



PROTECO

«УТВЕРЖДАЮ»

АО «ПРОТЕКО»

Чекова Е.С.

по Доверенности № 78 АВ 5341909

от 26.06.2024 г.

«19» сентября 2024 г.



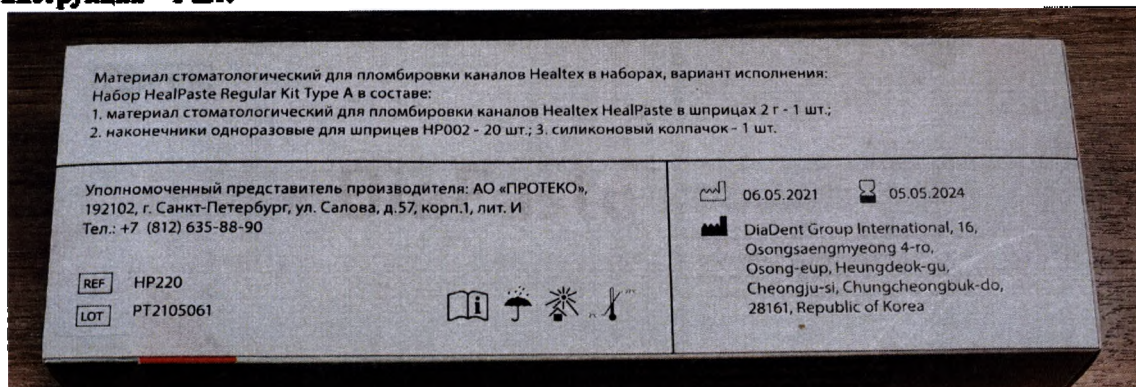
Фотографические изображения общего вида медицинского изделия

Материал стоматологический для временной пломбировки каналов
Healtex® в наборах

(наименование медицинского изделия)

Материал стоматологический для временной пломбировки каналов Healtex®. Набор HealPaste Regular Kit Type A в составе:

- материал стоматологический Healtex® HealPaste в шприцах 2 г - 1 шт.;
- наконечники одноразовые для шприцев HP002 - 20 шт.;
- силиконовый колпачок - 1 шт.;
- инструкция - 1 шт.



Материал стоматологический для пломбировки каналов Healtex HealPaste в шприцах 2 г
LOT PT2105061
05.05.2024



DiaDent®**DiaPaste™**

CE 0197

Root Canal Filling Material

Description

Diapaste is a calcium hydroxide paste with barium sulfate, used as a temporary root canal filling material.

Indication for use

Aqueous ointment material that temporarily fills the root canal for the following indications:

- Apexification
- Temporary root filling
- Root canal filling for primary teeth
- Vital pulpotomy
- Temporary pulp capping

Performance

Radiopacity: $\geq 3\text{mm}$ (ISO 6876 standard)
Flowability: $\geq 17\text{mm}$ (ISO 6876 standard)

Precaution

- 1 Check the product for leaks, discoloration, abnormal condition of the packaging, and expiration date.
- 2 A rubber dam should be used to protect patient's mouth and necessary accessories should be prepared in advance for the procedure.
- 3 Be familiar with the warning, side effects, contraindications and instructions.

Instruction for use

- 1 Open the protective cap and attach the disposable tip onto the syringe.
- 2 Insert the tip from the root opening to 1/5 of the length of the root canal.
- 3 Push the plunger slowly and gently to inject the material into the canal.
- 4 Remove excess material in the root canal and proceed with routine restoration procedure.
- 5 After use, remove the disposable tip attached to the syringe and attach a new disposable tip
- 6 Cover the new disposable tip with the provided silicone cap and make sure it is tightly sealed
- 7 After treatment, Take an X-ray to check the root canal filling status.

Expiration

3 years from the manufacture date when stored according to the directions

Storage

- 1 Keep the silicone cap tightly sealed on the new disposable tip for storage.
- 2 Avoid high temperature and high humidity.
- 3 Keep out of reach of children.
- 4 Avoid exposure to direct sunlight and store in a dry, cool place. Storage temperature: 2-27°C

Caution**General Caution**

- 1 This product should not be used for reasons other than the intended use.
- 2 This product should only be used by a dentist or a dental professional.
- 3 Do not use on patients with inflammation or allergy to any of this product's components.
- 4 Avoid contact with skin and eyes. In case of contact, rinse immediately with running water.
- 5 This product cannot be prescribed for internal use.
- 6 This filling should only remain in the body for 29 days or LESS.

Application note

- 1 Do not overfill and extrude the product beyond the apex as patient may experience acute pain.
- 2 Do not use products that have expired.
- 3 Do not mix with other products.

Contraindication

Very rarely, this product may cause hypersensitivity reactions. In such cases, discontinue use and consult a doctor

Symbols

Use by

LOT

Batch Code



Consult instructions for use



Manufacturer

EC REP

Authorized representative in the European Community



Temperature Limitation



Keep Dry



Keep Away From Sunlight



Caution

RX Only

Warranty

DiaDent Group International will replace product that is proven to be defective. DiaDent Group International does not accept liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

