

# Instructions for use



## Battery system for small bone surgery

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## Table of contents

<b>1 Introduction and product description</b> .....	<b>4</b>
<b>1.1 General information</b> .....	<b>4</b>
<b>1.2 Intended use</b> .....	<b>4</b>
1.2.1 Handpieces, rechargeable battery (power pack) and attachments.....	4
1.2.2 Cleaning and care accessories.....	4
<b>1.3 Indications</b> .....	<b>4</b>
1.3.1 Handpieces, rechargeable battery (power pack) and attachments.....	4
1.3.2 Cleaning and care accessories.....	4
<b>1.4 Contraindications</b> .....	<b>5</b>
1.4.1 Handpiece, rechargeable battery (power pack) and attachments.....	5
1.4.2 Cleaning and care accessories.....	5
<b>1.5 Application</b> .....	<b>5</b>
1.5.1 Duration of application.....	5
1.5.2 Patient population.....	5
1.5.3 User and field of application.....	5
1.5.4 Lifespan.....	5
<b>1.6 Safety instructions and warnings</b> .....	<b>6</b>
1.6.1 General safety instructions.....	6
1.6.2 Cleaning and care.....	6
1.6.3 Combination products and tools.....	6
1.6.4 User / Application.....	6
1.6.5 Users and/or patients.....	7
1.6.6 Operation and battery operation.....	7
<b>1.7 Combination products and accessories</b> .....	<b>7</b>
1.7.1 Accessories to be used/Scope of delivery.....	7
1.7.2 Combinability of diMAGNI-S system with diMAGNI5 system components.....	8
1.7.3 Combinability of the individual diMAGNI-S system components.....	9
1.7.4 Storage and transportation.....	9
1.7.5 Waste disposal.....	9
1.7.6 Warranty.....	9
<b>2 Operation of the device</b> .....	<b>10</b>
<b>2.1 Description of the operating elements, information functions and symbols</b> .....	<b>10</b>
2.1.1 Universal handpiece (33.302.01).....	10
2.1.2 Powerpack (33.302.10).....	10
2.1.3 Charging cable with mains adapter (33.302.11).....	11
<b>2.2 Commissioning</b> .....	<b>11</b>
2.2.1 Insert Powerpack.....	11
2.2.2 Remove Powerpack.....	13
<b>2.3 Battery capacity</b> .....	<b>13</b>
2.3.1 Available battery capacity.....	13
2.3.2 Overheating protection of the Powerpack.....	14
2.3.3 Energy saving function.....	14
<b>2.4 Charging, shipping and storing the Powerpack</b> .....	<b>15</b>
<b>2.5 LED indicator light</b> .....	<b>16</b>
2.5.1 LED display Powerpack during operation.....	16
2.5.2 LED display Powerpack during charging process.....	16
2.5.3 Power supply indicator light during charging.....	16
<b>2.6 Charger</b> .....	<b>17</b>
2.6.1 Putting the charging cable into operation.....	17
2.6.2 Cleaning the charging cable with mains adapter.....	17
2.6.3 Charging the power pack.....	17
2.6.4 Charging a new or unused Powerpack.....	17
2.6.5 Storing the Powerpack.....	18
2.6.6 Display on the Powerpack after removing the charging cable.....	18
2.6.7 Disconnect the charging cable from the mains supply.....	18
<b>2.7 General use of the various attachments</b> .....	<b>18</b>
2.7.1 Commissioning.....	18
2.7.2 Switching oscillation mode on and off.....	18
2.7.3 Mounting/dismounting the attachments.....	19

