

temporary
orthodontic
micro
anchorage
system

The manual.

CONTENTS.

5	tomas® – The concept
6	The tomas®-pin
6	Brief description
7	Indication
8	The thread
10	The gingival collar
10	The material
11	The heads SD and EP
12	Sterility
13	Information and documentation
14	The insertion
14	General requirements
15	Brief overview – ways of inserting a mini-implant
16	Insertion planning
16	<i>Preoperative planning</i>
18	<i>Diagnostic tools</i>
20	<i>Insertion in the palate</i>
22	<i>Interradicular insertion</i>
24	<i>Insertion on the edentulous alveolar ridge</i>
25	<i>Determining the type and length of the tomas®-pin</i>
25	<i>Selecting the head</i>
25	<i>Gingival thickness parameter</i>
26	<i>Bone thickness parameter</i>
28	Insertion preparation
28	<i>Instrument preparation</i>



29	<i>Hygiene information</i>
30	<i>Anesthesia</i>
31	<i>Measuring the gingival thickness</i>
32	Performing the insertion
32	<i>Transgingival perforation</i>
33	<i>Gingival punch-out technique</i>
34	<i>Preparing the bone site</i>
36	<i>Inserting the tomas®-pin in the bone</i>
38	Post insertion
38	<i>Connecting the coupling elements</i>
39	<i>Post-operative care</i>
39	<i>Removing the tomas®-pin</i>
40	<i>Final notes</i>
42	tomas® – More than just a pin
42	The tomas®-abutments
42	<i>Abutment and tomas®-pin</i>
44	<i>tomas®-transfer cap</i>
45	<i>tomas®-laboratory pin</i>
46	<i>Overview abutments</i>
48	<i>The tomas®-auxiliaries</i>
50	Additional information
50	<i>Explanation of symbols on label</i>
50	<i>Explanation of label</i>

The Dentaurem Group.
More than 130 years of dental experience.





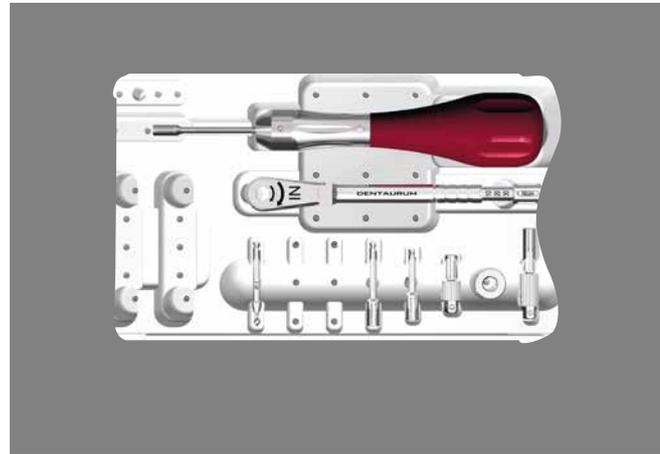
The concept.

Dentaurum is a leading company in the orthodontic sector and it also has considerable experience in the implantology sector with its affiliate Dentaurum Implants. This ensures that the expertise in these two areas in Dentaurum can be utilized in optimal synergy when developing products and defining treatment concepts for the benefit of the user and patient.

Orthodontists from all over the world work in collaboration with Dentaurum on continually perfecting the system. New scientific findings are integrated on an ongoing basis so that the operator can always be assured of using a state-of-the-art mini-screw system for skeletal anchorage.

The system not only includes the tomas®-pins, but also an ever increasing variety of coupling procedures for optimally connecting the pins with the actual orthodontic appliance. The only way to maximize treatment success is by optimally balancing the interaction of these two anchorage components.

The tomas[®]-pin.



Brief description.

The tomas[®]-pin SD and the tomas[®]-pin EP have been designed for endosteal insertion in the maxilla and mandible. A temporary, reliable anchorage option is created for orthodontic treatment with the aid of an endosteally anchored mini-screw (tomas[®]-pin). The head of the tomas[®]-pin can be coupled with different orthodontic appliances, depending on the indication, to attain or support the required tooth movement. tomas[®] is a system of coordinated components not only for the insertion of mini-screws, but for actual orthodontic treatment.

There are two distinct head versions of the tomas[®]-pin:

- tomas[®]-pin SD with a cross-slot head
- tomas[®]-pin EP with a mushroom head

The tomas[®]-pin SD has a 22 cross slot. This design allows the SD pin head to be used in the same way as a standard bracket. The new tomas[®]-pin EP has a mushroom head. This shape is well suited for attaching elastic elements.

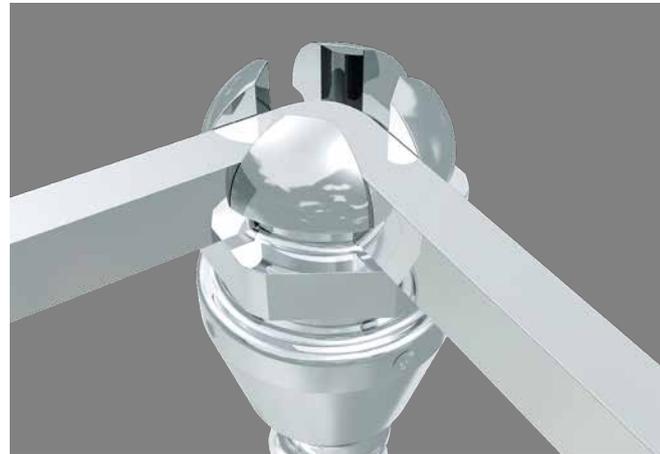


Indication.

The tomas®-pin SD and the tomas®-pin EP are used to provide temporary orthodontic anchorage for the following treatments:

- Distalization and mesialization of teeth
- Uprighting of molars
- Intrusion of teeth
- Space closure with Class I occlusion
- Sliding mechanics in Class II
- Preventing the protrusion of incisors
- Palatal expansion
- For oligodontia
- Altering the tooth position as part of preprosthetic treatment
- Anchoring temporary crowns

The tomas[®]-pin.



The thread.

The thread diameter of all tomas[®]-pins is 1.6 mm. It is available in three lengths. The packaging of the three lengths of the sterile tomas[®]-pins is color-coded.

The tomas[®]-pin has a self-drilling thread. This means that the thread has been optimized so that pre-drilling is not necessary. However, there are cases where a perforation of the cortical bone is recommended (see p. 36 Inserting the tomas[®]-pin). The shape of the thread tip allows it to penetrate the bone after half a turn without applying excessive force. Furthermore, the tip cannot penetrate the tooth root.



■ 6.0 mm ■ 8.0 mm ■ 10.0 mm

tomas[®]-pin SD



□ 6.0 mm ■ 8.0 mm ■ 10.0 mm

tomas[®]-pin EP

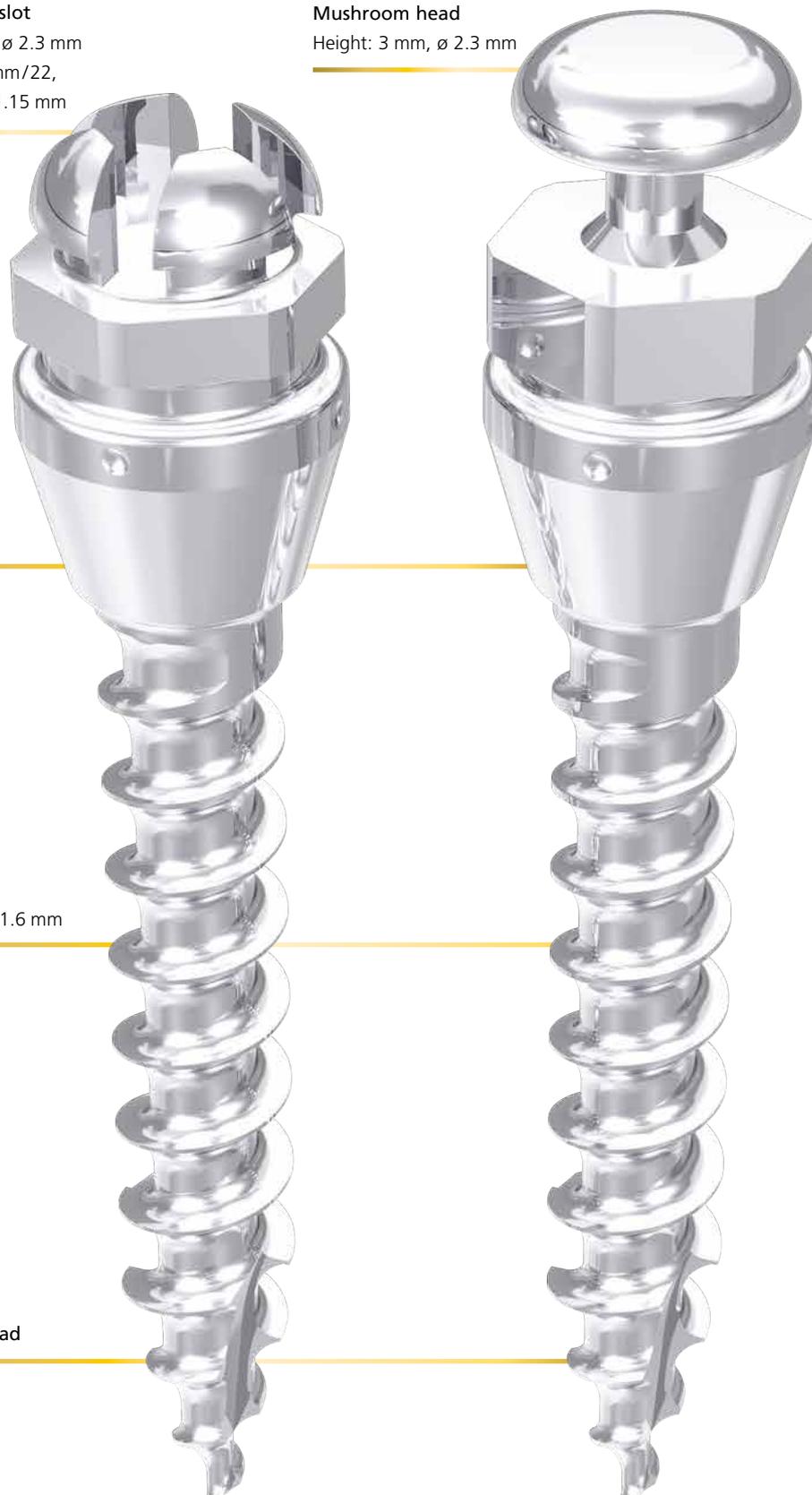
Head with cross slot
Height: 2.25 mm, \varnothing 2.3 mm
Slot width: 0.56 mm/22,
Slot depth: max. 1.15 mm

Mushroom head
Height: 3 mm, \varnothing 2.3 mm

Gingival collar
Height: 2 mm,
 \varnothing max. 2.8 mm

Thread lengths
6, 8 or 10 mm, \varnothing 1.6 mm

Self-drilling thread



The tomas[®]-pin.



The gingival collar.

The conical gingival collar of the tomas[®]-pins is machine polished to ensure optimal, close gingival adaptation and to prevent irritation. This feature can be optimally utilized if the gingiva at the insertion site is punched out as recommended. There are four marks on the cylindrical section of the gingival collar which indicate the midline of the slots. The height of the gingival collar is 2.0 mm and the maximum diameter 2.8 mm.

The material.

tomas[®]-pins are manufactured from Grade 5 titanium implant material in accordance with ASTM* (TiAl6V4, Material No. 3.7165). This material is widely used in the field of implantology due to its high biocompatibility and is comprehensively documented.

* American Society for Testing and Materials



The heads SD and EP.

