

Dentatus

Luscent Anchors®

INSTRUCTIONS FOR USE



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Luscent Anchors®

INSTRUCTIONS FOR USE

ENGLISH



Material:	<i>Post:</i> Transparent glass fiber/epoxy solid rod. <i>Depth Marker:</i> PVC-compound GFM/4E and PVC-compound GFM/4E-40-t. <i>Accessories</i> <i>Reamer:</i> Stainless Steel.	Intended Use/Patient Group:	Prefabricated fiberglass anchorage posts for retention of core materials in endodontically treated teeth.
Patient population group:	Patients with permanent teeth that are root filled and have extensive coronal damage.	Contraindications:	Relative contraindications for endodontic root canal therapy: - Patients suffering from bruxism or suspected bruxism - Deep overbite - Less than 2-3 mm residual tooth structure for ferrule Absolute contraindication: If patients are known to be allergic to materials.
Cleaning, Disinfection and Sterilization:	Posts are single use items; disinfect with alcohol & air-dry. Before first use , reamers can be chemically disinfected in a 5% solution of chlorhexidine alcohol for 3 minutes, or cleansed in ultrasonic baths. Autoclave at 134°C. Pressure: 30psi/2.07bar, Cycle time: 8 minutes, Dry time: 6 minutes. For reprocessing , wipe off the reamers after use to prevent debris from drying. Perform cleaning as soon as possible after use. Do not exceed 2 hours. Manual cleaning is performed using a soft brush and a mild alkaline detergent and rinsed thoroughly. Then follow disinfection and sterilization instructions above.	Safe disposal:	Posts that have been removed from tooth structure should be cleansed then the device can be disposed of in normal waste in the clinic, according to local regulations. Dull reamers should be disinfected then the device can be disposed of in normal metal waste in the clinic, according to local regulations.

PRECAUTIONS

- Delivered nonsterile and should be disinfected prior to use.
- Posts are intended for single use to avoid risk of infectious cross contamination.
- Reamers are delivered factory clean and should be cleansed and sterilized before use according to provided disinfection and sterilization instructions for an aseptic procedure.
- All other instrumentation used in the clinical procedure should be autoclaved with steam sterilization prior to use. The facility should validate its own autoclave steam sterilization machine in accordance with a recognized standard.
- Extreme care should be observed to prevent accidental swallowing or aspiration of endodontic posts or other related components used in this procedure. Preventive practices (rubber dam, floss ties or throat pack) should always be utilized. If such an accident should occur, immediately contact a physician.
- Dual cure adhesives and restorative materials may safely be combined with Luscent Anchors. Self-curing resins that may prematurely polymerize in the canal should be avoided.
- Damaged posts should be discarded.
- Posts are designed for passive cementation in root canals to prevent risk of root fracture.

NOTE: These instructions inform the user about the recommended procedures when using Luscent Anchors. They are intended for use by clinicians with a basic level of restorative dentistry and endodontic training. It is the responsibility of the clinician to stay informed, educated and trained. The printed guidelines, including Precautions and Notes, are to be regarded as additions to accepted clinical procedures and protocols.

Luscent Anchor Kits consist of reamers and specially fitted posts in different sizes. The posts are cemented temporarily or permanently in the prepared root canal. The anatomically shaped reamers and posts correspond to the natural morphology of the root canal. The system is to be used by trained dental personnel only.

Dentatus Reamers are designed to be used in standard contra angle hand pieces, at low speed, not exceeding 10,000 rpm. The shape of the reamers corresponds to the shape of the Luscent Anchors (see chart 1). Dentatus Reamers are available in various lengths, and in six different diameters, #1-6. Actual diameter is shown with corresponding number of grooves on the shank (see chart 2). The reamer system is size-matched to ensure passive seating; when utilizing a size 3 post with a size 3 reamer there is no engagement of the canal walls. This prevents tension build-up and risk of root fractures.

How to use:

After endodontic therapy, root-filling material is removed to the predetermined depth with a Pathfinder, Gates-Glidden drill, peeso reamer and/or hot instrument (Fig. 1). A minimum 4 mm of the root-filling material should remain apically. Radiographic verification is recommended.

The preparation should include at least 1.5 mm ferrule of sound tooth structure around the circumference of the preparation.

The preparation is commenced by using the Conical [RUH series] Reamers with a slow speed contra-angle in sequential order until the desired preparation has been achieved (Fig. 2). Preparation depth can be controlled by using the Depth Stoppers [MRA] on the reamers.

