**Announcement:** Recent PSR reports and case reports in Literature have been identified risk associated with Dental Intraosseous Injection Devices: X-Tip (Dentsply Maillefer) and Stabident (Fairfax Dental).

Recent PSR reports and case reports in the Literature have been identified risk associated with Dental Intraosseous Injection Devices. X-Tip (Dentsply Maillefer) and Stabident (Fairfax Dental) have both been named in cases involving breakage and separation of metal component from plastic drivers. Refer to DECS website for Instructions For USE (IFUs) and a tip sheet concerning techniques. Click the following links to view IFUs:

- Maillefer X-Tip-DFU
- Stabident IFU
- X-Tip Tech Card
DIRECTIONS FOR USE

DENTSPLE Maillefer
5100 E. Skelly Drive, Suite 300
Tulsa, OK 74125-8646
1-800-924-7393
www.maillefer.dentsply.com
U.S. and foreign patents pending

See Directions For Use
Non-Returnable If Opened
Shelf Life

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E. In all cases, a much smaller volume of anesthetic is required for profound anesthesia (1/3 to 1/2 of a cartridge per injection is usually all that is required). F. Injection between two teeth will usually numb both teeth, with slightly more profound anesthesia for the tooth mesial to the injection site. G. The drill and guide sleeve are disposable and should only be used once and discarded.

PROBLEM RESOLUTION:


Occasionally, the guide sleeve will be withdrawn as you begin to remove the drill. Use your finger or the plastic handle to hold the sleeve in place as you withdraw the drill.

Guide Sleeve Separates from Drill Before Entering the Bone.

To prevent premature separation, avoid pointing the sleeve downward and avoid running the hand piece until the drill has contacted the bone.

Incomplete Numbing of Lingual Tissue on the Mandible.

Intraosseous injections of the mandible may not provide profound anesthesia of the lingual tissue. When using intranasal anesthesia for the extraction of a mandibular tooth, it will usually be necessary to inject the lingual tissue separately. The best way to inject the lingual collar of tissue is to enter the buccal in the papilla area, and slowly blanch the lingual tissue. Injection of the lingual tissue is not necessary on maxillary teeth, therefore, no palatal injection is needed for endodontic treatment or extraction of maxillary teeth.

Incomplete Anesthesia

If the X-tip does not enter cancellous bone, anesthesia will not occur. In some cases, injecting mesial to the tooth will not provide adequate anesthesia, and it may be necessary to add more anesthetic solution, or to inject distal to the tooth. The unique design of the X-tip makes it easy to re-inject if anesthesia is inadequate or begins to wear off during a lengthy procedure.

OPENING NEEDLES

1. To open needles, align heat stake upward away from face, eyes, body and patient. Break tamper-evident stake by twisting the cap or by applying a downward snap.
2. DO NOT USE IF HEAT STAKE HAS BEEN PREVIOUSLY BROKEN.
3. Remove cap and using sheath as a wrench, attach the self-threading plastic hub to the syringe.
4. Leave sheath in place to protect needle until ready to inject.
5. After use: carefully remove needle from syringe and safely discard.

ALWAYS USE A LOW SPEED MOTOR AT 15,000 - 20,000 RPM. DO NOT OPERATE BELOW THIS SPEED.

DIRECTIONS FOR USE

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 PERSONAL ANESTHETIZING THE INJECTION SITE

A. As with the administration of all drugs, the minimum dose needed for profound anesthesia should be given. Much less solution is needed for intraosseous anesthesia than for infiltration (approximately 1/4 to 1/2 cartridge is adequate for most procedures). B. Practitioners should always be mindful of the toxic effects of local anesthetic and be prepared to cope with any emergency that may arise. C. When using vasoconstrictor-containing anesthetics, inform patients that they may experience a temporary rapid heartbeat, which is normal and will quickly pass. D. It is essential to inject slowly to avoid pain from pressure, and to avoid the possibility of heart palpitations if you are using anesthetic with a vasoconstrictor. E. In all cases, a much smaller volume of anesthetic is required for profound anesthesia (1/3 to 1/2 of a cartridge per injection is usually all that is required). F. Injection between two teeth will usually numb both teeth, with slightly more profound anesthesia for the tooth mesial to the injection site. G. The drill and guide sleeve are disposable and should only be used once and discarded.

SPECIAL NOTES FOR USING THE X-TIP

A. Always use a “pecking” motion rather than continuous pressure as you drill through the cortical plate to prevent “frictional burning” of the bone. B. Always use a low speed motor at 15,000 - 20,000 rpm. Do not operate below this speed. C. No longer than two to four seconds of drilling should be required if you have selected the proper site. Longer than two to four seconds means the bone is too thick, and you should try another site. D. If you encounter pressure on injection, you have probably not completely penetrated the cortical plate, and it may be necessary to move to another injection site.

