$\textbf{Unitek}^{{}^{\scriptscriptstyle {\rm T}\!\!\!\!\!\!\!\!\!\!\!\!}} \textbf{Temporary Anchorage Device System}$

Cope Placement Protocol[™]





Unitek[™] Temporary Anchorage Device System Anchorage Redefined Jason B. Cope, DDS, PhD

"Over the past six to eight years, a number of Temporary Anchorage Devices (TADs), primarily in the form of miniscrew implants, have hit the market. When you, the clinician, begin to evaluate the many systems available for use in your practice, there are several things you should consider before making a decision on which system to purchase. For instance, how many different types of screws must you inventory based on different head designs, screw lengths, transmucosal collar lengths and threaded diameters? Does the system require an injection, an incision and flap and/or a pilot hole? Is gingival overgrowth a problem? How many different ways can you attach to it?

Simplicity of use and integration into the daily orthodontic practice were our primary goals during the design process of the Unitek[™] Temporary Anchorage Device. With those goals in mind, we developed only one head design and one diameter with three different lengths. Three different lengths are necessary to facilitate placement in different locations within the oral cavity based on gingival thickness and bony depth. However, don't let the simplicity of design and only three Unitek TADs to choose from mislead you. The ingenious O-Ball head of the Unitek TAD makes the system universally adaptable; it serves as one component in a ball and socket joint. The other is the Unitek[™] Temporary Anchorage Device O-Cap, a stainless steel cap with an internal Unitek[™] Temporary Anchorage Device O-Ring that locks in place around the O-Ball. The cap can be placed and removed with little effort, but is stable enough that a patient can't inadvertently dislodge it. The beauty of the Unitek[™] TAD O-Cap is that, if the clinical situation warrants, it can be placed to suppress the soft tissues and prevent mucosal overgrowth. We also placed a groove in the Unitek TAD O-Cap, so that ligatures, elastics or power chain can be attached directly to it. And since it is made of stainless steel, the Unitek TAD O-Cap can be soldered to, thereby allowing different aTADchments[™] to be fabricated.

We have also taken the bite out of the placement procedure – no injections, no flap, and no pilot hole! The Cope Placement Protocol[™] utilizes a specially compounded high-strength topical anesthetic; local anesthetic injections are rarely required. No incision or flap is necessary either. In alveolar or mobile mucosa, the index finger and thumb are used to stretch the soft tissue so that the mucosa does not wrap around the Unitek TAD threads during insertion. This is not necessary in keratinized gingiva.

As Simple as fitting a headgear

Moreover, no pilot hole is required with the Unitek TAD. We designed the Unitek TAD so that it is self-drilling and self-tapping. There are two different types of self-tapping screws – thread-forming and thread-cutting. The Unitek TAD is thread-forming: it compresses bone in and around the screw threads during advancement instead of cutting and removing bone common with other screws. Threadcutting screws, on the other hand, have a notch cut out of the screw apex that cuts or taps the bone during screw placement. This feature tends to weaken screws smaller than about 1.6 mm in diameter, thereby necessitating a pilot hole. In lieu of a threadcutting notch, we tapered the apical 4 mm of the Unitek TAD from 0.3 mm to the full 1.8 mm, which compresses the bone around the screw during auto-advancement instead of cutting/removing bone as is common with thread-cutting screws.

Once the Unitek TAD is gently screwed into place, it can be loaded immediately with a light force; there is no reason to wait for the soft tissues or bone to heal. Neither is traumatized by this non-surgical procedure, which rarely even requires ibuprofen administration. Once in place, the Unitek TAD can be attached to via the grooved neck, the 0.030" holes in the O-Ball or the groove in the Unitek TAD O-Cap. In addition to the standard methods of attachment, hooks can be inserted through the 0.030" holes, or the Unitek TAD O-Caps can be soldered to individually, in series or even embedded into acrylic. The options are limited only by your imagination.

It will become readily apparent to orthodontists who investigate this product line that the Unitek TAD system is extremely simple to understand, simple to inventory and most importantly, simple to use. You'll be glad you chose the Unitek TAD...it truly is as simple as fitting a headgear.

The Unitek Temporary Anchorage Device System: Intelligent by design...for the thinking Orthodontist."