The tomas[®]-pin is available in two head versions: with a cross slot (SD) and a mushroom head (EP). A hexagon, size 2.5 mm, is used for insertion.

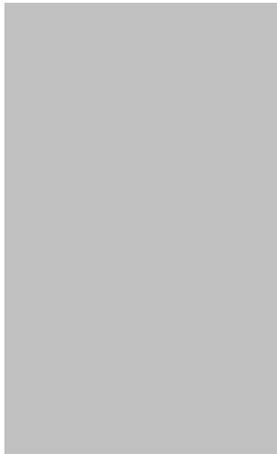
tomas[®]-pin SD

The head of the tomas[®] -pin SD has a 22 cross slot. This design allows the pin head to be used in the same way as a standard bracket. A drop of adhesive (resin, preferably light-curing) is used for ligation and fixation of the coupling elements (square wires, springs etc.). A ligature can also be used for fixation. The maximum depth of the slot is 1.15 mm. The height of the head is 2.25 mm and its diameter 2.3 mm.

tomas[®]-pin EP

The tomas[®]-pin EP has a mushroom head. This form is optimized for attaching elastic elements (springs, elastic rings and chains) and for fixing tomas[®]-abutments. The height is 3 mm and the maximum diameter 2.3 mm.

The tomas[®]-pin.



Sterility.

tomas[®]-pins are supplied gamma-sterilized in a combination of glass capsule (tomas[®]-cartridge) and blister pack in accordance with the requirements of EU guidelines for medical products. They are therefore ready for immediate use and, unlike other mini-screws, do not have to be sterilized prior to use.

The sterile version of the tomas[®]-pin is placed inside a metal holder. Push the insertion instrument into the metal holder and press until the head perceptibly engages in the retention of the instrument. The tomas[®]-pin can now be removed directly from the metal holder using the insertion instruments and can be inserted. This greatly facilitates the surgical procedure and ensures that there is no contact with the tomas[®]-pin – in particular the thread – when screwing in. The tomas[®]-pin is intended for single use only.

Reconditioning of tomas[®]-pins that have been inserted previously (recycling) or reuse on patients is not permitted.

Dentaurum guarantees the sterility of the tomas[®]-pin until the expiration date on the packaging, provided that the original packaging is undamaged. No guarantee can be given for the sterility after the expiration date and the tomas[®]-pin may no longer be used on patients after this date.



tomas®-pins that have been removed from the packaging but have not been inserted, must also no longer be used or resterilized. All tomas®-pin versions are also supplied non-sterile.

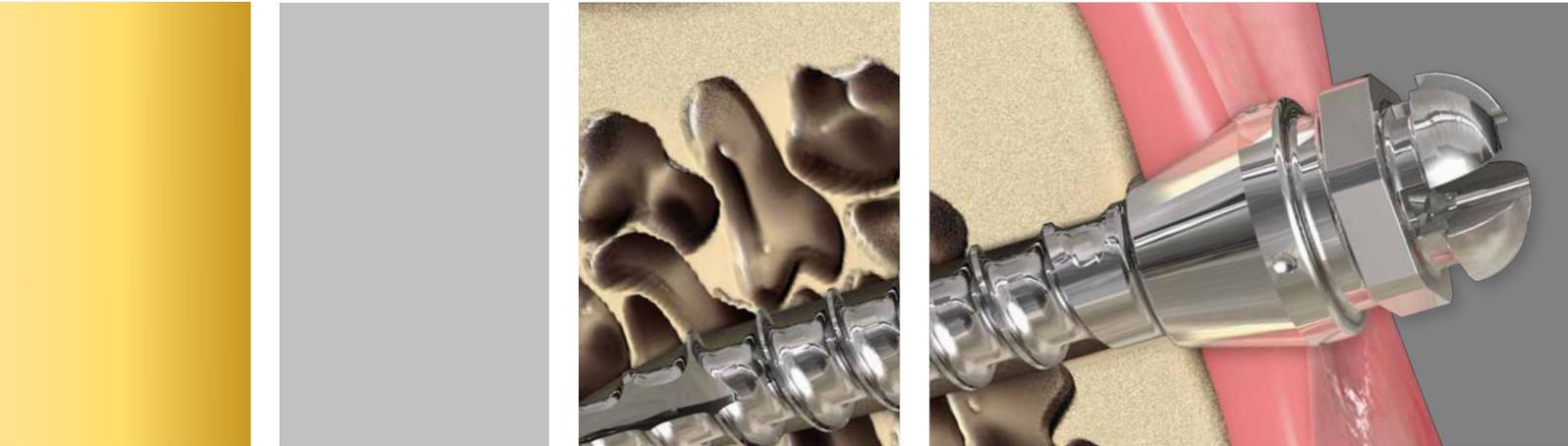
All other components are supplied non-sterile and must be sterilized before initial use and following each subsequent use.

Information and documentation.

The labels contain important information relating to the tomas®-pin: type, order number, sterility expiration date, LOT number etc. The LOT number of the tomas®-pin is required for certification and facilitates traceability.

Adhesive labels, which contain relevant information about the tomas®-pin, are provided on the blister packaging for the patient records. These labels can be removed as required and transferred to the patient file for documentation.

The insertion.



General requirement.

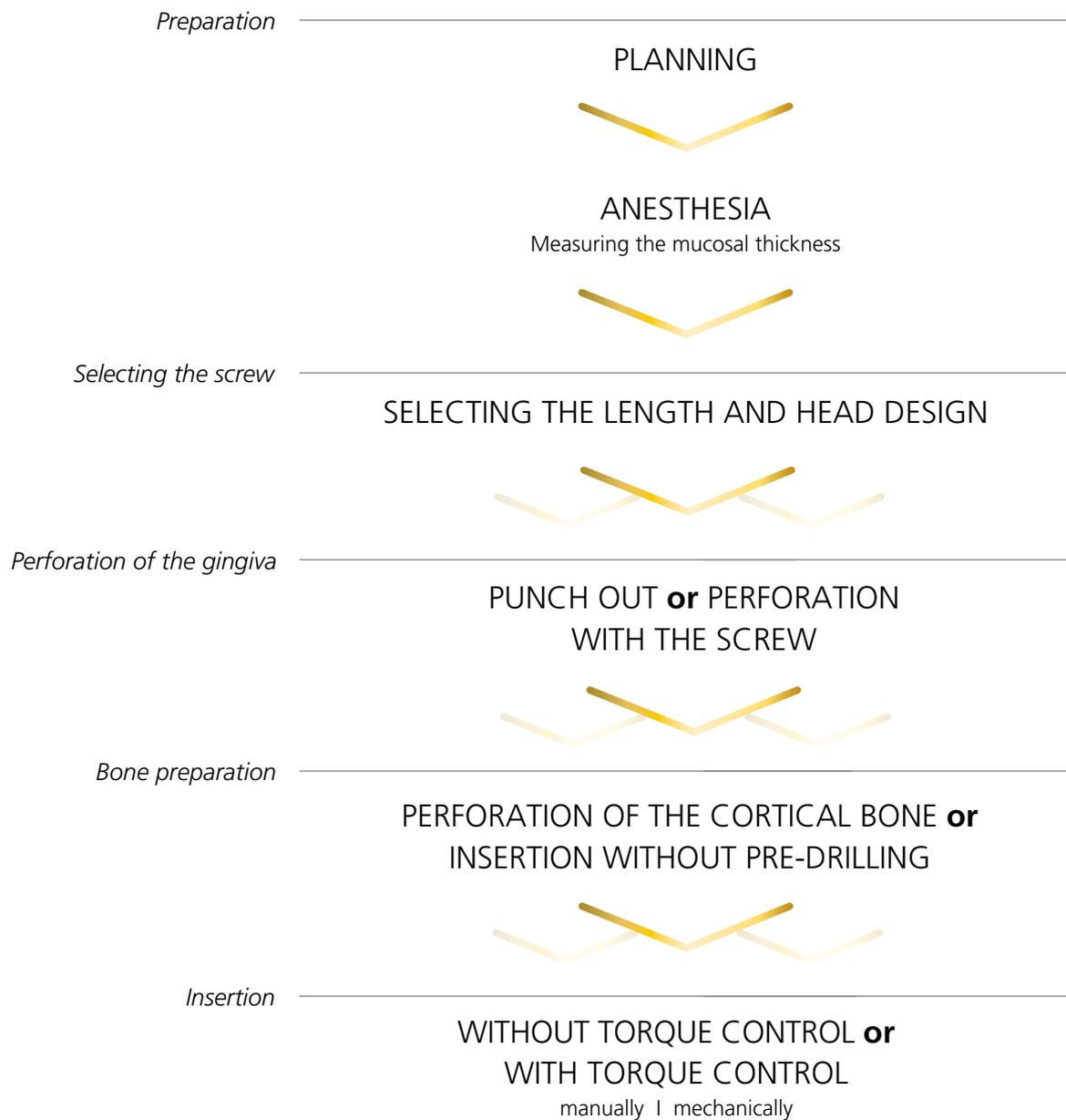
The tomas®-pin should only be inserted by orthodontists, dentists, oral surgeons or maxillofacial surgeons. The instructions for use should be read carefully beforehand.

The topics dealt with in this section are general illustrations and should be adapted to suit the individual conditions.

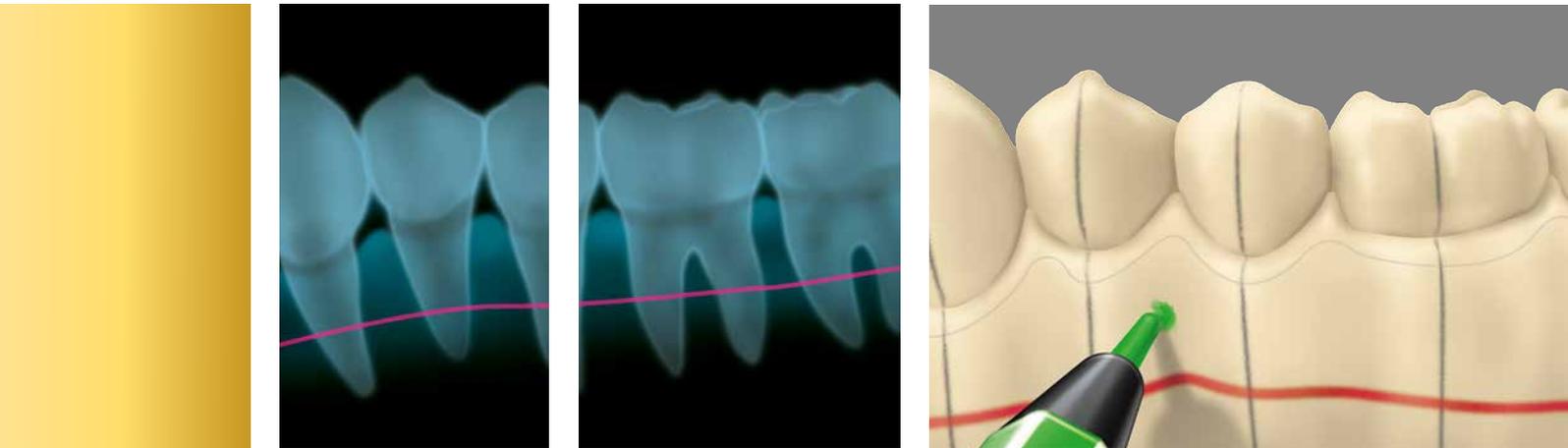
The following illustrations describe only insertion stages that provide a high degree of safety for the patient and physician.

In addition, this manual cannot describe all clinical details and scientific explanations. For further information, please refer to relevant dental literature.

Brief overview – ways of inserting a mini implant.



Insertion planning.



Preoperative planning.

