





Straumann is the exclusive industrial partner of the ITI (International Team for Implantology) in the areas of research, development and education.



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The Straumann Palatal Implant provides anchorage control for orthodontic corrections. The implant is inserted in the palate for the duration of the treatment, and is suitable for both adolescents (age 12 and older) and adults. The orthodontic forces are controllable and predictable during the treatment.

Reliable

- The Straumann Orthosystem and the associated surgical procedure have been documented in detail since 1996.
- Secure anchoring of the implant in the bone, and the fact that the superstructure is secured against rotation, ensures that the orthodontic construction remains stable throughout the entire treatment period.
- The desired treatment result is achieved reliably, efficiently and without any active patient involvement.

Simple

- The process of implantation is minimally invasive and based on the tried and trusted instruments and procedures of the Straumann® Dental Implant System.
- No fitting and removal of extraoral appliances is necessary.
- The patient's appearance is not compromised.
- The implant is easy to remove and the implant site heals in a matter of days.

Versatile

- The Palatal Implant is suitable for a wide variety of orthodontic indications.
- The dentist can control the biomechanical forces optimally.
- The implant can be used in both adults and adolescents (age 12 and older).

General note

The Palatal Implant is part of the Straumann Orthosystem and replaces the Ortho Implant (Art. No. 042.340/343/345), including accessories. The components of the Ortho Implant are not compatible with those of the Palatal Implant.



Palatal Implant

The Palatal Implant, made of pure titanium, is available in two different endosteal diameters (Ø 4.1 mm and Ø 4.8 mm). The endosteal part of the implant has an SLA® surface and is 4.2 mm long. The smooth neck of the implant is 1.8 mm high.



Ø 4.1 mm Art. No. 042.235



Top view

Ø 4.8 mm Art. No. 042.236





Top view

Superstructure

Healing cap

Post cap

laser welding.

During the healing phase, the implant is protected with a plastic healing cap with integrated SCS screw. The cap is inserted with the SCS screwdriver and handtightened.

The post cap, made of high-alloy stainless steel, is available in two heights

(3.5 mm and 5.5 mm) and its internal configuration with bihexagon allows it to be secured to the implant in 12 different positions. The material enables

a transpalatal arch to be attached by



Ø 4.8 mm, height 3.5 mm Art. No. 048.079



Top view

Ø 4.8 mm, height 5.5 mm Art. No. 048.076



The orthodontic wire for welding on by laser can be ordered separately (Ø 1.2 mm, length 150.0 mm, Art. No. 048.477)

Post cap with wire

A post cap with an orthodontic wire already welded on by laser (Remanium, hard, Ø 1.2 mm, length 150.0 mm) is also available. This post cap is available in the same two heights (3.5 mm and 5.5 mm). Ø 4.8 mm, height 3.5 mm Art. No. 048.077

Ø 4.8 mm, height 3.5 mm

4.8 mm

3.5 mm

Art. No. 048.075



Ø 4.8 mm, height 5.5 mm Art. No. 048.078 (not shown)

Instruments

The Palatal Implant is placed using the standard instrument set in the Straumann[®] Dental Implant System. In addition, a mucosal punch, a release key, the explantation instrument set and a special depth gauge are required. Given appropriate care, the drills are reusable up to 10 times. The explantation drill and guiding cylinder are for single use only.

A detailed list of all the instruments is given on page 18, 19 and 20. Please follow the instructions in our "INFO, Care and maintenance of surgical and prosthetic instruments" brochure (Art. No. 152.008).

Therapy planning

Preoperative planning comprises pre-surgery/orthodontic overall planning with consultation between the orthodontic surgeon and the implantologist. The following aspects must be assessed in the context of an overall treatment plan.

Requirements

- "Normal" wound healing capacity
- Good oral hygiene
- Adequate volume of healthy bone
- Compact sutural region
- Good general state of health

Indications

The Straumann Palatal Implant is suitable for implantation in the median to paramedian palatal region and provides anchorage in the maxilla. Application examples: Posterior anchorage for retraction of the anterior teeth (e.g. Angle Class II) and also anterior anchorage for distalization or mesialization (space closure, e.g. in cases of aplasia) of molars. The implant only remains in the palate temporarily and is removed again after completion of the orthodontic treatment.

The Palatal Implant can be used in adults and in adolescents from the age of 12. In the case of patients whose skeletal growth is not yet complete (recognizable, for example, from X-rays of the hand/wrist), the Palatal Implant should be placed in a paramedian position in the palate in order to avoid the palatine suture.

Important

Adequate mechanical primary stability following insertion of the Straumann Palatal Implant is an absolute prerequisite for successful osseointegration.