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3M Unitek acknowledges the contribution of Dr. Jason B. Cope in the design of the Unitek[™] Temporary Anchorage Device (TAD), Unitek TAD Constant Force Springs, Unitek TAD Contra Angle Driver, Unitek TAD 0-Cap and aTADchments[™].



Unitek[™] Temporary Anchorage Device (TAD)

Placement locations for the Unitek[™] Temporary Anchorage Device

Mandible

Ascending Ramus **Retromolar Area**

External Oblique Ridge

| Maxilla | Mandi |
|--|---|
| InfraZygomatic Crest | Ascending Rame |
| SubANS | Retromolar Area |
| Alveolar Bone • Facial Surface • Paltal Surface Palatal Bone • Anterolateral • Parasagittal Midpalate • Midpalatal Suture (Adults) | External Oblique |
| | Alveolar Bone |
| | Facial Surface Lingual Surface |
| | Symphysis |

| Unitek™ Temporary Anchorage Device Lengths | | | |
|--|----------------|------------------------|--|
| Implant Length | Tapered Length | 1.8 mm Diameter Length | |
| 6 mm | 4 mm | 2 mm | |
| 8 mm | 4 mm | 4 mm | |
| 10 mm | 4 mm | 6 mm | |

Common Locations for each Unitek[™] Temporary Anchorage Device

| Unitek [™] Temporary Anchorage Device Locations | | |
|--|--|--|
| Length | Implant Location | |
| 6 mm | Facial surface maxillary/mandibular alveolar ridge mesial to 1st molar, maxillary subANS region, mandibular symphysis | |
| 8 mm | Facial surface maxillary/mandibular alveolar ridge distal to 2nd premolar, parasagittal midpalate | |
| 10 mm | Maxillary tuberosity, zygomatic buttress, infrazygomatic crest or posterior lateral palate; mandibular ascending ramus, retromolar region, external oblique ridge | |

This should only be used as a guide since soft tissue and bone thicknesses vary from patient to patient.

Maxillary Bone Locations





Mandibular Bone Locations



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Unitek[™] Temporary Anchorage Device System

Quick Use Guide

Cope Placement Protocol™

- 1. Patient brushes teeth to remove plaque and debris
- 2. Patient rinses with 15 ml of 0.12% Chlorhexidine Gluconate for 30 seconds
- 3. Apply Dēpblū[™] Dental Gel topical anesthetic
- 4. Mark insertion site on soft tissue
- 5. Perform bone sounding with periodontal probe to measure soft tissue thickness
- 6. Determine Unitek[™] Temporary Anchorage Device (TAD) length based on:
 - Soft tissue thickness
 - Bone thickness
- Insert Unitek TAD with the Unitek[™] TAD Straight Driver or Unitek[™] TAD Contra Angle Driver
- Load by attaching directly to 0.030" holes, implant neck or groove in Unitek TAD 0-Cap

Cope Placement Protocol[™]

Step 1. Patient brushes teeth to remove plaque and debris Chlorhexidine interacts with detergents and fluoride in toothpaste. Therefore, the patient should rinse vigorously with water after brushing and before rinsing with Chlorhexidine, or use no toothpaste at all.

Step 2. Patient rinses with 15 ml of 0.12% Chlorhexidine Gluconate for 30 seconds

Chlorhexidine has been shown to provide antimicrobial activity during rinsing.

Step 3. Apply Dēpblū[™] Dental Gel topical anesthetic (Fig. 1)

Dēpblū[™] Dental Gel is a specially compounded high-strength topical anesthetic that provides profound soft tissue and periosteal anesthesia (available from www.stevensrx.com). It has limited anesthetic effect on bone and tooth roots via absorption. So, similar to extraction of teeth, the patient will feel pressure, but not pain, unless the periodontal ligament (PDL) or tooth root is contacted. If this occurs, the clinician needs to know, so that the orientation angle of the Unitek[™] Temporary Anchorage Device (TAD) can be altered prior to root damage.



Fig. 1A-1B: Application of $\mathsf{D\bar{e}pbl\bar{u}^{\scriptscriptstyle M}}$ Dental Gel

Step 4. Mark insertion site on soft tissue

Determine the Unitek TAD insertion site. Several methods are available to do this. It is important to place the Unitek TAD in locations with a minimum of 0.5-1.0 mm of bone around the circumference of the Unitek TAD.

