



PAIN CONTROL **LEADERSHIP**
THAT SHAPES THE DENTAL WORLD



Not all products shown on this cover are available in UK.



Septodont

in Pain Control

Since its founding in 1932 by Annie and Nestor Schiller, Septodont has been in the forefront of pharmaceutical dentistry. Today, Septodont is composed of over 1,000 employees, seven manufacturing facilities in France, North America and India, four R&D centers and an international distribution network, all 100% dedicated to serving the needs of dental professionals. With a commitment to developing new technologies that contribute to improved dentistry, Septodont has strengthened its position in endodontics, restoratives, periodontology and impressions with highly innovative and valuable products, like N'Durance, N'Durance Flow, Racegel and Biodentine. But pain control remains our core expertise.

Septodont: world leader in pain control

Anaesthetic procedures are performed every day by every dentist in the world. It's a key moment for both the dentist and the patient, and it drives the rest of the consultation. In a recent study, patients ranked the criteria involved in their judgement of their practitioner: their second highest priority was a dentist who does not hurt. And their highest priority? Painless injections! Clearly what you choose to use in your anaesthetic procedures is very important. When you choose Septodont you have a partner to help ensure that this potentially unpleasant moment is instead one that instills confidence.

We want to prevent pain from hurting your practice. That's what we call caring... caring about your patients, caring about you. It's why the world leader in injectables has become the world leader in pain control, developing, manufacturing and offering the most complete range of products used in dental anaesthetic procedures, including needles, syringes, safety devices, topicals and injectables.

This leadership has been built step by step thanks to a permanent commitment to high quality and innovation, earning the approval of almost 100 health authorities around the world.

- **1932: foundation of Septodont by the Schiller family.**
- **1950's: Septodont is among the forerunners to provide local anaesthetics in cartridge form.**
- **1960's: Septodont introduces its mepivacaine and lidocaine anaesthetics in many European countries.**
- **1970's: Septodont launches its articaine (Septanest) in France.**
- **1991: Septodont launches the first device to avoid needle stick injuries, called Safety Plus.**
- **1999: Septodont launches the first needle with larger bore (Septoject XL) for increased comfort during injection.**
- **1998: Septodont introduces Septanest (articaine) into the UK**
- **2000: Septodont introduces articaine in the United States.**
- **2000: Septodont launches Ultra Safety Plus, safety device with improved technology.**
- **2007: Septodont launches its innovative range of syringes adapted to every practitioner's hand size: Vivaject.**
- **2011: Septodont launches an innovative needle with a unique patented scalpel-designed bevel: Septoject Evolution.**





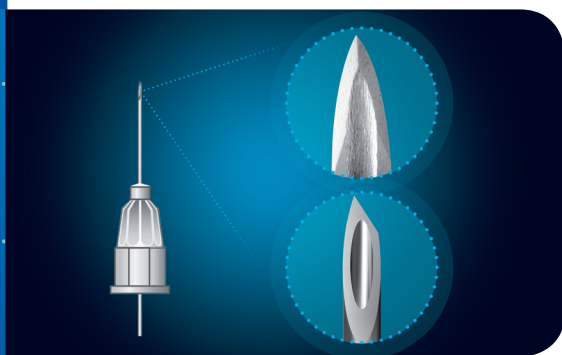
ANAESTHETICS

PAIN CONTROL



- SEPTOJECT
- SEPTOJECT XL
- SEPTOJECT EVOLUTION

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⦿ A needle is more than “just a needle”

Because an anaesthetic procedure is so important in your practice, every component of that procedure must be chosen carefully... and critical differences are evident when you compare the disposable needles available on the market.

Realizing that a needle is more than a commodity, Septodont has developed since 1990 an affiliate wholly dedicated to developing and manufacturing high quality needles. This facility, at the cutting-edge of technology produces 200 million needles annually, corresponding to 30% of the world production. Moreover, the R&D center has led to the introduction of breakthroughs such as the first dental XL needles (larger bore) and the first safety device (Ultra Safety Plus) to avoid needle stick injuries.

The story continues as we once again provide dental professionals with innovation in pain control, with Septoject Evolution. That's our approach to bringing value into the needles market.





Septodont Needles

☉ A Septodont affiliate 100% dedicated to dental needles

The Septodont needles operation is one of the world's most important manufacturing sites specialized in disposable dental needles. Based in Mazamet (France), more than 100 people work in developing, manufacturing, testing and marketing high quality dental needles.

Throughout its history, Septodont has maintained QUALITY as the core value in its day-to-day activities. But what exactly does QUALITY mean for Septodont needles?

Quality in:

1 Answering your needs with innovations:

During the last decade, Septodont has identified market needs through market research and round tables with authorities (WHO Safe Injection Global Network, ISO working groups on safety injection device standards, etc). This has enabled us to both anticipate and better understand the needs of dental professionals. Thanks to this constant listening, we were the very first company to provide XL needles with a larger bore for increased comfort and Ultra Safety Plus, the safety device to protect practitioners from needle stick injuries.

2 Providing safe and reliable products:

All the needles and safety devices shipped from our manufacturing facilities have passed over 40 technical and physical controls. Furthermore, every production site, every manufacturing process is audited on a regular basis by the most demanding health authorities around the world.

3 Continuous improvement:

If developing innovations is our vision, constantly improving them is our commitment. That's why we are so eager to get clinician's feedback and why we perform satisfaction surveys on a regular basis. Thanks to this feedback, we have been able to regularly introduce new improvements to needles and safety devices.

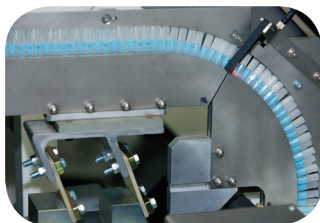
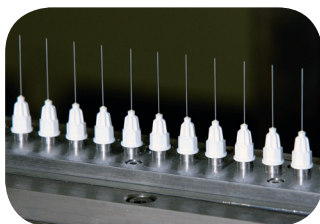
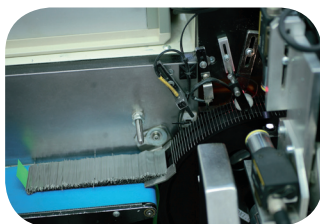
4 Environmental management processes:

Septodont's needle affiliate obtained its Environmental Certification in 1998, a time when very few companies were concerned with this issue. We pay close attention to the choice of materials, the reduction of waste during production and saving energy.

- **ISO 9001: quality management system.**
- **ISO 13485: quality management system for the design, development and manufacture of medical devices.**
- **ISO 13485 with CMDCAS: quality management system for the design, development and manufacture of medical devices.**
- **ISO 14001: environmental management system.**
- **EC Certificate: products complying with the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.**

A manufacturing process committed to quality

- Manufacturing a high quality dental needle is a long and technologically complex process that requires precision and specific technical mastery, from the selection of highest quality stainless steel to final sterilization step.