In larger canals utilizing post size 4 and above, the Probos II [RUD-4] can be used to create retention grooves in the canal for additional mechanical retention against debonding.

Choosing post dimension:

The appropriate size post is a combination of the diameter of the reamer, the length of the canal, and the height of the crown. The sleeve on the post is color coded to correspond with the post's diameter. The grooves on the shaft of the reamer correspond with the reamer's diameter (see chart 2).

The size number of the post coincides with the last used reamer and the length should be as long as possible without the post head interfering with shape, function and esthetic properties of the finished restoration.

The fit in the root canal is confirmed without rotating the post and the colored sleeve is moved to the intended post height. The excess is cut with a water-cooled diamond instrument and the post is disinfected with alcohol & air-dried (Fig. 4). The prepared root canal shall be acid etched then thoroughly cleansed and dried prior to cementation of the post

(Fig. 5).

Core Build-up:

Use a flowable dental composite of choice according to the manufacturer's instructions. The bonding agent is applied to the post and in the opening of the prepared root canal to coat the wall (Fig. 6). Light-cure composite is introduced into the canal (Fig.7). Dual-cure resin is recommended in canals deeper than 10 mm. Use an instrument of choice (i.e.: locking tweezer) to slowly insert














the post to full depth allowing excess composite to vent (Fig. 8). The light cure is placed directly over the Luscent Anchor supporting it in place (Fig.9). Light cure for 1-2 minutes depending on volume and depth. The core can now be prepared for the final aesthetic restoration (Fig. 10).

Post-Op:

Provide the patients with post operative instructions on hygiene and maintenance. In the event of any malfunction, patients should contact their dental provider.

Dentatus conforms to the vigilance system according to EU requirements. In the event of serious incident in relation to the device, events shall be reported to Dentatus and the competent authority of the Member State in which the provider and/or patient is established without delay.

 CE marking	 Medical device	 Catalogue number	 Lot number	 Date of manufacture	 Manufacturer	 Prescription only	 Do not re-use	 Sterilizable in a steam sterilizer (autoclave) at specified temperature	 Unique Device Identification	 Consult instructions for use or consult electronic instructions for use.
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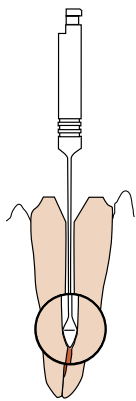
Surfer	Rain Laserent	Helix Classic Reamers			Standard Classic Reamers	
		Short 26 mm	Long 33 mm	X Long 37 mm	Short 26 mm	Long 33 mm
#1	-	RSA-1/3	RSB-1/3	RSC-1/2	RUA-1/3	RUB-1/3
#2	-	RSA-2/3	RSB-2/3	RSC-2/2	RUA-2/3	RUB-2/3
#3	White (XS)	RSA-3/3	RSB-3/3	RSC-3/2	RUA-3/3	RUB-3/3
#4	Yellow (S)	RSA-4/3	RSB-4/3	RSC-4/2	RUA-4/3	RUB-4/3
#5	Red (M)	RSA-5/3	RSB-5/3	RSC-5/2	RUA-5/3	RUB-5/3
#6	Blue (L)	RSA-6/3	RSB-6/3	-	RUA-6/3	RUB-6/3

Surfer	Rain Laserent	Conical Reamers			Conical Reamers	
		Short 26 mm	Long 33 mm	X Long 37 mm	Short 26 mm	Long 33 mm
Purple (XXXS)	-	RSG-3/3	RSH-3/3	RSH-3/2	RUG-1/2	-
Green (XXS)	-	RSG-4/3	RSH-4/3	RSH-4/2	RUG-2/2	-
White (XS)	-	RSG-5/3	RSH-5/3	RSH-5/2	RUG-3/2	-
Yellow (S)	-	RSG-6/3	RSH-6/3	-	RUG-4/2	RUH-4/2
Red (M)	-	-	-	-	RUG-5/2	RUH-5/2
Blue (L)	-	-	-	-	RUG-6/2	RUH-6/2

