

INSTRUCTION FOR USE

CONTEC CYTEC EXATEC

CE0197







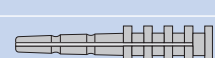
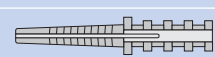




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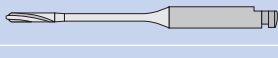


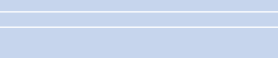
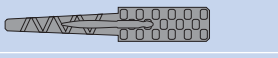

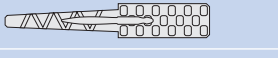

ATTACHMENTS: 2 EN ISO 17664 MANUFACTURER'S INFORMATION

2020-04

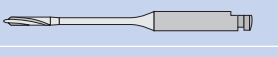



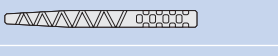
EXATEC, EXATEC-S, EXATEC-G

Exatec Titanium Root Post System		Post head-Ø apic. length apic. Stift Ø ▲ apic. Stift Ø ▼ mm	universal	2,6 6,6 1,461 0,98 mm	2,7 8,0 1,559 0,98 mm	2,8 9,7 1,681 0,98 mm	3,0 11,4 1,803 0,98 mm
		Code	-	white	yellow	blue	black
Instruments, universal for all Modules		package of	REF				
	Preshaping Drill with guiding tip	1	42 010				
	Preshaping Drill with cutting tip	1	43 000				
	Pilot Drill with partial cutting tip	1	42 100				
	Calibration Drill	1		42 001	42 002	42 003	42 004
	Measuring Template	1	42 050				
Exatec		Set Standard	Assortment	42 300			
	Test Set	Assortment	42 302				
	Titanium-Post	10		42 311	42 312	42 313	42 314
System Box + Organizer, empty		1	10 004 + 10 000				
Exatec-S		Set Standard	Assortment	45 500			
	Test Set	Assortment	45 502				
	Titanium Screw Post	10		45 511	45 512	45 513	45 514
	Screw Driver	1	45 522				
System Box + Organizer, empty		1	10 005 + 10 000				
Exatec-G		Set Standard	Assortment	42 700			
	Test Set	Assortment	42 702				
	Casting/ Impression Post Plastic	50	42 720				
	Impression Post Metal	10	42 750				
	Temporary Post Stainless Steel	10		42 731	42 732	42 733	42 734



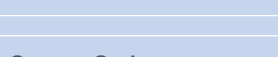
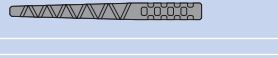

EXATEC

Exatec Root Post System		Post head-Ø	universal	2,6	2,7	2,8	2,2
		apik. length		6,6	8,0	9,7	-
		apic. Ø	1,461	1,559	1,681	-	
		apic. Ø	0,98	0,98	0,98	0,98	0,98
		mm	mm	mm	mm	mm	mm
		Code	-	white	yellow	blue	green
		package of	REF				
	Preshaping Drill with guiding tip	1	42 010				
	Preshaping Drill with cutting tip	1	43 000				
	Pilot Drill with partial cutting tip	1	42 100				
	Calibration Drill	1		42 001	42 002	42 003	
	Calibration Drill	1					42 005
Exatec Carbon HT-Carbonfiber							
	HT-Carbonfiber	10		42 411	42 412	42 413	
	HT-Carbonfiber	10					42 415
Exatec blanco HT-Glassfiber							
	Set Standard	Assortment	42 600				
	Trial Kit	Assortment	42 610				
	HT-Glassfiber	10		42 611	42 612	42 613	
	HT-Glassfiber	10					42 615
System Box		1	10 003				

CYTEC

Cytec Root Post System		universal	1,0 mm	1,2 mm	1,4 mm	NEW		
						1,6 mm	1,8 mm	2,1 mm
						Coding	-	red
		packing unit	REF					
	Preshaping Drill with guiding tip	1	42 010					
	Preshaping Drill with cutting tip	1	43 000					
	Calibration Drill	1		4300 D1,0	43 001	43 002	4300 D1,6	43 003 43 004
	Calibration Drill with long shank	1			43 001-L	43 002-L		
Cytec blanco HT-Glasfiber								
	Set Standard	assortment	43 600					
	Change Over Kit	assortment	43 600-U					
	Trial Kit	assortment	43 610					
	HT-Glasfiber	10		4360 D1,0	43 601	43 602	4360 D1,6	43 603 43 604
System Box		1	10 001					