- Selection** of highest quality stainless steel
- Rolling** of a stainless steel strip
- Welding** into a tube
- Calibrating** the tube
- Annealing** ➤ Hydrogen atmosphere > 1000°C
- Stretching** to obtain the final diameter ➤ 1.5 million 30 gauge needles obtained from a 1500 m long steel strip
- Straightening** the tube
- Cutting** to final length ➤ Single cut before bevel sharpening
- Sharpening** the bevel ➤ Automatic process for perfect sharpening
- Sanding** the cannula ➤ To remove any steel particles
- Polishing** the cannula ➤ To remove any rough edges
- Injecting** plastic parts (hub, sheath) ➤ In a controlled atmosphere room (< 105 particle/m³)
- Assembling** a cannula with a hub ➤ To securely position the cannula in the hub, and thus control the length available for injection
- Gluing** the 2 parts
- Coating** the cannula with silicone
- Sheathing** of the needle
- Sealing** with a label ➤ Ensures the integrity of the needle
- Packing** by 100 needles per box
- Sterilizing** with ethylene oxide ➤ Last and key step to ensure practitioner and patient safety

Q Quality Control



Septoject, your standard needle for any anaesthetic procedure

Features & benefits

- Excellent tissue penetration achieved with a high quality triple-bevel needle with polished and siliconized cannula.
- High grade surgical stainless steel tubing to reduce risk of breakage.
- Bevel mark to ensure good orientation of the bevel.
- Plastic hub with imperial thread.

Length	Gauge	Colour code
Short - 25 mm	30 G	Blue
Short - 25 mm	27 G	Orange
Long - 35 mm	27 G	Yellow



Every practitioner can experience difficulties with the penetration and trajectory of a dental needle, which is often directly related to the pain felt by the patient, both at the time of application and afterwards. The causes of these difficulties for the practitioner and discomfort for the patient are often attributable more to the dental needle itself than to the application technique.

An independent study, published in 2005^(1,2), performed an electron microscope scan to take a close look at seven commonly used brands of disposable dental needles. It revealed manufacturing defects at the needle point, such as burrs, jagged edges and blunt points.

Other Brands



Septoject



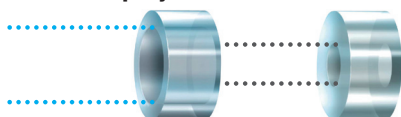
This comparative study concluded that among these seven well-known brands.

“...the best quality were the Septoject needles from Septodont”

(1) Evaluation microscopique des aiguilles dentaires. Diego Espinosa Sanchez and Roberto Espinosa Ferandez. University center of Health Sciences, Guadalajara, Mexico. Le Chirurgien Dentiste de France No. 1206, du 07 avril 2005





(2) Assessing dental needles. Diego Espinosa Sanchez and Roberto Espinosa Ferandez. University center of Health Sciences, Guadalajara, Mexico. The Dentist. January 2007. 66-68

Septoject XL Standard Needle



- **Comfort:** Larger bore requires less effort to inject even in dense tissues.
- **Increased flexibility** thanks to thinner walls.
- **Improved aspiration.**
- **Same tissue penetration** as a classical needle (triple bevel and siliconized cannula).

Septoject *XL*

Length	Gauge	Colour code
X Short - 10 mm	30 G	
Short - 25 mm	30 G	
Short - 25 mm	27 G	
Long - 35 mm	27 G	



● For nearly 30 years THE DENTAL ADVISOR has provided the dental profession with concise, accurate, objective, evidence-based information on dental products and equipment. THE DENTAL ADVISOR reports objective clinical evaluations – performed by a team of over 250 practicing clinicians, comprehensive long-term clinical performance studies, and unbiased laboratory testing in every issue of THE DENTAL ADVISOR.

Septoject XL was clinically evaluated by clinical consultants from THE DENTAL ADVISOR and was rated ++++1/2 and was also selected as one of the **2011 Preferred Products** in the Anaesthetic, Injectable category.



• Dental Product Shopper is an independent organization which has created an evaluation program of new products in order to help clinicians in their purchasing choices. Selected voluntary clinicians conduct a four-week evaluation of the product in their private practice and then report the results to Dental Product Shopper. In 2010, Septoject XL was evaluated by 11 US clinicians.

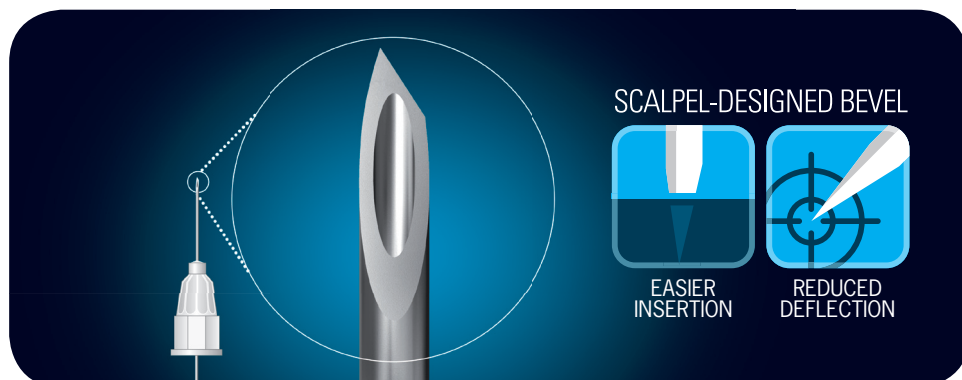
The clinicians involved rated Septoject XL at 4.3/5, which led it to being cited as the “Best Product 2010”.



Septoject Evolution

NEW

⦿ The innovative needle with a patented scalpel-designed bevel



Features & benefits

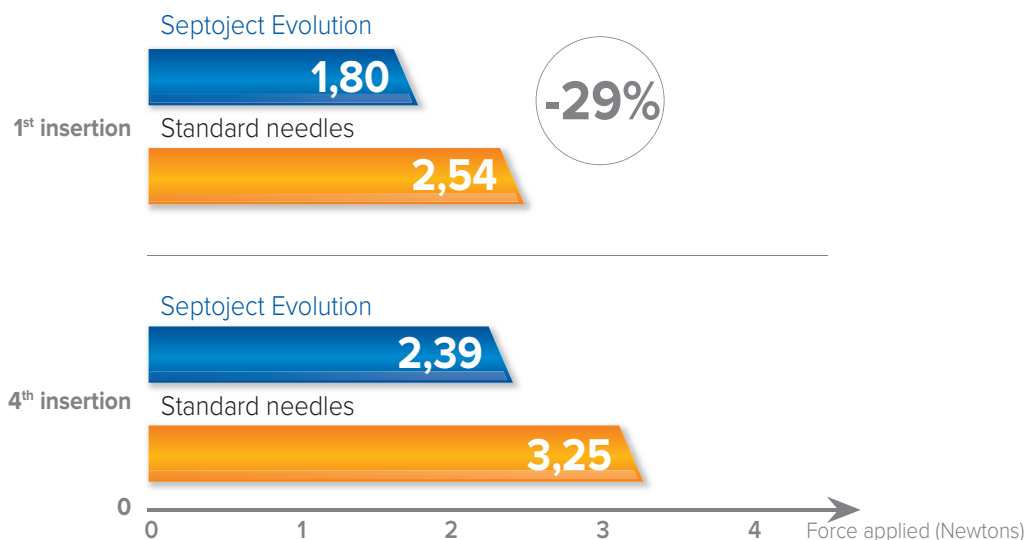
- **Reduced discomfort** for your patient
- **Increased control & accuracy** for you

Septoject Evolution is engineered for a smoother penetration with less tissue displacement. This means less discomfort for your patients, even when used for multiple injections. For you, less force required combined with the significantly reduced deflection brings you better control and accuracy.

⦿ Easier insertion

- ⦿ **Easy penetration:** 29% less force required for insertion with Septoject Evolution
- ⦿ **Ideal for multiple injections:** 4th insertion with Septoject Evolution still requires less force than 1st insertion with a standard needle

● Force required (Newtons) for a 10 mm penetration of a silicone block. ⁽¹⁾



(1) A. Steele *et al.* Submitted for publication.