Contraindications

- Serious internal medical problems
- Uncontrolled bleeding disorders
- Bone metabolism disturbances
- Uncooperative, unmotivated patient
- Drug, alcohol or tobacco abuse
- Psychoses

Relative contraindications

- Previously irradiated bone
- Diabetes mellitus
- Anticoagulation drugs/hemorrhagic diatheses
- Pregnancy
- Inadequate oral hygiene
- Treatable pathologic diseases of the jaw and changes in the oral mucosa

Local contraindications

• Inadequate bone volume and/or quality

- Prolonged, therapy-resistant functional disorders
- Xerostomia
- Weakened immune system and leukocyte dysfunctions
- Illnesses requiring periodic use of steroids
- Uncontrollable endocrine disorders
- Titanium or nickel allergy

Surgical procedure

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Implantation must be preceded by comprehensive orthodontic/implantological patient evaluation, preoperative diagnostics and therapy planning. Difficulties and errors during implantation and during subsequent orthodontic treatment can be avoided by thorough clarification and detailed case planning.

- Lateral cephalometric analysis is used to determine the optimal insertion site on the basis of the bone thickness and axial alignment.
 For exact planning, cephalometry can be carried out in situ with a vacuumformed template and suitable integrated metal pin. After the pin has been removed, the same template can be used as an aid to positioning when transferring the localization of the implantation site in the patient.
- **2.** First, remove the palatal mucosa from the insertion site under anesthesia, using the mucosal punch (Art. No. 044.333) and an elevator.

- 3. Smooth the exposed bone surface with a round bur and mark the implant site in the center of the round cut-out area, using the round bur Ø 1.4 mm (Art. No. 044.022). Then enlarge the marking in steps using the round burs Ø 2.3 mm (Art. No. 044.003) and Ø 3.1 mm (Art. No. 044.004) with continuous cooling with pre-cooled (+5 °C/41 °F) physiological saline or Ringer's solution. Do not exceed 800 rpm.
- **4.** Measure the thickness of the mucosa with a periodontal probe. This measurement is important for calculating the depth of drilling. Ensure that the probe is not in the depression made by the marking.











5. Define the drilling axis and prepare the implant bed with the pilot drills
Ø 2.2 mm (Art. No. 044.210/211) and Ø 2.8 mm (Art. No. 044.214/215).
Use the cephalometric analysis as a reference for defining the drilling axis.
The axis should be perpendicular to the bone surface.

When preparing the implant bed with the pilot and twist drills, be sure to drill intermittently and cool the drilled channel continuously with pre-cooled physiological saline or Ringer's solution.

Determining the depth of drilling

To be able to insert the SLA® surface fully into the bone, a drilling depth of 4.2 mm is required. As the small size of the hole cut in the mucosa makes direct vision of the bone impossible, the actual depth drilled must be measured at the margin of the mucosal surface.

The drilling depth at mucosal level is calculated as follows: SLA® length 4.2 mm + measured thickness of the mucosa. The laser markings on the drill allow the depth of drilling to be monitored during preparation of the implant bed. In the case of patients with a very thin mucosa, the implant can be placed somewhat deeper, provided that adequate bone is available, so that it does not project too far into the oral cavity.

Widen the implant bed with the twist drill Ø 3.5 mm (Art. No. 044.218/219) to the required width.

If a 4.8 mm diameter implant is placed, the drilled channel must be finished by widening with the \emptyset 4.2 mm twist drill (Art. No. 044.222/223).

Maximum speed (in rpm) for each drill diameter:

- Drill Ø 2.2 mm: max. 800 rpm
- Drill Ø 2.8 mm: max. 600 rpm
- Drill Ø 3.5 mm: max. 500 rpm
- Drill Ø 4.2 mm: max. 400 rpm

Remark

It is generally recommended to use the 4.1 mm diameter Palatal Implant. The 4.8 mm diameter Palatal Implant should only be used if the planning indicates that the requisite primary stability cannot be achieved with the 4.1 mm \emptyset implant.





- 6. Two depth gauges with Ø 4.1 mm (Art. No. 046.453) and Ø 4.8 mm are available, corresponding to the two implant diameters. The depth gauges are used for checking the depth of the drill hole and for determining the insertion depth of the implant.
 - 1. Check the depth of the drill hole.

Position the depth gauge in the prepared implant bed. Ensure that the depth gauge is inserted up to the mark which indicates the upper limit of the SLA® surface and rests cleanly on the bone.

