

## MACRO-LOCK POST® ILLUSION® X-RO® FOR DENTAL USE ONLY

### DESCRIPTION

**MACRO-LOCK POST ILLUSION® X-RO®** are dental posts used for reconstruction of devitalized teeth. They are made of X-RO yellow translucent fibers bound in a colored resin Epoxy-vinyl ester matrix, which becomes translucent in the mouth. The post color will re-appear on command under cold air, water spray or heat-treatment is required.

The **MACRO-LOCK POST ILLUSION® X-RO®** is a serrated-surfaced post, apically tapered with a length of 17.5 mm. The post has fluted slots around its axis for additional macro-retention to the adhesive used, by increasing the surface area available on the post for cement contact.

The radiopacity level of the **MACRO-LOCK POST ILLUSION® X-RO®** is 340% Al eq. (ISO 4049)

The devices are available in 6 sizes and are used in association with an universal pre-shaping drill to perform a first hole and finishing drill associated to each post size according to an O-ring part (See Figure 1). The drills associated to **MACRO-LOCK POST ILLUSION® X-RO®** are **MACRO-LOCK®** drills.

	• 1	• 2	• 3	• 4	• 5	• 6
Ø apical tip	0.80	0.80	1.00	1.00	1.30	1.30
Ø Post head	1.35	1.47	1.67	1.83	2.04	2.22
Starter drill	#1	#1	#2	#2	#2	#2
Finishing Drill	#1	#2	#3	#4	#5	#6

### COMPOSITION

**MACRO-LOCK POST ILLUSION® X-RO®** posts are fiber-reinforced polymer made of XRO fiber (80%) and epoxy resin matrix (20%) which contains colored pigment.

**MACRO-LOCK®** drills are made of stainless steel.

### INTENDED USE

**MACRO-LOCK POST ILLUSION® X-RO®** posts have been designed to support and secure the coronal restoration in case of insufficient residual tooth structure (<4 mm).

**MACRO-LOCK®** drills are intended to prepare the tooth for insertion of a post that will support and secure the coronal restoration where insufficient residual tooth structure (<4 mm) exists.

These products should only be used in hospitals, clinics or dental office with qualified dental personnel (dentists).

### INDICATIONS FOR USE

**MACRO-LOCK POST ILLUSION® X-RO®** posts and associated drills are indicated in case of insufficient residual tooth structure (<4 mm) to support and secure the coronal restoration.

### CONTRAINDICATIONS

**MACRO-LOCK POST ILLUSION® X-RO®** posts and associated drills are contraindicated if coronal tooth structure is less than 1.5 mm.

### WARNINGS

None known to date.

### PRECAUTIONS

There is no data for the use of **MACRO-LOCK POST ILLUSION® X-RO®** posts and associated drills for pregnant women, breastfeeding women and children under 18 years old (for posts only). It is not recommended for such use.

If the device is used in a way different than the one recommended in the DFDU, loosening, breakage of the post or extraction of the tooth might occur.

**MACRO-LOCK POST ILLUSION® X-RO®** posts:

The post must be immersed or soaked in isopropanol for 1 minute and dried gently with air spraying for 15 s at least prior to bonding before insertion in the canal. Avoid touching the posts with your fingers after that.

The post can neither be sterilized nor disinfected in thermodesinfector and the use of autoclave is not recommended.

• Posts are single use devices. They must not be re-used to avoid the risk of contamination.

• Shortening the post with a diamond disc should be done outside of the mouth. Never use a crimping instrument, such as wire cutters, as the pressure can destroy the structure of the post, or extraction of the dent.

• The use of rubber dam is recommended.

• The crown must cover the preparation of at least 1.5 mm of healthy dentin in order to get the férula effect.

**MACRO-LOCK®** drills:

• **MACRO-LOCK POST ILLUSION® X-RO®** drills are supplied non-sterile. Disinfect and sterilize instruments before each use. Disinfect instruments with disinfecting or cleaning agents adapted for rotary instruments\*. Do not disinfect instruments in thermodesinfector.

• Inspect instruments visually before each use: change new drills when they are damaged, corroded or dull.

