



博拉瑟勒贸易(上海)有限公司

GENIUS II 刨削头 · GENIUS II Shaver Blades



GENIUS II 刨削头

GENIUS II Shaver Blades

适用于微创手术（例如膝关节、髋关节和肩部骨骼）的第二代可重复使用型 GENIUS II 系列刨削头，完全由重新设计的产品组成，因此对手术的成功率提供了前所未有的促进。

The second generation of the range of reusable GENIUS II Shaver Blades for minimally invasive surgery - for example on knee, hip and shoulder bones - consists of completely redesigned products which promote the success of the operation more effectively than ever:

无需附加任何适配器
No additional adaptor required

可以重复使用—因此物有所值
Reusable - therefore cost-efficient



改进后的彩色识别环
Improved colour coding

改进后的彩色识别环可以更加简便的识别和安装组件—即便是在较为黑暗的手术室中也是如此。

Improved colour coding for easier recognition and allocation of the components - even in the darkened operating theatre.

- | | | |
|-----------|-----------|-----------|
| ■ GE 0135 | ■ GE 0142 | ■ GE 0155 |
| ■ GE 0242 | | |
| ■ GE 0335 | ■ GE 0342 | ■ GE 0355 |
| ■ GE 0435 | ■ GE 0442 | ■ GE 0455 |
| ■ GE 0542 | | |
| ■ GE 0642 | ■ GE 0655 | ■ GE 0665 |
| ■ GE 0755 | ■ GE 0765 | |
| ■ GE 0855 | | |



重新设计的开口
Redesigned opening

由于在外部套管末端重新设计了开口，因此减小了开口堵塞的现象。

Minimum clogging thanks to the redesigned opening at the end of the outer tube.

采用了校准的套管，因此在与电动装置配用时，振动也很小。

Even less vibration in the motor thanks to calibrated tubes.



高度的切削性能
High cutting ability

先进的制作工艺和最高级的材料、改进的刀片边缘斜面几何形状、逐渐变细（椭圆形）的钻头，使得器械具有优异的切削性能。

Excellent cutting ability thanks to the advanced manufacturing technology and the top-quality material used, in combination with the improved blade geometry of the bevel edge cutters and the tapered/oval burs.

- 切割边缘斜面：
由于采用了新的刀片外形，因此使其更具切割性。
- 逐渐变细（椭圆形）的钻头：交叉切口。

- Bevel edge cutter:
More aggressive thanks to new blade configuration.
- Tapered/oval bur:
Cross-cut for fragmenting chips.



外部套管的反向标志
Marking of the reverse of the outer tube

在外部套管上带有反向标志，可以改善在手术部位的定位。

The reverse of the outer tube is marked for improved orientation in the operative site.

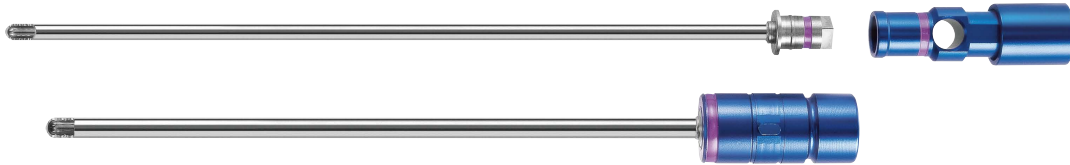


重新设计的接口
Redesigned connections

与Linvatec, Arthrex FMX, Dyonics EP1, Aesculap 和 Stryker 12K的动力系统相兼容。

Compatible with Linvatec, Arthrex, FMX, Dyonics EP1, Aesculap and Stryker 12K connections.

三件套设计
Three-component design



特殊的三件套设计使得在使用Komet Medical GENIUS II 刨削头时不会出现错误。由于这种特性，可以使用塑料刷清洁所有刨削头的内部套管。而且，这种清晰的构造可以对内部套管进行视觉检测。

这样，在进行灭菌操作前可以发现器械上存在的污染物，此时器械需接受其他的清洗操作。如果没有这种特性，则不可能进行人工清洗或者监控，并且可能造成下次手术器械准备的不完备性。