- The simplest method is to use a panoramic or periapical x-ray with direct clinical visualization to identify the site (Fig. 2)
- A modification of this approach is to use the curved end of an explorer to firmly indent the outline of the roots into the soft tissues prior to using direct clinical visualization to place the Unitek TAD (Fig. 3)



Fig. 2: Example of an x-ray with direct clinical visualization



Fig. 3A-3C: Curved end of an explorer

Step 5. Perform bone sounding with periodontal probe to measure soft tissue thickness

A marked periodontal probe with an endodontic stopper is probed through the soft tissue in the planned Unitek[™] Temporary Anchorage Device (TAD) location until bone is contacted. At this point, the stopper rests on the soft tissue. The probe is then removed and the soft tissue thickness is recorded from the periodontal probe (Fig. 4).



Fig. 4





Unitek[™] Temporary Anchorage Device System

Step 6. Determine Unitek TAD length based on:

- Soft tissue thickness
- Bone thickness

The Unitek TAD length is determined more by the soft tissue thickness than by the bony thickness (outer cortex plus medullary bone up to but not including contralateral cortex). The most critical part of the threaded body is the part that traverses the outer cortex – this should be the full 1.8 mm diameter body, not the tapered body.

If the soft tissue is greater than 1.5 mm thick, a longer Unitek TAD is required. For example, the 6 mm Unitek TAD has 4 mm of taper and 2 mm of the full 1.8 mm diameter threaded body. The most important factor is that the 2 mm of the full 1.8 mm diameter should reside in the cortex. So, if the soft tissue is more than 1.5 mm, then the neck of the Unitek TAD will be too close to the soft tissue or possibly even submerged. Therefore, a longer Unitek TAD should be used. It is not a problem to have part of the threaded portion traverse the soft tissue as long as the part of the Unitek TAD that resides in the outer cortex is not tapered (Fig. 5).



Step 7. Insert Implant with the Unitek[™] TAD Straight Driver or Unitek[™] TAD Contra Angle Driver

Remove the white cap containing the Unitek[™] Temporary Anchorage Device (TAD) from the sterile vial. While holding the white cap in one hand, either the Unitek TAD Straight Driver or Unitek TAD Contra Angle Driver is placed over the O-Ball and around the square head so that the Unitek[™] TAD O-Ring tightly holds the Unitek TAD (Fig 6). The Unitek TAD is unscrewed from the white cap and ready for placement.





Fig. 6A-6E

The Unitek TAD Straight Driver is applicable to most locations. The Unitek TAD Contra Angle Driver is a contra-angle screw driver that is usually more applicable in the retromolar regions for implants placed vertically, in the anterior palate for implants placed vertically and in the posterior palate for implants placed laterally.

The tip of the Unitek TAD should be placed against the bone, at the proper orientation and rotated clockwise into the bone with firm seating pressure at the base of the handle as the Unitek TAD Straight Driver is rotated with the fingers. The orientation should be verified

from the lateral and occlusal aspects (Fig. 7). If the Unitek TAD Contra Angle Driver is used, the handle is twisted clockwise into the bone with firm seating pressure applied with the palm of the contralateral hand (Fig. 8).



Fig. 7A-7B



Fig. 8

As the Unitek TAD is screwed into the bone, the resistance of the bone will most likely begin to increase. This occurs more often in the mandible as compared to the maxilla. It is important to recall that bone is viscoelastic and will expand in response to internal pressure. Therefore, when placing a Unitek[™] Temporary Anchorage Device (TAD) in dense bone (usually posterior mandible), it may be appropriate to screw the Unitek TAD from 1/2 to 2 complete revolutions until pressure increases considerably, then stop for 10 to 20 seconds, allowing the bone to expand around the Unitek TAD before continuing. This respite should be repeated as often as necessary, and is usually only required for the range between 2.0 to 4.0 mm of the tapered body. After the tapered body is through the cortex and the full 1.8 mm diameter body begins to enter the bone, the bone is no longer required to expand to accommodate the increasing diameter; therefore the pressure remains relatively constant and respites are usually no longer required. The Unitek TAD should be inserted until the polished

collar engages outer cortex or the square head penetrates the soft tissue by no more than 0.5 mm (Fig. 9). At the end of Unitek TAD placement, the inferior aspect of the polished transmucosal collar should contact the bone surface with the entire O-Ball, neck and part of the square head located supramucosally.





