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# **GUARANTEE**

- 1) Before being placed on the market, all equipment undergoes a thorough final check to ensure that it is are in proper working order.
- 2) We guarantees its products, purchased new from a dealer or importer, to be free from manufacturing or material

## defects for:

- -TWO YEAR from the date of purchase for the device;
- -ONE YEAR from the date of purchase for the handpiece with its cord.
- 3) Throughout the warranty period, undertakes to repair (or, at their sole discretion, to replace) free of charge any parts that, in their opinion, are faulty.

## Complete replacement of products is excluded

- 4) Cannot accept any liability for direct or incidental damage or personal injury in the following cases:
  - a) If the equipment is used for purposes other than that for which it is intended:
  - b) If the equipment is not used in accordance with all the instruction and requirement described in this manual;
  - c) If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements;
  - d) If any assemble operations, extensions, settings, alterations or repairs have been carried out by personnel not authorized;

- e) If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.
- 5) Accidental damages due to transport, incorrect use or carelessness or to connection to power supplies other than as envisaged and damage to the signaling lamps handpiece and all accessories are excluded from the warranty. The warranty will no longer apply if the apparatus has been tampered with or repaired by unauthorized personnel.
- 6) Warning:
- The warranty is valid only if the warranty slip enclosed with the product has been completed in full and returned to us or, if appropriate, to your dealer or importer within 20 days from the date of purchase, as proven by the consignment note/invoice issued by the dealer/importer.
- In order to benefit from the warranty service, the customer must return the apparatus to be repaired to the dealer/importer from which it was purchased, at his own expense.
- 7) The apparatus should be returned suitable packed (possibly in its original packing material).
- 8) Accompanied by all the accessories and by the following information:
  - a) Owner's details, including his telephone number;
  - b) Details of the dealer/importer;
  - c) Photocopy of the consignment note/purchase invoice of the apparatus issued to the owner and indicating, in addition to the date, also the name of the apparatus and its serial number:
  - d) A description of the problem.
- 9) Transport and any damages caused during transport are not covered by the warranty in the event of failure due to accidents or improper use, or if the warranty has lapsed, repairs to produces will be charged on the basis of the actual cost of the materials and labour required fro such repairs.

%			* *					
AI SURGERY PRO WARRANTY CARD			AI SURGERY PRO WARRANTY CARD		AI SURGERY PRO WARRANTY CARD			
Name of Cu			Name of Custo			Name of Custo		
Address Details	stomer		Address Details	mer		Address Details	mer	
Postal Code			Postal Code			Postal Code		
Tel			Tel			Tel		
Model			Model			Model		
Unit No.			Unit No.			Unit No.		
Handpiece N	lo.		Handpiece No			Handpiece No		
Purchase Da	te		Purchase Date			Purchase Date		
Contact pers	son		Contact person	n		Contact perso	n	
Date	Maintenance Record	Repairer	Date	Maintenance Record	Repairer	Date	Maintenance Record	Repairer
1.For Customer 2.For Distributor 3.Return to Manufacturer			1.For Customer 2.For Distributor 3.Return to Manufacturer		1.For Custome 2.For Distribut 3.Return to Ma	or		

## INTRODUCTION

## 1.1. Foreword

Before proceeding with the installation, use, maintenance or any other activities on the equipment please read the manual carefully.

Important: To avoid causing personal injuries or damages to property, read all the points concerning "safety requirement" contained in this manual with particular

Depending on the level of risk involved, safety requirements are classed under the following indications:



Danger(always referred to personal injury) Warning(referred to possible damage to property)

Not to position the device to make it difficult to operate the disconnection device. In the presence of electromagnetic interference environment, the device may be malfunctioning. Do not install AI Surgery Pro near equipment that releases magnetic

Device with electromagnetic launcher will affect the normal operation of Al Surgery Pro, do not run both devices at the same time.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

The purpose of this manual is to ensure that operators are aware of the safety requirements, of the installation procedures and of the instructions for correct use and maintenance of the apparatus.

The user is not authorized to tamper with the equipment under any circumstances.

If any problems are encountered, please contact a Manufacturer Service Centre.