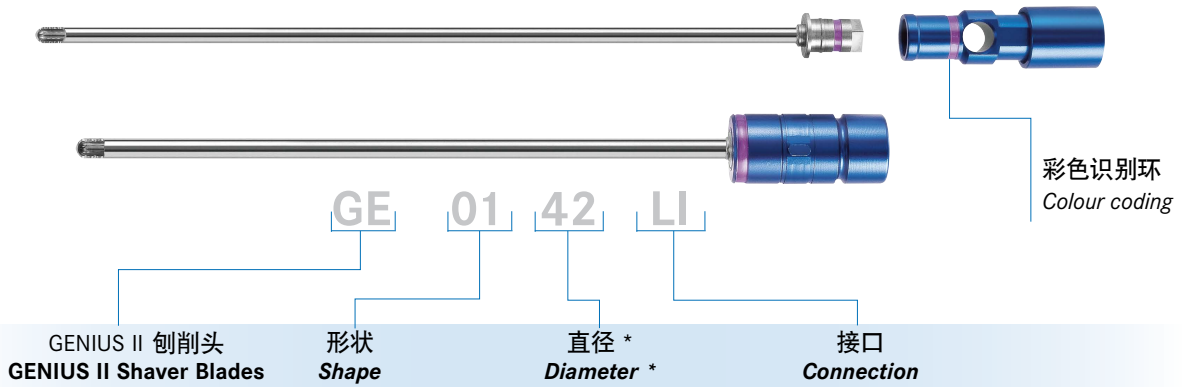
It's their special three-component design that makes the KOMET MEDICAL GENIUS II Shaver Blades so unmistakable. Thanks to this unique feature, the inner tube of all shavers can be cleaned with a plastic brush. Furthermore, this distinctive construction allows a visual inspection of the inner tube.

Contamination can be spotted before the sterilization procedure, in which case the instrument can be subjected to another cleaning cycle. Without this feature, neither manual cleaning nor control would be possible and the result of the preparation would therefore be uncertain.



9835 M
带有固定夹具的灭菌盒
Steri-box with clamping device
203 x 114 x 30 mm





* 套管外径
External diameter
of the outer tube

直径 mm Diameter mm	与以下接口匹配: compatible with the following connections:	Linvatec (Arthrex, FMS)	Dyonics	Aesculap	Stryker	转速 rpm Speed	刀片类型 Blade Type
3,5		GE0135.LI	GE0135.DY	GE0135.AC	GE0135.ST	6000	01 = 带齿半月板刨刀 Aggressive Meniscus Cutter
4,2		GE0142.LI	GE0142.DY	GE0142.AC	GE0142.ST	6000	02 = 双刨刀 BiCut
5,5		GE0155.LI	GE0155.DY	GE0155.AC	GE0155.ST	6000	03 = 全径刨刀 Full Radius Resector
4,2		GE0242.LI	GE0242.DY			6000	04 = 全径带齿刨刀 Aggressive Full Radius Resector
3,5		GE0335.LI	GE0335.DY	GE0335.AC	GE0335.ST	6000	05 = 斜边刨刀 Bevel Edge Cutter Resector
4,2		GE0342.LI	GE0342.DY	GE0342.AC	GE0342.ST	6000	06 = 圆头打磨器 · Round bur
5,5		GE0355.LI	GE0355.DY	GE0355.AC	GE0355.ST	8000	07 = 圆桶形打磨器 · Oval bur
3,5		GE0435.LI	GE0435.DY	GE0435.AC	GE0435.ST	8000	08 = 锥形打磨器 · Tapered bur
4,2		GE0442.LI	GE0442.DY	GE0442.AC	GE0442.ST		
5,5		GE0455.LI	GE0455.DY	GE0455.AC	GE0455.ST		
4,2			GE0542.DY		GE0542.ST		
4,2		GE0642.LI	GE0642.DY	GE0642.AC	GE0642.ST		
5,5		GE0655.LI	GE0655.DY	GE0655.AC	GE0655.ST		
6,5		GE0665.LI	GE0665.DY				
5,5		GE0755.LI	GE0755.DY	GE0755.AC	GE0755.ST		
6,5		GE0765.LI	GE0765.DY				
5,5		GE0855.LI	GE0855.DY	GE0855.AC	GE0855.ST		

Linovatec是ConMed Corporation的注册商标。Dyonics是Smith & Nephew Inc.的注册商标。Aesculap是Aesculap AG & CO. KG的注册商标。Stryker是Stryker Corporation的注册商标。
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KOMET MEDICAL is not affiliated with any of the above.