• The universal drill may be used only to remove root canal filling partially, and the finishing drills may be used only to prepare root canal.

• The use of rubber dam is recommended.

• The lifetime of use for the **MACRO-LOCK®** drills stated is 15 uses, following this the dental surgeon is informed that the drill should be replaced.

• Drills must be sterilized individually in an autoclave with the following settings\*\*:

✓ Wrap individually in disposable sterilization pouches or tubing that comply with the regulation standard in force in the country of use.

✓ Autoclave: type B complying with regulation standard in force.

✓ Sterilization temperature: 134 °C – sterilization time: 18 minutes;

✓ Store the sterilized components in a dry, dust-free place.

✓ If the packaging's integrity appears to be compromised, before using again, place the component in a new pouch and re-sterilize according to the protocol described in the IFU.

## PT-B

## MACRO-LOCK POST® ILLUSION® X-RO® APENAS PARA USO ODONTOLÓGICO

### DESCRIÇÃO

**MACRO-LOCK POST ILLUSION® X-RO®** são núcleos odontológicos utilizados para a reconstrução de dentes devitalizados. Eles são feitos com fibras X-RO de cor amarelo translúcido, unidas a uma matriz de resina epóxi éster vinílica colorida que se torna translúcida na cavidade oral. A cor do núcleo parecerá ao comando, sob ar frio, spray de água, se for necessário um retratamento.

O **MACRO-LOCK POST ILLUSION® X-RO®** é um núcleo com superfície serrilhada, apicalmente cônico, com um comprimento de 17.5 mm. O núcleo tem fendas estriadas ao redor de seu eixo para macroretenção ao adesivo utilizado, aumentando a área de superfície disponível no núcleo para o contato com o cimento.

A **MACRO-LOCK POST ILLUSION® X-RO®** é um núcleo com superfície serrilhada, apicalmente cônico, com um comprimento de 17.5 mm. O núcleo tem fendas estriadas ao redor de seu eixo para macroretenção ao adesivo utilizado, aumentando a área de superfície disponível no núcleo para o contato com o cimento.

O nível de radiopacidade do **MACRO-LOCK POST ILLUSION® X-RO®** é 340% Al eq. (ISO 4049)

Os dispositivos estão disponíveis em 6 tamanhos e são utilizados em associação com uma broca de moldagem prévia universal para realizar o primeiro orifício, e uma broca de acabamento associada a cada tamanho de núcleo de acordo com a parte colorida do O-ring (veja figura 1). As brocas associadas ao núcleo **MACRO-LOCK POST ILLUSION® X-RO®** são brocas **MACRO-LOCK®**.

	• 1	• 2	• 3	• 4	• 5	• 6
Ø ponta apical	0.80	0.80	1.00	1.00	1.30	1.30
Ø Post head	1.35	1.47	1.67	1.83	2.04	2.22
Starter drill	#1	#1	#2	#2	#2	#2
Finishing Drill	#1	#2	#3	#4	#5	#6

### INSTRUÇÕES PASSO A PASSO

1. Preparo do canal radicular: remover a gutta-percha até a profundidade pré-planejada com uma broca Gates-Glidden, Peeso reamer ou Largo Peeso. É recomendada a verificação radiográfica.

2. Seleccionar o tamanho correto do **MACRO-LOCK POST ILLUSION® X-RO®**. Determinar o tamanho do núcleo de acordo com a situação anatômica do dente usando a radiografia.

3. Determinar a extensão do preenchimento coronário, que representará 1/3 do comprimento final do núcleo. Remover o preenchimento radicular com a broca de moldagem prévia **MACRO-LOCK STARTER DRILL** selecionada (velocidade de rotação 800-1200 rpm) tão profundamente quanto necessário para que o núcleo seja inserido em 2/3 do comprimento da raiz. Ao menos 4 mm do preenchimento do canal radicular deve permanecer na região apical. O caso de canal curvo, este comprimento calculado não é adequado.

4. Preparar o canal com a broca de acabamento **Finishing Drill** correspondente ao tamanho do núcleo **MACRO-LOCK POST ILLUSION® X-RO®** selecionado (velocidade de rotação 1000-2000 rpm).

