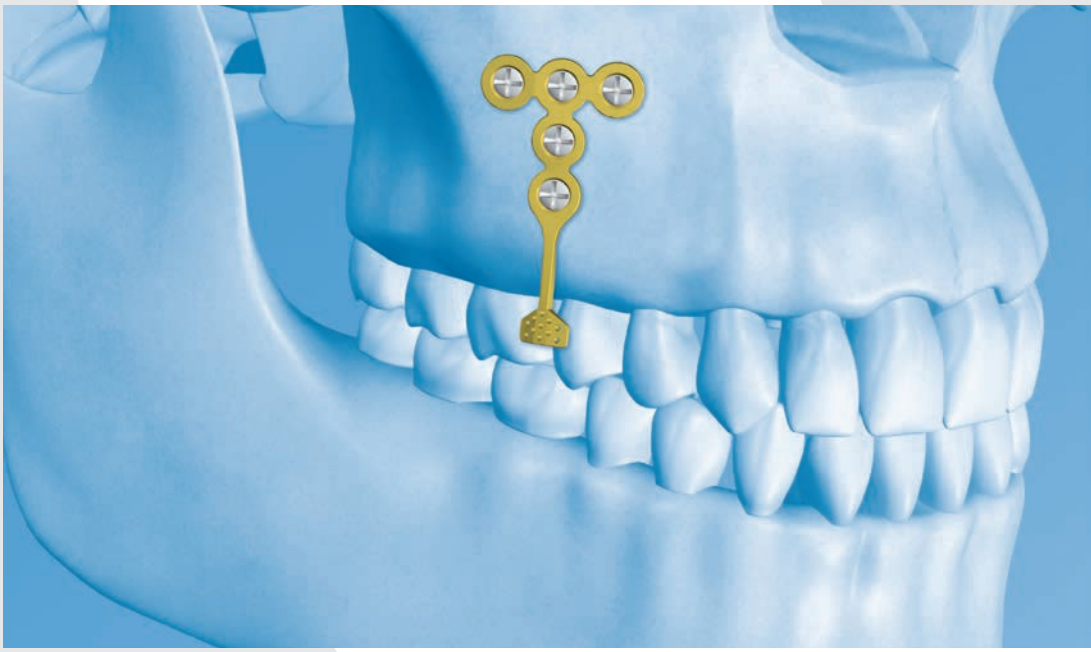
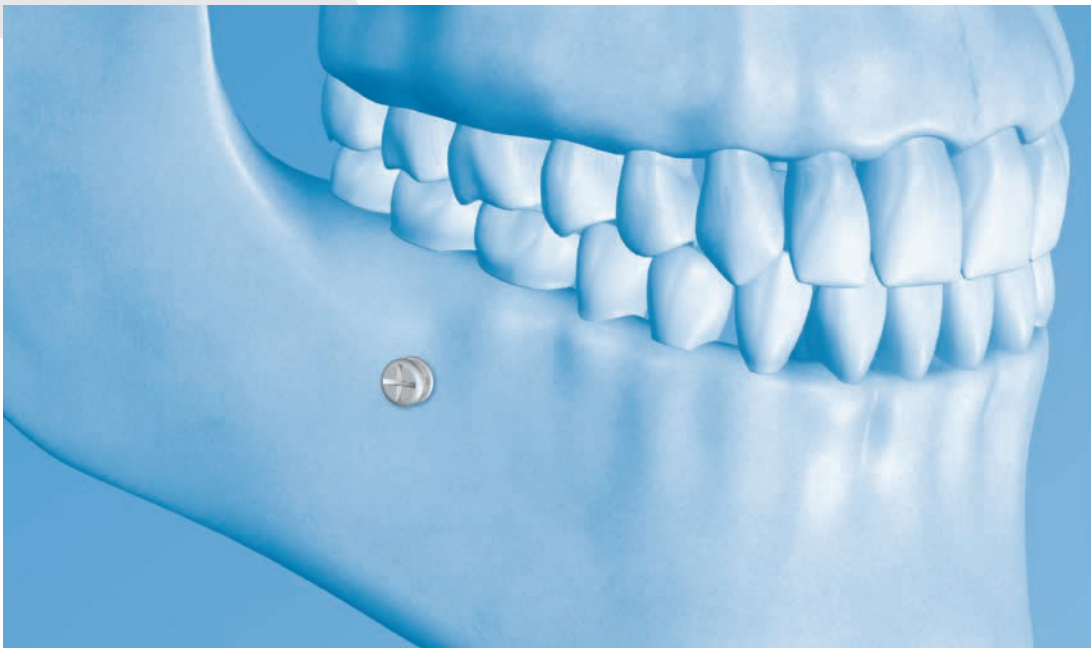
Skeletal implants for the orthodontic movement of the teeth

Orthodontic Bone Anchor (OBA) System

Surgical Technique





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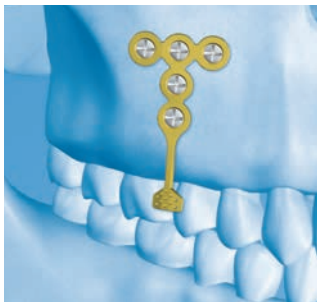
Orthodontic Bone Anchor (OBA) System. Skeletal implants for the orthodontic movement of teeth.

