



固美

使用说明与安全建议

Instructions for use and safety recommendations



Quality Products
Made in Germany



max.

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As at June 2018



对于口腔器械，针，根管桩和车针架的综合使用说明和安全建议。

General instructions for use and safety recommendations for the application of dental instruments, pins, posts and bur blocks

应用范围

这些综合使用说明和安全建议适用于所有产品，必须得到遵守。不遵守使用说明与安全建议会增加受伤的风险，并可能损伤器械的正常功能。

对于需要更详细的产品信息，其产品包装中附有单独的使用说明（含有标志☐¹）。这些要比综合说明更详细。

储藏

请保护好已包装的器械，避免受到紫外线和高温的影响。将器械储存在于干净和干燥的环境中。不要存放于有溶剂或化学物的环境里。

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 ☐¹ symbol). These take precedence over the general instructions.

Storage

Protect packed instruments from UV rays and high temperatures. Store all instruments in a clean and dry environment. Do not store in the same room as solvents or chemicals.

1. 正确使用

- 所提供器械是非无菌包装的，因此在首次使用前必须做消毒灭菌处理。
 - 确保只用于技术和卫生情况都完美的、清洁的动力系统（常规手机和反角手机）。
 - 取决于器械的柄部类型，插入器械时应当尽量插得深一点，确保器械在手机中正确锁紧。
 - 当器械接触组织或者材料时要确保其旋转速度适当。
 - 避免器械卡住和将器械当杠杆使用，也要避免接触压力过大。
 - 带眼罩保护眼睛。使用适当的呼吸防护措施（口罩）。在口腔技工室内使用适当的抽吸装置。
 - 避免接触器械的工作部位，因为这样会增加受伤的风险。
- 确保提供足够的气/水冷。当使用超长柄或工作部位超大的器械时，需要增加额外的冷却。损坏或者腐蚀的器械应该丢弃。

1. Proper use

- Those instruments that are supplied non-sterile have to be prepared prior to first use.
- Make sure that only technically and hygienically perfect and cleaned power systems (hand pieces and contra-angles) are used.
- 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. 建议转速

- 请确保遵守使用说明和产品包装上的使用建议和建议转速。
- $\bigcirc_{\max} 300\,000$ rpm 的意思是：适用于微型电动马达反角手机和带有稳定球形轴承的涡轮手机。不能用于气轴承的涡轮手机。
 - $\bigcirc_{\max} 200\,000$ rpm 的意思是：适用于微型电动马达直手机、反角手机或技工室打磨机，最高转速为提示转速。不能用于涡轮手机。
- 不遵守最高允许转速会提高使用的安全风险。

2. Recommended speeds

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

- $\bigcirc_{\max} 300\,000$ rpm means: Suited for micro-motor contra-angles and turbines with stable ball bearings. Do not use in turbines with air bearing.
- $\bigcirc_{\max} 200\,000$ 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. 接触压力

务必要避免接触压力过高(> 2N)

- 接触压力过高会在切割器械中导致工作部位受损以及造成切削刃上的缺口。同时会提高产热。
- 过高的接触压力会造成磨削类器械表面的砂粒脱落、器械堵塞以及产热过高。

过高的接触压力也可造成牙髓受伤或由于受损的切刃导致表面粗糙。特殊情况下也不排除造成器械损坏的后果。

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.

4. 旋转和摆动器械的使用次数指南

以下数值仅为参考指南。器械的使用寿命根据其应用领域和所处处理材质的不同，可能会偏离这些数值。

- 不锈钢器械： - 最多 4 x
- 钨钢器械： - 最多 15 x
- 金刚砂和陶瓷器械： - 最多 25 x
- 抛光器械和陶瓷研磨器械： - 最多 10x
- 根管器械：长根管： - 最高 8 x
- 一般根管： - 最高 4 x
- 窄根管： 仅使用 1 x

一次性产品的重复使用是不允许的。

4. Guideline on the number of times rotary and oscillating 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 and ceramic 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.

5. 回收处理

器械在具有可靠防脏污性能、不会断裂、不会刺破的密封容器中安全可靠地回收处理。

5. Disposal

To prevent contamination, discard instruments in tight, fracture and puncture resistant containers.

