

## INSTRUCTIONS FOR USE

### Bollard Skeletal Anchor

**INDICATIONS FOR USE:** The Bollard Plates are intended to be placed in the mouth for use as an anchor in orthodontic procedures

#### CLEANING

- Trained personal must perform cleaning
- Exact compliance is required with the manufacturers' user instructions
- For example mechanical cleaning & disinfection conform prEN 15883 with a validated standard program: 1)cold prewashing 2)cleaning 3)washing 4)neutralisation with alkaline cleaning 5)washing 6)washing 7) thermal disinfection 8)drying.
- When manual cleaning & disinfection for example: 1)cold prewashing 2)cleaning with neutral soap 3)washing 4)chemical disinfection with a product on basis of alcohol or quaternary ammonium.
- Cleaning is the responsibility of the user.

#### STERILISATION

- All products are supplied non-sterile
- Trained personal must perform sterilization
- Direct contact between bone anchors and screws during sterilization must be avoided.
- Exact compliance is required with the manufacturers' user instruction.
- The user facility is responsible for the application of special cleaning and sterilization procedures.
- Tita-Link screws and bone anchors are sterilized for example with saturated steam with a large sterilizer conform EN285 or a small sterilizer conform EN13060 with a validated program with prevacuum: 1)Minimally 2 prevacuum phases 2)Sterilization on 134°C during min. 34' or on 121°C min. 18' with a pressure of 3 bar 3)A dry phase
- Validation of the sterilization is the responsibility of the user.
- Health care personal bear the ultimate responsibility for ensuring the packaging method or material, including the reusable container system which is suitable for use in sterilization processing and sterility maintenance.

#### WARNING AND PRECAUTIONS

- The products must be handled and stocked with care. Scratching or damage can reduce the strength and the resistance of the product.
- The round bar of the bone anchors **should not be bended**. **Bending of the round bar may lead to fracture during or after surgery.**
- Bending of the miniplate should not exceed 10°. The plate may be bent only once. **Bending of the plate more than 10° and/or repetitive bending may lead to fracture during or after surgery.**
- Intraoperative fracture of the screws can occur if excessive force is applied when seating bone screws.
- The product should never be reused. Previous stresses may have created imperfections that can reduce its life time.
- The patient should be advised to report any unusual change of the operated site to his surgeon. The patient should be placed under supervision if a change at the fixation site has been detected.
- The Tita-Link screws and bone anchors are designed to be used together.
- The correct selection of the product is extremely important. The product should be used in the correct anatomic location, consistent with accepted indications for bone anchor placement.
- The screws and bone anchors can only be used by trained personal (maxillo-facial surgeons, stomatologists, neurosurgeons, plastic surgeons and implantologists/dentists)
- Orthodontic loading should not exceed 250 grams. **Loading exceeding 250 grams may lead to fracture of the bone anchor.**

The bone anchors shall be removed and eliminated when no longer needed for orthodontic treatment.

#### THE BOLLARD MINIPLATE

**Read the whole instruction guide carefully, because it contains valuable information in relation to the use of the Bollard Anchorage plate.**

Content of this instruction guide

- Description of the device
- Location of insertion
- Surgical technique

#### 1. Description of the device

The device consists of 3 parts: a 2 or 3 hole titanium mini-plate, a neck (round connecting bar) and a cylindrical fixation unit with a blocking screw. Through the holes in the mini-plate the bone anchor is fixed by mini-cortical titanium screws.

#### 2. Location of insertion

- in upper or lower jaw at a safe distance away from the root apices of the teeth
- most commonly on the infra-zygomatic crest of the maxillary buttress or in the lower canine region between lateral incisor and canine
- the device may also be inserted on the paranasal crest or molar region of the mandible

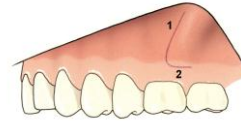
#### 3. Surgical technique

The devices are placed under local anesthesia. However, if problems of compliance are expected, it is recommended to place the devices under general anesthesia, or under local anesthesia with NO<sub>2</sub> or IV sedation. To reduce the risk for infections, placement of the medical devices should not be combined with extractions of teeth in the proximity of implant insertion.

