

SleeperOne ⑤

CLINICAL GUIDE



INTRODUCTION

This clinical guide is dedicated for SleeperOne5™ users only.

For main dental anesthetics, it proposes procedure to perform comfortable anesthesia for patient and practitioner. Practitioner will find information about needle, quantity to inject, gesture, preparation and operation for each anesthesia.

WARNING

The information in this guide is given only as general guidance and must be adapted to the patient and pathologies. It is the user's responsibility to systematically ensure that their clinical approach is well founded and takes into account the undesirable side effects or contraindications defined in the notices of pharmaceutical products and the needles used.

USE OF THE PRODUCT

It is not possible for Dentalhitec to warn the user about every possible danger related to use of SleeperOne5™.

The user must use his or her own common sense and good judgement when using the product.

In addition to their clinical experience, the practitioner must adapt the choice of anesthesia and the injection to the characteristics and pathologies of the patient. The user must use SleeperOne5™ in this context, as well as in accordance with the regulations applicable to the current scientific knowledge.

USER

SleeperOne5™ should be used only by qualified dentists who are suitably trained and authorized to carry out loco-regional dental anesthesia in the oral cavity.

SleeperOne5™ must always be used under the control of its user.

TARGET PATIENT POPULATION

SleeperOne5™ should only be used in adults and children from 4 years old. Refer to the user manual for injected anesthetic products concerning the dosage, warnings and precautions according to the age and state of health of the patient.

INDICATION

Dental pathology requiring local anesthesia for treatment.

CONTRAINDICATIONS

Refer to dental anesthetic injectable solutions manual and needle manual.

The use of SleeperOne5™ for intraosseous anesthesia is contraindicated when the patient's bone characteristics in relation to their growth are likely to prevent easy penetration of the needle.

The user must ensure, regarding state of the art technology, that the practice of the local anesthesia is not contraindicated with the patient characteristics.

ADVERSE SIDE EFFECTS

No adverse side effects specific to the use of SleeperOne5™ have been identified. However, the undesirable effects presented in the instructions for the products injected and the needles used should be taken into account.

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Risk of death, serious bodily injury, or serious property damage



Risk of minor or moderate injury to the user or patient or damage to the equipment or other property



Information considered important but not hazard related

N.B.: Your device is identified by a SN serial number SN. They are on 4 labels. They are present under the control box, on the back of the foot pedal, on the handpiece plug and on the packaging box.

The format to be entered on www.dentalhitec.com/mydht/ is: S5xxxxxxx

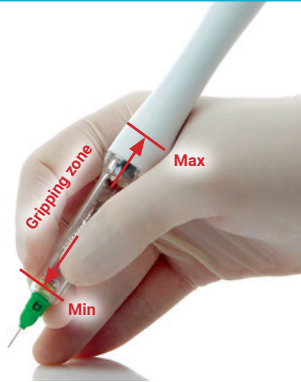
THE 4 GOLDEN RULES FOR SLEEPERONE5™

1 Gripping zone + efficient support points

Benefits:

- ▶ less effort for needle penetration
- ▶ less needle twisting
- ▶ more precision
- ▶ more stability

Work with **support points** on a tooth, the mandible or the maxilla. This is one of the key factors to perform painless anesthesia and to reduce needle twisting for PDL or intraseptal anesthesia.



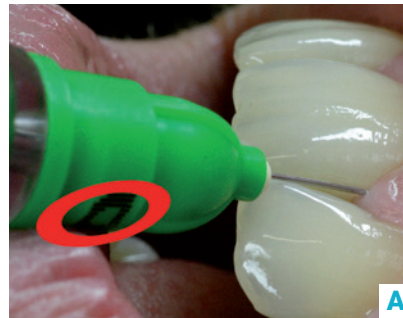
2 Correctly position the Effitec Needle indicator

Benefits:

- ▶ less pain
- ▶ less effort for needle penetration

A. PDL - Intraligamentary anesthesia: Align the indicator on the **opposite side of the tooth** (prevents the needle tip from «catching» on the root).

B. & C. Palatal and attached gingiva anesthesia: Align the indicator on the **opposite side of the gingival / mucosal surface** (allows an instantaneous injection and a limited penetration depth).