Septoject Evolution

⦿ Infiltrations

• Techniques:

Infiltrations (periapical)
PSA - posterior alveolar nerve block
MSA - Middle superior alveolar nerve block
Palatal anaesthesia

Gauge	Length	Colour
27 G	Short 25 mm	Orange
30 G	Short 25 mm	Blue



⦿ Intraligamentary injections

• Techniques:

Intraligamentary injections
Intraseptal injections
Intraosseous injections

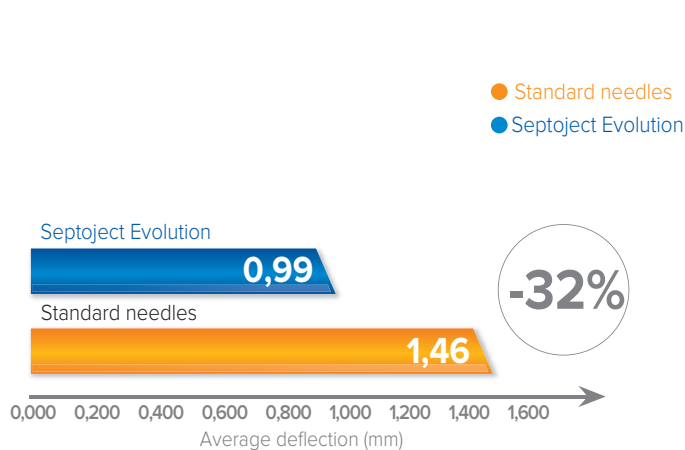
Gauge	Length	Colour
30 G	X - Short 9 mm	Purple



⦿ Reduced deflection

⦿ **Better accuracy** thanks to limited deflection of Septoject Evolution.

⦿ Comparative deflection (in mm) of the needle after penetration through a 10 mm block of silicone.⁽²⁾



(2) JG Meechan *et al.* Submitted for publication.



- **ULTRA SAFETY PLUS**





ⓘ Globally, injuries caused by needles and other sharp instruments are one of the most common and serious risks to healthcare workers and also represent a high cost for health services and society in general. Some studies estimate the number of needle stick injuries at approximately 1.2 million per year in Europe... and dental staff are of course particularly exposed to that risk.

Protection of health workers from needles stick injuries has been intensely debated in many countries. For instance, in June 2010 the Commission of the European Communities published a directive giving legal effect to the Framework Agreement on prevention of sharp injuries. Two of the main measures that have to be undertaken by healthcare professionals are to banish the practice of recapping and to use personal protective equipment when available.

For Septodont, being your partner in pain control means coming up with new technologies to improve safety. Septodont started a specific R&D program many years ago with the goal of reducing the risk of needle stick injuries in dentistry. Thanks to that investment, Safety Plus, the very first disposable safety device in dentistry, was launched in 1991 and then continuously improved to become what is now Ultra Safety Plus.

In 2010 in respond to customers feed-back we took a step forward to increase your safety and your comfort with the launch of sterile disposable handles for USP.





Ultra Safety Plus

NEW

100% sterile, 100% disposable

⦿ The original safety device that makes all your injections safer and easier

Disposable, sterile handle

New polypropylene handles are now sterile and individually packed for increased safety.



Disposable, sterile & protected needle

Ultra Safety Plus is fitted with high quality Septodent needles, protected by a sliding sheath.

For "How to use" instructions, please see next page.

Design to meet safety standards and protect the clinical team

Features & benefits

- Entire device is completely disposable ➔ saves time and trouble.
- Entire device is completely sterile ➔ protects against cross-contamination and also saves in reprocessing costs of handles.

SEPTOJECT
• ULTRA SAFETY PLUS
ARTICAINE PETITE

Feature Bevel indicator
Benefit Needle can be inserted into tissue correctly, needle blockage

Feature Clearly defined and tactile reversible first holding position
Benefit Protects the Practitioner and DSA during cartridge reloading

Feature Sterile and disposable handle
Benefit Increased ease of use, increased safety

Feature Improved and positive permanent final locking position
Benefit Protects the Practitioner and DSA during safe disposal

Feature Reloadable
Benefit Ideal for extended procedures and use of different anaesthetics

Feature Handle has been re-designed with a shorter length
Benefit Better comfort for small handed practitioners

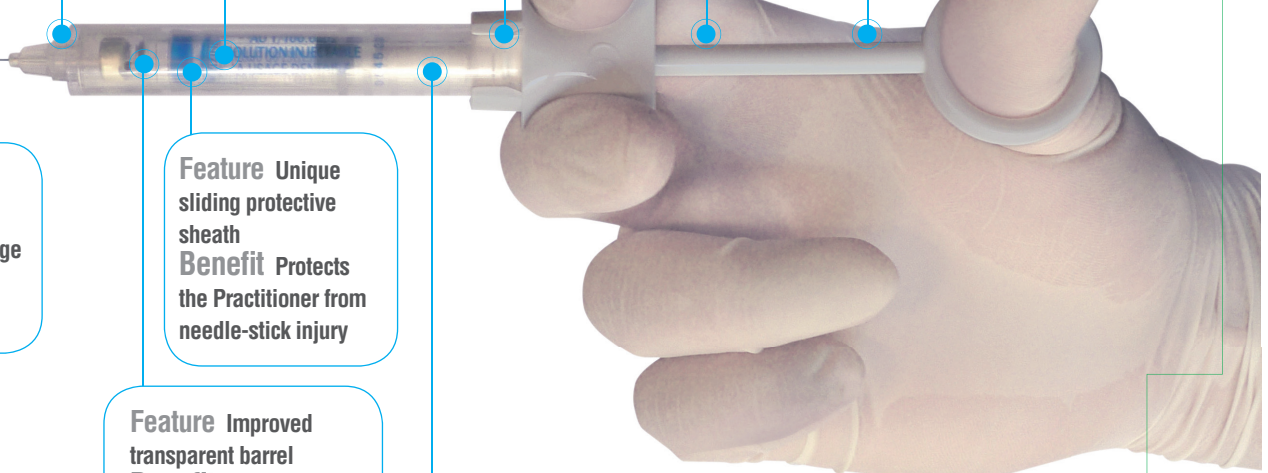
Feature Fitted with Septoject
Benefit No need to change your habits for increased protection

Feature Unique sliding protective sheath
Benefit Protects the Practitioner from needle-stick injury

Feature Improved transparent barrel
Benefit Aspiration is clearly visible

Feature Finger grips incorporated on the protective barrel
Benefit Wet gloved hands less likely to slip

