

# truFIX Complete Fixation System

Technique Guide



## truFIX Complete Fixation System

The truFIX System acts as a fixation device to assist in holding grafting tissues or materials to host bone segments in the oral cavity. The system provides everything a clinician needs for the fixation of bone blocks and plates as well as the stabilization of membranes. This system incorporates all the necessary components to pick up and drive the truSCREW, truTACK, and truTENT. The truFIX system eliminates the need for multiple systems and unnecessary components, making it more user-friendly.



## truSCREW

The truSCREW, with its aggressive cutting flutes, is the ideal bone screw for the fixation of small bone within the oral and maxillofacial environment. These cutting flutes eliminate or greatly reduce the need for any pre-drilling. The design of the screw ensures an effortless insertion into all types of bone. The tapered self-tapping screw design allows maximum fixation in areas where there is minimal bone available. A unique spline screwdriver is used to lock into, pick up and drive these bone screws.



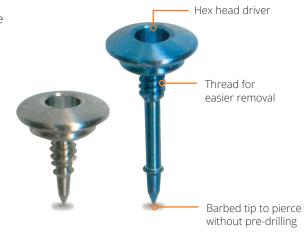
Total Length	1.2mm Thread Ø	1.5mm Thread Ø	2.0mm Thread Ø
4.5mm	45427202	-	-
6.0 mm	45427203	45427502	45428002
7.5 mm	45427204	45427503	45428003
9.0 mm	45427205	45427504	45428004
10.5 mm	45427206	45427505	45428005
12.0 mm	-	45427506	45428006
13.5 mm	_	45427507	45428007
15.0 mm	_	45427508	45428008



### truTACK

The truTACK makes membrane stabilization quick and trouble-free. The truTACK system is comprised of 3mm and 5mm self-tapping, pin-point length bone tacks. The pin-point tip is designed to locate, stabilize, and pierce the graft site. This tack incorporates a hexagon on its head and threaded shaft, allowing for easy removal. The truTACK is placed like a tack and removed like a screw, a unique feature that makes truTACK unlike any other tack. The tack's dome-shaped cylindrical head, which is oversized to retain the graft material, is picked up and driven by the truTACK Driver Tip.

Each tack has a 2.5mm head diameter and a 0.7mm thread diameter. Each truTACK package is sterile and consists of 10 tacks.



9600313 9600314 0.7mm x 3.0mm (Gray)

0.7mm x 5.0mm (Blue)

### truTENT

The truTENT is a refinement of the truSCREW. Its raised collar and wider head is designed to support a membrane or titanium mesh during augmentation procedures. The same unique spline screwdriver used for the truSCREW is used to lock into, pick up and drive these tenting screws.

truTENT is available in three different sizes and sold in separate sterile packages. Each available size incorporates a 1mm length x 5mm diameter domed head for draping the appropriate mesh over the grafted site and has a 1.5mm thread diameter.

454391001

454391002 454391003 1.5mm x 10mm, 4mm Collar Height 1.5mm x 12mm, 6mm Collar Height 1.5mm x 14mm, 8mm Collar Height



Self-drilling tapered thread design for strength and maximum stability

Pin-point tip for tissue penetration

### **Titanium Meshes**

The non-resorbable titanium mesh is provided non-sterile and is used as a cage to maintain and preserve the grafted augmented bone space for regeneration. The titanium mesh is available in various thicknesses and sizes depending on the grafted area requirements. Since the titanium mesh is provided non-sterile and customizable prior to use or implantation, it must be sterilized using the defined autoclave protocol described in the manufacturer's Instructions for Use.

Depending on the indication, implantation can be performed on one or two sides.

#### **Titanium Micro Mesh**

The titanium micro mesh is customizable and can be trimmed with wire cutting scissors.

0039429	Titanium Augmentation Micro Mesh, 34mm x 25mm, 0.1mm
0039430	Titanium Augmentation Micro Mesh, 120mm x 60mm, 0.1mm
0039433	Titanium Augmentation Micro Mesh, 152mm x 66mm, 0.2mm

0039444 Titanium Single Butterfly Mesh, 40mm x 50mm, 0.25mm



Micro Mesh 34mm x 25mm



Single Butterfly Mesh 40mm x 50mm

### **Titanium Tenting Mesh**

The pre-shaped titanium tenting meshes feature a 12-point center locking design that supports the connection for truTENT.

