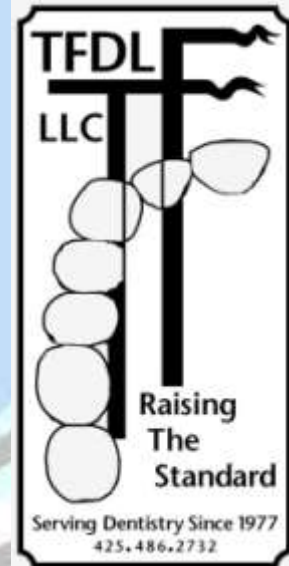
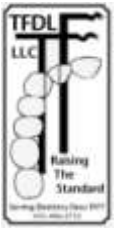


SLEEP APNEA APPLIANCES

2011 Thorn Ford Dental Laboratory LLC

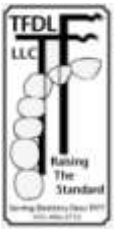


INDEX

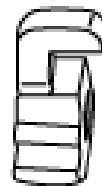
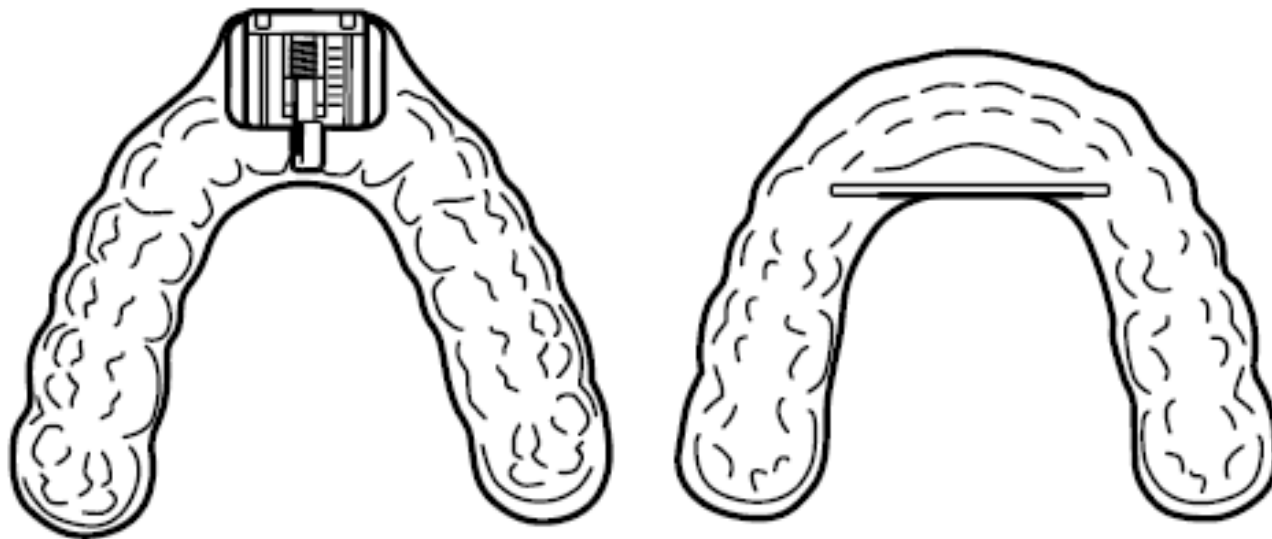


- **Sample Appliances:** TAP III, EMA, Somnomed, Silent Partner
- **Diagnosis:** Treatment Plan, Consent & Summary, Sleep Scales, Breath Report, Breath Index, Medical History, Q of L Index, Sleep Lab, Tool Kit
- **Fees:** Appliances, Diagnoses, Treatment, Followup
- **Bite registration:** TAP Gauge, George Gauge Steps
- **Delivery and Fitting:** Delivery Checklist, Fitting Video, Adjustment
- **Compliance:** Materials Tracking, GMP's, FDA Registration, Insurance
- **Manufacturing:** Step By Step for TAP Elite