Feature Active aspiration
Benefit Security for the patient





Ultra Safety Plus

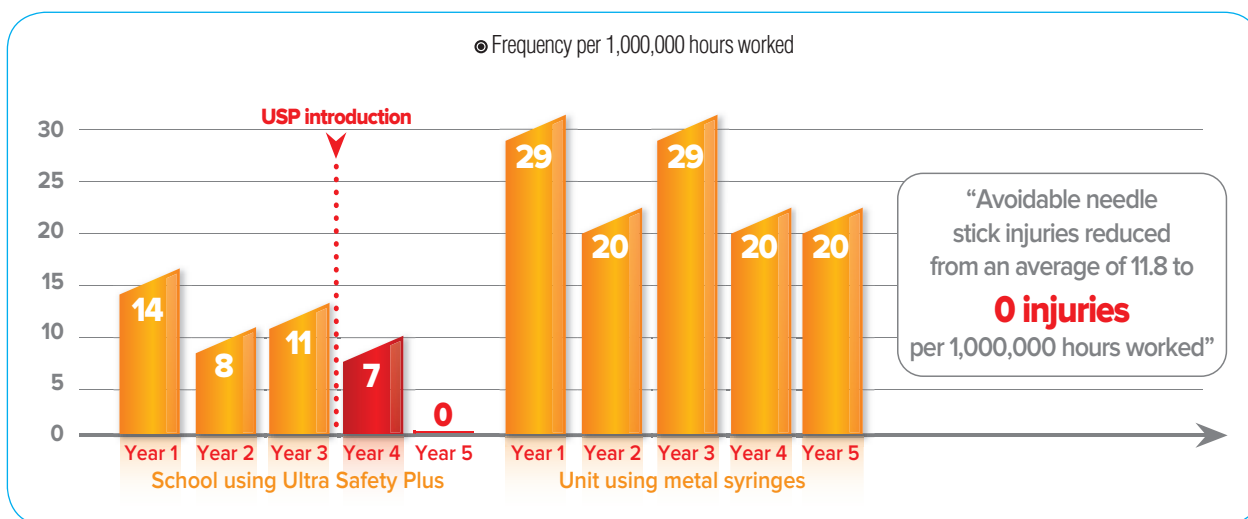
Ultra Safety Plus significantly reduces needle stick injuries ⁽¹⁾.

• Methodology:

All needle stick injuries were documented for five years at two different sites:

- 1 **A dental school**, where Ultra Safety Plus was introduced after the third year of this study.
- 2 **A busy surgical unit** (using metal syringes) was used as control in the study.

• Frequency of needle stick injuries



• Economical impact of a needle stick injury

A long-term study (published 2001) of the costs associated with the different levels of needle stick injuries has also been performed, with the following results:

- A needle stick injury, with no drugs, no starter pack: £136.04.
- A needle stick injury, with starter pack, no further drug course: £296.89.
- A needle stick injury, with full drug course, no work absence: £2,151.70.
- A needle stick injury, with starter pack, full drug course, no work absence: £3,845.31.

“The cost of safety syringes is comparable to non-disposable syringes but the reduction in cost of management of needle stick injuries, including the psychological effects is significant.”

(1) J.M Zakrzewska *et al.* Introducing safety syringes into a UK dental school – a controlled study. *Brit Dent J* 2001 ; 190; 88-92.

Ultra Safety Plus: a range of solutions



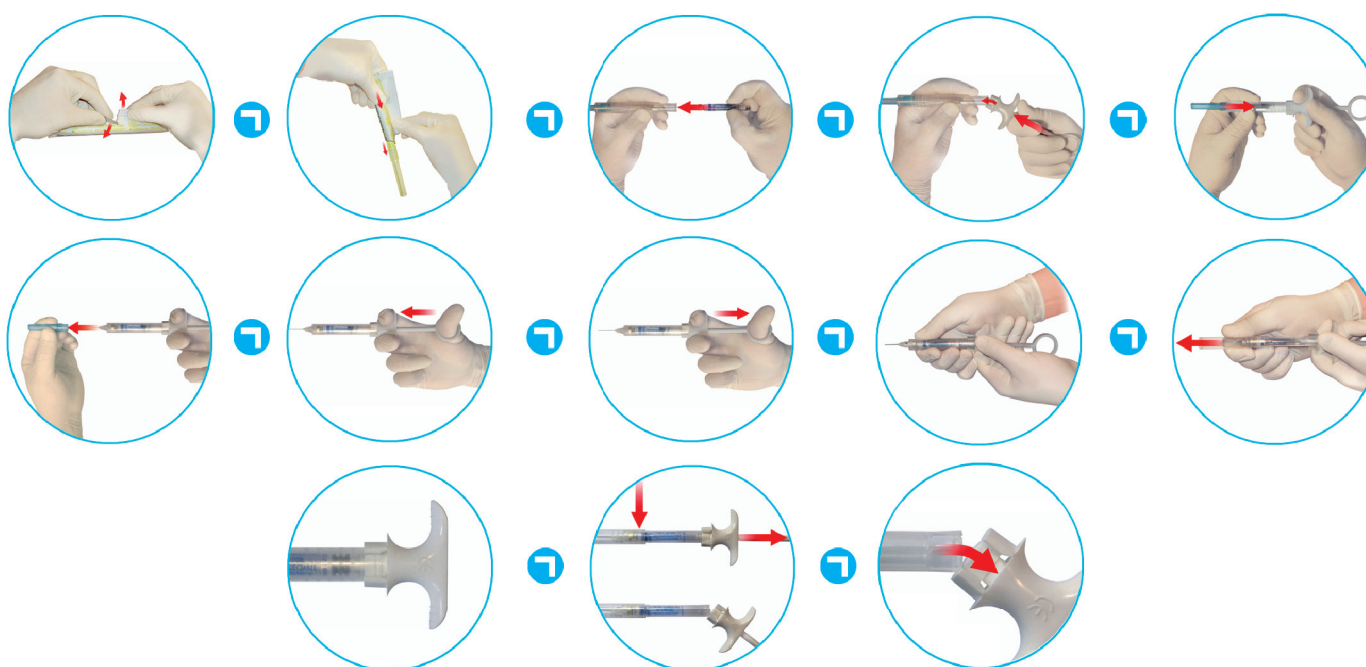
1 box of 50 STERILE protected needles
1 box of 50 handles



1 box of 100 STERILE protected needles
+ 1 autoclavable black handle

Length	Gauge	Colour code
X Short - 10 mm	30 G	Purple
Short - 25 mm	30 G	Blue
Short - 25 mm	27 G	Orange
Long - 35 mm	27 G	Yellow

How to use Ultra Safety Plus





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◎ Every second, 15 dental injections are carried out using Septodont local anaesthetics

Septodont is a pharmaceutical company dedicated 100% to improving dentistry. Anaesthetic molecules and drug formulations have long been our core expertise, and we have an ongoing commitment to research, development and continuous improvement. This dedication, combined with regular approval from health agencies throughout the world, has earned the trust of dental professionals and has made Septodont the world leader in pain control:

- Every year, over 500 million injections are performed with Septodont's local anaesthetics around the world.
- Our pain control line has been designed to serve the needs of dental professionals in almost 100 countries, offering the largest choice of molecules, pharmaceutical formulations and package sizes.

This unique pain control line is the result of our determination to answer your needs perfectly, based on a constant reexamination of anaesthesia procedures. Some key points reflect this vision:

- In 2000, US dental professionals welcomed for the first time articaine in their armamentarium, thanks to Septodont's launch of Septocaine, after performing six large scale clinical trials (safety-efficacy-hemostasis, maximum dosage). US dentists have since made Septocaine the #1 branded product in dentistry*.
- Septodont introduced articaine in 1 ml cartridges, for patients not requiring a full cartridge. Since 2007, Septodont has been the only pharmaceutical company that offers articaine in 2.2 ml, 1.7 ml** and 1 ml** cartridges to meet pain control needs precisely all over the world and for all patients, whatever their size.
- Septodont provides lidocaine, the historical gold standard local anaesthetic, not only in injectable cartridges (with or without epinephrine) but also in many other pharmaceutical forms throughout the world - gel, solution**, pellets** and spray - to work with every application of anaesthetic of anaesthesia.