#### Step-by-Step description of the Surgical Procedure for Placement of Bollard Anchorage devices:

##### Maxillary Placement

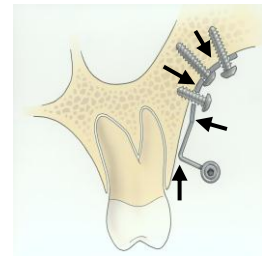
##### On the infra-zygomatic crest



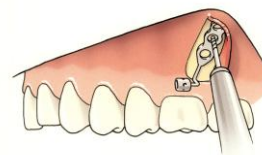
An L-shaped incision is made with anterior convexity. The vertical part of the incision (1) is made ± 1cm mesial from and parallel to the infra-zygomatic crest and up to 2mm below the muco-gingival boarder. The incision is extended distally (2) with a horizontal incision 2mm below and parallel to the muco-gingival boarder.



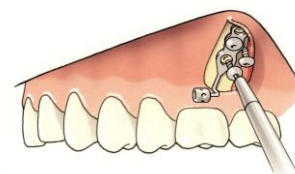
A posterior based mucoperiosteal flap is made for bone exposure.



The miniplate is slightly bended to obtain good contact to the cortical bone. The bending should be limited to the region between the holes (1) in the miniplate. This bending should not exceed 10° and may only be performed once. **Bending of the plate more than 10° and/or repetitive bending may lead to fracture during or after surgery.** The angulation between the miniplate and the neck (2) should not be modified in order to ensure good contact between the lower part of the neck and the alveolar bone (3). The round bar should not be bended. **Bending of the round bar may lead to fracture during or after surgery.**

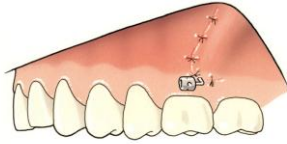


The device is positioned so that the round connecting bar of the neck penetrates the soft tissues exactly at the angle of the L-shaped incision 2mm below the muco-gingival boarder. The centre of the holes in the miniplate should be on top of the infra-zygomatic crest. The opening of the cylinder is anterior. A first hole with a diameter of 1.65 mm is drilled through the middle hole of the miniplate. Therefore a standard hard steel 1.65 mm twisted drill is used.



The screws, diameter of 2.3 mm and a length of 5 mm (for the upper screw also a 7 mm length screw can be used) are seated with a standard screw driver for orthopedic or maxillo-facial surgery. The first screw is not completely fixed in order to allow some rotation of the

miniplate. The lower hole is drilled and the screw is inserted, followed by the upper one and all are fixed for a strong stable retention.



After rinsing with saline solution, closure is obtained in one plane with 4/0 resorbable sutures. The mucoperiosteal flap is positioned by the first suture just anterior from the neck of the bone anchor. Additional sutures are placed until good closure is obtained. The fixation unit should be oriented parallel to the alveolar bone with the opening of the cylinder oriented to the front.

**Mandibular Placement**  
In the lower canine region



An inverted L-shaped incision is made with an angle slightly superior to 90°. The horizontal part of the incision is located 2 mm above the muco-gingival boarder.



A posterior based mucoperiosteal flap is made for bone exposure.



The device is positioned so that the round connecting bar of the neck penetrates the soft tissues at the angle of the L-shaped incision 2mm above the muco-gingival boarder. The centre of the holes in the miniplate should be in the middle of the axis of the 2 neighbouring teeth. The opening of the cylinder is oriented to the distal. A first hole is drilled through the upper hole of the miniplate at the level of the root apices. Therefore a standard hard steel 1.65 mm twisted drill is used.



The screws, diameter of 2.3 mm and a length of 5 mm are seated with a standard screw driver for orthopedic or maxillo-facial surgery. The first screw is inserted but not completely fixed in order to allow some rotation of the miniplate. The second hole is drilled and the screw is inserted in the mandibular body and both are fixed for a strong stable retention.



After rinsing with saline solution, closure is obtained in one plane with 4/0 resorbable sutures. The mucoperiosteal flap is positioned by the first suture just anterior from the

neck of the bone anchor. Additional sutures are placed until good closure is obtained. The fixation unit should be oriented parallel to the alveolar bone with the opening of the cylinder facing posteriorly.

