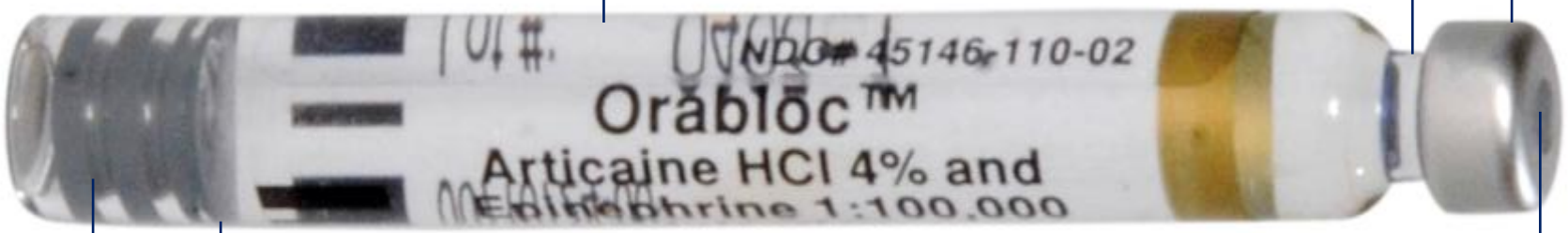
PIERREL

The Orabloc cartridges

Orabloc cartridge components



Aluminum Cap

Neutral USP Type I Glass

Neck

Rubber plunger

Sliding Plunger For Dose Administration

Special Rubber Cap Seal

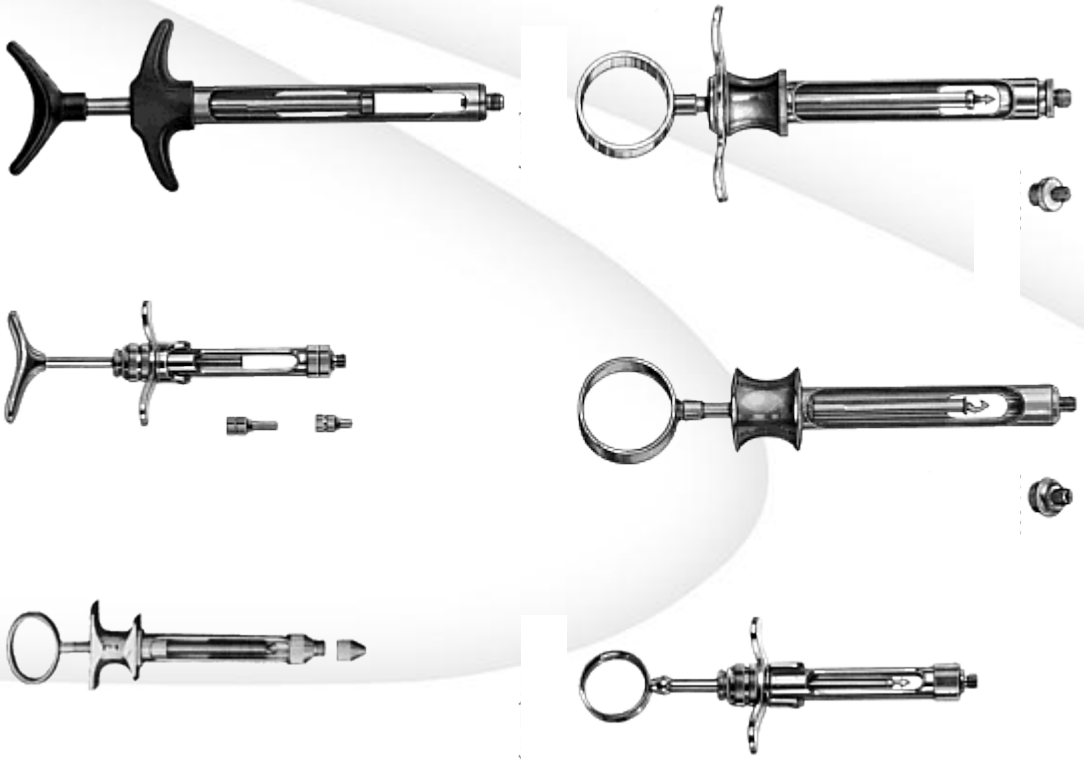
Orabloc cartridge components

The 1.8 ml (or 2.2 UK) dental cartridge consists of 3 parts:

1. Cylindrical glass tube
2. Plunger (Bung or stopper)
3. Combination aluminum cap and seal

N.B. Carpule is the German word for cartridge.