2.7.4	Fitting attachments.....	19
2.7.5	Inserting and removing cutting tools from attachments .....	19
2.7.6	Remove attachments .....	20
<b>2.8</b>	<b>Application of rotating attachments.....</b>	<b>20</b>
2.8.1	Drill attachment with key (33.302.40, 33.302.41, 33.302.42).....	20
2.8.2	Drill attachment keyless (33.302.43, 33.302.44).....	21
2.8.3	AO connection small (33.302.30).....	21
<b>2.9</b>	<b>Application Cribbed wire chuck (33.302.20).....</b>	<b>22</b>
2.9.1	Insert and position the cribbing wire chuck attachment .....	22
2.9.2	Insert the cribbing wire into the attachment .....	22
2.9.3	Inserting the cribwire into the bone .....	23
2.9.4	Remove the cribwire from the bone .....	23
2.9.5	Extension sleeve for cribbing wires (33.301.29).....	23
<b>2.10</b>	<b>Use of the oscillating saw attachment 33.302.50.....</b>	<b>24</b>
2.10.1	Inserting and positioning the saw attachment .....	24
2.10.2	Replacing saw blades .....	24
2.10.3	Working with the oscillating saw attachment.....	25
2.10.4	Instructions for handling saw blades .....	25
<b>2.11</b>	<b>Using the jigsaw attachment (33.302.51).....</b>	<b>25</b>
2.11.1	Inserting and positioning the saw attachment .....	25
2.11.2	Replacing saw blades .....	25
2.11.3	Working with the jigsaw attachment .....	26
2.11.4	Instructions for handling saw blades .....	26
<b>3</b>	<b>Care and maintenance (according to a validated cleaning and sterilization procedure).....</b>	<b>27</b>
<b>3.1</b>	<b>General information.....</b>	<b>27</b>
3.1.1	Unusual transmissible pathogens .....	27
<b>3.2</b>	<b>Preparation for cleaning.....</b>	<b>28</b>
3.2.1	Dismantling .....	28
<b>3.3</b>	<b>Machine cleaning after manual pre-cleaning.....</b>	<b>28</b>
3.3.1	Manual pre-cleaning of the handpiece .....	28
3.3.2	Manual pre-cleaning of the attachments .....	29
3.3.3	Machine cleaning .....	30
<b>3.4</b>	<b>Lubrication/ Maintenance.....</b>	<b>31</b>
3.4.1	Handpiece .....	31
3.4.2	Essays.....	31
<b>3.5</b>	<b>Packaging for sterilization process.....</b>	<b>32</b>
<b>3.6</b>	<b>Steam sterilization.....</b>	<b>32</b>
<b>3.7</b>	<b>Repair and technical service.....</b>	<b>33</b>
<b>4</b>	<b>Troubleshooting.....</b>	<b>34</b>
4.1	Device/handpiece and cover.....	34
4.2	Powerpack.....	36
4.3	Attachments and tools.....	37
4.4	Charging cable with mains adapter.....	38
<b>5</b>	<b>Technical data.....</b>	<b>39</b>
5.1	Operating cycle.....	39
5.2	Device specification.....	40
5.3	Ambient conditions.....	41
5.4	Applicable standards .....	41
5.5	Electromagnetic compatibility.....	42
<b>6</b>	<b>Order information .....</b>	<b>46</b>
6.1	Handpieces .....	46
6.2	Powerpack (battery, motor, electronics) with accessories.....	46
6.3	Essays.....	46
6.4	Cleaning and care of the diMAGNI-S system .....	47
6.5	Accessories .....	47
<b>7</b>	<b>Symbols used.....</b>	<b>48</b>
<b>8</b>	<b>Address / Message.....</b>	<b>49</b>
<b>9</b>	<b>System components .....</b>	<b>50</b>

# 1 Introduction and product description

## 1.1 General information



Reference to existing instructions for use, as these contain useful information.



Follow the instructions for use: Read these instructions for use carefully before each use and keep them easily accessible for the user or the relevant specialist personnel.



Read the cautions and warnings marked with this symbol carefully. Improper use of the products can lead to undesirable consequences and serious injury to the patient, the user or third parties.

This is an instruction manual for a battery-operated handpiece with various attachments including accessories. These can be purchased as a system or as separate units.

