joimax®
Endoscopic Spine Experts

Shrill®

Shaver Drill System

User Manual

Multifunctional Drill & Resection System

Table of Contents

1 Legal Notes

This manual contains information subject to copyright. All rights are protected by law. Without explicit written authorization by the manufacturer, it is prohibited to copy, publish or record this manual, wholly or in part, by photocopy, microfilm or other methods.

The manufacturer is grateful for information about any errors or inconsistencies in this document.

Due to continuous improvement of our products, we reserve the right to make technical changes that do not affect functionality and basic safety.

1.1 Liability

All procedures, notes and warnings described in this manual do not release the operator/user from his or her responsibilities regarding clinical judgment, experience and best clinical practice.

2 General Description

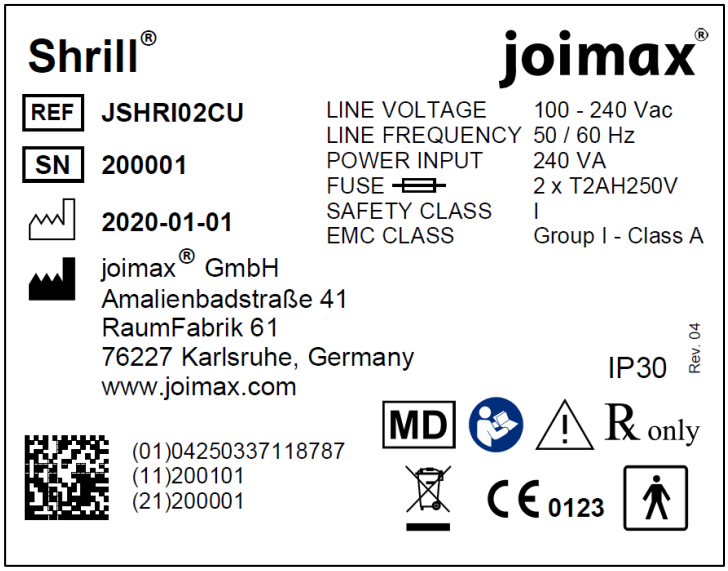
The joimax® methods for endoscopic and minimally invasive spinal surgery require the use of a surgical shaver system for resection of bone and soft tissue. The joimax® Shrill® system was specially developed for the removal of soft tissue and bone of the spine. It consists of a console, a shaver handpiece and various sterile Shaver Blade attachments.

3 Signs and Symbols

	Please note!
	Warning!
	Separate collection of electrical and electronic devices (in accordance with directive 2012/19/EU, WEEE)
	Applied part type BF
	CE marking in compliance with the Medical Device Regulation (EU) 2017/745
	Manufacturer
	Date of manufacture
	Follow Instructions for Use
	Item number
	Serial number
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
IP 30	Ingress protection class according to IEC 60529: 3: Protected against solid foreign objects of 2,5mm ∅ and greater 0: No protection
	Equipotential (potential equalization)
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from rain
	Keep away from sunlight
	Non-sterile

MD	Medical Device

3.1 Device Label



4 Intended Purpose and Characteristics

Warning:
The device must be used only for its intended purpose described in this manual!

4.1 Intended Purpose

Indications for Use
The joimax® Shrill® is intended to be used for removal of bone tissue and soft tissue, excluding all soft tissue structures of the central nervous system, namely spinal cord and meninges, in either open or minimal invasive orthopedic procedures.

Contraindications
The use of the device is contraindicated if, in the opinion of an experienced physician or according to current professional literature, the use would endanger the patient.

Intended Patient Population
The Shrill® System is intended to be used on adult patients of all genders with appropriate indications (except pregnant women). The use of the Shrill® System is at the discretion of the respective user on the basis of his training and experience.

Intended Users
The joimax® Shrill® is intended for use by medical professionals (e.g. surgeons).
It must be operated under the supervision of qualified and authorized personnel. Users are required to be trained and familiar with the basic principles, application rules, and risks of the device in order to reliably avoid a risk to the patient, user, and others.

Intended Use Environment
The Shrill® is intended for use in operating rooms.
The control unit is intended to be positioned stationary outside of the sterile patient environment, e.g. on a medical cart or table that is suitable in terms of tilting stability and weight of the device.

4.2 Characteristics

Performance Characteristics
The joimax® methods for endoscopic and minimally invasive spinal surgery, which have proven their clinical benefits, require the use of a surgical shaver system for resection of bone and soft tissue. The joimax® Shrill® System enables convenient use of tissue resecting instruments through an endoscope.

The system provides
- State of the art motor control technology for different hand pieces
- User-programmable memory locations for individual speed adjustment
- A shaver hand piece with rotation speed up to 10,000 rpm
- A small shaver hand piece suitable for joimax® cervical application
- Design according to the joimax® 4th generation including glass front panel
- An enhanced more flexible use concept with capacitive touch elements
- Integration in the joimax® 4th generation endoscopy system
- Ethernet based interface for communication with other joimax® devices via the proprietary joimax® Vitegra® "Command" protocol.

Principles of Operation
To achieve the desired treatment effect on tissue, different instruments are driven by a handpiece in rotating or oscillating motion. For this purpose, the respective handpiece is connected to the control unit and instruments (shaver blade, drills) are attached. These instruments consist of a long shaft, which allows the application through an endoscope and differently shaped tips that enable drilling, cutting or reaming. A rinsing system can be connected to the handpieces to remove free tissue parts from the patient through an adjustable suction opening.

Key Components
The system consists of the control unit and different handpieces to enable basic functionality, paired with various shaver blades for different joimax® procedures:

joimax® Shrill® Control Unit (JSHRI02CU)

A housing hosting the main hardware and software of the shaver system as well as a glass front with integrated touch display, which enables the control of the system and the display of device parameters.

joimax® Shrill® Shaver Handpiece, large (JSHRI02SHL)

A handpiece for connection of shaver blades with a rotation speed up to 10,000 rpm and buttons for manual activation, change of rotation speed and mode.

joimax® Shrill® Shaver Handpiece, small (JSHRI02SHS)

A smaller and lighter handpiece specifically designed for use at the cervical spine for connection of shaver blades with a rotation speed up to 6,000 rpm.

joimax® Shrill® Universal Motor Handpiece (JSHRI02UMH)

A universal handpiece, which can be used with different adapters to accommodate a variety of common tools for drilling, screwing and placing K-wires.

joimax® Shrill® Foot Switch (JSHRI02FS)

A foot switch that allows the control of the system as an alternative to the buttons of the handpieces.

4.3 Clinical Benefits

The application of minimal invasive surgical methods is favorable compared to open surgery in terms of the following clinical benefits: help gain easy access to the pathological site thus reducing the surgical duration, reduced blood loss, reduced infection and overall complications, smaller incision/less trauma, less scarring, less pain, faster recovery time/reduced hospitalization time and improved quality of life.

Endoscopic spinal surgery clearly profits from a surgical shaver system for resection of bone and soft tissue in terms of the following clinical benefits: minimally invasive intervention, used for all endoscopic procedures in which tissue is removed under endoscopic visual control (nucleotomies, stenoses, facet joint and ligament hypertrophies, endoscopically assisted fusions, stabilizations), suitable for all procedures in the area of the spine, traumatology and orthopedics, recess stenoses are treated transforaminally with joimax® Shaver Blades for gentle removal of soft and bony tissue.

5 Scope of Delivery

After delivery of the joimax® Shrill® System, the packaging must be checked for external damage. If any components are damaged or missing, please contact joimax® customer service.

<table>
<tr><th>Item number</th><th colspan="3">Description</th></tr>
<tr><td>JSHRI02S</td><td colspan="3">joimax® Shrill® System
Multifunctional Drill and Resection System

List of components:</td></tr>
<tr><td></td><td>Item number</td><td>Description</td><td>Quantity</td></tr>
<tr><td></td><td>JSHRI02CU</td><td>joimax® Shrill® Control Unit</td><td>1</td></tr>
<tr><td></td><td>JSHRI02SHL</td><td>joimax® Shrill® Shaver Handpiece large</td><td>1</td></tr>
<tr><td></td><td>JSHP06020</td><td>Sterilization Tray for Shrill® Handpiece, with lid</td><td>1</td></tr>
<tr><td></td><td>JFST061434</td><td>Stopper</td><td>2</td></tr>
<tr><td></td><td>JSHP06010</td><td>joimax® Cleaning Adapter for Shaver Handpiece</td><td>2</td></tr>
<tr><td></td><td>SHCS305005</td><td>Shaver Handpiece Cleaning Set</td><td>2</td></tr>
<tr><td></td><td>n/a</td><td>Instructions for Use</td><td>2</td></tr>
<tr><td></td><td>n/a</td><td>Quick-Info</td><td>1</td></tr>
</table>

6 Safety and Warning Notes

6.1 General Safety and Warning Notes

Warning:
This device must be used by trained professionals only!