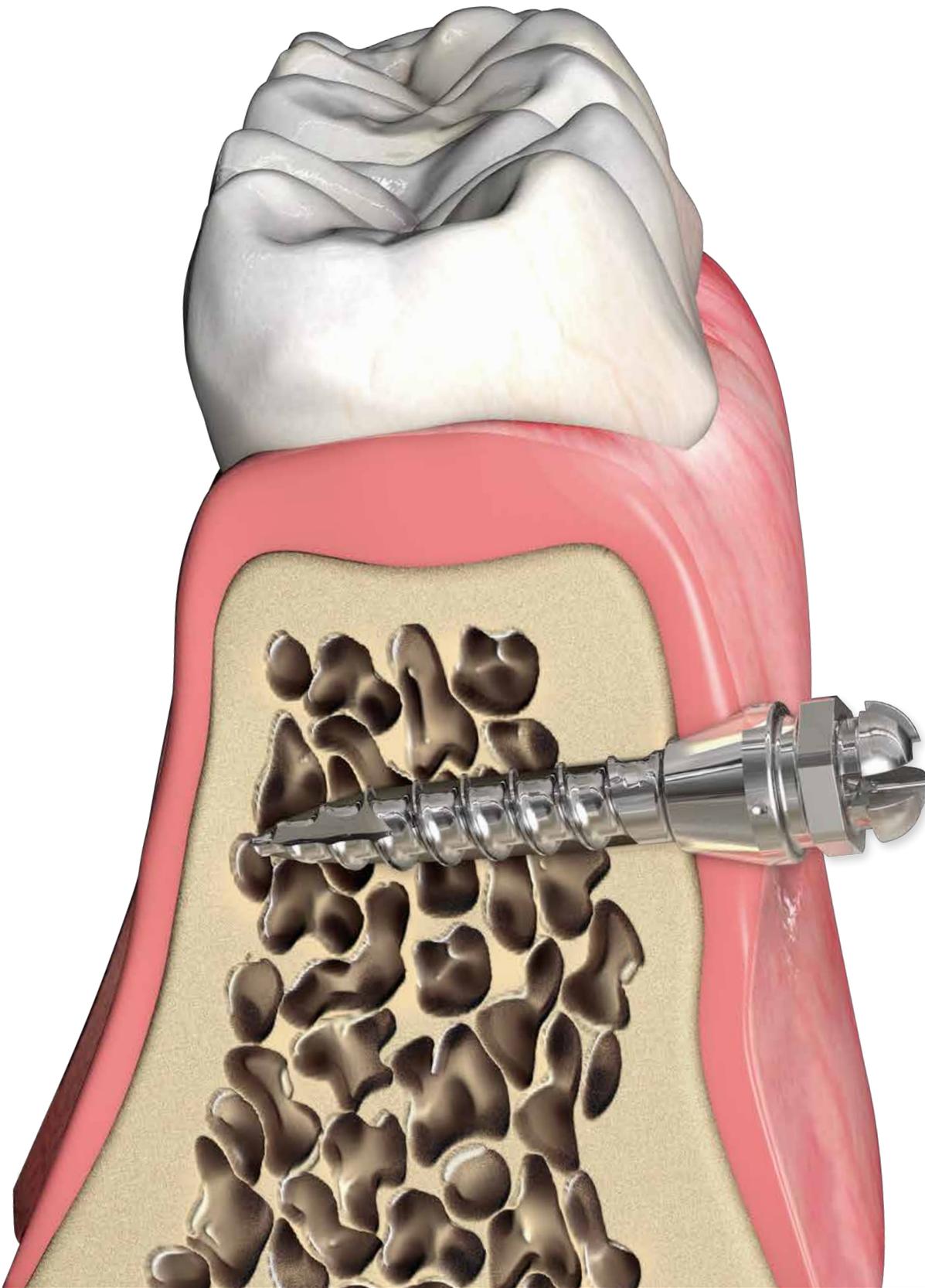
Accurate preoperative planning is essential for successful treatment with the tomas® concept. This also includes a full examination (contraindications should be eliminated) and explanation of treatment to the patient.

Cases require accurate planning. In orthodontic planning, the model analysis and X-ray allow an assessment of the relationship between the adjacent teeth and the position of the tooth root. This is the only way to establish the exact position for inserting the tomas®-pin. To ensure that the tomas®-pin functions effectively it is essential that it has stable anchorage in the bone (primary stability) and that the head is placed in the region of the attached gingiva (gingiva alveolaris).

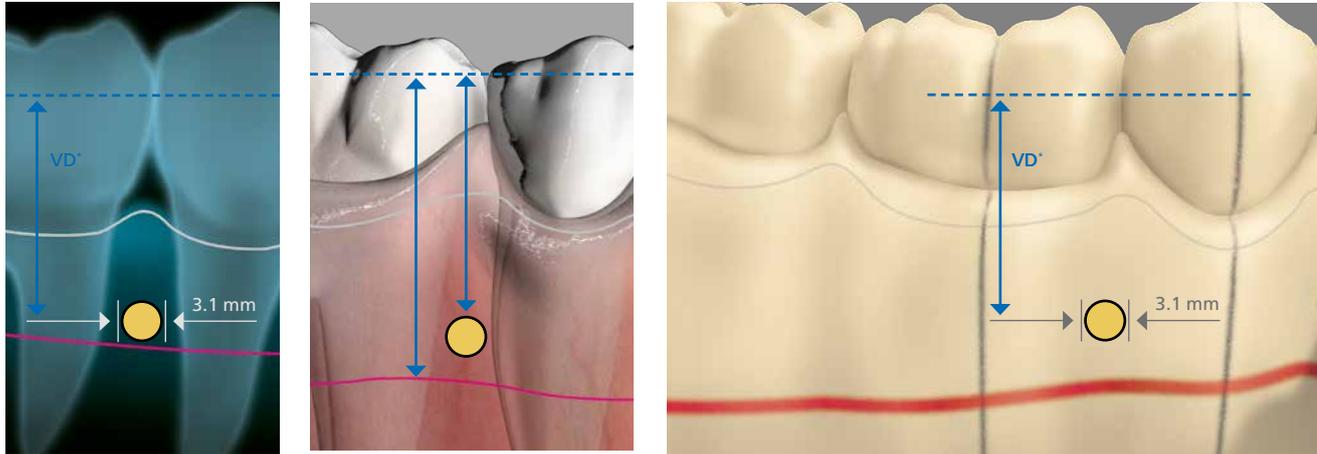
The insertion of a tomas®-pin can be performed in the following regions:

- anterior and lateral palate
- interradicular insertion from the buccal side in the maxilla and mandible.
- directly on the edentulous alveolar ridge

When using the tomas®-pin as an anchorage unit, ensure that the head and surrounding soft tissue are not subjected to detrimental mechanical influences (e. g. movement of the mucosa, interference from bands or the tongue or manipulation).



Insertion planning.



Diagnostic tools.

To find or determine the insertion site for a tomas®-pin, two-dimensional X-ray images (orthopantomogram, dental film and lateral cephalometric radiograph) and models are sufficient.

X-ray images help determine the two-dimensional space available through measurement. The magnification factor should be taken into account.

The formula is:

$$\text{Real distance} = \frac{\text{distance on the X-ray image}}{\text{magnification factor}}$$

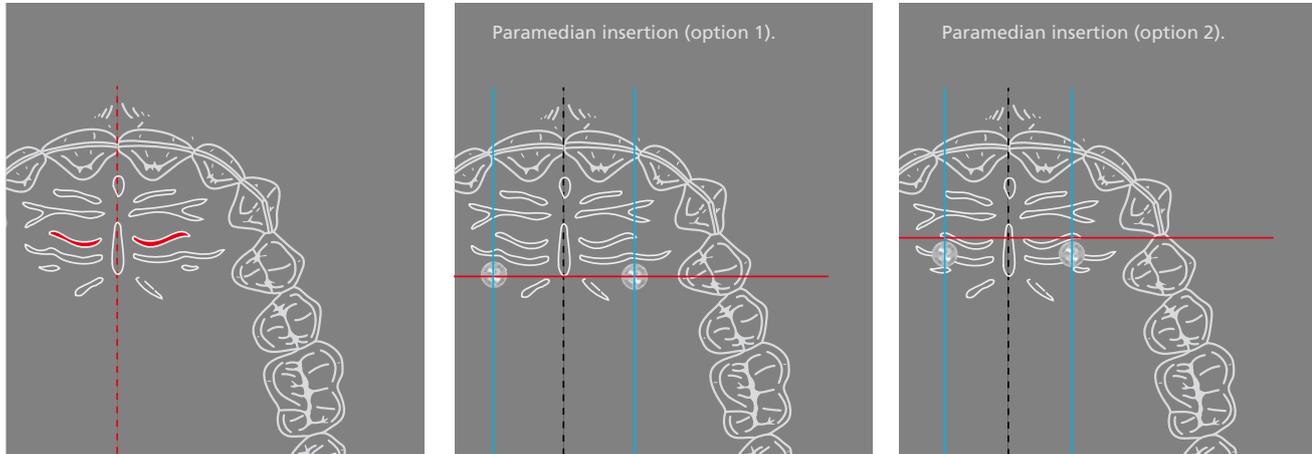
* VD = Vertical distance

Conversion of the distance in the X-ray image in real distance.

	Magnification factor				
	0.9	1.0	1.1	1.2	1.3
2.5	2.78	2.50	2.27	2.08	1.92
3.0	3.33	3.00	2.73	2.50	2.31
3.5	3.89	3.50	3.18	2.92	2.69
4.0	4.44	4.00	3.64	3.33	3.08
4.5	5.00	4.50	4.09	3.75	3.46
5.0	5.56	5.00	4.55	4.17	3.85
5.5	6.11	5.50	5.00	4.58	4.23
6.0	6.67	6.00	5.45	5.00	4.62
6.5	7.22	6.50	5.91	5.42	5.00
7.0	7.78	7.00	6.36	5.83	5.38
7.5	8.33	7.50	6.82	6.25	5.77
8.0	8.89	8.00	7.27	6.67	6.15
8.5	9.44	8.50	7.73	7.08	6.54
9.0	10.00	9.00	8.18	7.50	6.92
9.5	10.56	9.50	8.64	7.92	7.31
10.0	11.11	10.00	9.09	8.33	7.69

If, for other reasons, a three-dimensional X-ray image (CT or CBCT) is available, this can be used for planning. It is not necessary to create such an image merely for planning the insertion of a tomas®-pin.

Insertion planning.



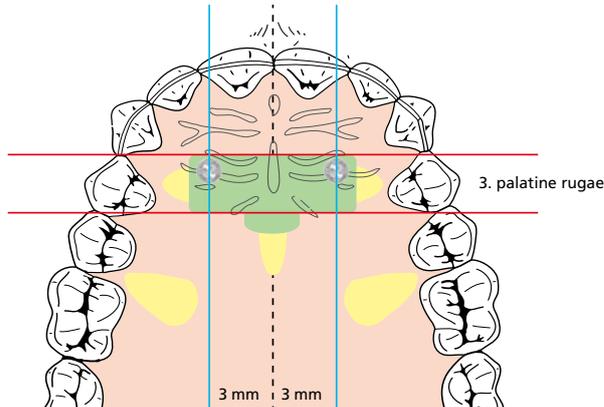
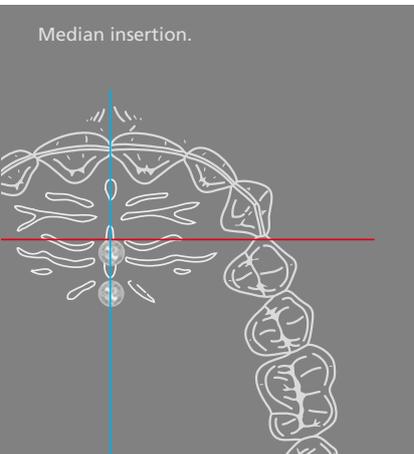
Insertion in the palate.