Types of steel syringes used with cartridges:



Parts of the Cartridge and potential problems

- Rubber plunger should be fully inserted, about 2-3 mm inside cartridge
- Do not use cartridges with plunger flush or protruding
- Always place the piston of the steel syringe at the center of the plunger in order to apply an even pressure
- Aluminum cap holds the rubber seal in position
- The rubber seal is penetrated by the syringe needle during use and is made of the same latex free rubber as the plunger; No potential allergies.

Parts of the Cartridge and potential problems

The cartridge must not be immersed in liquids before use:

- Liquid can diffuse into the solution and contaminate the local anesthetic solution (alcohol often used for disinfecting)

The cartridge is 'wrapped' in a transparent plastic label:

- Identifies the content and batch data, also prevents wounds from shattered glass fragments in the event of accidental shattering.

Composition of Local Anesthetic Cartridge

Component	Function	Plain anesthetic solution	Anesthetic solution with vasoconstrictor
Local anesthetic agent (eg USP lidocaine, bupivacaine, mepivacaine, prilocaine or articaine.	Blockade of nerve conduction	Yes	Yes
Sodium chloride USP	Isotonicity agent to keep injection painless	Yes	Yes
Vasopressor ie epinephrine USP	Depth and duration of anesthesia	No	Yes
Sodium metabisulphite USP	Antioxidant	Not necessay	Yes
Water for injection USP	Solvent	Yes	Yes

Purpose of the substances in the Orabloc solution for injection?

- **Articaine Hydrochloride USP: Local Anesthetic,** provides anesthesia; it is a stable and heat resistant drug substance
- **Sodium Chloride USP**: isotonic agent added to make the injection less painful, it is a stable and heat resistant substance
- **Water for injection USP**: Solvent, stable and heat resistant
- **L-Epinephrine tartrate USP:** Vasopressor, increases safety, duration and depth of anesthetic effect; relatively unstable and easily oxidized drug substance which requires protection with an anti-oxidant.
- **Sodium (meta) Bisulfite**: antioxidant (preservative) added to prevent the epinephrine from oxidation

Care and safety in handling the Orabloc cartridge

- Local anesthetic drug is **stable** and can be sterilized, heated, autoclaved, or boiled without being broken down
- The vasopressor and the metabisulphite are **heat labile and oxygen sensitive**, therefore, the cartridge must not be heated or autoclaved
- Each single Orabloc cartridge is **individually sealed** in the blister for maximum cleanliness and protection, the “blister packs” should be stored at room temperature and in the dark
- Bacterial cultures taken off newly opened “blister packs” produce **no bacterial growth** when cultured. Cartridges are ready to be used when removed from the package there is no need to rub the diaphragm with alcohol
- Cartridges must **not be soaked in alcohol** or other sterilizing solutions because there may be diffusion of the alcohol into the drug product.

Care and safety in handling the Orabloc cartridge

- **Cartridge warmers are not necessary**; the patient cannot discern between warmed and room temperature local anesthetic; patients do not complain of the local anesthetic solution feeling cold upon injection
- Local anesthetics that are warmed too much, i.e., > 80 F will be described as too hot or burning upon injection
- Local anesthetic warmers are deceptive if they claim that the injection will be less painful if the anesthetic is warmed
- **Do not hit the thumb ring of the syringe with excessive force** when engaging the plunger with the harpoon although the cartridge is wrapped with a plastic label, the pressure may shatter the glass.

Potential defective cartridges and related consequences

- **Bubble in the cartridge**:

It may be possible that a small bubble (-2 mm) is found in the cartridge, this **is sterile nitrogen gas** since the drug product is manufactured under inert sterile atmosphere to keep oxygen away and prevent oxidation of the sulphite and/or the epinephrine.

- **Extruded Stopper**:

Possibly due to freezing and/or heating at some point and no longer guaranteeing sterility. Discard such cartridges and do not soak the cartridge in ethanol since you may contaminate the solution to be injected.