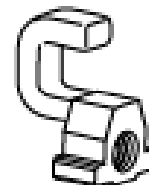
Sample Appliances: TAP III Edentulous,



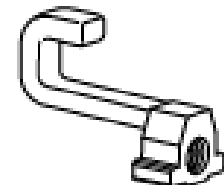
The TAP 3 Elite TL



Standard Hook



Class I Hook



Class II Hook

Sample Appliances:, Silent Partner



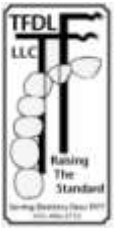
Sample Appliances: EMA,



Sample Appliances Somnomed,

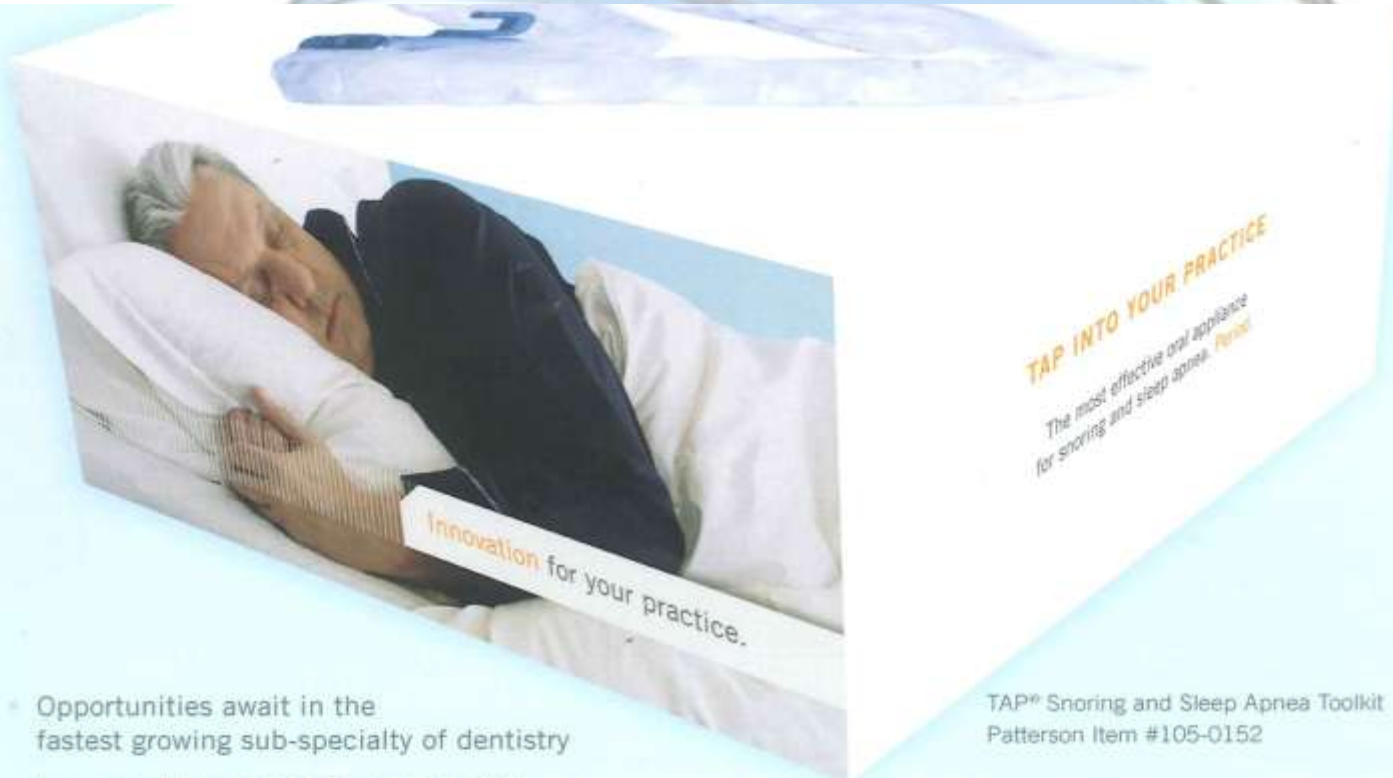


Diagnosis: Sleep Lab, Overnight Sleep Test



- **Local Sleep Labs;**
- ***WOODINVILLE SLEEP IMPROVEMENT CENTER***
17311 135th Avenue Northeast
Woodinville, WA 98072
(425) 286-6256
- ***BEL-RED SLEEP DIAGNOSTIC CENTER***
- **1414 116TH AVE. NE, Suite F Bellevue, WA**
98004 **425-451-8417**

TAP Toolkit --- Patterson Dental Supply



- Opportunities await in the fastest growing sub-specialty of dentistry
- Incremental revenue for your practice
- Improve your patient's overall health and quality of life

TAP® Snoring and Sleep Apnea Toolkit
Patterson Item #105-0152



CONTENTS

- FOR THE DENTIST**
- "TAP into Your Practice" Manual
 - "How to Seat the TAP® 3 Elite" Video
 - TAP® 3 Elite Demonstration Model
 - AM Aligners (Morning Exerciser)
 - TAP® Gauge
 - Lab Slips

- PATIENT MARKETING COLLATERAL**
- Patient Video
 - Patient Brochures
 - Posters

- PATIENT SCREENING**
- Epworth Pads
 - BMI/Adjusted Neck Circumference Chart
 - Tape Measure
 - Wrist Oximeter with Recording Software



Diagnosis: Epworth Sleep Scale,

- **EPWORTH SLEEPINESS SCALE**

- In contrast to just feeling tired, how likely are you to doze off or fall asleep in the following situations? Use the following scale to choose the most appropriate number for each situation:

- 0 = Would never doze
- 1 = Slight chance of dozing
- 2 = Moderate chance of dozing
- 3 = High chance of dozing

Date _____

- **SITUATION**

- Sitting and reading
- Watching Television
- Sitting inactive in a public place (i.e. theater)
- As a car passenger for an hour without a break
- Lying down to rest in the afternoon
- _____
- Sitting and talking to someone
- Sitting quietly after lunch without alcohol
- In a car, while stopping for a few minutes in traffic

	BEFORE THERAPY	AFTER THERAPY
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

TOTAL SCORE _____

- A score of 6 or greater indicates the possibility of sleep disordered breathing

Diagnosis: Thornton Sleep Scale



- **THORNTON SNORING SCALE**

- Snoring has a significant effect on the quality of life for many people. Snoring can affect the person snoring and those around him/her., both physically and emotionally. Use the following scale to choose the most appropriate number for each situation. (Go to question #4 if you have no bed partner.)

- 0 = Never
- 1 = Infrequently (1 night per week)
- 2 = Frequently (2-3 nights per week)
- 3 = Most of the time (4 or more nights per week)

-
-
- My snoring affects my relationship with my partner

BEFORE THERAPY	AFTER THERAPY
_____	_____

- My snoring causes my partner to be irritable or tired

_____	_____
-------	-------

- My snoring requires us to sleep in separate rooms

_____	_____
-------	-------

- My snoring is loud

_____	_____
-------	-------

- My snoring affects people when I am sleeping
away from home (i.e. hotel, camping, etc.)

_____	_____
-------	-------

TOTAL SCORE

_____	_____
-------	-------

- A score of 5 or greater indicates your snoring may be significantly affecting your quality of life



SHERMAN'S LAGOON

by Jim Toomey

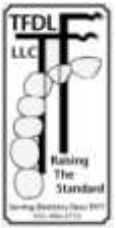


www.shermanslagoon.com

©2011 Jim Toomey. Dist. by King Features Syndicate, Inc. 5-22

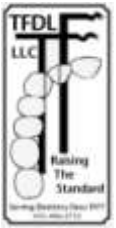
Fees: An Example

- **The fee for the treatment is approximately \$2,600. This includes the evaluation \$600 (CPT#99201-205), orthopantogram \$125 (CPT#7035), two sleep studies @ \$300 each (CPT 95806), the TAP oral appliance \$1,275(CPT# 21089) or (HCPCS S8620), and adjustments to the TAP for 3 months.**
- If you cannot wear the appliance, or the appliance is not effective in reducing your snoring significantly, \$890 of the fee will be refunded during the first 6 months on the return of the appliance.



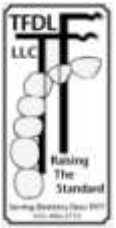
Fees: Treatment, Followup

- Follow-up appointments may be necessary, after the initial three months, to reevaluate the progress of the therapy, which will involve office visits (ranging from \$50-100), and post-treatment overnight sleep recorder testing-\$300 each.
- Depending on how well the appliance is cared for, there is always the possibility of repairs ranging from \$150-\$250 and even replacements-\$750.



- **Sleep Testing Codes, CPT 2002**

CPT Code Description 95805 "Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during **multiple** trials to assess sleepiness." **95806** "Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, unattended by a technologist." **95807** "Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist." **95808** "Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist." **95810** "Polysomnography; sleep staging with 4 or more additional parameters of sleep, attended by a technologist." **95811** "Polysomnography; sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist."