**THE BOLLARD MINIPLATE WITH HOOK**

Read the whole instruction guide carefully, because it contains valuable information in relation to the use of the **Bollard Anchorage plate**.

Content of this instruction guide

1. Description of the device
2. Location of insertion
3. Surgical technique

1. Description of the device

The device consists of 3 parts: a 2 or 3 hole titanium mini-plate, a neck (round connecting bar) and a cylindrical fixation unit with a blocking screw. Through the holes in the mini-plate the bone anchor is fixed by mini-cortical titanium screws.

2. Location of insertion

- in upper or lower jaw at a safe distance away from the root apices of the teeth
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- the device may also be inserted on the paranasal crest or molar region of the mandible

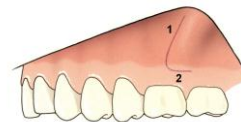
3. Surgical technique

The devices are placed under local anesthesia. However, if problems of compliance are expected, it is recommended to place the devices under general anesthesia, or under local anesthesia with NO2 or IV sedation. To reduce the risk for infections, placement of the medical devices should not be combined with extractions of teeth in the proximity of implant insertion.

**Step-by-Step description of the Surgical Procedure for Placement of Bollard Anchorage devices:**

**Maxillary Placement**

On the infra-zygomatic crest



An L-shaped incision is made with anterior convexity. The vertical part of the incision (1) is made ± 1cm mesial from and parallel to the infra-zygomatic crest and up to 2mm below the muco-gingival boarder. The incision is extended distally (2) with a horizontal incision 2mm below and parallel to the muco-gingival boarder.



A posterior based mucoperiosteal flap is made for bone exposure.



The miniplate is slightly bended to obtain good contact to the cortical bone. The bending should be limited to the region between the holes (1) in the miniplate. This bending should not exceed 10° and may only be performed once. Bending of the plate more than 10° and/or repetitive bending may lead to fracture during or after surgery. The angulation between the miniplate and the neck (2) should not be modified in order to ensure good contact between the lower part of the neck and the alveolar bone (3). The round bar should not be bended. Bending of the round bar may lead to fracture during or after surgery.



The device is positioned so that the round connecting bar of the neck penetrates the soft tissues exactly at the angle of the L-shaped incision 2mm below the muco-gingival boarder. The centre of the holes in the miniplate should be on top of the infra-zygomatic crest. The opening of the hook is to the distal. A first hole with a diameter of 1.65 mm is drilled through the middle hole of the miniplate. Therefore a standard hard steel 1.65 mm twisted drill is used.



The screws, diameter of 2.3 mm and a length of 5 mm (for the upper screw also a 7 mm length screw can be used) are seated with a standard screw driver for orthopedic or maxillo-facial surgery. The first screw is not completely fixed in order to allow some rotation of the miniplate. The lower hole is drilled and the screw is inserted, followed by the upper one and all are fixed for a strong stable retention.



After rinsing with saline solution, closure is obtained in one plane with 4/0 resorbable sutures. The mucoperiosteal flap is positioned by the first suture just anterior from the neck of the bone anchor. Additional sutures are placed until good closure is obtained. The fixation unit should be oriented parallel to the alveolar bone with the opening of the hook oriented to the distal.

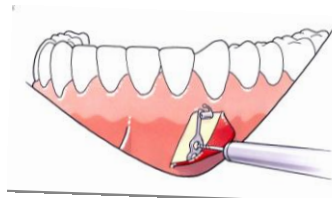
**Mandibular Placement**  
*In the lower canine region*



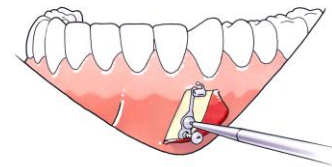
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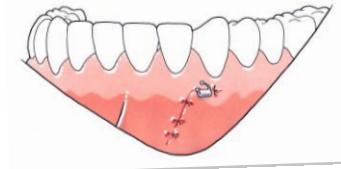
A posterior based mucoperiosteal flap is made for bone exposure.



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After rinsing with saline solution, closure is obtained in one plane with 4/0 resorbable sutures. The mucoperiosteal flap is positioned by the first suture just anterior from the neck of the bone anchor. Additional sutures are placed until good closure is obtained. The fixation unit should be oriented parallel to the alveolar bone with the hook facing to the mesial.