Warning:
Never touch the patient and any signal input or output connectors on the device at the same time!

***Warning*:**
Installation of the device on a medical trolley with multiple-socket outlet leads to the establishment of a ME system and can lead to a reduced level of safety. The requirements regarding ME systems of IEC 60601-1 must always be observed!

Warning:
The device is not intended for use in explosive areas (e.g. in the presence of anaesthetic gas)!

Warning:
Keep these instructions for use in a conspicuous place near the device!

Warning:
Read this manual carefully before first use. Protect yourself, patients, and third parties from damage by defective devices or improper operation!

Warning:
Mechanical stress, such as from falling, can damage or destroy the device!

Warning:
Do not open any component of the joimax® Shrill® System. Opening leads to a reduced level of safety. Never use the device with the housing open.

Warning:
Always make sure blood circulation is not impaired when positioning and sedating the patient.

6.2 Additional Notes regarding Electrosurgical Equipment

Warning:
If the device is used stacked in combination with electrosurgical devices, always position the device above the electrosurgical unit. Ensure that cables of active electrosurgical accessories are not positioned close to the control unit or the handpiece cable.

6.3 Additional Notes regarding MRI (Magnetic Resonance Imaging) and CT (Computer Tomography)

Warning:
Do not use the joimax® Shrill® System during MRI or CT scans.
Due to energetic interactions of magnetic fields and X-rays with the material of the handpieces the electrical components of the joimax® Shrill® System may be damaged. Unforeseeable side effects and visual disturbances may occur.

6.4 IT Security Requirements

Warning:
Good physical security must be provided to prevent unauthorized physical access to the device.

Warning:
This device must only be used by trained and authorized professionals.

Warning:
Service activities must only be carried out by authorized service personnel.

Cybersecurity considerations were made in accordance with the nature of the device, including the device type and the use environment (operating room) during its lifetime.

The Shrill® System software is embedded into the Shrill® System control unit (closed system) and provides network functionality for a closed internal communication network of joimax® electronic devices which has no internet access. The internal network is secured via https connection (machine authentication via certificate handling). The system must not be connected to any external network. All external digital interfaces providing service features are deactivated during the use of the device or secured by using dedicated communication protocols.

Therefore, no requirements concerning hardware and IT network characteristics are necessary to run the software as intended.

The healthcare provider is responsible to provide good physical security to prevent unauthorized physical access to the system. The following common best practice security controls ("security hygiene") in the operating environment are recommended to be followed:

- Ensure regulated and authenticated physical access via suitable technical measures (e.g. badges)
- Define roles and access rights, including those for physical access to medical devices
- Provide security awareness training
- Ensure that prescribed maintenance is done as required, including installation of security patches/updates

Contact the joimax® technical support for further information provided on device cybersecurity.

Cybersecurity Vulnerability Reporting
If you detect a cybersecurity weakness or vulnerability of the device or if a cybersecurity incident takes place involving the device, contact joimax® technical support. Depending on the actual event, joimax® technical support will advise which steps to take.

Security Patches/Updates
Security patches/updates are provided by joimax® and may only be installed by authorized personnel. The Shrill® System does not allow additional software for malware detection or anti-virus.

6.5 Residual Risks and Side-Effects

When using the product, residual risks exist and may lead to the following side effects for patient, user or third parties: electric shock, burns, transfer of pathogens, an abortion of the surgery or change of the technique.

7 Installation and Commissioning

Warning:
Examine the device, the accessories, and all electrical connections for function and damage prior to use! Defects in cables, connectors, housings or loose parts can impair performance and safety and must be rectified immediately!

Warning:
The joimax® Shrill® System must be cleaned and disinfected before first use according to the cleaning instructions!

Warning:
This device must be installed and commissioned by authorized personnel only. Improper installation could cause damage to the user, the patient, or others, and might damage the device or other medical equipment.

Warning:
Place the devices in a way that allows easy disconnection from the mains!

Warning:
The ambient temperature must not exceed 30 °C (86 °F) during operation!

Warning:
Place the control unit on a clean, flat surface. Ensure that you keep sufficient space behind the device for efficient airflow. Make sure that a minimum distance of 15 cm (6”) is maintained between the back of the device and other objects. All ventilation openings must not be obstructed.

The joimax® Shrill® System is recommended to be installed in the joimax® endoscopic trolley with a central on/off switch.

Keep the original packaging for possible shipment of the device.

The system and its accessories must be checked immediately upon receipt for completeness and obvious damage. Damages may be claimed only if the manufacturer is notified immediately (within a 24-hour period).

7.1 Connection of the System

Warning:
To avoid the risk of electric shock, this equipment must always be connected to potential equalization and a power supply with protective earth!

Warning:
Only joimax® accessories (cables, etc.) may be used for connection!

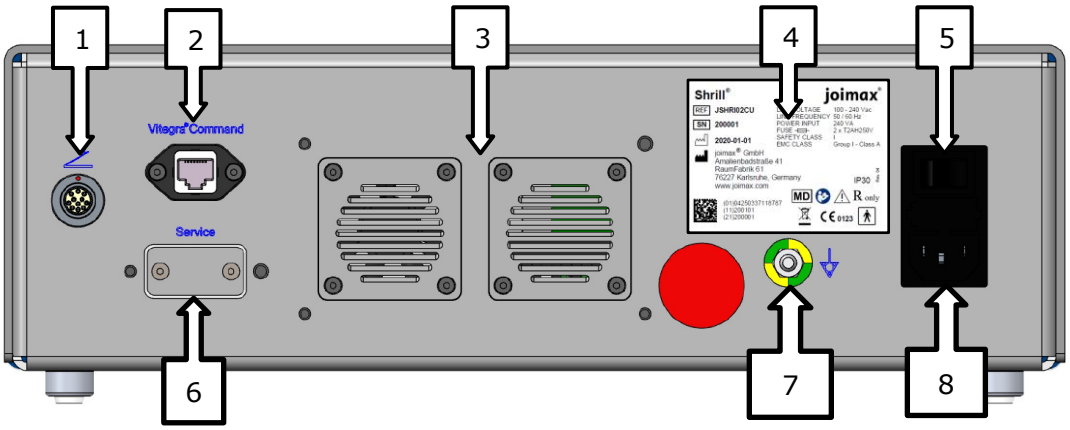
Warning:
Always keep cables out of passage areas in order to reduce the risk of stumbling.

Warning:
Make sure all connectors are free of coarse soiling before insertion.

Warning:
Before connecting and starting the system, all components must be visually inspected for integrity! Damaged parts must be replaced. This must be done by experts.

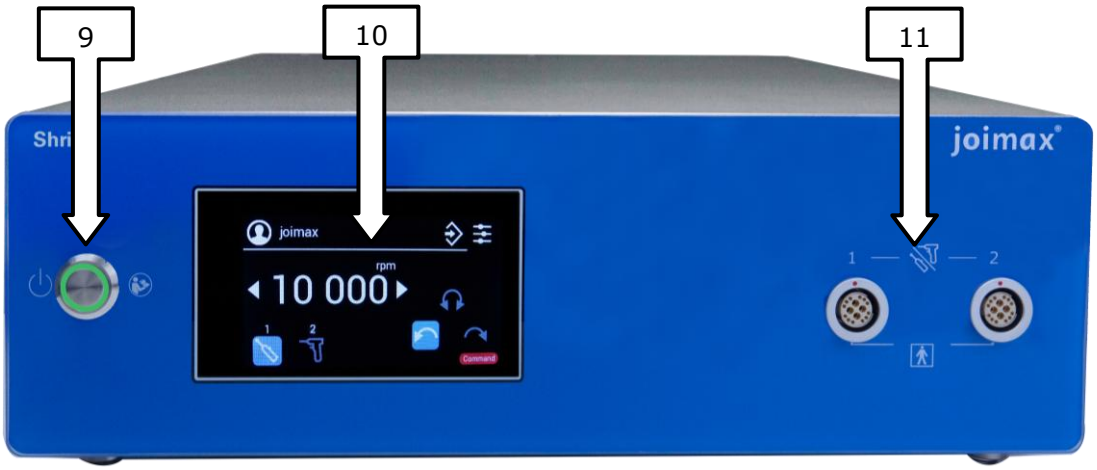
7.1.1 Control Unit

Rear Panel



1	Foot switch connector	2	Connection to Vitegra® Command	3	Air vents
4	Device label	5	Power switch with fuse holder	6	Service interface
7	Potential equalization connector	8	Mains socket		

Front Panel



9	“Standby” button	10	Touch display	11	Handpiece connectors

7.1.2 Connecting the Control Unit to a Power Supply Network and Potential Equalization

Warning:
Always connect the devices to a buffered power supply and make sure that the nominal voltage and power values are respected.