ADDITIONAL PHYSIOLOGIC PARAMETERS, FOR POLYSOMNOGRAPHY

EKG Extended EEG Airflow -- Penile tumescence

Respiratory effort -- GE Reflux

Gas Exchange by Continuous BP monitoring

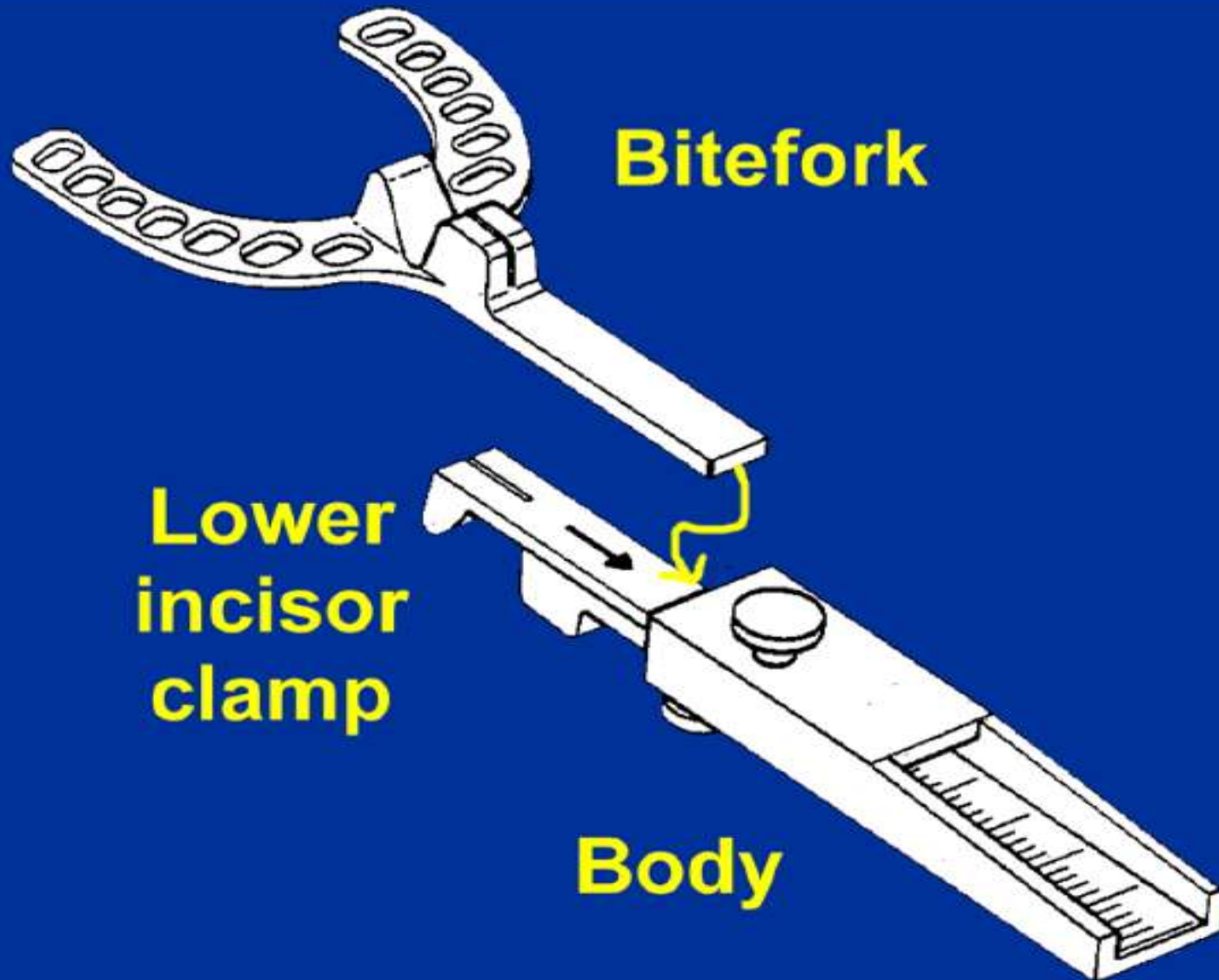
Oximetry -- Transcutaneous monitors

End-tidal gas analysis -- Body Position

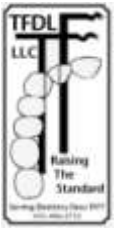
Limb muscle activity

	Attended?	Staging?	Other Data	Prof Fee 2002	Global Fee 2002
95805	y	Yes	0	\$ 95.57	\$ 293.58
95806	n	No	3	\$ 82.90	\$ 227.70
95807	y	No	3	\$ 82.17	\$ 461.91
95808	y	Yes	1-3	\$ 135.03	\$ 457.21
95810	y	Yes	4	\$ 177.74	\$ 757.30
95811	y	Yes	4+CPAP	\$ 190.77	\$ 777.58