灭菌和保养

刨削头专用于特定的外科手术。在设计、构造和生产方面均极为精密。

GENIUS II 刨削头可以重复使用。在正确使用
的情况下，这种高质量的器械可以确保
最佳的工作效果和较长的使用寿命。
因此，在器械准备和使用过程中必须给予
特别的注意。

使用不当可能造成组织的损伤、器械过早
的磨损和损坏，或者造成操作人员、患者
和其他人员的伤害。必须严格遵守以下清
洗和使用指导。

可以从我公司的网站下载有效的方法：

Sterilization and maintenance

*The Shaver Blades are perfectly suited for
their specific surgical use. They are designed,
constructed and produced with utmost care.*

*The Shaver Blades are suitable for reuse.
These quality instruments assure the best
working results and a long service life, provided
they are used in the proper manner.
Special care must therefore be taken during
their use and preparation.*

*Improper use may damage tissue and may lead
to premature wear, destruction of the instru-
ments and injury to the operator, patient or
other persons. The below instructions for clean-
ing and use have to be closely observed.*

***A validated method can be downloaded
from our website:***



GENIUS适配器 有效清洁

KOMET MEDICAL公司最新生产的GENIUS适配器是确保有效清洁的附属装置, 在使用有效清洁方法的前提下, 可以使GENIUS II刨削头清洁, 并且随时进行该操作。这就表明, 我们的GENIUS II刨削头设计是可反复使用的, 并且不会有难以操作的部位, 因而可以安全有效的配备。上述方式是有效的, 并且由co. SMP GmbH公司确认。

GENIUSadapter Validated cleaning

The newly developed GENIUSadapters provided by KOMET MEDICAL are an auxiliary device to ensure **validated cleaning**, making the cleaning result of GENIUS II Shaver Blades, in conjunction with a validated cleaning method, repeatable at any time. This means that our GENIUS II Shaver Blades - designed for reprocessing and therefore without hard-to-access areas - can be prepared in total safety. This was validated and confirmed by co. SMP GmbH.



使用后	视觉监控/清洗	准备方式	After use	Visual control/ Cleaning	Preparation Method
<p>旋转的内管可以从静止的外部套管中拉出分开。</p> <p>如需清洗GE-LI, GE-DY和GE-ST型的内管, 可以简单的将适配器拉出内管。</p> <ul style="list-style-type: none"> 使用直径相匹配的适用清洁刷清除顽固的污渍(例如由Medical Instrument Cooperation生产的塑料刷, www.anaesthesie-produkte.com), 不能使用金属刷!) <p>或者使用超声设备, 在使用时应特别注意不能使刀片之间相互接触, 否则会造成刀片的损坏。</p>	<p>在每次使用前, 仔细检查GENIUS II刨削头有无损坏和缺陷。在使用过程中应避免机械性损坏。机械性损坏可能会造成金属磨损, 这种情况下应该更换新的刀片。</p> <ul style="list-style-type: none"> 插入内管后手动检查GENIUS II刨削头。必须可以转动内部刀片, 并且插在外部套管中。 我们建议在7-10次手术使用后应更换新的GENIUS II刀片。 	<p>此时, 可以按照有效并被认可的方法准备灭菌。</p> <p>我们建议在高压灭菌器内进行蒸汽灭菌。不能采用暴露在热空气下的方式灭菌。低温下的灭菌只能经认证/有效的准备工作后进行。</p>	<p>The rotary inner tube is separated by being pulled out of the stationary outer blade.</p> <p>In order to clean the inner tube of models GE-LI, GE-DY and GE-ST, simply pull the adapter off the inner tube.</p> <ul style="list-style-type: none"> Stubborn contamination is removed with suitable cleaning brushes of a matching diameter (for example plastic brushes made by co. Medical Instrument Cooperation, www.anaesthesie-produkte.com - no metal brushes!) and/or by cleaning in an ultrasonic device, in which case great care must be taken to prevent the instrument blades coming contact with one another as this might lead to damage to the blades. 	<p>Check GENIUS II Shaver Blades for damages, cracks or other defects prior to each use. Avoid mechanical damages, even during use. Mechanical damage might lead to abrasion of the metal, in which case the Shaver Blade is to be replaced by a new one.</p> <ul style="list-style-type: none"> Test the GENIUS II Shaver Blades manually with the inner tube inserted. It must be possible to turn the inner blade evenly and effortlessly inside the outer blade. We recommend to exchange each GENIUS II Shaver Blade for a new GENIUS II Shaver Blade after 7 - 10 surgical uses. 	<p>The GENIUS II Shaver Blades are now ready to be sterilized according to a validated and approved method.</p> <p>We recommend the vapour method in the autoclave. Do not sterilize by exposure to hot air. Sterilization at low temperature should only be carried out by certified/ validated preparation services.</p>