Overview

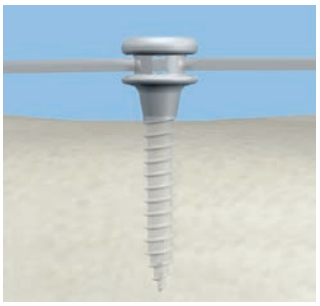
System
The Orthodontic Bone Anchor (OBA) System is intended to be implanted intraorally and used as an anchor for orthodontic procedures. It includes anchor screws, anchor plates, screws for plate fixation, instruments, and a module case for storage and sterilization.

- Provides fixed anchorage for improved control of tooth movement
- Compatible with a variety of orthodontic devices including archwires, elastics and springs
- Allows immediate loading
- Eliminates the need for extraoral anchorage (headgear)
- Anchor plates can be adapted to the patient's bony anatomy
- Manufactured from commercially pure (CP) titanium and titanium alloy*

*Ti-6Al-7Nb



Anchor plate



Profile of an archwire in an anchor screw

Anchor screw

Anchor plates
- Allow placement away from tooth roots
- Can be contoured and/or trimmed to conform to patient anatomy
- Implanted using up to five self-drilling titanium screws for stability
- Three designs

Mesh design
Orthodontists can mount preferred dental bracket to anchors using standard adhesive

Bracket design
May simulate orthodontic bracket and allows attachment of various orthodontic appliances

Domed design
Allows attachment of archwires from three different vectors, or attachment of elastics or springs

04.500.012,
4-hole anchor plate,
bracket design

04.500.013
4-hole anchor plate,
domed design

04.500.014
4-hole anchor plate,
mesh design

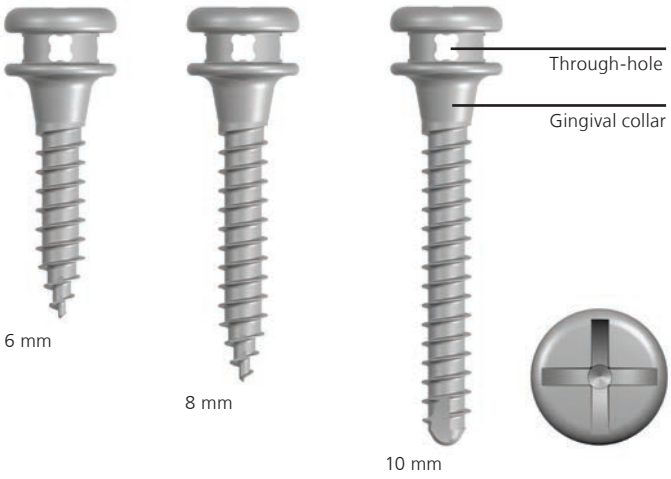
04.500.015
5-hole anchor plate,
bracket design

04.500.016
5-hole anchor plate,
domed design

04.500.017
5-hole anchor plate,
mesh design

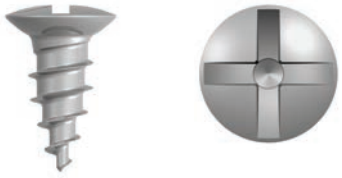
Anchor screws

- Thread diameter of only 1.55 mm for placement between tooth roots
- Two through-holes in screwhead accept archwires with a cross section of up to 0.55 mm × 0.7 mm (0.022 in. × 0.028 in.)
- Shape of through-holes prevents unintended rotation of rectangular archwires
- Nonthreaded 1.5 mm long gingival collar beneath the screwhead protects soft tissue
- Self-drilling thread lengths of 6 mm and 8 mm, and self-tapping thread length of 10 mm
- Groove in anchor screw head accepts elastics, wires, or springs



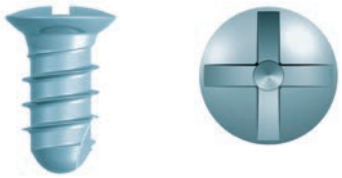
Screws for plate fixation

- Used to secure anchor plates to the bone
- Diameter of 1.55 mm
- Lengths of 4 mm, 6 mm, and 8 mm
- Self-drilling threads



Emergency screws

- Used if an anchor screw becomes loose upon insertion in the bone
- Slightly larger sized diameter of 1.85 mm
- Lengths of 4 mm, 6 mm, and 8 mm
- Self-tapping threads

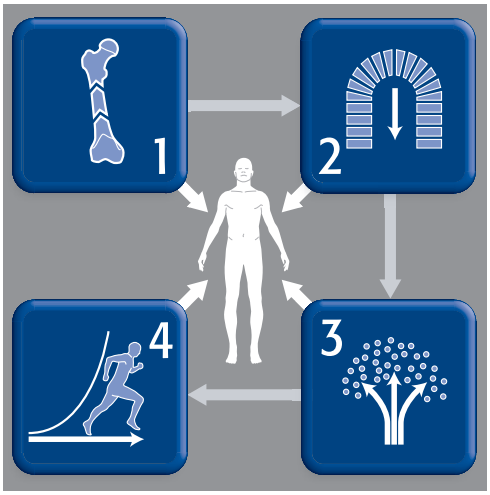


AO Principles

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation[1,2].