Any attempts on the part of the user or any unauthorized personnel to tamper with or alter the apparatus will invalidate the warranty and release the Manufacturers from any liability in respect of any harm or damage to persons or property.

The information and illustration contained in this manual are up-dated to the date of publication indicated on the last page.

We are committed to continuous up-dating of the products, which may entail changes to components of the equipment. If there are any discrepancies between the descriptions contained in this manual and your equipment, please contact your dealer or the Manufacturer after-sale service for explanations.

Using this manual for purposes other than those relating to the installation, use and maintenance of the equipment is strictly prohibited.

## 1.2. Description of the Device

Thanks to its controlled three-dimensional ultrasound oscillations, the original AI Surgery Pro technique rings in a new age for osteotomy and osteoplasty in Implantology, Periodontology, Endodontics, and Orthodontic Surgery.

It's main features are:

Micrometric cutting: Maximum surgical precision and intra-operative sensibility; Selective cutting: Maximum safety for the soft tissues; Cavitation effect: Maximum intra-operative visibility (bloodless field);

The equipment has an automatic tuning circuit that offsets wear of the tips, thus ensuring work in constant conditions of maximum efficiency.

## 1.3. Intended Use

The Al Surgery Pro is a piezoelectric device for bone surgery that enables osteotomy and osteoplasty techniques to be applied to in almost any anatomical situation. This equipment can be used in the following fields:

a) Oral surgery;

b) Orthopedic surgery;

c) Maxillofacial surgery;

d) Cosmetic surgery; e) Neurosurgery;

f) Otolaryngology.



This equipment cannot function in places where there is an inflammable atmosphere (anaesthetic mixture, oxygen, etc).

## 1.4. Safety requirements

We will not accept any liability for direct or incidental personal injury or damage to property in the following cases:

- 1) If the equipment is used for purposes other than that for which it is intended;
- 2) If the equipment is not used in accordance with all the instructions and requirements described in this manual;
- If the wiring system in the room where the equipment is used does not comply with the applicable standard and appropriate requirements;
- 4) If any assembly operations, extensions, settings, alterations, or repairs have been carried out by personnel not authorized;
- 5) If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.



Danger: Qualified and specialized personnel.

This equipment may be used only by specialized and suitably trained personnel such as surgeons. If correctly used, this equipment does not give rise to side effects. Improper use, on the other hand, will give rise to the transmission of heat to the tissues.

Danger: Intended use.

Use the equipment solely for the purpose for which it is intended (see point 1.3), failure to comply with this requirement could lead to serious harm to the patient and/or to the operator and/or damage to/failure of the equipment.

Danger: Contraindications.

Do not use the Al Surgery Pro on patients with pace-makers or other implantable electronic devices. The same requirement applies also to the operator.

Danger: Contraindications.

An electrosurgical knife could interfere with the correct functioning of the device.

Danger: Cleaning, disinfection and sterilization of new or repaired products.

All new or repaired products are delivered in no sterile conditions. Before being used for treatments, all new or repaired products should be cleaned, disinfected and sterilization following the instructions provided under point 8 strictly.

Danger: Use only original accessories and spare parts.

Danger: Check the condition of the device before treatment.

Always make sure that there is no water under the apparatus. Before each treatment always check that the equipment is in proper working order and that the accessories are efficient. Do not carry out the treatment if any problems are encountered in operating the device. If the problems concerning the equipment contact an authorized technical service center.

Danger: Breakage and wear of the tips.

The high-frequency vibrations and wear may, very occasionally, lead to breakage of the tip. Tips of which the shape has been changed or which are otherwise damaged are liable to break during use. Any such tips should definitely not be used. It is necessary to instruct the patient to breathe through his nose during the treatment in order to avoid ingestion of the broken off fragment of the tip.

Danger: Do not install this equipment anywhere there is a risk of explosions.

This equipment cannot function in places where there is an inflammable atmosphere. (anaesthetic mixture, oxygen, etc)

Danger: Personnel injury.

The foot switch of the Al Surgery Pro must not be activated when the door of the peristaltic pump open. (Fig.3-Ref.A). Moving parts could injure the operator.

Danger: Contraindication.