Always respect the requirements of section 8.6.7 of IEC 60601-1 regarding medical electrical systems!

a) Connect the potential equalization plug at the back of the control unit to grounding.
b) Connect the power inlet at the back of the control unit to a power outlet.
c) Set the power switch to position "I".

For safe disconnection of the device from mains power supply, set the power switch at the backside of the device to position "0" and unplug the power cord from the mains connection.

7.1.3 Connecting the Handpieces to the Control Unit

Connect the handpiece cable to one of the sockets marked with at the front of the control unit.

Warning:
Make sure that the plug is in the correct position (red dot on plug and socket) and the locking sleeve snaps forward and locks after insertion of the plug.

To pull the plug, the locking sleeve must be pulled backwards (release the lock).

Color marking

7.1.4 Connecting the Foot Switch

Connect the foot switch cable to the respective socket at the back of the control unit.

7.2 Functional Tests

After correct wiring, start the device. The control unit performs a self-diagnosis after turning-on, this process takes some seconds. Make sure no button on the control unit or on a connected handpiece is pressed during this period.

Check the display at the control unit for any errors given by the system. Refer to chapter 13 for troubleshooting.

7.2.1 Behavior in the Event of Malfunctions

In the event of malfunction of the device or changes in its performance that may affect safety (e.g. deviations from the permissible operating conditions) have the faults corrected immediately.

The Shrill® can be switched off at any time by using the power switch as an emergency stop switch.

Proceed as follows in case of malfunctions:

1. Immediately remove the shaver blade from the working channel of the endoscope.
2. Inspect the Shrill® and perform a functional test.
3. Contact the joimax® technical support.
4. Report any serious incident to joimax® GmbH and the competent authority having jurisdiction in your locale, see Chapter 18.

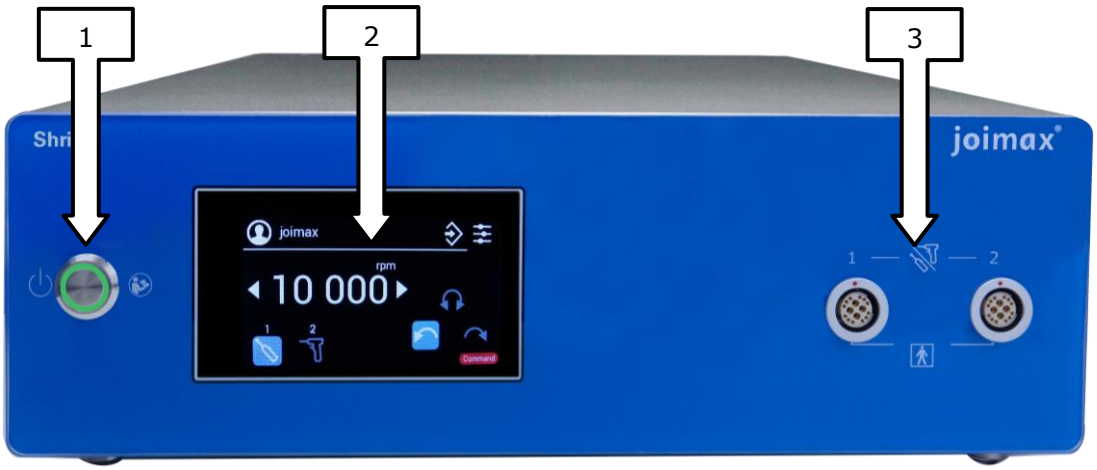
8 Operation

Warning:
Functional and visual inspections must be performed prior to every use.

Warning:
Turn on the device only after checking if it is completely wired.

8.1 Control Elements

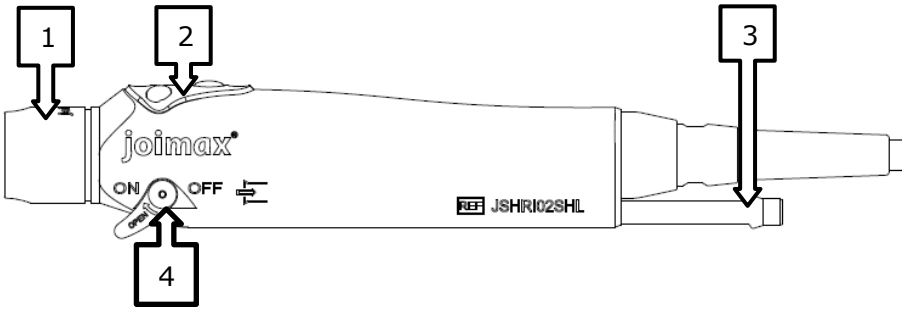
8.1.1 Control Unit



1	"Standby" button	2	Touch display	3	Handpiece connectors

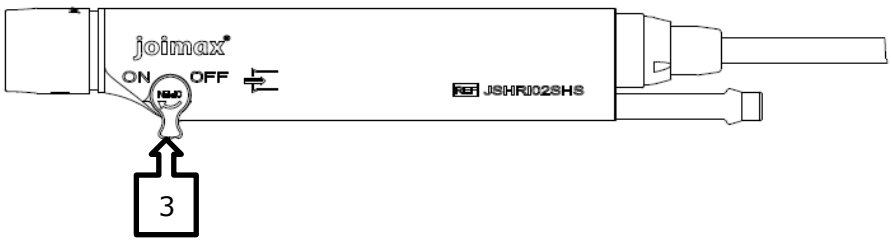
8.1.2 Handpieces

Shaver Handpiece large



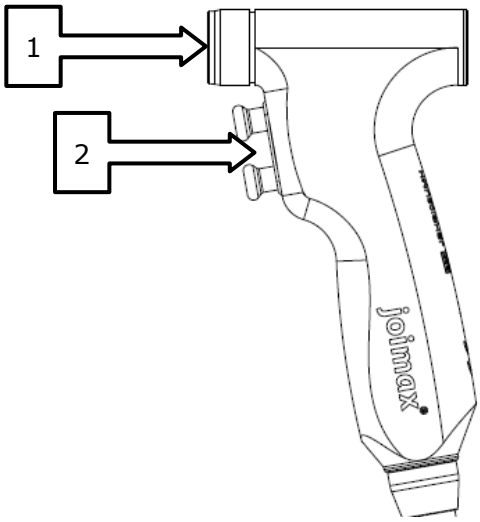
1	Shaver blade coupling	2	Handpiece buttons	3	Flush connection
4	Flush control				

Shaver Handpiece small



1	Shaver blade coupling	2	Flush connection	3	Flush control

Universal Motor Handpiece



1	Handpiece drill attachment coupling	2	Handpiece buttons

8.2 Starting the Device

1) Make sure that the device is wired correctly according to the connection instructions in Chapter 7.
2) Switch the power switch at the back of the device from "O" to "I".
3) Push the "Standby" button at the front panel of the control unit to activate it.
4) Wait for a few seconds until the user interface appears on the touch display.
5) Select the desired user account/memory slot.

8.3 Shutting Down the Device

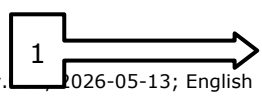
1) The control unit is shut down by pressing the "Standby" button at the device front.

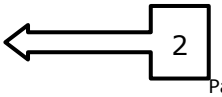
For full disconnection from the power supply, the power switch at the back of the control unit must be switched from "I" to "O".

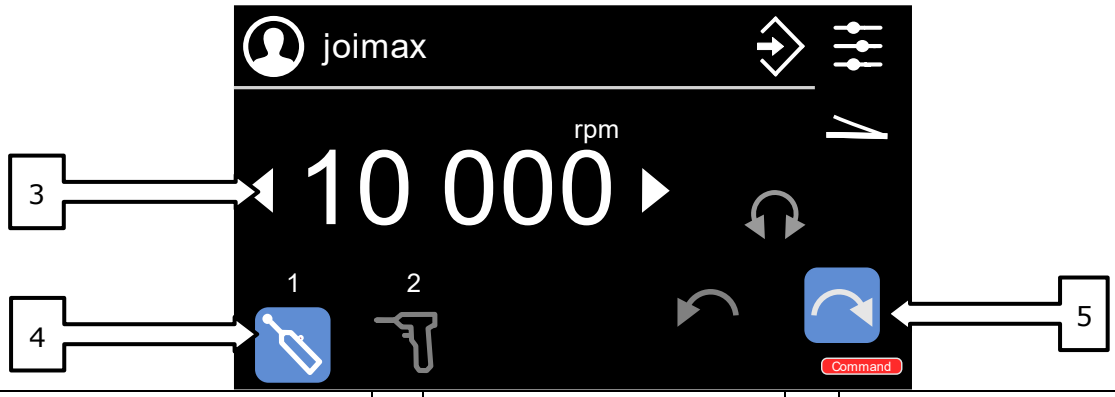
8.4 Operation of the Control Unit

8.4.1 Elements on the Touch Display

The joimax® Shrill® System is operated via the touch display at the front of the control unit by simply tapping on the corresponding icons.