Anatomic reduction
Fracture reduction and fixation to restore anatomical relationships.

Early, active mobilization
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.



Stable fixation
Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

Preservation of blood supply
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

[1] Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991.
[2] Rüedi TP, Buckley RE, Moran CG. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

Indications, Contraindications and Warnings

Indications
The Orthodontic Bone Anchor (OBA) System is indicated for intrusion and extrusion of teeth, distal and mesial movement of teeth, treatment of anterior cross bite and open bite, space closure, 3-D control of teeth.

Contraindications
- When cortical bone is less than 5 mm thick, or when there is insufficient quantity or quality of bone
- In deciduous or mixed dentition
- When active or latent infection is present
- In patients with an abnormal habit of mastication, as this may affect the retention and stability of the device after implantation
- Patients with mental or neurosurgical conditions who are unwilling or incapable of following post-operative care instructions.

Warnings:
- These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the patient, the broken part should be removed.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-14 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 5.4 T/m. The largest image artifact extended approximately 31 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F 2182-11a

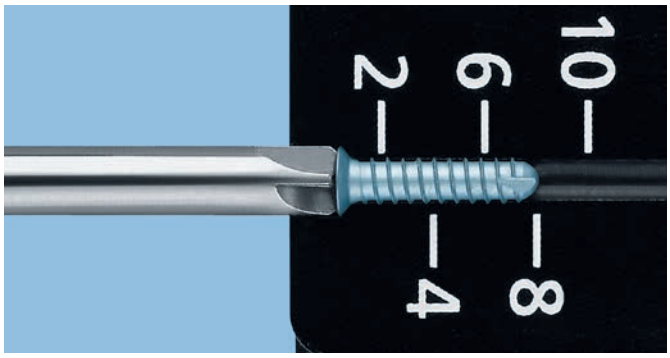
Non-clinical electromagnetic and thermal simulations of worst case scenario lead to temperature rises of 13.7 °C (1.5 T) and 6.5 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- **It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.**
- **Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.**
- **Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.**
- **Using the ventilation system may further contribute to reduce temperature increase in the body.**

Determination of Screw Length Using the Screw Measurement Scale

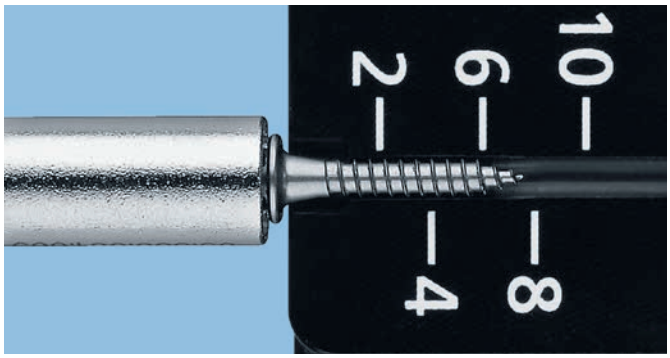
1a Determine the length of the screws for plate fixation (MatrixMIDFACE screws)



Instruments	
03.503.201–	Screwdriver Shaft MatrixMIDFACE, short
03.503.203	self-holding, with Hexagonal Coupling length 52–96 mm

Use the Screwdriver Shaft MatrixMIDFACE, self-holding, with Hexagonal Coupling to pick up the chosen screw for plate fixation. Place the screw for plate fixation in the measuring gauge as shown in the image. Make sure that the bottom of the screw head rests against the bottom of the measuring gauge counterbore. Read the number adjacent to the screw tip to identify the screw's length.

1b Determine the length of the anchor screws



Instruments	
03.500.001	Screwdriver Shaft, short, with Holding Sleeve, short, for OBA Screws, with Hexagonal Coupling
03.500.002	Screwdriver Shaft, long, with Holding Sleeve, long, for OBA Screws, with Hexagonal Coupling

Use the Screwdriver shaft for OBA screws with Holding Sleeve, with Hexagonal coupling to pick up the chosen OBA screw. Place the OBA screw in the measuring gauge as shown in the image. Make sure that the bottom surface of the screw head (before non-threaded gingival collar starts) rests against the outer surface of the module. Read the number adjacent to the screw tip to identify the screw's length.

Implanting an Anchor Screw

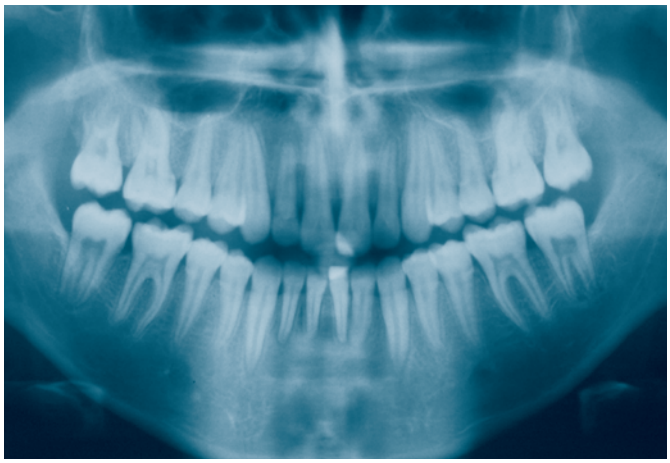
1 Locate the implantation site

Choose the implantation site according to the treatment objective and the quality and quantity of bone. Confirm that the implantation site allows adequate clearance from the tooth roots and nerves.

