**Ledermix Paste and Ledermix Cement** 



**Tried Tested Trusted** 



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### The LEDERMIX® Materials

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#### Introduction

One of the most common reasons for patients to seek dental care is the presence of pain. There can be many reasons for oral and dental pain but the most common pain conditions in general dental practice are usually related to pulp and periapical diseases. These conditions have a variety of clinical presentations depending on the particular disease condition.<sup>1,2</sup> The pain can range from being a very mild, occasional ache to a spontaneous, very intense, severe and continuous pain.

**Acute reversible pulpitis** is a common although not very painful condition. It is generally characterized by reactions to extreme temperature changes in the mouth such as those caused by eating or drinking very hot or very cold foods and drinks – typical examples are ice cream and hot coffee or tea. The pain is typically short and sharp in nature, and it disappears almost immediately after the stimulus is removed from the tooth in question.\(^1\)
Reversible pulpitis is usually a result of bacterial invasion of the tooth – such invasion typically occurs via caries, breakdown of a restoration, cracks in the tooth, fracture of the tooth or restoration.\(^1\)

**Acute irreversible pulpitis** is one of the most severe dental pain conditions and it is characterized by a sharp intense pain (typically associated with mild temperature changes such as tap water) which then becomes a dull lingering pain. The tooth may be sore to bite on or even just to light touch. The pain can be spontaneous, may be worse when the patient is lying down and it may wake them at night.\(^1\) Acute irreversible pulpitis is usually a result of bacterial invasion of the tooth – such invasion typically occurs via caries, breakdown of a restoration, cracks in the tooth, fracture of the tooth or restoration.\(^1\)

**Acute apical periodontitis** is an inflammatory condition within the periapical tissues and it is usually a result of either inflammation in the pulp (i.e. pulpitis) or an infection within the root canal system. Infected root canal systems can occur when there is a necrotic pulp, when the tooth is pulpless or when the tooth has had previous endodontic treatment.<sup>2</sup> The infection within the root canal system is a result of bacterial invasion of the tooth and this can occur via the same pathways mentioned above for pulpitis.<sup>1,2</sup> In addition, the infection may be a result of bacteria that have survived previous endodontic treatment procedures. The pain associated with acute apical periodontitis is characterized by the tooth being very sore to bite on. Occasionally, there may be some swelling of the overlying mucosa.<sup>2</sup>

**Acute apical abscesses** can also cause severe pain. Such teeth are extremely tender to even just light biting pressure. There will be swelling which is tender to palpation and





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the patient may feel generally unwell with increased body temperature and lymph node involvement. An apical abscess is a sequel to an infected root canal system and apical periodontitis so the same pathways for bacterial invasion are the original cause of the disease process. Apical abscesses can progress to become facial cellulitis so this condition requires immediate and comprehensive management to avoid further complications.<sup>2</sup>

Management of the above conditions requires a thorough and accurate diagnosis of the disease conditions and an evaluation of what has caused these diseases. The cause must be identified so it can be removed as the first stage of treating the patient.<sup>3</sup> Attempts to manage the pain just with analgesics and/or antibiotics are not appropriate and usually have little effect.4

All teeth with pulp and periapical disease should be carefully evaluated during the initial examination and early treatment phases to determine whether the tooth is suitable for further restoration3 - if there is insufficient tooth structure remaining and the tooth is not suitable for further restoration, then extraction should be considered. Otherwise, conservative pulp therapy or endodontic treatment should be considered.

Teeth with reversible pulpitis can usually be managed by removing the irritant from the tooth and restoring it to normal function although the adjunctive use of a therapeutic material on exposed pulp and/or dentine can be advantageous in relieving pain for the patient.1

Teeth with irreversible pulpitis should also be managed by removing the cause of the diseases as well as by removing the inflamed pulp. This treatment can be enhanced by placing an intracanal medicament to ensure effective and rapid pain relief.<sup>5,6</sup>

Teeth with infected root canal systems should be managed by debridement of the debris from within the root canal followed by the placement of an intracanal medicament which will lead to effective and rapid pain relief.<sup>2,5-8</sup> Previously root-filled teeth will require removal of the root filling before debridement can be done.

As outlined above, an intracanal medicament should be used as an adjunct to the mechanical phases of root canal treatment. 5,6,9 There are two major functions of medicaments – namely, anti-inflammatory action and antimicrobial action.<sup>6,9</sup> These two actions address the primary problems encountered with pulp and periapical diseases which helps to ensure effective and rapid pain relief for patients. Other functions of medicaments include the inhibition of clastic cells that are responsible for root resorption, 10,11 and the stimulation of hard tissue repair (such as bone and cementum). 5,6,9

### The LEDERMIX® Materials

The LEDERMIX® materials were developed in 1960 by Prof. Andre Schroeder from Switzerland. There is a paste form and a cement form of this material. Both of these materials have been widely researched and used extensively in clinical practice since becoming commercially available in 1962. A wide range of researchers and clinicians have investigated and reported the use of these materials. A partial list of these articles is included in this booklet<sup>7,8,10-27</sup> and readers should be aware that there are numerous other articles in the dental literature which support the use of these materials.