Bite registration: George Gauge

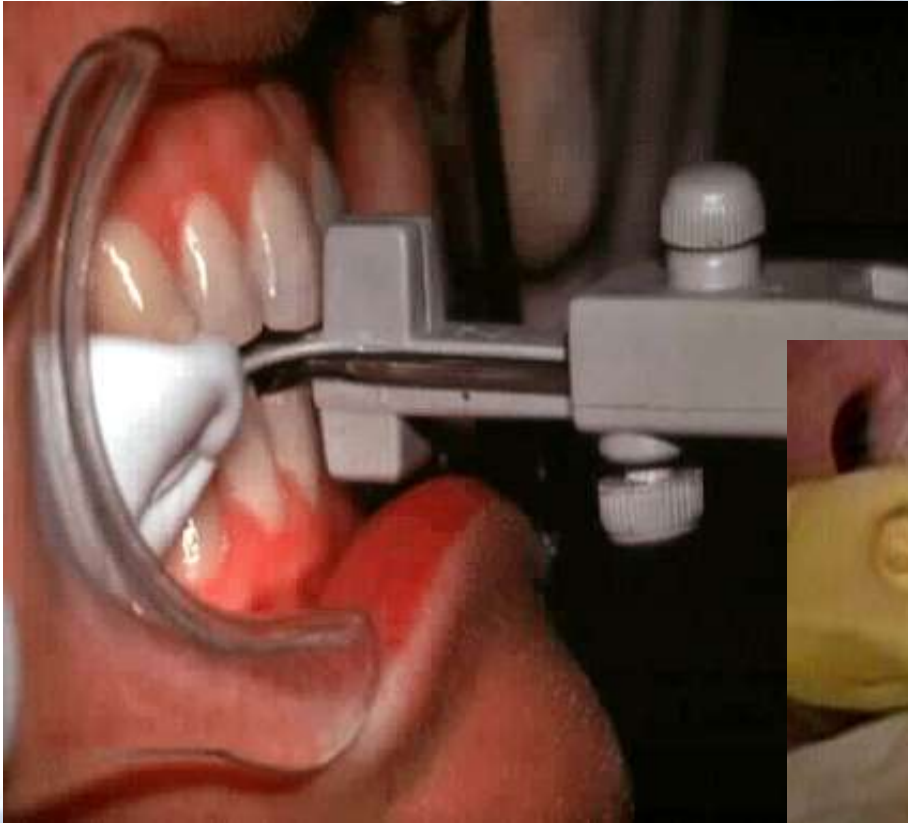


Bite registration: George Gauge



- 2mm-Use the 2mm fork if the patient has a regular or close to ideal bite; 1/8th of an inch incisal overlap and a flat curve of spee.
- •5mm-Use the 5mm fork if the patient has a deep overbite or the curve of spee is excessive.
- •If the incisal edge of the central incisor does not touch the bottom of the groove because of crowding or a large cingulum, adjust the palatal portion of the incisal guide and not labially.
- •Line up the facial and skeletal midlines and note any deviations (Skeletal Midlines should be aligned).
- •Measure a start and finish position, then set bite at 60% -70% of the finish position.
- •Ensure an adequate range of movement (4mm –6mm is the minimal in most patients).

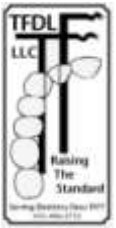
Bite registration: George Gauge



Delivery and Fitting: Delivery Checklist

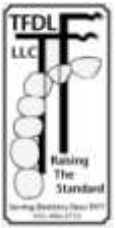
- *Insertion and Removal of OA* – Patient was shown how to insert and remove the OA.
- *Activation of OA* – Patient was shown how to make correct adjustments to OA.
- *Possible Side Effects* – Side effects that the patient might experience during the treatment with the OA were explained. Side effects they might experience are as follows: tooth, muscle, and/or joint discomfort; increased salivation flow; chance of dry mouth if patient is mouth breather; dislodgement of dental work; and change in patient's bite.

Delivery and Fitting: Delivery Checklist

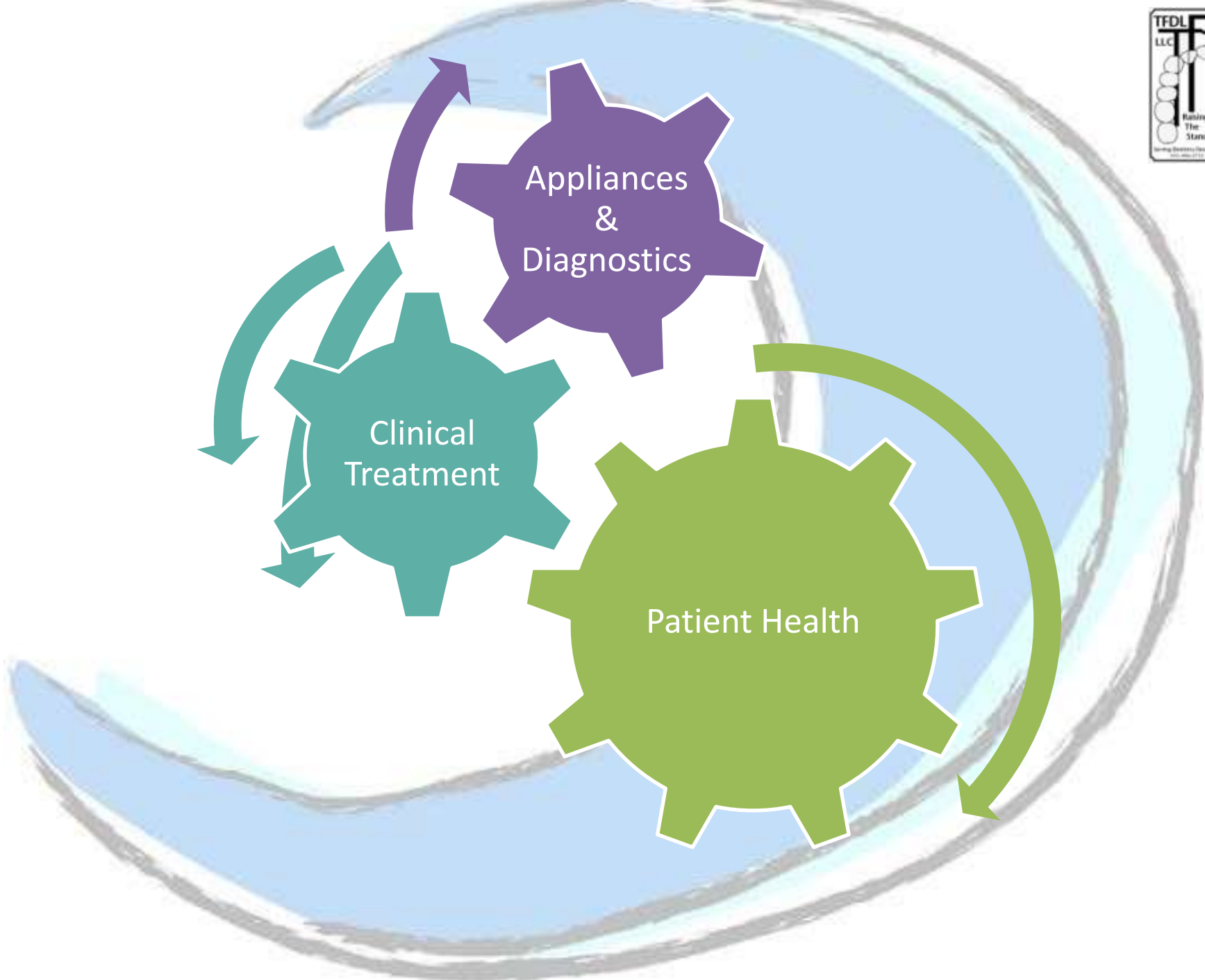


- *Expected Results* – Patient was told that the OA should be worn as given until physical and psychological adaptation is complete.
- *of Exercise Leaf Gauge* – Patient was instructed how to use the Exercise Leaf Gauge in the morning
- *Home Care for OA* – Patient was provided a take home sheet explaining home care for the OA.