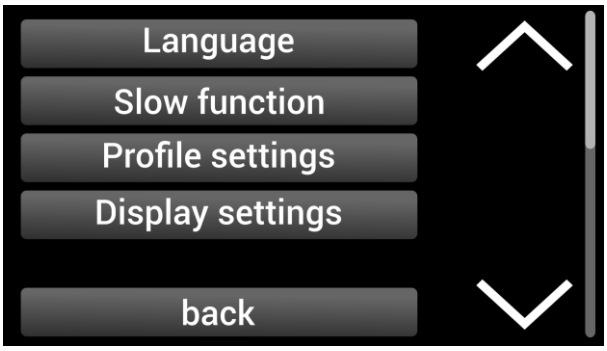




1	**Select memory slot** The name of the currently selected memory slot is displayed	2	**Open system setting menu**	3	**Set rotation speed** The currently set rotation speed is displayed
4	**Select connected handpiece** The active handpiece is highlighted	5	**Set rotation direction/mode** The currently selected rotation direction/mode is highlighted		

8.4.2 System Settings

The system settings menu is activated by pressing the button on the touch display. The different sub-menus can be accessed by pressing the respective touch field. The settings menu can be scrolled via the scroll bar or the arrow buttons on the right.



The following sub-menus are available:

- **Language** — Set display language (German, English, French, Italian, Spanish, Portuguese, Russian)
- **Slow function** — Move the shaver blade very slow for setting a defined motor stop position
- **Profile settings*** — Set default speed for all handpieces for every memory slot and rename user accounts. Press the handpiece icon to change the handpiece.
- **Display settings** — Set brightness, toggle touch sound and calibrate the touch display
- **Service mode** — The service mode is only available for trained service personnel
- **Device information** — Display the current system configuration

- **Advanced profile settings*** — Assign functions to handpiece and foot switch buttons for every memory slot, toggle defined motor stop position (cutting window)
- **Set factory settings** — Load factory settings
- **Acceleration ramp** — Set the starting behavior of the handpiece motor

* Be aware, there are some settings shown for applied parts, which are not available yet (e.g. Shaver Handpiece small and Foot Switch).

8.5 Operation of the Handpieces

8.5.1 General Operation

Warning:
When not in use, the connected handpieces must never be placed on the patient and must always be removed from the patient and be placed in a safe place to avoid danger from unintended activation.

Warning:
If RF surgery is applied, the connected handpieces must be removed from the patient to avoid unintended activation.

All joimax® Shrill® Handpieces are activated in a so-called dead man mode. This means, the handpiece motors run as long as the activation button on the handpiece or the foot switch is pressed and automatically stops when the button is released.

As soon as two handpieces are connected to the control unit, the desired handpiece can be selected by pressing the respective handpiece symbol on the touch display or by briefly activating it.

Shaver Handpieces

1) Make sure that the handpiece is connected correctly according to the connection instructions in Chapter 0.
2) Wait for a few seconds until the respective device symbol is visible on the touch display.
3) If another handpiece is already connected to the device, the newly connected handpiece must be selected by pressing the respective handpiece symbol on the touch display or by briefly activating the handpiece.
4) Attach the desired shaver blade to the handpiece coupling.
5) Set the desired rotation speed and direction/mode via the touch display, the foot switch or the handpiece buttons (pay attention to the note below).
6) The handpiece can be operated via the handpiece buttons or the optional foot switch.

The Shaver Handpiece, large has an automatic instrument detection, which detects the connection of a joimax® Deflector® Shaft and limits the maximum speed to 6000 rpm and sets the rotation direction to clockwise only.

The Shaver Handpiece, small does not provide a changeable rotation direction/mode. It exclusively runs in the clockwise direction.

Universal Motor Handpiece

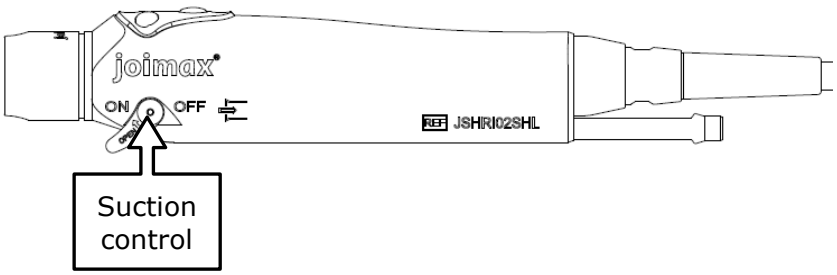
1) Make sure that the handpiece is connected correctly according to the connection instructions in Chapter 0.

2) Wait for a few seconds until the respective device symbol is visible on the touch display.
3) If another handpiece was already connected to the device, the newly connected handpiece must be selected by pressing the respective handpiece symbol on the touch display or by briefly activating the handpiece.
4) Attach the desired drill attachment to the handpiece coupling.
5) Set the desired rotation speed limit via the touch display.
6) The Universal Motor Handpiece can only be operated via the handpiece buttons and the touch display of the control unit. Press the upper button only for clockwise rotation, press both buttons for counter-clockwise rotation. The rotation speed is adjusted up to the set limit, by pressing the upper button with differential pressure.

8.5.2 Suction Function of Shaver Handpieces

A controlled suction of the rinsing fluid enables an improved view during use of the joimax® Shrill® Shaver System since loose tissue particles are immediately extracted. Furthermore, heating of the handpiece is prevented due to cooling by the extracted rinsing fluid through the Shaver Handpieces.

A suction system can be connected to the Shaver Handpieces suction channel.
The suction capacity can be adjusted via the suction control.



Warning:
Setting the suction capacity above the rinsing pressure of the used irrigation pump must be avoided. A negative pressure might lead to collapse of the operation cavity which might cause patient injury.

Before starting the suction system, the suction control must be fully closed and only opened slowly and under clear view. If the operation cavity collapses or the view is impaired by bubbles, the suction capacity must be reduced.

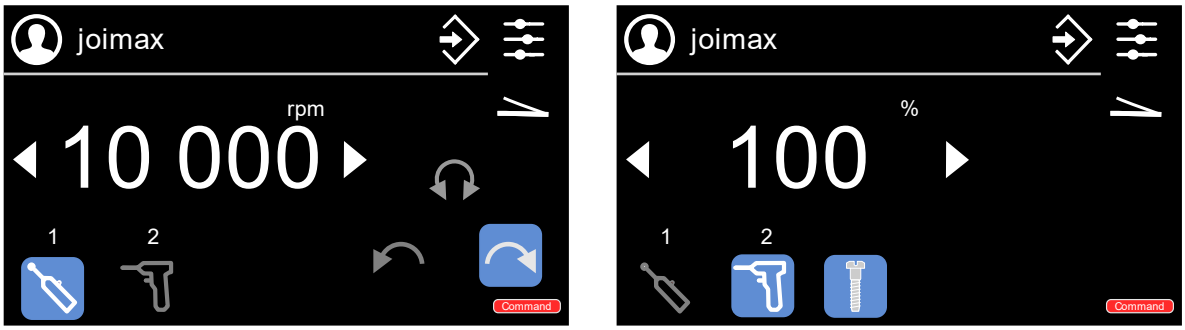
8.5.3 Stopping of Handpieces

When all handpiece and foot switch buttons are released, the handpiece motor stops immediately without overshoot.

An individual motor stop position (e.g. defined window position for soft tissue cutting blades) can be set via the slow function in the system settings. The motor will always stop at that defined position. This function can be switched on and off in the advanced profile settings.

8.5.4 Display Elements shown during Use

When a connected handpiece is activated, the motor starts and the direction of rotation is shown on the touch display.

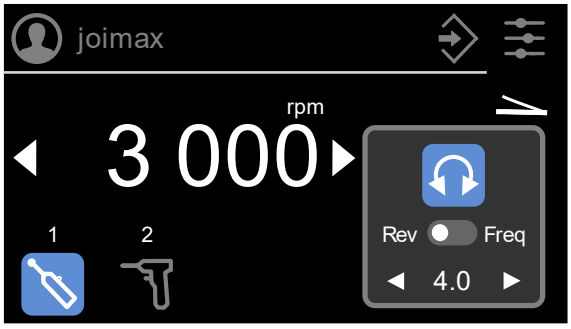


For Shaver Handpieces, the set rotation speed is shown in rpm on the touch display. For the Universal Motor Handpiece, without activation the set speed limit is shown and during activation the current speed is shown in percent.