Although the two forms of Ledermix have different uses in Dentistry, they have two common active components, triamcinolone (a corticosteroid) and demeclocycline (a tetracycline antibiotic). The bases in which these components are presented dictate the way each material is used and their indications for use.

LEDERMIX Paste is formulated to be used as an intracanal medicament with a watersoluble paste base. 18 It is presented as a single paste in a tube so there is no need to mix this material prior to use.28

LEDERMIX Cement is a hard-setting material for use on dentine as a lining, as a pulp capping agent and as a pulpotomy agent.<sup>16</sup> This material is presented as a powder and a liquid that must be mixed immediately prior to use in a tooth.<sup>28</sup> There are two forms of the liquid component – a fast-setting formulation and a normal setting formulation – and the majority of the liquid is eugenol (85%). 27,28 The powder component contains zinc oxide (47.2%) and calcium hydroxide with the latter making up 33.4% of the powder.<sup>27</sup> Once the powder and liquid are mixed, the cement is a zinc oxide-eugenol cement containing triamcinolone, demeclocycline and calcium hydroxide as its active ingredients.<sup>27</sup>

Triamcinolone is used in the LEDERMIX materials because of its anti-inflammatory action which assists with rapid pain relief following the commencement of treatment. It also inhibits clastic cells (osteoclasts, cementoclasts and dentinoclasts) and therefore it can be used to manage root resorption. <sup>6,10,11</sup> The triamcinolone is present in **LEDERMIX** Paste at a concentration of 1.0%9,18 and in LEDERMIX Cement at a concentration of 0.67%.16,27





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### The LEDERMIX® Materials

**Demeclocycline** is used for its antimicrobial action and it also has some limited ability to inhibit the clastic cells involved in root resorption.<sup>6,10,11</sup> It is present in **LEDERMIX Paste** at a concentration of 3.21%<sup>9,18</sup> and in **LEDERMIX Cement** at a concentration of 2.0%.<sup>16,27</sup>

The purpose of this manual is to provide dentists with information and directions to assist them in their endodontic treatment through the use of **LEDERMIX Paste**.



### How do the LEDERMIX® Materials Work?

In general, **LEDERMIX Paste** has two main therapeutic actions as a result of its two active components – one reduces inflammation whilst the other reduces the viable microbial flora within the root canal system.<sup>5,6,9</sup> A further therapeutic action is by inhibition of clastic cells when managing inflammatory root resorption.<sup>10,11</sup>

The pain associated with pulp and periapical diseases is a result of inflammation of the pulp and/or periapical tissues.<sup>1,2</sup> Hence, in order to reduce the patient's pain, it is essential to remove the cause of the inflammation.<sup>6</sup> In addition, reduction of the inflammatory reaction will help to reduce pain more rapidly.<sup>5,6</sup>

The management of **acute irreversible pulpitis** can be greatly enhanced by placing **LEDERMIX Paste** in the root canal system after the inflamed pulp has been removed.<sup>6</sup> The **LEDERMIX Paste** can then work by the direct contact and anti-inflammatory action of the triamcinolone component on any remaining pulp tissue. It can also act by diffusing through the apical foramen of the root canal to the periapical tissues which may also be inflamed.<sup>18</sup> Direct action by the triamcinolone component on these tissues can help to reduce the inflammation that is present. Furthermore, the demeclocycline component can provide some useful antimicrobial action in pulpitis cases as there may be bacteria within the inflamed pulp (although insufficient for the pulp to have necrosed and become infected).

The management of pain associated with **infected root canal systems** can also be enhanced by placing **LEDERMIX Paste** in the root canal following initial debridement of the canals.<sup>6,7,8</sup> In these cases, the **LEDERMIX Paste** has dual functions. The first function is similar to the direct action described above for pulpitis cases where the triamcinolone diffuses through the apical foramen to the inflamed periapical tissues to help reduce the inflammation there.<sup>18</sup> The second function is the inhibition of bacteria within the root canal system.<sup>9</sup>

Periapical diseases are usually a result of bacterial invasion of the root canal system.<sup>2</sup> Initially, the pulp may become inflamed through direct bacterial invasion of the pulp or as a reaction to the bacterial metabolic by-products and endotoxins diffusing through the dentinal tubules to irritate the pulp.<sup>1</sup> Once the bacteria have invaded the pulp space, they progress through the entire tooth root and root canal system. The root canal system is a very complex maze of places where bacteria can establish colonies. The root canal system consists of the root canals themselves, lateral canals, accessory canals, interconnections between the main canals, fins, and dentinal tubules.<sup>9</sup> Hence, the bacteria can exist in





all parts of the tooth root, many of which are inaccessible to mechanical endodontic procedures such as filing and irrigation.

