



Patents Pending  
FDA 510(k) Clearance

## DEMONSTRATION & PRACTICE OF BENTIPSTM<sup>TM</sup> MOCK CLINICAL USE

1. **Scope:** This DEMONSTRATION & PRACTICE OF BENTIPSTM<sup>TM</sup> MOCK CLINICAL USE document (hereon, “Document”) is designed for end-user clinicians. Reading and understanding all of the information in this Document, and demonstrating the tasks, is a required step in the BENTIPSTM<sup>TM</sup> END USER TRAINING PROTOCOL leading to BENTIPSTM<sup>TM</sup> CERTIFICATION.

Demonstration and practice will be carried out by reading, understanding and following the instructions of Steps 2 through 5 detailed below with either trainer-guidance or self-guidance, or a combination of both. All steps will be demonstrated sequentially and thoroughly.

Upon completion of the above, the trainee shall resume following the BENTIPS END USER TRAINING PROTOCOL steps sequentially.

It must be understood that this Document is an adjunct to, not a substitute for, reading and understanding the entire CONSOLIDATED IFU (hereon referred to as the “IFU”) that is located at [www.bentipsusa.com/IFU](http://www.bentipsusa.com/IFU) before carrying out the tasks in this Document.

If at any time you have any questions or need clarification then you must contact BenTips at <https://bentipsusa.com/contact-us> or email your assigned BenTips representative.

### 2. **Review the Current Product Lists and Uses:**

1. Refer to [www.bentipsusa.com/members](http://www.bentipsusa.com/members), login and download the latest version of the document **CPIS INSERTS PRODUCT LIST and BENTIPS GOLD INSERTS PRODUCT LIST**.
2. Familiarize yourself with all the products and uses in these documents.
3. Upon completion, you must be able to identify and name all the different products and their uses.

### **3. Preparation, Setup and Use**

Refer to [www.bentipsusa.com/ifu](http://www.bentipsusa.com/ifu) for all of the following steps that refer to the IFU:

1. Go to the IFU Section 5 - LIST OF INCLUDED PARTS, ACCESSORIES AND COMPONENTS
  - Verify that all parts, accessories and components on this list are present in your shipment.
  - Contact BenTips if any are missing.
2. Go to the IFU Section 6 - INSTALLATION
  - Follow all the steps, but stop at Step 6.3.8 to choose the appropriate tip to be used as part of this mock clinical use as outlined below in this Document Section 3. Mock Clinical Use.
  - Upon choosing the appropriate tip/shaft/insert, proceed with the IFU Step 6.3.9 until completion of the entire IFU Section 6.
3. Re-read the IFU Section 7 INSTRUCTIONS FOR USE.
4. Stop at the IFU Subsection 7.5 Instructions for Use.  
Perform all the steps in this subsection through the end of the IFU Section 7.

### **4. Mock Clinical Use (For Demonstration and Practice):**

1. Use one of the tips in your armamentarium in combination with one of the shafts in your possession to perform the following motions and mock clinical use on the simulation item as assigned by BenTips:
  - a. External ablation - with the tip approximately perpendicular to the root surface.
    - i. Cutting with the distal-most section of the tip
    - ii. Ablating with the distal-most section of the tip
    - iii. Ablating with the lateral surface with lateral movement
    - iv. Ablating with the lateral surface with circular movement
    - v. Ablating with the lateral surface with linear movement
  - b. Internal ablation - with the tip approximately parallel to the root surface.
    - i. Ablating with the distal-most section of the tip
    - ii. Ablating with the lateral surface with lateral movement
    - iii. Ablating with the lateral surface with circular movement
    - iv. Ablating with the lateral surface with linear movement
2. Use each of the additional tips in your armamentarium in combination with each of the additional shafts in your armamentarium as outlined in the steps above to familiarize yourself with the use, mode of action, and anatomical access for each of the tips and its combination with each of the shafts. Continue to do this until you are satisfied with your proficiency and feel ready to perform the procedure on a patient. If you have any doubts regarding the above, contact BenTips to obtain pig jaw specimens to practice on.
3. Use each of the Gold Inserts in your armamentarium either on a typodont tooth or extracted natural tooth or pig jaw specimen for demonstration and practice.