Since the primary stability of the Unitek TAD comes from the cortex, it is also important to have the entire cortex traversed by the 1.8 mm diameter body with the tapered end in medullary bone. The Unitek TAD must be stable upon initial placement or should be placed in an alternate location.

| Range of bone expansion during Unitek™ Temporary Anchorage Device (TAD) placement | | |
|--|---|--|
| 0-2 mm | Usually no respites required | |
| 2-4 mm | Respites sometimes required in dense bone | |
| 4 mm | Usually no respites required | |

Unitek[™] Temporary Anchorage Device (TAD) Placement Checklist:

- The O-Ball, neck and at least half of the square head should be supramucosal
- The 1.8 mm diameter body should be in the cortex
- The tapered apex should be in the medullary bone
- The tapered apex should not touch the contralateral cortex
- The variable is primarily in the soft tissue depth





Uses of the Unitek[™] Temporary Anchorage Device (TAD) O-Cap

With some miniscrew implant systems, the alveolar/mobile mucosa will grow over the head of the implant. This, however, is rarely a problem with the innovative design of the Unitek TAD.

There are 4 reasons for placing the Unitek TAD 0-Cap:

- To suppress the alveolar/mobile mucosa and prevent soft tissue overgrowth of the O-Ball (Fig. 10A).
- When in place, the groove on the Unitek TAD 0-Cap is 1.0 mm ٠ higher and 1.5 mm lateral to the Unitek TAD neck, which in certain cases is beneficial to prevent the orthodontic attachment mechanics from impinging the soft tissue (Fig. 10B).
- Since the O-Ball is so small, it may irritate some patients in certain ٠ circumstances (i.e., when placed laterally in the alveolar bone anteriorly). In these cases, because the Unitek TAD O-Cap is larger, it makes the emergence profile feel smoother to the patient (Fig. 10C).
- Because the Unitek TAD O-Cap is made of stainless steel, various ٠ attachments can be soldered to it, thereby making the Unitek TAD even more versatile. It is important to note that the force must pass through the long axis of the Unitek TAD. If two Unitek TAD O-Caps are soldered together in series, this is not as critical since the rotational tendency is no longer present (Fig. 10D).

Loading Protocol for Unitek **Temporary Anchorage Device**

Step 8. Load by attaching directly to 0.030" holes, implant neck or Unitek TAD O-Cap

It is important to note that it is not necessary to remove a Unitek TAD during loading (if in place more than a month) with subtle mobility (perio mobility score of 1). As long as the Unitek TAD is clinically stable and usable with no frank mobility, there is no indication for removal. It is also not necessary to remove a stable Unitek[™] Temporary Anchorage Device (TAD) with localized soft tissue infection. Unitek TAD removal is only indicated in cases with frank mobility, in cases of infection that do not respond to antibiotic therapy within 10-14 days or infection with suppuration.

After the Unitek TAD is seated, it can be loaded immediately. There is no need to wait days or even weeks to load for either soft tissue or bony healing. Attachment mechanics can be placed either directly through the 0.030" holes (Fig. 11A), around the implant neck (Fig. 11B), around a cotter pin placed through the 0.030" holes





Fig. 10A-10D















(Fig. 11C), around the groove in Unitek[™] TAD O-Cap (Fig. 11D) or to soldered Unitek TAD O-Caps (Fig. 11E), if placed. Postoperative pain is negligible and at most 800 mg of ibuprofen is administered. It is not necessary to prescribe antibiotics postoperatively for prophylactic reasons.