0039434	Titanium Tenting Micro Mesh, 7mm x 14mm, 0.2mm
0039440	Titanium Tenting Mesh, 13mm x 33mm, 0.2mm
0039442	Titanium Custom Tenting Mesh, 13mm x 33mm, 0.2mm



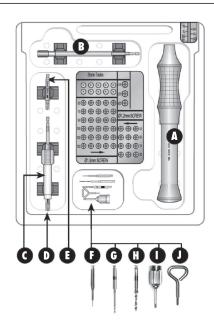
Tenting Micro Mesh 7mm x 14mm



Tenting Mesh 13mm x 33mm

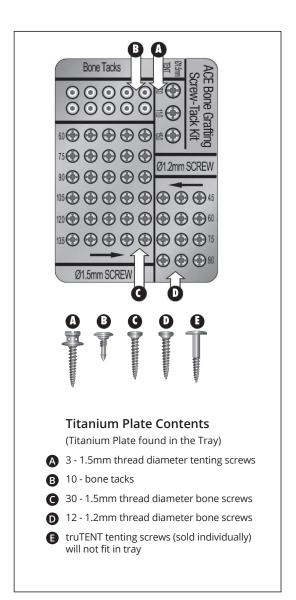


Custom Tenting Mesh 13mm x 33mm



#### **Tray Contents**

- A truFIX Driver Handle
- **B** truTACK Driver Tip
- **©** truSCREW Driver Removal Sleeve
- turSCREW Driver Tip
- **E** truSCREW Driver Tip Contra-Angle
- **f** truTACK Pilot Bur, Ø = 0.45mm
- **G** 1.1mm Pilot Twist Drill, 29.8mm
- ★ truSCREW Step Drill (Long Screw)
- 1 truTACK 0.88 External Hex Hand Driver
- truSCREW Packaging Removal Tool



### truSCREW Bone Screw Procedure

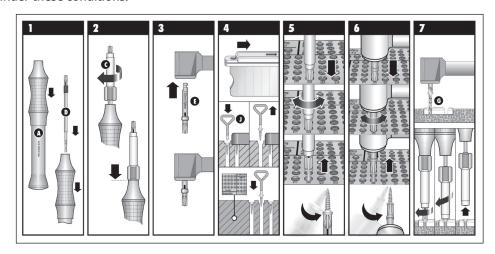
- 1. Screw Driver Assembly
- 2. Driver Tip Removal Sleeve Assembly
- 3. Assembly of Contra-angle Driver Tool
- 4. Remove Screw from Cassette\*
- 5. Pick up Bone Screw with Hand Driver
- 6. Pick up Bone Screw with Contra-angle Driver
- 7. Pre-drilling optional:
  Place Bone Screw into Surgical Site
  truSCREW insertion torque must not exceed:
  - Ø 1.2mm thread 10 N-cm
  - Ø 1.5mm thread 15 N-cm

Note: truSCREW Self-Drilling Bone Screws are sterile products sold separately; please refer to device label.

\* truSCREWs are multi-packaged and suspended in a sealed, GAMMA sterilized, polycarbonate plastic cassette. Do not autoclave the truTACKs in their gamma sterilized plastic packaging cassette as these cassettes will melt under these conditions.



The driver's true-centered locking connection holds the truSCREW securely. The removal sleeve disengages the driver from the screw without compromising the screw or the stability of the graft.



#### truTACK Placement Procedure

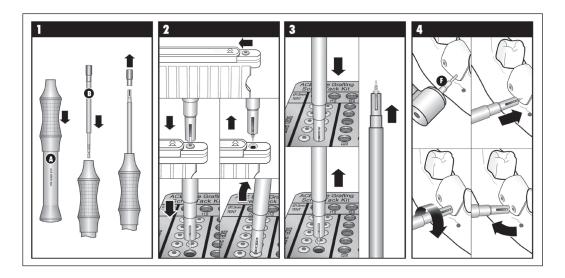
- 1. Tack Driver Tip Assembly
- 2. Removing Tack from Cassette\*
- 3. Pick-up Bone Tack with Driver Tool
- Pre-drilling optional:
   Place the tack into the surgical site by pushing and screwing the tack into the bone.

Optional: If necessary, a gentle tap with a mallet can be applied to the back end of the truTACK Hand Driver tool to assist in the initial insertion of the tack top into the bony site. However, if a mallet is used, care must be taken not to bend the tack, and complete seating of the tack is only accomplished by screwing in the micro thread of the tack in with the driver handle. Excessive force to the tack can lead to bending or breaking the tack.

Note: truTack Self-Tapping Threaded Bone Tacks are sterile products sold separately; please refer to device label.

\* truTACKs are multi-packaged and suspended in a sealed, GAMMA sterilized, polycarbonate plastic cassette.

Do not autoclave the truTACKs in their gamma sterilized plastic packaging cassette as these cassettes will melt under these conditions.

