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
Instructions for use and safety recommendations Navodila za uporabo in varnostna priporočila

General instructions for use and safety recommendations for the application of dental instruments

Splošna navodila za uporabo in varnostna priporočila za zobozdravstvene instrumente

Area of application

These general instructions for use and safety recommendations apply to all products and have to be generally observed. Non-observance of these instructions for use and safety recommendations increases the risk of injury and may impair the proper function of the instruments.

Separate instructions for use are enclosed in the packaging of products that require more detailed information (packaging is provided with the  symbol). These take precedence over the general instructions.

Storage

Store wrapped devices protected from UV radiation and high temperatures in a clean and dry environment. Do not store in the same room as solvents or chemicals.

Medical devices without direct identification marking have to be stored with their original packaging.

1. Proper use

- Those instruments that are supplied non-sterile have to be prepared prior to first use.
- Make sure that the power systems (hand-pieces and contra-angles) used are clean and perfect from a technical and hygienic aspect.
- Depending on their shank type, insert the instrument into the chuck as deeply as possible. Make sure that they are properly locked.
- The instrument must be rotating at the desired speed before contact is made with the tissue or material.
- Avoid jamming and using the instrument as a lever. Excessive contact pressure has to be avoided.
- For eye protection wear safety glasses. Use appropriate respiratory protection (mouth and nose). In the dental laboratory, use appropriate suction unit.
- Avoid contact with the instruments' working parts as this may increase the risk of injury.
- Make sure to provide sufficient cooling by means of air/water spray. Additional external cooling is required when using instruments with extra-long shanks or oversized working parts.
- Damaged or corroded instruments have to be discarded.

2. Recommended speeds

Please make sure to observe the recommendations for use and recommended speeds as indicated in the instructions for use and on the packaging of the products.

- \odot_{\max} 300 000 rpm means: Suited for micro-motor contra-angles and turbines with stable ball bearings. Do not use in turbines with air bearing.
- \odot_{\max} 200 000 rpm means: Suited for micro-motor hand pieces and contra-angles or lab hand pieces up to the speed indicated. Do not use in turbines.

Not observing the maximum permissible speed leads to an increased safety risk.


3. Contact pressure

Excessive contact pressure (> 2N) has to be avoided.

- In cutting instruments, this can lead to damage to the working part and to chipping of the blades as well as an excessive generation of heat.
- In abrasive instruments, increased contact pressure may lead to stripping of the grit or to clogging of the instruments and increased heat generation.
- Increased contact pressure may also lead to thermal damage to the pulp or, in case of damaged blades, to rough surfaces.
- In the extreme cases, instrument breakage may even occur.

Področje uporabe

Ta splošna navodila za uporabo in varnostna priporočila veljajo za vse izdelke in jih je treba na splošno upoštevati. Neupoštevanje teh navodil za uporabo in varnostnih priporočil poveča nevarnost telesnih poškodb in lahko ogrozi pravilno delovanje instrumentov.

Ločena navodila za uporabo so priložena embalaži izdelkov, za katere so potrebne podrobnejše informacije (embalaža je označena s simbolom ). Ta navodila imajo prednost pred splošnimi navodili.

Shranjevanje

Ovite pripomočke, zaščitene pred UV-sevanjem in visokimi temperaturami, shranjujte v čistem in suhem okolju. Ne shranjujte jih v istem prostoru kot topila ali kemikalije.

Medicinske pripomočke brez neposredne identifikacijske oznake je treba shranjevati z njihovo originalno embalažo

1. Pravilna uporaba

- Instrumente, ki so dobavljeni nesterilni, je treba pripraviti pred prvo uporabo.
- Prepričajte se, da so uporabljeni napajalni sistemi (ročniki in kolenčniki) čisti ter s tehničnega in higienskega vidika brezhibni.
- Instrument glede na njegovo vrsto stebila vstavite čim globlje v vperjalno glavo. Prepričajte se, da je pravilno zasvočen.
- Instrument se mora vrteti z želeno hitrostjo, preden pride v stik s tkivom ali materialom.
- Preprečite zatikanje in uporabo instrumenta kot vzvoda. Preprečite prekomerno uporabo kontaktne sile.
- Za zaščito oči uporabljajte zaščitna očala. Uporabljajte ustrezno zaščito dihal (usta in nos). V zobozdravstvenem laboratoriju uporabljajte ustrezno sesalno enoto.
- Preprečite stik z delovnimi deli instrumentov, saj to lahko poveča nevarnost telesnih poškodb.
- Zagotovite zadostno hlajenje z zrakom/pršenjem. Pri uporabi instrumentov z izjemno dolgimi stebli ali prevelikimi delovnimi deli je potrebno dodatno zunanje hlajenje.
- Poškodovane ali korodirane instrumente je treba zavreči.