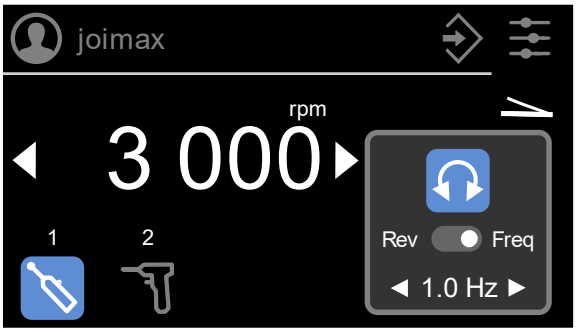
8.5.5 Set Oscillation Mode

A single stroke on the touch element  will put the respective Shaver Handpiece to oscillating mode. A second stroke will enter the oscillation menu.
In the oscillation menu the oscillation type (number of revolutions or frequency) and oscillation speed can be set.

By default, the oscillation is achieved by a certain number of revolutions in each direction. The number of revolutions can be set from 1.5 up to 4.



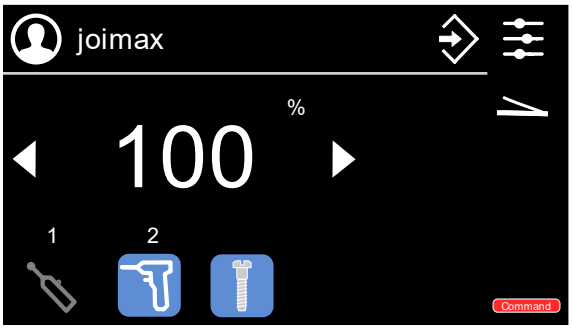
The oscillation type can be changed to frequency in a range from 0.5 Hz to 2 Hz.



8.5.6 Set Threading Mode

When set to threading mode, the Universal Motor Handpiece will turn three revolutions clockwise and one revolution counter-clockwise (when using a drill chuck without gear).

To activate the threading mode, press  while the Universal Motor Handpiece is selected. Press the symbol again to deactivate treading mode.



8.5.7 Show Button Assignment of the Shaver Handpiece Large and Foot Switch

Pressing the active Shaver Handpiece or the Foot Switch icon on the touch display will show the current assignment of the buttons.

The assignment of the buttons can be changed via the system settings menu (Advanced profile settings).

8.5.8 Recommended Operating Cycle

Warning:
The temperature of the handpieces might exceed 48 °C when used in continuous operation. To prevent excessive heating and damage to the handpieces or used attachments, the handpieces and shaver blades must never be used in continuous operation with high load or without load!

Use of the suction function of the Shaver Handpiece may prevent heating of the handpiece, as this achieves a certain cooling effect.

The operating cycle of the control unit and the handpieces should correspond to the usual application time with respective activation duration.

Shaver Handpieces
5 usages per operation, 5 minutes each, with a duty cycle time of 20% and a maximum speed of 60%.

Universal-Motor Handpiece
3 usages per operation, 2 minutes each at a duty cycle of 20% and a maximum speed of 60%.

9 Processing

Warning:
The joimax® Shrill® components must be cleaned and disinfected before first use.

Warning:
The joimax® Shrill® Control Unit and Foot Switch are not suitable for sterilization and must not be sterilized.

Warning:
Before cleaning or disinfection, turn off the device and disconnect it from the power source. Also, disconnect it from all other devices connected to a power source.

Warning:
Check the components and all accessories after processing and prior to each use for damage and for proper operation.

Always respect locally applicable regulations and hygiene procedures of the hospital.

9.1 Cleaning and Disinfection of the Control Unit and Foot Switch

Warning:
Ensure no liquid enters the joimax® Shrill® Control Unit or Foot Switch during cleaning and disinfection.

Warning:
Before cleaning or disinfection, disconnect all components from the Shrill® Control Unit and disconnect the control unit from its power source.

Warning:
In case of severe soiling, the front panel of the control unit can be carefully cleaned with a cotton swab soaked in alcohol. Do not use any sharp objects for cleaning!

For effective wipe disinfection of the joimax® Shrill® Control Unit and Foot Switch, use of Mikrozid® sensitive wipes (Schülke & Mayr) is recommended by joimax® GmbH.

Pay particular attention to the connectors at the front of the control unit and the plugs of the handpieces. Make sure to let them dry thoroughly before connecting any components.

The surfaces of the joimax® Shrill® Control Unit can be cleaned and disinfected with a suitable alcohol-free varnish- and plastic-friendly cleaning and disinfection detergent using the following procedure:

1) Turn off the device.
2) Disconnect all components from the control unit (e.g. handpieces) and disconnect the control unit from the power supply.
3) Wipe the surfaces of the control unit with a clean, soft cloth, moistened with a suitable detergent or disinfectant.
4) Wipe the surfaces again with a sponge or a soft cloth, moistened with clean water.
5) Dry the surfaces with a clean and lint-free cloth.

9.2 Processing of the Handpieces and Drill Attachments

Warning:
Do not process the Universal Motor Handpiece with a drill attachment mounted. Always disconnect the drill attachment from the handpiece and process the drill attachment separately.

Warning:
The joimax® Shrill® Handpieces are not suitable for ultrasonic cleaning.

Warning:
Immediately after use (within a maximum of 1 hour, coarse soiling must be removed from the handpieces and drill attachments by applying the pre-treatment steps according to chapter 9.2.1.

For easy and convenient reprocessing, the joimax® Sterilization Tray for joimax® Shrill® Handpieces (REF: JSHP06020) is recommended.

For cleaning and disinfection, an automated procedure should be used if possible. A manual method should be used only in case of unavailability of an automated method due to the significantly lower efficiency and reproducibility.
The pre-treatment must be carried out in both cases!

9.2.1 Pre-Treatment

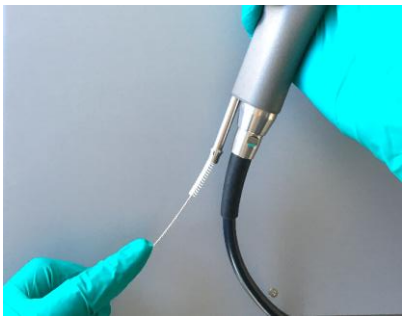
Warning:
To remove soiling manually, use a soft brush or a clean, soft cloth designed exclusively for this purpose. Never use a metal brush, steel wool or any sharp objects for cleaning.

***Warning**:*
Do not use abrasive cleaners, waxes or solvents for cleaning.

1) Disconnect the handpiece from the control unit.
2) Disconnect any drill attachment or shaver blade from the handpiece.
3) Remove coarse soiling from the handpieces and drill attachments by rinsing the components with cold running tap water with the aid of the following cleaning brushes:

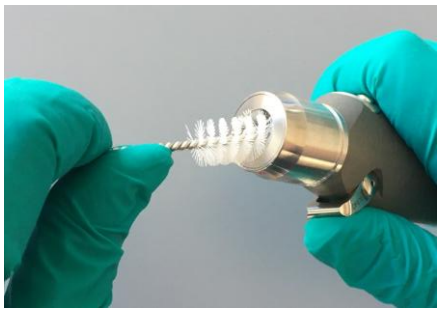
   - SHCB305005 Cleaning brush with loop and rounded tip, L=300mm; for cleaning of the suction channel

     Insert the cleaning brush into the suction channel of the shaver handpiece and push it through to the shaver blade coupling with the suction control fully opened. Repeat 5 times.



- SHCB154013 Cleaning brush with loop and curved tip, L=150mm; for cleaning of the shaver blade coupling front section and the outer surfaces

  Insert the cleaning brush into the shaver blade coupling and clean it with circular movements with the suction control fully opened. Repeat until visually clean.

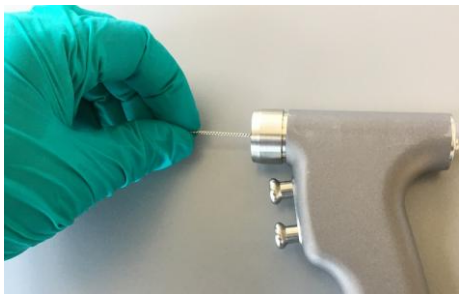


- SHCB152010 Cleaning brush with loop, L=150mm; for cleaning of the shaver blade coupling in the subjacent area

  Insert the cleaning brush into the shaver blade coupling and clean the subjacent area of the coupling with the suction control fully opened. Repeat until visually clean.

