **The short implants with reduced diameter make it possible to use either a screwed or a cemented prosthesis**
- ▶ **Immediate load must be applied by directly inserting the final prosthesis on a stabilizing bar**
- ▶ **Thanks to the bar-stabilized prosthesis, the conditions for immediate loading must not necessarily be met by all of the implants but at least by 75% of all implants (at least 3 out of 4 implants in the mandible and at least 5 out of 6 implants in the maxilla)**

# ► Components tightening torque.

The tightening torque of the prosthetic components plays a fundamental role to avoid connection failures or retaining screw loosening. The torque must, in fact, be calibrated to maintain the retaining screw in its elastic phase. For that reason, moreover with flat-to-flat like connection, the implant should not be positioned with angulation greater than 10-15° to avoid local plasticization of the retaining screw's body and consequently to avoid a reduced elastic strength of the screw itself.

RECOMMENDED TIGHTENING TORQUE		
	COVER SCREW	MAX 10 Ncm
	IMPRESSION POST SCAN ABUTMENT	20 Ncm
	HEALING ABUTMENT	20 Ncm
	PROSTHODONTICS ABUTMENTS	30 Ncm

# ► Surgical tray maintenance.



# ► Instructions & Maintenance

## REPROCESSING INSTRUCTIONS

After surgery, all instruments are contaminated due to the contact with blood, saliva and potentially infected organic substances. Therefore, all instruments must be properly cleaned, disinfected and sterilized before each use.

### Initial treatment at the point of use:

Immediately after use, or not more than 30 minutes, remove gross soil by means of absorbent paper wipes.

### Containment and transportation:

It is recommended that instruments are reprocessed as soon as is reasonably practical following use, or not more than 30 minutes. To avoid mechanical damages, do not mix heavy devices with delicate ones. Pay particular attention to drills' cutting edges. Preparation before for cleaning: Disassemble the tools if composed by more than one part. Disassemble kit boxes.

### Manual cleaning:

1. ► Immediately after use, or not more than 30 minutes, place the tools in an appropriate solution of high-quality decontamination medium (ENZYMAL<sup>®</sup>, 0.8% v/v with demineralized water), at 35°C contained in a suitable support (i.e. becker), the tools must be totally covered by the solution. Allow 10 minutes before removing. Pay attention that there is no contact between the instruments;
2. ► using a soft plastic brush (e.g. soft nylon brush), carefully clean each tool to remove any organic residual;  
**Warning:** do not use brushes on retention systems.

**Warning:** do not clean any instruments using metal brushes or steel wool.

3. ► carefully rinse the tools under clean running or distilled water to remove any trace of detergent (i.e. enzymatic).
4. ► place the tools in a solution as in point 1 inside a suitable support (i.e. becker) and then put the support in an ultrasonic washing machine for 10 minute at 35°C. Note: the instruments must be opportunely positioned to avoid collisions between instruments and container itself; appropriate supports are recommended (i.e. becker);
5. ► carefully rinse the tools under clean running or distilled water to remove any trace of detergent (i.e. enzymatic).

**Warning:** prolonged immersion time and/or excessive solution concentration can cause corrosion of the instruments; always comply with the recommendations for immersion time provided by the producer of the disinfectant solution.

### Manual disinfection:

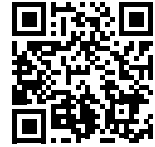
Immediately after manual cleaning, or not more than 30 minutes, place the tools in an appropriate solution of high-quality disinfection medium (PROSEPT<sup>®</sup> Burs, ready-to-use solution), contained in a suitable support (i.e., becker); the tools must be totally covered by the solution. Put the support in an ultrasonic washing machine for 1 minute at 20°C before removing. Pay attention that there is no contact between the instruments;

**Warning:** to avoid corrosion, do not rinse rotating instruments with water at this stage of reprocessing. Automated cleaning/disinfection: Not applicable.

**Drying:** Carefully dry each tool by means of compressed air (maximum 2 bar) using only filtered air (oil-free,



Use the QRcode to download the instruction of use and maintenance of the surgical kit



low contamination with microorganism and particles). The presence of humidity on tools' surface may favor bacterial growth and compromise sterilization process. The drying of the parts is of utmost importance before storage and sterilization, because the accumulation of moisture on the products is harmful and may cause oxidation.

**Maintenance:** At the end of each cleaning, disinfection and drying cycle, the instruments must be subjected to a visual inspection in order to make sure that they are macroscopically clean. Damaged instruments must be discarded to prevent the reuse of blunt or damaged tools. This visual control is absolutely essential for any instrument that affects the result of the operation. A blunt, corroded or contaminated instrument can damage or infect healthy tissue.

**Note:** The visual inspection is as important as cleaning, disinfection, drying and sterilization.

Instruments that are not totally clean must undergo another cleaning, disinfection and drying cycle. Damaged instruments always have to be discarded.