Antimicrobial irrigants may reach some of the bacteria beyond the main canals but irrigants are typically only used for a short period of time and therefore their effectiveness is somewhat limited. In order to reach all areas of the root canal system, adequate time is required for diffusion of the antimicrobial substance though the dentine – this requires at least several hours but days and even weeks for most materials to reach their full potential and to be effective. Studies have shown that the major components of **LEDERMIX Paste** will diffuse through the tooth root when the paste is placed in the root canal as a medicament. This diffusion can persist for up to six weeks in adult teeth. Studies of **LEDERMIX Cement** have also shown that the triamcinolone can diffuse into the pulp space when placed in a coronal cavity. 16,27

#### Pharmacokinetics of the LEDERMIX Materials

The active components of **LEDERMIX Paste**, triamcinolone and demeclocycline, are released from the preparation following placement in the root canal. They then diffuse through the main root canals themselves, lateral canals, accessory canals, interconnections between the main canals, fins, and dentinal tubules. These components exit the tooth root via any openings such as the apical foramina or lateral canal foramina, as well as via diffusion through the cementum. The rate of diffusion is affected by factors such as the presence of smear layer on the canal walls, the presence of cementum, the permeability of the dentine and cementum, the size and structure of the molecules that are diffusing, the initial amount of paste used and the concentrations of the components.

The majority of both active components are released within the first few days<sup>18-20</sup> and this ensures rapid action and particularly pain relief for the patient. Diffusion will continue at a progressively reducing rate and therapeutic amounts are released for up to about six weeks in adult teeth, based on an *in vitro* study.<sup>18</sup> In that study, after application of radioactively-marked **LEDERMIX Paste** into prepared root canals of freshly extracted teeth, release and diffusion of demeclocycline and triamcinolone through dentine could be detected after one hour (Fig.1). The triamcinolone had a slight increase in release and diffusion over the next seven hours and then it decreased gradually until about six weeks when it could no longer be detected at therapeutically-useful amounts. The demeclocycline had a much greater initial rate of release and diffusion, and this reduced steadily over the first day before slowing to a gradual decrease for up to 14 weeks.<sup>18</sup> The different pattern of release and diffusion of demeclocycline is likely to be a result of

the higher initial concentration in the paste (3.21% compared to 1% for triamcinolone) and the effects of the tetracycline binding with the calcium of the dentine. This latter effect helps to maintain the drug in the dentine for a longer period of time which is advantageous and provides some antimicrobial substantivity. 18,29

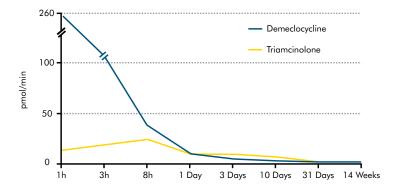


Fig. 1 - Mean rates of release and diffusion (pmol/min) through human tooth roots of the active components of **LEDERMIX Paste** (from Abbott et al. 18)

In the same study,  $^{18}$  the concentration of demeclocycline within the root dentine was also measured. By the end of the first day, a concentration of 200  $\mu$ g/ml was found in the dentine close to the root canal. A concentration gradient occurred across the dentine with concentrations of 21  $\mu$ g/ml in the middle layer of dentine and 17  $\mu$ g/ml in the dentine adjacent to the cementum. After one week, these concentrations reduced by a factor of about ten in all levels of the dentine. The concentration of demeclocycline in the dentine is high enough to inhibit most endodontic bacteria in the dentine immediately adjacent to the root canal in the first few days. However, the levels reached further out in the dentine and over longer periods was not sufficient to inhibit most bacteria that are likely to be present.  $^{18}$  Hence, further antimicrobial strategies (e.g. the use of calcium hydroxide) should be employed to ensure complete disinfection of the root canal system prior to placement of the root canal filling.  $^6$ 

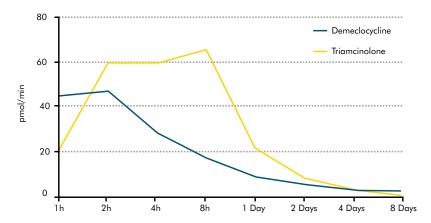
**LEDERMIX Paste** can also be used in a coronal cavity as a sedative dressing under a temporary restoration in cases of reversible pulpitis. The triamcinolone and demeclocycline





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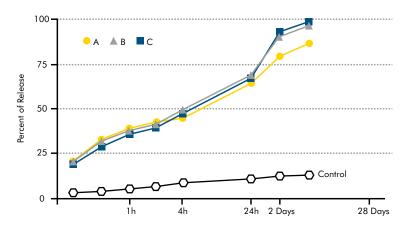
have been shown to be released and diffuse through coronal dentine to reach the pulp space.<sup>19</sup> The demeclocycline release reached its peak rate after two hours and then dropped throughout the remainder of the first day to a rate that was maintained for at least 8 days (Fig.2). The triamcinolone reached its maximum release rate in the period between 2 to 8 hours and then dropped over the next two days and had almost been completely eliminated by the end of the eighth day.<sup>19</sup>