CONTEC

Contec Root Post System		universal	1,1 mm	1,3 mm	1,5 mm	1,75 mm	2,0 mm							
								Code	-	red	white	yellow	blue	black
								package of	REF					
	Preshaping Drill with guiding tip	1	42 010											
	Preshaping Drill with cutting tip	1	43 000											
	Calibration Drill	1		44 00 D1,1	44 001	44 002	44 003 44 004							
Contec Carbon HT-Carbonfiber														
	HT-Carbonfiber	10			44 401	44 402	44 403							
Contec blanco HT-Glasfiber														
	Set Standard	Assortment	44 600											
	Change Over Kit	Assortment	44 600-U											
	Trial Kit	Assortment	44 610											
	HT-Glasfiber	10		44 60 D1,1	44 601	44 602	44 603 44 604							
System Box		1	10 002											

MATERIALS

Titan Grade 5:	Ti6Al4V-US-Norm ASTM F 136, DIN ISO 5832-3
Stainless Steel:	Mn 2,0 - Ni 10,0 - P 0,06 - C 0,12 - S 0,35 - Si 1,0 Cr 19,0 - Mo 0,7 - Rest: Fe
Fibre reinforced composites:	HT glass fibre FRC epoxy resin with HT glass fibre Bio-compatibility tested in accordance with EN ISO 10993 (Irritation, sensitisation and cytotoxicity)

INDICATIONS FOR USE

Root posts are indicated for anchoring of coronal restoration for teeth with high coronal damage.

When properly used, there are no unwanted side effects.

Root posts are intended for single use.

PREPARATION

Preparation according to EN ISO 17664

Rotary instruments and root posts are supplied **non-sterile** in blister packs, these are **unsuitable** for sterilisation.

Rotary instruments must be processed before first use according to our Manufacturer’s Information (EN ISO 17664) enclosed.

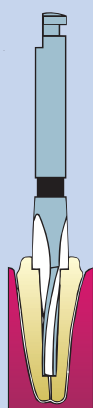
The end of the product service life is determined by wear caused by use. To achieve optimal drilling results and to prevent potential hazards due to blunt or damaged instruments, the instruments are to be inspected prior to every use according to the manufacturer’s information on processing (EN ISO 17664); see “Inspection and functional testing”.

Root posts must be processed before first use according to our Manufacturer’s Information (ENISO 17664) enclosed. Root posts are not designed for reprocessing or reuse. There is a risk of cross-contamination with unauthorised reuse.

DISINFECTING / CLEANING / STERILISING

X = applicable	Plastic Impression Casting post	Titanium Stainless steel root posts	Instruments	Carbon fibre Glass fibre root posts
Disinfection:				
Disinfection solution: recommended by the manufacturer for the respective product.	X	X	X	X
Thermo-Disinfection	X	X	X	—
Cleaning:				
Ultrasonic	X	X	X	—
Alcohol: Ethanol 70% highly pure DAB	—	X	X	X
Sterilisation:				
Autoclave	X	X	X	X
Hot-air steriliser	—	X	X	—

PREPARING THE POST ANCHORAGE

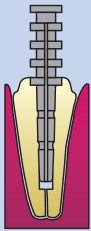


Initial situation:

The tooth must be pre-treated lege artis and must not have any pathological modifications. The root canal lumen must have a linear course and must be prepared up to no more than 3 mm from the physiological foramen.

- Determining the post size This is done by placing the measuring template on the X-ray.
- Apply cofferdam.
- Open and extend the root canal with manual instruments up to about ISO 80.
Preparing the root canal as widely as possible with manual instruments reduces the use of machinery such as drills that may possibly generate dentine-damaging heat.
- Extend mechanically by using the enlarging drill (REF 43000 or REF 42010) and with Exatec follow up with the pilot drill (REF 42100). Take the post length selected into account and mark it with a rubber ring on the drill if necessary.
- Calibrate the post anchorage with the calibrating drill so that with the Exatec the bridge for the posthead is embedded at least 2mm in the dentine.
 - *The integrated face-cutter guarantees that the bridge is centred and at right angle to the canal axis.*
 - *To prevent the generation of heat damaging the dentine, drills should only be used*
 - **under water cooling or gel cooling**
 - **at 500-1000 revolutions r.p.m.**
 - **with as low a pressure as possible and a ‘dabbing’ motion**
 - *Check the instruments at regular intervals during the drilling process.*
Remove drilling shavings and clean of abrasions. Rinse drill channel.
- Clean root canal and dry.