5. Provar o núcleo, para checar se o núcleo está assentado adequadamente no canal.

6. Encurtar o núcleo até o comprimento final com um dril diamantado, fora da cavidade oral. Nunca use instrumentais de crimpagem, como cortadores de fio, uma vez que a pressão pode destruir a estrutura do núcleo.

7. Limpar o núcleo com álcool.

8. Aplicar etchant no post space and to the exposed dentin for 15 seconds\*. Rinse for 10 seconds.

9. Remove the excess water with paper points but leave surface moist. Do not put the etchant in contact with the gingiva.

10. Apply 2 coats of the primer with a thin brush (e.g. Composibrush RTD) in the post space. Remove excess using paper points and gently air dry all surfaces. Enamel and dentin surfaces should have a uniform, glossy appearance. If not, repeat application. Light-cure the primer\* inside the post space for 10 to 20 seconds.

11. If using a dual cure resin cement for both cementation and core build up such as **Corecem™** (recommended technique): Mix the cement and apply it in the post space from bottom to the top using the root canal tips. Seal the post immediately. Light-cure for 40 to 60 seconds. Continue applying the core build up using a plastic form and directly on the tooth.

12. If using a core resin cement for both cementation and core build up such as **Corecem™** (recommended technique): Mix the cement and apply it in the post space from bottom to the top using the root canal tips. Seal the post immediately. Light-cure for 40 to 60 seconds. Continue applying the core build up using a plastic form and directly on the tooth.

13. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

14. After etching, rinsing, drying of involved tooth structure, apply 2 coats of bonding agent\* to the exposed post(s), cement and involved tooth structure. Remove excess and air dry with jet of air. Light-cure for 20 seconds (if needed).

15. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

16. If using a core resin cement for both cementation and core build up such as **Corecem™** (recommended technique): Mix the cement and apply it in the post space from bottom to the top using the root canal tips. Seal the post immediately. Light-cure for 40 to 60 seconds. Continue applying the core build up using a plastic form and directly on the tooth.

17. If using a core resin cement for both cementation and core build up such as **Corecem™** (recommended technique): Mix the cement and apply it in the post space from bottom to the top using the root canal tips. Seal the post immediately. Light-cure for 40 to 60 seconds. Continue applying the core build up using a plastic form and directly on the tooth.

18. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

19. After etching, rinsing, drying of involved tooth structure, apply 2 coats of bonding agent\* to the exposed post(s), cement and involved tooth structure. Remove excess and air dry with jet of air. Light-cure for 20 seconds (if needed).

20. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

21. If using a core resin cement for both cementation and core build up such as **Corecem™** (recommended technique): Mix the cement and apply it in the post space from bottom to the top using the root canal tips. Seal the post immediately. Light-cure for 40 to 60 seconds. Continue applying the core build up using a plastic form and directly on the tooth.

22. If using a core resin cement for both cementation and core build up such as **Corecem™** (recommended technique): Mix the cement and apply it in the post space from bottom to the top using the root canal tips. Seal the post immediately. Light-cure for 40 to 60 seconds. Continue applying the core build up using a plastic form and directly on the tooth.

23. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

24. After etching, rinsing, drying of involved tooth structure, apply 2 coats of bonding agent\* to the exposed post(s), cement and involved tooth structure. Remove excess and air dry with jet of air. Light-cure for 20 seconds (if needed).

25. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

26. After etching, rinsing, drying of involved tooth structure, apply 2 coats of bonding agent\* to the exposed post(s), cement and involved tooth structure. Remove excess and air dry with jet of air. Light-cure for 20 seconds (if needed).

27. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

28. After etching, rinsing, drying of involved tooth structure, apply 2 coats of bonding agent\* to the exposed post(s), cement and involved tooth structure. Remove excess and air dry with jet of air. Light-cure for 20 seconds (if needed).

29. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

30. After etching, rinsing, drying of involved tooth structure, apply 2 coats of bonding agent\* to the exposed post(s), cement and involved tooth structure. Remove excess and air dry with jet of air. Light-cure for 20 seconds (if needed).

31. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

32. After etching, rinsing, drying of involved tooth structure, apply 2 coats of bonding agent\* to the exposed post(s), cement and involved tooth structure. Remove excess and air dry with jet of air. Light-cure for 20 seconds (if needed).

33. If using a self-etching cement\*, there is no need to etch and prime the post space. Mix the cement and apply it in the post space from bottom to the top using a root canal tip. Seal the post immediately. Remove excess cement.

34. After etching, rinsing, drying of involved tooth structure, apply 2 coats of bonding agent\* to the exposed post(s), cement and involved tooth structure. Remove excess and air dry with jet of



## 용어 및 기호 확인

- 제조사 :
- LOT 번호 :
- REF 카탈로그 번호 :
- 단위 수/제품 구성 :
- 작사광선 노출 금지 :

**제조사:**  
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영어가 포함 텍스트입니다.

**RU**

## MACRO-LOCK POST® ILLUSION® X-RO® TOLJKO DLA STOMATOLOGICZNEGO KOMPLEKSOWEGO PRZEMIENIENIA

### ОПИСАНИЕ

MACRO-LOCK POST ILLUSION® X-RO® представляют собой стоматологические штифты для восстановления дефектов зубов. Они состоят из жёлтых полупрозрачных волокон X-RO со связующим и окрашенной матрицы из эпоксидной смолы, приобретающей свойства полупрозрачности в полости рта. Цвет штифта проявляется при необходимости под воздействием холодного воздуха или распыляемой струи воды, если требуется повторное печение.

Штифты MACRO-LOCK POST ILLUSION® X-RO® имеют шероховатую поверхность, коническая апикальная часть, их длина составляет 1,5 мм. Штифт снабжен рифлёными прорезями вокруг своей оси для дополнительной макрорентгеники к используму адгезиву за счет увеличения доступной площади штифта для контакта с цементом.

Уровень рентгеноконтрастности MACRO-LOCK POST ILLUSION® X-RO® составляет 340 % алюм. эквивалента (ISO 4049).

Изделия предлагаются 6 различных размеров и применяются в сочетании с универсальной формирующей дрелью для выполнения первого отверстия и финишной дрелью, соответствующей размеру штифта, согласно цветовой маркировке (см. рис. 1). Штифты MACRO-LOCK POST ILLUSION® X-RO® соответствуют дрели MACRO-LOCK®.

	• 1	• 2	• 3	• 4	• 5	• 6
Ø верхушки	0,80	0,80	1,00	1,00	1,30	1,30
Ø головки штифта	1,35	1,47	1,67	1,83	2,04	2,22
Формирующая дрель STARTER DRILL	#1	#1	#2	#2	#2	#2
Финишная дрель FINISHING DRILL	#1	#2	#3	#4	#5	#6

### СОСТАВ

Штифты MACRO-LOCK POST ILLUSION® X-RO® выполнены из армированного стекловолокном полимера, состоящего из волокон X-RO (80 %) и матрицы из эпоксидной смолы (20 %), которая содержит цветной пигмент. Дрели MACRO-LOCK® изготовлены из нержавеющей стали.

### НАЗНАЧЕНИЕ

Штифты MACRO-LOCK POST ILLUSION® X-RO® предназначены для опоры и фиксации реставрации коронковой части при недостатке твёрдых тканей зуба (<4 mm).

Дрели MACRO-LOCK® предназначены для препарирования зуба под введение штифта для опоры и фиксации реставрации коронковой части, когда оставшихся твёрдых тканей зуба недостаточно (<4 mm).

Изделия разрешается использовать только в условиях больниц, клиник и стоматологических кабинетов с квалифицированным медперсоналом (стоматологами).

### ПОКАЗАНИЯ К ПРИМЕНЕНИЮ

Штифты MACRO-LOCK POST ILLUSION® X-RO® и соответствующие им дрели предназначены для опоры и фиксации реставрации коронковой части при недостатке твёрдых тканей зуба (<1,5 mm).