2. Priporočene hitrosti

Upoštevajte priporočila za uporabo in priporočene hitrosti, kot je navedeno v navodilih za uporabo in na embalaži izdelkov.

- Optimalna hitrost \odot_{\max} 300 000 vrt./min pomeni: primerno za mikromotorne kolenčnike in turbine s stabilnimi krogličnimi ležaji. Ne uporabljajte v turbinah z zračnim ležajem.
- Optimalna hitrost \odot_{\max} 200 000 vrt./min pomeni: primerno za mikromotorne ročnike in kolenčnike ali laboratorijske ročnike do navedene hitrosti. Ne uporabljajte v turbinah.

Neupoštevanje največje dovoljene hitrosti vodi do povečanega varnostnega tveganja.

3. Kontaktna sila

Preprečite prekomerno uporabo kontaktne sile (> 2 N).

- Pri rezalnih instrumentih lahko to povzroči poškodbe delovnega dela in odkrušenje rezil ter čezmerno ustvarjanje toplote.
- Pri instrumentih za brušenje lahko povečana kontaktna sila povzroči odstranitev brusnih zrn ali zamašitev instrumentov in povečano nastajanje toplote.
- Povečana kontaktna sila lahko povzroči tudi toplotne poškodbe pulpe ali (v primeru poškodovanih rezil) grobih površin.
- V skrajnih primerih se lahko instrument zlomi.

4. Guideline on the number of times rotary instruments can be used

The below values are guidelines. The service life of instruments may differ from these values as this depends on the application and/or the material treated.

Stainless steel instruments:	up to 4 x
Tungsten carbide instruments:	up to 15 x
Diamond instruments:	up to 25 x
Polishers and ceramic abrasives:	up to 10 x
Endodontic instruments:	
Wide canals:	- max. 8 x
Average canals:	- max. 4 x
Narrow canals:	just use 1 x

The reuse of disposable products is not permitted. These are intended for single use and cannot be reprocessed.

5. Disposal

The devices have to be disposed of in tight, non-breakable and puncture-proof containers (protection from contamination).

6. Disinfection, cleaning and sterilisation

Those instruments that are supplied non-sterile have to be prepared prior to first use. Information on reprocessing, as amended, can be downloaded from our website <http://ifr.drendel.com> or ordered from the manufacturer Drendel + Zwielling DIAMANT GmbH.

7. Specific instructions for individual instrument types

- Avoid any contact with H₂O₂ (hydrogen peroxide). Make sure that the specified immersion times in the cleaning and disinfecting agents are not exceeded. The carbide working parts would be attacked (a typical indication is black staining of the instrument) reducing the instrument's service life.
- Tool steel instruments corrode and can therefore not be sterilized with a sterilization method using saturated steam (e. g. autoclave).
- To achieve an optimal surface roughness, subsequent finishing is necessary after using a diamond grinding instrument with coarse or very coarse grit.
- Use a disc guard for diamond discs when working intraorally.
- When using diamond separating strips and diamond strips please avoid contact with the gingiva as there is a risk of injury.
- To avoid overstressing of the instrument, root canal instruments made of nickel titanium have to be used in a torque limited motor.
- Stainless steel root canal reamers (type "Gates", "Müller") are only intended for preparation of the coronal portion of the canal.
- Clean and sharpen Sintered Diamonds every now and then with the cleaning stone.
- Always use polishers and brushes with low pressure to minimize heat generation. Always polish in circular motion. To achieve brilliant high shine, use the polishers in the indicated sequence when using multiphase polishing systems.
- Polishers and Arkansas abrasives have to be prepared with suitable, alcohol free agents (e.g. DC EVO, Komet Dental/Alpro Medical).
- Surgical instruments with FG shank may only be used in a micromotor (red contra-angle). They are not authorized for use in a dental turbine.

8. Potential effects of using worn instruments

- Discard any instruments with damaged or worn working parts as the use of damaged or worn instruments would have a negative effect on the work result.
- Damaged and deformed cutting blades will cause the instrument to vibrate and lead to poor preparation margins and rough surfaces.
- Void spots on the surface of diamond instruments are a sign of missing diamond particles and reduce the instrument's abrasive efficiency. An inferior diamond coating quality will result in excessive heat generation. Excessive contact pressure or temperatures may cause damage to the tissue.

4. Smernice o številu uporab rotacijskih instrumentov

Spodnje vrednosti so priporočene. Življenjska doba instrumentov se lahko razlikuje od teh vrednosti, saj je to odvisno od uporabe in/ali obdelanega materiala.