### **5. Breakdown, Cleaning & Storage:**

1. Go to the IFU Section 8 and follow all steps to completion.
2. Continue on to the IFU Section 9 and follow all steps to completion.

## 6. **Review BenTips™ Terms**

Review the following BenTips Terms.

Upon completion, you must be able to recite these Terms and their significance.

Internal Ablation (aka Internal Bevel): Any BenTips procedure in which the long axis of the BenTip is pointing toward the tooth apex. This procedure performs gingival curettage for visualization of the root surface for debris removal and other purposes for which visualization is needed.

External Ablation (aka External Bevel): Any BenTips procedure in which the long axis of the BenTip is pointed either perpendicular to the root surface or more toward the crown (as opposed to the tooth apex).

Horizontal Ablation (aka Horizontal Bevel): A subtype of External Ablation in which the long axis of the BenTip is aligned approximately perpendicular to the long axis of the tooth. This may create a horizontal section of gingiva that may create gingival anatomy that is not optimal for meticulous oral hygiene by the patient. In these cases a more obtuse angle of the gingiva in relation to the tooth surface is desirable.

Primary Pocket Reduction - Gentle reshaping of the gum tissue for pocket reduction with external bevel tissue ablation.

Secondary Pocket Reduction - The unintentional but nonetheless beneficial pocket reduction that can be attained by reduction of the height of the free gingiva that often, but not always, occurs during internal bevel procedures, especially in thin tissue biotype patients.

Open or Opening - when performing a BenTips internal bevel procedure, to Open or perform Opening refers to widening the area of ablation laterally away from the tooth surface to promote improved access for visualization and patient OH.

### **Review BenTips™ Case Types**

Review the following BenTips Terms.

Upon completion, you must be able to recite these Terms and their significance.

#### BenTips™ Type I (B1)

This case is quick and easy to treat, and good for beginner BenTip™ users and will typically only require light to moderate instrument loading. Must have all of the following

- Thin to Moderately Thick Tissue Blotype
- 5-6 mm pockets or shallower
- No tori or exostosis
- No furcation beyond class I
- No infrabony pockets beyond 1 mm in depth.

### BenTips™ Type II (B2):

This case is challenging to treat, and only appropriate for advanced/experienced BenTip™ users

Thick Tissue Biotype

7-8 mm pockets

Some tori or exostosis that will only allow horizontal g'plasty

No furcation beyond Class II

Infrabony defects 2-3 mm in depth from the osseous crest to the depth.

### BenTips™ Type III (B3):

This case can be very difficult to treat, and should only be attempted by the most advanced and experienced BenTips™ users.

Very Thick Biotype

Pockets 8+ mm in depth

Tori and/or exostosis that form infrabony defects such that horizontal g'plasty would result in residual pocket depth or denuding the thin tissue of the torus/exostosis.

Class III furcations

Infrabony defects beyond 3mm in depth from the osseous crest to the depth.

\*\*BenTips™ recommends that if you are new to the BenTips™ protocols, that you only treat BenTips™ Type B1 cases initially until you feel very comfortable with the BenTips™ system, at which point you can start treating more challenging cases, but only if you so desire. There is nothing wrong with only treating Type B1 cases as these will likely be the most cost effective choice.

### **Issues for End-User to be aware of:**

- ❖ IFU can be accessed through [www.bentipsusa.com](http://www.bentipsusa.com)
- ❖ Avoid using excess force when using BenTips to prevent shaft breakage which can result in tissue damage and possible aspiration of tip and broken shaft.
- ❖ Presence of known risk of tip breakage which can result in aspiration of broken pieces of tip or broken pieces of tip becoming wedged under the gum line/between teeth causing tooth movement/infection.
- ❖ Extensive use can cause tip wear resulting in ineffective bone removal/soft tissue debridement.
- ❖ Importance of using the correct irrigant flow; if not the handpiece may become nonfunctional, and the handpiece and tip may become excessively hot, which can burn the operator and burn the patient