Delivery and Fitting: Delivery Checklist



- *Reline of OA* – Patient was told that in approximately 18 months from when they receive the OA there might be a need to reline or replace the appliance
- *Questions/Concerns* – Patient was told to contact the office if they have any problems with fit of OA,



Compliance: Materials Tracking, GMP's

TAP III Log Sheet	
Patient Name	Clinician name
[REDACTED]	PETERSEN, KIRK
Invoice Date	Invoice Number
5/5/2010	77507
Serial Number Stickers	
TAP 3 Kit TL 120 Round 174 12K-880G-10	
Materials Used	
IPS Weld-on #4 Solvent Cement Lot #: MAR/09/A	Dentsply Repair Material Liquid Lot #: 090204
Dentsply Ortho Resin Powder Lot #: 080617	
Device History Record	
5/7/2010 - moved Lower hardware back to allow more adjustment via wrench. 5/17/2010 - didn't adj. appliance, but suggested engaging link behind socket for more intrusion. 9/14/2010 too tight - adjusted borders	
Delivery Checklist	
Appliance	✓
TAP Box	✓
Bite Tabs	✓
Wrench	✓
Serial Number	✓
Instructions for Serial Number	✓
Patient Care Booklet	✓
Clinician Instruction Booklet	✓

Thorn Ford Dental Laboratory Manufacturing Procedures and Quality Systems

Modified 12/01/2010

- Contents:
- 1) Manufacturing
 - 2) Packaging and Labeling
 - 3) Storage and Delivery
 - 4) Servicing and Record Storage
 - 5) Tracking Failures
 - 6) Registered Devices
 - 7) Forms

1) Manufacturing procedures Thorn Ford Dental Laboratory (TFDL) adheres to material supplier and manufacturer recommended procedures and instructions for use whenever possible. These instructions are usually available at the corresponding work area, but are also available in the Standard Operating Procedure (SOP) file box located in the main office. This box is divided by production department, with a section for equipment maintenance.

When a material supplier cannot provide instructions for use, typical procedures in a step by step format will be written by the technician most experienced in that procedure and a copy saved in the SOP file.

2) Packaging and Labeling All outgoing "removable" products are packaged in a sealed plastic bag with a mild disinfectant solution. All "fixed" cases are sterilized after final inspection in the department of origin and placed in a plastic box with bottom padding. Products, along with related models indexes and other materials are packaged in a larger box labeled with the company name and phone number for delivery by courier or US Mail. Boxes delivered by courier will have a delivery slip taped to the top with the clinic information and Patient ID exposed. If the case is to be mailed this slip is inside the package.

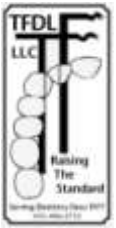
3) Storage and Delivery There is no long term storage of finished work since all items are manufactured by custom order. Work in progress that has been returned to the clinic for patient appointment will still have a case pan which contains all related material not needed by the Dr. These pans are filed alphabetically in cupboards in the front office. When the case returns for further work it is reunited with the correct pan. Case invoices remain "open" till the case is ready for final delivery at which time the invoice is finalized, printed and included in the package.

Compliance: FDA Registration, Insurance

- Contact Name: Loren M Ford Company: THORN FORD DENTAL LABORATORY LLC Address: 10107 Woodinville Drive Bothell, WASHINGTON, 98011, UNITED STATES Telephone: 425-4862732 Fax: 425-4876756 E-mail: loren@thornford.com

Device Listings

- **Listing Number** **Premarket Submission Number** **Product Codes** **Device Name** **Activities** D090849 K062951 LRK Device, anti-snoring Manufacturer Date of Initial Registration: 2009-12-29 02:47:08.0
- Owner / Operator 10031171
- PIN 50043649-PCN 11151954

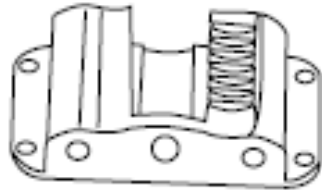


Fabricating the TAP[®] 3 Elite TL (Triple Laminate)

Presented By:
Airway Management Incorporated

Manufactured by Airway Management Inc.
866.AMI.SNORE • contactami@amisleep.com • www.tapintosleep.com

The TAP 3 TL Elite - Parts



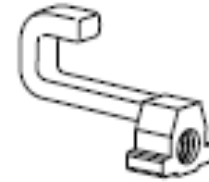
Base Plate



Standard Hook



Class I Hook



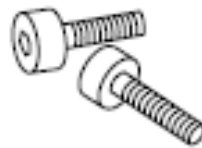
Class II Hook



Front Plate



Adjustment Screw



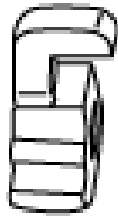
Locking Screws



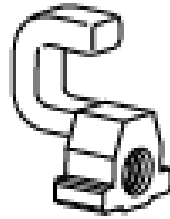
TAP[®] 3 Elite
Adjustment Key

The TAP 3 Elite TL

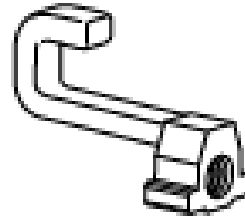
Choosing the Correct Hook



Standard Hook



Class I Hook



Class II Hook



There are three different hooks available for use with the TAP 3 Elite; Standard, Class I, and Class II. The appropriate hook will be selected by the fabricator depending on the bite registration of the patient. The different size hooks allows the fabricator and the dentist the greatest range of adjustment without having to reset the hardware.

Materials and Equipment

Any mandibular advancement orthotic used for the management of obstructive sleep apnea has been categorized as a Class II medical device with controls. In order to be in compliance with CFR Part 820 which regulates medical devices, Airway Management, Inc. has developed the Quality Management System (QMS) for the fabrication of TAP® Appliances. This system specifies the necessary guidance policies and procedures for dental laboratories fabricating TAP® Appliances. The materials, equipment and procedures specified in this presentation will assure that the dental laboratory will be in compliance with current Good Manufacturing Practices (GMP) required by the FDA. Please refer to the Customer Policy Manual.

- 1. Block-out resin**
- 2. 1.8 mm Durasoft (2)***
- 3. 2.0 mm ThermoBlend (2)***
- 4. Self-cure acrylic**
- 5. Weld-on Acrylic #4 – bonding agent**
- 6. Dexter Spray**
- 7. Liquid Foil**
- 8. Finishing Wheel or Buffing Wheel**
- 9. Buffing Wheel**
- 10. Cutting Wheel**
- 11. Trimming burs**
- 12. Smoothing bur**
- 13. Allen Wrench**
- 15. Thermo-forming machine**
- 16. TAP 3 TL Elite Kit***

* Included in the TAP 3 TL Elite Kit

Laboratories that fabricate TAP® Appliances are expected to be compliant with OSHA and all applicable local, state and federal regulations.