6. 消毒、清洁和灭菌

所提供器械是非无菌包装的，因此在首次使用前必须做消毒灭菌处理。欲知详情，请访问我们的网站 ▶ 信息中心 ▶ 厂家信息

6.1 手动再处理

器械的消毒要使用推荐用于这些产品的适当清洗消毒剂(比如Komet(固美)的DC1)。对于清洗消毒剂的使用建议(浸泡时间、浓度、冲洗、干燥)请见这些消毒剂生产厂家提供的说明书。确保器械在超声波清洗时不发生相互碰撞。

6.2 机械再处理

器械建议以适合的清洁剂与消毒剂清洁。请遵守制造商提供的使用说明。检查清洁仪器的外观。如果器械处理后仍然有污染残留物，则重复再处理过程。分离和丢弃损坏或钝器。彻底清洁的器械是成功灭菌的必要条件。

6.3 灭菌

确保器械根据有效的、适用于医疗产品灭菌的处理流程完成灭菌处理。成功的灭菌也取决于被灭菌产品的种类、包装和灭菌装置负荷设定。医疗产品的使用者有责任确保灭菌过程依照德国罗伯特·科赫研究所(RKI)医院卫生和防感染委员会(KRINKO)的建议，由具备资质的人员完成、使用适当的材料和合适的设备。

6. Disinfection, cleaning and sterilisation

Those instruments that are supplied non-sterile have to be prepared prior to first use. For further information, please refer to our Homepage ▶ InfoCenter ▶ Manufacturer's information.

6.1. Manual reprocessing

The instruments are to be disinfected with appropriate cleaning and disinfecting agents recommended for these products (e.g. with Komet DC1). For recommendations for use (immersion time, concentration, rinsing, drying) of cleaning and disinfecting agents see instructions of the manufacturers of these agents. Make sure that the instruments do not come in contact with each other during ultrasonic cleaning.

6.2. Mechanical reprocessing

The instruments have to be treated with suitable detergents and disinfectants that are recommended for this purpose. Observe the instructions of use provided by the manufacturer. Inspect the clean instruments visually. If after mechanical reprocessing there are still visible residues of contamination, repeat the reprocessing process. Separate and discard damaged or blunt instruments. Thoroughly cleaned instruments are an essential condition for a successful sterilization.

6.3. Sterilization

Make sure that the instruments are sterilized according to a validated procedure suitable for the sterilization of medical products. Successful sterilization also depends on the type of product to be sterilized, the packaging and the loading set-up of the sterilization device. The operator of medical products is responsible for seeing that proper treatment is carried out by qualified personnel, using the appropriate materials and suited equipment, as recommended by the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute.

7. 个别器械种类的特殊说明

- 避免接触H₂O₂(过氧化氢)。确保浸泡在清洗消毒剂中的时间不超过规定值。过度浸泡会使碳化钨工作部位被腐蚀(典型现象就是器械上出现黑色的污点),缩短器械的使用寿命。
- 不锈钢器械易腐蚀,因此不能用饱和蒸汽进行消毒(例如高温高压消毒)。
- 为了生成最佳表面粗糙度,使用带有粗砂粒或很粗砂粒的钻石磨削器械后要用精修钻进行随后的修整处理。
- 金刚砂片在口内使用时需要使用安全保护罩。
- 当使用金刚砂条时请避免和牙龈的接触而造成伤害。
- 由于往复锉符合人体工学的平坦设计,请避免卡住,弯曲或将锉当杠杆使用。并且确保锉被正确固定在反角手机内,并达到需要深度。
- 为了避免器械受力过度,镍钛材料制成的根管器械只用于可限制扭矩的马达。
- 不锈钢根扩大器械(“Gates”钻、“Müller”钻、“P”钻)只能用于根管的冠部预备。
- 经阳极氧化处理的氧化铝车针架的再处理,必须使用适用于铝制材料的清洗消毒剂。其他消毒剂可能会损伤铝制车针架的阳极电镀层。铝制车针架通常不适用于热消毒。灭菌之前,用流水冲洗车针架并充分干燥(例如,用气流干燥)。经常重复处理可能会导致车针架掉色。
- 由纤维加强树脂或PMMA制成的根管桩不能做灭菌处理。因此,必须用医用酒精对其清洗消毒。根管桩仅供一次性使用。
- 经常用清洁石清洁DSB研磨器械,并使之保持锋利。
- 应始终以低压力使用抛光器械和抛光刷来减少产热。始终以圆周运动抛光。使用多步法抛光系统时,若想实现出色的高亮度抛光效果,请按照提示的步骤逐步使用抛光器械。
- 抛光器械以及阿肯色石请用适宜的、不含酒精的清洗消毒剂(例如Komet DC1)消毒处理。