Contact Information

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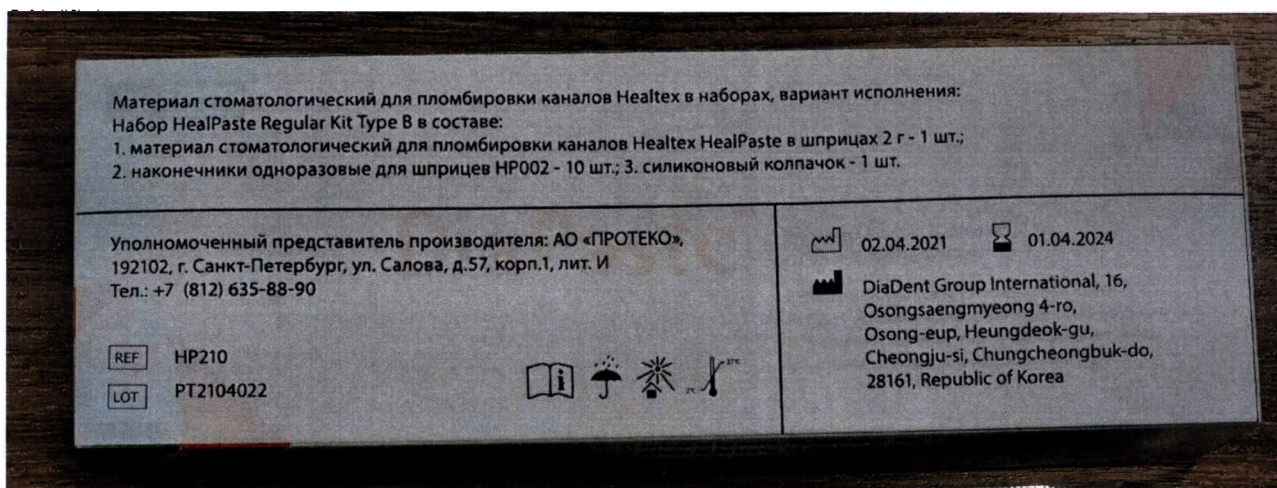
EC REP

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Almere, the Netherlands
Tel : 31-36-549-8607

Copyright: Mar 95, 2004 (4) DiaPaste (Rev. 1)

Материал стоматологический для временной пломбировки каналов Healtex®. Набор HealPaste Regular Kit Type B в составе:

- материал стоматологический Healtex® HealPaste в шприцах 2 г - 1 шт.;
- наконечники одноразовые для шприцев HP002 - 10 шт.;
- силиконовый колпачок - 1 шт.;
- инструкции – 1 шт.



Материал стоматологический для пломбировки каналов Healtex HealPaste в шприцах 2 г

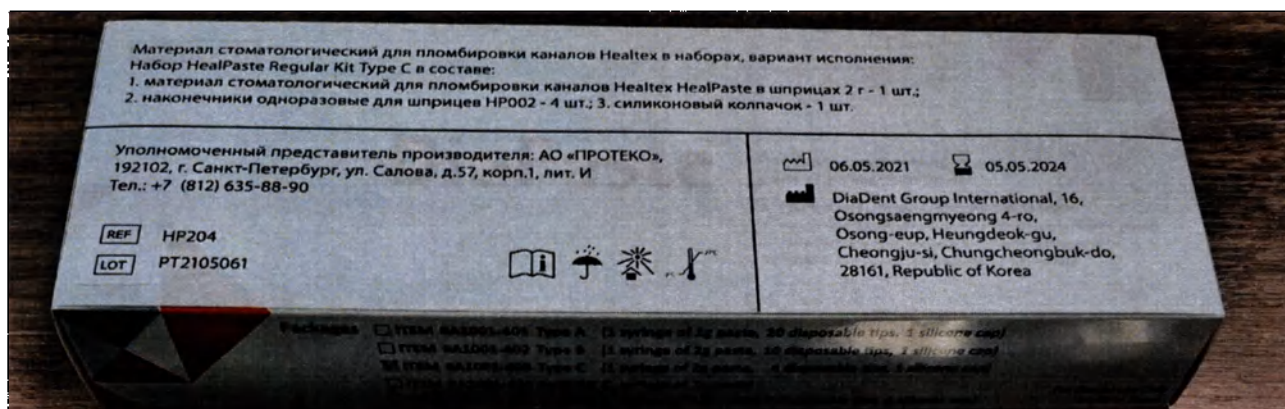
LOT PT2104022
01.04.2024



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Материал стоматологический для временной пломбировки каналов Healtex®. Набор HealPaste Regular Kit Type C в составе:

- материал стоматологический Healtex® HealPaste в шприцах 2 г - 1 шт.;
- наконечники одноразовые для шприцев HP002 - 4 шт.;
- силиконовый колпачок - 1 шт.;
- инструкция – 1 шт.



Материал стоматологический для пломбировки каналов Healtex HealPaste в шприцах 2 г
LOT PT2105061
05.05.2024



DiaDent®**DiaPaste™**

CE 0197

Root Canal Filling Material

Description

DiaPaste is a calcium hydroxide paste with barium sulfate, used as a temporary root canal filling material.

Indication for use

Aqueous ointment material that temporarily fills the root canal for the following indications:

- Apexification
- Temporary root filling
- Root canal filling for primary teeth
- Vital pulpotomy
- Temporary pulp capping

Performance

Radiopacity: ≥ 3 mm (ISO 6876 standard)

Flowability: ≥ 17 mm (ISO 6876 standard)

Precaution

- ① Check the product for leaks, discoloration, abnormal condition of the packaging, and expiration date.
- ② A rubber dam should be used to protect patient's mouth and necessary accessories should be prepared in advance for the procedure.
- ③ Be familiar with the warning, side effects, contraindications and instructions.

Instruction for use

- ① Open the protective cap and attach the disposable tip onto the syringe.
- ② Insert the tip from the root opening to 1/5 of the length of the root canal.
- ③ Push the plunger slowly and gently to inject the material into the canal.
- ④ Remove excess material in the root canal and proceed with routine restoration procedure.
- ⑤ After use, remove the disposable tip attached to the syringe and attach a new disposable tip.
- ⑥ Cover the new disposable tip with the provided silicone cap and make sure it is tightly sealed.
- ⑦ After treatment, Take an X-ray to check the root canal filling status.

Expiration

3 years from the manufacture date when stored according to the directions

Storage

- ① Keep the silicone cap tightly sealed on the new disposable tip for storage.
- ② Avoid high temperature and high humidity.
- ③ Keep out of reach of children.
- ④ Avoid exposure to direct sunlight and store in a dry, cool place. Storage temperature: 2-27°C

Caution**General Caution**

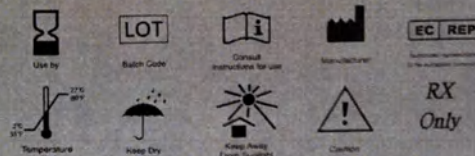
- ① This product should not be used for reasons other than the intended use.
- ② This product should only be used by a dentist or a dental professional.
- ③ Do not use on patients with inflammation or allergy to any of this product's components.
- ④ Avoid contact with skin and eyes. In case of contact, rinse immediately with running water.
- ⑤ This product cannot be prescribed for internal use.
- ⑥ This filling should only remain in the body for 29 days or LESS.