There are three insertion sites in the palate: the anterior palate and the interradicular spaces on each lateral side between the second premolars and the first molars. The insertion of tomas®-pins at the front of the palate offers some advantages compared with the interradicular placement on the buccal side:

- Insertion is easy to perform.
- Bone volume is high.
- The success rate is very high.
- Tooth movements are not hindered since the tomas®-pin is far from the tooth roots.
- Numerous appliances for distalization, mesialization, intrusion and palatal expansion are available.

At the anterior palate, always insert two tomas®-pins which are splinted together by parts of the appliance. This provides a high primary stability for the subsequent, directly anchored appliance but also for indirect anchoring. No rotary forces can be transmitted to single tomas®-pins through splinting.

The middle line and the third large palatine rugae at the anterior palate can help find the correct insertion spot. The bone availability can be measured by means of a lateral cephalometric radiograph (LCR) (see page 19). There are three different protocols for the insertion of tomas®-pins in this region.



Paramedian insertion (option 1 – Rp3 position).

Trace an imaginary, transversal line between the distal contact points of the upper cuspids. If these are nonexistent or malpositioned, use the third palatine rugae as orientation. Position the two tomas®-pins (8 mm length each) each three millimeters from the middle line obliquely to the occlusal plane. During insertion align the tips of the tomas®-pins with the root tips of the upper incisors.

Paramedian insertion (option 2 – M4 position).

Trace an imaginary, transversal line between the palatal cusps of the first premolars. Half way between the cusps and the middle line, insert the two tomas®-pins (10 mm length) at an angle of 90° from the occlusal plane and swivelled by 10° in the lateral/ cranial direction.

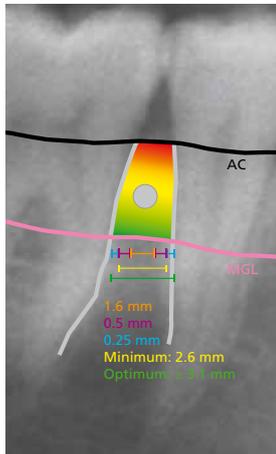
Median insertion.

Use the third palatine rugae as orientation. At the intersection point of this line with the middle line, insert the first tomas®-pin (8 mm length). At least six millimeters behind it, insert the second tomas®-pin (6 mm length) on the middle line. Insertion is performed at an angle of 90° to the bone surface.

Insertion in the lateral palate.

Only the interradicular space between the second premolar and the first molar is suitable for the insertion at the lateral palate. The guidelines on page 22 "Interradicular insertion" apply for the selection of the insertion site. Moreover, the transversal profile of the palate and the mucosal thickness in the insertion direction should be taken into account. This information is important for selecting the length of a tomas®-pin. It shall be ensured that the part of the tomas®-pin that is inside the bone is at least as long as the part outside the bone or longer.

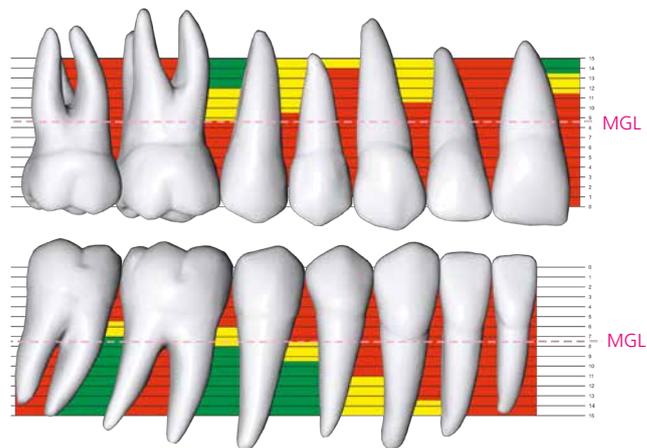
Insertion planning.



Interradicular insertion.

An important factor for successful interradicular insertion is the space available between the roots of the teeth. The space required results from the diameter of the tomas®-pin (1.6 mm), the minimum quantity of circular bone (2 x 0.5 mm) and the periodontal ligament (PDL; 2 x 0.25 mm). Therefore, a gap of at least 2.6 mm, or even better 3.1 mm or more, is required between the roots over the entire length of the tomas®-pin. Besides the tooth spacing, the position of the crestal bone edge $X = (AC)$ and the mucogingival line $Y = MGL$ are also important. These limitations determine the insertion window. To define the exact insertion site for the tomas®-pin, it is important to know the exact position of these anatomical structures.

The course of the muco gingival line can also be seen clinically on the model with some restrictions. The position of the crestal bone edge and the adjacent root can only be seen on the X-ray image. Measurements can also be performed on the X-ray image and on the model or intraorally. A common starting point for measurement is required in order for the X-ray image to be compatible with the model. Suitable here is the proximal contact point, since it is recognizable clinically, radiographically and on the model. The position of the mucogingival line can thus be marked on the X-ray image and conversely the position of the roots and crestal bone edge be transferred to the model. This information helps determine the two-dimensional space available for the tomas®-pin at the intended insertion site in a reliable way.



The tomas®-pin should be inserted in such a way that it is located, if possible, at the same distance to the adjacent tooth roots. Proximity to the root increases the risk of loss.

It is known from numerous anatomical studies where there are suitable insertion sites, so-called safe zones. For the inter-radicular spaces on the buccal side, these are as follows*:

In the maxilla between:

- the 1st incisors
- the 2nd incisors and cuspids
- the 2nd premolar and the 1st molar (buccal and palatal)

In the mandible between:

- the 1st and the 2nd premolar
- the 2nd premolar and the 1st molar
- the 1st and 2nd molar

Outside these zones, failure, that means the loss of a tomas®-pin, is more likely to happen since there is insufficient space between the roots. However, studies commonly use average values of a small population and therefore serve only as guidance when looking for a suitable insertion site. Individual conditions should always be taken into account. If the conditions stated at the beginning – i.e. sufficient gap between the roots – are fulfilled, insertion can also be successful outside the "safe zones". The patient must be informed about the high risk of loss of mini-implants inserted interradicularly.

* Measurement values and illustration (modified) according to:

Ludwig, B, Glasl, B, Kinzinger, GS, et al.: Anatomical Guidelines for Miniscrew Insertion: Vestibular Interradicular Sites. J Clin Orthod; 2011, 45 (3): 165-173

Insertion planning.



Insertion on the edentulous alveolar ridge.

The tomas®-pin can be used not only as a skeletal anchorage, but also as a temporary implant for a temporary prosthetic restoration, for example in cases of tooth agenesis where the tomas®-pin is used as a holder for a temporary crown.

The position of the tomas®-pin can be freely selected if it is to be inserted in areas where there is no risk of damage to tooth roots, nerves, blood vessels or maxillary sinus (perforation) – depending on the planned treatment outcome, relevant anatomical structures and the above-mentioned prerequisites.

The insertion path should take into account the profile of the edentulous jaw segment.



Determining the type and length of the tomas®-pin.

Depending on the type of treatment, you can choose either the tomas®-pin SD (head with cross slot) or the tomas®-pin EP (mushroom head). Bone availability and mucosal thickness in the insertion path are important factors when selecting the length of the tomas®-pin.

Selecting the head

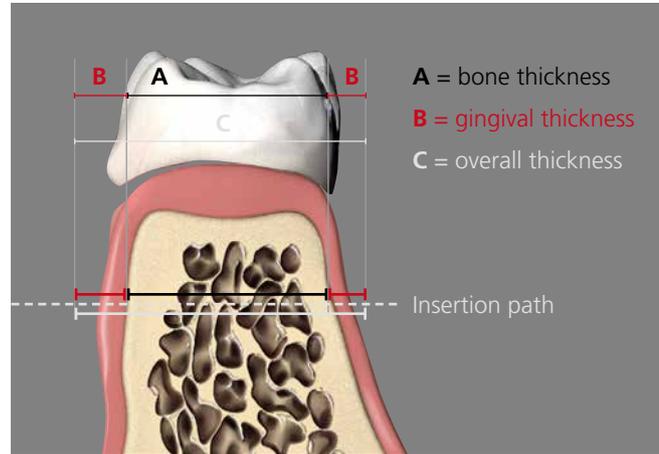
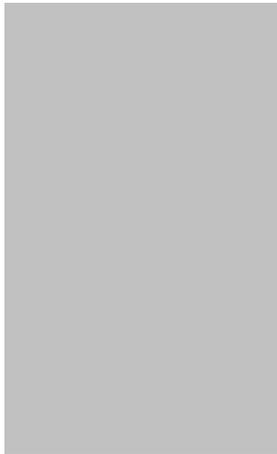
The head of the tomas®-pin SD has a 22 cross slot. This pin is therefore eligible for treatments involving primarily square wires. This is for example the case for indirect anchorage with the tomas®-T wire or for direct anchorage using a tomas®-uprighting spring.

The tomas®-pin EP has a mushroom head and a slightly higher hexagon. It is optimally suited for appliances where tension springs, elastic rings or chains are to be attached to the head of the pin, including the skeletally anchored distalization appliance (amda®) of Dentaureum. Due to the higher hexagon, the tomas®-pin EP is more suitable for abutments with a rotating attachment than the tomas®-pin SD (see page 46 Overview abutments).

Gingival thickness parameter

The mucosal thickness in the retromolar region of the lower jaw and at the palate is often more than 2 mm. The section of the tomas®-pin that is inside the bone has to be at least as long as the section outside the bone. The combined height of the gingival collar and head of the tomas®-pin SD is 4.3 mm (tomas®-pin EP = 5 mm). As the head of the tomas®-pin is never inside the gingiva, its height is of secondary importance at this stage. If the gingiva at the insertion site is 4 mm thick (for example), 2 mm of the thread are not in the bone. In total 6.3 mm (tomas®-pin SD) or 7 mm (tomas®-pin EP) are outside the bone. Consequently the tomas®-pin should be at least 8 mm long. In this case a 10 mm tomas®-pin should be selected.

Insertion planning.



Bone thickness parameter

With interradicular monocortical insertion, the screw head should be in the attached gingiva, as already illustrated, though it should also have stable anchorage in the bone. The thickness of the alveolar ridge is less than 8 mm, particularly in the region of the lower premolars. In this case, a 6 mm long tomas®-pin should be used.

Selection of the tomas®-pin length is based on the thickness of the bone in the planned insertion path:

- Bone thickness > 10 mm; use tomas®-pin 10
- Bone thickness < 10 mm and > 6 mm; use tomas®-pin 8 or 6
- Bone thickness < 6 mm; angle tomas®-pin 6 or select another insertion site.

It is possible in such cases to compensate to a certain extent for the difference between the length of the mini-screw and thickness of the bone by altering the angle of insertion. A better solution, however, is to select an insertion site with more bone availability. The following is a guide for selecting the length of a tomas®-pin:

- 8 mm or 10 mm for the maxilla
- generally 6 mm or 8 mm for the mandible

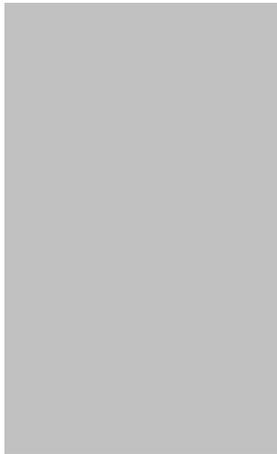
From a biomechanical perspective, it is much better, when mesializing lower molars, to have the attachment point for the required tensile forces bilaterally at the height of the center of resistance.