Postoperative Instructions:

- Take 800 mg ibuprofen immediately, then 400 mg as needed for dental discomfort
- Rinse with 15 ml of 0.12% Chlorhexidine Gluconate for 30 seconds twice a day for 10 days
- After 10 days, rinse with 15 ml of 0.12% Chlorhexidine Gluconate for 30 seconds as needed for peri-implant erethema
- Avoid tongue or finger contact with the Unitek TAD
- Do not eat anything hard, chewy, or sticky in the vicinity of the Unitek TAD
- Call if Unitek TAD or orthodontic attachments become loose or if there are any concerns about Unitek TAD stability

Removal Protocol for Unitek[™] Temporary Anchorage Device (TAD)

A Unitek TAD's removal is indicated after its use for anchorage/tooth movement is complete. In certain cases of molar intrusion for openbite correction, it may be desirable to leave the unloaded Unitek TAD in place for several months after active use in the event that dental relapse occurs.

Unitek TAD removal occurs without topical or local anesthetic by simply unscrewing the Unitek TAD. Topical anesthetic may be indicated in cases where the soft tissue has slightly overgrown the square head in order to anesthetize the superficial soft tissues as they are compressed during square head engagement for Unitek TAD removal.

No pain is associated with the Unitek TAD removal; therefore, analgesics are not indicated, and no sutures warranted (Fig. 12A). The soft tissue and bone heal uneventfully within 3 to 7 days (Fig. 12B).





Fig. 12A-12B

Diagnostic Protocol for Unitek[™] Temporary Anchorage Device

The diagnostic records required for treatment planning a Unitek[™] Temporary Anchorage Device (TAD) placement are identical to what an orthodontist usually obtains to reach an orthodontic diagnosis and formulate a treatment plan.

- Clinical exam allows inspection and palpation of the periodontal tissues, keratinized gingiva and alveolar mucosa, and frena attachments in the region of the planned Unitek TAD placement, as well as in the line of attachment mechanics. The patient should be moved through functional movements and the lips and cheeks manually moved to determine the extent of frena attachment/displacement.
- Extraoral photos allow the clinician to evaluate the patient's profile and lip strain in combination with the lateral cephalometric x-ray to determine the need for extraction and anchorage requirements (Fig. 13).



Fig. 13





• Intra-Oral photos – allow the clinician to determine keratinized tissue dimensions, mucogingival junction heights and frena attachments (Fig. 14).





Fig. 14A-14B

• Orthodontic casts – allow the clinician to determine keratinized tissue dimensions, mucogingival junction heights and frena attachments. In combination with the panoramic and periapical x-rays, the clinician can determine the crestal bone heights relative to the gingival margins or occlusal surfaces (Fig. 15).



Fig. 15A-15B

 Lateral cephalometric x-ray – allows the clinician to evaluate the patient's profile and lip strain in combination with the extraoral photos to determine the need for extraction and anchorage requirements. It also allows the determination of palatal bone thickness and incisor root proximity relative to the symphysis (Fig. 16).



Fig. 16

 Panoramic x-ray – a good screening x-ray to determine bone height, relative density and relationships between Unitek TAD size and adjacent anatomic structures. It can often be used without a periapical x-ray when interradicular spaces are fairly large (Fig. 17).





Fig. 17A-17B

 Periapical x-ray – a more specific x-ray to determine the mesiodistal interradicular and intraradicular space and the coronoapical availability of bone stock (Fig. 18).



Fig. 18

 Cone Beam CT – a three-dimensional x-ray technique that allows the most accurate evaluation of bone morphology and density as well as the visualization of local anatomic structures.

Indications and Contraindications for Unitek[™] Temporary Anchorage Device (TAD) INDICATIONS

- Traditional malocclusions in need of additional or maximum anchorage, such as in space closure (retraction of anterior teeth or protraction of posterior teeth)
- Preprosthetic tooth movement
- Molar uprighting
- · Intrusion of super-erupted teeth
- Distalization of Class II or Class III end-on malocclusions to ideal Class I occlusions
- Skeletal malocclusions unable or unwilling to undergo surgical treatment
- Occlusal cants

- Maxillomandibular fixation during oral and maxillofacial surgery
- Due to patient variability, the amount of force will vary depending upon the patient needs. It is not recommended to apply forces to the long axis of the implant. To achieve maximum results, the Unitek[™] Temporary Anchorage Device (TAD) should be placed where the load is perpendicular to the long axis (90° angle) of implant.
- Any orthodontic force module may be used as long as the total forces applied do not fall outside the recommended forces/ applications for the force module. The implant should withstand forces up to 300 grams without failure.