**Fig. 2** - Mean rates of release and diffusion (pmol/min) through coronal dentine of the active components of **LEDERMIX Paste** (from Abbott et al<sup>19</sup>)

As outlined above, **LEDERMIX Cement** is a hard-setting material. It can be used as a sedative dressing or lining under temporary or definitive restorations in teeth with reversible pulpitis with or without pulp exposures. <sup>16,27,28</sup> As it is a hard-setting cement, it is preferred for this situation rather than using the paste form. **LEDERMIX Cement** has been shown to release triamcinolone which then diffuses through the dentine to reach the pulp space. <sup>16</sup> Approximately 70% of the triamcinolone is released by the end of the first day and the remainder is released by the end of the third day following application to a cavity floor (Fig 3). <sup>16</sup> The results of this *in vitro* study are consistent with a clinical study<sup>27</sup> of the use of Ledermix cement as an indirect pulp capping or lining material in 85 teeth with reversible pulpitis due to the presence of cracks in the teeth. After removal of

the crack and caries followed by the placement of Ledermix cement and an interim glass ionomer restoration, complete resolution of symptoms occurred immediately in 71% of the patients. A further 21% of cases had resolution of the symptoms within 1 day, 6% took 2 days and 3% took 3 days. On follow-up after three months, 98% of the teeth showed signs of the pulpitis having completely resolved and the pulps had returned to a clinically normal state (Fig 4).<sup>27</sup>



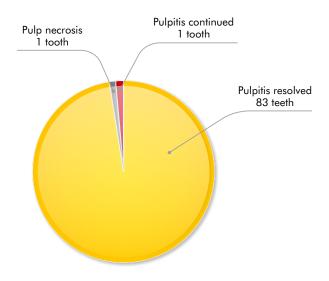
**Fig. 3** - Percentage release and diffusion through coronal dentine of triamcinolone from **LEDERMIX Cement** in three experimental teeth (A, B, C) and one control tooth (with no Ledermix cement) (Adapted from Hume & Kenney<sup>16</sup>)

After the triamcinolone is released from LEDERMIX Cement, the remaining cement is essentially a zinc oxide-eugenol material with calcium hydroxide. Both of these components have well known and researched therapeutic effects on the pulp. Calcium hydroxide has beneficial effects on the healing of dental pulps and the formation of reactionary/reparative dentine<sup>30,31</sup> whilst the eugenol can be both anti-inflammatory and anti-bacterial,<sup>32,34</sup> depending on the concentration reaching the dentine and pulp as it is released by progressive hydrolysis occurring at the cavity floor.





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**Fig. 4** - 97.6% of teeth treated with Ledermix Cement had their Reversible Pulpitis resolved. Pulp status at the three-month review for 85 teeth that had conservative pulp treatment with Ledermix cement. (Adapted from Abbott & Leow<sup>27</sup>)

#### Indications for Use

#### **LEDERMIX PASTE**

**LEDERMIX Paste** is indicated for use as an intracanal medicament in teeth undergoing root canal treatment<sup>5,6</sup> in the following situations:



- Acute irreversible pulpitis.
- Acute apical periodontitis due to an infected root canal system. Other medicaments then need to be used as subsequent dressings (e.g. calcium hydroxide) to ensure maximum disinfection since the demeclocycline has a limited antibacterial spectrum of activity.
- Inflammatory root resorption both internal and external as the initial dressing
  when the resorption is established. Other medicaments then need to be used as
  subsequent dressings (e.g. calcium hydroxide) to promote hard tissue repair.
- To prevent the development of inflammatory resorption<sup>10,11,35</sup> following avulsion of fully developed teeth and other injuries (e.g. intrusion of fully developed teeth) where this type of resorption is likely to occur. Its use in these situations may also reduce the amount of replacement resorption that can occur following these injuries.<sup>35</sup>
- To reduce post-operative pain by reducing the periapical inflammation.<sup>7,8</sup> If the pain
  is associated with an infected root canal system, then other medicaments then need
  to be used as subsequent dressings (e.g. calcium hydroxide) to ensure maximum
  disinfection since the demeclocycline has a limited antibacterial spectrum of activity.
- To inhibit & reduce the number of bacteria within infected root canals. Other
  medicaments then need to be used as subsequent dressings (e.g. calcium hydroxide)
  to ensure maximum disinfection since the demeclocycline has a limited antibacterial
  spectrum of activity.

**LEDERMIX Paste** can also be used as a pulpotomy agent in the emergency management of acute irreversible pulpitis<sup>5,6</sup> - in these cases, it should only be used as an interim pain relief measure that must be followed by more comprehensive treatment such as pulpectomy and root canal therapy.





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**LEDERMIX Paste** can be used in both deciduous and permanent teeth for the above purposes.

