The Mechanics of the Dental Anesthetic Cartridge

Sponsored by Pierrel, makers of Orabloc®
(Articaine hydrochloridre 40mg/ml and epinephrine Injection)

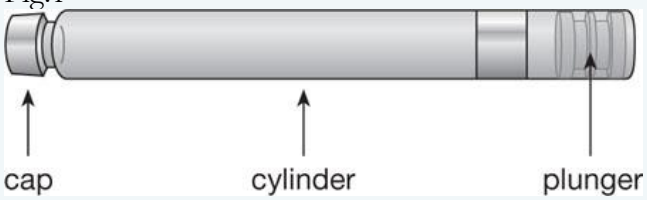
Abstract

Local anesthesia is the fundamental part of the pain-control technique where dental therapeutic progress has been possible thanks to the prevention and elimination of pain.

Not only have new anesthetic drugs been developed, but also the components of the cartridges have been improved in order to allow a safer and pain free experience during dental procedures.

The aim of this short article is to allow professionals to be familiar with dental cartridge components and thus to understand how the mechanics and components of the cartridge work.

Fig.1



Cartridge components

The dental cartridge consists of three parts (Fig . 1):

1. Cylinder
2. Plunger or stopper
3. Cap

1. The Cylinder

The cylinder is the main part of a dental cartridge.
It is a cylindrical glass tube containing the local anesthetic drug and other excipients, closed by a plunger and a cap. While the diameter of the cylinder is the same, the cartridge length can be different depending on the volume of solution. In the United States and in many other countries, the standard is 1.8/1.7 mL. In the UK and Australia, the 2.2 mL volume is still used.

Some manufacturers have tried to introduce plastic cartridges into the market because they are less expensive. This has resulted in negative experiences such as leakage of solution during injection, mostly due to an increased friction factor between the plastic cartridge and the rubber plunger. Plastic cartridges are also permeable to air, and this means that an increased exposure to oxygen leads to more rapid degradation of the vasoconstrictor, and consequently reduced shelf life for the local anesthetic.

Usually, the best quality cartridges are made of clear glass type I (compliant to Pharm. EU / USP / JP), certified for dimension, 100% visually inspected, and designed according to international standards, e.g. DIN ISO 11040-1 and 13926-1.

2. The Stopper (or Plunger)

The stopper (plunger or bung) is made of rubber that can be of a different quality and type. Today two classes of rubber are mainly utilized: one of chlorobutyl rubber, the other made of bromobutyl rubber. The stoppers must comply to the EP (European Pharmacopeia) 3.2.9 requirements applicable for rubber closures and must also comply to some physical (hardness, specific gravity), biological and others characteristics like UV reference, moisture vapor transmission, and oxygen transmission, etc[1].

Plungers found in cartridges are of two types:

- Solid
- Hollow

The hollow one is designed to fit with the special plunger rod typical of self-aspirating syringe systems.

In the past stoppers were sealed with paraffin in order to produce an airtight seal against the glass walls of the cartridge. Glycerin was added into the channels around the stopper as a lubricant, allowing it to slide into the glass cylinder more easily. Today, most plungers are siliconized thus eliminating the need of both the paraffin and the glycerin. As a matter of fact, "Sticky stoppers" (stoppers that do not move smoothly down the glass cartridge) are infrequent today.

3. The Cap

The cap is located at the opposite end of the cartridge from the rubber plunger, and it is composed of a rubber diaphragm contained into an aluminum metal ring. The aluminum is usually in a natural grey color but sometimes it can be colored in association to the type of the solution inside the cartridge. The diaphragm rubber is typically made of the same kind as the plunger rubber (usually Bromobutyl rubber).

The cap is gripped around the neck of the cartridge, and the diaphragm is penetrated by the needle, allowing the needle lumen access to the anesthetic solution.

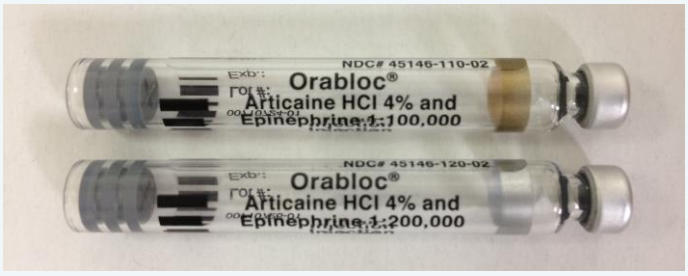
The diaphragm is a semipermeable membrane that would allow any solution in which the dental cartridge could be immersed to diffuse into the cartridge, thereby contaminating the local anesthetic solution.

4. Cartridge Components Processing

Cartridge component processing can be a source of risk and variability. For that reason it is important the supplier guarantees the best manufacturing and control in accordance to the EU and US Pharmacopeia.

The Orabloc® glass cylinder is produced from borosilicate glass tubing and 1% hydrolytic glass, according to the current editions of the USP and EuP. The Orabloc® plunger and cap are made with latex free bromobutyl rubber, eliminating the risk of latex related allergies. The plungers are siliconized.

The rubber composition of the plungers and caps complies with the chemical requirements in the corresponding monographs 3.2.9 for "rubber closures" Type 1 in the valid version of the Eu Pharmacopeia, as well as with the physicochemical tests, as described in the current USP General chapter "Elastomeric closures for injection".