- SHCB305005 Cleaning brush with loop and rounded tip, L=300mm; for the continuous, integrated cleaning of the motor handpiece

  Insert the cleaning brush into the drill attachment coupling of the Universal Motor Handpiece and push it through to the other side. Repeat 5 times.



4) Flush the suction channel with cold tap water for 60 seconds with the suction control fully opened and simultaneous multiple closing and opening of the suction control. Since straight-line flushing is not possible, the following cleaning adapters must be used:

   - joimax® Cleaning Adapter for Shaver Handpiece, JSHP06010
   - joimax® Cleaning Adapter for Universal Motor Handpiece, JSDWD150A

9.2.2 Cleaning and Disinfection

9.2.2.1 Automated Cleaning and Disinfection

Warning:
With chemical disinfection, there is a risk of disinfectant residues remaining on the handpieces and drill attachments.

Warning:
Never leave the handpiece wet after reprocessing. This can lead to corrosion and germ growth. If the handpiece is not completely dry after completion of the automated reprocessing, manually re-dry (see point Drying below) and then store the handpiece accordingly.

For effective automated cleaning and disinfection, use of the cleaner Neodisher MediClean forte 0.5% (Chemische Fabrik Dr. Weigert) is recommended by joimax® GmbH.

Automated cleaning is validated with the machine Miele PG8581 (Program: "Vario TD Dental". Step 1: Precleaning with cold tap water for 2 minutes – Step 2: Cleaning with cleaner (Neodisher MediClean forte 0.5% (Chemische Fabrik Dr. Weigert)) at 55°C for 5 minutes with demineralized water – Step 3: Rinsing with demineralized water for 1 minute.

Keep in mind that every cleaning and disinfection process should be validated.

The validated parameters correspond to a process with an A0 value of >3000s. joimax® GmbH recommends to use only processes that are in compliance with this.

When selecting the disinfector, make sure that:

- the disinfector has proven effectiveness (e.g. DGHM or FDA approval or CE marking according to DIN EN ISO 15883)
- if possible, a tested program for thermal disinfection (i. e. at least 5 min at 93° C/199.4° F) is used
- the used program is suitable for the handpieces and drill attachments (see chapter 9.3) and contains sufficient rinsing cycles
- for rinsing only sterile or low-germ (max 10 germs/ml) and endotoxin-poor (maximum 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used
- the air used for drying is filtered
- the disinfector is regularly maintained and checked

When selecting the detergent, make sure that:

- it is suitable for the cleaning of medical products made of metals and plastics (see chapter 9.3)
- if thermal disinfection is not used, in addition, a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA approval or CE marking) is used and that it is compatible with the cleaning agent used

Procedure:

1) Disconnect the handpiece from the control unit.
2) Disconnect any drill attachment or shaver blade from the handpiece.
3) Perform the pre-treatment according to chapter 9.2.1.
4) Place the components in the disinfector (e.g. in the joimax® Sterilization Tray for joimax® Shrill® Handpieces REF: JSHP06020) with the suction control of the handpieces fully opened.
5) Make sure that the components do not touch each other. Loosely insert the cables; they must not be kinked or squashed.

6) Connect the corresponding cleaning adapter to the handpiece coupling and the disinfector rinsing tube via Luer-Lock.
7) Start the program.
8) At the end of the program, remove the components from the disinfector.
9) Ensure that the components are thoroughly dry. After thermo-disinfection, a drying step can be added to the program of the washer/disinfector.
10) Inspect and pack the components immediately after removal in a clean place.

Drying:
The drying process is normally part of the cleaning process of the thermal disinfection device. Please follow the instructions for the used thermal disinfection device.

In case that moisture remains on the handpiece after the automated reprocessing and in case that a manual process is used, further manual drying of the handpiece is necessary.

To avoid any kind of deterioration of the handpiece, make sure that the handpiece is dry inside and outside after each cycle.

If moisture remains on or in the handpiece after the cleaning process, dry it with a lint-free cloth, also checking the suction channel of the handpiece for dryness and drying with medical compressed air if necessary.

9.2.2.2 Manual Cleaning and Disinfection

Warning:
Use appropriate cleaning agents and disinfectants.

For effective manual cleaning and disinfection, use of the cleaner Prolystica® Ultra Concentrate Enzymatic Cleaner (STERIS) 0.2ml/L, holding time 15 minutes and the disinfectant CIDEX® OPA (Johnson & Johnson Medical), ready to use, holding time 12 minutes is recommended by joimax® GmbH.

Combined cleaning/disinfecting agents should not be used!

When selecting the cleaning agents and disinfectants, make sure that:

- they are suitable for the cleaning or disinfection of medical products made of metals and plastics (see chapter 9.3)
- a disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval or CE marking) is used and that it is compatible with the used cleaning agent

Procedure:

1) Disconnect the handpiece from the control unit.
2) Disconnect any drill attachment or Shaver Blade from the handpiece.
3) Perform the pre-treatment according to chapter 9.2.1.
4) Insert the components into the cleaning bath with the suction control of the handpieces fully opened for 15 minutes so that the components are sufficiently covered (if necessary, gently brush with a soft brush). Make sure, the components do not touch each other. Loosely insert the cables; they must not be kinked or squashed.
5) Remove the components from the cleaning bath and rinse them thoroughly with purified water at least 3 times. Also make sure to flush the suction channel.
6) Ensure that the components are thoroughly cleaned and visually clean. Repeat step 3) to 5) if necessary.
7) Check the components for damage.
8) Place the cleaned and controlled components in the disinfectant bath with the suction control of the handpieces fully opened for 12 minutes so that the components are sufficiently covered. Make sure the components do not touch each other. Loosely insert the cables; they must not be kinked or squashed.
9) Remove the components from the disinfection bath and rinse them thoroughly with purified water at least 5 times. Also flush the suction channel.
10) Dry the components with filtered compressed air. Ensure that the components are thoroughly dry.
11) Inspect and pack the components immediately after removal in a clean place.

9.2.3 Inspection

After cleaning and disinfection, check all components for corrosion, damaged surfaces, chipping or any remaining soiling or cleaning and disinfection agents.

9.2.4 Packing

Put the components in disposable packaging that meet the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607-1; 11607-2
- suitable for steam sterilization and plasma sterilization
- adequate protection of the components or sterilization packaging against mechanical damage
- regular maintenance according to the manufacturer's instructions (sterilization container)
- cleared by the FDA

As effective packaging for steam sterilization, use of Stericlin® see-through reel, single wrapped is recommended by joimax®.

As effective packaging for plasma sterilization, use of Tyvec foil 4057B, single wrapped is recommended by joimax®.

9.2.5 Sterilization

Warning:
The joimax® Shrill® Handpieces must be sterilized before first and every use.

Warning:
Uncleaned components must not be sterilized as the effectiveness of the sterilization is only guaranteed after prior cleaning and disinfection. Make sure the components are clean before sterilization!

Warning:
Other sterilization methods and cycles than specified may have negative effects on the sterilization result and the function of the components.

Warning:
Please note that overloading the sterilizer may reduce the sterilization result. Also, in case of overload there is the possibility of undesirable condensation, which increases the formation of corrosion on components. Observe the manufacturer's instructions for maximum loading of the sterilizer.

It is the responsibility of the user to carry out the recommended sterilization procedures with regard to achieving the desired or required sterilization effect.

Applicable national legal regulations must be observed.

It is not recommended to use other sterilization methods (such as flash sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization).

When selecting the sterilizer, make sure that:

- the sterilizer has proven effectiveness (according to EN 13060/EN 285/EN ISO 14937 or ANSI AAMI ST79, for USA: FDA clearance)
- the sterilizer is validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))

The joimax® Shrill® Handpieces and drill attachments can be sterilized using the following methods:

Out of the United States:

STEAM STERILIZATION		
Fractionated Vacuum / Dynamic-air-removal		
Temperature:	134°C (273°F)	135°C (275°F)
Min. exposure time:	3 minutes	3 minutes
Min. drying time:	16 minutes	16 minutes
PLASMA STERILIZATION		
STERRAD® 100NX system Cycle: Duo Comply with STERRAD® Advanced Sterilization Product instructions.		

In the United States:

STEAM STERILIZATION
Fractionated Vacuum / Dynamic-air-removal Temperature: 132°C (270°F) Exposure time: 4 minutes Min. drying time: 20 – 30 minutes

9.2.6 Storage

After sterilization, the components must be stored dry and dust-free in the sterilization packaging.

