



GEISTER®

INSTRUCTIONS FOR USE SURGIMOTOR™ SAW



ДИРЕКТОР ООО «АССОМЕДИКА»

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КОПИЯ ВЕРНА

ПОДПИСЬ

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GEISTER®



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Read usage instructions



Non sterile



Medical product higher class I and shortcut for Notified Body TÜV SÜD Production Service GmbH, München, Germany



Batch code



Catalogue number

RxOnly

Prescription - U.S. federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner



Do not immerse the device into fluids



Protect from humidity



The equipment meets the requirements of Type B - electric shock and electrical leakage. For use on the patient, the device is suitable in accordance with standard IEC 60601-1.



Instrument contains batteries (Li-Ion = chem. symbol of the pollutant). Used batteries should be disposed via specialized dealers. For proper disposal of used products in accordance with these local provisions in the mentioned countries respectively according to the European guideline 2006/66/EG.

Warning: Risk of fire, explosion and burning. Do not disassemble, short circuit, crush, heat over +60°C and burn the batteries.

cMETus

With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1.

Thank you for purchasing the SURGIMOTOR™ saw. Please read the following instructions carefully before use.



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1 Introduction

1.1 General information

This is an Instruction for use for single devices including accessories. These can be acquired as a system or as a separate unit.

1.1.1 General function

The system consists of battery operated drive machines with a range of attachments and accessories. The sternum saw from the system is used for operations in the thorax region; applied for cutting through the thorax. It is no contraindication known which is a compelling reason not to use the drive machines and the accessories.

Caution:

An ulterior use of the system than described above is not intended or audited and is forbidden.

1.1.2 Safety instructions

Only use the system at patients after reading this Instruction for use carefully.

Caution:

To prevent injuries the locking mechanism must be activated before putting down the device, that means the selector switch must be put on the position LOCK (Symbol closed lock). Only put the device in operation with fully charged PowerPack. For this ensure that the PowerPack gets charged in time. We recommend to put the PowerPack back into the recharger straight after the operation. The PowerPack must in no case get conditioned (manual or mechanical cleaning) or sterilized.

1.1.3 Accessories to be used/scope of delivery

An overview of the components corresponding to the system is at the end of this Instruction for use.

1.1.4 Storage and transport

Use for distribution and transport the original packing. If these are no longer available please contact Geister Medizintechnik GmbH. For information about the environmental conditions for storage and transport see the chapter „Environmental condition”.

1.1.5 Warranty

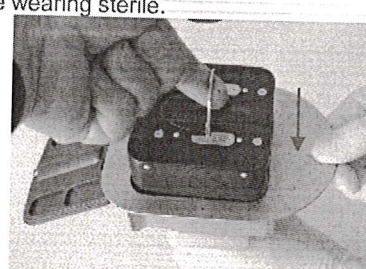
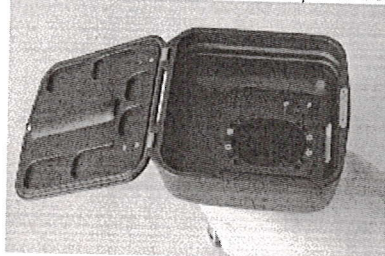
The warranty for devices and accessories is excluded in case of improper use, injured seals of approval or improper storage and transport. Also the manufacturer does not take responsibility for damage which occurs by repair or maintenance by unauthorized agencies. For this also see our general terms and conditions.

2 Operation of the device

2.1 Commissioning

2.1.1 Insert PowerPack

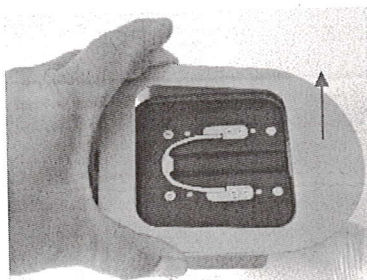
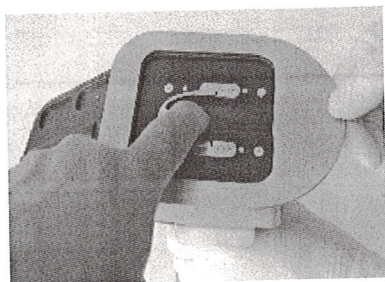
Execute the following procedure with all hand samples. To keep sterility the insertion of the PowerPack into the sterile case of the hand sample is done by two people, of which one must be wearing sterile.



The „sterile” person holds the open, sterile hand sample with the open side up.

The „sterile” person lays the sterile funnel onto the hand sample and checks the correct fitting
Note: The sterile funnel ensures that the unsterile PowerPack doesn't get in touch with the outside of the sterile hand sample.

The „unsterile” person pushes the unsterile PowerPack with the aid of the unfolded lever carefully through the sterile funnel into the hand sample.



Ensure with steady pressure onto the PowerPack that it fits correctly in the hand sample. Retract the lever. Pay attention that during the insertion the PowerPack is aligned correctly and that the „unsterile“ person doesn't touch the outside of the sterile hand sample.

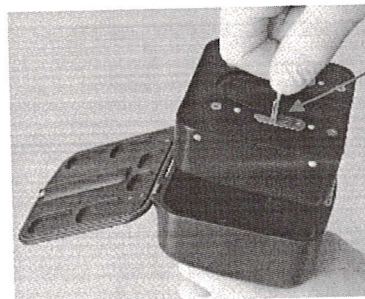
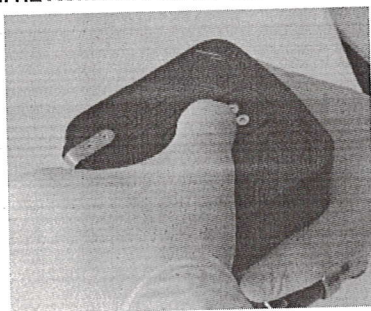
The „unsterile“ person takes the sterile funnel down from the hand sample

The person wearing sterile closes the lid.



Hold the hand sample as in the picture and press on the lid with both thumbs at the marks. The slide for unlocking the lid slips back while pressing and then jumps forward again into the locked position.

2.1.2 Remove PowerPack



Hold the hand sample with the lid up in one hand. Pull the slide for unlocking the lid with the other hand and the lid bursts open. Don't turn around the hand sample until the PowerPack is removed.

Grasp the lid with thumb and index finger and open it.

Unfold the lever at the PowerPack and use it to pull the PowerPack out of the hand sample.
Note: When replacing it during an operation the PowerPack must be removed by the „unsterile“ person. Afterwards put the PowerPack back into the recharger. Give hand sample, attachments and accessories into reconditioning.