In such cases the tomas®-pin should be inserted bicortically. This means that the tip of the tomas®-pin perforates the cortical bone and the gingiva on the lingual side. The tip of the tomas®-pin should protrude one to two millimeters from the mucosa in order to fix elastic elements to it. Select the required length by measuring the thickness of the alveolar ridge on the model in the path of insertion and add two millimeters.

Measure the available bone thickness at the palate using the X-ray image and subtract one millimeter (see page 20 Insertion in the palate).

Group	Localization	Characteristics	Prognosis
D1	Lower anterior	<ul style="list-style-type: none"> ■ dense compact bone 	<ul style="list-style-type: none"> ■ good primary stability ■ reduced blood supply ■ caution → overheating during pre-drilling
D2	Upper anterior Lower posterior	<ul style="list-style-type: none"> ■ dense, porous compact bone ■ tight-meshed cancellous bone 	<ul style="list-style-type: none"> ■ good primary stability ■ good healing property
D3	Upper anterior Lower posterior	<ul style="list-style-type: none"> ■ dense, porous compact bone ■ tight-meshed cancellous bone 	<ul style="list-style-type: none"> ■ limited primary stability ■ good blood supply ■ caution → extension of drill hole
D4	Upper posterior (retromolar)	<ul style="list-style-type: none"> ■ little compact bone ■ wide-meshed cancellous bone 	<ul style="list-style-type: none"> ■ low primary stability ■ caution → extension of drill hole

Insertion preparation.



Instrument preparation.

Only original components should be used with tomas®-pins. Specially coordinated preparation instruments are available for the insertion of tomas®-pins. With the exception of the gingival punch, i.e. the tomas®-punch (sterile packaged single-use product), all other instruments must be disinfected, cleaned and sterilized before use. They are intended for multiple use. The service life of individual instruments can differ greatly. The sharpness and condition of rotary instruments should be checked at regular intervals to ensure atraumatic and smooth preparation of the bone site.

The instruments in the tomas®-tray are arranged in separate storage compartments in a logical sequence according to individual working stages. It can therefore be recognized immediately whether all instruments required for treatment are available. The tray contains several tomas®-cartridge holders, which allow the cartridge with the pin to be stored upright or lengthwise and to be easily removed or replaced. All instruments can be placed upright in the tomas®-tray during insertion of the tomas®-pin for optimal, efficient operation.



Hygiene information.

Ensure that hygiene measures are followed carefully throughout the surgical procedure. The treatment room and the patient should be prepared accordingly. Adhere to all essential hygienic measures for invasive surgery such as sterile surgical area, sterile gloves, facemask etc. during insertion of the tomas®-pin. All surgical instruments required for the operation should be checked to ensure that they are complete, functional and sterile. Insertion of the tomas®-pin is always carried out under local anesthetic. The patient should rinse with a disinfectant solution immediately prior to treatment or an appropriate disinfectant solution should be applied locally.

The patient should be positioned to ensure a clear overview of the operating site. The instruments should be thoroughly disinfected, cleaned and conditioned immediately after use.

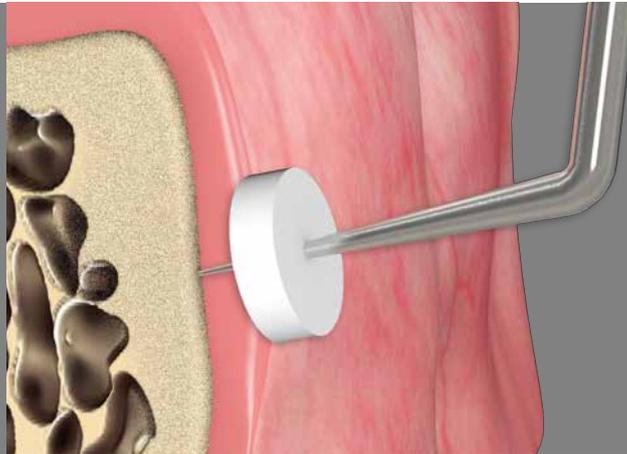
Insertion preparation.



Anesthesia.

The sensitivity of the periodontium of the adjacent teeth should be protected during interradicular insertion of the tomas®-pin. The mucosa at the insertion site should therefore only be anesthetized superficially. Gel surface anesthesia can also be used and should be applied approx. 10 min prior to insertion. Another option is local infiltration anesthesia. Only a small amount (0.2 - 0.5 ml) should be injected at the insertion site and not deep into the mucobuccal fold. Block anesthesia is not required.

For the insertion of the tomas®-pins in the palate, only the insertion regions are anesthetized.

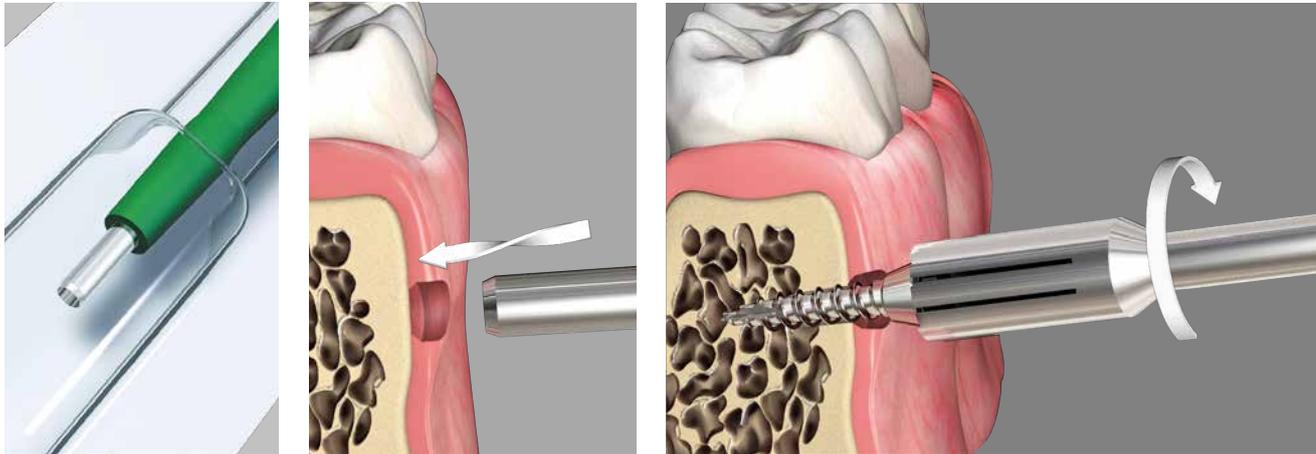


Measuring the gingival thickness.

When the effect of the anesthesia starts to become apparent, the gingival thickness can be measured in the path of insertion.

This can be achieved using a sharp probe with a rubber ring attached. This information is required for determining the actual screw length and when inserting the tomas®-pin.

Performing the insertion.



Transgingival perforation.

The tomas[®]-pin has to automatically penetrate the gingiva. The gingiva must therefore be perforated during insertion. Options include incision with flap formation, punching out the mucosa and directly inserting the screw through the gingiva. There does not appear to be any advantage in using the incision technique due to the small dimensions of the tomas[®]-pin and possible post-operative difficulties. The more minimally invasive the transgingival perforation is, the fewer the post-operative issues.

Two techniques can be used for perforating the gingiva:

- Punching out the gingiva
- Direct insertion of the tomas[®]-pin through the gingiva

Direct insertion through the gingiva causes localized bruising and anemia. No blood flows. Which can be an important psychological aspect, for the patient.



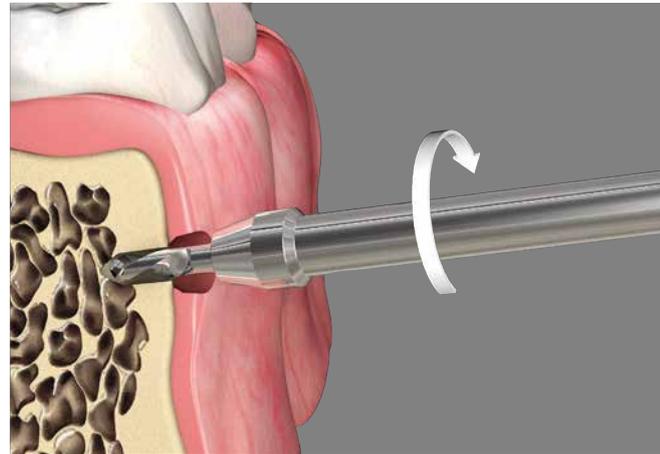
Gingival punch-out technique.

A perforation is punched out of the mucosa at the marked site using the tomas®-punch. It is important that the mucosa is perforated right through to the bone. If several tomas®-pins are to be inserted during an operation, we recommend using the corresponding number of tomas®-punches.

The mucosal punch-out technique creates sharp wound edges, which promote rapid regeneration and virtually inflammation-free healing within a few days. Blood flows when punching out the mucosa. The diameter of the tomas®-punch is 2 mm and the maximum diameter of the conical collar of the tomas®-pin is 2.8 mm. The difference in diameters and the smooth, conical gingival collar of the tomas®-pin allow the mucosa to settle very closely to the collar, immediately sealing the area.

There are currently no publications that have examined the influence of the two types of gingival perforation techniques on post-operative difficulties, histological effects and the failure rate of mini-screws, though from a theoretical standpoint the gingival punch-out technique before insertion is recommended.

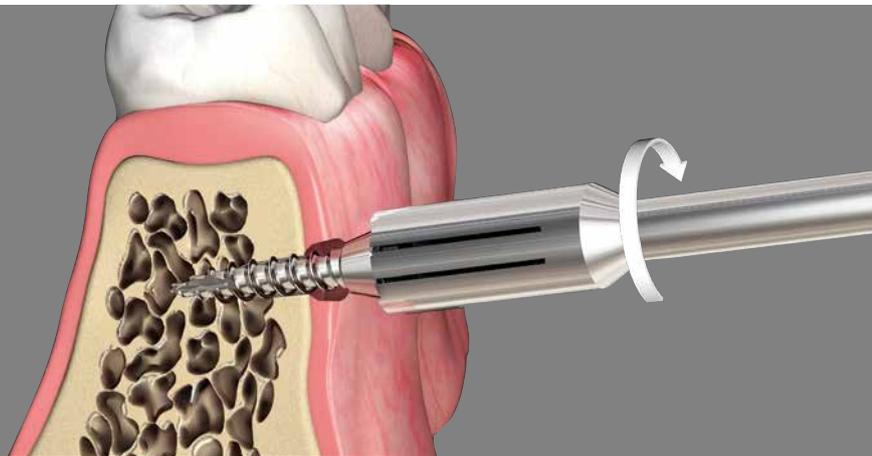
Performing the insertion.



Preparing the bone site.

Advantages of pilot drilling – the tomas®-pin has a self-drilling thread. This means pre-drilling is actually not required for insertion since the tomas®-pin creates its own site in the bone during the screwing-in process. This is achieved by combining tissue ablation (cutting effect) and tissue displacement (bone compression). Which part predominates is highly dependent on the bone structure. Pilot drilling (max. depth 4 mm), however, is also an advantage in the case of self-drilling threads, as it can avoid a number of problems.

The high stresses created in the bone and possible resulting post-operative complaints are the main concern. Bone displacement can greatly distort the periosteum, particularly if the tomas®-pin is inserted near to the alveolar bone ridge (limbus alveolaris). This in turn causes uncomfortable or even painful tensions, which can last for several days. The thickness of the cortical bone determines the insertion torque to a great extent, particularly in the mandible. Here, the cortical bone from a thickness of two millimeters up should always be perforated by pre-drilling. To this end, use the tomas®-drill SD (Ø 1.1 mm; length 4 mm REF 302-103-00).