Vendor and Ordering Information

Item Name	Item #	Vendor	Contact Info
Biostar Thermo-Forming Machine Erkopress Drufomat	N/A N/A N/A	Great lakes Orthodontic Lab Glidewell Laboratories Rantree Essix	(800) 828-7672 or greatlakesortho.com (800) 854-7256 or glidewell dental.com (800) 883-8733 or Essix.com
Universal Clear #1 (1lb) Universal Clear #1 (6lb) Liquid Monomer (1 Qt) Liquid Monomer (4 Qts) Clear Monomer (1 Qt) Clear Splint Polymer (1 lb) 1 Lb. Split Acrylic Resin Kit	24027-001L 24027-006L 9088-00 9089-00 040-033 040-010 040-008	Fricke Dental International Great lakes Orthodontic Lab	(800) 537-4253 or frickedental.com (800) 828-7672 or greatlakesortho.com
Porcelain Brushes Liquid Foil Gray Bur (Medium Grit) Yellow Bur (Shiny Finish) Wheels (won't cut metals) Mandrel (for use w/ wheel)	093-8340 093-5502 115-9227 115-9219 255-9854 088-6911	Patterson Dental Supply Co.	(800) 422-3306 or PattersonDental.com
Undercut Block-Out Resin	242	Ultradent	(800) 552-5512 or ultradent.com
*Cutting Wheel (or Dentsply Wheel Saw) Trimming Bur 1 - Large square shaped Tripping Bur 2-Large round shape	946 (size 180mm) H79GSQ (size 070) H251FSQ (size 090)	Brasseler USA	(800) 841-4522 or brasseler.com
Polishing Brush, Fine (burgundy) Retainer Border Polisthers (medium) Retainer Border Polishers (fine) **Wheel Saw (or Brasseler Cutting Wheel)	18983 18972 18971 18320	Dentsply/ Raintree Essix	(800) 883-8733 or essix.com
Weld-On Acrylic #4 (IPS Corp.)	N/A	Local Hardware Store (usually found at small specialty hardware stores)	IPS corporation is the manufacturer. Call to find a distributor in your area. (310) 898-3300
Final Polisher Compound (Fabulustre)	230-008	Great lakes Orthodontic Lab	(800) 828-7672 or greatlakesortho.com

*The Brasseler Cutting Wheel is a large wheel and is recommended by Airway Labs

**The Dentsply Wheel saw is a small wheel and is an alternate option to the Brasseler Cutting Wheel

Vendors and Ordering Information

Item Name	Item Number	Vendor	Contact Info
Loc Tite Liff	#83551	Loc Tite	(800) 562-8483 x6187 www.loctite.com
Jeldent Arcylic Polishers Long Taper	<i>PN251404 course</i> <i>PN2511408 fine</i>	Jelenko	(800) 431-1785
Tap tool for threading locator assembly (grind off tip) (This part is available from any local hardware store – 2/56 NC)	#4AKH2	W.W. Grainger	www.grainger.com

Note: Pre-dry the Durasoft sheets in a conventional oven or Ministar drying oven before use (for a minimum of 6 hours no longer than 24 hours). The plastic may bubble if it is not pre-dried.

Prepare the Models



Die stone is recommended. The denser stone results in a greater clarity of the finished appliance and is more resistant to fracture.

Trim the casts to a perfectly flat base and to a thickness of $\frac{3}{4}$ " to 1" total from the base to the occlusal plane. Exceeding this thickness may cause undesirable thinning of the thermo-formed sheets.



Using a number 8 round bur, drill holes as shown in the lowest points to prevent air entrapment during thermoforming. Bevel or fill in the cast peripheries to eliminate air entrapment potentials. A hole directly under the socket placement area is essential for proper thermo-forming.

Gently rinse the model with water so that all excess particles are removed. Set the model aside to air dry or use a dryer to speed up the process.

Articulate the Models



Before you prepare the models for thermo-forming, use the bite registration markings, hand articulate the upper and lower cast.



Mark the midline on the anterior gum line and two marks on the opposing labial sides as indicators of desired protrusive setting.



Mark the midline of the upper cast and set the incisal pin even with the upper mark.

Block Out Imperfections

Remove cast imperfections with a carver or pick, and fill any voids with Blue Resin Block-Out (Refer to *Vendors and Ordering Information*) or gypsum. A material should be used for this procedure that will not melt or become incorporated in the hot, thermo-formed sheet material.

Block out any imperfections and undercuts on the lower and upper casts with a conservative amount of Block Out resin (light cure).

Light cure the lower and upper casts until the block out resin has cured

Note: If any teeth have been fractured off the cast, you should request a new cast from the dentist in order to achieve optimum fit and retention.



Apply Liquid Foil and Mold Release



Use a brush to paint the casts with a generous amount of Liquid Foil. Avoid any accumulation in the embrasures and undercuts. Use a hair dryer or let the casts air dry.

Apply a second coat of Liquid Foil to the cast and repeat drying.



Spray the casts with a light layer of silicone mold release.

Pre-Drying Durasoft

Pre-drying:

Durasoft can absorb humidity which create bubbles when heated. To avoid this, pre-dry the Durasoft in a BIORSTAR® / MINISTAR®-Drying Oven* or any similar oven at a temperature of approximately 80°C for at least 4 hours (8 hours at most), depending on the strength of the material. Storing the material in the drying oven for more than 8 hours is not recommended as the material may change color and become yellow.



Storage:

Store Durasoft foils in a dark cool place. Durasoft is sensitive to ultraviolet light and will react by discoloring and turning yellow.

**If you are interested in purchasing a Biostar Drying Oven, contact Great Lakes Orthodontics at (800) 828-7627.*

Example of the drying oven built into the Biostar.

Thermo-forming Durasoft

Upper and Lower Trays

NOTE: Any thermo-form machine can be used to make the TAP 3 Elite TL, such as the Biostar, Erkopress, Drufoomat. A *vacuum form machine is not recommended* to make TAP 3 Elite TLs. AMI's presentation shows the fabrication process with the Biostar machine.

Set the temperature code and heat per the manufacturer's instructions (codes are located on the individual sheets).