### ПРОТИВОПОКАЗАНИЯ

Штифты MACRO-LOCK POST ILLUSION® X-RO® и соответствующие им дрели противопоказаны, если остаток коронковой части зуба составляет менее 1,5 mm.

### ПРЕДОПРЕДЕЖЕНИЯ

На данный момент неизвестны.

### МЕРЫ ПРЕДОСТОРОЖНОСТИ

Отсутствуют данные о применении штифтов MACRO-LOCK POST ILLUSION® X-RO® и соответствующих им дрелей у беременных и кормящих женщин и детей младше 18 лет (только для штифтов). Не рекомендуется использовать их в этих ситуациях.

В случае применения изделия иным способом, кроме рекомендованного в инструкции, может произойти расщепление, поломка штифта или потребоваться удаление зуба.

Штифты MACRO-LOCK POST ILLUSION® X-RO®

• Штифт следует погрузить или пропитать в изопропиоловое спирте в течение 1 минуты, затем аккуратно просушить продубонным ширпом не менее 15 секунд, прежде чем насытить бондинг и вводить в канал. После этого не прикасайтесь к штифту руками. Запрещается стерилизовать и дезинфицировать штифты в термодезинфекторе. Использовать авто-клав не рекомендуется.

• Штифты являются одноразовыми изделиями. Во избежание риска заражения не используйте их повторно.  
• Укорачивание штифта алмазным диском следует выполнять вне полости рта. Ни в коем случае не используйте обжиговый инструмент, например кусачки, так как при сдавливании может нарушиться структура штифта.  
• Рекомендуется использовать коффердам.

• Коронка должна охватывать не менее 1,5 мм здорового дентина, чтобы добиться эффекта манжеты.

### Дрели MACRO-LOCK®

• Дрели MACRO-LOCK POST ILLUSION® X-RO® поставляются в нестерильном виде. Дезинфицируйте и стерилизуйте инструменты перед каждым применением. Дезинфицируйте инструменты дезинфицирующими или чистящими средствами, адаптированными для врачающихихся инструментов\*. Не дезинфицируйте инструменты в термодезинфекторе.

• Внимательно осматривайте инструменты перед каждым применением: при повреждении, корозии или затуплении используйте новые дрели.

• Универсальная дрель UNIVERSAL DRILL можно использовать только для частичного удаления пломбы из коронкового канала, а финишные дрели FINISHING DRILL используются только для препарирования коронкового канала.

• Рекомендуется использовать коффердам.

• Номинальный срок службы дрели MACRO-LOCK® 15 применений. Затем согласно инструкции стоматолог-хирург должен заменить дрель.

• Дрели необходимо стерилизовать отдельно в автоклаве при следующих условиях\*\*:

✓ упаковать индивидуально в одноразовые стериллизационные пакеты или пробирки, которые соответствуют действующим стандартам в стране применения;

✓ авто-клав: типа В согласно действующему стандарту;

✓ температура стериллизации: 134 °C, время стериллизации: 18 минут;

✓ хранить стерилизованные компоненты в сухом месте без юти;

✓ при наличии признаков нарушения целостности упаковки, перед применением поместите компонент в новый пакет и стерилизуйте повторно.

• Тип MACRO-LOCK®牙钻为一次性使用器械。为防止传染风险，不可重复使用。

• Компания RTD гарантирует отсутствие изъязв материялов и производственного брака в данном изделии. Компания RTD не предоставляет никаких иных гарантит, в том числе подразумеваемой гарантиты товарной пригодности или пригодности для определенной цели. Пользоваться обязанностью в соответствии с условиями гарантии.

• Рекомендуется использовать коффердам.

• Номинальный срок службы дрели MACRO-LOCK® 15 применений. Затем согласно инструкции стоматолог-хирург должен заменить дрель.

• Дрели необходимо стерилизовать отдельно в автоклаве при следующих условиях\*\*:

✓ упаковать индивидуально в одноразовые стериллизационные пакеты или пробирки, которые соответствуют действующим стандартам в стране применения;

✓ авто-клав: (анализатором музыки);

✓ изогнутое лезвие впереди, чтобы не повредить ткань;

✓ изогнутое лезвие впереди, чтобы не повредить ткань;