Application note

- ① Do not overfill and extrude the product beyond the apex as patient may experience acute pain.
- ② Do not use products that have expired.
- ③ Do not mix with other products.

Contraindication

Very rarely, this product may cause hypersensitivity reactions. In such cases, discontinue use and consult a doctor

Symbols**Warranty**

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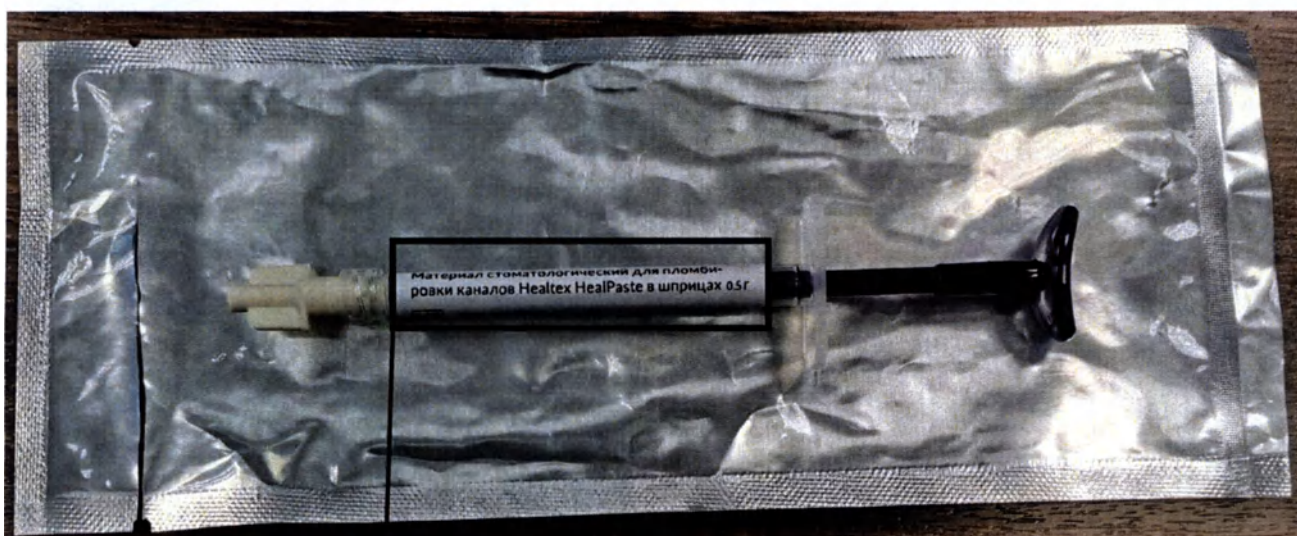
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Copyright: Mar. 09, 2023REV : DiaDentRev 1.1

Материал стоматологический для временной пломбировки каналов Healtex®. Набор HealPaste Intro Kit в составе:

- материал стоматологический Healtex® HealPaste в шприцах 2 г - 1 шт.;
- наконечники одноразовые для шприцев HP002 - 4 шт.;
- силиконовый колпачок - 1 шт.;
- инструкция - 1 шт.



Материал стоматологический для пломбировки каналов Healtex HealPaste в шприцах 0,5 г
LOT PT2102231
22.02.2024



Description

DiaPaste is a calcium hydroxide paste with barium sulfate, used as a temporary root canal filling material.

Indication for use

Aqueous ointment material that temporarily fills the root canal for the following indications:

- Apexification
- Temporary root filling
- Root canal filling for primary teeth
- Vital pulpotomy
- Temporary pulp capping

Performance

Radiopacity: ≥ 3 mm (ISO 6876 standard)
Flowability: ≥ 17 mm (ISO 6876 standard)

Precaution

- 1 Check the product for leaks, discoloration, abnormal condition of the packaging, and expiration date.
- 2 A rubber dam should be used to protect patient's mouth and necessary accessories should be prepared in advance for the procedure.
- 3 Be familiar with the warning, side effects, contraindications and instructions.

Instruction for use

- 1 Open the protective cap and attach the disposable tip onto the syringe.
- 2 Insert the tip from the root opening to 1/5 of the length of the root canal.
- 3 Push the plunger slowly and gently to inject the material into the canal.
- 4 Remove excess material in the root canal and proceed with routine restoration procedure.
- 5 After use, remove the disposable tip attached to the syringe and attach a new disposable tip
- 6 Cover the new disposable tip with the provided silicone cap and make sure it is tightly sealed
- 7 After treatment, Take an X-ray to check the root canal filling status.

Expiration

3 years from the manufacture date when stored according to the directions

Storage

- 1 Keep the silicone cap tightly sealed on the new disposable tip for storage.
- 2 Avoid high temperature and high humidity.
- 3 Keep out of reach of children.
- 4 Avoid exposure to direct sunlight and store in a dry, cool place. Storage temperature: 2-27°C

Caution**General Caution**

- 1 This product should not be used for reasons other than the intended use.
- 2 This product should only be used by a dentist or a dental professional.
- 3 Do not use on patients with inflammation or allergy to any of this product's components.
- 4 Avoid contact with skin and eyes. In case of contact, rinse immediately with running water.
- 5 This product cannot be prescribed for internal use.
- 6 This filling should only remain in the body for 29 days or LESS.

Application note

- 1 Do not overfill and extrude the product beyond the apex as patient may experience acute pain.
- 2 Do not use products that have expired.
- 3 Do not mix with other products.