The result of our unique commitment is a real partnership established between Septodont and dental professionals around the world. In a 2009 satisfaction survey performed in Germany, the United Kingdom and the United States, dental professionals graded Septodont at 8.5/10 on overall satisfaction***.

This gives strong encouragement to Septodont to continue developing products for improved pain control.

* (Source: SDM data 2009)

** Not available in UK

*** 7 items evaluated: "Offers safe and reliable products / Manufactures high quality products / Good personal experience with this manufacturer / Innovative Company / Leader in the field of dentistry / Dedicated to the field of dentistry / Offers a broad range of products"

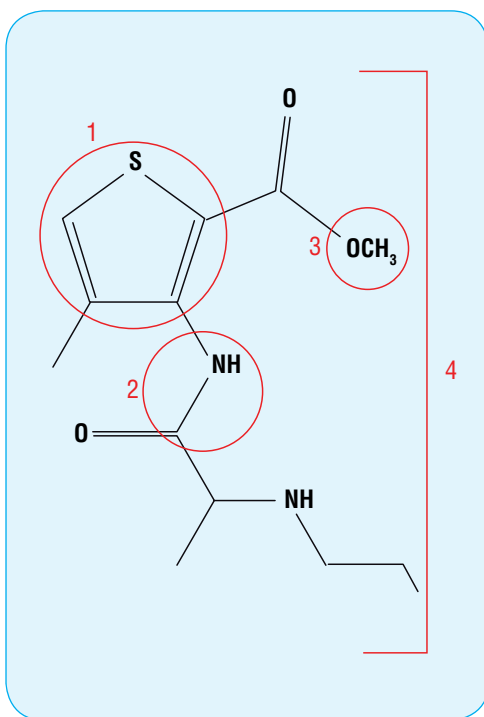


Articaine

Originally introduced for clinical use in Europe in 1976 and in UK in 1998, articaine has become a **leading local anaesthetic** in almost every country into which it has been introduced.

- Germany: 96.8% of injectables used in dentistry⁽¹⁾.
- USA: 32.4% of injectables used in dentistry⁽²⁾.
- UK: 27% of injectables used in dentistry⁽²⁾.

Why is that?



	Features	Advantages	Benefits
1. Thiophen ring	Increased liposolubility	Increased potency Increased diffusion	Less volume required = SAFETY
2. Amide	pKa closer from physiological pH	Quick Onset	Less waiting time
3. Ester	Increased degradation in plasma by esterases	Short plasmatic half-time	Increased tolerability = SAFETY
4. 3D structure	Increased protein binding	95% binded to protein	longer duration of anaesthetic effect

(1) Source: GFK data 2009
(2) Source: SDM data 2009

Clinical superiority

The charts and study that follow present a comparison of articaine 4% 1:100,000 Epi to lidocaine 2% 1:100,000 Epi as there is no clinical trial available comparing articaine 4% 1:100,000 Epi to lidocaine 2% 1:80,000 in the literature.

Articaine vs lidocaine in buccal infiltration of mandibular posterior teeth. *Robertson et al. The anaesthetic efficacy of articaine in buccal infiltration of mandibular posterior teeth. J Am Dent Assoc 2007;138;1104-1112.*

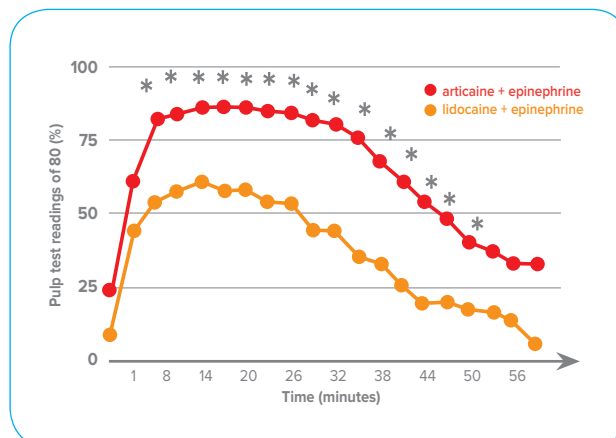
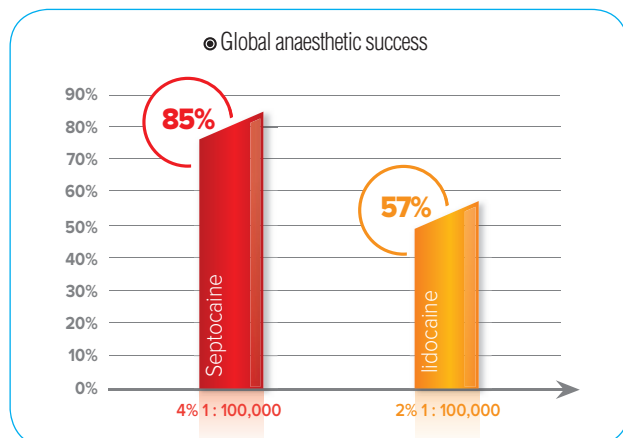
• Methodology

Double blind, cross-over, randomized comparative study, comparing lidocaine 2% 1:100,000 epinephrine with articaine 4% 1:100,000 epinephrine. n=60 patients receiving 2 injections (1 of each product) in 2 appointments spaced at least 1 week apart.

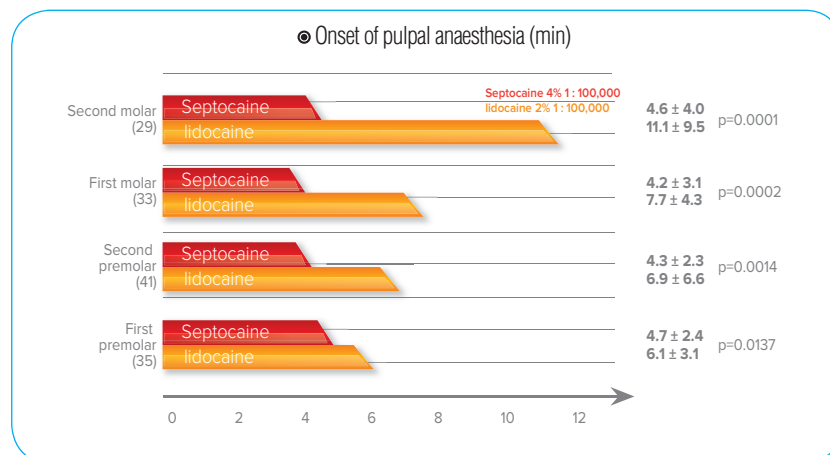
• Evaluation

- Efficacy through non-response to sensitivity pulp-test (= anaesthetic success)
- Onset evaluation

🕒 **Clinical efficacy: the articaine formulation was significantly better than lidocaine formulation in achieving pulp anaesthesia for each of the 4 teeth.**



🕒 **Onset: the articaine formulation was significantly faster than lidocaine formulation for each of the 4 teeth.**



A thesis published in Norway⁽¹⁾ comprehensively compares articaine to lidocaine at different formulations used in dentistry, and suggest s that “articaine 4% 1:200,000 might be a better choice than lidocaine 2% 1:80,000”, particularly when it comes patients where adrenaline represents a risk.

(1) O. Johansen. Comparison of articaine and lidocaine used as dental local anesthetics. Thesis. Faculty of Dentistry. University of Oslo. May 2004.