Instrumenti iz nerjavnega jekla:	do 4-krat
Instrumenti iz volframovega karbida:	do 15-krat
Diamantni instrumenti:	do 25-krat
Polirni instrumenti in keramični instrumenti za brušenje:	do 10-krat
Endodontski instrumenti:	
Široki kanali:	največ 8-krat
Povprečni kanali:	največ 4-krat
Ozki kanali:	uporabite samo 1-krat

Ponovna uporaba izdelkov za enkratno uporabo ni dovoljena. Ti so namenjeni za enkratno uporabo in jih ni mogoče pripraviti za ponovno uporabo.

5. Odlaganje

Pripomočke je treba odstraniti v tesnih, nezlomljivih in neprebodnih vsebnikih (zaščita pred kontaminacijo).

6. Razkuževanje, čiščenje in sterilizacija



Instrumente, ki so dobavljeni nesterilni, je treba pripraviti pred prvo uporabo. Spremenjene informacije o pripravi za ponovno uporabo lahko prenesete z našega spletnega mesta <http://ifr.drendel.com> ali jih zahtevate o proizvajalca Drendel + Zwielling DIAMANT GmbH.

7. Posebna navodila za posamezne vrste instrumentov

- Preprečite kakršen koli stik s H₂O₂ (vodikov peroksid). Pazite, da ne presežete navedene čase potopitve v čistilnih in razkužilnih sredstvih. To bi vplivalo na delovne dele iz karbida (običajen znak je črno obarvanje instrumenta), kar bi skrajšalo življenjsko dobo instrumenta.
- Instrumenti iz orodnega jekla so korozivni, zato jih ni mogoče sterilizirati s sterilizacijsko metodo z uporabo nasičene pare (npr. v avtoklavu).
- Da bi dosegli optimalno površinsko hrapavost, je po uporabi diamantnega instrumenta za brušenje z grobo ali zelo grobo zrnatostjo potrebna naknadna končna obdelava.
- Pri intraoralnem delu za diamantne diske uporabite ščitnik diska.
- Kadar uporabljate diamantne ločilne trakove in diamantne trakove, preprečite stik z dlesnijo, saj obstaja nevarnost telesnih poškodb.
- Da bi preprečili preobremenitev instrumenta, je treba instrumente za koreninske kanale, izdelane iz niklja in titana, uporabiti v motorju z omejenim navorom.
- Povrtala za koreninske kanale iz nerjavnega jekla (tipa »Gates«, »Müller«) so namenjena samo za pripravo kronskega dela kanala.
- S čistilnim kamnom občasno očistite in nabrusite brusilne materiale s sintranim vezivom.
- Zaradi zmanjšanja nastajanja toplote polirnih instrumentov in ščetk nikoli ne pritiskajte močno. Vedno polirajte s krožnimi gibi. Če želite doseči visok sijaj, pri uporabi večfaznih polirnih sistemov uporabite polirne instrumente v navedenem zaporedju.
- Polirne instrumente in brusne materiale Arkansas je treba pripraviti s primernimi sredstvi brez vsebnosti alkohola (npr. DC EVO, Komet Dental/Alpro Medical).
- Kirurški instrumenti s stebлом FG so pooblašeni samo za uporabo v mikromotorju (rdečem kolenčniku). Ne uporabljajte jih v zobozdravstveni turbini.

8. Možne posledice uporabe obrabljenih instrumentov

- Zavrzite vse instrumente s poškodovanimi ali obrabljenimi delovnimi deli, saj bi uporaba poškodovanih ali obrabljenih instrumentov negativno vplivala na rezultat dela.
- Poškodovana in deformirana rezila lahko povzročijo vibriranje instrumenta ter slabe robove za pripravo in grobe površine.
- Prazne lise na površini diamantnih instrumentov so znak manjkajočih diamantnih delcev in zmanjšujejo učinkovitost brušenja instrumenta. Slabša kakovost diamantne prevleke bo povzročila prekomerno nastajanje toplote. Prekomerna kontaktna sila ali temperatura lahko poškoduje tkivo.