The PowerPack must get in no case submerged into liquid, washed or sterilized.



2.1.3 Available battery capacity

During the operation you can see the battery charge condition of the PowerPack at the LED-display.

2.1.4 Overheat control of the PowerPacks

Under constant load the machines heat up. To prevent exceeding the acceptable surface temperature of the device you need to comply with the corresponding cooling phases, see „cycle of operation“. A safety system protects battery and motor from damage from overheating. If you don't comply with the cooling phases and battery and motor become too hot the device cuts off automatically. You can restart the machine only after the PowerPack cooled down.

2.1.5 Charging and storage of the PowerPack

The Power Pack contains motor, battery and electronics and must be handled with care. To guarantee proper functioning of the device you need to consider the following points:

Charging

- Fully charge the PowerPack before use.
- Charge the PowerPack by an environmental temperature of +10°C to +40°C.

Storage

- In no case expose the PowerPack to temperatures over +55°C.
- The battery cells of the PowerPack discharge also by nonuse minimal (physical effect). It is strongly recommended to keep the PowerPack also by nonuse always in the recharger.
- Always check if the PowerPack is fully charged before use.

2.1.6 Light indicators when operating with a hand sample

During commissioning of the hand sample by pressing the push button certain information in the device get requested and visually displayed as described below. After releasing the push button there gets information about the battery charge condition displayed for two seconds. Don't look straight into the white illumination LEDs.

2.1.7 Light indicators push button pressed

White light displays permanent on	The white light displays signal a rotating motor and serve as lighting support for the surgical field.
White light displays blinking	Blinking white light displays signal that the automatic safety shutdown of the device sets in shortly because of too high temperatures.
Green light displays	The remaining battery capacity is over 50% of the total capacity.
Yellow light displays	The remaining battery capacity is between 50% and 10% of the total capacity.
Red light displays	The remaining battery capacity is below 10% of the total capacity. To prevent a total discharge of the battery cells the automatic safety shutdown sets in shortly. It is not possible to continue to work in this state.
Red / green blinking light displays	Red / green blinking light displays signal that the automatic safety shutdown of the device set in because of too high temperatures. The red light display symbolizes the increased temperature, the green light display indicates the remaining battery capacity; now the remaining battery capacity is over 50% of the total capacity. To continue to work is only possible after the device cooled down.
Red / yellow blinking light displays	Red / yellow blinking light displays signal that the automatic safety shutdown of the device set in because of too high temperatures. The red light display symbolizes the increased temperature, the yellow light display indicates the remaining battery capacity; now the remaining battery capacity is between 50% and 10% of the total capacity. To continue to work is only possible after the device cooled down.
Red light displays	If the light display changes to red during operation (push button pressed) the motor stops and at the same time the white light displays go out, then the strain is too big and the machine turns off for safety reasons.

2.1.8 Light indicators push button not pressed (light time two seconds after releasing the push button)

Green light displays	The remaining battery capacity is over 50% of the total capacity.
Yellow light displays	The remaining battery capacity is between 50% and 10% of the total capacity.
Red light displays	The remaining battery capacity is below 10% of the total capacity. To prevent a total discharge of the battery cells the automatic safety shutdown sets in shortly. It is not possible to continue to work in this state.

2.1.9 Rechargers

Before the commissioning of the recharger ensure that there is no PowerPack in the charging slot. Use the included POAG-cable to establish the connection between recharger and building side potential compensating rail. Cleaning the rechargers

2.1.10 Cleaning the rechargers

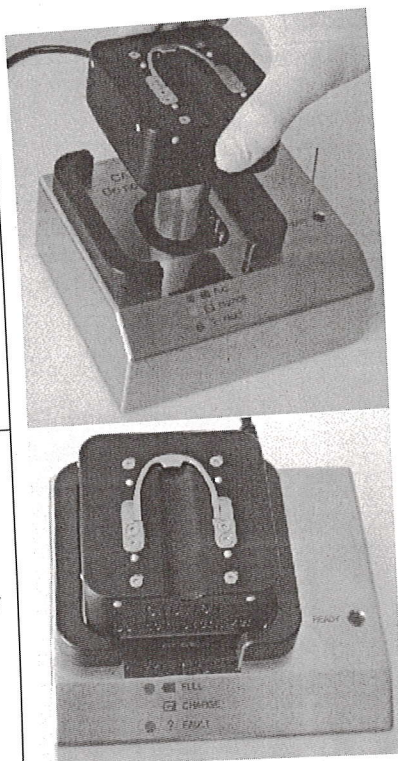
Clean the rechargers only when the power plug is pulled out. Wipe the recharger from time to time with a dry cloth (don't use a dissolver).

2.1.11 Charging the Power Pack

Insert the PowerPack which is to be charged in the correct orientation into a free charging slot.

There can only one PowerPack be charged per slot. But all charging slots can always be used at the same time (only at devices with more than one charging slots). After the automatic charge recognition the charging process starts (indicator of the PowerPack glows yellow, / indicator recharger glows yellow respectively reddish).

As soon as the PowerPack is fully charged the recharger switches to conservation charging (display PowerPack glows green / display recharger glows green).



2.1.12 Charging a new or for a longer time unused PowerPack

New PowerPacks and PowerPacks which were not in use for longer than a month and were not in the recharger reach their full battery capacity only after three to five charging cycles.

Display at the charging slot glows yellow (reddish) and the display at the PowerPack glows yellow	The PowerPack is charging.
Display at the charging slot glows yellow (reddish) and the display at the PowerPack glows green	The PowerPack is ready for operative use but not charged to 100% yet.
Display at the charging slot glows green and the display at the PowerPack glows green	The PowerPack is ready for operative as well as charged to 100% and should stay in the recharger for optimal storage and charge retention until someone uses it.
Display at the PowerPack glows red	The temperature of the PowerPack is too high; it needs to cool down before the charging process restarts automatically. If the PowerPack is not noticeable heated and the display glows for longer than 60 minutes then you have to take the PowerPack out of the charging slot shortly and reinsert it. If the display repeats the PowerPack is damaged and must be send back to the manufacturer for inspection and repair if necessary.
Display at the PowerPack blinks yellow	The recharger is not connected to the mains power supply; remove the PowerPack from the charging slot, connect the recharger to the power supply and reinsert the PowerPack.
No display glowing at the recharger	The device has no power supply or it is broken. If it is broken it needs an inspection and repair if necessary.
No display glowing at one of the charging slots	The charging slot has no power supply or it is broken. If it is broken it needs an inspection and repair if necessary.