Septanest

Why choosing Septanest?

pH: 4 to 5,5
(day of manufacture)



Avoids the problems of longer onset and more painful injections correlated to lower pH levels

100% latex free



Increased peace of mind for the practitioner and the patient, knowing that all components and the manufacturing process are totally latex-free, regarding patient allergy

Terminal sterilization



Septodont's manufacturing process includes a "terminal sterilization" stage that guarantees dental professionals and patients the highest degree of sterility, for safety

Worldwide approval



Production expertise approved by Government Health Agencies throughout the world including the most stringent ones

1 ml cartridges*
1.7 ml cartridges*
2.2 ml cartridges



Septodont offers the widest range of dosage volumes to meet various clinical requirements

Mylar wrapped cartridges



Eliminates risk of shattering, for increased safety

Blister packs of 10 cartridges



Reduced risk of cross-contamination

150 million Septanest
cartridges manufactured every year



Septanest has earned the trust of dental professionals throughout the world

* Not available in UK

LATEX-FREE

Septanest



Septanest 1/100,000

Product license No: PL 08313 / 0039 (P.O.M)
See API on page 28

Septanest 1/200,000

Product License No: PL 0831 / 0038 (P.O.M)
See API on page 28

Septanest 4% characteristics

- **pH:** 4.0 to 5.5 (manufacturing day)
- **Onset (Infiltrations or block):** 1-3 min
- **Duration (1:100,000 Epi):** • Pulpal: 75 min
(1:200,000 Epi): • Pulpal: 60 min
- **Plasmatic Half-Life:** 20-30 min

Maximum dosage

mg	Cartridges
mg/lb Body Wt: 3.2	5 cartridges (2.2 ml)
440 mg (Adult)	
88 mg per 2.2 ml cartridge	



Lidocaine

⦿ Lidocaine was the first amino-amide type of local anaesthetic. It was first synthesized in 1943 and represented a real pharmaceutical breakthrough because it offered a lower risk of allergic reactions compared to ester anaesthetics. Over the years, it has attained the status of gold standard for dental analgesia and it is still the historical reference.

Septodont manufactures and provides you lidocaine in several forms.



Injectables: Lignospa Special 2% (1/80,000)

LATEX-FREE

Lignospa S/P 2%

Product license No: PL 08313 / 0019 (P.O.M)
See API on page 29



⦿ Lignospa Special characteristics

- **pH:** 3 to 5.5 (manufacturing day)
- **Onset:** 2-3 min
- **Duration (1/80,000):** • Pulpal: 60 min
- **Plasmatic Half-Life:** 90 min

⦿ Maximum dosage

mg	Cartridges
mg/lb Body Wt: 3.2	3 cartridges (2.2 ml)
132 mg (Adult)	
44 mg per 2.2 ml cartridge	

● Gel: Xylonor Gel 5% (lidocaine)

Features & benefits

- 5% lidocaine analgesic gel with mint flavour gel
- Gel consistency prevents wash away to improve activity
- Fast acting, gives anaesthesia within 2-5 minutes
- Improves patient comfort during many procedures

Xylonor Gel

Product license No: PL 08313 / 0027 (P)
See API on page 29



Xylonor Gel

● Spray: Xylonor Spray 10% (lidocaine)

Features & benefits

- A safer dosage of the active ingredients due to the metered dose spray
- Fast acting, gives anaesthesia within 2-5 minutes

Xylonor Spray

Product license No: PL 08313 / 0032 (P.O.M)
See API on page 29



Xylonor Spray

Mepivacaine

Scandonest

Features & benefits

- Scandonest (mepivacaine) is the preferred molecule for short procedures and periodontal treatments
- Latex free plungers and seals

With or without vasoconstrictor, the adapted solution for each patient

LATEX-FREE

Scandonest



Scandonest 3% Plain

Product license No: PL 08313 / 0023 (P.O.M)
See API on page 30

Scandonest Special 2%

Product License No: PL 08313 / 0026 (P.O.M)
See API on page 30

Scandonest characteristics

Formulation	pH (manufacturing day)	Max. dosage (Adult)	Max. Number of cartridges (2,2 ml)
Scandonest Special 2% + Epi	3,5 - 5	132 mg	3
Scandonest 3 % Plain	6,4 - 6,8	198 mg	3



Other anaesthetics

Pharmaethyl: Cryoanaesthesia

Production of topical cryo-anaesthesia in the oral cavity, prior to the extraction of deciduous or periodontally compromised teeth or to the lancing of abscesses.

Features & benefits

- Tetrafluoroethane has a greater cryo-anaesthetic activity than ethyl chloride
- Quicker and deeper cooling action to improve efficacy
- 150 ml spray bottle with metered dose



Pharmaethyl



Septanest 1:100,000

SEPTANEST 1:100,000. COMPOSITION: Articaine Hydrochloride 4%, Adrenaline (INN: epinephrine) tartrate expressed as base 1:100,000. **THERAPEUTIC INDICATIONS:** Local or loco-regional dental anaesthesia in patients of at least 4 years in case of classic or muco-gingival operations or dental surgical procedures where bone removal is necessary. **DOSAGE AND ADMINISTRATION:** For most common operations, one infiltration with 1.7 ml is sufficient. Do not exceed the equivalent of 7 mg articaine hydrochloride per kilo of weight. Dosage in children should be commensurate with their weight. The recommended dose in 20 kg child is about $\frac{3}{4}$ cartridge of 1.7 ml or $\frac{1}{2}$ cartridge of 2.2 ml and in 40 kg child is about 1.5 cartridge of 1.7 ml or 1 cartridge of 2.2 ml. **CONTRA-INDICATIONS AND PRECAUTIONS FOR USE:** Hypersensitivity to any local anaesthetic agent or any component of SEPTANEST. Do not use SEPTANEST in patients who have experienced bronchospasms after administration of products containing sulphites, patients with deficiency in plasma cholinesterase activity, patients receiving MAOI or tricyclic anti-depressants, patients in whom general anaesthesia might be required to complete the procedure and in children under 4 years of age. **SPECIAL WARNINGS:** SEPTANEST should be used with caution in patients with hepatic disease, thyrotoxicosis, cardiovascular disease, abnormalities of cardiac conduction, epilepsy, and in diabetic patients. Intra-vascular injection is strictly contra-indicated. Resuscitative equipment, anti-convulsant medicines and other resuscitative drugs should be available for immediate use. The product should only be used in pregnancy when the benefits are considered to outweigh the risks. Breast feeding should be avoided for 48 hours after use of SEPTANEST. **ABILITY TO DRIVE AND USE MACHINES:** No demonstrated effects upon motor coordination, however subjects who suffer adverse effects should not drive or use machines until symptoms have resolved. **INTERACTIONS:** SEPTANEST should be administered with caution to any patient receiving drugs with sympathomimetic properties or with agents whose therapeutic actions may be antagonised by adrenaline. Articaine should be given with caution in patients receiving an antiarrhythmic agent. **UNDESIRABLE EFFECTS:** Hypersensitivity, over dosage or intra-vascular injection may result in excitatory or depressant manifestations of the CNS, depressant cardio-vascular reactions, respiratory and allergic reactions. Patients with peripheral or hypertensive vascular disease may develop ischemic injury or necrosis. **PHARMACEUTICAL PRECAUTIONS:** Store in the original container, below 25°C. Protect from light. **PHARMACEUTICAL FORM:** Solution for injection contained in 1.7 and 2.2 ml dental cartridges. **LEGAL CATEGORY:** POM. **FOR FURTHER INFORMATION CONTACT THE PRODUCT LICENCE HOLDER:** SEPTODONT LTD, Units R&S, Orchard Business Centre, St Barnabas Close, Allington, Maidstone, Kent ME16 0JZ, UK. PL 08313/0039.