Contraindication

Very rarely, this product may cause hypersensitivity reactions. In such cases, discontinue use and consult a doctor

Symbols

Use By



Batch Code



Consult Instructions for Use



Manufacture



Authorized representative in the European Union



Temperature Limitation



Keep Dry



Keep Away from Sunlight



Caution



RX Only

Warranty

DiaDent Group International will replace product that is proven to be defective. DiaDent Group International does not accept liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

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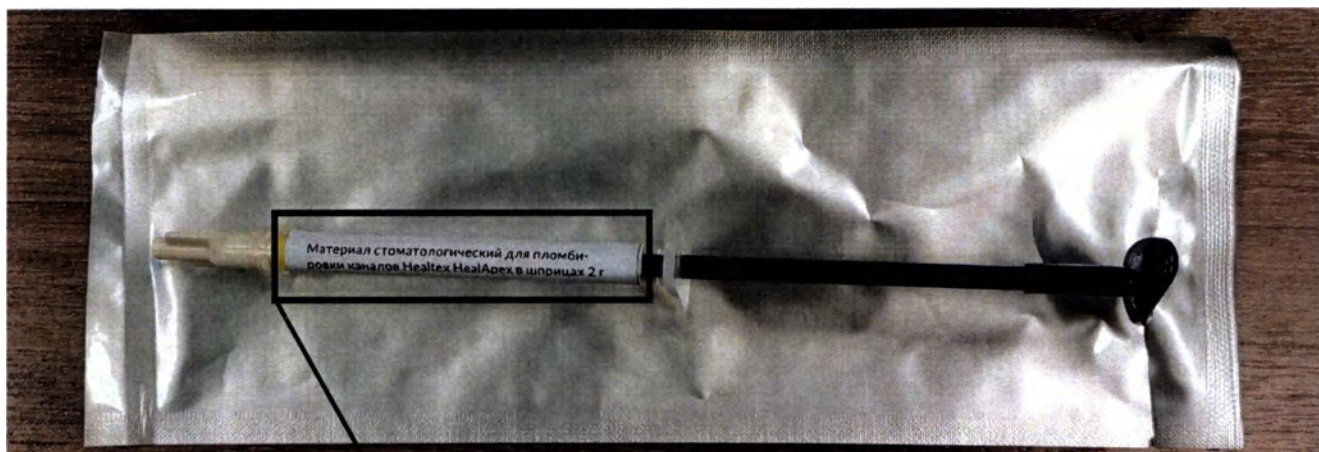
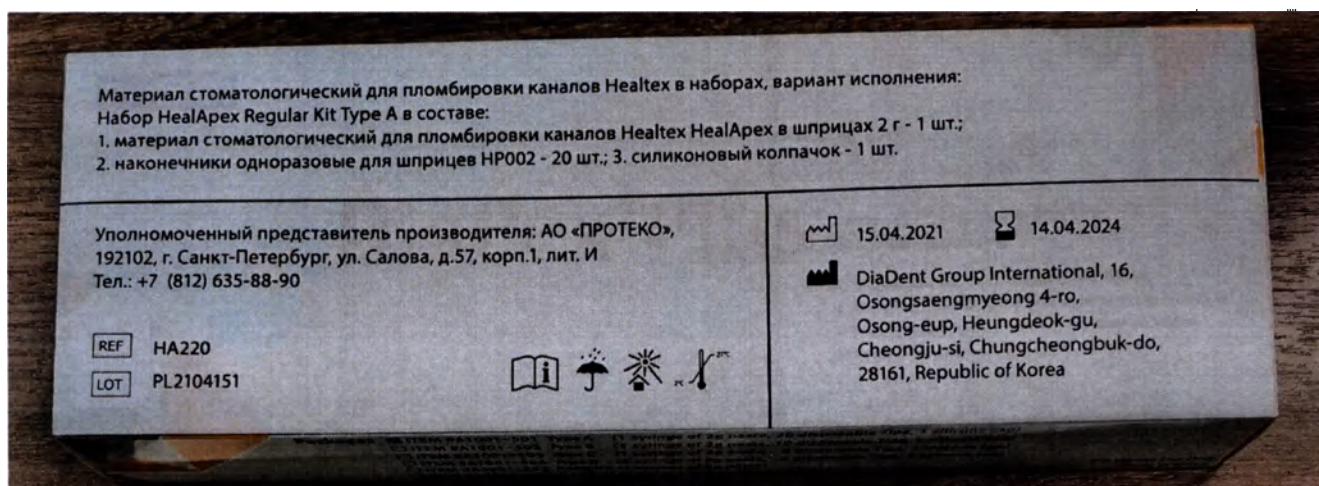


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Материал стоматологический для временной пломбировки каналов Healtex®. Набор HealApex Regular Kit Type A в составе:

- материал стоматологический Healtex® HealApex в шприцах 2 г - 1 шт.;
- наконечники одноразовые для шприцев HP002 – 20 шт.
- силиконовый колпачок – 1 шт.;
- инструкция – 1 шт.



Материал стоматологический для пломбировки каналов Healtex HealApex в шприцах 2 г
LOT PL2104151
14.04.2024



DiaDent®**DiaPex® Plus**

Root Canal Filling Material

DiaPex Plus is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material

Applications

- Root canal filling material
- Apexification and hard tissue formation
- Apexogenesis

Advantages & Effectiveness

- Quick and simple application, one hand use
- Premixed paste eliminates messy mixing and comes in a convenient syringe
- Promotes apexification and apexogenesis
- Easy removal
- Performance
 - Radiopacity : ≥ 3 mm (ISO 6876)
 - Flowability : ≥ 17 mm (ISO 6876)

Directions

1. Before using DiaPex Plus, ensure that the syringe and tip are free of damage. (e.g. chips, cracks, deformation, and/or other defects)
2. Protect the oral cavity by using a rubber dam.
3. Wipe and disinfect the outer syringe and tip with alcohol as tips come unsterilized.
4. After root canal preparation, the canal is irrigated and dried.
5. Insert the tip of the DiaPex Plus syringe to one fifth of root canal length from the apex. The tip is bent to obtain easier access to canal.
6. Slowly and gently press the piston of the syringe to extrude the paste. The paste should reach the periapical tissue and the tip should be pulled out slowly. The paste should reverse back to the pulp chamber.
7. After placing the paste in the canal and fully removing the syringe, clean off any excess paste.
8. After each application, the used tip should be discarded and a new tip or the silicon cap put back on.
9. Once the procedure is done, take an X-Ray to check the seal.