Do not carry out this treatment on metal or ceramic prosthetic artifacts. The ultrasonic vibrations could lead to decrementing of such artifacts.

Danger: Contraindication.

After autoclave sterilizing of the handpiece, wait for it to cool down completely before using it.

## IDENTIFICATION COMPONENTS DATA LIST

## 2.1. Identification data

An exact description of the model including the serial number of the equipment will make it easier for our After-Sale Service to respond quickly and efficiently to

Always provide the above information whenever you contact a Manufacturer Service Centre.

## 2.2. Data plate of the device

Each device has its own data plate (Fig.1), on which technical specifications and serial numbers are indicated. The data plate is on the rear

of the device.

The remaining data are included in this manual (see Page 16).

## **Pizeo Bone Surgery**

Model: Al Surgery Pro Input: 100-240V~50/60Hz 150VA









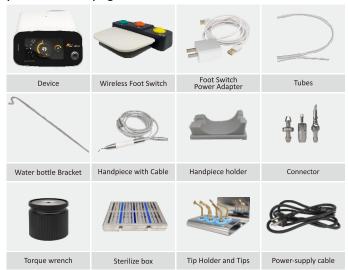
## 2.3. Data plate of the handpiece

The serial number of the AI Surgery Pro handpiece is engraved on the ring nut (Fig.2)



Fig.2

3. The materials included in the supply may vary in the case of promotional campaigns.





# INSTALLATION

## 4.1. Safety requirements during Installation



Danger: The wiring system of the premises where the apparatus is installed and used must comply with the applicable standards and the relevant electrical safety requirements.

Danger: Do not install the apparatus in places where there is a risk of explosion. The apparatus may not be used in areas where there are inflammable atmospheres (anaesthetic mixtures, oxygen, etc).

**Danger:** Install the apparatus in a place where it will be protected from blows and from accidental sprays of water or other liquids.

Danger: Do not install the device on or in the vicinity of sources of heat. Install it such a way that there is an adequate circulation of air around it. Leave sufficient free space around it, in particular with reference to the fan on the rear. (Fig. 4)

Warning: Do not expose the apparatus to direct sunlight or to sources of UV light.

**Warning:** The apparatus is transportable, however it must be handled with care when it is moved.

**Warning:** Before connecting the cord to the device, make sure that the electrical contacts are perfectly dry. If necessary, dry them with the air syringe.

**Warning:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

**Warning:** The capacity of brine bottle hang on brine bottle holder should not be more than 1000ml, and the weight should not exceed 1Kg.

## 4.2. Initial installation

To ensure perfect operation of the equipment, it is installed by technical personnel authorized. The equipment will be installed in a suitable and handy place for it to be used. The technician must:

- 1) Install the device in a suitable place;
- 2) Explain the main aspects of correct installation to the user;
- 3) Fill in the installation form, including the purchaser's data;



## 4.3. Connection the accessories

The accessories listed as follow should be connected with the AI Surgery Pro:

- 1) Insert the silicone tube into the peristaltic pump, proceeding as follows:
- a) Open the door(Fig.3)as far as it will go.
- b) Position the tube in the impeller.
- c) Close the door completely.

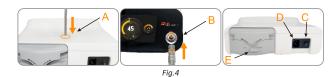


Danger: personnel injury.

The footswitch of the AI Surgery Pro must not be activated when the door of the peristaltic pump open .Moving parts could injure theoperator.

- 2) Insert the rod for supporting the bag into the holes provided for it (Fig.4-Ref.A);
- 3) Plug the power cable into the connector on the casting of the device (Fig.4-Ref.D) and then into the power outlet;
- 4) Insert the tube of Al Surgery Pro cord to the cord connector on the device (Fig.4-Ref.B);
- 5) Connect end of the tube of the peristaltic pump;
- 6) Connect the flow-control system to the bag containing the appropriate liquid for the treatment;

7) Use the torque wrench to screw the tip (Fig.5) till the clattering voice;



8) Press the button "on/off" (Fig.4—Ref.C), then can use the device.