Potential defective cartridges and related consequences

Potential causes of burning on injection:

- Normal response to the pH of the drug (generally pH 3 to 4)
- Overheated cartridge (local anesthetic warmer) (heating increases reaction/degradation)
- Cartridge containing a vasopressor (decreased pH)
- Vasopressor decreases the pH from 5.5 (plain) to 3.0 – 4.0
- Sodium Bisulfite → epinephrine sulphonic acid and sulphuric acid (much more acidic and lowers the pHs during the shelf life)

Potential defective cartridges and related consequences

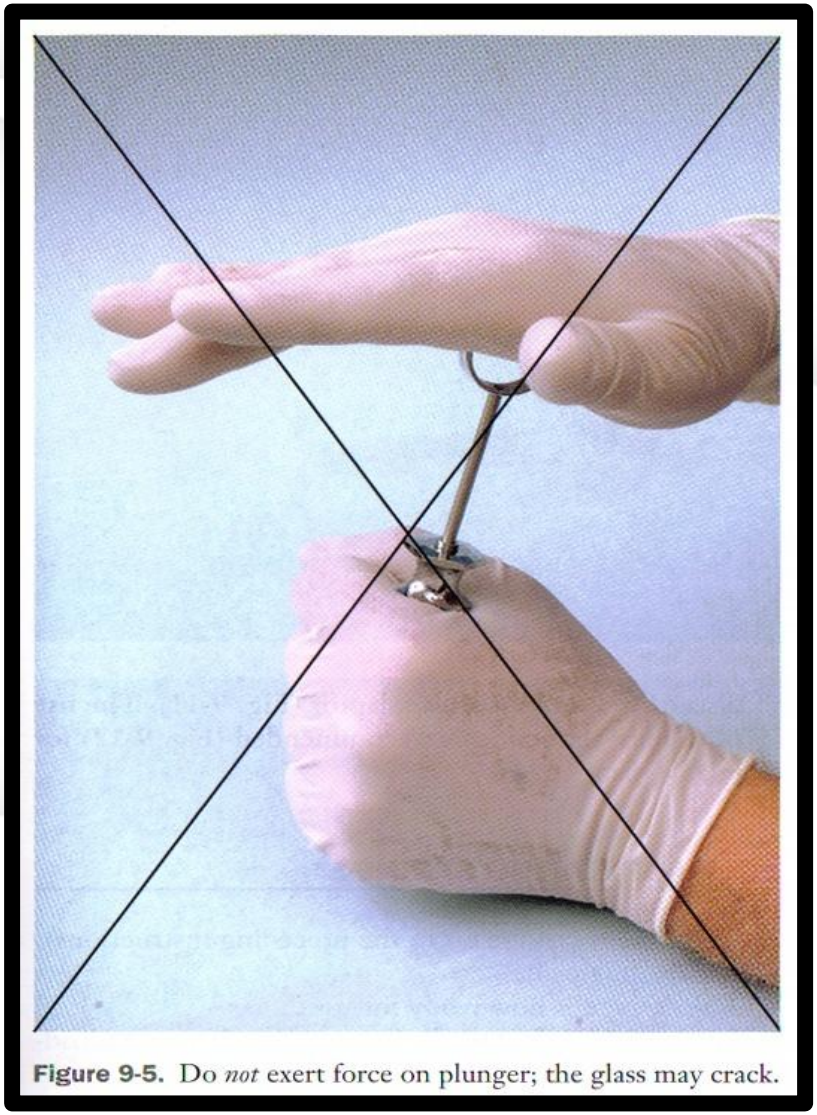


Figure 9-5. Do *not* exert force on plunger; the glass may crack.

Typical complaints from dentists and potential causes

- **Lack of anesthetic effect**: A lot of Orabloc consists of about 250000 cartridges and it is unlikely that only one cartridge does not contain the anesthetic agent. The cause is most probably due to erroneous injection in a vein.

- **Cartridge leaks during injection**: Possible causes are the syringe piston has not centered the plunger and caused it to twist or manipulation of the syringe during injection which has caused needle movement in the rubber cap seal

- **Necrosis at the injection point:** Possible cause is due to excessive movements of needle during injection which causes laceration of local tissues and/or patient's sensitivity.

Typical complaints from dentists and potential causes

- **Paresthesia:** Has been reported but is rare and we suspect that it is due to injection technique and/or patient sensitivity since it is sporadic and never reported several times for the same lot of anesthetic.

- **Visible bubble:** A very small bubble may be present but it should not be visible below the cap. If present in a sealed cartridge it is a sterile nitrogen bubble due to the fact that the product is manufactured under sterile nitrogen atmosphere.

- **Cracked cartridge**: The cartridge has been damaged at some stage during or after packaging, distribution or usage. The cartridge must not be used and the batch statistical incidence should be evaluated.

- **Very important**: Always note lot number of every complaint so that the % incidence of the lot can be evaluated in order to exclude possible manufacturing or testing causes and take appropriate actions.

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Thank you for your attention

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