刨削头的使用说明和清洁建议

适应症:

根据器械的标准直径,可重复使用型刨削头可以用于多种关节手术(例如:膝关节、髋关节、肩关节、踝关节和肘关节、腕关节等)。该刀片特别设计用于组织的切除和治疗(例如骨骼、肌肉、肌腱、韧带等)。

禁忌症:

适用所有骨关节手术的一般禁忌症。

适用的动力系统:

GENIUS II 刨削头与以下手术动力系统相匹配:

Dynamics EP -1, Stryker 12K, Aesculap, Linvatec Arthrex FMS和Concept。在正确使用的前提下,不会出现相关动力系统损坏的危险。

只要制造公差尽可能保持原始产品的精确性,销售法中的相关法律条款可以保证与兼容设备配用时不受影响。这一情况已经由 Krieger & Graf von der Groeben (Düsseldorf) 法律公司确认。可以在需要时获得专家的意见。

材料:

刨削头中带有中蓝色氧化铝制成的适配器,用来将其固定在手持装置上。此外还包含金属管,在内、外管的末端装有不锈钢刀片。目前的O型环由橡胶制成。

清洁和消毒:

- 在首次使用前,新的GENIUS II 刨削头也需要如同使用过的刀片一样进行清洗和消毒(参见器械的准备过程)。
- 为了避免狭窄管腔内在干燥时出现物质残留,应该在使用后立即清洗器械。
- 必须在喷射水流下或适当的清洗消毒液中冲洗单个组件,使其表面不存在任何可见污渍。
- 我们建议在含有清洁剂的热消毒机中准备GENIUS II刨削头,而所使用的清洁剂必须已证实与器械的材料相容。我们建议使用deconex 28 Alka one(Borer Chemie公司生产)。
- 为避免矿物质沉淀对材料的损害,必须使用完全不含矿物质的水对其进行最终冲洗。
- 可以使用清洁的医用压缩气体清洗GENIUS II 刨削头。
- 确保不会错误使用刀片。
- 清洗后,对组件进行视觉检查,确保其干净并且可以随时使用,状态良好。
- 使用新的GENIUS II刨削头替换已经损坏、弯曲、磨损或变钝的刀片。如果污渍持续存在,可以重复清洗过程。在任何情况下都不能只更换某个单独的组件(例如只更换内部刀片!)
- 完全检查型号GEXXX.LI, GEXXX.DY和GEXXX.ST后,重新安装内部套管。

灭菌之前:

- 在灭菌之前必须完全清洗刨削头。
- 为了减小阻力,使用油脂润滑剂润滑内管。
- 将组件放置在适当的容器内,建议在拆卸的状态下进行灭菌。

灭菌:

- 此时,可以使用有效的并通过认可的方法对GENIUS II刨削头灭菌。建议的方法为在高压灭菌器内进行蒸汽灭菌。不适用于热空气和低温等离子灭菌。低温下的灭菌只能经认证/有效的准备工作后进行。

灭菌后:

- 理想条件下,刀片应保存在密闭、无菌的容器中。
- 在下次手术前,将内管插入相应的外管内,并且施加一定的轴向外力锁定(型号为GEXXX.ST不能锁定)。确保只能将带有相应颜色编码的组件相配用。
- 此时,可以随时将GENIUS II刨削头用在您的刨削电动系统中。更多资料请参见刨削器电动系统的使用说明书。

注意事项和警告:

- 始终不能使GENIUS II刨削头干转,即不带有冲洗剂,因为这样可能会造成卡住或者内部刀片的损坏。
- 手术中使用的长度取决于手术的类型和需要切除组织的量。当刀片变钝或者出现性能下降的现象时应立即更换GENIUS II 刀片。
- 蓝色褪色并不表明刨削头的质量下降。这种情况仅是由于使用了不适当的清洁剂造成的。
- 出于安全因素的考虑,必须注意观察所指示的速度。只能在短时间内使用允许的最大速度。高速度会降低切割的效能,并且增加器械阻塞的可能性,导致设备的使用寿命降低。
- 不按建议的速度使用GENIUS II刨削头会造成金属的磨损。过高的速度同样会增加设备卡住的风险。

Instructions for use and recommendations for cleaning Shaver Blades

Indications:

Depending on their nominal diameter, the reusable Shaver Blades can be employed in various joints (e.g. knee, hip, shoulder, ankle and elbow joints and wrists). They have been developed especially for the resection and treatment of tissue (for example bones, menisci, tendons, ligaments etc.).