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PROCEDURE: INITIAL STEP - Selecting a site for injection

**LATERAL PERFORATION**

*General Rule*
Imagine a horizontal line along the gingival margins of the teeth and a vertical line through the interdental papilla. A point about 2mm apical to where these lines meet is usually a suitable site for a lateral perforation.

**VERTICAL PERFORATION**

*General Rule*
Edentulous areas may be treated, if preferred, by choosing a site on the alveolar crest (where the cortical plate is thinnest) to provide a vertical perforation rather than a lateral perforation.

**Additional Notes**

### Site selection in the mandible

(a) Inject distal rather than mesial, where possible, because a smaller dose suffices.
In most cases, a mesial injection will provide adequate anesthesia, but in a small number it will not.

(b) Avoid perforating between the lower central incisors (because good cancellous spaces are not present in this area).

(c) Avoid the mental foramen area. Preferably, a site between the bicuspids should be avoided, even though a perforation at a distance of 2mm from the gingival margin would usually be well clear of the mental foramen.

### Site selection in the maxilla

(a) Avoid perforating between the upper central incisors (because good cancellous spaces are not present in this area).

(b) Avoid perforating into the maxillary sinus. Penetrating the maxillary sinus would not cause permanent damage but local anesthesia would not be achieved.
PROCEDURE: STEP 1 - Anesthetizing the attached gingiva

(a) Disinfect and topically anesthetize the attached gingiva over the injection site.

(b) Assemble an injection-needle with a standard cartridge and syringe (the needle supplied with the kit may be used, unless it is of the "modified" type with a flattened tip, as described at the end of the Components Section). Advance the needle towards the surface of the gingiva at a flat angle so that the flat surface of the bevel is almost parallel to the surface of the gingiva. Gently penetrate the surface of the gingiva and slowly inject one or two drops of anesthetic, causing a slight blanching of the tissue. This will indicate that anesthesia of the attached gingiva and periosteum has occurred.

If, in spite of using topical, and penetrating the gingiva at a shallow angle, the patient still experiences some sensitivity, an alternative to anesthetizing the attached gingiva is to move the infiltration injection into alveolar mucosa just next to its border with the attached gingiva. Wait for about 30 seconds to allow the anesthetic to diffuse.

PROCEDURE: STEP 2 - Perforating through the cortical plate

(a) Secure a Stabident perforator in a contra-angle handpiece (or in a straight handpiece designed for latching-type burs) and remove the cap from the perforator.

(b) Hold the perforator perpendicular to the cortical plate and, without activating the handpiece, gently push the perforator through the attached gingiva until it is in contact with the bone.

(c) Now activate the handpiece at full speed, while pushing the perforator with light pressure against the bone for about one second before slightly withdrawing the perforator out of contact with the bone, followed by once again pushing it with light pressure against the bone for about one second. The "pecking" motion should be repeated as many times as necessary until breakthrough into the softer cancellous bone is achieved, this usually taking place in about two to five seconds of total drilling time. Completion of the perforation is easily sensed because there is a sudden "give" when the cortical plate is perforated and the softer cancellous tissue is entered.

It is very important to use the "pecking" movements rather than trying to drill through the bone in one long continuous movement because the latter may cause overheating of the bone. Overheating of the bone may result in postoperative soreness and/or some mild infection of the bone and overlying gingiva. Cases of bone overheating will have to be treated according to the severity of the reaction. Mild inflammation will usually heal uneventfully and will probably not require any treatment other than mild analgesics. More severely inflamed tissue may become infected and require antibiotic therapy. Severe reactions may involve necrosis of a small portion of bone and may necessitate the raising of a flap and the curettage of the necrotic area. Avoiding one long continuous movement is particularly important in the mandibular molar area where the cortical bone is thickest. Mandibular perforations will generally take a little longer than maxillary (i.e. perhaps five seconds or so of total drilling time).
(d) Withdraw the perforator and dispose of it safely without recapping. If another Stabident perforation is required at the same site or at another site on the same patient, it is best to use a new perforator because the point may be “dulled” during the first perforation.

**Step 2 - Example DVD Clip**

There is a narration explaining what you are about to see before the DVD clip begins to play.

This clip is taken from the Stabident DVD and is one of many different examples on how to effectively use the Stabident System.