Removal

1. Find an appropriate size of file to insert into the canal to scatter the paste and to obtain canal patency.
2. Irrigate with 5.25% sodium hypochlorite solution.
3. Irrigate with an ultrasonic irrigation tip (preferably a nickel titanium tip) to irrigate the canal for at least a minute. (Recommendation)
4. Repeat the above step at least 3 times to ensure complete removal of paste remnants. Dry the canal with paper points after.

Storage

1. Store in a dry and cool place. (2-27°C)
2. Avoid exposure to direct sunlight.
3. Shelf life is 3 years from manufacturing date.

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EC REP
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Tel : 31-36-549-8607

Caution

1. It is prohibited to the product for reason other than the Intended use.
2. Use only under the described directions.
3. For professional use only.
4. Do not use this product on patient with past history of allergy or irritation to DiaPex Plus or iodine compounds.
5. DiaPex Plus can cause severe eye and skin irritations. In case of contact with the eye, flush with ample amount of water and seek medical attention immediately. In case of contact with skin, wash with soap and water immediately.
6. DiaPex Plus cannot be used as a permanent root canal filling.
7. Do not press the piston to extrude the paste with excess force as the patients may feel acute pain.
8. Take note of the graduation marks on the syringe to avoid overfilling the apex with excess paste.
9. DiaPex Plus should only be applied if the exudates are stopped.
10. Pay attention to the location of the mandibular canal under the lower molar teeth.
11. Pay attention to the positional relationship between the maxillary sinus and the upper molar teeth
12. This filling should only remain in the body for 29 days or less

Application notes

Do not fill pass the apex. Overfilling may cause pain or other adverse symptoms in the patient.

Contraindication

Hypersensitivity to epoxy resins, amines, or other components of DiaPex Plus.

Symbols**Warranty and Limitation of Liability**

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Tel : 31-36-549-8607

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DiaDent®**DiaPex® Plus**

Root Canal Filling Material

DiaPex Plus is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material

Applications

- Root canal filling material
- Apexification and hard tissue formation
- Apexogenesis

Advantages & Effectiveness

- Quick and simple application, one hand use
- Premixed paste eliminates messy mixing and comes in a convenient syringe
- Promotes apexification and apexogenesis
- Easy removal
- Performance
 - Radiopacity : $\geq 3\text{mm}$ (ISO 6876)
 - Flowability : $\geq 17\text{mm}$ (ISO 6876)

Directions

1. Before using DiaPex Plus, ensure that the syringe and tip are free of damage. (e.g. chips, cracks, deformation, and/or other defects)
2. Protect the oral cavity by using a rubber dam.
3. Wipe and disinfect the outer syringe and tip with alcohol as tips come unsterilized.
4. After root canal preparation, the canal is irrigated and dried.
5. Insert the tip of the DiaPex Plus syringe to one fifth of root canal length from the apex. The tip is bent to obtain easier access to canal.
6. Slowly and gently press the piston of the syringe to extrude the paste. The paste should reach the periapical tissue and the tip should be pulled out slowly. The paste should reverse back to the pulp chamber.
7. After placing the paste in the canal and fully removing the syringe, clean off any excess paste.
8. After each application, the used tip should be discarded and a new tip or the silicon cap put back on.
9. Once the procedure is done, take an X-Ray to check the seal.

Removal

1. Find an appropriate size of file to insert into the canal to scatter the paste and to obtain canal patency.
2. Irrigate with 5.25% sodium hypochlorite solution.
3. Irrigate with an ultrasonic irrigation tip (preferably a nickel titanium tip) to irrigate the canal for at least a minute. (Recommendation)
4. Repeat the above step at least 3 times to ensure complete removal of paste remnants. Dry the canal with paper points after.

Storage

1. Store in a dry and cool place. (2~27°C)
2. Avoid exposure to direct sunlight.
3. Shelf life is 3 years from manufacturing date.

Caution

1. It is prohibited to the product for reason other than the Intended use.
2. Use only under the described directions.
3. For professional use only.
4. Do not use this product on patient with past history of allergy or irritation to DiaPex Plus or iodine compounds.
5. DiaPex Plus can cause severe eye and skin irritations. In case of contact with the eye, flush with ample amount of water and seek medical attention immediately. In case of contact with skin, wash with soap and water immediately.
6. DiaPex Plus cannot be used as a permanent root canal filling.
7. Do not press the piston to extrude the paste with excess force as the patients may feel acute pain.
8. Take note of the graduation marks on the syringe to avoid overfilling the apex with excess paste.
9. DiaPex Plus should only be applied if the exudates are stopped.
10. Pay attention to the location of the mandibular canal under the lower molar teeth.
11. Pay attention to the positional relationship between the maxillary sinus and the upper molar teeth
12. This filling should only remain in the body for 29 days or less

Application notes

Do not fill pass the apex. Overfilling may cause pain or other adverse symptoms in the patient.

Contraindication

Hypersensitivity to epoxy resins, amines, or other components of DiaPex Plus.