Choose the anchor screw with the appropriate thread length: 6 mm and 8 mm self-drilling or 10 mm self-tapping.

Precautions:

- **To avoid damage to anatomic structures, place implant away from tooth roots, tooth buds, vessels, nerves, and/or sinuses.**
- **In adolescent patients, care should be taken to avoid sutures and structures that are not fully developed.**



Preoperative x-ray

2 Prepare the implantation site

If desired, make a small incision at the implantation site and dissect through the soft tissue to the bone.

3 Implant a 6 mm or 8 mm anchor screw

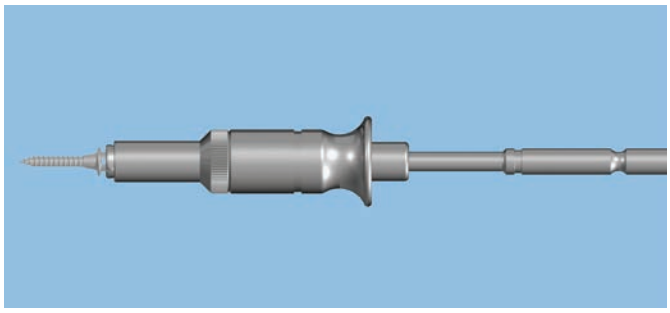
Instruments	
03.500.001	Screwdriver Shaft, short, with Holding Sleeve, short, for OBA Screws, with Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling
or	
311.007	Handle, large, with Hexagonal Coupling
Optional instruments	
03.503.246	Drill Bit ∅ 1.1 mm with Stop, length 44.5/6 mm, for J-Latch Coupling
or	
03.503.248	Drill Bit ∅ 1.1 mm with Stop, length 44.5/8 mm, for J-Latch Coupling

Using the screwdriver shaft, cruciform 1.55, with holding sleeve and the screwdriver handle with hexagonal coupling, load the anchor screw of the desired length and implant it until the distal lip of the anchor screw head sits on top of the soft tissue.

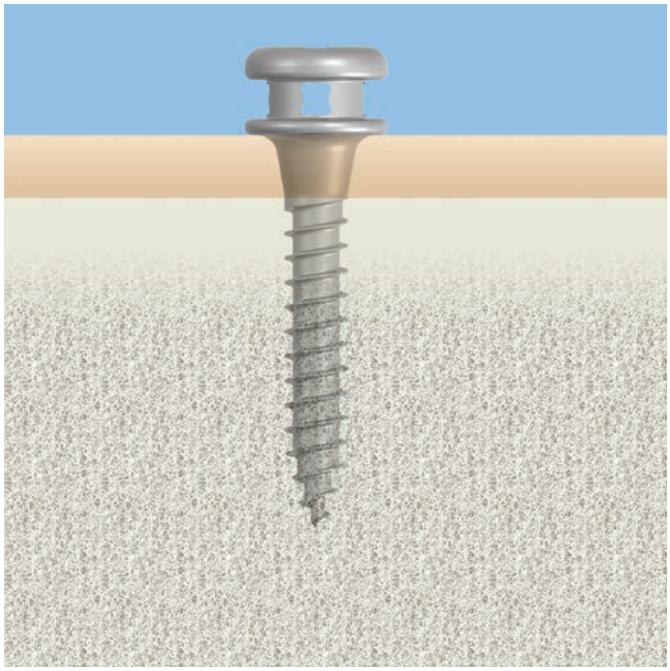
Note: **For optimal retention, insert screw perpendicular to cortical bone.**

If a pilot hole is desired, use the appropriate 1.1 mm drill bit with stop and a surgical power drill. Irrigate thoroughly to prevent overheating of the drill bit and bone.

Note: **To implant a 10 mm self-tapping anchor screw, continue with Steps 4 –5.**



Anchor screw mounted on screwdriver shaft with holding sleeve



Precautions:

- **Confirm screw length prior to implantation.**
- **Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation or bone stripping. If bone becomes stripped, remove the screw from the bone and replace with an emergency screw.**
- **To avoid damage to anatomic structures, place implant away from tooth roots, tooth buds, vessels, nerves, and/or sinuses.**

4 Drill a pilot hole for a 10 mm self-tapping anchor screw

Instrument	
03.503.110	MatrixMIDFACE Drill Bit ∅ 1.25 mm with Stop, length 44.5/10 mm, 2-flute, for J-Latch Coupling

Before implanting a 10 mm self-tapping anchor screw, drill a pilot hole using the 1.25 mm MatrixMIDFACE drill bit with 10 mm stop and a surgical power drill. Irrigate thoroughly to prevent overheating of the drill bit and bone.