9.3 Reusability

Warning:
When selecting cleaning agents and disinfectants, make sure they do not contain the followings substances:

- *organic, mineral and oxidizing acids (minimum permissible pH-value 3)*
- *strong alkalis (maximum permissible pH-value 10, neutral/enzymatic, slightly alkaline or alkaline cleaner recommended)*
- *organic solvents (e.g. alcohols, ethers, ketones, gasolines)*
- *oxidizing agents (e.g. hydrogen peroxide)*
- *halogens (chlorine, iodine, bromine)*
- *aromatic/halogenated hydrocarbons*
- *salts of heavy metals*

Warning:
The lifetime of the components is limited, because they are subject to natural wear and aging. Inappropriate handling, e.g. overloading, unsuitable cleaning agents, high temperatures, etc. may reduce the lifetime of the equipment.

A discoloration of the handpieces may occur using certain cleaning agents and disinfectants or sterilization methods. This is solely an optical effect and does not impede the functionality of the handpiece.

The lifetime of the joimax® Shrill® Handpieces is verified for 100 reprocessing cycles. Any further re-use or the use of damaged and/or contaminated instruments is in the responsibility of the user. Improper handling, e.g. by overload, unsuitable detergents, high sterilization temperatures etc. may reduce the lifetime of the handpieces.

The manufacturer recommends a preventive maintenance after 50 reprocessing cycles.

In case of any doubt about product quality we recommend to return the handpiece for inspection or for replacement to joimax®.

An inspection of the components for integrity must be carried out during the reprocessing process after disinfection and prior to sterilization. If a defect is detected, the handpiece must be replaced immediately and must not be used any further. The use of damaged and/or contaminated components is the responsibility of the user.
Failure to comply will exclude any liability of joimax®.

10 Technical Data

joimax® Shrill® Control Unit	
Power supply	100 – 240 V AC
Power consumption	max. 240 VA
Frequency	50 / 60 Hz
Fuse	2 x T2AH250V
Dimensions	11.5 x 37.4 x 43.4 cm / 4.5 x 14.7 x 17.1 ” (L/W/D)
Weight	6.5 kg / 14.3 lb
joimax® Shrill® Handpieces	
Speed ranges	Shaver Handpiece large • Unidirectional: 500 - 10 000 rpm • Deflector Blades: 500 – 6 000 rpm • Oscillation: 500 – 3 000 rpm Shaver Handpiece small • Clockwise: 500 - 6 000 rpm Universal Motor Handpiece • 0 – 1 500 rpm
Dimensions	Shaver Handpiece large 21.0 x 2.6 x 3.9 cm / 8.3 x 1.0 x 1.5 ” (L/W/D) Shaver Handpiece small 18.3 x 2.1 x 3.2 cm / 7.2 x 0.8 x 1.26 ” (L/W/D) Universal Motor Handpiece 18.0 x 2.5 x 8.7 cm / 7.1 x 0,98 x 3.4 ” (L/W/D)
Weight (without cable)	Shaver Handpiece large 0.42 kg / 0.93 lb Shaver Handpiece small 0.22 kg / 0.49 lb Universal Motor Handpiece 0.6 kg / 1.32 lb
Acoustic emission	< 73 dB(A) < 86 dB
General	
Transport and storage conditions	Temperature: -10 °C to +70 °C / +14 °F to 158 °F Relative humidity: 30 % to 75 %, non-condensing Atmospheric pressure: 80 kPa to 110kPa Keep the device dry and protected from sunlight.
Operating conditions	Temperature: +15 °C to +30 °C / 59 °F to 86 °F Relative humidity: 30 % to 75 %, non-condensing Atmospheric pressure: ≥ 79.5 kPa
Ingress protection	IP30
Applied standards	IEC 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, IEC 62304:2015, IEC 62366-1:2016
IEC 60601-1 Safety class	I
IEC 60601-1 Applied part	Type BF
IEC 60601-1-2 Group / Class	I / A
IEC 61000-3-2 Class	A
Risk class	IIa
The system is completely closed for access by the user during intended use. The joimax® Shrill® software is embedded into the control unit and provides network functionality for a closed internal communication network of joimax® electronic devices which has no internet access. The internal network is secured via https connection (machine authentication via certificate handling). No requirements concerning hardware or special IT security measures are necessary to run the software as intended.	

11 EMC Notes

Warning:
The joimax® Shrill® System mandates special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Warning:
The use of the accessories or cables of the Shrill® System with medical electrical equipment and medical electrical systems other than those specified may result in increased emissions or decreased immunity of the medical electrical equipment or medical electrical system.

Warning:
Use of this device adjacent to or stacked with other devices should be avoided because it might result in improper operation. If the device must be used in a stacked configuration or adjacent with other electronic devices, this device and the other devices must be observed to ensure normal operation.

Warning:
This product may emit radio frequency energy and, if not installed and used according to the instructions, may cause harmful interferences to other devices in the vicinity. If this product interferes with other devices, the user is encouraged to try the following in order to correct the interference:

- *Increase the distance between interfering components.*
- *Consult the manufacturer of the other device for help.*

Warning:
Portable RF communications equipment should be used no closer than 30 cm (12”) to any part of the joimax® Shrill® System. Otherwise, the performance of this equipment might be impaired.

Warning:
Avoid magnetic field sources in close proximity (< 15 cm / 6”) to the device.

This equipment has been tested and found to comply with the requirements regarding electromagnetic compatibility (EMC) according to IEC 60601-1-2:2014 (Ed.4). The customer or user of the joimax® Shrill® System has to ensure that it is operated in such environments.

The joimax® Shrill® System is suitable to be used in close proximity of RF surgical equipment (both the enclosure and the cables). The device was tested according to IEC 60601-2-2, BB.4 and can withstand the emissions produced by such equipment. No specific conditions of intended use are required during RF surgery.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 group 1, class A). If it is used in a residential environment, (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The joimax® Shrill® System is suitable for use in professional healthcare facility environments according to IEC 60601-1-2:2014 (Ed.4).

Phenomenon	Compliance	Electromagnetic environment – guidance
Conducted and radiated RF emissions	Group 1	The joimax® Shrill® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The joimax® Shrill System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion	Not applicable	
Voltage fluctuations and flickers	Not applicable	

Enclosure Port				
Phenomenon	**Basic EMC standard or test method**	**Immunity test Levels**	**Compliance levels**	**Electromagnetic environment – guidance**
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be made from wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the joimax® Shrill® including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communication equipment	IEC 61000-4-3	See table "Enclosure port immunity to RF wireless communication equipment" below		Minimum distances between the joimax® Shrill® and wireless communication equipment as specified in table "Enclosure port immunity to RF wireless communication equipment" must not be undercut.
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz	30 A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Input AC power port				
Phenomenon	**Basic EMC standard or test method**	**Immunity Test Levels**	**Compliance Levels**	**Electromagnetic environment – guidance**
Electrical fast transients/ bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV	±0.5 kV, ±1 kV	
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2kV	±0.5 kV, ±1 kV, ±2kV	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the joimax® Shrill®, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d= 1.2 √P d= 1.2 √P 80 MHz to 800 MHz d= 2.3 √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Voltage dips	IEC 61000-4-11	0 % UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT ; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the joimax® Shrill® requires continued operation during power mains interruptions, it is recommended that the joimax® Shrill® be powered from an uninterruptible power supply or a battery.
		0 % UT; 1 cycle At 0°	0 % UT; 1 cycle At 0°	
		70 % UT; 25 / 30 cycles At 0°	70 % UT; 25 / 30 cycles At 0°	
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycles	0 % UT; 250/300 cycles	

Signal input/output parts port				
Phenomenon	**Basic EMC standard or test method**	**Immunity Test Levels**	**Compliance Levels**	**Electromagnetic environment – guidance**
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be made from wood, concrete or ceramic tiled. If floors are covered with synthetic material, relative humidity should be at least 30 %.
Electrical fast transients/ bursts	IEC 61000-4-4	±1 kV 100 kHz repetition frequency	±1 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-ground	IEC 61000-4-5	n/a	n/a	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the joimax® Shrill® including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

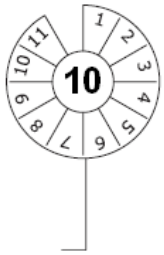
Enclosure port immunity to RF wireless communication equipment							
Test Frequency (MHz)	**Band**	**Service**	**Modulation**	**Max. Power** (W)	**Distance** (m)	**Immunity Test Level** (V/m)	**Compliance Level** (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
870							
930							
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

12 Service / Maintenance

Warning:
Do not use the device during service activities.

joimax® GmbH recommends performing a function and safety inspection at regular intervals according to EN 62353 or to other corresponding country-specific regulation.

The joimax® Shrill® System is low maintenance. Regardless of the device being low maintenance, regular service can contribute to early recognition of defects and faults and, thus, extend the operating life of the devices.