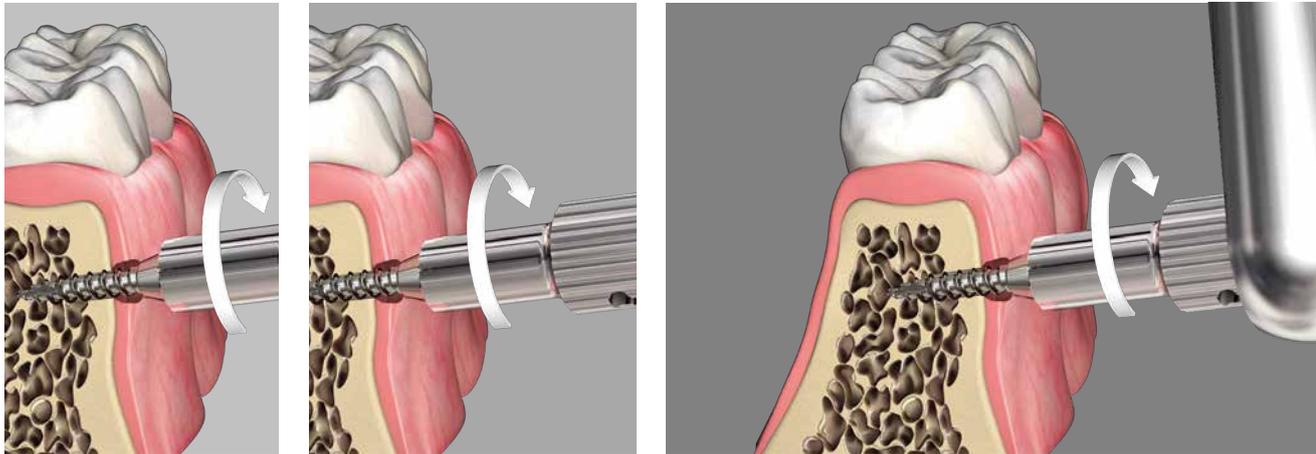


There is one more reason in favor of pre-drilling. It is sometimes difficult to maintain the planned path of insertion with the instrument when screwing in the pin without pilot drilling. It is much easier to align the drill, which then penetrates the bone very quickly and maintains the path of insertion. Pilot drilling is essential for attaining the correct path. The tomas[®]-pin automatically follows the predrilled path, even if the drill depth is only minimal. In addition, the cortical bone is not as severely compromised during drilling and the screw is subjected to less torsional stress.

Important information!

Drilling should be carried out orthogonally to the bone surface depending on the specific conditions and any particular aspects of treatment. The maximum motor rotation speed is 1500 min⁻¹ (optimal 800 min⁻¹). The site should be cooled externally with a sterile, cooled physiological saline solution (5 °C) during preparation to exclude the possibility of thermal damage to the bone. Drill intermittently without applying pressure! It is important that the tomas[®]-drill constantly maintains an axial direction during drilling to ensure rigid retention of the tomas[®]-pin and prevent premature failure. tomas[®]-drills should be replaced after approx. 20 drilling procedures or single-use drills should be used to ensure optimal, atraumatic insertion.

Performing the insertion.



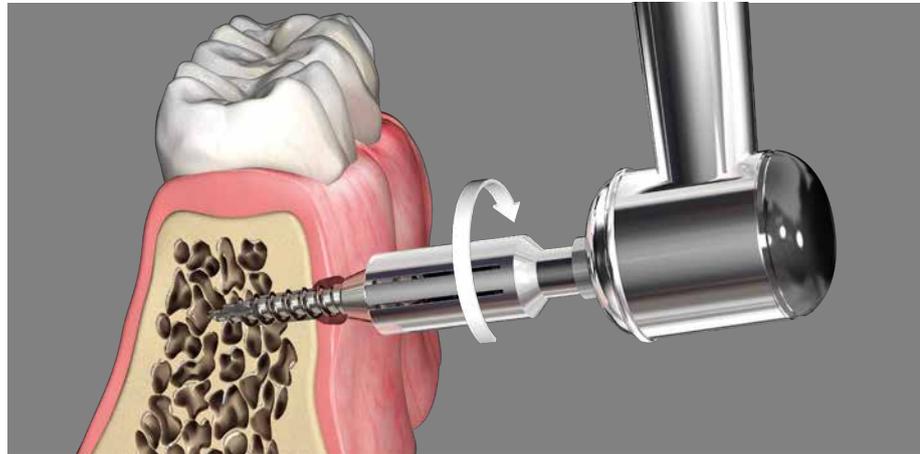
Inserting the tomas®-pin.

The glass capsule with the tomas®-pin should be removed from the blister pack using sterile gloves and not until immediately before insertion. Open the cap and remove the tomas®-pin.

When the glass tube is opened the tomas®-pin sits in the metal holder of the cap and is secured in position by a silicone plug to prevent it from accidentally falling out. Hold the silicone plug upwards and carefully remove it. Insert instrument into metal holder and press until the head of the tomas®-pin perceptibly engages in the retention of the instrument. Caution: the head of the tomas®-pin must engage securely in the holder of the insertion instrument.

Ensure that there is no contact with the thread of the tomas®-pin between removal from the glass tube and insertion into the bone. Insertion should always be completed using a steady rotary movement and a torque that is as constant as possible.

The tomas®-pin can be inserted in the bone manually or using a handpiece. The tomas®-screw driver (REF 302-004-10) or tomas®-applicator (REF 302-004-20 or 302-004-70) with or without the tomas®-wheel (REF 302-004-30) can be used as a manual insertion instrument. The tomas®-torque ratchet (REF 302-004-40) is available as an additional aid for the manual procedure. The torque of the ratchet should be set to 20 Ncm, please refer to the relevant instructions for use. The pin should be inserted using a rotary movement that is as steady as possible.

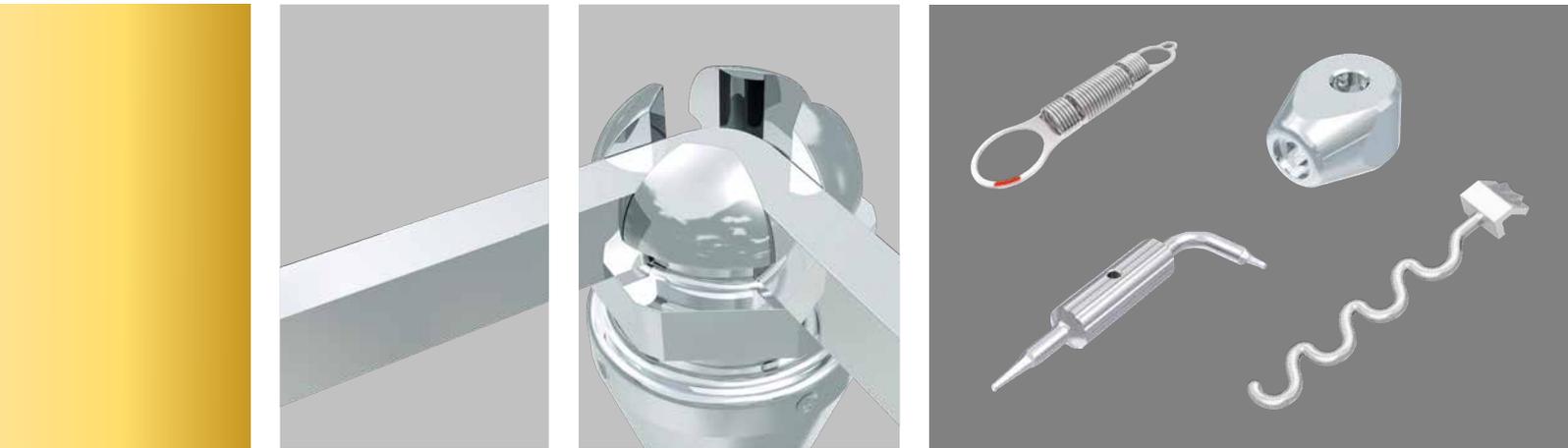


The tomas[®]-driver (REF 302-004-50 or 302-004-60) is available for insertion using a handpiece. A motor and contra-angle with adjustable torque should be used. The torque must be set to 20 Ncm and the speed to a maximum of 25 min⁻¹.

The insertion depth depends on the thickness of the gingiva. If the gingiva is thicker than 2 mm in the insertion path, screw the tomas[®]-pin into the bone until the insertion instrument touches the gingiva. If the gingiva is thinner than 2 mm, insert the tomas[®]-pin into the bone only until the junction between the thread and gingival collar is reached. The gingival collar (height 2 mm) is used as a control. If the tomas[®]-pin is inserted deeper, the thread may skid in the bone. In this case there would not be sufficient primary stability.

Insertion instruments hide the slot marking on the gingiva collar. Nevertheless, the slot alignment of the tomas[®]-pin SD can be controlled with a fitted insertion instrument. All insertion instruments have two grooves. The slot of the tomas[®]-pin SD is always on the right or the left edge of the instrument grooves or in the middle.

Post insertion.



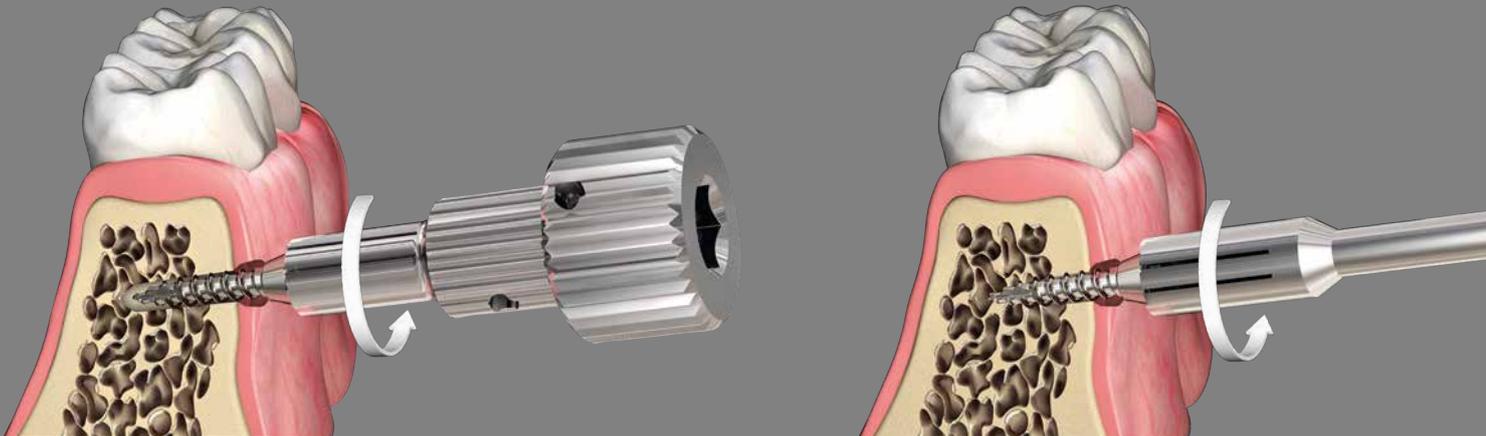
Connecting the coupling elements.

The tomas®-pin can be loaded immediately following insertion. A healing period is not required. The selected abutment or coupling element should be prepared accordingly. The coupling elements of the tomas®-pin SD should be inserted in the slot. Square wires up to a maximum dimension of 0.56 x 0.70 mm/22 x 28 can be used. The coupling wire should be adapted so that it fills at least the entire slot in the longitudinal direction.

The wire can also be angled to prevent displacement of the coupling wire.