NOTICE: The indicator on Effitec Needle hubs' is special compared to other brands, which do not allow correct bevel positioning.

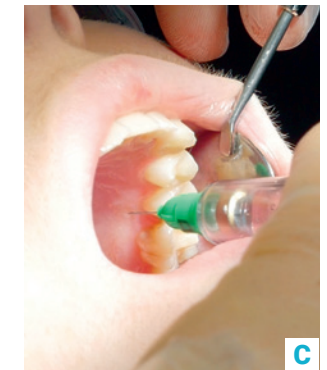
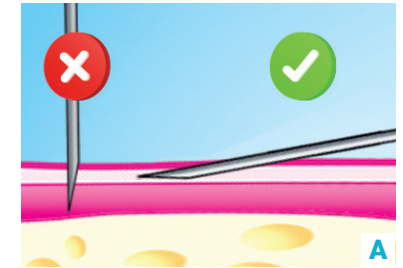
3 Effitec needle angle for gingiva anesthesia

Benefit:

- ▶ less pain

The Effitec needle's almost parallel angle of penetration to the gingiva (B, C) allows to reduce the depth of penetration (A).

This technique reduces the risk of contact with the highly sensitive periosteum.



4 Be accurate and gentle

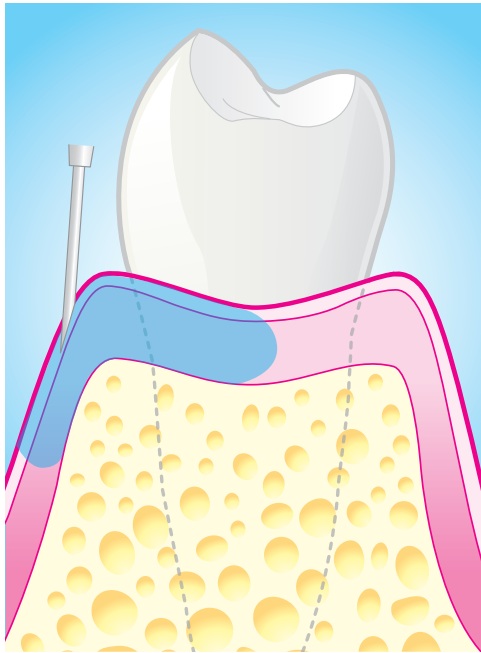
Benefit:

- ▶ less pain

You are on the way to obtain a local anesthesia **without leaks, twisted needles or failures** by applying and combining the points above.



GUIDANCE FOR INFILTRATION (ATTACHED GINGIVA)



CHARACTERISTICS

PATIENTS

Adults / Children

FIELD OF ACTION

- Surface anesthesia.

INDICATIONS

- Preparation for intraligamentary, intraseptal or intraosseous anesthesia for children.
- Applying rubber dam clamps.
- Periodontics.

⚠ CAUTION

- Does not anesthetize the tooth.

OPERATION GUIDE

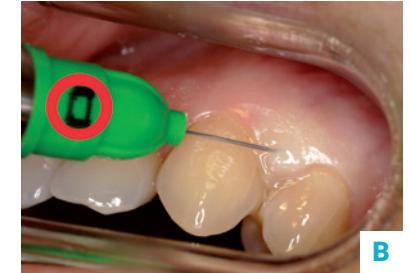
PREPARATION

- In order to provide maximum precision, the handpiece must be held on the container, **as close as possible** to the needle.
- To increase the precision of your movements, **it is imperative to work with support points (A)**.

OPERATION

Respecting the following steps should allow you to perform painless gingiva penetration and injection, even for anesthesia near the frenum, or for children:

- The indicator of the Effitec Needle must be visible and on the opposite side of the gingiva (B).
- The handpiece must be almost parallel to the gingiva.
- Start the injection.
- Slowly penetrate the needle into the superficial layer of the gingiva, avoiding touching the periosteum (painful)(C).
- The appearance of a white circular patch indicates that the periosteum has been anesthetized (B).