Symbols**Warranty and Limitation of Liability**

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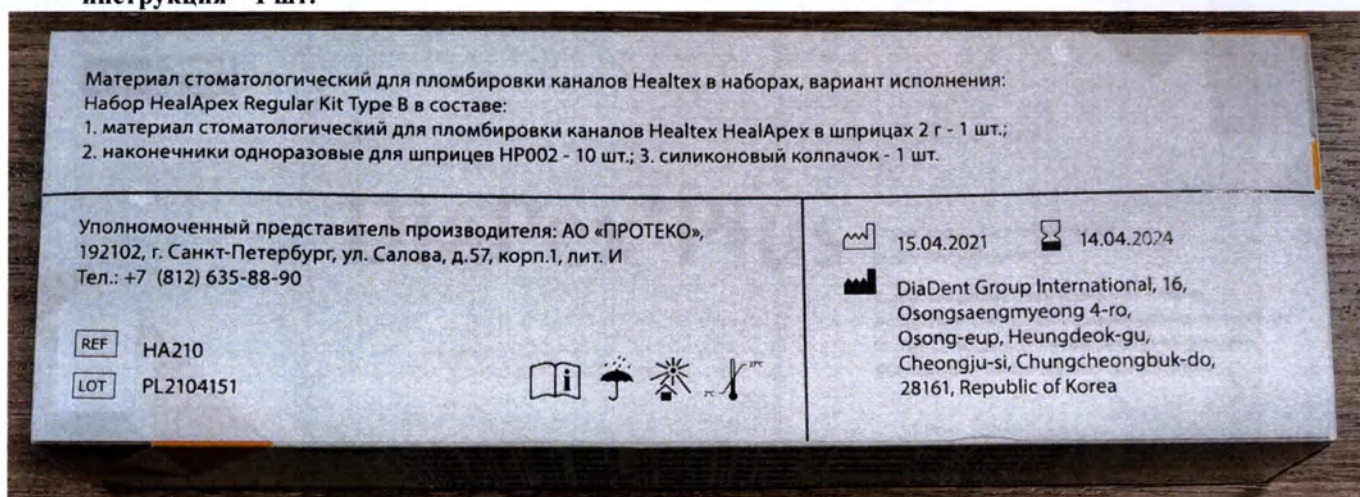
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- материал стоматологический Healtex® HealApex в шприцах 2 г - 1 шт.;
- наконечники одноразовые для шприцев HP002 – 10 шт.
- силиконовый колпачок – 1 шт.;
- инструкция – 1 шт.



Материал стоматологический для пломбировки каналов Healtex HealApex в шприцах 2 г
LOT PL2104151
14.04.2024



DiaDent® DiaPex® Plus

Root Canal Filling Material

DiaPex Plus is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material

Applications

- Root canal filling material
- Apexification and hard tissue formation
- Apexogenesis

Advantages & Effectiveness

- Quick and simple application, one hand use
 - Premixed paste eliminates messy mixing and comes in a convenient syringe
 - Promotes apexification and apexogenesis
 - Easy removal
 - Performance
- Radiopacity : $\geq 3\text{mm}$ (ISO 6876)
Flowability : $\geq 17\text{mm}$ (ISO 6876)

Directions

1. Before using DiaPex Plus, ensure that the syringe and tip are free of damage. (e.g. chips, cracks, deformation, and/or other defects)
2. Protect the oral cavity by using a rubber dam.
3. Wipe and disinfect the outer syringe and tip with alcohol as tips come unsterilized.
4. After root canal preparation, the canal is irrigated and dried.
5. Insert the tip of the DiaPex Plus syringe to one fifth of root canal length from the apex. The tip is bent to obtain easier access to canal.
6. Slowly and gently press the piston of the syringe to extrude the paste. The paste should reach the periapical tissue and the tip should be pulled out slowly. The paste should reverse back to the pulp chamber.
7. After placing the paste in the canal and fully removing the syringe, clean off any excess paste.
8. After each application, the used tip should be discarded and a new tip or the silicon cap put back on.
9. Once the procedure is done, take an X-Ray to check the seal.

Removal

1. Find an appropriate size of file to insert into the canal to scatter the paste and to obtain canal patency.
2. Irrigate with 5.25% sodium hypochlorite solution.
3. Irrigate with an ultrasonic irrigation tip (preferably a nickel titanium tip) to irrigate the canal for at least a minute. (Recommendation)
4. Repeat the above step at least 3 times to ensure complete removal of paste remnants. Dry the canal with paper points after.

Storage

1. Store in a dry and cool place, (2~27°C)
2. Avoid exposure to direct sunlight.
3. Shelf life is 3 years from manufacturing date.

Caution

1. It is prohibited to the product for reason other than the Intended use.
2. Use only under the described directions.
3. For professional use only.
4. Do not use this product on patient with past history of allergy or irritation to DiaPex Plus or iodine compounds.
5. DiaPex Plus can cause severe eye and skin irritations. In case of contact with the eye, flush with ample amount of water and seek medical attention immediately. In case of contact with skin, wash with soap and water immediately.
6. DiaPex Plus cannot be used as a permanent root canal filling.
7. Do not press the piston to extrude the paste with excess force as the patients may feel acute pain.
8. Take note of the graduation marks on the syringe to avoid overfilling the apex with excess paste.
9. DiaPex Plus should only be applied if the exudates are stopped.
10. Pay attention to the location of the mandibular canal under the lower molar teeth.
11. Pay attention to the positional relationship between the maxillary sinus and the upper molar teeth
12. This filling should only remain in the body for 29days or less

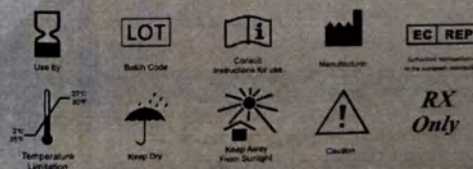
Application notes

Do not fill pass the apex. Overfilling may cause pain or other adverse symptoms in the patient.

Contraindication

Hypersensitivity to epoxy resins, amines, or other components of DiaPex Plus.