2.1.13 Cutting recharger from power supply

Before you cut the power cable from the mains power supply you have to ensure that there is no PowerPack in the charging slot. When the power cable is removed you can cut the POAG-cable which establishes the connection between recharger and building side potential compensating rail.

2.2 Use of the sternum saw (14-6700)

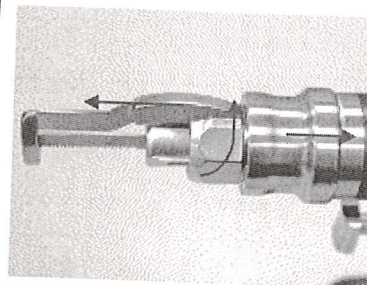
Put the slide to ON. You can use the push button for speed regulation to adjust the stroke frequency. When you release the push button the device stops. You can use the switch lever to preselect the maximum stroke frequency. If the switch lever is on position I then the mode „normal“ is selected. On position II the mode „fast“ is selected.

2.2.1 Safety bar

The safety bar can get locked in four different positions (90°-partition).

To adjust the desired position pull the sleeve for positioning the safety bar back and turn the safety bar into the chosen position. Release the sleeve. Turn the saw head slight left or right until it catches at the proper position.

For removing the safety bar you need to pull the sleeve for positioning / removing the safety bar back and then you can pull out the safety bar against the sleeve.



2.2.2 Replacing the saw blades

Only use saw blades with the GEISTER's pin. We cannot give any warranty for saw blades of other manufacturers.

2.2.3 Working with the sternum saw

Let the device start before hitting the ground. Don't apply exceeding pressure onto the saw blade to prevent jamming it. When operating it calmly you can do very accurate cuts. Inaccurate cuts indicate worn out saw blades, exceeding pressure or a jammed saw blade.

Note

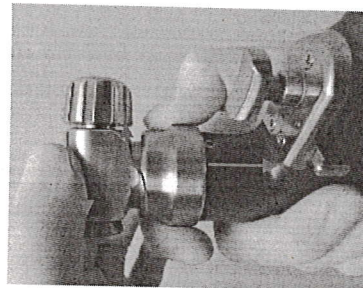
For revision surgery and non-linear cutting (ex. L sternotomy) we recommend the application with the oscillating saw (14-6710). For anatomically related cutting depths >30mm use the deep guard (14-6703), and use the mesh saw blade.

2.3 Use of the oscillating saw (14-6710)

Put the slide to ON (slide to the left or to the right). You can use the push button for speed regulation to adjust the oscillation frequency. When you release the push button the device stops. You can use the switch lever to preselect the maximum stroke frequency. If the switch lever is on position I then the mode „normal“ is selected. On position II the mode „fast“ is preselected.

2.3.1 Positioning of the saw head

To adjust the desired position pull the sleeve for positioning the saw head back and turn the saw head into the chosen position. Release the sleeve. Turn the saw head slight left or right until it catches at the proper position.



2.3.2 Replacing the saw blades

Only use saw blades with the GEISTER's pin. We cannot give any warranty for saw blades of other manufacturers.

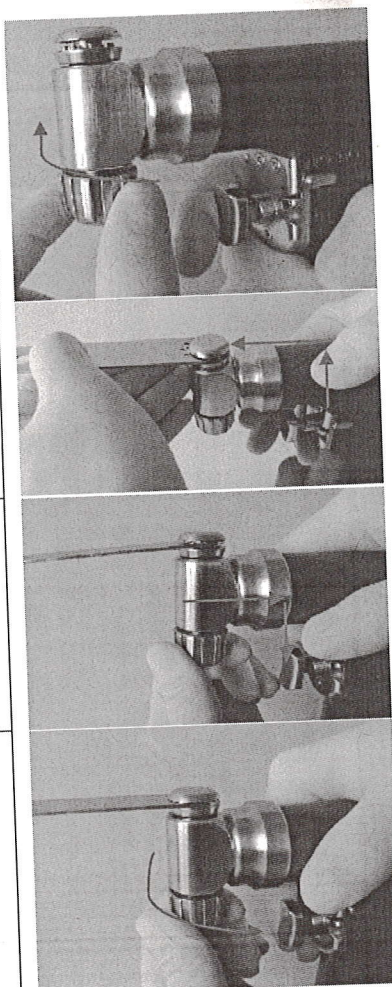


Open the saw blade quick coupling by turning the locking ring anticlockwise.

Lift and remove the saw blade.

Insert the new saw blade and turn it into the desired position. The saw blade can get locked in five different positions.

Turn the locking ring clockwise to close the saw blade quick coupling. Make sure, that the locking ring is tightened. Otherwise the screw can loose and the saw blade starts to flutter.



2.3.3 Working with the oscillating saw

Let the device start before hitting the bone. Don't apply exceeding pressure onto the saw blade to prevent jamming it. To reach optimal sawing performance move the device slightly see-saw on the level of the saw blade so that the blade swings slightly beyond the bone on both sides. When operating it calmly you can do very accurate cuts. Inaccurate cuts indicate worn out saw blades, exceeding pressure or a jammed saw blade.

3 Care and maintenance (according to a validated cleaning and sterilization process)

3.1 General Information

Drive machines and attachments have because of their frequent mechanical strain no unlimited service life. Proper use and regular maintenance increase the service life of surgical tools and instruments. The repeated clinical conditioning has little influence on the service life of the drive machine and the attachments. Careful care and maintenance as well as rigorous lubrication can clearly increase reliability and life span of the system components. Geister Medizintechnik GmbH recommends annual inspection and maintenance through the original manufacturer or selected authorized service agencies. The manufacturer takes no responsibility for damage caused by improper handling or unauthorized maintenance. With proper handling and prescribed maintenance the device has a life span of at least 5 years.

3.2 Preparation for cleaning

3.2.1 Dismantling

As far as possible disassemble the machine, make sure that all movable components are open and remove the PowerPack from the machine/hand sample. PowerPacks and rechargers can get wiped with a cloth. Insert PowerPack into the recharger after every use.