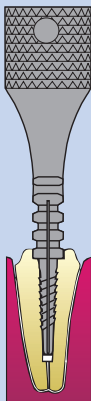
INSERTION: EXATEC (PASSIVE)



- Insert the Exatec root post on a trial basis and check the biting position.
 - Mark the post height as and when required and shorten extraorally with a fine-grained silicon carbide abrasive tool, thin carbide cutter or abrasive wheel in the handpiece.
 - Clean the root canal:
 - Rinse with e. g. 37% phosphoric acid, NaOCl, H₂O₂
 - If necessary remove smear and condition
 - Dry with paper tips, finally with warm air
- !! Attention:** Do not use eugenol-containing temporary cements or remove it **totally**. Do not use NaOCl or H₂O₂ when using composites, because polymerisation could be affected.
- Clean Exatec root post (e.g. alcohol, Orthoskavident C, sodium hypochloride)
 - Fill root canal with **low-viscosity** cement composite in portions with the Lentulo so that no air bubbles form. Only low-viscosity cement can drain off sufficiently through the post's drainage grooves
Phosphate or glasionemer cements and composite are ideal fixing agents. Materials with a small filling grain size are preferable (e.g. Ketac Cem Radiopaque, grain size: 0.1-1.2µm)
 - Insert Exatec root post slowly into the post anchorage, turning slightly, until the post-head is well set. Insert Exatec root post in the supporting surface.
 - Allow the fixing agent to set
 - Remove superfluous fixing agent
 - Adjust the posthead according to the occlusion circumstances with cylindrical diamonds under water cooling.

Manufacture the Post and final restoration in accordance with the Information on Use of the products and processes being used.

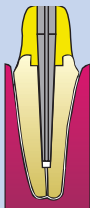
INSERTION: EXATEC-S



- Fit Exatec-S post onto the screwdriver:
 - Precaution: Please ensure by drawing the protective through the drilling that the screw driver is at safety.
 - Mount the screwdriver onto the post
 - Turn the screwdriver until the nuts lock in place
 - Insert post
 - **Check that the post is securely fitted in the screwdriver**
 - Screw in the Exatec-S root post to test
The self-cutting thread cuts into the dentine. Due to the taper, all the threads grip at the same time and it is possible to screw in with a comparatively minimal torque of 7.9±1.7Ncm with maximum 3 turns. The motion of the post towards the apex is stopped at exactly the right position owing to the perfect-fit bridge.
 - Clean the root canal:
 - Rinse with e. g. 37% phosphoric acid, NaOCl, H₂O₂
 - If necessary remove smear and condition
 - Dry with paper tips, finally with warm air
- Attention:** Do not use eugenol-containing temporary cements or remove it **totally**. Do not use NaOCl or H₂O₂ when using composites, because polymerisation could be affected.
- Clean Exatec root post, removing dentine shavings (e.g. alcohol, Orthoskavident C, sodium hypochloride)
 - Fill root canal with **low-viscosity** cement composite in portions with the Lentulo so that no air bubbles form.
Only low-viscosity cement can drain off sufficiently through the post's drainage grooves
Phosphate or glasionemer cements and composite are ideal fixing agents. Materials with a small filling grain size are preferable (e.g. Ketac Cern Radiopaque, grain size: 0.1-1.2µm)
 - Screw the Exatec-S root post in. Starting with a slight turn to the left, so that the post locks into place in the pre-cut threads, then screw the root post in, turning to the right (no more than 3 turns).
 - Pull off the screw driver axial to the post to avoid deformation of the claws.
 - Allow the fixing agent to set and remove superfluous fixing agent.
 - Adjust the posthead according to the occlusion circumstances with cylindrical diamonds under water cooling.

Manufacture final restoration in acc. with the Information on Use of the products and processes being used.

INSERTION: EXATEC-G



Direct method

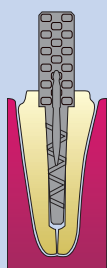
- Insert post to test. Check biting position
- Mark requisite post height and shorten extraorally. The post may protrude some 2mm from the modelled post. After modelling, the post including the post can be removed easily with pincers.
- Insulate root canal and all other contact surfaces with a very thin covering (e.g. of oil)
- Re-insert post
- Model post with castable plastic (e.g. Palavit G). Check biting position.
- Remove modelled post with post and despatch to the dental laboratory
- Insert temporary Exatec-G root post
- Apply temporary crown to tooth, following the Information on Use relating to the products being applied

Indirect method

- Insert post to test. Check biting position
- Mark requisite post height and shorten extraorally
- Insulate dentine and enamel contact surfaces with a very thin covering (e.g. of oil)
- Insert post
- Make up the cast by the desired method. Using copper rings or ATR caps produces the most precise post results.
- Remove cast and despatch together with a post to the dental laboratory
- Insert temporary Exatec-G root post
- Apply temporary crown to tooth, following the Information on Use relating to the products being applied

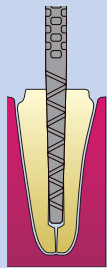
The dental laboratory makes a post cast by the standard procedure. Once the temporary post is removed, the post cast is integrated as usual into the prepared post bed.