Septanest 1:200,000

SEPTANEST 1:200,000. COMPOSITION: Articaine Hydrochloride 4%, Adrenaline (INN: epinephrine) tartrate expressed as base 1:200,000. **THERAPEUTIC INDICATIONS:** For dental anaesthesia only. Local or loco-regional dental anaesthesia in patients of at least 4 years in case of classic, or muco-gingival operations. **DOSAGE AND ADMINISTRATION:** For most common operations, one infiltration with 1.7 ml is sufficient. Do not exceed the equivalent of 7 mg articaine hydrochloride per kilo of weight. Dosage in children should be commensurate with their weight. The recommended dose in 20 kg child is about $\frac{3}{4}$ cartridge of 1.7 ml or $\frac{1}{2}$ cartridge of 2.2 ml. and in 40 kg child is about 1.5 cartridge of 1.7 ml or 1 cartridge of 2.2 ml. **CONTRA-INDICATIONS AND PRECAUTIONS FOR USE:** Hypersensitivity to any local anaesthetic agent or any component of SEPTANEST. Do not use SEPTANEST in patients who have experienced bronchospasms after administration of products containing sulphites, patients with deficiency in plasma cholinesterase activity, patients receiving MAOI or tricyclic anti-depressants, patients in whom general anaesthesia might be required to complete the procedure and in children under 4 years of age. **SPECIAL WARNINGS:** SEPTANEST should be used with caution in patients with hepatic disease, thyrotoxicosis, cardiovascular disease, abnormalities of cardiac conduction, epilepsy, and in diabetic patients. Intra-vascular injection is strictly contra-indicated. Resuscitative equipment, anti-convulsant medicines and other resuscitative drugs should be available for immediate use. The product should only be used when the benefits are considered to outweigh the risks. Breast feeding should be avoided for 48 hours after use of SEPTANEST. **ABILITY TO DRIVE AND USE MACHINES:** No demonstrated effects upon motor coordination, however subjects who suffer adverse effects should not drive or use machines until symptoms have resolved. **INTERACTIONS:** SEPTANEST should be administered with caution to any patient receiving drugs with sympathomimetic properties or with agents whose therapeutic actions may be antagonised by adrenaline. Articaine should be given with caution in patients receiving an antiarrhythmic agent. **UNDESIRABLE EFFECTS:** Hypersensitivity, over dosage or intra-vascular injection may result in excitatory or depressant manifestations of the CNS, depressant cardio-vascular reactions, respiratory and allergic reactions. Patients with peripheral or hypertensive vascular disease may develop ischemic injury or necrosis. **PHARMACEUTICAL PRECAUTIONS:** Store in the original container below 25°C. Protect from light. **PHARMACEUTICAL FORM:** Solution for injection contained in 1.7ml and 2.2 ml dental cartridges. **LEGAL CATEGORY:** POM. **FOR FURTHER INFORMATION CONTACT THE PRODUCT LICENCE HOLDER:** SEPTODONT LTD, Units R&S, Orchard Business Centre, St Barnabas Close, Allington, Maidstone, Kent ME16 0JZ, UK. PL 08313/0038.





Lignospan

LIGNOSPAN SPECIAL 2%. COMPOSITION: Lidocaine Hydrochloride 2%, Adrenaline (Epinephrine) tartrate expressed as base 1:80,000. **THERAPEUTIC INDICATIONS:** Local anaesthesia for dental procedures by infiltration or nerve block injections. **DOSAGE AND ADMINISTRATION:** Adults: 1 cartridge is generally sufficient. Do not exceed 3 cartridges. Adolescents between 14 and 17 and the elderly: usual dose 1.8 ml. Do not exceed 3.6 ml. Children between 6 and 14: usual dose 1.35 ml. Do not exceed 2.7 ml. Children between 3 and 6: 0.9 to 1.8 ml. Do not use under 3 years of age. **CONTRA-INDICATIONS AND PRECAUTIONS FOR USE:** LIGNOSPAN SPECIAL is contra-indicated in patients with a known history of hypersensitivity to local anaesthetics of the amide-type or to any component of the injectable formulation. LIGNOSPAN SPECIAL due to the presence of a vasoconstrictor (adrenaline) in the formula is contra-indicated in patients suffering from: arterial hypertension, coronary disease, vascular cardiac disease (particularly sequelae to acute rheumatic fever). **SPECIAL WARNINGS:** for professional dental use only. Lignospan Special should be used with caution in patients with peripheral vascular disease or hepatic disease. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use. Caution should be exercised when the product is administered during early pregnancy or to nursing women. Do not inject into a blood vessel. Aspiration should be performed before injection. Inject slowly. Local anaesthetic procedures should be used with caution where there is inflammation and/or sepsis in the region of injection. The lowest dosage that results in effective anaesthesia should be used. The cartridge should be used on one patient during one session of treatment only. **INTERACTIONS:** Avoid concurrent use with MAOI, tricyclic antidepressants or phenothiazines. Concurrent administration of vasopressor drugs and ergot-type oxytocic drugs may cause severe, persistent hypertension or cerebrovascular accidents. Reduce doses of anaesthetic solution if sedatives are employed. Concurrent use of beta-adrenergic blocking agents may result in hypertension and bradycardia. **UNDESIRABLE EFFECTS:** Hypersensitivity, over dosage or diminished tolerance may result in: excitatory or depressant manifestations of the central nervous system, depressant cardiovascular manifestations and allergic reactions. **PHARMACEUTICAL PRECAUTIONS:** Store in the original package, in a dry place below 25°C and protect from light. Do not freeze. **PHARMACEUTICAL FORM:** Solution for injection contained in 1.8 and 2.2 ml dental cartridges. **LEGAL CATEGORY:** POM. **FOR FURTHER INFORMATION CONTACT THE PRODUCT LICENCE HOLDER:** SEPTODONT LIMITED, Units R&S, Orchard Business Centre, St Barnabas Close, Allington, Maidstone, Kent ME16 0JZ, UK. PL 08313/0019.

Xylonor Gel 5%

XYLONOR GEL 5%. COMPOSITION: Lidocaine 5 %, Cetrimide 0.15 %. **THERAPEUTIC INDICATIONS:** production of topical anaesthesia in the buccal cavity. **DOSAGE AND ADMINISTRATION:** Apply 0.1 - 0.5 g locally using cotton pellet. Do not use in children under 3 years. **CONTRA-INDICATIONS AND PRECAUTIONS FOR USE:** XYLONOR GEL is contraindicated in patients with history of hypersensitivity to local anaesthetics of the amide type, to cetrimide or to other components of the gel. The lowest dose resulting in effective anaesthesia should be used. Dosage should always be adapted to the physical state of the patient. **SPECIAL WARNINGS:** XYLONOR GEL should be used with caution if there is sepsis or extremely traumatised mucosa in the area of application and in persons with known drug sensitivities. Patients should not take any food before they have recovered sensitivity. There is a possibility of positive results on doping tests performed on sportsmen. Caution should be exercised when the product is administered during early pregnancy or to nursing women. **UNDESIRABLE EFFECTS:** systemic adverse reactions are extremely rare with lidocaine ointments. However, hypersensitivity, over dosage or diminished tolerance may result in excitatory and/or depressant CNS manifestations, depressant cardiovascular and respiratory system manifestations and allergic reactions. **PHARMACEUTICAL PRECAUTIONS:** soaps and amionic surfactants are known to decrease the bactericidal activity of cetrimide. The tube should be kept well-closed below 25°C. **PHARMACEUTICAL FORM** gel (tube: 15 g). **LEGAL CATEGORY:** P. **FOR FURTHER INFORMATION CONTACT THE PRODUCT LICENCE HOLDER:** SEPTODONT LIMITED, Units R&S, Orchard Business Centre, St Barnabas Close, Allington, Maidstone, Kent ME16 0JZ, UK. PL 08313/0027.