**Inspection and function:** we recommend to check frequently the wear conditions of surgical instruments and immediately replace the worn-out ones. In particular:

- ▶ cutting tools: it is very important to check the cutting performance before each use; replace the tools that cannot guarantee adequate cutting performance, leading to inaccurate cut and bone overheating. We recommend to do not use more than 10 times on hard bone and not more that 50 times on medium/soft bone;
- ▶ coupling parts of tools: parts of the tools that are mechanically coupled are subjected to wear (screwdrivers, hand-piece tools, drill extension, hand-piece connections). We recommend to check after each cleaning, disinfection and sterilization cycle the wear of screwdriver's retention systems and replace those which may not guarantee the

correct retention anymore;

- ▶ we recommend to check periodically the calibrated instruments to ensure their proper functionality (e.g. torque wrench).

**Packaging:** Place the instruments back in the correspondent slot inside the surgical tray. The surgical kit must be placed into a sterilization pouch, which fulfil the following requirements: EN ISO 11607 (e.g. medical grade paper); suitable for steam sterilization; sufficient protection for instruments as well as for maintenance of sterilization packaging against mechanical damage (the pouch protects the kit during sterilization and keeps it sterile until further use).

Pack the surgical tray with sterilization pouch and put it inside the autoclave in a horizontal position; do not turn it upside down to ensure the proper drying.

## STERILIZATION

This product is reusable and supplied non-sterile, being unitarily packaged. This product must be correctly cleaned, disinfected and sterilized before each use.

**Warning:** Do not autoclave this product in its original packaging.

The use of an autoclave for steam sterilization of the surgical tray is recommended, which fulfil the following requirements: EN ISO 17665. Carefully observe the instructions and recommendations of steam sterilizer manufacturer. Follow the instructions for maintenance and calibration of the autoclave. It has been validated that a steam sterilization cycle at 134°C, 2 bar, 4 minutes, 1 hour lasting has produced a sterile condition of the surgical kit; this condition has been certified by an accredited laboratory.

If not already present on the sterilization pouch, it is recommended to place a chemical indicator inside the

## ► Instructions & Maintenance

autoclave during the process to confirm sterilization effectiveness.

It is recommended to sterilize the instruments arranged in the appropriate position inside the surgical tray.

Pack the surgical tray with sterilization pouch and put it inside the autoclave in a horizontal position; do not turn it upside down to ensure the proper drying. Note: Users must ensure that the sterilizer and all sterilization accessories (sterilization sheets, envelopes, sterilization trays, biological and chemical indicators) are correctly calibrated and approved for the intended sterilization cycle. If there are visible signs of humidity (damp spots on the sterile package, stagnant water in the load) at the end of the sterilization cycle, repackage and re-sterilize. When removing the instruments from the sterile package, follow the aseptic principles. The sterile packaging must not be opened until immediately before the use of the instrument. Instruments with damaged sterile packaging should not be used. We recommend keeping a replacement instrument handy.

## STORAGE

Store in dark, cool and dry place. It is recommended to keep the pouch closed until next surgical procedure. Follow the instructions of the manufacturer of the pouches regarding storage conditions and expiration date of sterilized goods.

## FURTHER INFORMATION

Advan surgical instruments are made of materials suitable for surgical use and for severe conditions occurring during cleaning, disinfection and sterilization. We recommend not to exceed with disinfection and sterilization processes (too higher disinfectant concentrations, temperatures, times, etc.) since it may reduce tools' lifetime. We recommend to follow the manufacturer's instructions for all products used in combination with Advan surgical instruments. Instruments that have not been used must be, in any case, washed and sterilized before the next use; new instruments provided in original packaging by Advan must be washed and sterilized before use. The instructions above provided have been validated by

the manufacturer of the medical devices to be capable of preparing a medical device for reuse. It is user's responsibility to ensure that the reconditioning, carried out with the equipment and materials available in the reconditioning facility, has achieved the desired result. This normally requires verification and/or validation and routine monitoring of the process. For more information on the use of Advan products, contact Advan customer service.

## DISPOSAL

Disposal must be managed in an environmentally sustainable way, in compliance with local regulations. Hazardous waste from contaminated devices or sharp objects must be disposed in suitable containers that meet specific technical requirements.

## LIFECYCLE

The Advan Kit is recommended for up to 50 uses, as long as the conditions of use indicated by Advan are respected. Concerning the cutting tools' lifecycle, please refer to paragraph inspection and function point 1. Anyway, regardless of the number of times that the instrument has been used, the professional must always evaluate its condition after each use.

## NOTES

Doctors who use the Advan Product are required to have appropriate technical knowledge and training, in order to ensure its safe use. The Advan Product must be used in accordance with the instructions for use provided by the manufacturer. The doctor is responsible for the use of the device in accordance with these instructions for use and for determining the suitability of the device for the individual patient situation. The Advan Product is part of a complete program and must only be used in conjunction with its original components and tools distributed directly by Advan and all Advan national dealers. The use of third part products not distributed by Advan voids any warranty or other obligation, implicit or explicit, of Advan.



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