Place the Durasoft ready to be thermo-formed with the shiny side down. The dull rubbery surface should be up and next to the heating element. The dull side is the polyurethane layer and should be in contact with the cast during thermo-forming.

The platform of stainless steel beads can be used for this procedure. Adaptation to the cast where retention is critical may be enhanced.

Use utility scissors to remove the excess Durasoft to the base of the maxillary and mandibular casts.



Preparing the Durasoft Layer

Upper and Lower Trays

Remove the excess material 2mm above the gingival margin using a wheel saw.
Trim excess material from the Lingual of the cast to uncover the pressure relief holes using a pick.



Adjust the Drape to the Survey Line

Upper and Lower Trays

The finish line should be a uniform depth below the estimated survey line (height of contour). When Durasoft layer is placed lightly on the casts it should rest on the height of contour around the entire arch as shown. This will often require significant reduction of the labial extension on the anterior teeth, adequate posterior retention permitting. In general, the greater the labial inclination of the anterior teeth, the greater the anterior reduction is required. The goal is to produce a directly vertical application of the trays to the teeth.

When properly adjusted, slight vertical pressure will seat the Durasoft layer into place on the cast. The retention of this first layer should be slightly sub-optimal. The finish line will define the drape of the finished appliance. **Special attention should be given to accurately accomplishing this procedure.** The next layer will increase the retention to optimum and provide the ideal finish line for fast and accurate finishing.



Mounting the Lower Hardware

Lower Tray



On the lower cast, trim the Lingual Shelf to fit and set on the lingual incisal edge off of the incisal edge of the lower anteriors. Hold it in place with a light application of cold cure acrylic (orthodontic acrylic).



Once the acrylic has set, apply the lingual bar to the posterior of the lingual shelf. This will provide additional stability to the shelf.

To properly cure the acrylic, place the lower cast in a heated pressure pot for a minimum of 1 minute.



Remove the lower cast from the pressure pot and set aside for later use.

Preparing to Place the Base Plate

Upper Tray

Prepare the Durasoft for placement of the Base Plate by slightly thinning and flattening the anterior of the upper tray, as shown. Do not perforate the Durasoft layer, which can damage the cast.



Mounting the Base Plate

Upper Tray



Trim the size of the locator sleeve to half the size of the base plate.

Set the upper hardware assembly in the plastic locator sleeve.

On the upper cast, apply a small coating of acrylic to the incisal edge of the central incisors.



Press the upper hardware assembly and locator sleeve into the acrylic and let it set.

Once the initial acrylic has set, apply more acrylic to the underside of the sleeve on both the labial and lingual.



Place the upper cast in the pressure pot for 1 minute to secure the sleeve.

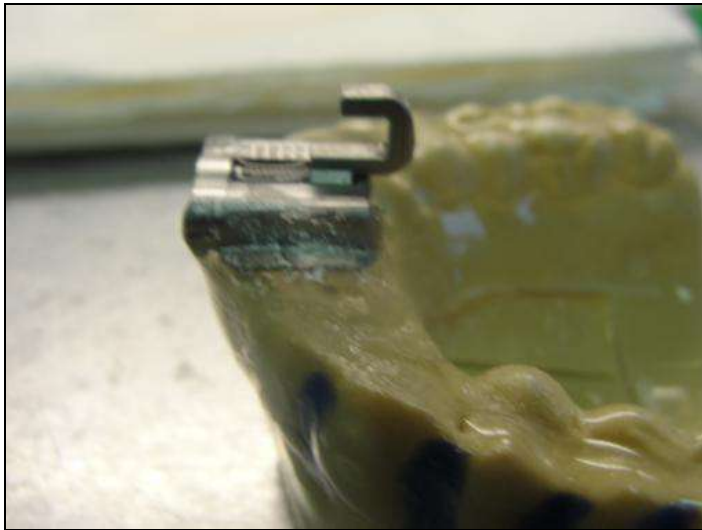
Mounting the Base Plate

Upper Tray

Remove the cast and hand articulate the upper and lower casts to the markings made based on the Doctor's protrusive bite registration.

Move the upper hardware forward or backward to properly engage the lower lingual shelf at this protrusive setting.

Check the positioning of the hardware in relation to both casts.



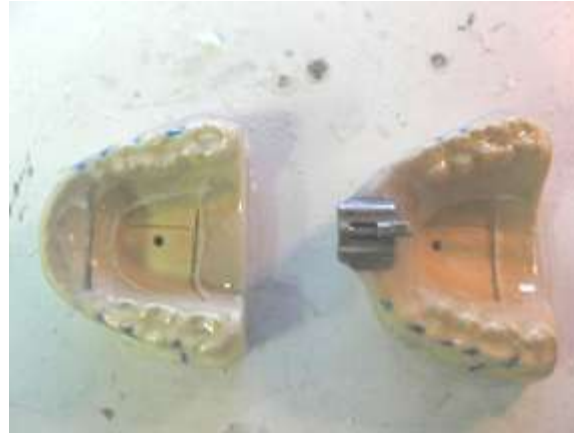
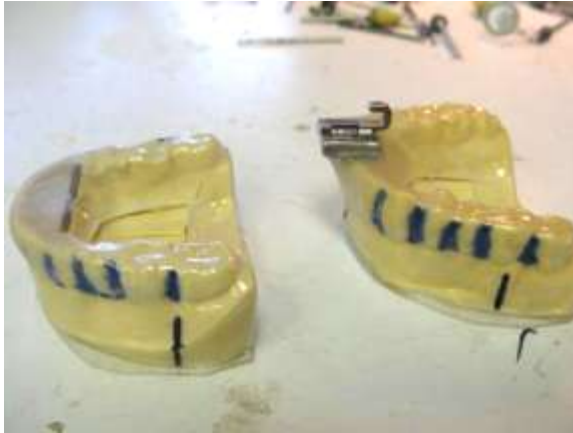
Cure the bond in a heated pressure pot for 1 minute.

Remove the cast and re-check the position of the hardware.

Fill in the gaps under and around the sleeve.

Be sure not to block the locking screw holes or the adjustment screw key hole. If it is blocked, the patient will not be able to adjust the hook nor will the front plate be able to be removed to add different size hooks.

Prepare Trays for ThermoBlend



Clear any acrylic blocking the locking screws or the adjustment screw key hole.

Trim and smooth the area around the upper and lower hardware with an acrylic bur.

Evaluate the posterior space between the upper and lower trays.

Adjust the posterior of the lower tray as needed to achieve 1mm of space between the trays.