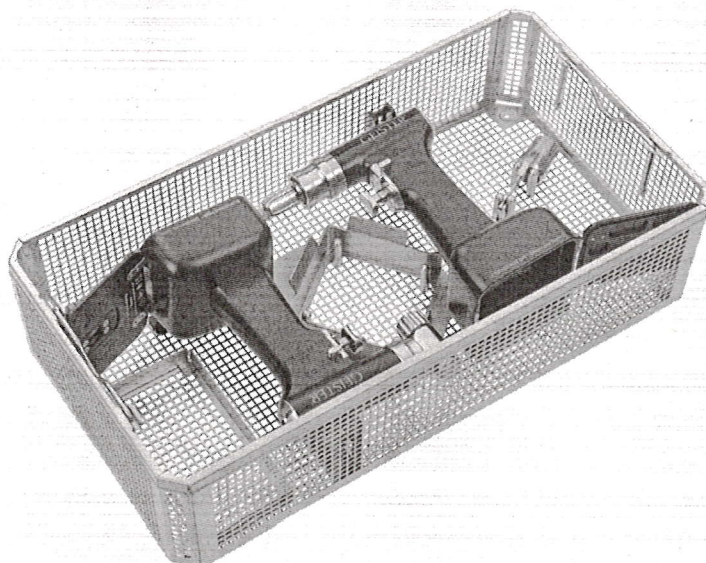
3.3 Manual cleaning

Removing arrears	Flush the hand samples (machine housing e.g. oscillating saw) for at least 3 minutes under flowing, cold tap water. Remove rough contaminations and arrears with a sponge, a lint-free cloth and/or a soft brush. Clean all cannulations with the intended cleaning brush (14-6735). Move push button, sleeves for attachments, operating mode selector switch and other movable components under flowing, cold water at least 5 times over the whole range of motion and operation to solve and remove rough arrears.
Spraying with detergents	Spray all components with an enzyme detergent, a cleaning solution or cleaning foam, let it influence for at least 3 minutes and then wipe it. For the correct dilution, temperature, residence time and water quality follow the instructions of the manufacturer of the enzymatic cleaners or the detergents to reach the optimal cleaning efficiency.
Flushing with tap water	Flush under flowing, cold tap water for at least 2 minutes. Use a spraying device, pipette or water-pressure gun to flush the cannulas and other places difficult to access.
Cleaning with cleaning solution	Clean for at least 5 minutes under flowing water with an enzymatic cleaner or a cleaning solution. Move movable components at least 5 times under flowing water over the whole range of motion and operation. Remove visible contaminations and arrears with a soft brush and/or a lint-free cloth. For the correct dilution, temperature, residence time and water quality follow the instructions of the manufacturer of the enzymatic cleaners or the detergents to reach the optimal cleaning efficiency.
Flushing with tap water	Flush the components thoroughly under cold to lukewarm flowing tap water for at least 2 minutes. Use a spraying device, pipette or water-pressure gun to flush the cannulas and channels. Move hinges, handles and other movable components at least 5 times over the whole range of motion and operation to flush these areas thoroughly under flowing water.
Checking components visually	Check cannulas, clutch sleeves etc. for visible contaminations. Repeat the steps 1 to 6 until all components are free from any visible contamination.
Concluding flushing with VE/PURW water	Flush components concluding for at least 2 minutes with totally demineralized water (VE/PURW).
Drying	Dry hand samples and components with a soft, lint-free cloth or cleaned compressed air.

3.4 Mechanical cleaning

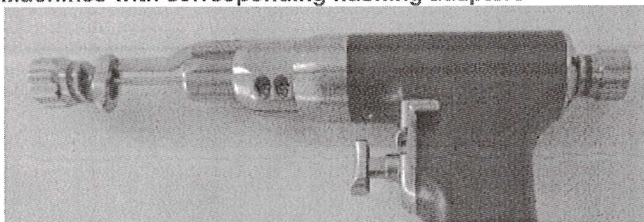
Load washing machine basket

Lay all articles into the especially for the system developed wire basket (14-6740.BO) of Geister Medizintechnik GmbH. Make sure that all cannulas (attachments) are vertical, that means in an upright position. Put the flushing adapter (14-6737/38) up on the hand samples. Connect the flushing adapter over the washing machine basket to the flushing fluid system (internal flushing of the hand samples).



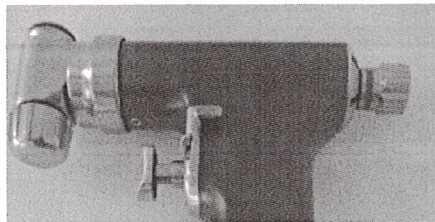


Machines with corresponding flushing adapters



Sternum saw (14-6700) with:

- Flushing adapter universal (14-6736)
- Flushing adapter jig saw and sternum saw (14-6737)



Oscillating saw (14-6710) with:

- Flushing adapter universal (14-6732)

Cleaning procedure

Note: The cleaning/disinfection device should meet with the requirements of the international norm ISO 15883 (cleaner: Neodischer MediClean (Dr. Weigert, Hamburg)):

- 2 minutes pre-washing with cold tap water
- Emptying
- 5 minutes cleaning at 55°C with 0.5% cleaning solution
- Emptying
- 2 minutes neutralization (Neodisher® Z)
- Emptying
- 3 minutes flushing with cold totally demineralized water
- Emptying
- 2 minutes final flushing with cold totally demineralized water
- Emptying
- 5 minutes thermal disinfection with hot totally demineralized water ($\geq 93^{\circ}\text{C}$)
- 40 minutes drying ($\geq 90^{\circ}\text{C}$)

Checking the components

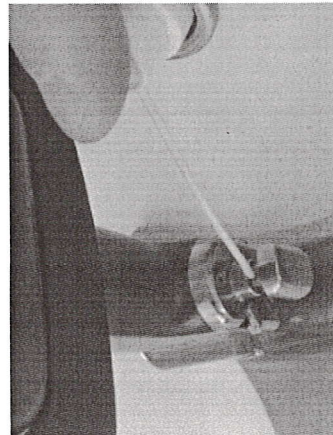
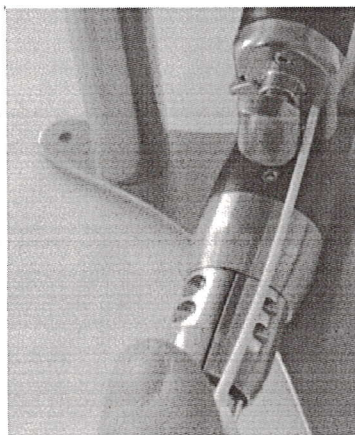
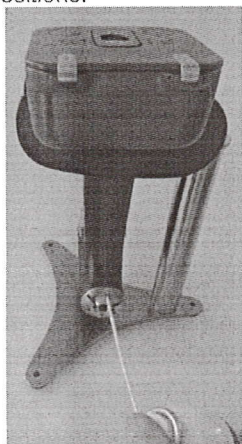
Take all components out of the washing machine basket. Check cannulas, sleeves, etc. for visible contaminations. If necessary repeat automatic cleaning with manual pre-cleaning. Devices/hand samples, particularly seals and bearings are especially stressed at the mechanical cleaning/disinfection. Check especially the framed seal at the lid carefully for damage after cleaning. Components have to get lubricated and maintained regular.