MATERIAL



Mode to select:
Drop by drop



⚠ WARNING

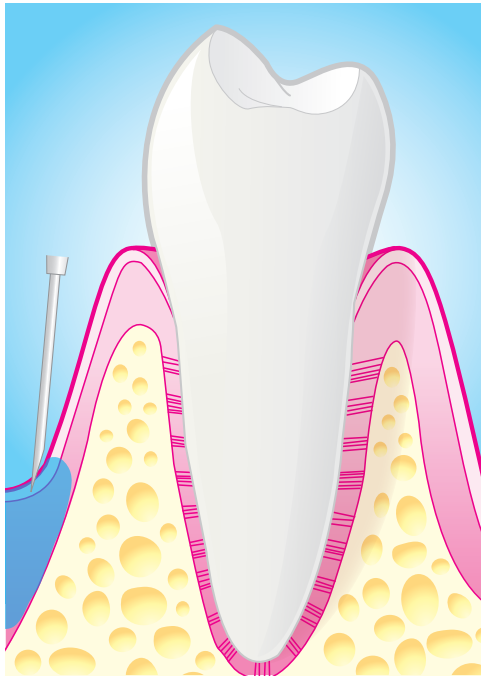
This is a general information guide. This information must be adapted and adjusted to each individual patient and type of pathology.

(*2) It is the responsibility of the user to ensure that they adhere to the most current clinical standards of patient care, and have adequate knowledge of the pharmacological products (e.g. local anesthetics) and equipment (e.g. needles) they use.

The orientation of the indicator on the plastic hub is specific for Effitec Needles. This orientation is therefore not applicable for the other needles on the market.

To watch videos of anesthesia performed with SleeperOne5™ :
www.dentahitec.com/mydht
Notice you have to log in and use your password to get access.

GUIDANCE FOR INFILTRATION (FREE MUCOSA) - PERIAPICAL



CHARACTERISTICS

PATIENTS
Adults / Children

⚠ CAUTION

Not recommended for children because of the risk of lip biting.

FIELD OF ACTION

- anesthesia of 2 teeth after lag-time.

INDICATIONS

- Conventional infiltration anesthesia as performed with a traditional syringe.

NOTICE

- Palatal injection sometimes required for maxillary molars.
- Lingual injection sometimes required for the mandibular incisor-canine block.

MATERIAL



Mode to select:



OPERATION GUIDE

PREPARATION

- In order to provide maximum precision, the handpiece must be held on the container (gripping zone), **as close as possible** to the needle.
- To increase the precision of your movements, **it is imperative to use support points (A)**.

OPERATION

- Correct orientation of the bevel of the Effitec needle **(B)**.
- Slowly penetrate the mucosa and inject.
- In case aspiration is required, hold foot down on the return/aspiration button on the foot pedal (it is essential that the plunger is sufficiently advanced in the cartridge to enable this operation) **(C)**.

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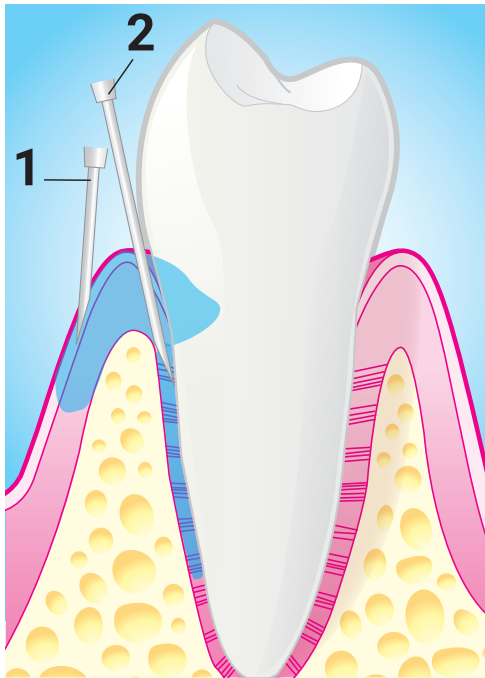
⚠ WARNING

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GUIDANCE FOR INTRALIGAMENTARY - PDL



CHARACTERISTICS

PATIENTS
Adults / Children

FIELD OF ACTION
- Immediate anesthesia of one tooth.

INDICATIONS
- Maxillary and mandibular teeth.

⚠ WARNING

- **Do not bend** the needle when performing an intraligamentary anesthesia.
- 1/100,000 (.01 mg/ML) and higher is not advised: risk of loss of ligamentary attachment (sulcular necrosis).
- Not advised in the presence of periodontal disease since it will produce postoperative periodontal ligament pain and inflammation.