NOTE: LEDERMIX Paste can be used in conjunction with calcium hydroxide in order to improve the overall disinfection of the root canal system.<sup>36,37</sup> As mentioned above, the antibacterial spectrum of demeclocycline is limited, particularly in the peripheral parts of the root dentine and over time. Calcium hydroxide can be mixed with the LEDERMIX Paste (as an approximate 50:50 mixture)<sup>5,6,36,37</sup> or it can be used as a separate subsequent dressing in the canal.<sup>5,6</sup> If the calcium hydroxide is being mixed with the LEDERMIX Paste, then the formulation of calcium hydroxide will dictate how this should be done,<sup>5,6</sup> as follows:

- Calcium hydroxide in a saline-based paste approximately equal amounts of the **LEDERMIX Paste** and the calcium hydroxide paste can be mixed on a glass slab or on a mixing pad. The mixture can then be inserted into the canal in the same manner as when placing LEDERMIX Paste alone.
- Calcium hydroxide in a methylcellulose-based paste the LEDERMIX Paste should be placed into the root canal by itself with the spiral filler or hand file (as described above although less will be required). Then, the calcium hydroxide paste should be placed into the canal in the same way and whilst doing so, the two pastes are mixed together inside the canal. This method is recommended because the methylcellulose base in these pastes causes the mixture to become quite thick or "alugay" and therefore it is difficult to insert to the full length of the root canal as it does not flow easily.
- · Calcium hydroxide powder the powder can be mixed into the LEDERMIX Paste prior to insertion of the mixture into the root canal. The powder will cause the paste to become thicker and therefore it may be more difficult to "spin" down the canal with a spiral filler as it will not flow as easily.

#### LEDERMIX CEMENT

NOTE: LEDERMIX Cement is NOT suitable for use in teeth with irreversible pulpitis - such teeth require pulpectomy and root canal therapy, or extraction. Hence, an accurate diagnosis is essential and should be based on a thorough history, clinical examination, pulp sensibility tests and periapical radiograph(s).

LEDERMIX Cement is indicated for use<sup>15,16,27,38-44</sup> in the following situations:

- For the management of reversible pulpitis in both deciduous and permanent teeth by indirect pulp capping - that is, where there has not been a pulp exposure.
- · For the management of reversible pulpitis in both deciduous and permanent teeth by direct pulp capping or as a pulpotomy agent where the pulp has been exposed. In this situation, the clinician must decide whether to perform a direct pulp cap or a pulpotomy - this will depend on many factors including the age of the patient, status of the tooth, the size of the exposure, the type of restoration required, which tooth is being treated and its strategic value, financial considerations, etc.
- · Use as a lining or indirect pulp capping material in asymptomatic teeth with deep carious cavities prior to placing a restoration in order to reduce the inflammation that may have been present due to the caries and also to reduce the inflammatory effects of the operative procedures.
- · Use to cement interim crowns following preparation of the tooth for a crown restoration in order to reduce the inflammatory effects of the operative procedures.
- Use as a root filling material in deciduous teeth with irreversible pulpitis or an infected root canal system following thorough canal cleaning and preparation.





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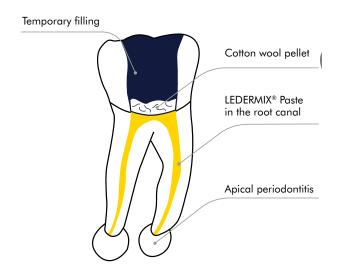
#### **Directions for Use**

#### **LEDERMIX PASTE**

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When used as an intracanal medicament, **LEDERMIX Paste** can be placed into the canal in two ways. The method chosen will depend on the size of the canal and whether it has been enlarged at all.<sup>5,6</sup> The aim is to fill as much of the root canal space as possible with the paste so the maximum amount possible is placed. The paste needs to be in contact with the dentine walls of the root canal to ensure diffusion through the dentine.<sup>5,6,18,20</sup>

It is extremely important to ensure that **NONE** of the paste touches the access cavity walls or remains in the coronal part of the tooth as this can lead to discolouration of the tooth structure<sup>45,46</sup> with resultant aesthetic complications for the patient. Although tetracycline staining can be removed via internal bleaching following endodontic treatment, it is highly desirable and advantageous to avoid discolouration by very careful placement of the paste. The paste only needs to be in the root canal and not in the pulp chamber in order to achieve its therapeutic effects.