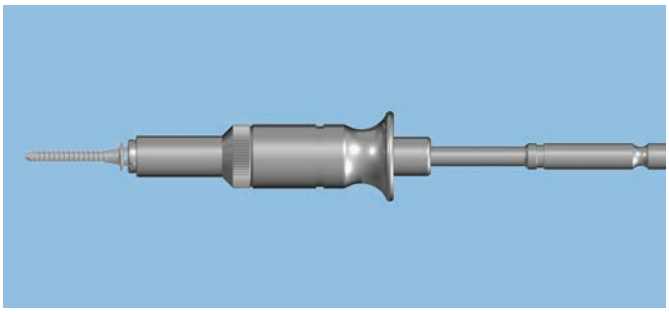
Note: **Always drill a pilot hole for the 10 mm self-tapping anchor screw.**

Precautions:

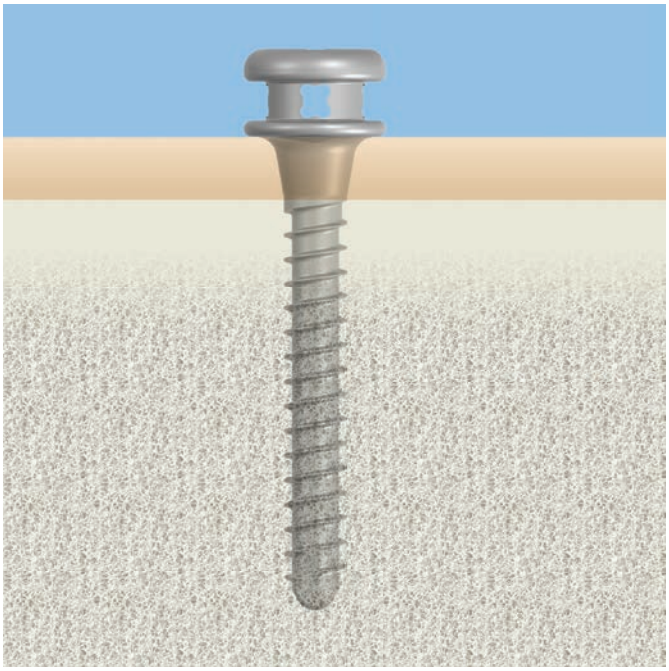
- **Confirm that drill bit length and diameter correspond to selected screw length prior to drilling.**
- **Drill rate should never exceed 1,800 rpm. Higher rates can result in thermal necrosis of the bone, soft tissue burns, and an oversized hole to be drilled. The adverse effects of an oversized hole include reduced pullout force, increased ease of the screws stripping in bone, and/or suboptimal fixation and/or the need for emergency screws.**
- **Always irrigate during drilling to avoid thermal damage to the bone. Irrigate and apply suction for removal of debris potentially generated during implantation or removal.**
- **Avoid drilling over nerve or tooth roots.**
- **Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures. Be sure to keep drill clear of loose surgical materials.**
- **Handle devices with care and dispose worn bone cutting instruments in a sharps container.**

5 Implant a 10 mm self-tapping anchor screw

Instruments	
03.500.001	Screwdriver Shaft, short, with Holding Sleeve, short, for OBA Screws, with Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling
or	
311.007	Handle, large, with Hexagonal Coupling



Anchor screw mounted on screwdriver shaft with holding sleeve



Using the screwdriver shaft, cruciform 1.55, with holding sleeve, short and the screwdriver handle with hexagonal coupling implant the 10 mm anchor screw until the distal lip of the anchor screw head sits on top of the soft tissue.

Note: **For optimal retention, insert screw perpendicular to cortical bone.**

6 Implant additional anchor screws

Repeat the preceding steps for additional anchor screws, as needed.

7 Screw Removal

Using standard technique, remove OBA screws using the screwdriver with holding sleeve.

Implanting an Anchor Plate

1 Locate the implantation site

Choose the implantation site according to the treatment objective and the quality and quantity of bone. Confirm that the implantation site allows adequate clearance from the tooth roots and nerves.

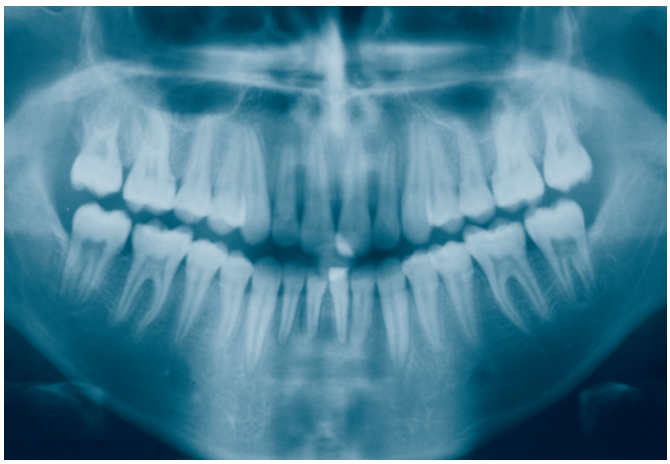
Select the appropriate anchor plate between the mesh design, bracket design or domed design with either 4 or 5 holes.

Consider in advance the reshaping and/or trimming of the plate that may be required to conform to the patient's bony anatomy.

Precaution: **To avoid damage to anatomic structures, place implant away from tooth roots, tooth buds, vessels, nerves, and/or sinuses.**

2 Prepare the implantation site

Make an appropriately sized incision where the anchor plate neck will protrude through the soft tissue, orienting the incision perpendicular to the long axis of the anchor plate neck, and dissect through the soft tissue to the bone. Make a submucosal pocket large enough to allow insertion of the anchor plate and implantation of the screws for plate fixation.