The load of the coupling element should be between 0.5 and 2 N (approx. 50 to 200 g) to prevent damaging the teeth to be moved. The coupling element is fixed in position using a standard bracket adhesive. We recommend using a light-curing adhesive. Ensure that the adhesive completely encapsulates the head of the tomas®-pin. Avoid contact between the adhesive and gingiva. Smooth and cure the surface of the adhesive. (Keep to the instructions for use for the adhesive!)

If the coupling element has to be exchanged, remove the adhesive using Weingart pliers (REF 003-120-00). After the coupling element has been exchanged, the adhesive cap should be renewed as described above.



Post-operative care.

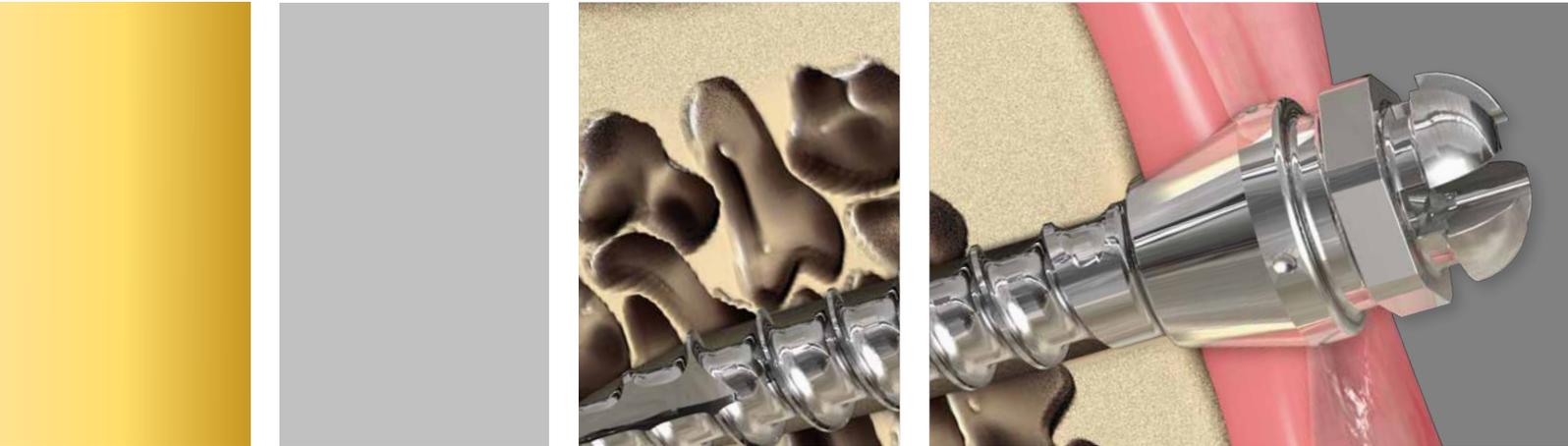
Following insertion of the tomas[®]-pin, the patient should rest for approx. 1 hour and be cooled extraorally if necessary (avoid hypothermia). Gingival healing and oral hygiene should be regularly monitored during the entire time the tomas[®]-pin is in situ.

The patient should be instructed to avoid manipulating the head of the tomas[®]-pin with the fingers, tongue, lips and/or cheek, as this may cause premature failure of the tomas[®]-pin. All instruments used during the operation should first be thoroughly disinfected and cleaned and then sterilized. Blunt instruments should be discarded and replaced, as they could cause overheating of the bone and in certain circumstances premature failure of the tomas[®]-pin.

Removing the tomas[®]-pin.

The tomas[®]-pin can be removed without local anesthesia. The coupling element should be removed before unscrewing the tomas[®]-pin. The tomas[®]-pin can be removed with the same instruments that were used for insertion. We recommend using the tomas[®]-applicator or tomas[®]-screw driver. Loosen the tomas[®]-pin by carefully turning it anticlockwise; it can then be completely unscrewed. The resulting wound does not require any special treatment and generally heals within a very short time.

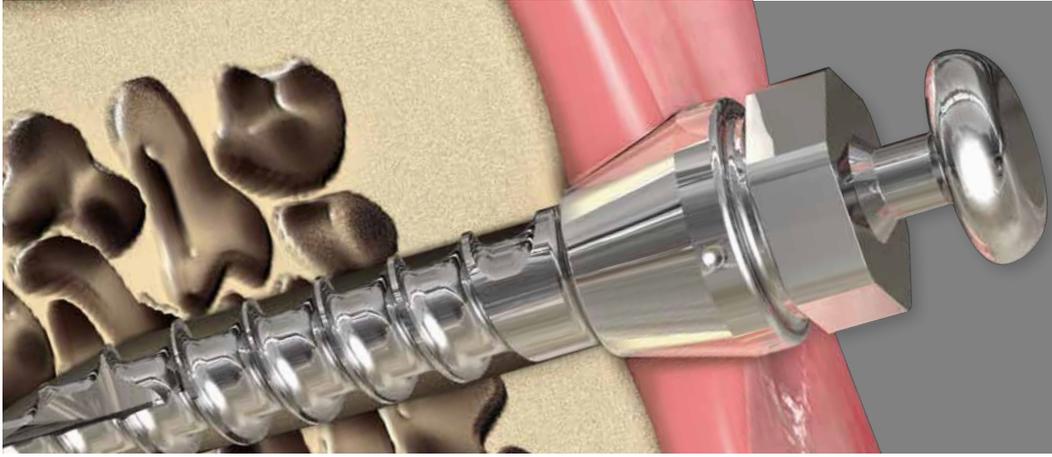
Post insertion.



Final notes.

Premature failure of the tomas®-pin is virtually excluded provided all the instructions and recommendations are followed. The main possible causes of premature failure of the tomas®-pins are:

- Immediate proximity to the tooth roots
- Poor oral hygiene before, during and after treatment, particularly if there is contamination of tomas®-pin components that are in direct contact with the tissue (bone, gingiva)
- Excessive drill speed during pre-drilling (max. 1500 min⁻¹) or during handpiece insertion (max. 25 min⁻¹) of the tomas®-pin
- Excessive torque during insertion (max. 20 Ncm)
- No or insufficient primary stability
- Unfavorable positioning of the tomas®-pin (not in the attached gingiva, in direct contact with bands)
- Patient habits or manipulation interfering with the head of the tomas®-pin
- Peri-implantitis caused by mucosal irritation



tomas® – more than just a mini-implant.



The concept.

Temporary orthodontic micro anchorage system – tomas® is, as the name suggests, a system related to skeletal anchorage of orthodontic appliances. That is why, aside from the tomas®-pins and relevant insertion instruments, there is a series of accessories for the fabrication of various appliances for dento-alveolar and skeletal corrections. In the following, the tomas®-abutments and other accessories are presented in detail.

The abutments.

The tomas®-abutments/tomas®-transfer caps/tomas®-laboratory pins extend the range of tomas®-pin indications.

Abutment and tomas®-pin connection.

The tomas®-abutments – with the exception of the tomas®-abutment EP – and tomas®-pin are coupled by a snap mechanism. This form-fitting connection uses the hexagon of the tomas®-pin. When sliding the tomas®-abutment on the head of the tomas®-pin, it is important to observe the position of the hexagon. The tomas®-abutment snaps into place by using the finger to press lightly. Due to its construction it can be somewhat difficult to slide the abutment on the first time.



The tomas®-abutment is correctly positioned, if the hexagon and the groove of the tomas®-pin are completely covered. To release the snap mechanism the tomas®-abutment is pulled vertically from the tomas®-pin.

The tomas®-abutment universal is a one-piece construction. The abutment wings have indents lengthways and crossways to insert wires (\varnothing 1.1 mm). For temporary fixation or first fixation you can insert a wire in the deeper groove running lengthwise. The wire can be permanently fixed by welding, but also with adhesive or ligatures.

If the lower groove lengthways is used to fixate the wire, the tomas®-abutment universal cannot be used with the tomas®-pin EP!

The other tomas®-abutments with the snap mechanism consist of three pieces. The base body of the abutment is the connection to the tomas®-pin. The upper part has a groove that fits a ring with a welded coupling element (tube or wire). Due to the welded lid, the coupling elements can be turned 360°. This way, the appliance can be positioned in any direction independent from the position of the tomas®-pin. Rotating forces from the appliance or tooth movements are not transferred onto the tomas®-pin.

The tomas®-abutment EP consists of a loop with a welded tube. This abutment can only be used with the tomas®-pin EP. This tube (\varnothing 1.05 mm) enables the connection to an orthodontic appliance. The loop of the tomas®-abutment EP is slid over the mushroom head of the tomas®-pin EP. The reciprocal force of the appliance pushes the loop under the mushroom head and anchors the abutment to the pin. As an additional safety measure, the head of the tomas®-pin EP and the tomas®-abutment EP can be coated with adhesive.

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tomas®-transfer cap.

The tomas®-transfer caps are made of plastic and their main purpose is to transfer the mouth situation onto the model. They fit on all tomas®-pin heads. The tomas®-transfer caps are vertically plugged onto the hexagon of the tomas®-pin. The hold is achieved by the fit only. Together with the tomas®-pin EP, the tomas®-transfer caps can be used as a support for temporary crowns.

To transfer the clinical position of the tomas®-pin to a model, slide the tomas®-transfer cap over the head of the tomas®-pin. In the case of the tomas®-pin SD, the tomas®-transfer cap should be positioned so that the retention wings follow the course of a slot. On the bottom of the tomas®-transfer cap there are additional markings of the slots for positioning.

The tomas®-transfer cap is anchored by the fit on the hexagon of the tomas®-pin and the upper cylindrical part of the gingival collar. The cap is positioned correctly if the lower border of the tomas®-transfer cap is aligned with the lower border of the cylinder. If parts of the cylinder or the entire cylinder lie beneath the gingiva, the tomas®-transfer cap has to be shortened. If an impression of two tomas®-pins next to each other is required, the retention wings of the tomas®-transfer caps should not touch one another. The wings can be shortened by milling.



Before taking the impression, make sure the tomas®-transfer cap is fitted correctly on the tomas®-pin. Transferring the position of the tomas®-pin correctly can only be guaranteed with a distortion-resistant impression tray and a silicone or polyether as impression material. Using alginate or plastic impression trays can lead to inaccuracies. To fix the tomas®-transfer cap securely in the impression, the cap has to be surrounded with impression material before taking an impression of the jaw. After the impression material has hardened completely, remove the impression tray from the mouth carefully. It is important to observe the insertion direction of the tomas®-pins.

tomas®-laboratory pin.

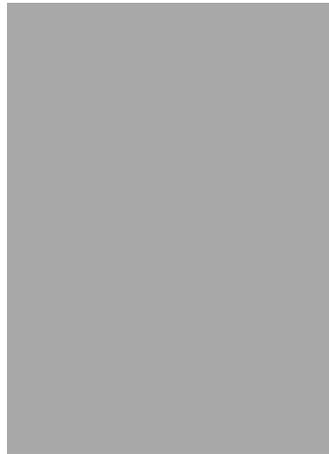
The tomas®-laboratory pins are used to fabricate skeletal anchoring appliances in the laboratory. As there are two different tomas®-pin heads available, there are two versions of the tomas®-laboratory pin. The tomas®-laboratory pin SD has a head with cross slot and the tomas®-laboratory pin EP a mushroom head. The tomas®-laboratory pins are provided with retentions that guarantee secure fixing in the model material.

The tomas®-laboratory pin is the laboratory analog for the respective tomas®-pin. Before making the model, make sure the tomas®-transfer cap is securely fixed within the impression material. Then position the tomas®-laboratory pin into the tomas®-transfer cap. With the tomas®-laboratory pin EP, the direction is irrelevant.

If an exact reproduction of the slot position of the tomas®-pin SD is required, use the arrows on the base of the tomas®-transfer caps as a guide to align the laboratory analog. These markings show the course of the slots and serve as a guide when positioning the tomas®-transfer cap.