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**PROCEDURE: STEP 3 - Inserting the injection-needle and injecting**

(a) Compress a cotton roll against the mucosa for a few seconds in order to absorb any slight gingival bleeding. This will also aid identification of the perforation.

(b) Holding the syringe in “pen-gripping” fashion, and remembering the angle at which the perforator was withdrawn from the bone, align and gently insert the injection-needle at approximately the same angle.

It is important to bring in the needle at the same angle at which the perforator was withdrawn. The needle must be in line with the perforation to enable it to advance into the perforation. The injection-needle should be allowed to engage with the cortical bone with only very light pressure so as to avoid any tendency for the tip of the bevel to “dig” into the bone or to buckle, thereby hindering or preventing insertion of the needle. If “digging” into the bone is still a problem, modified injection-needles with a flattened tip, referred to in the Components section, should be used.

(c) Slowly and gently inject the anesthetic. It will be found that with the Stabident System the syringe can be operated with a much lighter pressure than in the case of infiltration and block injections. Particularly in the case of an anesthetic containing epinephrine, it is essential to inject very slowly, and the patient should be in the supine position. Even so, injection of epinephrine- and levonordefrin-containing solutions will cause a transient heart rate increase (palpitations) in the majority of patients. This is not a problem for many or most patients, but it may be desirable to raise the point with the patient before proceeding with an epinephrine-containing anesthetic.

In the event that considerable force is required to inject, it must be assumed that the needle has not entered a suitable cancellous space, and an alternative site for injection must be chosen. In some cases the explanation is that the needle has become blocked.
Step 3 Regular - Example DVD Clip

Watch Windows Media
Watch Quicktime

There is a narration explaining what you are about to see before the DVD clip begins to play.

This clip is taken from the Stabident DVD and is one of many different examples on how to effectively use the Stabident System.

PROCEDURE: FINAL STEP - Safe Disposal of injection-needle and perforator needle

Because of the short length and rigidity of both the injection-needle and perforator needle, it is dangerous to recap after use. The injection-needle and perforator needle must be disposed of safely, for example by using pliers.
Step 1: Anesthetizing the Injection Site
- Select site for injection.
- Apply topical anesthetic.
- Inject a few drops of local anesthetic with Vasoconstrictor in muco-buccal fold.
- The injection site should be two to four millimeters apical to the crest of the bone and immediately distal to the tooth for treatment.
- Examine pre-operative radiographs of proposed injection site.
- Make certain there is room between adjacent roots to accommodate X-Tip drill and guide sleeve.
- Use cotton pliers to press attached tissue against the bone for a few seconds to confirm anesthesia of perforation site.
- A slight dimple will remain on tissue, marking exact site of penetration.

Step 2: Perforation of Cortical Plate
- Place X-Tip drill and guide sleeve in a slow speed 15,000-20,000 RPM hand piece.
- Secure guide sleeve against drill with finger while withdrawing red protective cover.
- Gently push perforator through attached gingiva until tip contacts bone.
- Hold drill at a 90° angle to bone.
- Run hand piece at maximum speed.
- Use intermittent light pressure (forward & neutral motion) to penetrate cortical plate.
- Penetration of bone should take no longer than two to four seconds. X-Tip drill and guide sleeve will drop into cancellous bone.
- Hold guide sleeve in place with finger while detaching & removing drill from guide sleeve.

Step 3: Injection into Cancellous Bone
- Slowly and gently inject anesthetic through guide sleeve into cancellous bone.
- Inject slowly as rapid injection may cause discomfort to patient.
- If considerable force is required, X-Tip drill and guide sleeve have not entered suitable cancellous space. Select new injection site.
**Important Tips**
- To prevent premature separation of X-Tip drill and guide sleeve, avoid pointing guide sleeve downward or running hand piece until drill has contacted bone.
- To prevent “frictional burning” of bone, always use light intermittent (forward & neutral motion) pressure, rather than continuous pressure.
- Always operate hand piece at 15,000-20,000 RPM.
- If proper site is selected, no more than 2-4 seconds of drilling will be required. If more than 2-4 seconds is required, bone is too thick. Select another site.
- To avoid patient discomfort from pressure, always inject anesthetic slowly.
  - Use drill, guide sleeve and needle once, then discard.

**Removal Of The Guide Sleeve**
- If desired, leave guide sleeve in place throughout procedure for re-injections as needed.
- Check site for numbness after injection of anesthetic. Re-inject if necessary.
- To remove guide sleeve, use instrument such as hemostat or needle holder.
- Dispose of drill, guide sleeve and needle under biohazard conditions in “sharps container.”