Preoperative x-ray

3 Reshape and/or trim the anchor plate

Instruments	
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function
391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending

The anchor plate may need to be reshaped and/or trimmed to conform to the patient's bony anatomy. If so, use the bending pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function and/or combined pliers for plates 1.0 to 2.0, for cutting and bending. The anchor plate has a T-configuration, but it may be trimmed to an L- or I-configuration if required.

If desired, use the bending pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function to reshape the anchor plate neck where it will protrude through the soft tissue.

Precautions:

- **If contouring is necessary, avoid sharp bends, reverse bends, or bending the implant at a screw hole. Avoid notching or scratching the implant. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.**
- **Plates should be cut so that the integrity of the screw hole is not compromised.**

Note: Care should be taken to remove any sharp edges after cutting the plate to avoid soft tissue irritation or injury.

4 Insert the screws for anchor plate fixation

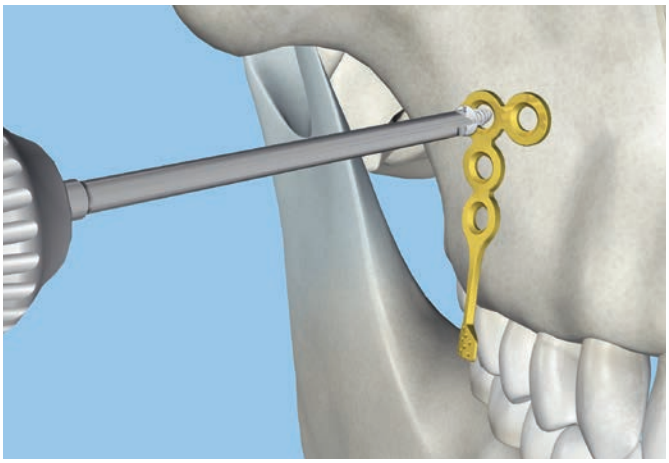
Instruments	
03.503.202	Screwdriver Shaft MatrixMIDFACE, medium, self-holding, length 76 mm, with Hexagonal Coupling
03.503.244	Drill Bit ∅ 1.1 mm with Stop, length 44.5/4 mm, for J-Latch Coupling
03.503.246	Drill Bit ∅ 1.1 mm with Stop, length 44.5/6 mm, for J-Latch Coupling
03.503.248	Drill Bit ∅ 1.1 mm with Stop, length 44.5/8 mm, for J-Latch Coupling
311.006	Handle, medium, with Hexagonal Coupling
or	
311.007	Handle, large, with Hexagonal Coupling

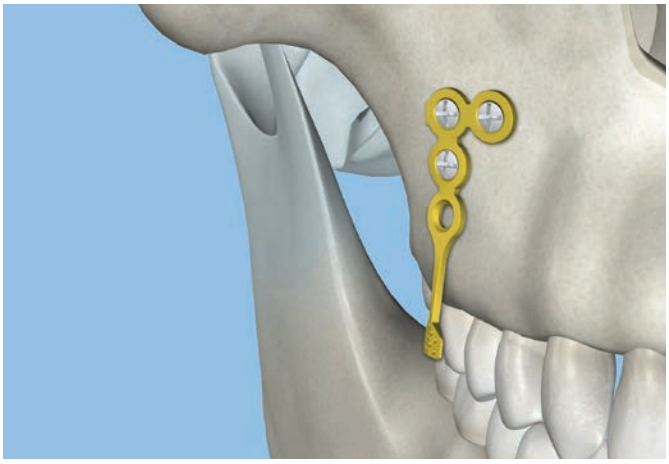
Choose the screws for plate fixation of the appropriate length(s). Make certain that they will avoid the tooth roots and nerves.

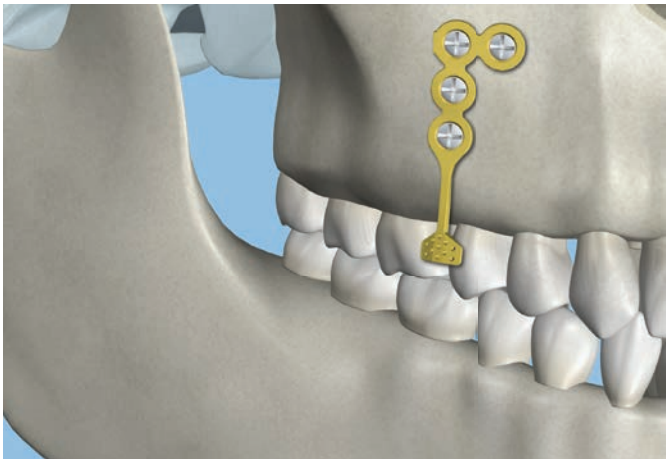
While holding the anchor plate in the desired location in the submucosal pocket, use the screwdriver shaft MatrixMIDFACE, self-holding, with hexagonal coupling and the screwdriver handle with hexagonal coupling to insert the first screw.

Repeat this process for the remaining screws. It is recommended to use at least three screws to secure the anchor plate.