3.5 Lubricating / Maintenance

Regular lubricating of the devices/hand samples as well as the attachments ensures a long life span and a failure-free operation. All accessible, movable components of the devices/hand samples, lids and attachments have to get lubricated with the spray oil (14-6729) or physiologically inert instrument oil (5ml per position). Wipe surplus oil away with a cloth.

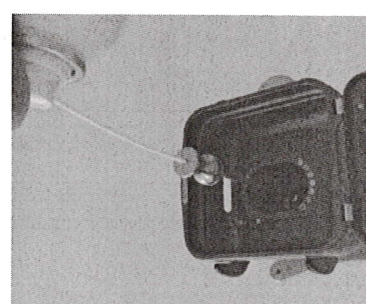
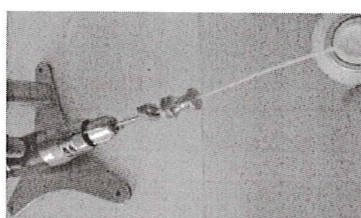
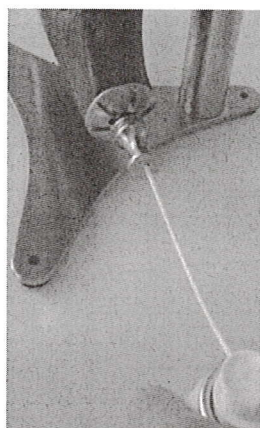
Sternum saw (14-6700)

There are two positions where you have to spray in the oil directly with the spraying tube. For that purpose insert the end of the spraying tube as far as it will go into the intended position and remain there. Following spray for approx. 1 second. Then remove the spraying tube from the position. Repeat the procedure at the other selected positions.





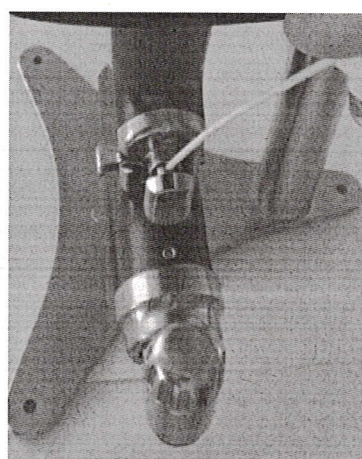
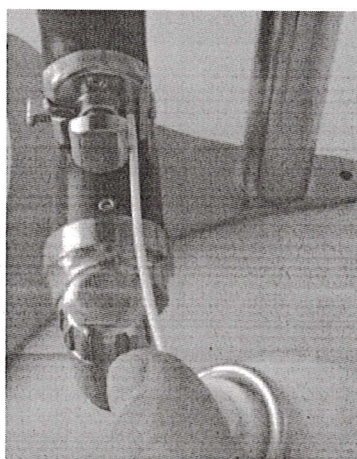
Lid	Front cover	Push button and lever Spray with the spraying tube oil onto the guiding of the push button on both sides (brief spray). Press the push button several times to spread the oil.
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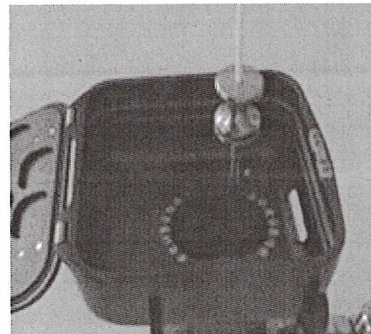
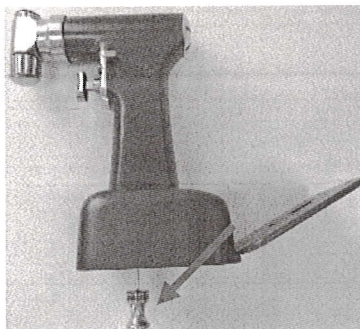
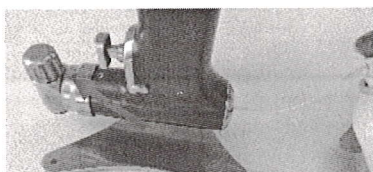
Central lid: Use oil spraying adapter 14-6731	Front side: Use oil spraying adapter 14-6730	PowerPack intake: Use oil spraying adapter 14-6732 Rub surplus oil at the surface of the device off with a dry cloth.
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Oscillating saw (14-6710)

There are two positions where you have to spray in the oil directly with the spraying tube. For that purpose insert the end of the spraying tube as far as it will go into the intended position and remain there. Following spray for approx. 1 second. Then remove the spraying tube from the position. Repeat the procedure at the other selected positions.



Lid	Front cover	Push button and lever Spray with the spraying tube oil onto the guiding of the push button on both sides (brief spray). Press the push button several times to spread the oil.
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Central lid	You have to spray in at three positions with the particular oil spraying adapter. For that purpose insert the end of the spraying tube into the tube of the adapter. Following insert the adapter as far as it will go into the saw and remain there. Spray for approx. 1 second. Then remove the spraying tube and the adapter from the position. Spraying adapter universal (14-6732) Colour: purple	PowerPack intake: Use oil spraying adapter 14-6732 Wipe away surplus oil at the surface of the device with a cloth.
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3.6 Packing

Lay the cleaned and dry products into the intended positions in the wire basket. Pack the wire basket additionally into a sterile multibarrier according to ISO 11607, e.g. in an for that purpose intended sterilization mat or a reusable sterilization container. Prevent pointed or sharp instruments from damaging through mutual touch.

3.7 Sterilization

Caution:

Remove PowerPack from the device/hand sample. Never sterilize PowerPacks, otherwise they get damaged.

The systems can get resterilized by validated autoclaving (ISO 17665 or national norms). For instruments and wire baskets packed in the sterile multibarrier Geister Medizintechnik GmbH recommends the following parameters:

Sterilization process (cycle)	Sterilization period	Sterilization temperature	Drying time
Autoclaving (fractionated fore-vacuum) (minimum 3 intervals)	at least 4 minutes	minimum 132°C maximum 138°C	20–60 minutes
	at least 5 minutes	minimum 134°C maximum 138°C	20–60 minutes

The drying time varies between 20 and 60 minutes because of different packaging materials (multibarrier consisting of sterilization mat or a reusable sterilization container), steam quality, materials of the products to be sterilized, total weight, characteristics of the sterilizer and variable cooling times.