7.1. 内冷却器械和声波/超声器械

- 手动再处理:
用流水彻底冲刷器械表面的脏污。将器械浸入洗涤液中并不断转动器械,用一把尼龙刷彻底除去难以去除的粘固脏污。用清洁丝确保通孔畅通。随后使用诸如注射器等设备冲洗冷却水道,直到干净得完全没有一点残留污物。
- 机械再处理:
声波和超声器械使用冲洗适配器进行热消毒(请看操作指南)。

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.
- Due to the ergonomically flat design of reciprocating files, please avoid jamming, bending or using the file as a lever during use. Please make sure that the files are properly fixed in the chuck of the reciprocating contra-angle to the required depth.
- 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”, “P”) are only intended for preparation of the coronal portion of the canal.
- For reprocessing anodized aluminium bur blocks, cleaning and disinfecting agents suitable for aluminium must be used. Other agents would destroy the anodized layer of the bur block. Aluminium blocks are generally not suited for preparation in the thermo disinfectant. Prior to sterilization, rinse bur block under running water and dry thoroughly (e.g. by air blasting). Frequent reprocessing may lead to colour deviations.
- Root canal posts made of fibre reinforced composite or PMMA cannot be sterilized. Therefore, they must be cleaned and disinfected with medical alcohol. Root posts are intended for single use only.
- Clean and sharpen DSB abrasives 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. Komet DC1).

7.1. Instruments with internal cooling and sonic/ultrasonic instruments

- Manual reprocessing:
Rinse off surface contamination under running water. Remove all stubborn contamination with a nylon brush under water level, turning the instrument constantly. To assure patency of the internal cooling channel, penetrate the perforation with the cleaning wire. Rinse the cooling channel, e.g. with a syringe, until it is clean without any further contamination at all.
- Mechanical reprocessing:
Sonic and ultrasonic instruments are placed into the thermo disinfectant using the rinse adapter (see instructions for use).



8. 使用磨损器械的潜在影响

- 丢弃任何损坏或工作部位已经磨损的器械，因为使用该类器械会对工作效果带来负面影响。
- 损坏和变形的刀片会导致器械震动并导致预备边缘不佳，以及预备后表面粗糙。
- 金刚砂器械表面的空白斑点是金刚砂颗粒脱落的标志，意味着器械的磨削效率下降。金刚砂涂层表面不完整会导致产热过高。过高的接触压力或过高的温度会导致损伤组织。
- 使用时请避免过高的接触压力，因为这样会导致工作部位损伤(刀片出现缺口、过早变钝和产热过多)。
- 对于磨削类器械，过高的接触压力会导致器械表面的砂粒脱落和产热增加。
- 在预备时避免产热过多，请确保用喷气/喷水提供足够的冷却(至少50毫升/分钟)。
- 器械总长超过22毫米或头部直径超过2.5毫米时需要增加额外的外部冷却。
- 不遵守最大允许转速会增加受伤风险。
- 重复使用没有被适当消毒处理的器械会增加感染风险。
- 一次性器械(在包装上有②字样)不允许重复使用(例如薄片类的抛光器械和牙医用的刷子)。重复使用这些产品会有感染风险和/或不能确保产品的安全性(例如根管器械中会有断裂危险)。

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.
- 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.
- There is an increased risk of infection in reusable instruments which have not been properly reprocessed.
- The reuse of disposable instruments (marked ② 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).

9. 安全提示和可能产生的副作用

请遵守上述相关建议，尤其是关于产品处理、冷却、接触压力、消毒、清洁和灭菌的建议。这些器械仅能用于预定应用领域，这些应用领域有相关图标提示。不遵守相应安全提示会导致动力系统损伤和/或诸如热坏死、不希望出现的组织预备、组织或神经受损、生物学宽度受损或感染等伤害患者的情况。制备过程中，一些器械可能会有金属磨损现象，这可能会在后续的磁共振体层摄影(MRT)中造成假影。

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 indicated by the symbols provided. 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.

10. 职责

使用者有义务，自己负责确认本产品是否适合预期用途。如因使用者的疏忽造成的损害，Gebr.Brasseler将部分和全部免责。特别是由于使用者未能遵守我们的使用提示或警示以及因使用者无意误用而造成的伤害，Gebr.Brasseler将部分和全部免责。避免儿童触及产品。产品仅限口腔使用。

10. Liability

It is the responsibility of the user to check the products prior to use to ensure that they are suited for the intended purpose. In case of contributory negligence by the user, Gebr. Brasseler partially or totally declines liability for all resulting damages, particularly if these are due to non-observance of our recommendations for use or warnings as well as inadvertent misuse by the user. Store products out of children's reach. For dental use only.