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The two methods of application of **LEDERMIX Paste** are as follows:

- For narrow or unprepared canals use a small hand file to place the paste (e.g. at an emergency appointment for pain relief when there has been insufficient time available to enlarge/biomechanically prepare the canals).<sup>5,6</sup>
  - o Place a very small amount of **LEDERMIX Paste** on a small file (e.g. size 10 or 15 Hedström file) and insert the file into the canal as far as possible without forcing the instrument. Use a slight anti-clockwise rotation action (approximately one-eighth turn maximum) and an "in and out vertical pumping" action (i.e. move the file 2-3 mm vertically). The slight rotation wipes some of the paste off the file by contact with the canal wall whilst the vertical movement helps to distribute the paste over the canal wall. Remove the file and repeat this process with another very small amount of paste on the file.
- For large canals and canals that have been biomechanically prepared/ enlarged – use a spiral filler rotating in a low-speed handpiece to insert the paste.<sup>5,6</sup>
  - o Place a very small amount of the paste on the end of the spiral filler only 2-3mm of the spiral filler needs to be covered with the paste.
  - o Insert the spiral filler into the canal and then start the handpiece spinning in the forward (i.e. clockwise) direction. The spiral filler should not be rotated until it has been fully inserted into the canal in order to avoid the paste being placed in the pulp chamber of the tooth.
  - The spiral filler should be kept 3-4 mm short of the canal's Working Length and a very low speed is recommended.
  - Use the spiral filler with an "in and out pumping" action that is, move it up and down inside the canal but only move it 2-3 mm vertically each time. At the same time, keep spinning it in the forward direction.
  - o Keep spinning the spiral filler at a low speed as you remove it from the canal so it keeps pushing the paste material down into the canals and it does not draw the paste back out of the canal with the instrument. This will minimise the possibility of the paste being placed in the pulp chamber, and subsequent discolouration of the tooth.
  - o If any excess paste is inadvertently left in the pulp chamber, remove it with an excavator and then wipe the pulp chamber clean with a dry sterile cotton pellet.





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#### Time of Use

Since **LEDERMIX Paste** releases its active components over a period of time, it has a limited time of therapeutic use. <sup>5,6,18,20</sup> This applies in all of the situations where **LEDERMIX Paste** is indicated for use. There are minimum and maximum times that this paste should be used for.

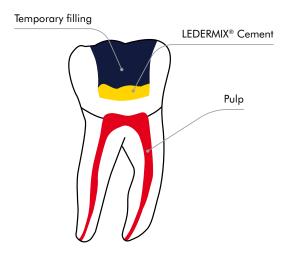
- MINIMUM TIME OF USE: Although most of the release and diffusion of the
  components occurs within the first few days, <sup>18</sup> the minimum time of use should be
  TWO WEEKS since inflamed tissue needs at least 10-14 days for the inflammation
  to resolve and for the tissues to heal initially.<sup>5</sup>
- MAXIMUM TIME OF USE: The maximum time of effective use of LEDERMIX Paste
  in adult teeth is about SIX WEEKS. After this, the remaining concentrations of the
  active components are very low and insufficient to provide a therapeutic effect. In
  young teeth with wider dentinal tubules and open apical foramina, a shorter period
  of time of action should be expected.<sup>5,18</sup>
- IDEAL TIME OF USE: The ideal time of use of LEDERMIX Paste is between FOUR and SIX WEEKS since bone repair can take longer than two weeks.<sup>5,6</sup>
- SPECIFIC TIMES RECOMMENDED<sup>5,6</sup> FOR SPECIFIC INDICATIONS
  - o As an intracanal medicament for acute irreversible pulpitis: **4-6 weeks**.
  - As an intracanal medicament for acute apical periodontitis due to an infected root canal system: 4-6 weeks.
  - As an intracanal medicament for inflammatory root resorption both internal and external - as the initial dressing when the resorption is established: 6 weeks followed by a further application of fresh paste for another 6 weeks.
  - As an intracanal medicament to prevent the development of inflammatory resorption following avulsion of fully developed teeth and other injuries (e.g. intrusion of fully developed teeth) where this type of resorption is likely to occur:
     6 weeks followed by a further application of fresh paste for another 6 weeks.
  - As an intracanal medicament to reduce post-operative pain by reducing the periapical inflammation: 4-6 weeks.
  - o As an intracanal medicament to inhibit & reduce the number of bacteria within infected root canals: **4-6 weeks**.
  - As a pulpotomy agent in the emergency management of acute irreversible pulpitis: 4-6 weeks.

#### **LEDERMIX CEMENT**

The powder and liquid components of **LEDERMIX Cement** must be mixed immediately prior to use.<sup>28</sup> The powder can be mixed with either the "Normal Set" or the "Fast Set" liquid, according to the dentist's preferences and the clinical situation. The setting time with both forms of liquid will be dependent on the thickness of the mix – i.e. the more powder that is used, the faster the setting time.<sup>28</sup> The powder:liquid ratio is not critical to the performance of the material and generally a creamy-like consistency should be used. There are no special mixing requirements although it is advisable to progressively add small amounts of powder in order to gauge the thickness of the mixture as it is being mixed. This will avoid wastage that can occur if too much powder is added at one time.

Methods of application for LEDERMIX Cement are:

1. For the management of reversible pulpitis in both deciduous and permanent teeth by indirect pulp capping – that is, where there has not been a pulp exposure. Mix the powder and liquid to form a creamy paste-like mixture. Place this mix on the dentine and allow it to set hard. Then place a suitable restoration as required for the particular tooth. In some cases, the dentist may choose to place an interim or temporary restoration for a period of time to reassess the tooth and the pulp response. In all cases, the pulp status should be reviewed after 3-6 months to determine whether it has healed adequately.