3.8 Used symbols

The following symbols are placed on the device or single components:

	Device meets the classification Typ B against electric strike and electric heat losses. The device is suited for use at the patient according to the norm IEC 60601-1.
	Device contains batteries (Li-Ion = chemical sign of the toxic element). Batteries have to be disposed professionally for environment protection reasons. Disposal according to national laws respectively the European Battery Directive 2006/66 / EC. Caution: Danger of fire, explosions and combustion. Don't disassemble, short-out, crush, heat over +60°C or burn the battery cells.
cMETus	Concerning electric strike, fire and mechanical dangers only according to UL 60601-1



	Push button extended → machine off Push button retracted → machine on Push button in interim position → rotation speed depending on position of the push button
	Slide in center position → LOCKING / SAFETY POSITION; Device cannot get started accidentally
	Slide retracted → clockwise rotation
	Slide extended → anticlockwise rotation
	Oscillation mode on
	Oscillation mode off
	Slide retracted → on
	Slide extended → off
	Frequency/rotation speed on step „I“
	Frequency/rotation speed on step „II“
	Lid locked (in direction of arrow)
	Open lid (in direction of arrow)
	Position for pressing with the thumb (for locking the lid)
	PowerPack shows green light displays and is fully charged (PowerPack in the recharger)
	PowerPack shows yellow light displays and is charging (PowerPack in the recharger)
	PowerPack has a malfunction, battery doesn't charge: Follow instruction for use (PowerPack in the recharger)
	Recharger is ready for operation
	Recharger is charging PowerPack (yellow / orange / reddish display) Ladegerät lädt PowerPack (gelb / orange / rötliche Anzeige)

3.9 Repair and technical service

In case of a defect or malfunction send in the device for repair at Geister Medizintechnik GmbH respectively an authorized agency.

3.10 Disposal



The devices contain Lithium-Ion-batteries (Li-Ion = chemical sign of the toxic element) and have to be disposed professionally for environment protection reasons. Disposal according to national laws respectively according to the European Battery Directive 2006/66 / EC as well as Electrical and electronic equipment 2002/96/EC.

4 Troubleshooting

4.1 Device/hand sample and lid

Problem	Possible cause	Corrective
Machine doesn't start running	No PowerPack in the hand sample	Insert charged PowerPack.

Dateiname mit Revisionsstand:
14-67XX SURGIMOTOR™ Säge_EN_D

erstellt/geändert am:
20.11.2018

erstellt/geändert von:
ssta

geprüft von:
cgro

freigegeben von:
cgro

Seite
15 von 21



	PowerPack is discharged	Charge PowerPack.
	Safety system activated (slide in safety position)	Position slide to clockwise or anticlockwise rotation respectively to „on“.
	PowerPack is defect	Send in PowerPack to the Geister Medizintechnik GmbH Service point.
	Overheat control activated; the white displays has already blinked	Let the machine cool down.
Machine has insufficient performance	PowerPack is discharged; Display at PowerPack is already red	Charge PowerPack.
	Machine and/or Attachments are poorly maintained	Send in machine and attachments to the Geister Medizintechnik GmbH service point.
Machine stops suddenly	PowerPack is discharged; display at PowerPack glows read	Charge PowerPack.
	Machine is overheated, the white display has already blinked. Display at PowerPack glows read	Let the machine cool down.
	Machine or PowerPack are defect	Insert a fully charged PowerPack into the machine. If that doesn't help send in the machine to the Geister Medizintechnik GmbH service point.
Machine continues running after releasing the push button	Push button is blocked through scaling (e.g. blood)	Press push button several times, clean and maintain machine according to instructions.
	PowerPack is defect	Remove PowerPack and let it run until it stops. Then send it in to the Geister Medizintechnik GmbH service point.
Machine becomes noticeable warm/hot	Machine was in strain	Let the machine cool down.
Machine saws too slow	Wrong frequency/rotation speed for sawing adjusted (e.g. Step I instead of Step II)	Adjust correct frequency/rotation speed for sawing (Step II).
Machine saws too fast	Wrong frequency/rotation speed for sawing adjusted (e.g. Step II instead of Step I)	Adjust correct frequency/rotation speed for sawing (Step I).
Oscillating saw vibrates too strong	Saw blade fixation isn't tightened or it loosened	Tighten the lock of the saw blade quick coupling.
Attachments cannot be mounted to the machine	Machine coupling is clogged through scaling	Remove scaling through thoroughly cleaning, then lubricate.
	Locking mechanics defect	Lubricate and move mechanics, if it doesn't work then send in the machine to the Geister Medizintechnik GmbH service point.
Attachments cannot be demounted from the machine	Sleeve for attachments is blocked / clogged through scaling	Control and possibly clean and lubricate sleeve.
	Locking mechanics defect	Send in the machine to the Geister Medizintechnik GmbH service point.
Push button is difficult to move	Push button is blocked through scaling	Clean and lubricate push button.
	Locking mechanics defect	Send in the machine to the Geister Medizintechnik GmbH service point.

4.2 PowerPack

Problem	Possible cause	Corrective
PowerPack cannot be inserted into the hand sample	PowerPack is inserted in the wrong direction	Turn PowerPack by 180° and reinsert is. Pay attention to the form of PowerPack and hand sample
	PowerPack is deformed, eventually through falling down	Send in the machine to the Geister Medizintechnik GmbH service point, look after the point „Repair and technical service“.
PowerPack cannot be removed from the hand sample	PowerPack fits hard through the rubber buffer	Pull stronger at the PowerPack so that it loosens.
	PowerPack is blocked in the hand sample	Send in the machine to the Geister Medizintechnik GmbH service point.



Fully charged PowerPack doesn't work	Safety system is activated (slide in safety position)	Position slide to clockwise or anticlockwise rotation respectively to „On“.
	The PowerPack is defect because it e.g. fell down after removal from the recharger or it came in contact with liquid	Send in the machine to the Geister Medizintechnik GmbH service point, look after the point „Repair and technical service“.
Charge level indicator glows permanently	The PowerPack is inside the recharger	No defect. The charge level indicator glows permanently at the activated recharger.
	The fully charged PowerPack was removed from the recharger and not used yet in the hand sample verwendet	No defect. After removing a fully charged PowerPack from the recharger the green charge level indicators glow for 2 hours.
Charge level indicator doesn't glow. PowerPack blinks yellow.	Power cable of the recharger is not plugged	Connect recharger with the included power cable to the mains power supply.
PowerPack got washed, submerged into liquid or sterilized accidental and is defect	Carelessness of the employees	Send in the machine to the Geister Medizintechnik GmbH service point, look after the point „Repair and technical service“.
Charge level indicator doesn't glow. PowerPack inserted in the recharger.	Power cable of the recharger is not plugged	Connect recharger with the included power cable to the mains power supply.
	Recharger has a disturbance	Let the recharger get checked and if necessary repaired by the Geister Medizintechnik GmbH service point.
	PowerPack has a disturbance	Send in the machine to the Geister Medizintechnik GmbH service point, look after the point „Repair and technical service“.
The case of the PowerPack has visible damage	The PowerPack got broiled	Send in the machine to the Geister Medizintechnik GmbH service point, look after the point „Repair and technical service“.
	Someone dropped the PowerPack	Send in the machine to the Geister Medizintechnik GmbH service point, look after the point „Repair and technical service“.
The PowerPack is not efficient enough	PowerPack was for longer than 1 month stored outside of the recharger and not in use	3-5 charging/discharging cycles are necessary to reach the optimal capacity of the PowerPack again