5. Handling cartridges with care

Cartridge must not be immersed in liquid before use.

Liquid can diffuse into the solution and contaminate the local anesthetic solution (usually alcohol which is often used for disinfecting).

Cartridges are ready to be used when removed from the package. Today most cartridges are individually sealed in blister packs of 10 cartridges each, where the cartridges remain clean and uncontaminated if kept in this container before use.

Cartridges must **not be soaked in alcohol** or other sterilizing solutions because there may be diffusion of the alcohol into the drug product.

The cartridge must not be sterilized before use.

Even if the local anesthetic drug is stable at high temperature, the vasoconstrictor (epinephrine) and the metabisulphite are **heat labile and oxygen sensitive**, therefore, the cartridge must not be heated or autoclaved.

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.

Storing cartridges

The "blister packs" should be stored at room temperature and in the dark (i.e. in the original box).
In the case of Orabloc®, each single cartridge is **individually sealed** in the blister for maximum cleanliness and protection.

Do not hit the thumb ring of the syringe with excessive force.

When engaging the plunger with the harpoon, the pressure may shatter the glass even though the cartridge is wrapped with a plastic label.

6. Q&A

Potential issues with any cartridge components

The cartridge should not be used if one of the following defects are observed:

- ***Plunger flush or protruding***

The rubber plunger should be fully inserted, about 2-3 mm inside cartridge. Plunger flushed means that the volume of expected anesthetic solution is not in the cartridge and the cartridge should be discarded.

Extruded plunger

Plunger protruded means a possible extrusion of the plunger from the end of the cartridge, possibly due to freezing or heating at some point and sterility is no longer guaranteed. Possible contamination may occur, so the cartridge must be discarded. Do not soak the cartridge in alcohol since the solution to be injected can be contaminated.

Technical tip: always place the piston of the syringe at the center of the plunger in order to apply an even pressure.

Actions: *discard the cartridge and inform the manufacturer of the issue providing full details of the complaint (lot number, defect description, etc.).*

- ***Cleaning, heating and storing of the cartridge***

When chemical disinfection of the cartridge is necessary, swabbing the cartridge with either isopropyl alcohol (91%) or ethyl alcohol (70%) is recommended.

Heating of the cartridge is not recommended as stability of the cartridges, and more specifically of the epinephrine contained in the dental cartridge might be compromised if the cartridge is exposed to temperatures over 25°C.

Store at 25°C (77°F) with brief excursions permitted between 15° and 30°C (59°-86°F) [see USP Controlled Room Temperature]. Protect from light.

Actions: *Do not soak the cartridge in alcohol since the solution to be injected can be contaminated. Do not warm cartridges above 25°C (77°F.) Do not freeze.*

- ***Damaged cap***

A damaged cap (at the aluminum side or at the diaphragm rubber side) indicates that the seal of the cap is not guaranteed and the solution could exit from the neck of the cartridge into the mouth of the patient (Leakage effect). It also means that air may have entered the cartridge causing contamination and/or degradation of the vasoconstrictor inside.

Actions: *in the case of a damaged cap, discard the cartridge and inform the manufacturer of the issue providing full details of the complaint (lot number, defect description, etc.)*

- ***Cartridge leaks during injection***

Another possible cause of leakage effect is the syringe piston has not been centered on the plunger. Manipulation of the syringe during injection can also cause needle movement in the diaphragm rubber seal.

Actions: *always place the piston of the syringe at the center of the plunger in order to apply an even pressure. If a leak appears, discard the cartridge and inform the manufacturer.*

- ***Bubble in the cartridge***

Small bubble

Small bubbles may be present but should not be visible below the cap. It may be possible that a small bubble (less than 2mm) is found in the cartridge. Since Orabloc® is manufactured under inert sterile atmosphere to keep oxygen away and prevent oxidation of the sulphite and/or the epinephrine, the eventual small bubble is sterile nitrogen gas.

Large bubble

Actions: *shake the cartridge and place it vertically with the cap uppermost. Bubbles should disappear in the neck; if not, then the bubble is too large and the cartridge must not be used. Discard the cartridge and inform the manufacturer.*

- ***Cloudy solution***

Cloudy solution might indicate contamination by microorganisms and lead to the transmission of infected material to the patient.

Actions: *as with all parenteral drug products, cartridges should be inspected visually for particulate matter and discoloration prior to administration*

- ***Cracked cylinder***

The cartridge has been damaged at some stage after packaging, during distribution or usage. Cracked cartridges can be highly risky because they may break during use, and solution and/or pieces of broken glass could go into the patient's mouth.

In addition, the crack may allow liquid solution contamination. Cracked cartridges must not be used.

Actions: *in the case of a cracked cylinder, discard the cartridge and inform the manufacturer of the issue providing full details of the complaint (lot number, defect description, etc.)*

Summary

In summary, the mechanical components of anesthetic cartridges are similar but with varying distinguishing differences. Careful handling and storage is also important to maintain the integrity of these products as well as their safe administration in the clinic.

References

[1] Public Assessment Report Scientific discussion Change in qualitative and quantitative composition of rubber stoppers of West Pharmaceutical Services, July 2008

[2] Meechan, JG. Pratical Dental Local Anesthesia, 2010