Symbols



Warranty and Limitation of Liability

DiaDent Group International will replace product that is proven to be defective. DiaDent Group International does not accept liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

Contact Information

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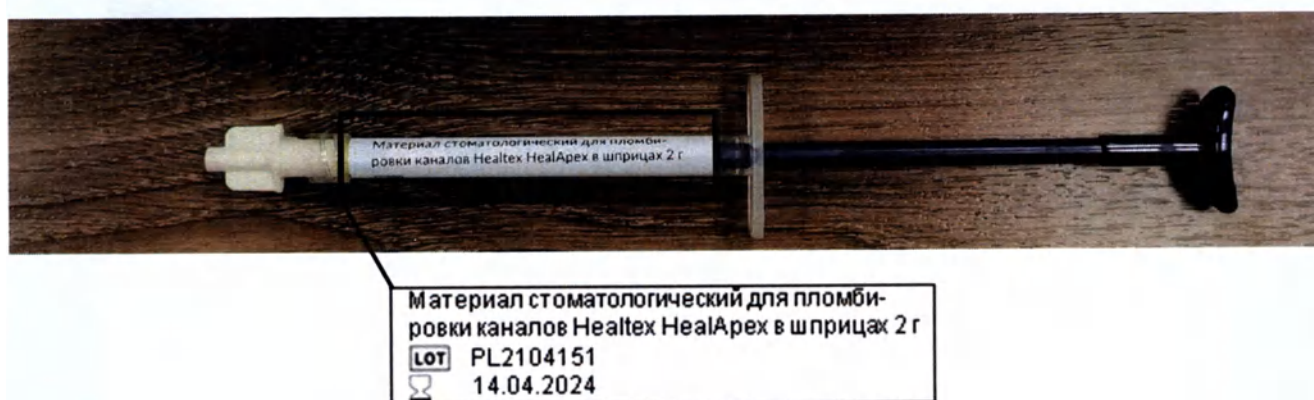
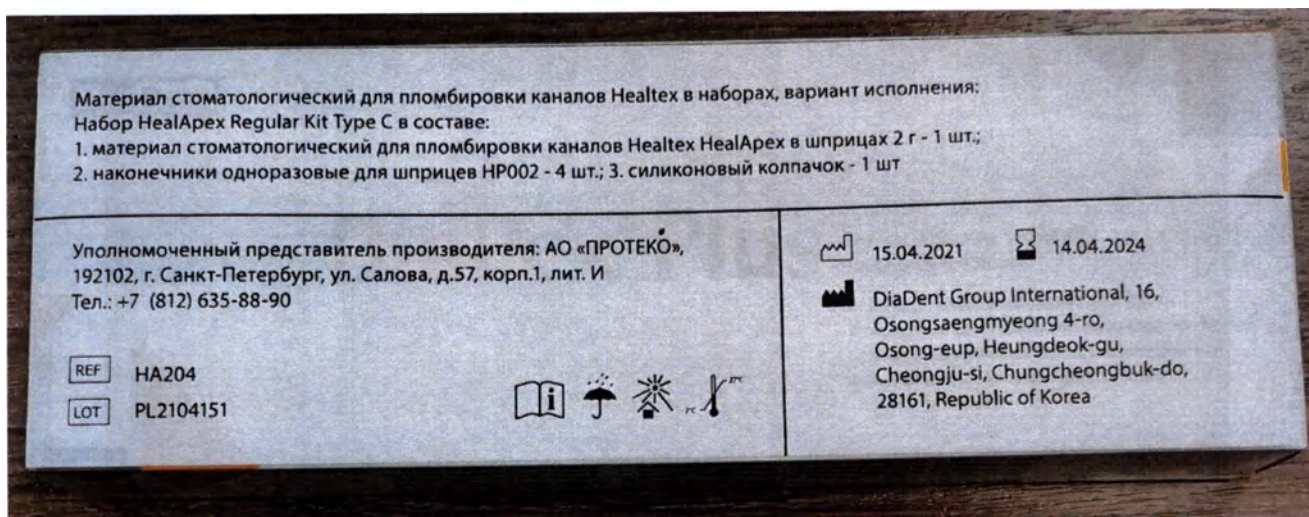
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Материал стоматологический для временной пломбировки каналов Healtex®. Набор HealApex Regular Kit Type C в составе:

- материал стоматологический Healtex® HealApex в шприцах 2 г - 1 шт.;
- наконечники одноразовые для шприцев HP002 – 4 шт.
- силиконовый колпачок – 1 шт.;
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Applications

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Directions

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2. Protect the oral cavity by using a rubber dam.
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4. After root canal preparation, the canal is irrigated and dried.
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12. This filling should only remain in the body for 29 days or less.

Application notes

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Contraindication

Hypersensitivity to epoxy resins, amines, or other components of DiaPex Plus.

Symbols



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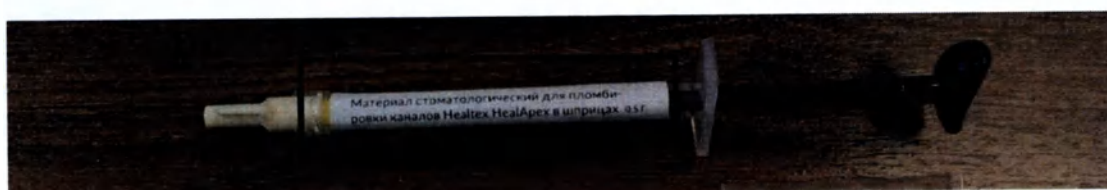
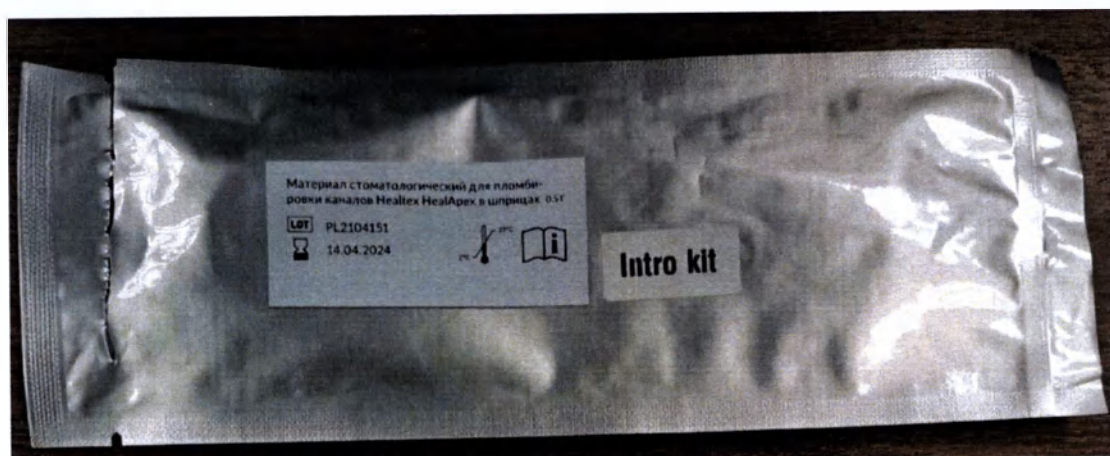
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Symbols