CONTRAINDICATIONS

The Unitek TAD should not be placed in patients with the following:

- Absolute Contraindications: History of bisphosphonate therapy, hypersensitivity, titanium allergies, metabolic bone disorders, bone pathologies, poor bone healing, cardiovascular disease, psychosomatic disease, uncontrolled periodontitis, undergoing radiation therapy, unsuitable for surgical procedures, decreased bone quality/quantity or localized active infection.
- Relative Contraindications: Use of drugs, tobacco or alcohol, oral mucosal pathologies, poor oral hygiene, poor patient compliance, physical handicaps that prevent adequate oral hygiene and/or maintenance, insufficient interradicular/ intraradicular space or para-functional habits.
- Precaution: It is recommended that these devices be placed in children over the age of 13. The implants may be used in younger patients in very select cases. Special care must be taken to avoid developing teeth. Powder free gloves are recommended when placing implants.

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Unitek[™] Temporary Anchorage Device System

Before and After Photos Unitek[™] Temporary Anchorage Device (TAD)

Incisor Intrusion









Fig. 19A-19B: Before

Fig. 20A-20B: After 4.5 months

Posterior Protraction



Fig. 21A-21B: Before





Fig. 22A-22B: After 3 months



Posterior Intrusion



Fig. 23A-23D: Before







Before and After Photos Unitek[™] Temporary Anchorage Device (TAD)

Posterior Intrusion



Fig. 24A-24C: After 12 months

Molar Intrusion/Uprighting



Fig. 25A-25B: Before



Fig. 26A-26B: After 3 months



Anterior en Masse Retraction



Fig. 27A-27B: Before







Fig. 28A-28B: After 7 months





Jason B. Cope, DDS, PhD

Dr. Jason B. Cope got an early introduction to orthodontics, beginning his informal education at 13 years of age by making retainers and grinding study models in his father's lab. By age 15, he was helping his father as an orthodontic chair-side assistant. He now runs a private orthodontic practice in Dallas, Texas, where he treats patients three days a week while also

developing new orthodontic products, lecture materials, and educational aides, which are available at www.CopestheticCE.com.

A recognized innovator in the field of orthodontics, Dr. Cope has recently focused on developing clinical protocols and products to enhance Temporary Anchorage Device (TAD) use, particularly Miniscrew Implants (MSIs), the most popular subcategory of TADs. In 2003, he partnered with IMTEC Corp. to develop the Ortho Implant, one of the first U.S. manufactured orthodontic miniscrew implants. Since then, he developed the Cope Placement Protocol™, the first minimally invasive protocol to utilize drill-free MSI placement with topical anesthetic only, a patented life-like triple-density typodont for teaching MSI placement methods, and several other TAD protocols and products relating to openbite closure and Class II distalization.

A prolific author and lecturer, Dr. Cope has published eight non peer-reviewed and 19 peerreviewed journal articles, 37 book chapters, a research handbook, and a 400-page dissertation. He also co-edited a multimedia CD-ROM and a 600-page textbook, *Craniofacial Distraction Osteogenesis*, and self-published a 500-page textbook entitled *OrthoTADs: The Clinical Guide and Atlas*, available exclusively at www.UnderDogMedia.us. He has given over 250 lectures nationally and internationally, and has been involved in the development of several educational websites. Dr. Cope is an ad hoc reviewer for the *American Journal of Orthodontics and Dentofacial Orthopedics*, the *World Journal of Orthodontics, The Angle Orthodontist*, the *Journal of Clinical Orthodontics*, the *Journal of Oral and Maxillofacial Surgery*, the *Journal of Dental Research*, *Archives in Oral Biology*, and was the guest editor for the March 2005 issue of *Seminars In Orthodontics* on OrthoTADs.

Dr. Cope received his DDS, Orthodontic Certificate, and PhD in craniofacial bone biology from the Baylor College of Dentistry. He has been a researcher on over 20 funded research projects, and has served as a committee member on numerous orthodontic graduate student thesis projects. He also serves as an adjunct associate professor in the Department of Graduate Orthodontics at St. Louis University, is a visiting professor at several universities, and has lectured to graduate students at 11 universities in North America, Central America, South America, and Australia.



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