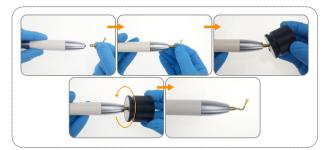


Fig.5

## 4.4. Testing of the device

All the devices are checked and tested by , including all the parts. When testing, all the parts will work in intermittent operation. The test emphasized that all the problems are from the failure parts. This procedure ensures the function and reliability of all the parts.

# **CONTROLS**

## **5.1. Description of the controls**

This section illustrates the parts of the front panel of the Al Surgery Pro unit, enabling the controls described in this manual to be located immediately.



Fig.6

1	Bone function	2	Endo function		
3	Perio function	4	Custom function		
6	Clean function	6	Display the status of foot switch		
7	Display handpiece connection status	8	Display Water flow rate, press to adjust the water flow rate.		
9	Decrease, adjust the Power	•	Increase, adjust the Power		
1	Display the current Power rate				



In Clean function, press the foot switch, the device can clean the tube .(Recommed at least 30 seconds)

## 5.2. Safety requirements during use



## Danger: Contraindications.

Do not use the Al Surgery Pro on patients with pacemakers or other implantable electronic devices. This requirement also applies to the operator.

## Danger: Breakage and wear of the tips.

The high-frequency vibrations and wear may, very occasionally, lead to breakage of the tip. Tips of which the shape has been changed or which are otherwise damaged are liable to break during use. Any such tips should definitely not be used. It is necessary to instruct the patient to breathe through his nose during the treatment in order to avoid ingestion of the broken fragment of the tip.

### Danger: Control of infections.

For maximum safety of both the patient and the operator, clean, disinfect and sterilize the piezo electronic handpiece, the tips and the torque wrench after each treatment.

## Warning: Contraindication.

Do not carry out this treatment on metal or ceramic prosthetic artifacts. The ultrasonic vibrations could lead to decrementing of such artifacts.

## Warning: Contraindication.

After autoclave sterilizing of the handpiece, wait for it to cool down completely before using it.

## Warning: The electrical contacts inside the cord connector must be dry.

Before connecting the handpiece to the device, make sure the electrical contacts of the connector are perfectly dry, in particular after the autoclave sterilization cycle. If necessary, dry the contacts by blowing air onto them with the syringe.

## Warning:

To use the device correctly, it is necessary to press the footswitch and start it up without letting the tip rest on the part to be treated. This will allow the electronic circuit to detect the point where resonance of the tip is without any interference, thus enabling optimum performance.

If this is not done, contact with the part to be treated or with other surfaces before start-up could cause tripping of the protection systems.

Warning: For spray treatment, use only tips through which liquid is passed.

## 5.3. Instruction for use

- 1) Open the air intake on the drip system;
- 2) Screw the chosen tip onto the AI Surgery Pro handpiece until it is flush against it;
- 3) To use the torque wrench correctly (Fig.5) proceed as follow;
  - a) Hold the body of the handpiece firmly;

Warning

Do not grip the end part of the handpiece or the cord, only the plastic casting (Fig.5) and do not turn it while fastening the tip in place;

- b) Turn the wrench in a clockwise direction until the cultch engages (till making clicking sound);
- c) The tip is now properly tightened in place;
- 4) Make sure that the Al Surgery Pro handpiece is correctly connected to the handpiece connector (Fig.4-Ref.B):
- 5) Check the display to see the power level that has been set, if the type of power required differs from the level that has been set, use the key "+" and "-" on Multi-founction foot pedal for selecting, depending on the type of function that has been set;
- 6) Check the display to see the delivery rate of the peristaltic pump, if the delivery rate required is other than the level that has been set, use the key "Water" on Multifounction foot pedal to choose, depending on the type of function that has been set.

## 5.4. Rules for keeping the device in proper working order

- Check the state of wear of the tips periodically and replace any for which a drop in performance is noted;
- 2) Do not alter the shape of the tips by bending or filling them;
- 3) Replace any tip that has become deformed or damaged by impacts;
- 4) Always make sure that any threaded parts and their contact surfaces are perfectly clean:
- 5) If a tip becomes too worn, the device will stop working.