MATERIAL



Mode to select:



⚠ WARNING

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OPERATION GUIDE

STEP 1 - ATTACHED GINGIVA ANESTHESIA

Proceed as indicated on page 4. This step allows to reduce pain for attached gingiva anesthesia.

STEP 2 - PDL - INTRALIGAMENTARY ANESTHESIA

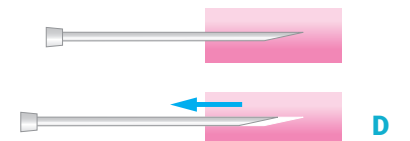
- Position your Effitec needle almost parallel to the axis of the tooth (A).

PREPARATION

- The handpiece should be held as described on page 4 to ensure accurate needle position and avoid needle twisting (A).
- The Effitec needle bevel must be oriented opposite to the tooth for an easy penetration into the periodontal ligament space (B, C).

OPERATION

- On a single rooted tooth, it is generally easier to penetrate PDL space distally (wider ligament).
- On a multi-rooted tooth, the injection can be performed either distally or mesially (B, C).
- Gently penetrate the PDL space by a few millimeters, sliding along the root. Before proceeding with the injection, slightly draw back (D) then proceed with the injection.
- We recommend to not inject more than 1/4 of a cartridge at a maximum of 1/200,000 (.005 mg /ML) of vasoconstrictor (adrenaline / epinephrine).
- This type of anesthesia typically requires significant injection pressure, it is therefore normal for the light on the handpiece to flash faster (see User guide).

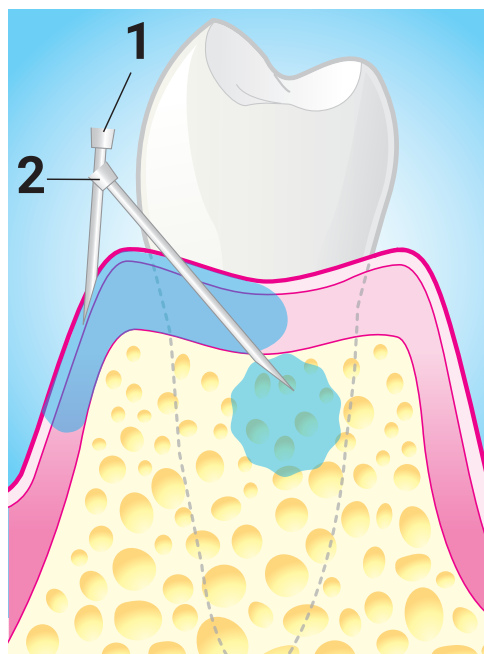


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GUIDANCE FOR INTRASEPTAL



CHARACTERISTICS

PATIENTS

Adults / Children

FIELD OF ACTION

- Immediate anesthesia of the two teeth adjacent to the injection site.

INDICATIONS

- Maxillary and mandibular teeth.

CAUTION

- Not advised in case of periodontal inflammation.
- Hyperdense septum may not be penetrable (to be verified priorly on X-ray, e.g. bitewing).
- Perform on permanent teeth only for Children

We recommend to not inject more than 1/2 of a cartridge at a maximum of 1/200,000 (.005 mg/ML) of vasoconstrictor (adrenaline) to reduce risk of necrosis.

WARNING

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The orientation of the indicator on the plastic hub is specific for Effitec Needles. This orientation is therefore not applicable for the other needles on the market.

OPERATION GUIDE

STEP 1 - ATTACHED GINGIVA ANESTHESIA

Proceed as indicated on page 4.

This step allows to reduce pain for attached gingiva anesthesia.

STEP 2 - INTRASEPTAL ANESTHESIA

PREPARATION

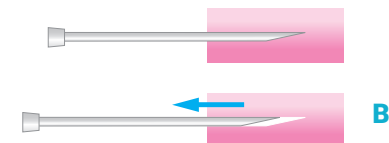
- The anesthesia is ideally performed **distally** to the tooth to be treated.
- Place the Effitec needle at an angle of 45° compared to the tooth's axis (A).
- The handpiece should be held as described on page 4 to ensure accurate needle position and avoid needle twisting.