The tomas®-laboratory pin must be fixed securely within the impression cap. In order for the tomas®-laboratory pin not to loosen from the tomas®-transfer cap during the filling process of the impression material, it is important to fix the pins with wax. Then, manufacture the model.

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Overview abutments.

The tomas®-abutments are designed to fabricate a wide variety of skeletal anchoring appliances. The following product overview lists some of the possible indications. Further information can be found on the Dentaurem website (www.dentaurem.com).

- Direct coupling means that the orthodontic appliance is directly connected to the tomas®-pin via the tomas®-abutment. The tomas®-pin serves as counter bearing for the force exerted by the appliance.
- Indirect coupling means that the orthodontic appliance is fixated on the teeth, as with conventional techniques. The tooth or the group of teeth that serve as counter bearing are coupled with the tomas®-pin via the tomas®-abutment using a sufficiently dimensioned wire.

Caution

If wires or similar elements are soldered onto tomas®-abutments, the pieces can deform. A perfect fit can no longer be ensured. Consequently, avoid soldering.

Figure	Name	REF	Quantity	Indication
	tomas®-abutment universal	302-025-00	2 pieces	Indirect coupling. Direct coupling with various appliances for skeletal anchorage.
	tomas®-abutment tube 1.1	302-025-11	1 piece	Direct coupling of various appliances for bilateral or unilateral mesialization, distalization, intrusion. The tomas®-abutment wire 6 and the tomas®-abutment wire 12 can also be used.
	tomas®-abutment tube 1.5	302-025-15	1 piece	Can be used for hybrid RPE appliance or skeletal RPE appliance using Pin-First® approach.
	tomas®-RPE eyelet	302-602-00	12 pieces + 2 holders	Can be used for hybrid RPE appliance or skeletal RPE appliance using Pin-Last® approach.
	tomas®-abutment tube square 22	302-025-22	1 piece	Abutment with rotatable square tube for direct coupling between the tomas®-pin and various appliances, e.g. for intrusion etc.
	tomas®-abutment double tube 1.5	302-025-30	1 piece	Abutment with rotatable double tube for direct coupling between tomas®-pin and various appliances, e.g. for bi- or unilateral mesialization, distalization, intrusion etc. The tomas®-abutment U-wire can be used in addition.
	tomas®-abutment U-wire	302-025-21	1 piece	Abutment with rotatable bilateral wire for direct coupling between the tomas®-pin and various appliances, e.g. for bi- or unilateral mesialization, distalization etc. The tomas®-abutment double tube 1.5 can be used in addition.
	tomas®-abutments median	302-025-51	1 piece	Combination is intended for two tomas®-pins which are placed sagittally to the mid-palatal suture. tomas®-abutment U-wire (REF 302-025-21) and tomas®-abutment double tube 1.5 (REF 302-025-30).
	tomas®-abutment wire 6	302-025-06	1 piece	Indirect coupling. Direct coupling of various appliances for unilateral mesialization, distalization, intrusion. The tomas®-abutment tube 1.1 can also be used.
	tomas®-abutment wire 12	302-025-12	1 piece	Indirect coupling. Direct coupling of various appliances for mesialization, distalization, intrusion. The tomas®-abutment tube 1.1 can also be used.
	tomas®-abutment plain	302-026-00	1 piece	To weld individual elements. Anchoring temporary crowns.
	tomas®-abutment EP	302-027-00	2 pieces	Direct coupling between tomas®-pin EP and amda® (advanced molar distalization appliance). Direct coupling of various appliances for bilateral or unilateral mesialization, distalization, intrusion.
	tomas®-transfer cap	302-028-01	2 pieces	Transferring mouth situation to a model. Anchoring temporary crowns.
	tomas®-laboratory pin EP	302-029-01	1 piece	Laboratory analog for the tomas®-pin EP to manufacture skeletal anchoring orthodontic appliances in the laboratory.
	tomas®-laboratory pin SD	302-030-01	1 piece	Laboratory analog for the tomas®-pin SD to manufacture skeletal anchoring orthodontic appliances in the laboratory.

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The tomas®-auxiliaries.

The tomas®-auxiliaries are designed to fabricate different skeletal anchoring appliances. The following product overview lists some of the possible indications. Further information can be found on the Dentaurem website (www.dentaurem.com).

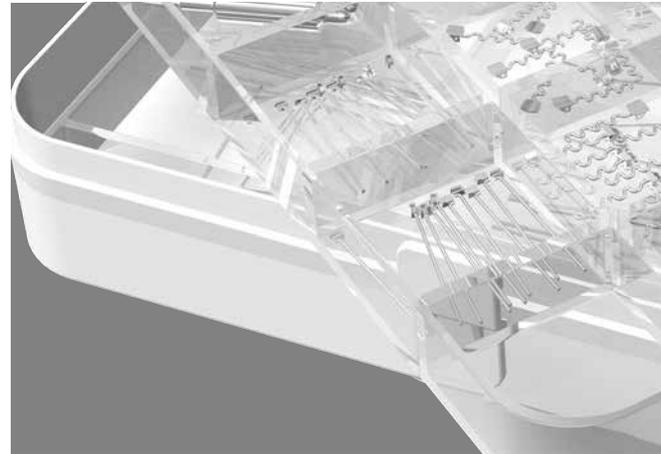
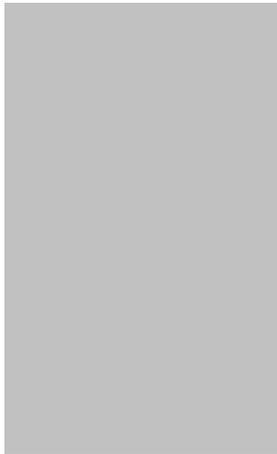


Figure	Description	REF	Quantity	Included in the auxiliary kit	Indication
	tomas®-coil spring, light (8 mm) code blue (Nickel-titanium tension spring)	302-012-00	10 pieces	✓	
	tomas®-coil spring, medium (8 mm) code yellow (Nickel-titanium tension spring)	302-012-10	10 pieces	✓	Tension spring for direct coupling between the tomas®-pin and a multi-bracket appliance, e.g. for distalization, en masse retraction and mesialization.
	tomas®-coil spring, heavy (8 mm) code red (Nickel-titanium tension spring)	302-012-20	10 pieces	✓	
	SUPER Elasto-Force plastic chains (Plastic chain)	774-221-01	1 piece	–	Elastic chain for direct coupling between the tomas®-pin and a multi-bracket appliance, e.g. for distalization, en masse retraction and mesialization.
	tomas®-uprighting spring	302-009-00	10 pieces	✓	Spring for molar uprighting with and without intrusion or extrusion. For details, please refer to the instructions for use of the tomas®-uprighting spring (REF 989-651-00).
	rematitan® LITE compression spring	758-361-00	3 pieces	✓	Compression spring for horizontal tooth movement (mesialization, distalization).
	tomas®-stop screw (Stop screw without hexagon socket key)	302-013-01	10 pieces	✓	The stop screw is fixed to the arch and can be used to repeatedly put a compression spring under tension without the arch having to be removed. The hexagon socket screw is secured against unscrewing.
	Hexagon socket key 0.9	607-129-00	1 piece	✓	Key for activating the tomas®-stop screw and the stop screws for amda® (advanced molar distalization appliance).

Figure	Description	REF	Quantity	Included in the auxiliary kit	Indication
	tomas®-slotted stops 18 (stop tubes, slotted, slot 18 technique)	302-021-18	100 pieces	–	As stop for compression spring in the slot 18 technique.
	tomas®-slotted stops 22 (stop tubes, slotted, slot 22 technique)	302-021-22	100 pieces	–	As stop for compression spring in the slot 22 technique.
	tomas®-hook (wire hook)	302-009-10	10 pieces	–	If the tomas®-pin SD is initially meant for other anchorage purposes and should later be used to hang a tension spring, use the tomas®-hook (see also the Instructions for use REF 989-656-00). If it is clear from the outset that only tension springs will be used for the treatment, a tomas®-pin EP should be inserted immediately.
	tomas®-T-wire	302-024-00	10 pieces	✓	Multifunctional square wire, e.g. for fabricating an indirect anchorage, individual hook, etc.
	tomas®-cross tube 18 (cross tube, slot 18 technique)	302-014-18	10 pieces	–	For direct connection between the tomas®-pin SD and the main arch for the slot 18 technique.
	tomas®-cross tube 22 (cross tube, slot 22 technique)	302-014-22	10 pieces	–	For direct connection between the tomas®-pin SD and the main arch for the slot 22 technique.
	tomas®-power arm, square (crimping tube with wire, square)	302-015-00	10 pieces	✓	Torsion-resistant square wire for the fabrication of customized hooks, e.g. for bringing the point of force application of a tension spring near the center of resistance. Coupling to the tomas®-pin SD is performed directly, e.g. for distalization, en masse retraction and mesialization. Indirect coupling between the tomas®-pin SD and the main arch.
	tomas®-power arm, round (crimping tube with wire, round)	302-019-00	10 pieces	✓	Round wire for the fabrication of customized hooks, e.g. for bringing the point of force application of a tension spring near the center of resistance. Coupling to the tomas®-pin SD is performed directly, e.g. for distalization, en masse retraction and mesialization.
	tomas®-crimp hook upper jaw l./lower jaw r. (crimping tube, left)	302-020-00	10 pieces	✓	Prefabricated hook, can be shortened, e.g. for varying the point of force application of a tension spring in relation to the center of resistance. Coupling to the tomas®-pin SD is performed directly, e.g. for distalization, en masse retraction and mesialization.
	tomas®-crimp hook upper right/lower left (crimping tube, right)	302-020-10	10 pieces	✓	Prefabricated hook, can be shortened, e.g. for varying the point of force application of a tension spring in relation to the center of resistance. Coupling to the tomas®-pin SD is performed directly, e.g. for distalization, en masse retraction and mesialization.
	tomas®-aligner hook upper left/lower right (adhesive hook, left)	302-021-00	10 pieces	✓	Hook to be bonded on teeth or aligner for direct coupling with the tomas®-pin EP. For fixing the hook on the acrylic of the aligner, special adhesive is required (e.g. Bond Aligner™ from Reliance).
	tomas®-aligner hook upper right/lower left (adhesive hook, right)	302-021-10	10 pieces	✓	Hook to be bonded on teeth or aligner for direct coupling with the tomas®-pin EP. For fixing the hook on the acrylic of the aligner, special adhesive is required (e.g. Bond Aligner™ from Reliance).

Additional information.



Explanation of symbols on label.

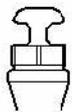


Please refer to the label. Additional information can be found on www.dentaurum.com
(Explanation of symbols REF 989-313-00).

All components of the tomas® system should be stored in a dry, dark area at room temperature.

Explanation of the label.

- | | | | |
|---|---------------------------------------|----|---|
| 1 | Contents | 7 | Order number |
| 2 | Length (in mm) | 8 | Sterility expiration date |
| 3 | Quantity | 9 | Refer to instructions for use |
| 4 | Symbol for gamma sterilized | 10 | Manufacturer according to the Directive 93/42 EEC |
| 5 | Reference number of the notified body | 11 | For single use only |
| 6 | LOT number on self-adhesive label | | |

	982-872-15	DENTALPRODUKT / DENTAL PRODUCT	
		Anwendung nur durch Fachpersonal / for professional use only	
1			
	pin EP 06 (Elastic Palatal)		
	selbstbohrend/self-drilling		
2	Länge/length 6 mm		
	REF 302-206-00		LOT 123456
3	1 Stück/piece		LOT 123456
4	STERILE R	 2021-02-27	REF 302-206-00
5	  		REF 302-206-00
		D DENTAURUM	
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