# 清洁、消毒和灭菌

手机、扭力扳手、泵管、手机支架、蠕动泵电线和软管的连接、吸头、吸头 支架、手术托盘和硅胶手机支架的清洁、消毒和灭菌如下。除非另有说明, 以下统称为"产品"。

## 警告:

使用强力洗涤剂和消毒剂 (碱性 pH>9 或酸性 pH <5) 会缩短产品的使用寿 命。 在这种情况下,制造商不承担任何责任。 产品不得暴露在135°C以上 的高温下。

## 处理限制: .

这些产品专为大量灭菌循环而设计。 相应地选择了制造中使用的材料。 然 而,每次重新准备使用时,热应力和化学应力都会导致产品老化。

手机和硅胶手机座的最大允许灭菌次数为100次; 吸头最大允许灭菌次数为 工具: 压电骨手术扭力扳手、托盘、软刷、干净且干燥的软布

蠕动泵的线管连接、盐水瓶接头、手机支架、扭力扳手、手术托盘的最大允 1)将机器调至清洁模式,踩下踏板3秒,开始清洁程序; 许灭菌次数为300次。

## 6.1. 初步处理

## 1) 处理原则

只有在完成有效的清洁和消毒后,才能进行有效的灭菌。 请确保,作为您对 托盘中。

产品在使用过程中的无菌性,仅使用经过充分验证的设备和产品特定程序进行清洁/消 毒和灭菌,并且在每个周期中都遵守经过验证的参数。

另请遵守您所在国家/地区适用的法律要求以及医院或诊所的卫生规定,尤其是关于灭 活朊病毒的附加要求。

## 2) 术后处理

术后处理必须立即进行,不得迟于手术完成后30分钟。 步骤如下:

- 1. 超声骨科在冲洗模式下运行20-30秒冲洗手机和尖端;
- 2. 从超声骨科手术机上取下手机,用纯净水(或蒸馏水/去离子水)冲洗掉产品表面的

- a) 使用的包装符合ISO 11607;
- b) 能耐135℃高温, 有足够的透汽性;
- c) 必须定期清洁包装环境和相关工具,确保清洁,防止污染物的引入:
- d) 包装时避免接触不同金属的零件。

## 6.2. 清洗前的准备

此时应使用纯净水、蒸馏水或去离子水。

- 2) 将机器的手机接口密封套拧入接口,确保接口不被水侵蚀;
- 3) 用制造商提供的压电骨手术扭矩扳手从产品上取下尖端, 然后将尖端和扭矩扳手放入干净的

- 4) 逆时针拧下手机前端的喷嘴 方向,取下灯管和LED灯,放入托盘中。
- 5) 用干净的软毛刷仔细刷洗前螺纹、灯罩、喷嘴、LED灯, 直到看不到表面 污垢为止。 然后用软布擦干机头和配件,放入干净的托盘中。 清洗剂可以 2) 清洗消毒机清洗消毒步骤: 是纯水、蒸馏水或去离子水。

## 6.3. 使用说明

清洁应在手术后 24 小时内进行。 清洗可分为自动清洗和人工清洗。 有条件 产品。 的优先采用自动化清洗。

## 自动清洗

根据 EN ISO 15883, 该清洁剂通过 CE 认证证明是有效的。

- ●产品内腔应有冲洗接头。
- ●适合产品的清洗程序,冲洗周期短足够了。
- 请勿使用超声波清洗机头。

建议使用符合 EN ISO 15883 的清洗消毒器,具体流程请参考下一节(消毒) 中的自动消毒部分。

## 注意:

- a) 清洗剂不必是纯净水。 可以是蒸馏水, 去离子水或多酶。 但请确保选择的清洁剂与产品相容。
- b) 洗涤阶段, 水温不要超过45。C, 否则蛋白会凝固, 不易去除。
- c) 清洗后化学残留物应小于10mg/L。

## 6.4. 消毒

消毒必须在清洁阶段结束后不迟于2小时进行。有条件的优先采用自动化消毒。

1) 自动消毒-清洗-消毒器

- ●根据EN ISO 15883, 清洗消毒机通过CE认证证明有效。
- ●使用高温消毒功能。 温度不超过134℃,温度下消毒时间不超过20分钟。
- ●消毒周期按照EN ISO 15883中的消毒周期。
- ●小心地将产品放入消毒篮中。 需要固定产品