- Please avoid excessive contact pressure during use as this may result in damage to the working part (Nicks on the blades, premature blunting and excessive heat generation).
- In abrasive instruments, excessive contact pressure can lead to stripping of the grit or clogging of the instruments and increased heat generation.
- To avoid undesirable heat generation during preparation, make sure to provide sufficient cooling by means of air/water spray (at least 50 ml/min).
- Additional external cooling is required when using instruments with a total length of more than 22 mm or a head diameter exceeding 2,5 mm.
- Not observing the maximum permissible speed will result in an increased risk of injury.
- The use of reusable instruments that have not been reprocessed properly increases the risk of infection.
- The reuse of disposable instruments (marked  on the packaging) is not permitted (e. g. polishers with lamellae and dental brushes). The reuse of these products poses a risk of infection and/or the safety of the products can no longer be guaranteed (e. g. due to the risk of fracture with root canal instruments).
- Med uporabo instrumentov preprečite uporabo prekomerne kontaktne sile, saj lahko s tem povzročite poškodbo delovnega dela (zareze na rezilih, prezgodnja topost in prekomerno nastajanje toplote).
- Pri instrumentih za brušenje lahko prekomerna kontaktna sila povzroči odstranitev brusnih zrn ali zamašitev instrumentov in povečano nastajanje toplote.
- Da preprečite neželeno nastajanje toplote med pripravo, zagotovite zadostno hlajenje z zrakom/pršenjem (vsaj 50 ml/min).
- Pri uporabi instrumentov s skupno dolžino več kot 22 mm ali premerom glave, večjim od 2,5 mm, je potrebno dodatno zunanje hlajenje.
- Če ne upoštevate največje dovoljene hitrosti, se poveča nevarnost telesnih poškodb.
- Uporaba instrumentov za večkratno uporabo, ki niso bili pravilno pripravljene na ponovno uporabo, poveča nevarnost okužb.
- Ponovna uporaba instrumentov za enkratno uporabo (označenih z znakom  na embalaži) ni dovoljena (npr. polirni instrumenti z lamelami in zobnimi ščetkami). Ponovna uporaba teh izdelkov predstavlja nevarnost okužb in/ali varnosti izdelkov ni več mogoče zagotoviti (npr. zaradi tveganja zloma pri instrumentih za koreninske kanale).

9. Safety and possible side effects

The above mentioned recommendations with respect to cooling, contact pressure, disinfection, cleaning and sterilization are to be strictly observed. The instruments should only be used for the intended application, as per the symbolic identification. Non-observance of these safety recommendations may lead to damage of the power system and/or injury, such as thermal necrosis, undesired preparation of tissue, damage to tissue or nerves, violation of the biological width, or infections. During preparation, some instruments may generate metallic abrasion which may lead to the presence of artifacts in MRI diagnostics.

9. Varnost in možni stranski učinki

Zgoraj navedena priporočila glede hlajenja, kontaktne sile, razkuževanja, čiščenja in sterilizacije je treba strogo upoštevati. Instrumente lahko uporabljate samo za predvideno uporabo, ki jo prikazuje ustrezna ikona. Neupoštevanje teh varnostnih priporočil lahko privede do poškodb električnega sistema in/ali telesnih poškodb, kot so termična nekroza, neželena priprava tkiva, poškodbe tkiva ali živcev, kršitev biološke širine ali okužbe. Med pripravo lahko pri nekaterih instrumentih pride do kovinske obrabljenosti, ki pri diagnostičnih preiskavah s slikanjem MR lahko povzroči prisotnost artefaktov.

10. Liability

The user is solely responsible for checking the devices prior to use to ensure that they are suited for the intended purposes. The correct application of the devices is the responsibility of the user and the operator. In case of contributory negligence by the user, Drendel + Zweiling DIAMANT GmbH partially or totally declines liability towards the user for all resulting damages, particularly if these are due to the non-observance of the recommendations for use or other misuse by the user. Store products out of children's reach. For dental use only.

10. Odgovornost

Uporabnik je sam odgovoren, da pred uporabo preveri, ali so pripomočki primerni za predvideni namen. Za pravilno uporabo pripomočkov je odgovoren uporabnik. V primeru uporabnikove malomarnosti je družba Drendel + Zweiling delno ali v celoti zavrača odgovornost do uporabnika za vso nastalo škodo, zlasti če je ta posledica neupoštevanja priporočil za uporabo ali druge nepravilne uporabe s strani uporabnika.

Shranjujte zunaj dosega otrok. Samo za zobozdravstveno uporabo

11. Contains hazardous substances

Devices marked with a CAS number (CAS: 7440-48-4) contain more than 0.1 % weight percent of cobalt. As a CMR substance of class IB, cobalt is classed as possibly carcinogenic, mutagenic and/or toxic to reproduction. Evidence has shown that the quantities of cobalt released by medical devices are so low that they do not pose a risk and no precautions have to be taken, provided that the medical device is used correctly and according to its intended purpose.

11. Vsebuje nevarne snovi

Pripomočki, označeni s številko CAS (CAS: 7440-48-4), vsebujejo več kot 0,1 masnega odstotka kobalta. Kot snov CMR razreda IB se kobalt uvršča med snovi, ki so potencialno rakotvorne, mutagene in/ali strupene za razmnoževanje. Dokazi kažejo, da so količine kobalta, ki se sproščajo iz medicinskih pripomočkov, tako majhne, da ne predstavljajo tveganja in ni treba sprejeti nobenih previdnostnih ukrepov, če se medicinski pripomoček uporablja pravilno in v skladu s predvidenim namenom.

12. Procedure in case of serious adverse events

In case of serious adverse events, please proceed in line with the legal regulations in your country.

12. Postopek v primeru resnih neželenih dogodkov

V primeru resnih neželenih dogodkov nadaljujte v skladu z zakonskimi predpisi v svoji državi.