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For the management of reversible pulpitis in both deciduous and permanent teeth by direct pulp capping or as a pulpotomy agent where the pulp has been exposed.

Mix the powder and liquid to form a creamy paste-like mixture. Place this mix on the exposed pulp and adjacent dentine and allow it to set hard. Then place a suitable restoration as required for the particular tooth. In some cases, the dentist may choose to place an interim or temporary restoration for a period of time to reassess the tooth and the pulp response. In all cases, the pulp status should be reviewed after 3-6 months to determine whether it has healed adequately.

3. Use as a lining or indirect pulp capping material in asymptomatic teeth with deep carious cavities prior to placing a restoration.

Mix the powder and liquid to form a creamy paste-like mixture. Place this mix on the dentine in the deepest part of the cavity floor and on any pulp walls of the cavity. Then place a base using a glass ionomer cement or other hard setting material followed by the final restoration as required for the particular tooth. In some cases, the dentist may choose to place an interim or temporary restoration for a period of time to reassess the tooth and the pulp response. In all cases, the pulp status should be reviewed after 3-6 months to determine whether it has healed adequately.

- 4. Use to cement interim crowns following preparation of the tooth for a crown. Mix the powder and liquid to form a creamy paste-like mixture. Coat the fitting surface of the interim crown with this mixture, seat the crown on the tooth with light pressure to ensure complete seating. Allow the cement to set hard and then clean any excess cement away from the margins with a suitable hand instrument (e.g. scaler or probe). Review the pulp status prior to fitting and cementing the definitive crown at a subsequent appointment.
- Use as a root filling material in deciduous teeth with irreversible pulpitis
  or an infected root canal system following thorough canal cleaning and
  preparation.

Mix the powder and liquid to form a creamy paste-like mixture. Place the mixture into the root canal system using a spiral filler (as described above for Ledermix Paste) or other appropriate method (e.g. hand file) and allow it to set hard. Then place a suitable restoration as required for the particular tooth. Review the tooth and the periapical healing response after 6-12 months.

#### References

- Abbott PV, Yu C. A clinical classification of the status of the pulp and the root canal system. Aust Dent J 2007;52(Suppl 1):S17-S31.
- Abbott PV. Classification, Diagnosis and Clinical Manifestations of Apical Periodontitis. Endo Topics 2004;8:36-54.
- Abbott PV. Assessing restored teeth with pulp and periapical diseases for the presence of cracks, caries and marginal breakdown. Aust Dent J 2004;49:33-9.
- Therapeutic Guidelines: Oral and Dental. Therapeutic Guidelines Ltd. North Melbourne, Australia, Version 1, 2007.
- Abbott PV. Medicaments: Aids to success in Endodontics. Part 2. Clinical recommendations. Aust Dent J. 1990;35:491-6.
- Heithersay GS, Hume WR, Abbott PV. Conventional root canal therapy, II: Intracanal medication. IN: Harty FJ, Ed. Endodontics in Clinical Practice 3rd Edition. Dental Practitioner Handbook No. 24, Wright Butterworth Scientific, London 1990;162-85.
- Ehrmann EH, Messer HH, Adams GG. The relationship of intracanal medicaments to postoperative pain in endodontics. Int Endo J 2003;36:868-875.
- Negm MM. Intracanal use of a corticosteroid-antibiotic compound for the management of posttreatment endodontic pain. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2001;4:435-439.
- Abbott PV. Medicaments: Aids to success in Endodontics. Part 1. A review of the literature. Aust Dent J 1990;35:438-48.
- Pierce AM, Lindskog S. The effect of an antibiotic/corticosteroid paste on inflammatory root resorption in vivo. Oral Surg Oral Med Oral Pathol 1987;64:216-20.
- 11. Pierce AM, Heithersay GS, Lindskog S. Evidence for direct inhibition of dentinoclasts by a corticosteroid/antibiotic paste. Endod Dent Traumatol 1988;4:44-5.
- 12. Schroeder A. Cortisone in dental surgery. Int Dent J 1962;12:356-73.
- Schroeder A. Zur frage der konservativen und chirurgischen behandlung der pulpitis.
   Österreichische Zeitschrift für Stomatologie 1962;59:81-7.
- Schroeder A. Der gerbrauch von kortisonderivaten in der endodontie. Schweiz Monatschr Zahn 1963;73:825-9.
- 15. Schroeder A. Corticosteroids in endodontics. J Oral Therap Pharmacol 1965;2171-9.
- 16. Hume WR, Kenney AE. Release of 3H-triamcinolone from Ledermix. J Endod 1981;7:509-14.





