

DIRECTIONS FOR USE

DENTSPLY
MAILLEFER

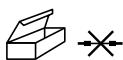
X-TIP™ SINGLE USE ANESTHESIA DELIVERY SYSTEM

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U.S. and foreign patents pending



See Directions For Use

STERILE



Non-Returnable If Opened



Shelf Life

INDICATIONS FOR USE:

Intraosseous injection of anesthesia

CONTRAINDICATIONS:

Because of the risk of drilling into a tooth bud or possible overdose of anesthetic, the X-tip is not recommended for use on young children (anyone who does not have a fully formed dentition).

WARNINGS AND PRECAUTIONS:

- 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. Dental Syringe Needle Use: Do not alter needle shaft prior to use, as needle breakage and possible injury may result. To ensure safety, always handle needles with care. If bent or damaged, no attempt should be made to straighten needle or use product. **Do not recap needles except as permitted by OSHA, CDC or local policy.**
- E. Always dispose of the X-tip drill and guide sleeve under biohazard conditions and use universal precautions while working on patients.

LOCAL ANESTHETIC

As with all dental procedures, don't exceed the maximum safe dosages for intraosseous anesthesia.

DOSAGE GUIDELINES

1. Do not use more than one or two cartridges of local anesthetic during any single, 1-2 hour dental visit.
2. Do not use any local anesthetic containing a greater than 1:100,000 concentration of epinephrine.

ADVERSE REACTIONS:

SENSITIVITY DURING PERFORATION OR INJECTION

To avoid sensitivity, pre-inject a small amount of anesthetic solution into the mucco-buccal fold, and after waiting a few

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seconds, inject a few drops of anesthetic directly over the perforation site. Apply pressure to the injection site with a pair of cotton pliers or an explorer to test for complete numbness and to create a "dimple" marking the site of injection. Use the X-tip in the hand piece to penetrate the attached gingiva down to the bone before activating the hand piece. Perforation of the cortical plate must be done in short bursts to avoid overheating the bone. Perforation should be completed in three or four seconds, and if breakthrough is not achieved in that time, an alternate perforation site should be selected. A perforation site must be chosen that will allow adequate access to cancellous bone, without drilling through unattached gingiva. If the anesthetic is injected through the X-tip with too much speed or force, the patient may feel pressure or pain. Inject very slowly, and remember that injecting under pressure is not necessary or advisable. 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.

POSTOPERATIVE PAIN

Postoperative pain is extremely rare, but may occur if the X-tip encounters the periodontal ligament. In such cases, the patient will usually experience immediate discomfort, and a new perforation site should immediately be selected. The other possible source of post-op pain is overheating the bone during perforation. In rare cases (less than one percent) the patient may experience a localized swelling with or without infection. These problems usually heal uneventfully but in some cases may require antibiotic therapy. Always activate the X-tip in a series of short bursts and NEVER SPEND MORE THAN THREE OR FOUR SECONDS perforating the cortical plate. If perforation does not occur after four seconds, select another perforation site.

PROCEDURE:

INJECTION SITES

- Crest of ridge in area of missing tooth
- Best to inject distal rather than mesial
- Avoid upper or lower central incisor area because the bone is too thick
- Avoid mental foramen area
- Avoid perforating into the maxillary sinus
- The bone in the most distal aspect of the mandible may be too thick to allow for easy penetration

STEP 1

ANESTHETIZING THE INJECTION SITE

Select a site for injection, apply topical anesthetic and inject a few drops of a local anesthetic with vasoconstrictor in the mucco-buccal fold. The injection site should be approximately two millimeters apical to an imaginary line along the gingival margins of the teeth. Carefully examine pre-op x-rays of the proposed injection site to make certain there is adequate room between adjacent roots to accommodate the X-tip. Use a pair of cotton pliers to confirm anesthesia of the perforation site by pressing the attached tissue against the bone for a few seconds. This action will also leave a slight dimple in the tissue, marking the exact site of penetration.



STEP 2

PERFORATION OF THE CORTICAL PLATE

Place the X-tip in a slow speed 20,000 rpm hand piece. Secure the guide sleeve against the drill with your finger as you withdraw the red protective cover. Gently push the perforator through the attached gingiva until the X-tip contacts the bone. Holding the drill at a 90-degree angle to the bone, run the hand piece at maximum speed and use a gentle "pecking" motion to penetrate the cortical plate. Penetration of the bone should take no longer than two to four seconds, at which time you will feel the X-tip drop into the cancellous bone. Detach the drill from the guide sleeve by using the plastic handle or your finger to hold the insert in place.



STEP 3

INJECTION INTO THE CANCELLOUS BONE

SLOWLY and GENTLY inject approximately 1/2 cartridge of the remaining anesthetic through the insert into the cancellous bone. You must inject slowly, as rapid injection may cause dis-

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comfort to the patient (practice will determine the optimal rate of injection). If re-injection is necessary for the longer procedures, anesthetic with vasoconstrictor may be used (Marcaine), always remembering to inject SLOWLY with light pressure. When using vasoconstrictor-containing anesthetics, inform patients that they may experience a temporary rapid heartbeat, which is normal and will pass in a few moments.



Note: If considerable force is required for injection, the X-tip has not entered a suitable cancellous space, and a new injection site should be selected.

REMOVAL OF GUIDE SLEEVE

Since anesthesia is immediate, inject and check site for numbness, re-inject if necessary. To remove the guide sleeve, use an instrument such as a hemostat or needle holder. Dispose of the drill and guide sleeve under biohazard conditions in a "Sharps Container" as you would a dental needle.

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. 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 (1/2 to 3/4 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:

Guide Sleeve Does Not Stay in the Bone When Drill is Withdrawn.

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 intraosseous 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.