2. Determining the insertion depth of the implant.

The depth gauge has the same dimensions as the Palatal Implant with the implant carrier attached. The grooves on the depth gauge correspond to the grooves in the brown plastic ring of the implant carrier. To determine the insertion depth, insert the depth gauge into the prepared implant bed. Then record the position of a groove on the depth gauge relative to the mucosa. Subsequently, the implant has to be inserted into the bone until the equivalent groove on the implant carrier is in the same position. Then remove the depth gauge from the implant bed again.

- 7. Open the outer ampoule and place the inner ampoule on a sterile cloth. The implant is securely fixed in the inner ampoule. Contamination caused by non-sterile parts must be avoided.
- **8.** Secure the ratchet adapter (Art. No. 046.460/461/462 with dental floss to prevent aspiration, and press it onto the implant carrier. A "click" indicates that the adapter has engaged correctly on the carrier.





Reference grooves on the plastic ring of the transfer part



9. Remove the implant from the inner ampoule via the side opening. When doing this, rest your forearms on the table top. The implant is securely connected to the ratchet adapter via the implant carrier. Then put the ratchet (Art. No. 046.119) onto the adapter. The arrow on the knob at the end of the ratchet must point clockwise.

10. Insert the implant with the adapter and ratchet, as a unit, into the implant bed, and stabilize it with the holding key for the transfer part (Art. No. 046.064). Then, check the axial direction.

Bring the implant into its final position by turning the ratchet slowly clockwise.

The final position is reached when the groove on the implant carrier corresponding to the groove noted on the depth gauge (Step 6.2) is in the same position relative to the mucosa.

11. Carefully remove the ratchet and ratchet adapter from the implant carrier.







12. Detach the implant carrier using the release key (Art. No. 046.179). To do this, slide the release key over the implant carrier.

At the same time, observe the two opposing grooves in the brown plastic part of the implant carrier. The two opposing pins inside the release key must grip in these two grooves.

Turn slightly to seat the release key correctly.

Carefully turn the release key further clockwise, without applying any great force and without pulling.

An audible "click" signals that the implant carrier has detached from the implant. Now, and not before, pull the release key off the implant vertically. The implant carrier is now located in the release key, secured against aspiration, and can be removed from the mouth.









13. The implant is now covered with the healing cap (Art. No. 048.079) until the healing phase is complete. Pick up the healing cap with integrated SCS occlusal screw, using the SCS screwdriver (Art. No. 046.400/401/402), and attach it to the implant manually. Handtighten the screw.



14. The healing phase of the Palatal Implant lasts 12 weeks.The postoperative follow-up schedule below should be observed: Examination after: 1 day, 1 week, 1 month, 2 months

Important

The Palatal Implant must not be subjected to functional loading during the healing phase.

Osseointegration of the implant is complete when:

- the patient has no subjective discomfort
- the peri-implant soft tissue has completely healed and is healthy
- a high-pitched sound is produced by percussion
- the implant is immobile

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1st to 14th day post-op

- The implant must not be cleaned with a brush.
- Rinse mouth 3 times a day with disinfectant solution (e.g. chlorhexidine digluconate solution) and cover the implantation site with chlorhexidine gel.

After the 14th day post-op

- Clean the implant two to three times a day with a toothbrush and interdental brush in the same way as normal toothbrushing. Continue to apply chlorhexidine gel once or twice a day.
- In the event of peri-implant soft tissue inflammation, rinse with chlorhexidine, as instructed by a physician.

Taking the impression

The impression is taken at the end of the healing phase (after 12 weeks).

 Remove the healing cap (Art. No. 048.079) from the implant using the SCS screwdriver (Art. No. 046.400/401/402).

- 2. To take the impression, place the impression cap (Art. No. 048.094) on the implant. Ensure that the cap is positioned vertically on the implant and that its internal configuration is aligned with the head of the implant. The cap is correctly seated when it snaps over the shoulder of the implant.
- **3.** Use a special impression tray and an elastomeric impression material for taking the impression. After curing, remove the impression together with the impression cap.
- 4. Replace the healing cap until the final restoration is placed.





Fabrication and integration of the superstructure

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 Align the analog (Art. No. 048.126) and insert it into the impression cap, which is in the impression, until the shoulder audibly engages. The analog snaps into place when it is correctly positioned.

Make the working cast in the usual way with special hard plaster, Type 4 (DIN 13911).

Place the post cap (Art. No. 048.075, height 3.5 mm or 048.076, height 5.5 mm) on the analog; secure with the SCS screw (Art. No. 048.350 or 048.360) and mark the position of the transpalatal arch (TPA) that will be used later. Make a corresponding recess at the marked point for mounting the TPA.