4.3 Attachments and tools

Problem	Possible cause	Corrective
Attachments cannot be mounted to the machine	Attachment coupling is clogged through scaling	Remove scaling through thoroughly cleaning, then lubricate.
Attachments cannot be demounted from the machine	Sleeve for attachments is blocked / clogged through scaling	Control and possibly clean and lubricate sleeve. If necessary send in machine to the Geister Medizintechnik GmbH service point.
Cutting tools cannot or can only hard be mounted to an attachment	Locking mechanics is clogged through scaling	Remove scaling through thoroughly cleaning, then lubricate.
	Attachment or tool are deformed by incorrect use (e.g. drop) or wear out	Replace attachment or tool or send it in to the Geister Medizintechnik GmbH service point.
Attachment becomes noticeable warm/hot	Attachment was in strain	Let the attachment cool down and lubricate it before the next use.
Bone and tool heat up through the operation	The cutting tool is blunt	Replace tool.

4.4 Rechargers

Problem	Possible cause	Corrective
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No light display at the recharger	Power cable is not plugged	Connect recharger with the included power cable to the mains power supply.
	Recharger has a disturbance	Let the recharger get checked and if necessary repaired by the manufacturer.
At the inserted PowerPack glows no display	Power cable is not plugged	Connect recharger with the included power cable to the mains power supply.
	Recharger has a disturbance	Let the recharger get checked and if necessary repaired by the manufacturer.
	PowerPack has a disturbance	Let the PowerPack get checked and if necessary repaired by the manufacturer.
PowerPack with red display	The temperature of the PowerPack is too high	Let the PowerPack remain in the charging slot, the charging process starts automatically after it cooled down.
	Total discharge of the PowerPack	The totally discharged PowerPack didn't get recharged straight after use and didn't get used for several weeks. Several charging/discharging cycles are necessary to reach the optimal capacity of the PowerPack again.
PowerPack blinks yellow	Power cable is not plugged	Connect recharger with the included power cable to the mains power supply.

Note: If the above-named proposals for solution don't lead to success please contact your responsible Geister Medizintechnik GmbH service point.

5 Technical data

5.1 Cycle of operation

Device	Turn-on time	Turn-off time	Cycles
14-6700 Sternum saw	60 Seconds	60 Seconds	5
14-6710 Oscillating saw	60 Seconds	60 Seconds	5

5.2 Device specification

14-6700 Sternum saw	
Dimensions hand sample (without attachment)	217 x 93 x 197 mm
Weight hand sample with PowerPack	1750 g
Continuous adjustable rotation speed	0 – 7500 rpm (Step I) 0 – 10000 rpm (Step II)
Protection class	B, EN 60601-1
Power supply	Internal battery

14-6710 Oscillating saw	
Dimensions hand sample (without attachment)	163 x 93 x 202 mm
Weight hand sample with PowerPack	1760 g
Continuous adjustable rotation speed	0 - 9000 rpm (Step I) 0 - 11000 rpm (Step II)
Protection class	B, EN 60601-1
Power supply	Internal battery

14-6720 PowerPack (battery)	
Dimensions	89 x 87 x 102 mm
Weight	760 g
Type	Li-Ion
Max. voltage	16,8 V
Operating voltage (rated voltage)	14,4 V
Capacity	2,1 Ah
Typical charging time	< 90 min

14-6725 Recharger (1 charging slots)	
Dimensions	157 x 140 x 79 mm
Weight	1740 g
Type	Li-Ion battery charger



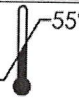
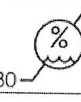
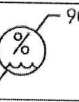
Input	100-240 VAC 50-60 Hz 0,9 A
Output	16,8 VDC 2,0 A

14-6726 Recharger (4 charging slots)	
Dimensions	636 x 140 x 79 mm
Weight	6960 g
Type	Li-Ion battery charger
Input	100-240 VAC 50-60 Hz 0,9 A
Output	16,8 VDC 2,0 A

Note: All technical data have tolerances.

To ensure safe operation of the SURGIMOTOR™ (Cat. No. 14-6710) Resectomy Oscillation Saw it is necessary:
The total working time with the oscillating saw for resectomy without personal hearing protection during an 8-hour work shift (day) must not exceed 0.8 hours. The permissible working time of personnel with the oscillating saw for resectomy in a work shift with the use of personal hearing protection, providing a reduction in sound levels by 10 dBA or more, shall not be limited.

5.3 Environmental conditions

	Operating	Transport and storage
Temperature	 35°C	 -55°C
Relative humidity	 90%	 90%
Air pressure	 1060 hPa	 1060 hPa

5.4 Valid Norms

The devices meet the following norms and guidelines:

- Medical Devices Directive 93/42 / EC and 2007/47 / EC
- IEC 60601-1 , 3rd Edition

5.5 Electromagnetic compatibility

Table 1:

Guidelines and manufacturer's declaration – electromagnetic emitted interferences		
The system is appropriated for operating in an electromagnetic environment as stated below. The customer or the user of the system has to make sure that it gets operated in such an environment.		
Emitted interference - measurements	Concordance	Electromagnetic environment – guideline
HF-emissions according to CISPR 11	Category 1	The system uses HF-Energy only for its inner function. Therefore its HF-emission is very slight and it is unlikely that nearby electronical devices are interfered. The system is suited for the use in other institutions than the living quarters an in such that are connected directly to the public power supply which also supplies buildings used for residential purposes.
HF-emissions according to CISPR 11	Class B	
Emission of harmonics according to IEC 61000-3-2	Nonapplicable	
Emissions of voltage fluctuation / flicker according to IEC 61000-3-3	Nonapplicable	

Table 2:

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The system is appropriated for operating in the electromagnetic environment stated below. The customer or the user of the system has to make sure that it gets operated in such an environment.			
Immunity-checks	IEC 60601-test level	Concordance-level	Electromagnetic environment-guidelines
Discharge of static electricity according to IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material the relative humidity must be at least 30%.
Quick transient electrical disturbance variables / bursts according to IEC 61000-4-4.	± 2 kV for power lines ± 1 kV for entry and exit lines	Nonapplicable	The quality of the supply voltage should correlate with a typical business or hospital environment.