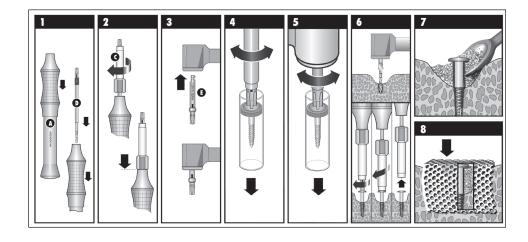


#### truTENT Bone Screw Procedure

- 1. Screw Driver Assembly
- 2. Driver Tip Removal Sleeve Assembly
- 3. Assembly of Contra-angle Driver Tool
- 4. Pick up truTENT screw from sterile vial with Hand Driver
- 5. Pick up truTENT screw from sterile vial with Contra-angle Driver
- 6. Pre-drilling optional:
  - Place desired length truTENT tenting screw into the host surgical bone site. Insertion torque must not exceed 15 N-cm.
- 7. Pack bone graft material around non-engaging cylindrical shaft diameter of the truTENT screw
- 8. Drape the appropriate custom fabricated titanium mesh over dome head truTENT tenting screw and bone grafted site. During customer fabrication of the titanium mesh care must be taken prevent sharp exposed edges that could lead to soft tissue irritation.

As needed, the draped titanium mesh can be fixated to the host bone using truSCREWs or truTACKs.

Note: truTENT Self-Drilling Tenting Screws are sterile products sold separately; please refer to device label.



## Ordering Information



### truFIX Complete Fixation Kit

Item numbers	Item Description
45418015	truFIX Complete Fixation Kit



### truFIX System Tray & Instruments

Item numbers	Item Description
45418501*	truFIX Tray (empty)
45419001*	truFIX Driver Handle, 98mm (3.875") long
45417001*	truTACK Driver Tip (includes blue Tip Cover)
45415001*	truSCREW Driver Tip
45417901*	truSCREW Driver Removal Sleeve
45415201*	truSCREW Driver Tip, Contra-Angle
45440203*	truSCREW 2-Step Countersink Bur Drill, Ø 0.8mm and 1.6mm, Contra-Angle (Lag Screw)
45440202*	1.1mm Pilot Twist Drill, 29.8mm
502700045*	Pilot Bur, 0.45mm, 27mm long, Contra Angle
20157702*	External Hex Hand Driver, 0.88mm
45450201*	truSCREW Packaging Removal Tool

### truFIX Accessory

(not included in kit, individually packaged)



Item numbers	Item Description
45419501	Optional Small Driver Handle

<sup>\*</sup> Item numbers can be ordered separately for replacement purposes.

### truTACK, pack of 10 (Head Ø2.5mm, sterile, single-use)



Item numbers	Item Description
item numbers	Thread Ø / Total length
9600313	0.7mm / 3.0mm (Gray)
9600314	0.7mm / 5.0mm (Blue)

### truSCREW, pack of 5



(Head Ø3.0mm, sterile, single-use)

(Flead 25.011111, Sterile, Single-use)		
Item numbers	Item Description Thread Ø / Total length	
45427202	1.2mm / 4.5mm	
45427203	1.2mm / 6.0mm	
45427204	1.2mm / 7.5mm	
45427205	1.2mm / 9.0mm	
45427206	1.2mm / 10.5mm	
45427502	1.5mm / 6.0mm	
45427503	1.5mm / 7.5mm	
45427504	1.5mm / 9.0mm	
45427505	1.5mm / 10.5mm	
45427506	1.5mm / 12.0mm	
45427507	1.5mm / 13.5mm	
45427508	1.5mm / 15.0mm	
45428002	2.0mm / 6.0mm	
45428003	2.0mm / 7.5mm	
45428004	2.0mm / 9.0mm	
45428005	2.0mm / 10.5mm	
45428006	2.0mm / 12.0mm	
45428007	2.0mm / 13.5mm	
45428008	2.0mm / 15.0mm	

## Ordering Information

#### truTENT



(Head Ø5.0mm, sterile, single-use)

Item numbers	Item Description Thread Ø / Total length / Collar height
454391001	1.5mm / 10.0mm / 4.0mm
454391002	1.5mm / 12.0mm / 6.0mm
454391003	1.5mm / 14.0mm / 8.0mm

#### **Titanium Meshes**







Item numbers	Item Description
0039429	Titanium Micro Mesh, 34mm × 25mm, 0.1mm thick
0039430	Titanium Micro Mesh, 120mm × 60mm, 0.1mm thick
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0039434	Titanium Tenting Mesh, 7mm × 14mm, 0.2mm thick
0039440	Titanium Tenting Mesh, 13mm × 33mm, 0.2mm thick
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All information within this technique manual is based on S-ACE truFIX Product Catalog and manufacturer's Instructions for Use REV A.

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