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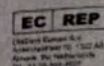
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LOT



HEALTEX[®] **0,5г**

МАТЕРИАЛ СТОМАТОЛОГИЧЕСКИЙ
для временной пломбировки каналов Healtex[®] HealPaste



**«DiaDent Group International»**
(«ДиаДент Груп Интернейшнл»)
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chung-cheongbuk-do, 28161, Republic of Korea

LOT



HEALTEX[®] **2г**

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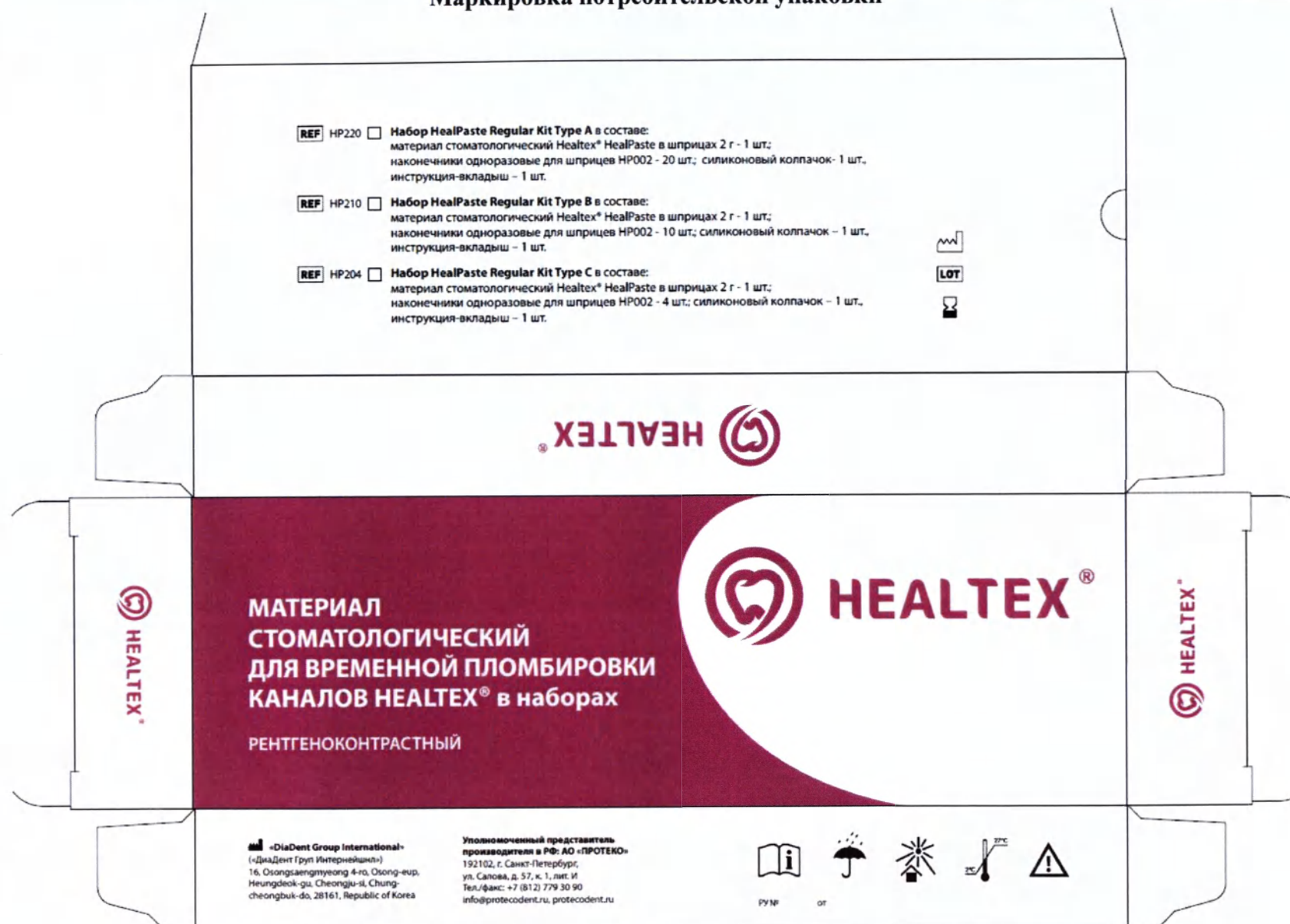
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Маркировка потребительской упаковки



Фотографические изображения общего вида медицинского изделия:

Материал стоматологический для временной пломбировки каналов HealTex® в наборах



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**МАТЕРИАЛ СТОМАТОЛОГИЧЕСКИЙ
ДЛЯ ВРЕМЕННОЙ ПЛОМБИРОВКИ КАНАЛОВ Healtex® в наборах**

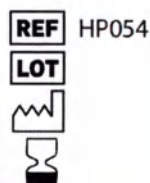
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**МАТЕРИАЛ СТОМАТОЛОГИЧЕСКИЙ
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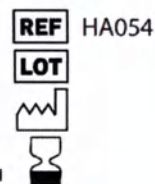
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производителя в РФ: АО «ПРОТЕКО»**
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Прошито, пронумеровано и скреплено печатью

22 (902/2024) листа(ов)

АО «ПРОТЕКО» Чекова Е.С.

на основании Доверенности № 78 АВ 5341909 от 26.06.2024 г.