Next inspection

An operating life of 8 years is specified for the joimax® Shrill® Control Unit. Any use beyond this depends on the results of the safety inspections. The operating life of the Shrill® handpieces is verified for 100 autoclave cycles at 132°C (270°F) for 3 minutes. Any use beyond this depends on the results of the safety inspections.

joimax® GmbH recommends this inspection to be performed at least once a year.
This inspection should be documented with a test-label on the device.

12.1 Replacing the Fuse

Warning:
Always observe the specifications on the device label and follow the instructions below when replacing the fuse. Non-observance may result in malfunction of the device and possible injury.

Warning:
Always disconnect the device from the power supply when performing service activities.

1) Turn off the control unit via the power switch at the backside and disconnect it from the power supply.
2) Open the fuse holder.
3) Check the type of replacement fuse on the device label and replace the defective fuses.
4) Plug the power cord into the control unit.
5) Turn on the control unit via the power switch at the backside, press the button “Standby” at the device front and check the function of the device.

13 Troubleshooting

Problem	Possible cause	Possible solution
AWG voltage missing	Electronic error in the device	1. Disconnect handpieces until the error disappears 2. Remove the defective handpiece 3. If the error is still displayed, contact joimax® customer service
Motor controller error	Error in the motor controller	1. Restart the control unit 2. If the error is still displayed, contact joimax® customer service
Unknown device Socket: 1 / 2	Connected handpiece not compatible or defective	1. Disconnect handpieces until the error disappears 2. Remove the defective handpiece or foot switch 3. If the error is still displayed, contact joimax® customer service
Start button pressed Socket: 1 / 2	A handpiece button is pressed or defective	1. Release all handpiece buttons and wait for 3 seconds 2. If the error is still displayed, disconnect handpieces until the error disappears 3. Remove the defective handpiece 4. If the error is still displayed, restart the control unit 5. If the error is still displayed, contact joimax® customer service
Button left pressed Socket: 2	Left handpiece button is pressed or defective	
Button right pressed Socket: 2	Right handpiece button is pressed or defective	
Button left pressed Socket: 1	Left handpiece button is pressed or defective	
Button right pressed Socket: 1	Right handpiece button is pressed or defective	
Button left pressed Socket: Foot Switch	Left foot switch button is pressed or defective	1. Release all foot switch buttons and wait for 3 seconds 2. If the error is still displayed, disconnect the foot switch until the error disappears 3. Remove the defective foot switch 4. If the error is still displayed, restart the control unit 5. If the error is still displayed, contact joimax® customer service
Button right pressed Socket: Foot Switch	Right foot switch button is pressed or defective	
Button left pressed Socket: 1 / 2 Socket: Foot Switch	These error messages occur, if a button of a connected foot switch is pressed without a handpiece connected	
Button right pressed Socket: 1 / 2 Socket: Foot Switch		
Software incompatible	Software versions of mainboard, touch display and motor controller are not compatible	Contact joimax® customer service
Communication error motor controller / mainboard	Communication error in-between software modules	1. Restart the control unit 2. If the error is still displayed, contact joimax® customer service
Ext. flash is empty	No language data found in the display memory	1. Update language files 2. If the error is still displayed, contact joimax® customer service

Problem	Possible cause	Possible solution
Ext. flash data and software incompatible	Language data in the display memory not compatible with system software version	Contact joimax® customer service
 shown on the touch display	<u>Without error message</u> The used combination of handpieces / foot switch and control unit is incompatible <u>With error message "Unknown device"</u> Handpiece / foot switch not compatible with Shaver System or defective	<u>Without error message</u> 1. Disconnect handpieces and foot switch until the error disappears <u>With error message "Unknown device"</u> 1. Disconnect handpieces and foot switch until the error disappears 2. Remove the defective handpiece or foot switch 3. If the error is still displayed, contact joimax® customer service
Motor controller overheated	Motor controller is overheated	1. Do not activate any handpiece or foot switch 2. Let the motor controller cool down until the error disappears 3. Reduce handpiece load during further use 4. If the error is still displayed, restart the control unit 5. If the error is still displayed, contact joimax® customer service
Motor controller overcurrent / undervoltage	Motor control detects an electrical error	1. Do not activate any handpiece or foot switch until the error disappears 2. Reduce handpiece load during further use 3. If the error is still displayed, restart the control unit 4. If the error is still displayed, contact joimax® customer service
Motor controller hall position	Invalid handpiece motor position detected	1. Do not activate any handpiece or foot switch until the error disappears 2. Activate the handpiece 3. If the error is still displayed, restart the control unit 4. If the error is still displayed, contact joimax® customer service
Others	Others	Contact joimax® customer service

14 Warranty

Warning:
Do not open any component of the joimax® Shrill® System. Unauthorized opening, repair or modification of the devices releases joimax® GmbH from any liability for the operating safety of the devices and results in any claims becoming void even during the warranty period.

Warning:
In case of return of the devices or accessories, the original packaging material must always be used!

Warning:
To protect your staff and the joimax® GmbH employees, please clean and disinfect the device and its accessories before returning it.
Should this be impossible due to temporal constraints, please reprocess the components as much as possible and label it accordingly.

The warranty period for the joimax® Shrill® System depends on the legal regulations of the specific country. Failure due to faulty material and/or poor processing must be rectified by the manufacturer free of charge within this period.
Transport costs and shipment risks are excluded hereof.
In addition, the details in our general terms and conditions apply.

To facilitate quick processing of service requests, we ask you to send the product with the following information:

- Model/Item number (REF)
- Serial number (SN)
- A description of the error as accurate as possible
- Invoice of the device if available
- Contact person for questions

15 Accessories

Warning:
Only the accessories by joimax® GmbH listed below are to be used with the joimax® Shrill® System! Use of accessories other than those specified or provided by joimax® GmbH may result in improper operation.

Optional Handpieces

Item number	Description
JSHRI02SHS	joimax® Shrill® Shaver Handpiece small *UPCOMING*
JSHRI02UMH	joimax® Shrill® Universal Motor Handpiece

Accessories

Item number	Description
JSHRI02FS	joimax® Shrill® Foot Switch
JSDCKL032	joimax® Drill chuck, keyless
JSDCAO100	joimax® Drill chuck, keyless, AO
JSWDA0618	joimax® Wire Driver Adapter
JSHP06020	Sterilization Tray for Shrill® Handpiece, with lid
JSDWD150A	joimax® Cleaning Adapter for Universal Motor Handpiece
JSHP06010	joimax® Cleaning Adapter for Shaver Handpiece
SHCB305005	Shrill® Handpiece Cleaning Brush 300x50x5mm
SHCB154013	Shrill® Handpiece Cleaning Brush 150x40x13mm
SHCB152010	Shrill® Handpiece Cleaning Brush 150x20x10mm
SHCS305005	Shaver Handpiece Cleaning Set **List of components:**

Item number	Description	Quantity
SHCB305005	Shrill® Handpiece Cleaning Brush 300x50x5	1
SHCB154013	Shrill® Handpiece Cleaning Brush 150x40x13mm	1
SHCB152010	Shrill® Handpiece Cleaning Brush 150x20x10mm	1

16 Compatibility

Warning:
The joimax® Shrill® System must not be used with other medical devices than those explicitly declared compatible by joimax® GmbH in this chapter!
Use of instruments other than those specified or provided by joimax® GmbH may result in improper operation and harm to the patient.

16.1.1 Compatible Shaver Blades

A complete list of compatible joimax® Shrill® Shaver Blades with detailed information can be found in the corresponding product overview joimax® Shrill® Shaver Blades and the product catalog.

For more information about compatible products, directly contact the joimax® customer service or your joimax® representative.

16.1.2 Compatible Drill Attachments

The following joimax® attachments can be used with the joimax® Shrill® Universal Motor Handpiece:

Item Number	Description
JSDCKL032	joimax® Drill chuck, keyless
JSDCAO100	joimax® Drill chuck, keyless, AO
JSWDA0618	joimax® Wire Driver Adapter

17 Disposal of the Device

Warning:
This symbol indicates that medical devices must be disposed of separately from household waste. Dispose of electrical waste in accordance with the applicable national and local regulations.

Warning:
This symbol must be affixed to the waste container or the device when discarding it.

Dispose of packing material, unless it is contaminated, in accordance with national and local regulations.

According to the implementation of European law into national laws and regulations, you are obliged to properly dispose of medical devices.

Discard used and contaminated medical devices at a collection point of an appropriate disposal carrier. "Medical waste" is classified according to dangerous goods law (for transportation) by UN number UN 3291.

18 Incidents Reporting

Any serious incident that has occurred in relation to the device should be reported to joimax® GmbH and the competent authority having jurisdiction in your locale.

Please notify us at the following telephone number:

For the US	**+1 949-859-3472**	**(24-hour availability)**
For all other countries	**+49 (0)721 25514 – 999**	**(24-hour availability)**

Thank you for your support!

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