INSERTION: EXATEC, CYTEC, CONTEC (HT-CARBON FIBRE OR HT-GLASS FIBRE)



Exatec

- Insert the post to test and check the biting position.
- Mark the requisite post height (occlusion height) and shorten the post extraorally with a fine diamond wheel. Avoid the creation of dust by using sharp instruments and moisten the post.
!!Attention: Never use a pincer, as this would destroy the fibre structure.
- Clean the post with alcohol and dry it with warm air.
- Preparing the root canal: Condition the dentin by Adhesive Technique.
!!Attention: Do **not** use eugenol-containing temporary cements or remove it totally. Do **not** use H₂O₂ or NaOCl because polymerisation could be affected.

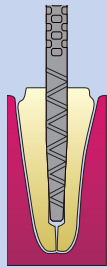


Cytec

Adhesive Technique - for example:

- Condition the root canal and cavity (e.g. 37 % phosphoric acid)
- Remove the acid by rinsing with water
- Rinse the canal with alcohol (e.g. 70 %)
- Dry the canal with paper tips
- Apply the Primer and absorb the surplus with paper tips
- Apply the Bonder and absorb the surplus with paper tips
!!Attention: Do **not** polymerise Bonder with light.

Take care to the Instructions of Use of all products and processes being used.



Contec

- Optional: Apply dual-polymerising Bonder **thin, do not** polymerise with light.
• *Alternatively: Apply dual-polymerising Bonder, blow out **very thin** and polymerise with light.*

e.g.: Optibond Solo Plus + Aktivator, Kerr; Clearfil Liner Bond 2 V, Kuraray; Excite DSC, Ivoclar Vivadent
- Apply **low-viscosity, dual-polymerising, X-ray visible composite** with lentulo to the root canal in accordance with the corresponding Instructions on Use.

e.g.: Bifix QM, VOCO GmbH; Panavia F, Kuraray; Rely X Unicem, 3M Espe; Variolink II, Ivoclar Vivadent; Dual Cement radiopaque, Ivoclar Vivadent
- Apply composite quickly to the post and insert it immediately and **slowly**, by turning it slightly, into the root canal and keep it in position until the composite is hardened to the extent that the post is firmly in position.
- Distribute surplus material evenly on the protruding post and cavity. Remove remaining surplus composite.
- Set for about 40 sec with a polymerisation lamp (Follow the Instructions of Use relating to the composite)
- Make the final restoration quickly by using a viscous Core Composite. For forming the restoration, you can use - if necessary - a transparent plastic shell (frasco) or a matrixband (HAHNENKRATT).

e.g.: Cavex Clearfil Core, Kuraray; Rebuilda, Voco; Corepaste, Kerr
- Make final corrections under water cooling with a diamond-coated abrasive instrument.

Take care to the Instructions of Use of all products and processes being used.

PRECAUTIONS AND SOURCES OF ERROR

Taking into consideration the clinical conditions and indication, it should be borne in mind that there are limits to the breaking and bending strength of a prefabricated root post due to the material and selected post diameter.

But this is also the case with other components: residual tooth structure or core and crown can be the cause for failure of a restoration.

Aspects that positively influence the stability have already been listed in the information on preparation and insertion. Careful grinding in of a balanced occlusion is of vitally important for the stability and durability of the restoration. Dynamic loading by the opposing dentition must also be kept to a minimum. Incorrect loading or overloading can result in the restoration loosening, moving orthodontically or even fracturing.

SOURCES OF ERROR

Failure of a restoration is indicated by:

- A) Loosening or detaching of the root post
- B) Fracture of the root post
- C) Fissuring or fracturing of the root

Possible causes:

- Incorrect bonding between the luting material and dentine (inadequate preparation of the root canal)
- See A)
- Too high dynamic loading by the opposing dentition (see above)
- Excessive, sudden loading
- Selection of a root post that is too small
- As listed at B)
- Sclerotic root dentine

PRECAUTIONS

Root posts are **not** reusable. The manufacturer preparation information EN ISO 17664, therefore, does **not** describe any preparation after use. Unauthorised reuse would thus carry the risk of cross-contamination.

Also take into account the information of the two EN ISO 17664 manufacturer's information enclosed.

ADDITIONAL INFORMATION

All serious incidents concerning the product have be reported to the manufacturer to the competent authority of the Member's State where the user and/or patient is located.

MANUFACTURER



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SYMBOLS



Not for reuse



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eIFU



Warnings