Contraindications:

All the general contraindications of arthroscopic joint surgery apply.

Suitable power systems:

GENIUS II Shaver Blades are compatible with the following power systems: Dynonics EP-1, Stryker 12K, Aesculap, Linvatec, Arthrex, FMS and Concept. When used properly there is no risk of damage to the respective power system.

The legal provisions governing warranties under the sales law remain unaffected by the use of compatible instruments, as long as the manufacturing tolerances are adhered to as precisely as with the original product. This fact was confirmed by the law firm Krieger Mes & Graf von der Groeben (Düsseldorf). Expert opinion available on request.

Materials:

The shavers are composed of adaptors made of blue anodised aluminium which allow anchoring in the hand piece, as well as metal tubes with stainless instrument steel blades at the inner and outer tube. The existing o-rings are made of rubber.

Cleaning and disinfecting:

- Prior to first use, new GENIUS II Shaver Blades have to undergo the same cleaning and disinfecting procedure as used instruments (see preparation cycle).
- In order to prevent residues from drying in the narrow lumen, clean and disinfect Shaver Blades immediately after use.
- The individual components must be rinsed under a water jet or in a suitable cleaning and disinfecting solution until there is no more visible contamination.
- We recommend a preparation of the Genius II Shaver Blades in the thermo disinfectant with a cleaning agent with proven material compatibility. We recommend deconex 28 Alka one (made by co. Borer Chemie).
- In order to avoid damage to the material caused by lime stains, fully demineralised water should be used for the final rinse.
- The GENIUS II Shaver Blades are to be cleaned with medically clean compressed air.
- Make sure not to mistake the blades.
- After cleaning, the components are to be examined visually to ensure that they are clean, ready for use and in perfect condition.
- Replace damaged, bent, worn or blunt Shaver Blades with new GENIUS II Shaver Blades. Repeat cleaning process if contamination persists. Do not under any circumstances exchange individual components only (for example just the inner blade!)
- After completed examination of models GEXXXX.LI, GEXXXX.DY and GEXXXX.ST, the blue adaptor and the inner tube are remounted.

Prior to sterilization:

- The Shaver Blades must be completely clean prior to sterilization.
- Lubricate the inner tube with a suitable oil-based lubricant in order to guarantee low friction.
- Place the components in a suitable container. We recommend sterilizing the Shaver in disassembled condition.

Sterilization:

- The GENIUS II Shaver Blades are now ready to be sterilised according to a validated, approved method. The recommended method is vapour sterilization in the autoclave. Not suitable for sterilization by hot air and plasma sterilization. Sterilization at low temperature should only be carried out by certified/validated preparation services.

After sterilization:

- The Shaver Blades should ideally be stored in a sealed, sterile container.
- Prior to the next surgical use, the inner tube is inserted back into the corresponding outer tube and locked by applying axial pressure (in model GEXXXX.ST locking is not possible). Make sure that only components with identical colour codes are combined.
- The GENIUS II Shaver Blades are now ready for use in your Shaver power system. For further instructions please refer to the instructions for use provided with your Shaver power system.

Precautions to be taken / Warnings:

- Never allow GENIUS II Shaver Blades to run dry, i.e. without rinsing agent, as this may lead to jamming and ensuing destruction of the inner blade.
- The length of surgical use is determined by the type and amount of tissue to be removed. Immediately exchange the GENIUS II Shaver Blade if there is obvious blunting of the blades or in case of poor performance.
- A fading of its blue colour does not indicate a deterioration of the quality of the Shaver adaptor. This merely cosmetic change is caused by unsuitable cleaning agents.
- For safety reasons it is imperative to observe the indicated speed. The permitted maximum speed should only be used for short periods of time. High speed decreases the cutting efficiency, increases the tendency to clog and leads to reduced durability of the instrument.
- Non-observance of the recommended speed for GENIUS II Shaver Blades may lead to attrition of the metal. Excessive speed also increases the risk of the instrument seizing.

For additional information regarding the proper use and preparation of the instruments please refer to the brochure "Proper Maintenance of Instruments" issued by the working group "Preparation of instruments". (AKI - www.a-k-i.org)





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