仅当产品在设备中可移动时。 不允许产品相互接触。

- ●用合适的清洗接头将产品内腔与清洗消毒器的冲洗接头连接起来。
- ●启动程序。
- ●程序结束后,将产品从清洗消毒机中取出,进行检验和包装。如有必要,反复干燥

## 注意:

- 1) 使用前必须仔细阅读设备制造商提供的使用说明书。熟悉消毒流程和注意事项。
- 2) 使用本设备,清洗、消毒、烘干一起进行。
- 3) 清洗:
- (a) 清洁程序应适合待处理的产品。 冲洗时间应足够 (5-10 分钟)。 预洗3分钟, 再 洗5分钟,漂洗两次,每次漂洗1分钟。
- (b) 洗涤阶段, 水温不要超过45℃, 否则蛋白会凝固, 很难去除。
- (c) 使用的溶液可以是纯水、蒸馏水、去离子水或多酶溶液等。只能使用新配制的溶
- (d) 使用清洁剂时, 应遵守制造商规定的浓度和时间。
- (a) 消毒后直接使用: 温度≥90℃, 时间≥5min或A0≥3000; 消毒后灭菌使用: 温度 ≥90°C,

时间≥1分钟或A0≥600

- (b) 此处使用的消毒温度为 93°C, 时间为 2.5 分钟,
- A0>3000
- 5)仅含少量微生物(<10 cfu/ml)的蒸馏水或去离子水

可用于所有漂洗步骤。 (如符合欧洲药典或美国药典规定的纯净水)。

- 6) 清洗后化学残留物应小于10mg/L。
- 7) 用于干燥的空气必须经过HEPA过滤。
- 8) 定期对消毒器进行维修和检查。

## 6.5. 烘干

如果您的清洁消毒过程没有自动烘干功能,请在清洁消毒后进行烘干。

## 方法:

- 1. 在平台上铺一张干净的白纸 (白布), 将产品靠在白纸 (白布)上, 然后用过滤后的干燥压缩空气 (最大压力3bar)吹干产品。 直至白纸 (白布)上无液体喷出,产品干燥完成。
- 2. 也可直接在医用干燥柜(或烘箱)中干燥。 这 推荐干燥温度为80°C~120°C,时间为15~40分钟。

## 注意:

- 1) 产品的干燥必须在干净的地方进行。
- 2) 干燥温度不应超过135℃;
- 3) 所使用的设备应定期检查和维护。

## 6.6. 检查和维护

在本章中,我们只检查产品的外观。 检查无问题后,应立即重新组装机头,依次将LED、导光管、锥头安装到机头上,然后顺时针拧紧锥头。

- 1) 检查产品。 如果清洁/消毒后产品上仍有可见污渍, 则必须重 复整个清洁/消毒过程。
- 2) 检查产品。 如有明显破损、撞坏、脱落、腐蚀或弯曲等现象,必须报废,不得继续使用。
- 3) 检查产品。 如果发现附件损坏,请更换后再使用。 更换的新配件必须清洗、消毒、晾干。
- 4) 如果产品的服务时间(次数)达到规定的使用寿命(次数),请及时更换。

## 6.7. 包装

将消毒干燥后的产品装入医用灭菌袋(或专用支架、灭菌盒)中快速包装。

## 注意:

- 1) 使用的封装符合ISO 11607:
- 2) 可耐135℃高温。具有足够的透汽性:
- 3) 包装环境及相关工具必须定期清洁,保证清洁,防止引入污染物;
- 4) 包装时避免接触不同金属的零件。

## 6.8. 消毒

仅使用以下蒸汽灭菌程序(部分预真空程序)进行灭菌,禁止使用其他灭菌程序:

- 1) 蒸汽灭菌器符合 EN13060 或根据 EN 285 认证符合 EN ISO 17665:
- 2) 最高灭菌温度为135℃;
- 3) 灭菌时间在132℃/134℃, 压力2.0bar~2.3bar条件下至少4分钟。
- 4) 在 134° C 下最长灭菌时间为 20 分钟。 产品对有效蒸汽灭菌的基本适用性的验证由经过验证的测试实验室提供。