Chart 1

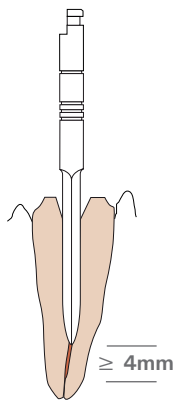
#1	#2	#3	#4	#5	#6	#3
XXXXS	XXS	XS	S	M	L	XS
L (mm)	15	15	15	15	17	19
Ø (mm)	1	1,15	1,30	1,45	1,60	1,75

Chart 2



Pathfinder

Fig. 1



Dentatus Conical Reamer

Fig. 2

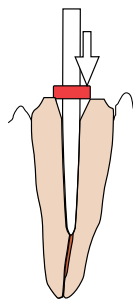
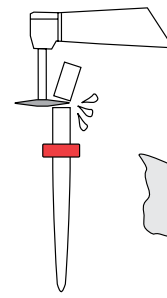


Fig. 3

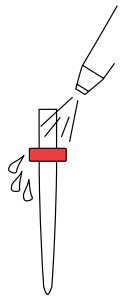


Diamond

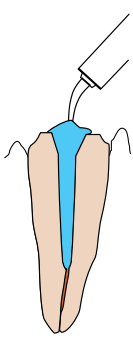


Alcohol

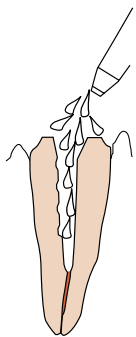
Fig. 4



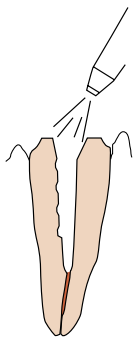
Dry



Etch

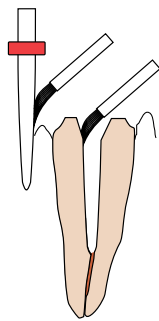


H₂O



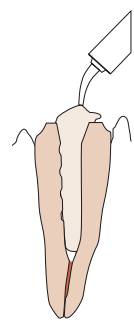
Dry

Fig. 5



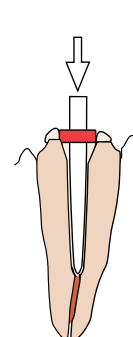
Bonding Agent

Fig. 6



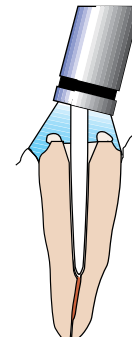
Flowable Resin

Fig. 7



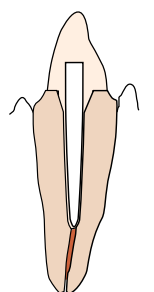
Core Build-up

Fig. 8



Core Preparation

Fig. 9



Core Preparation

Fig. 10

Luscent Anchors®

INSTRUKTIONER

SVENSKA



Material: (THIS TABLE IN SWEDISH)	<i>Post:</i> Transparent glass fiber/epoxy solid rod. <i>Depth Marker:</i> PVC-compound GFM/4E and PVC-compound GFM/4E-40-t. <i>Accessories</i> <i>Reamer:</i> Stainless Steel.	Intended Use/Patient Group:	Prefabricated fiberglass anchorage posts for retention of core materials in endodontically treated teeth.
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PRECAUTIONS (IN SWEDISH)

- Etc.
- Etc.
- Etc.

Surfax	Tain Luscent	Well's Classic Reamers	Standard Classic Reamers
		Short 28 mm Long 33 mm X Long 37 mm	Short 28 mm Long 33 mm
#1	-	RSA-1/3	RUA-1/3
#2	-	RSA-2/3	RUA-2/3
#3	White (XS)	RSA-3/3	RUA-3/3
#4	Yellow (S)	RSA-4/3	RUA-4/3
#5	Red (M)	RSA-5/3	RUA-5/3
#6	Blue (L)	RSA-6/3	RUA-6/3
		RSB-1/3 RSB-2/3 RSB-3/3 RSB-4/3 RSB-5/3 RSB-6/3	RUB-1/3 RUB-2/3 RUB-3/3 RUB-4/3 RUB-5/3 RUB-6/3
		RSC-1/2 RSC-2/2 RSC-3/2 RSC-4/2 RSC-5/2	
	Luscent	Conical Reamers	Conical Reamers
	Purple (XXXS) Green (XXS)		RUG-1/2
	White (XS)	RSG-3/3	RUG-2/2
	Yellow (S)	RSG-4/3	RUG-3/2
	Red (M)	RSG-5/3	RUG-4/2
	Blue (L)	RSG-6/3	RUG-5/2
		RSH-3/3 RSH-4/3 RSH-5/3 RSH-6/3	RLH-4/2 RLH-5/2 RLH-6/2
		RSH-3/2 RSH-4/2 RSH-5/2	