For ease of handling, the post cap holder (Art. No. 046.238) is available. The post cap can be fixed to the post cap holder by means of an occlusal screw. The post cap holder fits into the handle (Art. No. 046.240).

 Adapt the TPA (Art. No. 048.477) by bending and cutting to length. The wire is 1.2 mm in diameter and 150.0 mm long. Other wire variants are available from the specialist orthodontic trade. Weld the TPA to the steel cap using a laser. Fixation by soldering is not recommended due to the resulting loss of elasticity!

If the post cap with pre-lasered wire (Art. No. 048.077, height 3.5 mm and 048.078, height 5.5 mm) is used, all that is required is to adapt the alignment and length of the TPA.

The ends of the TPA which will be bonded with adhesive are sandblasted.

Remark

For production reasons, there is slight rotational play of approx. 3° between the post cap and the implant when they are assembled. This 3° may result in an anchorage loss of 1.12 mm on the lever arm of approx. 20.0 mm. To prevent this, the TPA must be pre-activated, prior to bonding, by 1.0 mm in the opposite direction to that in which the orthodontic forces act.



Orthodontic for



"click"

Removal of the implant

When the implant is no longer required for anchorage, remove the post cap with the TPA. If explantation does not follow immediately, cover the implant with the healing cap or post cap.

- 1. Remove the healing cap or post cap with the SCS screwdriver.
- **2.** Carry out local anesthesia using the same procedure as for implantation. Then screw the guiding cylinder (Art. No. 049.145) onto the implant.

3. Using the explantation drill (Art. No. 044.336), drill over the guiding cylinder, through the mucosa down to bone level. Rinse away the soft tissue pieces and then proceed with trepanation in the bone as far as the limit stop. Explantation is carried out at 400–700 rpm with continuous cooling with pre-cooled (+5 °C/41 °F) physiological saline solution or Ringer's solution. Ensure that there is no soft tissue between the guiding cylinder and the drill.



4. Remove the Palatal Implant by turning with forceps.

Wound care

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- Carry out the nose-blowing test. If there is oroantral communication, give the patient a bite guard as a protective dressing.
- Rinse the wound with 3% H_2O_2 .
- To stop the bleeding, ask the patient to press a sterile swab on the wound with his thumb for approx. three minutes.
- Give the patient swabs to take home and inform him that for the next 24 hours postoperative bleeding is possible. If necessary, the patient should press a swab on the wound for 15 minutes.
- Give the patient a mild analgesic to take home (although it is not necessary in most cases).
- Instruct the patient to contact the practice, as after a normal tooth extraction, if the situation has not improved after two to three days.



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Product overview

Palatal Implant, specific components:

Art. No.		Article	Dimensions	Material	User
042.3355	台	Palatal Implant	Ø4.1 mm, SLA®4.2mm	titanium	Surgeon
042.3365	畠	Palatal Implant	Ø 4.8 mm, SLA® 4.2 mm	titanium	Surgeon
048.079		Palatal Implant healing cap	Ø 4.8 mm	PEEK, titanium	Surgeon
048.075		Palatal Implant post cap	Ø 4.8 mm, height 3.5 mm	stainless steel	Orthodont.
048.076		Palatal Implant post cap	Ø 4.8 mm, height 5.5 mm	stainless steel	Orthodont.
048.077	R	Palatal Implant post cap with wire	Ø 4.8 mm, height 3.5 mm	stainless steel	Orthodont.
048.078	not shown	Palatal Implant post cap with wire	Ø 4.8 mm, height 5.5 mm	stainless steel	Orthodont.
048.077 V10		Wire for palatal arch	Ø 1.2 mm, length 150.0 mm	stainless steel	Orthodont.
048.094	9	Palatal Implant impression cap	Ø 4.8 mm, height 7.0 mm	plastic	Surgeon/ Orthodont.
044.333		Palatal Implant mucosal punch	Ø 5.4 mm	stainless steel	Surgeon
046.179	-0	Palatal Implant release key	length 20.0 mm	stainless steel	Surgeon
049.145	Π	Palatal Implant guiding cylinder	Ø 4.9 mm, length 7.0 mm	stainless steel	Surgeon
044.336		Palatal Implant explantation drill	Ø 5.5 mm	stainless steel	Surgeon
046.453		Palatal Implant depth gauge	Ø 4.1 mm, length 30.0 mm	titanium	Surgeon
046.454	not shown	Palatal Implant depth gauge	Ø 4.8 mm, length 30.0 mm	titanium	Surgeon

Art. No.		Article	Dimensions	Material	User
048.126		Palatal Implant analog	Ø 4.8 mm, length 13.0 mm	stainless steel	Dent. tech.
046.238	1	Palatal Implant post cap holder	Ø 4.8 mm, length 15.0 mm	stainless steel	Dent. tech.
041.042		Palatal Implant Cassette	230 x 175 x 40 mm	plastic	Surgeon/ Orthodont.