## 注意:

- 1) 只有经过有效清洁和消毒的产品才允许进行灭菌;
- 2) 在使用灭菌器进行灭菌之前,请阅读设备制造商提供的使用说明书,并按照说明进行操作。
- 3) 请勿使用热风灭菌和辐射灭菌,否则可能导致产品损坏;
- 4)请使用推荐的灭菌程序进行灭菌。 不建议与环氧乙烷、甲醛、低温等离子灭菌等其他灭菌程序一起灭菌。
- 制造商对未经过验证的程序不承担任何责任建议,请遵守相关有效标准并验证其适 用性和有效性。部分预真空程序 = 重复预真空蒸汽灭菌真空。 这里使用的程序是 通过三个预真空。

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## 6.9. 贮存

- 1. 储存于清洁、干燥、通风、无腐蚀的气氛中,相对湿度为10%~93%,大气压为70KPa~106KPa,温度为-20°C至+55°C;
- 2、灭菌后的产品应装入医用灭菌袋或洁净的密封容器内,存放于专用的储藏柜内。 贮存时间不应超过7天。 若超标,应重新处理后方可使用。

## 注意:

- 1) 存放环境要清洁,必须定期消毒;
- 2) 产品入库必须分批、标记、记录。

## 6.10. 运输

- 1、运输过程中防止过度冲击和振动,轻拿轻放。
- 2、运输时不得与危险品混装。
- 3. 运输过程中避免暴晒或雨雪。 主机清洗消毒如下:
- ●每次使用前,擦拭机器表面和尾线 用浸有 75% 医用酒精的软布或纸巾擦拭手机。 重复擦拭至少 3 次。
- ●每次使用前,请让设备在灌溉模式下工作20-30秒, 然后安装机头。
- ●每次使用后,请让设备在冲洗模式下工作20-30秒,然后取下手机。
- ●每次使用后,用蘸有清水(蒸馏水或去离子水)的软布或干净的一次性 抹布擦拭设备表面和机头尾绳。 重复擦拭至少 3 次。

- 7、定期保养
- 1) 轻拿轻放本装置,远离震动源,并应安装和存放。
- 2) 勿与有毒、腐蚀性、易爆、可燃物混放。
- 3) 本设备应存放在相对湿度为10%~93%、大气压为70kPa~106kPa、温度为-20° C~+55° C的室内。
- 4) 如果设备长时间运行不用,最好每月通一次电,每次5分钟。
- 5) 断开设备与电源的连接。



## ↑ 危险:

定期检查电源线是否完好,如有损坏,更换备用。

## 8. 更换保险丝



## 危险:

∠! 关闭设备。

在进行以下维护活动之前,请始终通过开关关闭设备并断开其与电源插座的连接。

- 1) 将螺丝刀的平头插入电源插座下方保险丝盒的凹槽中,并将其用作杠杆(图 7-Ref.A);
- 2) 拉出保险丝盒(图 7-Ref.B);
- 3) 危险: 更换保险丝, 使用标明型号的保险丝底部的识别标签仪器;
- 4) 将隔间放回原位(图 7-Ref.B)。





Fig.

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## 9. 交货

运输时避免过度震荡、摇晃、遮盖。 不得与危险品混放。 运输时避免日晒、雨雪。

十、处置程序及注意事项



危险: 医院垃圾。

将以下物品作为医院垃圾处理

- 提示, 磨损或损坏时。
- 蠕动泵管, 经过 8 次灭菌循环后。
- 磨损或破损时用于拧紧尖端的扭矩扳手。

## 11. 工作尖

## 1) 尖锐的工作尖

这些尖端的锋利边缘可用于高效且有效地治疗骨骼结构。 当需 要在相关的骨骼结构中进行精细和明确的切割时, 在截骨术和骨 成形术中使用锋利的尖端, 也有用于骨成形术技术和去除骨碎片 的带有锋利边缘的尖端。