OPERATION

- Insert gingiva of the interdental papilla by a few millimeters, towards the middle of the septal bone.
- Before proceeding with the injection, slightly draw back then proceed with the injection (B).

NOTICE

This type of anesthesia typically requires significant injection pressure, it is therefore normal for the light on the handpiece to flash faster (see User Guide).



MATERIAL



Effitec
(30 G - 9 mm)



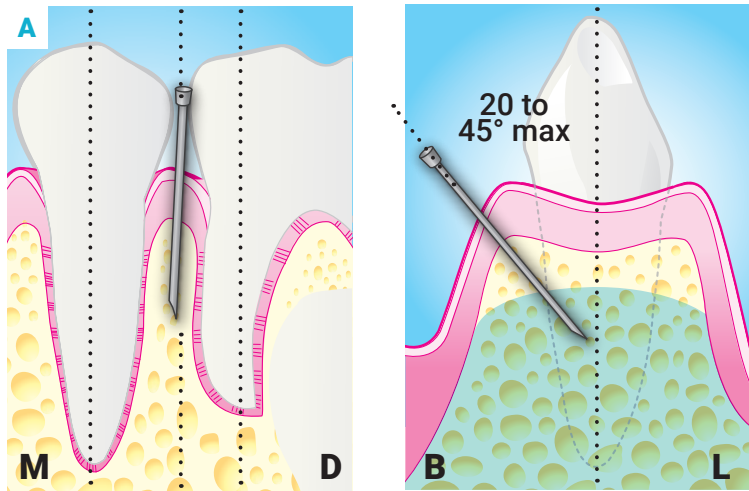
1/2

Mode to select:



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GUIDANCE FOR INTRAOSSEOUS FOR CHILDREN



Mesio-distal plane

Bucco-lingual plane

MATERIAL



Effitec
(30 G - 9 mm)



1/2

Mode to select:



CHARACTERISTICS

PATIENTS
Children

FIELD OF ACTION

- Immediate anesthesia of up to 6 teeth.

INDICATIONS

- Maxillary and mandibular teeth.
- Primary teeth.

⚠ WARNING

- Never inject into an infected site.
- The use of SleeperOne5™ for intraosseous anesthesia is contraindicated when the patient's bone characteristics in relation to their growth are likely to prevent easy penetration of the needle (always check X-ray for bone density).

OPERATION GUIDE

STEP 1 - ATTACHED GINGIVA ANESTHESIA

Proceed as indicated on page 4.

This step allows to reduce pain for attached gingiva anesthesia.

STEP 2 - INTRAOSSEOUS ANESTHESIA FOR CHILDREN

PREPARATION

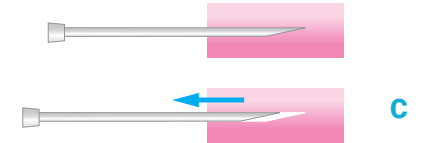
- In the mandible, the anesthesia is ideally performed **distally** to the tooth to be treated.
- Place the Effitec needle at the summit of the papilla directing it between the apices of the 2 adjacent teeth.
- The handpiece should be held as described on page 4 to ensure accurate needle position and avoid needle twisting (B).

OPERATION

- Penetrate the interdental septum towards its middle. You may feel the same sensation as if passing through an egg shell when the needle enters the spongy bone. (A).
- Before proceeding with the injection, slightly draw back (C).



B



C

⚠ WARNING

Use of a radiograph is highly recommended to identify an interdental space where there is enough spongy bone to make the Effitec needle penetration. Never inject in the furcation of multi rooted teeth.

Adapt needle angle to stay in the middle of the bucco-lingual plane.

It is important to penetrate at least ¾ of the length of the 9 mm Effitec needle before intraosseous injection in order to avoid any bone necrosis.

It's not recommended to insert the whole needle, to remove it easily in case of needle breakage.

If the intraosseous technique is not possible, opt for other anesthesia technique.