Surgical Instruments and Accessories

Art. No.		Article	Dimensions	Material	User
044.022		Round bur	Ø 1.4 mm	stainless steel	Surgeon
044.003	F0	Round bur	Ø 2.3 mm	stainless steel	Surgeon
044.004		Round bur	Ø 3.1 mm	stainless steel	Surgeon
044.210		Pilot drill 1	Ø 2.2 mm, short	stainless steel	Surgeon
044.211		Pilot drill 1	Ø 2.2 mm, long	stainless steel	Surgeon
044.214		Pilot drill 2	Ø 2.8 mm, short	stainless steel	Surgeon
044.215		Pilot drill 2	Ø 2.8 mm, long	stainless steel	Surgeon
044.218		Twist drill	Ø 3.5 mm, short	stainless steel	Surgeon
044.219		Twist drill	Ø 3.5 mm, long	stainless steel	Surgeon
044.222		Twist drill	Ø 4.2 mm, short	stainless steel	Surgeon
044.223		Twist drill	Ø 4.2 mm, long	stainless steel	Surgeon
046.460		Adapter for ratchet	length 11.0 mm	stainless steel	Surgeon
046.461		Adapter for ratchet	length 18.0 mm	stainless steel	Surgeon
046.462		Adapter for ratchet	length 28.0 mm	stainless steel	Surgeon
046.119		Ratchet	length 84.0 mm	stainless steel	Surgeon
046.049	- Toronto -	Torque control device	length 82.0 mm	stainless steel	Surgeon
046.064	·	Holding key for transfer part	length 75.0 mm	stainless steel	Surgeon
046.400	D -	SCS screwdriver	length 15.0 mm	stainless steel	Surgeon/ Orthodont.
046.401		SCS screwdriver	length 21.0 mm	stainless steel	Surgeon/ Orthodont.
046.402		SCS screwdriver	length 27.0 mm	stainless steel	Surgeon/ Orthodont.
048.350 048.350V4		SCS occlusal screw	length 4.4 mm for 048.075, 048.077	titanium	Orthodont./
048.360 048.360V4		SCS guide screw	length 6.0 mm for 048.076, 048.078	titanium	Orthodont./ Dent. tech.

Disclaimer of liability

The Straumann ortho implant is part of an overall concept and may only be used in conjunction with the associated original components and instruments according to Institut Straumann AG's instructions and recommendations.

Use of products made by third parties in conjunction with the Straumann orthosystem will void any warranty or other obligation, express or implied, of Institut Straumann AG.

Instructions as to application of our products take place verbally, in writing, by electronic media or in hands-on trainings corresponding to state of the art at the time of introduction of the product. The user of Straumann Ortho products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Straumann disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use or installation of Straumann ortho products.

The user is also obliged to study the latest developments of the Straumann Orthosystem and their applications regularly.

Please note

The descriptions given are insufficient to allow immediate use of the Straumann Orthosystem. Guidance in the handling of these instruments by a doctor experienced in their use is strongly recommended.

Availability

Not all products listed in this brochure are available in all countries.

Validity

Upon publication of this brochure, all previous versions are superseded.

Caution

As a general rule, our products must be secured against aspiration when used intra-orally.

Federal law restricts these devices to sale by or on the order of dentists, orthodentists, oral surgeons, and dental laboratories.

Units per package

Unless stated otherwise, there is one unit in each package.

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Definition SLA®

Sand-blasted, Large grit, Acid-etched

Explanation of the symbols on labels and instruction leaflets

LOT	Lot/batch number
REF	Article number
STERILE R	Sterile by gamma irradiation
STERILE	Nonsterile
	Lower limit of temperature
	Upper temperature limit
	Temperature limitation
Rx only	Caution: Federal (USA) law restricts this product to sale by or on the order of a dentist or physician.
×	Do not use on patients
2	Do not reuse
	Refer to instructions for use
\sum	Use before expiration date
AMA AND AND AND AND AND AND AND AND AND AN	Protect from exposure to strong light or heat
	Straumann products carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42 EEC.
Colored warning lo	bels
YELLOW = CAUTIC	 N: indicates hazards or unsafe handling which might cause minor injury or damage to property.

ORANGE = WARNING:	indicates hazards which might cause
	serious or fatal injury.

RED = DANGER:	indicates hazards	which might cause
	immediate serious	or fatal injury.



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