## 2) 平滑技巧

平滑尖端的表面形状使其可用于以精确和可控的方式处理骨骼结 构。 当需要准备困难和精细的结构 (例如准备上颌窦窗或完成 植入部位的准备)时,在截骨术中使用平滑尖端。

## 3) 钝头

钝头用于分离软组织, 例如分离 施耐德氏膜或用于侧化神经。 在牙周病学中,这些尖端用于平 滑牙根表面。

# 符号说明



遵循使用说明



仅在室内使用



交流电



脚踏开关



可以高压灭菌



制造商日期



保护接地



SN

B型应用部分



F10A 250V 保护管





储存大气压



存储湿度限制



输入电压

序列号



存储温度限制



# 故障排除

问题	导致原因	解决方案
该设备不打开 时将其置于 ON 位置。	电源线末端的接头 已正确插入设备背 面的插座中。	电源末端的连接器 电缆已插入插座上的 设备的后部正确。
江道。	电源线有故障。	检查电源插座是否正常工作 适当地。 更换电源线。
	保险丝烧断了。	保险丝烧断了。
电源线末端的连 接器正确插入设	脚踏开关的接头没 有正确插入插座。	正确插入脚踏开关连接器。
备背面的插座 中。	脚踏开关将不起作用。	联系最近的经销商或授权制 造商服务中心。
操作过程中可以听到手机发出微弱的哨声	尖端未正确拧紧到手柄上。	拧下尖端并将其拧回正确位 置。
设备工作常,但泵正在受力。	蠕动泵管上的叶 轮压力过大。	检查蠕动泵中的管子是否已 正确插入。

问题	导致原因	解决方案
	尖端是没有液体流过的类型。	使用与通过类型的尖端液体 的流动。
期间没有液体从	那袋液体是空的。	将袋子换成一个完整的袋子。
尖端流出手术。	打开与水管相连的 泵盖。	关闭盖子。
	尖端堵塞。	· 检查管子的连接。
期间没有液体 · 从尖端流出手 · 术。	. 机头堵塞。	· 联系最近的经销商或 · 授权厂商服务中心。
泵运行正常,但 当它停止时,液 体会从机头中流 出	蠕动泵的门没有关好。	确保蠕动泵的门已正确关闭。
电量不足	尖端未正确安装到 手机上	拧下尖端并更换尖端
七里小人	尖端磨损、破损或变 形	V 1 7 C 10 7 1 7 C 0 C 7 C 10
· 屏幕混乱或显示 不完整。	电压干扰。	停止任何操作,更改模型, 然后返回原始模型或重新启 动机器。

# 技术数据

机器型号:	AI Surgery Pro
根据 EN60529:	IPX1 (设备和脚踏开关)
电源电压:	~100V-240V 50Hz/60Hz 150VA
保险丝:	2*F10A 250V
工作频率:	24kHz ~ 36kHz
水流:	60~100毫升/分钟
水应用部分:	手机和尖端

## APC 的保护系统和跳闸时间:

III C B1 Nr 1 / Nr	
未连接机头:	8ms
电源线中断:	8ms
尖端损坏或未正确拧紧:	<400ms
对地放电保护:	8ms

## 运行环境:

√ ○ 11 ~1.00 •	
环境温度:	+5°C ~ +40°C
相对湿度:	30% ~ 75%
大气压力:	70kPa ~ 106kPa

水冷设备进水口温度不高于25℃

运输及存放环境: 本设备应存放在 相对湿度10%~93%, 大气压70kPa~106kPa, 温度-20℃~ +55℃的房间。

- ●泵管:强烈推荐小于8次灭菌循环
- ●主机尺寸: 300mmx280mmx128mm
- ●主机重量: 2.8kg
- ●防触电保护类型: I类设备
- ●防触电等级: B型应用部分

## 12. 售后服务

我们根据保修卡对设备提供两年免费维修。 设备的维修应由我们的专业技术人员进行。 对于非专业人士造成的任何不可挽回的损失,我们概不负责。

## 13. 环境保护

请根据当地法律进行处置。

## 14. 制造商的权利

我们保留随时更改设备设计、技术、配件、使用说明书和原始装箱单内容的权利, 恕不另行通知。 如图纸与实物有差异, 以实物为准。