If pilot holes are desired, make one for each screw using the appropriate 1.1 mm drill bit with stop and a surgical power drill. Irrigate thoroughly to prevent overheating of the drill bit and bone.







Note:

- **If the screw for plate fixation becomes loose in the bone, remove the screw and replace it with the appropriate length of MatrixMIDFACE emergency screw ∅ 1.8 mm, self-tapping.**
- **For optimal retention, insert screw perpendicular to cortical bone.**

Precautions:

- **Confirm screw length prior to implantation.**
- **Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation or bone stripping. If bone becomes stripped, remove the screw from the bone and replace with an emergency screw.**
- **To avoid damage to anatomic structures, place implant away from tooth roots, tooth buds, vessels, nerves, and/or sinuses.**

5 Confirm stability of anchor plate

Irrigate the submucosal pocket until it is free of debris, and surgically close the incision. Confirm that the stability of the anchor plate is satisfactory.

The anchor plate neck is malleable and can be adjusted if necessary.

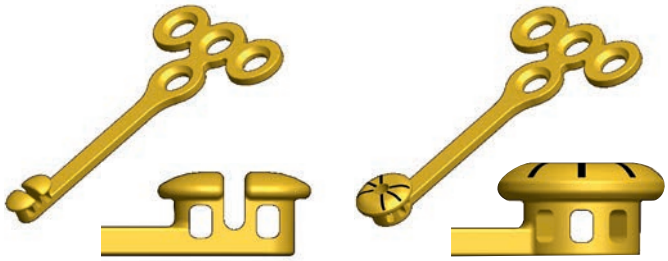
6 Implant Removal

Using standard technique, remove MatrixMIDFACE screws and OBA plate.

Using Orthodontic Appliances with Anchor Plates

1a Using bracket and domed anchor plates

Apply orthodontic devices directly to abutment on plate as desired.



1b Mounting orthodontic bracket to mesh anchor plate

Mount a standard orthodontic bracket to the mesh anchor plate using a standard adhesive approved for this intended use and indication.

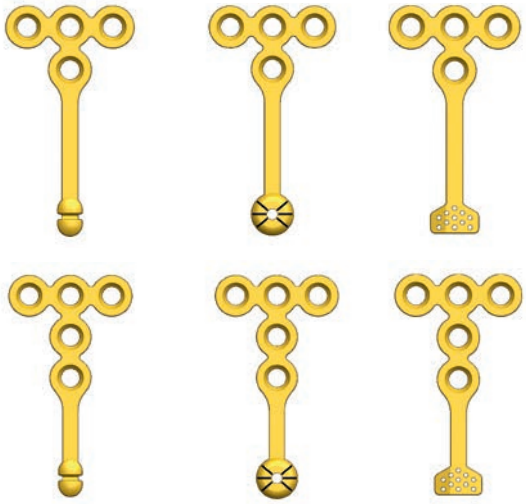
Apply the standard adhesive directly to the top surface at the end of the mesh anchor plate and spread it evenly over the surface. Add adequate adhesive to the mesh pad of the orthodontic bracket and firmly press the bracket onto the surface of the anchor plate, adjusting the orientation of the bracket as needed. Excess adhesive may be wiped away from the sides and bottom of the mesh anchor plate.

Follow the instructions for use of the manufacturer of the adhesive.

Implants

Orthodontic Bone Anchor Plate, 4 Holes	
04.500.012	bracket design
04.500.013	domed design
04.500.014	mesh design

Orthodontic Bone Anchor Plate, 5 Holes	
04.500.015	bracket design
04.500.016	domed design
04.500.017	mesh design



Orthodontic Bone Anchor Screw, self-drilling	
04.500.006	Length 6 mm
04.500.008	Length 8 mm

Orthodontic Bone Anchor Screw, self-tapping	
04.500.010	Length 10 mm

MatrixMIDFACE Screw 1.5 mm, self-drilling Titanium Alloy (TAN), pack of 4 units in Clip	
04.503.224.04C	length 4 mm
04.503.226.04C	length 6 mm
04.503.228.04C	length 8 mm

All MatrixMIDFACE screws 1.5 mm are also available in single clip (.01c) Single packed sterile (.01S), 4 units pack sterile (.04S) or non sterile packed (.01). Replace suffix ".04C" with "01c", "01S", "04S" or ".01" to order the corresponding product.

MatrixMIDFACE Emergency Screw, 1.8 mm, self-tapping, Titanium Alloy (TAN), pack of 1 unit in Clip	
04.503.234.01C	length 4 mm,
04.503.236.01C	length 6 mm,
04.503.238.01C	length 8 mm

All MatrixMIDFACE Emergency screws are also available single packed sterile (.01S) or non sterile packed (.01). Replace suffix ".01C" with ".01S or ".01" to order the corresponding product.

All implants are available sterile or non sterile packed. Add suffix "s" to article number to order sterile product.