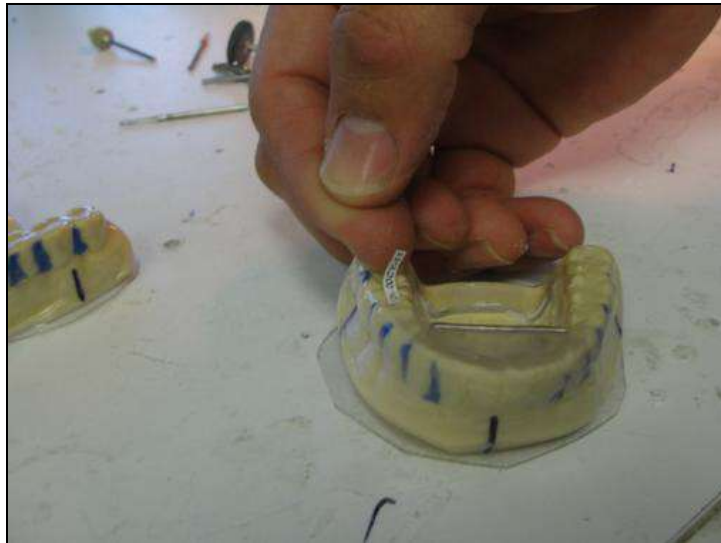
- If posterior stops are prescribed, apply to the lower molar area with acrylic. (**See Slide 22 for further instruction**)
- Add acrylic (putty form) to the lower posterior of the tray.
- Let the acrylic sit for a minute before placing the lower tray in a pressure pot to cure the acrylic.
- Trim the posterior stops and polish with a bur.

Place Lot Number

Under the lid of the Kit is the lot number label.

Take one of the smaller labels for the upper and lower tray **each**. Place the on the occlusal surface of the Durasoft layer.

It is important that each tray have a lot number label embedded between the layers.



Note: On the lower tray, you can place either the bite Button or the Lot Number Label first. Simply confirm that they do not interfere with each other.

Posterior Stops

Lower Tray

The dentist may prescribe Posterior Stops on the patient's TAP. These stops provide posterior support for the TMJ and an even bite plane for the patient. See the *Clinician Booklet* for more information on Posterior Stops. It's critical that the clinician understand that he will have final adjustments to make based on the patient's final treatment position.

To add posterior stops:

1. After the first blow down and the hardware is set add acrylic to the occlusal surface of the mandibular tray in the areas of the 1st and 2nd molars.
2. Hand articulate the upper and lower trays together and build the stops to the necessary vertical height to allow for contact
3. After the stops have been added you will need to set the tray in the pressure pot for proper curing before you continue on with the second blow down
4. The clinician will have to add or remove the stops vertically depending on the patients treatment position.



hand articulating the posterior stops before curing

The ThermoBlend Layer

Upper and Lower Trays



Place the cast into the Biostar cup. Pour beads around the cast.

Start the Biostar with 182 heat code, at 20-25 seconds prior to the start of the blow down, paint the Durasoft layer of the cast with a light even coat of Weld-on Acrylic #4. . **NOTE:** Avoid brushing the Lot Number Label which may lead to smearing.

Pressure-form the Thermoblend sheet.

Release pressure from the chamber and remove the cast from the Biostar.



Cutting out the Trays

Upper and Lower Trays



Trim the excess plastic from around the base of the cast using utility scissors.

Remove the upper and lower tray and trim excess plastic.



In order to remove the plastic trays from the casts, mark the extent of the flange on the cast 2mm beyond the junction of the tooth and gingival.

Use a mini wheel saw to cut the trays from the mold at the above location.

After cutting out the tray, fit the lower tray back on the lower cast and the upper tray on the upper cast.

Exposing Hardware

Upper and Lower Trays



Remove the plastic layer covering the Hook, Adjustment Screw and the Front Plate.

When removing the plastic from the Hook, do not expose the wings on the upper hardware as it may come loose between the Durasoft and Thermoblend layers.



Clean any remnants out of the Adjustment Screw area so the Hook can function properly by traveling up and down the Adjustment Screw.

Trim plastic from the posterior side of the bar of the lingual shelf, leaving the bar exposed for direct contact with the hook.

Finish trimming the plastic from around the Hook, Adjustment Screw, and Front Plate using a trimming bur.



Finishing the Trays

Upper and Lower Trays



Polish the acrylic around the upper and lower hardware using an acrylic bur.

Connect the trays to evaluate the placement and polish of the base plate/ hook assembly and the shelf.

Trim the flanges of the tray and polish the edges using a polishing bur/rough 3M polishing wheel.

Buff out imperfections using a rag wheel with pumice to smooth all edges.

Place finished trays back on the casts and hand articulate.

Verify the retention on the cast is proficient and that the trays fit snugly on the casts.

Hook the trays together.

Place the trays back on the articulator to evaluate the final fit.



Final Cleaning Upper and Lower Trays

Use the pressure steamer to blast out any loose particles.

Drop the trays into the Ultra-sonic cleaner using Cavicide to disinfect.

Remove the trays from the cleaner and let stand to dry for a few minutes.



Final Inspection

Upper and Lower Trays

- ✓ Verify there are no flaws or particles remaining from the Blow Down process including the clarity of the trays within the plastics contains no visible clouds or air bubbles.
- ✓ No sharp edges on the inside or outside of the lower and upper trays.
- ✓ Verify that the hook can fully engage with the lingual bar and can move freely over the lingual shelf.
- ✓ Verify that the lower lingual shelf is free of debris and excess plastic.
- ✓ The opening of the front plate spindle and locking screws) are free of debris.
- ✓ The hook travels freely on the entire spindle.
- ✓ Evaluate the final fit. (The upper and lower trays seat onto the models with tension with a slight snap.)
- ✓ Survey the final positioning of the hardware.

Finished TAP 3 Elite TL



Congratulations! You have finished fabricating a TAP 3 TL Elite anti-snoring and sleep apnea device.



When shipping the TAP 3 TL Elite to the practitioner, be sure to include the following:

- Clinician Instruction Booklet* (if it's a new clinician)
- Patient Instruction Booklet**
- TAP storage container
- AM Aligner
- Adjustment Key
- Lot Number sticker for patient records

***Clinician Booklets are not provided in the kit. They can be ordered separately for free for new TAP clinicians.**

****Be sure to check the box on the front of the booklets indicating the TAP 3Elite liner – TL or ThermAcryl so that the patient and clinician can properly seat and care for the their TAP 3 Elite**

Thank You !

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