TAD Implant Screw: Instructions for use.

G&H® Wire Company
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1. **Manufactured by**

Paragon Medical
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Pierceton, Indiana 46562 USA

2. **Product Description**

The G&H® Orbit™ TAD Implant Screw System consists of titanium self tapping screws with various sizes for applications in the orthodontic field. It is intended to serve as a fixed anchorage point for the attachment of orthodontic and pre-prosthetics appliances, in order to facilitate the orthodontic movement of teeth. G&H® Orbit™ TAD Implant Screws and associated accessories are supplied “NON STERILE” and should be sterilized before use. The device is used temporarily with the intention to be removed after orthodontic treatment. Screws are intended for single use only.

3. **Indications for use**

Temporary anchorage screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. The screw is used temporarily and is removed after orthodontic treatment has been completed.

4. **Contraindications**

- Insufficient bone quantity and/or poor bone quality in the receiving site.
- Poor oral hygiene.
- Heavy smoking, tobacco and alcohol abuse.
- Systemic blood disorders.
- Uncontrolled diabetes.

5. **Warnings**

- Placement of surgical screws requires specific knowledge of anatomy and techniques and this procedure must be carried out by qualified and trained people. Improper patient selection and/or incorrect technique can cause placement failure and/or loss of supporting bone.

- An implanted device or used screw should never be reused. Any screws which have been contaminated with blood or bodily fluids should be discarded.

6. **Precautions**

- Effective and complete screening of screw application candidates must be performed. Visual inspection as well as panoramic and periapical radiographs are recommended to determine anatomical landmarks and bone adequacy. Lateral teleradiographs and other types of X-ray examination are recommended.

- Detailed instructions, limitations and possible adverse effects of the procedure should be given to the patient.

- G&H® Orbit™ TAD Implant Screw application procedures have some risks which include the insult of delicate anatomical structures both of the superior jaw-bone and of mandibular bone, if existing conditions are not carefully considered.

- The G&H® Orbit™ TAD Implant Screw has been designed to achieve anchorage with immediate loading and of limited duration. Consequently, the efficiency of this system should not be dependent upon osseointegration. The G&H® Orbit™ TAD Implant Screw is highly polished and not designed for osseointegration anchorage (deferred loading).
7. **Adverse Effects**

After G&H® Orbit™ TAD Implant Screw application, untimely anchorage loss may occur. Potential causes include but are not limited to:

- Bone poor quantity and/or quality, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone leading to non-union.
- Infections
- Poor oral hygiene or patient’s cooperation and/or genetic diseases (diabetes).
- Migration, bending, fracture or loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Increase fibrous tissue response around the fracture site and/or the implant.
- Necrosis of bone.
- Inadequate healing.
- Localized swelling, edema and tissue reaction.

Apart from these adverse effects, there are always possible complications such as, but not limited to, infection, nerve damage and pain which may or may not be related to the implant.

8. **Cleaning and Sterilization**

It is the responsibility of and incumbent on the user to make certain and to validate that appropriate cleaning and sterilization methods are used.

**Sterilization:**

The G&H® Orbit™ TAD Implant Screw is supplied clean and non-sterile and is intended to be sterilized prior to use. Use of a G&H® Sterilization Cassette (#OTCAS) is recommended to sterilize simultaneously all instruments, components and screws. Components including screws, drivers and shafts may also be sterilized individually using a sterilization pouch.

The validated sterilization procedures as described require the use of FDA cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI.

Sterilization studies with the Orbit™ Anchorage Screw Implant System were conducted by an independent laboratory and based on protocol parameters per NAMSA Protocol 08G_45872_01 and Protocol Supplement 1 in accordance with AAMI TIR 12:2004 – ANSI/AAMI/ISO 17665-1:2006. Those studies confirmed the following recommendations for Steam Sterilization cycles.

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity</td>
<td>121°C</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Pre-vacuum</td>
<td>132°C</td>
<td>8 minutes</td>
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Sterilization results confirmed for a single micro screw or a fully loaded cassette using one pouch and a dry time.
9. **Direction for use**

No pilot drilling is required prior to insertion of G&H® Orbit™ TAD Implant Screws with a self-drilling thread in the maxilla. When inserting the Orbit™ TAD Implant Screw, ensure that all the hygiene measures required for invasive surgery are completed, e.g. sterile working area, sterile gloves, face mask etc.

Reliable functioning of the Orbit™ TAD Implant Screw depends on rigid anchorage in the bone (primary stability) and placing the head in the region of the attached gingiva (alveolar gingiva). When using the Orbit™ TAD Implant Screw as an anchor, ensure that the head and surrounding tissue are not subjected to any detrimental mechanical effects (e.g. movement of the mucosa, effect of bands and/or tongue, manipulation). Maximum load force is 300G per screw. The direction of force must be perpendicular to the long axis of the implant for immediate loading.

**Step 1:** Select the insertion area.

Suitable placement sites for the Orbit™ TAD Screw are listed below:

- Retromolar.
- Buccal and lingual interradicular alveolar zone of the mandible and maxilla.
- Mandibular symphysis.

**Step 2:** Local anesthetic.

**Step 3:** Punch a hole in the gingiva using a gingival punch.

**Step 4:** Screw Placement and Insertion

Pick up a sterile Orbit™ Screw and transfer it to the prepared site for placement using the G&H® Handle Driver instrument. (G&H® #OTDRVR and #OTDSOC Socket Shaft or #OTDSCR Screwdriver Shaft.)

**Step 5:** Screw Placement and Insertion (cont.)

In most cases the Orbit™ TAD Implant Screw can be inserted without any drilling depending upon the bone density. It is the responsibility of the professional to determine suitability on a case by case basis before use.

**Step 6:** Screw Placement and Insertion (cont.)

Use G&H® Handle Driver (#OTDRVR) for insertion and final height positioning. Always insert the screw to ensure all threaded portions of the screw are sub cortical.

10. **Removal of the G&H® Orbit™ TAD Implant Screw:**

- Local anesthetic *(optional).*
- Remove all wires, auxiliaries and attachments.
- Unscrew the G&H® Orbit™ TAD Implant Screw using the G&H® handle driver instrument and head shaft of choice.


- Manufactured in the U.S.A.
- Constructed of 100% biocompatible Titanium
- Highly polished to prevent osseointegration