使用说明与安全建议

Instructions for use and safety recommendations

象形图 · Icons



窝洞预备
Cavity preparation



冠预备
Crown preparation



清除陈旧填充物
Removal of old fillings



拆除牙冠
Crown removal



处理填充物
Working on fillings



根管预备
Root canal preparation



根管桩系统
Post systems



口腔预防
Prophylaxis



根面平整
Root planing



正畸
Orthodontics



口腔外科
Oral surgery



种植
Implantology



冠桥修复体
Crown and bridge technique



丙烯酸类修复体
Acrylic technique



加工石膏模型
Model fabrication



精密研磨
Milling technique



铸造支架
Model casting technique

8



角度
Angle



半径
Radius



半径
Radius



引导针的长度
Length of guide pin



安全倒角
Safety chamfer



椎体角度
Cone angle



斜角切割 (研磨)
Bevel cut (milling)



边缘圆角
Rounded edges



圆形顶端
Rounded tip



尖端无切割力
Non cutting tip



尖端无切割力
Non cutting tip



尖端有切割力, 尖角
Cutting tip, pointed



尖端有切割力
Cutting tip



尖端无切割力
Non cutting tip



仅尖端有切割力
End cutting only



仅尖端有切割力
End cutting only



仅尖端有切割力, 带倒角
End cutting only, with chamfer



仅尖端有切割力, 圆弧形
End cutting only, with radius



尖端有切割力
End cutting



含金刚砂
Diamond interspersed



可查阅视频
Video



可查阅更多信息
Further information available



双面带砂
double sided



上层带砂
Upper side coated



下层带砂
Lower side coated



边缘带金刚砂
diamond interspersed edge



双面砂片, 两种金刚砂颗粒
Two-grit disc, double sided



超声波清洗
Ultrasonic bath



热消毒
Thermodisinfector



高压灭菌
Autoclave



避免光照
Keep off sunlight



内含乳胶
Contain Latex



勿使用含酒精的清洁剂
Do not use cleaning agents containing alcohol



勿施加接触压力
Do not apply contact pressure

	最佳转速 <i>Recommended speed</i>		辐射灭菌 <i>Sterilized using irradiation</i>
	最大允许转速 <i>Maximum speed</i>		用环氧乙烷灭菌 <i>Sterilized using ethylene oxide</i>
	包装单位 <i>Packing unit</i>		使用 ¹ <i>Use by¹</i>
	订货号 <i>Order number/reference number</i>		如包装破损请勿使用 ² <i>Do not use in case of damaged packaging²</i>
	批号 <i>Lot number</i>		
	注意随附的使用和安全说明 <i>Consult instructions</i>		生产日期 <i>Date of manufacture</i>
			一次性使用 ³ <i>For single use only³</i>

¹过期后，无菌包装中的器械会有感染危险并不再能够保证产品功能完好。

¹ After the expiration date, the use of sterile packed instruments carries a risk of infection, and the proper function of the product can therefore not be guaranteed.




²包装受损不得再使用，因为无法确保灭菌。可重复使用的器械必须对其未破损情况加以检查，并在使用前进行相应处理。

² Do not use in case of damaged packaging as the sterility of the product is no longer guaranteed. Make sure to check that reusable instruments are in perfect condition and reprocess prior to use.












³在重新使用这类产品情况下，不能确保使用时没有危险，可能会有感染风险和/或产品不再安全可靠。

³ The reuse of these products carries a risk of infection. A safe, risk-free use can therefore not be guaranteed.

碳化钨精修器械的刀片数量 · Number of blades for carbide finishers

	超细 · <i>ultra-fine</i>	30 刀片 · <i>blades</i>
	细 · <i>fine</i>	16/20 刀片 · <i>blades</i>
	普通 · <i>normal</i>	8/12 刀片 · <i>blades</i>

金刚砂颗粒度尺寸 · Diamond grit sizes

	超细 · <i>ultra-fine</i>	8 μm	- 中等 · <i>medium</i>	107 μm *	
					
	极细 · <i>extra-fine</i>	25 μm		粗糙 · <i>coarse</i>	151 μm *
					
	细 · <i>fine</i>	46 μm		超粗 · <i>super-coarse</i>	181 μm *
					

* 对于某些器械而言，根据其形状和大小，其金刚砂颗粒的大小可能与标准值不同

* With some instruments the grit size may deviate from the specified value, depending on their shape and size.





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