Xylonor Spray 10%

XYLONOR SPRAY. COMPOSITION: per metered dose: lidocaine 10.00 mg, cetrimide 0.10 mg **THERAPEUTIC INDICATIONS:** production of topical anaesthesia and disinfection of the mucous membrane in the buccal cavity. **DOSAGE AND ADMINISTRATION:** one metered dose (10 mg) is usually sufficient. The maximum single dose is 20 mg. Up to 5 sites may be treated simultaneously, though no more than 3 in each quadrant, and only one quadrant should be anaesthetised during one sitting. Not to be used in children aged under 3 years. **CONTRA-INDICATIONS**





AND PRECAUTIONS FOR USE: XYLONOR SPRAY is contraindicated in patients with history of hypersensitivity to local anaesthetics of the amide type, to cetrimide or to other components of the solution. The lowest dose resulting in effective anaesthesia should be used. Dosage should always be adapted to the physical state of the patient. **SPECIAL WARNINGS:** XYLONOR SPRAY should be used with caution if there is sepsis or extremely traumatised mucosa in the area of application, and in patients with known drug sensitivities. Avoid spraying back of throat or mouth. Beta adrenergic blocking agents and cimetidine may slow the metabolism of lidocaine and increase the risk of toxicity. Caution should be exercised when the product is administered during early pregnancy or to nursing women. **UNDESIRABLE EFFECTS:** systemic adverse reactions are extremely rare with lidocaine ointments. However, hypersensitivity, overdosage or diminished tolerance may result in excitatory and/or depressant CNS manifestations, depressant cardiovascular and respiratory system manifestations and allergic reactions. **PHARMACEUTICAL PRECAUTIONS:** store below 25°C. **PHARMACEUTICAL FORM:** metered aerosol (flask: 36 g). **LEGAL CATEGORY:** POM. **FOR FURTHER INFORMATION CONTACT THE PRODUCT LICENCE HOLDER:** SEPTODONT LIMITED, Units R&S, Orchard Business Centre, St Barnabas Close, Allington, Maidstone, Kent ME16 0JZ, UK. PL 08313/0032.

Scandonest 2% special

SCANDONEST 2% SPECIAL. COMPOSITION: Mepivacaine hydrochloride 2%, Adrenaline (Epinephrine) base 1/100,000. **THERAPEUTIC INDICATIONS:** Local anaesthesia for dental procedures by infiltration or nerve block injections. **DOSAGE AND ADMINISTRATION:** Adults: 1 cartridge for routine work. Do not exceed 3 cartridges. Children: Age 6 to 14: usual dose 1.6 ml. Do not exceed 3.3 ml. Age 3 to 6: 1.1 to 2.2 ml. Do not use under 3 years of age. **CONTRA-INDICATIONS AND PRECAUTIONS FOR USE:** SCANDONEST 2% SPECIAL is contra-indicated in patients presenting allergy to amide type anaesthetics or to any component of the formulation. SCANDONEST 2% SPECIAL due to the presence of a vasoconstrictor (adrenaline), is contra-indicated in patients suffering from: arterial hypertension, coronary disease, valvular affection or under MAOI or tricyclic anti-depressant treatment. **SPECIAL WARNINGS:** For professional dental use only. Should be used with caution in patients with peripheral vascular disease, hepatic disease, renal disease, a history of disturbances of cardiac rhythm or heart block, epilepsy or impaired respiratory function. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use. Caution should be exercised when the product is administered during early pregnancy or to nursing women. Do not inject into a blood vessel. Aspiration should be performed before injection. Inject slowly. Local anaesthetic procedures should be used with caution where there is sepsis and/or inflammation in the region of infection. The lowest dosage that results in effective anaesthesia should be used. The product should not be injected repeatedly at the same site. The cartridge should be used on one patient during one session of treatment only. **INTERACTIONS:** Avoid concurrent use with phenothiazines, vasopressor drugs and ergot-type oxytocic drugs, beta-adrenergic drugs and chloroform, halothane, cyclopropane, trichloroethylene, or other related agents. Reduce doses of anaesthetic solution if sedatives are employed. **UNDESIRABLE EFFECTS:** Hypersensitivity, over dosage or diminished tolerance may result in: excitatory or depressant manifestations of the central nervous system, depressant cardiovascular manifestations and allergic reactions. **PHARMACEUTICAL PRECAUTIONS:** Store in the original package, in a dry place below 25°C and protect from light. **PHARMACEUTICAL FORM:** Solution for injection contained in 1.8 and 2.2 ml dental cartridges. **LEGAL CATEGORY:** POM. **FOR FURTHER INFORMATION CONTACT THE PRODUCT LICENCE HOLDER:** SEPTODONT LIMITED, Units R&S, Orchard Business Centre, St Barnabas Close, Allington, Maidstone, Kent ME16 0JZ, UK. PL 08313/0026.

Scandonest 3% plain

SCANDONEST 3% PLAIN. COMPOSITION: Mepivacaine hydrochloride 3%. **THERAPEUTIC INDICATIONS:** local anaesthesia for dental and chiropody procedures. **DOSAGE AND ADMINISTRATION:** - in dentistry: Adults 1 cartridge for routine work. Do not exceed 3 cartridges. Children from 4 years of age and older: recommended dose: 0.025 ml / kg body weight. Do not exceed 0.1 ml / kg body weight. - in chiropody: Adults 2.2 to 4 ml. Do not exceed 4.4 ml / digit and 6 mg / kg body weight / 24h. **CONTRA-INDICATIONS AND PRECAUTIONS FOR USE:** SCANDONEST 3% PLAIN is contra-indicated in patients presenting specific allergy to amide type anaesthetics. **SPECIAL WARNINGS:** For professional dental use only. Should be used with caution in patients with hepatic disease, renal disease or a history of disturbances of cardiac rhythm or heart block. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use. Caution should be exercised when the product is administered during early pregnancy or to nursing women. Do not inject into a blood vessel. Aspiration should be performed before injection. Inject slowly. Local anaesthetic procedures should be used with caution where there is sepsis and/or inflammation in the region of infection. The lowest dosage that results in effective anaesthesia should be used. The cartridge should be used on one patient during one session of treatment only. **INTERACTIONS:** Reduce doses of anaesthetic solution if sedatives are





employed. **UNDESIRABLE EFFECTS:** Hypersensitivity, overdosage or diminished tolerance may result in: excitatory or depressant manifestations of the central nervous system, depressant cardiovascular manifestations and allergic reactions. **PHARMACEUTICAL PRECAUTIONS:** Store in the original package, in a dry place below 25°C and protect from light. **PHARMACEUTICAL FORM:** Solution for injection contained in 1.8 and 2.2 ml dental cartridges. **LEGAL CATEGORY:** POM. **FOR FURTHER INFORMATION CONTACT THE PRODUCT LICENCE HOLDER:** SEPTODONT LIMITED, Units R&S, Orchard Business Centre, St Barnabas Close, Allington, Maidstone, Kent ME16 0JZ, UK. PL 08313/0023.



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