Impulse voltages / surges according to IEC 61000-4-5	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-ground	Nonapplicable	The quality of the supply voltage should correlate with a typical business or hospital environment.
Voltage drops, short interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ drop of the U_T) for 1/2 period $40\% U_T$ (60% drop of the U_T) for 5 periods $70\% U_T$ (30% drop of the U_T) for 25 periods $< 5\% U_T$ ($> 95\%$ drop of the U_T) for 5 seconds	Nonapplicable	The quality of the supply voltage should correlate with a typical business or hospital environment. If the user of the system demands continued function also when interruptions in the power supply occur, it is recommended to supply the system from an uninterruptible power supply or from a battery.
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the power frequency should correlate with the typical values which are found in a business or hospital environment.

Note: U_T is the alternating supply voltage before the application of the test levels

Table 3:

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The system is appropriated for operating in the electromagnetic environment stated below. The customer or the user of the system has to make sure that it gets operated in such an environment.			
Immunity-checks	IEC 60601- test level	Concordance-level	Electromagnetic environment- guidelines
Conducted HF- disturbance variables according to IEC 61000-4-6 Radiated HF- disturbance variables according to IEC 61000-4-3	3 V _{effective value} 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5GHz	Nonapplicable 3 V/m	Portable and mobile radio units shouldn't be used in a smaller distance to the system including the lines than the recommended protection ratio which is calculated after the equation that fits for the transmission frequency. Recommended protection ratio: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ for 800 MHz to 2,5 GHz with P as the rated power of the transmitter in watt (W) according to the data of the transmitters manufacturer and d as the recommended protection ratio in meters (m). The transmitter field intensity of stationary radio transmitters should according to a local examination ^a be less than the compliance level ^b . Around devices which have the following symbol are interferences possible. 
Note 1	At 80 MHz and 800 MHz is the superior frequency range effective.		
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is affected by absorptions and reflections of buildings, objects and humans.		
^a The transmitter field intensity of stationary transmitters like e.g. base stations of cell phones and handheld radios, amateur radio stations, AM- and FM-broadcasting- and television transmitters can theoretically not be predestinated exactly. To determine the electromagnetic environment regarding stationary transmitters you should consider a study of the electromagnetic phenomena of the location. If the measured field intensity at the location where the system is used exceeds the above mentioned compliance levels then the system should be monitored to verify the normal function. If extraordinary performance features are monitored there may be additional actions necessary like e.g. an altered alignment or another location of the system.			
^b Above a frequency range of 150kHz to 80MHz the field intensity should be less than 3 V/m.			

Table 4:

Recommendend protection ratio between portable and mobile HF-telecommunication devices and the system



The system is appropriated for the use in an electromagnetic environment where the HF-disturbance variables are controlled. The customer or the user of the system can help to prevent electromagnetic disturbances by complying with the minimum distance between portable and mobile HF- telecommunication devices (transmitters) and the system – depending on the output power of the communication device as stated below.

Rated power of the transmitter W	Protection ratio, depending of the transmitter frequency		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	12 cm	12 cm	23 cm
0,1	38 cm	38 cm	73 cm
1	1,2 m	1,2 m	2,3 m
10	3,8 m	3,8 m	7,3 m
100	12 m	12 m	23 m

For transmitters, whose maximum rated power isn't stated in the table above the recommended protection ratio d in meters (m) can be determined using the equation which belongs to the particular column, whereat P the maximum stated power of the transmitter in watt (W) is according to the statement of the manufacturer.

Note 1	At 80 MHz and 800 MHz is the superior frequency range effective.
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is affected by absorptions and reflections of buildings, objects and humans.

6 Ordering information

6.1 Machines

14-6700	Sternum saw
14-6710	Oszillating saw

6.2 Accessories

14-6702	Sternum Saw Guard
14-6702.FO	Oszillating Saw Guard
14-6703	Deep Sternum Saw Guard
14-6719	Instruction for use
14-6720	PowerPack
14-6728	Lubrication rack
14-6722	Sterile funnel
14-6725	Recharger (1 charging slot)
14-6726	Recharger (4 charging slots)
14-6726.2	Recharger (2 charging slots)
14-6727.EU	Country-specific plugs for rechargers (EU)
14-6727.UK	Country-specific plugs for rechargers (UK)
14-6727.US	Country-specific plugs for rechargers (US)
14-6727.AA	Country-specific plugs for rechargers (AU)
14-6724	POAG-cable for rechargers
14-6729	Spray oil sterilizable
14-6730	Spraying adapters ahead for saws (for 14-6700)
14-6731	Spraying adapters for saws (for 14-6710 / 14-6700)
14-6732	Spraying adapters universal (for all machines)
14-6735	Cleaning brushes-set
14-6736	SURGIMOTOR™ Flushing Adapter Sternum Saw, red
14-6737	Flushing adapter for sternum saw (for 14-6700)
14-6738	Flushing set
14-6739.ML	Flushing adapter Miele/Stielco/Webeco
14-6739.BL	Flushing adapter Belimed
14-6739.GE	Flushing adapter Maquet/MediKomp/Getinge
14-6740	Wire basket with lid
14-6740.LD	Lid for wire basket
14-6740.BO	Wire basket

6.3 Saw blades

14-6705	Sternum Saw Blade 32mm (sterile, single use, pack of 10)
14-6705N	Sternum Saw Blade 32mm nonsterile
14-6706	Sternum Saw Blade 42mm (sterile, single use, pack of 10)
14-6706N	Sternum Saw Blade 42mm nonsterile
14-6714	Sternum Saw Blade oscillating 35x20mm (sterile, single use, pack of 10)
14-6714N	Sternum Saw Blade oscillating 35x20mm nonsterile
14-6715	Sternum Saw Blade oscillating 50x40mm (sterile, single use, pack of 10)
14-6715N	Sternum Saw Blade oscillating 50x40mm nonsterile
14-6716	Sternum Saw Blade oscillating 35x75mm (sterile, single use, pack of 10)
14-6716N	Sternum Saw Blade oscillating 35x75mm nonsterile