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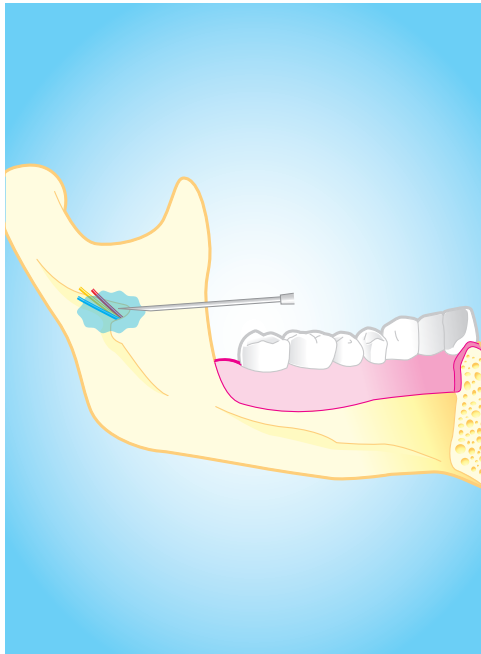
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GUIDANCE FOR INFERIOR ALVEOLAR NERVE BLOCK (IANB)



CHARACTERISTICS

PATIENTS
Adults

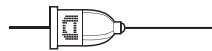
FIELD OF ACTION
- anesthesia of a half mandible.

INDICATIONS
- Conventional IAN block as performed with a traditional syringe.

CAUTION

- Additional anesthesia may be required.
- This type of anesthesia can be the cause of lip biting.

MATERIAL

 Standard nerve block needle

 x 1

Mode to select:



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OPERATION GUIDE

- The use of support points on the mandible makes it easier to place the needle in the correct position (A).
- Superficial soft tissue anesthesia can be performed similar as described with infiltration anesthesia (page 5).
- Then perform the alveolar nerve anesthesia.
- Correct orientation of the bevel of the Effitec needle (bevel indicator opposite the ramus of the mandible).
- Slowly penetrate the mucosa and inject.
- For aspiration, hold foot down on the return/ aspiration button on the foot pedal (it is important that the plunger is sufficiently advanced into the cartridge to enable this operation) (B).
- Proceed with the injection if aspiration result is negative (no blood visible in the cartridge).



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GUIDANCE FOR PALATAL



CHARACTERISTICS

PATIENTS

Adults / Children

FIELD OF ACTION

- Anesthesia of 2 teeth after lag-time.
- Additional procedure for supra-periosteal anesthesia.

INDICATIONS

- Maxillary teeth (extractions, prolapsed sinus...).

NOTICE

Additional buccal anesthesia may be required.

WARNING

- 1/100,000 (.01 mg/ML) and higher is not advised. Quantity over 1/4 of 1.8 ML cartridge is not advised).

WARNING

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OPERATION GUIDE

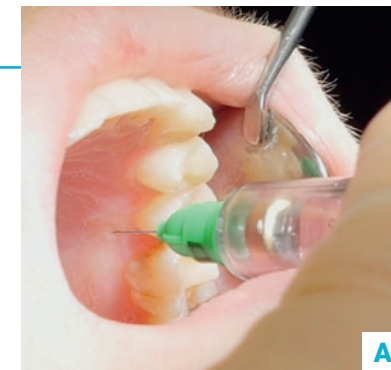
PREPARATION

Respect the golden rules of SleeperOne5™:

- The handpiece must be held as close as possible to the needle, in order to give maximum precision (A).
- The bevel of the Effitec Needle must be correctly oriented (B) for a painless penetration.
- Angulation almost parallel to the surface of the mucosa is necessary to avoid contact with the periosteum (B).

OPERATION

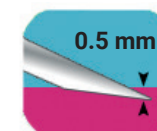
- Start the injection and slowly penetrate the needle into the superficial layer of the palatal mucosa, avoiding touching the periosteum (painful) (C).



A

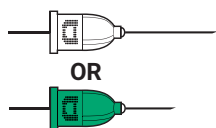


B



C

MATERIAL



OR

Effitec
(30 G - 16 mm)
Effitec
(30 G - 9 mm)



Approx. 1/4

Mode to select:



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SleeperOne ⑤

The practitioner can view an online version of the Manual on the Dentalhitec website in the event that he ever loses his/her copy or in the event that Dentalhitec updates the Manual. Dentalhitec retains the right to modify the Manual as it deems appropriate.

The practitioner is charged with the knowledge of the modifications set forth in the Manual.

See new version if available : www.dentalhitec.com/mydht
Section "Support"

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Dentalhitec

Les stylos d'anesthésie
qui changent la vie



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