Instruments

03.500.001	Screwdriver Shaft, short, with Holding Sleeve, short, for OBA Screws, with Hexagonal Coupling
03.500.002	Screwdriver Shaft, long, with Holding Sleeve, long, for OBA Screws, with Hexagonal Coupling

03.503.244	Drill Bit ∅ 1.1 mm with Stop, length 44.5/4 mm, for J-Latch Coupling
03.503.246	Drill Bit ∅ 1.1 mm with Stop, length 44.5/6 mm, for J-Latch Coupling
03.503.248	Drill Bit ∅ 1.1 mm with Stop, length 44.5/8 mm, for J-Latch Coupling
03.503.110	MatrixMIDFACE Drill Bit ∅ 1.25 mm with Stop, length 44.5/10 mm, 2-flute, for J-Latch Coupling

03.503.201	Screwdriver Shaft MatrixMIDFACE, short, self-holding, length 52 mm, with Hexagonal Coupling
03.503.202	Screwdriver Shaft MatrixMIDFACE, medium, self-holding, length 76 mm, with Hexagonal Coupling
03.503.203	Screwdriver Shaft MatrixMIDFACE, long, self-holding, length 96 mm, with Hexagonal Coupling

347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function	
391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending	
311.006	Handle, medium, with Hexagonal Coupling	
311.007	Handle, large, with Hexagonal Coupling	

Set (01.500.009)

Module	
61.500.009	Module for Orthodontic Bone Anchor System

Implants		**Qty**
04.500.012	Orthodontic Bone Anchor Plate, Bracket Design, 4 holes	2
04.500.013	Orthodontic Bone Anchor Plate, Domed Design, 4 holes	2
04.500.014	Orthodontic Bone Anchor Plate, Mesh Design, 4 holes	2
04.500.015	Orthodontic Bone Anchor Plate, Bracket Design, 5 holes	2
04.500.016	Orthodontic Bone Anchor Plate, Domed Design, 5 holes	2
04.500.017	Orthodontic Bone Anchor Plate, Mesh Design, 5 holes	2
04.500.006	Orthodontic Bone Anchor Screw, self-drilling, Length 6 mm	5
04.500.008	Orthodontic Bone Anchor Screw, self-drilling, Length 8 mm	5
04.500.010	Orthodontic Bone Anchor Screw, self-tapping, length 10 mm	5
04.503.224.04C	MatrixMIDFACE Screw B 1.5 mm, self-drilling, length 4 mm, Titanium Alloy (TAN), pack of 4 units in Clip	2
04.503.226.04C	MatrixMIDFACE Screw B 1.5 mm, self-drilling, length 6 mm, Titanium Alloy (TAN), pack of 4 units in Clip	2
04.503.228.04C	MatrixMIDFACE Screw B 1.5 mm, self-drilling, length 8 mm, Titanium Alloy (TAN), pack of 4 units in Clip	2
04.503.234.01C	MatrixMIDFACE Emergency Screw ∅ 1.8 mm, self-tapping, length 4 mm, Titanium Alloy (TAN), pack of 1 unit in Clip	2
04.503.236.01C	MatrixMIDFACE Emergency Screw ∅ 1.8 mm, self-tapping, length 6 mm, Titanium Alloy (TAN), pack of 1 unit in Clip	2
04.503.238.01C	MatrixMIDFACE Emergency Screw ∅ 1.8 mm, self-tapping, length 8 mm, Titanium Alloy (TAN), pack of 1 unit in Clip	2

Instruments		Qty
03.503.202	Screwdriver Shaft MatrixMIDFACE, medium, self-holding, length 76 mm, with Hexagonal Coupling	1
347.964	Bending Pliers 3D, left, for Plates 1.0 to 2.0, with contour-bending function	1
391.965	Combined Pliers for Plates 1.0 to 2.0, for Cutting and Bending	1
03.500.001	Screwdriver Shaft, cruciform 1.55, with Holding Sleeve, short	1
03.503.244	Drill Bit ∅ 1.1 mm with Stop, length 44.5/4 mm, for J-Latch Coupling	2
03.503.246	Drill Bit ∅ 1.1 mm with Stop, length 44.5/6 mm, for J-Latch Coupling	2
03.503.248	Drill Bit ∅ 1.1 mm with Stop, length 44.5/8 mm, for J-Latch Coupling	2
03.503.110	MatrixMIDFACE Drill Bit ∅ 1.25 mm with Stop, length 10/44.5 mm, 2-flute, for J-Latch Coupling	2
311.006	Handle, medium, with Hexagonal Coupling	1

Additionally available	
04.503.224.01C	MatrixMIDFACE Screw ∅ 1.5 mm, self-drilling, length 4 mm, Titanium Alloy (TAN), pack of 1 unit in Clip
04.503.226.01C	MatrixMIDFACE Screw ∅ 1.5 mm, self-drilling, length 6 mm, Titanium Alloy (TAN), pack of 1 unit in Clip
04.503.228.01C	MatrixMIDFACE Screw ∅ 1.5 mm, self-drilling, length 8 mm, Titanium Alloy (TAN), pack of 1 unit in Clip
03.503.201	Screwdriver Shaft MatrixMIDFACE, short, self-holding, length 52 mm, with Hexagonal Coupling
03.503.203	Screwdriver Shaft MatrixMIDFACE, long, self-holding, length 96 mm, with Hexagonal Coupling
03.500.002	Screwdriver Shaft, cruciform 1.55, with Holding Sleeve, long
311.007	Handle, large, with Hexagonal Coupling

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