Chart 1

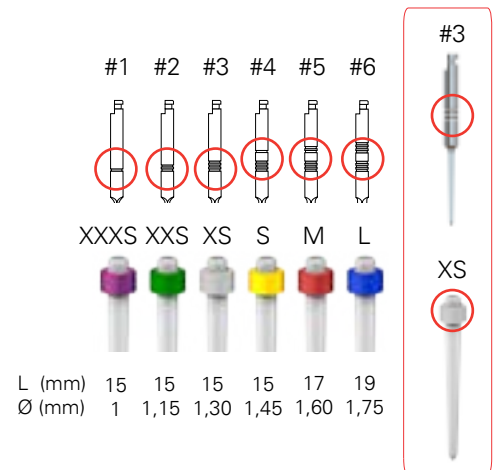











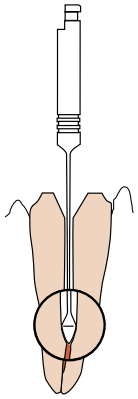


Chart 2

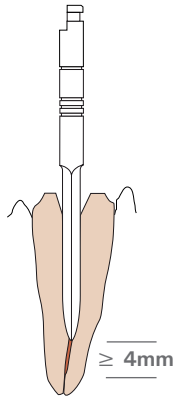


 CE marking	 Medical device	 Catalogue number	 Lot number	 Date of manufacture	 Manufacturer	 Prescription only	 Do not re-use	 Sterilizable in a steam sterilizer (autoclave) at specified temperature	 Unique Device Identification	 Consult instructions for use or consult electronic instructions for use.
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Pathfinder

Fig. 1



Dentatus Conical Reamer

Fig. 2

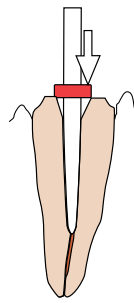
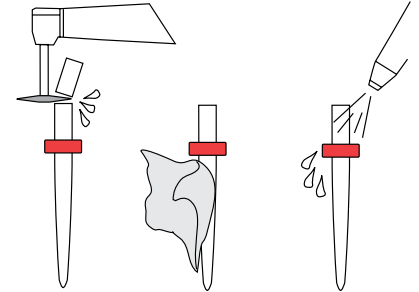


Fig. 3

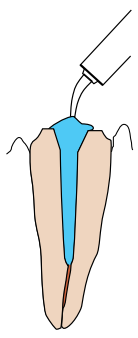


Diamond

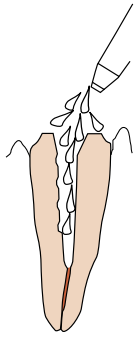
Alcohol

Dry

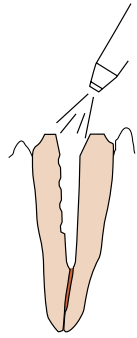
Fig. 4



Etch

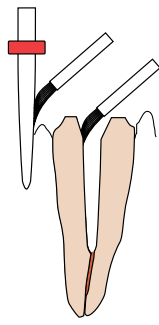


H₂O



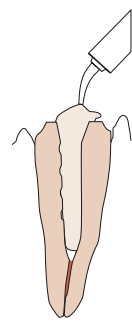
Dry

Fig. 5



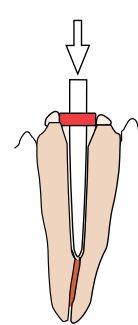
Bonding Agent

Fig. 6



Flowable Resin

Fig. 7



Core Build-up

Fig. 8

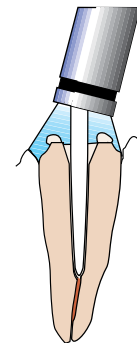
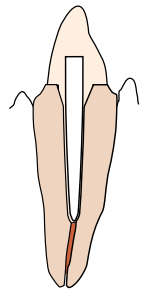


Fig. 9



Core Preparation

Fig. 10

Luscent Anchors®
ANLEITUNG
DEUTSCH

R_x Only CE 2862  MD

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INSTRUCCIONES
ESPAÑOL

R_x Only CE 2862  MD

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INSTRUCTIONS

FRANÇAIS

R_x Only CE 2862  MD



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