# The LEDERMIX® Materials

- 17. Ehrmann EH und Geurtsen N. Die Apexifikation von marktoten Zahnen ohne abgeschlossenes Wurzeiwachstum. Dtsch Zahnarztl Z 1985;40:986-992.
- Abbott PH, Heithersay GS, Hume WR. Release and diffusion through human tooth roots in vitro
  of corticosteroid and tetracycline trace molecules from Ledermix paste. Endod Dent Traumatol
  1988;4:55-62.
- Abbott PH, Heithersay GS, Hume WR. The release and diffusion through human coronal dentin in vitro of triamcinolone and demeclocycline from Ledermix paste. Endod Dent Traumatol 1988;5:92-97.
- Abbott PV, Hume WR, Heithersay GS. Barriers to diffusion of Ledermix paste in radicular dentine. Endod Dent Traumatol 1989:5:98-104.
- Barbakow F, Lutz F, Toth L. Materialien und Techniken bei Wurzelkanalbehandlungen in der Schweiz –eine Standortbestimmung. Schweiz Monatsschr 1995;105:1412-1417.
- Schroeder A. Die Kortikoid-Antibiotikum-Medikation in der Endodontie 35 Jahre Ledermix. Quintessenz 1997;48:49-55.
- 23. Schroeder A, Lussi A. Endodontie aktueil: Einsatz von Ledermix. Dental Spiegel 1997;3:36.
- Hagedorn B, Robing P, Willershausen B, Briseno Marroquin B. Ledermix Ergebnisse einer Praxisumfrage. ZWR 2000;109:689-693.
- Briseno Marroquin B, Viola E, Christoffers AB, Willerhausen B. Die antibakterielle Wirkung von Ledermix als medikamentose Wurzelkanaleinlage – eine in-vitro-Versuchsreihe. Dtsch Zahnarztl Z 2004;59:650-654.
- Ehrmann EH. Therapieresistente Schmerzen bei manifester Peri-Zementitis. Dent Tribune (German Edition) 2005;7:2-3.
- Abbott PV, Leow N. Predictable management of cracked teeth with reversible pulpitis. Aust Dent J 2009:54:306-315.
- 28. Lederle Laboratories. Product pamphlet accompanying "Ledermix". Wolfratshausen 1962.
- 29. Mohammadi Z, Abbott PV. Antimicrobial substantivity of root canal irrigants and medicaments: a review. Aust Endod J 2009;35:131-139.
- 30. Eidelman E, Finn SB, Koulourides T. Remineralization of carious dentin treated with calcium hydroxide, J Dent Child 1965;32:218–25.
- 31. Graham L, Cooper PR, Cassidy N, et al. The effect of calcium hydroxide on solubilisation of bioactive dentine matrix components. Biomaterials 2006;27:2865-73.
- 32. Hume WR. An analysis of the release and the diffusion through dentin of eugenol from zinc oxide-eugenol mixtures. J Dent Res 1984;63:881-4.
- 33. Hume WR. Effect of eugenol on respiration and division in human pulp, mouse fibroblasts and liver cells. J Dent Res 1984;63:1262-5.

- Hume WR. The pharmacologic and toxicological properties of zinc oxide-eugenol. J Am Dent Assoc 1986;113:789-91.
- Bryson E, Levin L, Banchs F, Abbott P, Trope M. Effect of immediate intracanal placement of Ledermix paste on healing of replanted dog teeth after extended dry times. Dent Traumatol 2002;18:316-21.
- Abbott PV, Hume WR, Heithersay GS. Effects of combining Ledermix and calcium hydroxide pastes on the diffusion of corticosteroid and tetracycline through human tooth roots in vitro. Endod Dent Traumatol 1989;5:188-92.
- 37. Taylor MA, Hume WR, Heithersay GS. Some effects of Ledermix paste and Pulpdent paste on mouse fibroblasts and on bacteria in vitro. Endod Dent Traumatol 1989;5:266-73.
- Schroeder A. Indirect capping and the treatment of deep carious lesions. Int Dent J 1968;18:381-91
- 39. Ehrmann EH. The effect of triamcinolone with tetracycline on the dental pulp and apical periodontium. J Prosthet Dent 1965;15:149-52.
- Clarke NG. The corticosteroid-antibiotic dressing as a capping for inflamed dental pulps. Aust Dent J 1971;16:71-6.
- 41. Schroeder A. The problem of direct pulp capping. J Brit Endod Soc 1972;6:72-9.
- 42. Ehrmann EH. The endodontic management of the acute pulpal or periapical lesion. Aust Dent J 1972:11:279-82.
- 43. Barker BCW. Conservative treatment of cariously exposed vital pulps in posterior teeth with a glucocorticosteroid-antibiotic compound. J Brit Endod Soc 1975;8:5-15.
- 44. Ehrmann EH. Pulpotomies in traumatized and carious permanent teeth using corticosteroid antibiotic preparation. Int Endod J 1981;14:149-56.
- 45. Kim ST, Abbott PV, McKinley P. The effects of Ledermix paste on discolouration of mature teeth. Int Endod J 2000;33:227-32.
- Kim ST, Abbott PV, McKinley P. The effects of Ledermix paste on discolouration of immature teeth. Int Endod J 2000;33:233-7.





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