## 1.2 Intended use

### 1.2.1 Handpieces, rechargeable battery (power pack) and attachments

The battery-powered system is intended for the processing of bone or hard tissue in a surgical procedure by a professional surgeon. The battery-powered system is designed for drilling, milling, screwing, sawing and cutting bone as well as inserting wires and pins.

### 1.2.2 Cleaning and care accessories

The cleaning and care accessories are used to clean and reprocess the battery-powered system during transportation and storage through to surgical use.

## 1.3 Indications

### 1.3.1 Handpieces, rechargeable battery (power pack) and attachments

The diMAGNI-S system is a hand-held, battery-powered surgical machine for treatment in minor bone surgery for the preparation of bone or hard tissue in hand and foot surgery including shoulder. The system consists of a battery-powered drive unit with a range of attachments and accessories for drilling and screwing, for placing pins and wires and for cutting bone, bone material or hard tissue in small bone surgery and sports medicine.

### 1.3.2 Cleaning and care accessories

The cleaning and care accessories are used to clean and reprocess the battery-powered system during transportation and storage through to surgical use. The maintenance kit is also used to store and repair the relevant components. A sterile funnel is used as an accessory outside the immediate operating area to transfer the non-sterile power pack into the sterile handpiece housing.

Date 14.05.2024	<b>1001-2</b>	Revision 01	Page 4 of 50
--------------------	---------------	----------------	-----------------

## 1.4 Contraindications

### 1.4.1 Handpiece, rechargeable battery (power pack) and attachments

The contraindications diabetes and osteoporosis must be observed when using the drive units and accessories with regard to reduced bone stability.

The system should not be used in an area that has already been treated (e.g. scarred tissue) so as not to negatively influence the healing process.

When using cutting, drilling and reaming tools on patients with Creutzfeldt-Jakob disease (CJD), who are considered high-risk patients due to the associated risk of infection, the procedures must always be performed with disposable instruments.

Any applications of the system that are not listed under the above-mentioned intended use are neither designed nor tested and are therefore prohibited.

### 1.4.2 Cleaning and care accessories

The cleaning accessories may only be used for their intended purpose in medical specialties by appropriately trained and qualified personnel. The attending physician or the relevant specialist personnel are responsible for the selection of the cleaning accessories, for the specific applications, the appropriate training and the correct handling.

## 1.5 Application

### 1.5.1 Duration of application

The products are intended for short-term use (<60 min).

### 1.5.2 Patient population

Apart from the contraindicated applications listed above in 1.4, there are no restrictions regarding the patient population.

### 1.5.3 User and field of application

The diMAGNI-S system (including cleaning and care accessories) may only be used by appropriately trained and qualified personnel. The products are intended exclusively for medical use and must therefore be used in a suitable surgical environment. It is mandatory that the user and the relevant specialist personnel familiarize themselves with the instruments before using them.

### 1.5.4 Service life

Dimeda Instrumente GmbH recommends annual inspection and maintenance by authorized service centres (e.g. Dimeda Instrumente GmbH). Dimeda Instrumente GmbH accepts no responsibility for damage caused by improper operation or unauthorized maintenance. With proper handling and prescribed maintenance, the device has a service life of at least 3 years. (excluding wearing parts).

However, as the products are subject to normal wear and tear, they must be inspected and maintained regularly. Corresponding instructions are specified in the individual sections of these instructions for use.



The date of manufacture can be taken from the manufacturing date number.

## 1.6 Safety instructions and warnings

The general safety instructions and warnings are listed below. These are individually supplemented and specified in individual sections of these instructions for use.

### 1.6.1 General safety instructions

- A replacement system must always be kept ready, as technical problems can never be completely ruled out. The same applies to lengthy and protracted operations.
- Components with visible damage (e.g. after being dropped) must not be used.
- The system must not be operated in the presence of oxygen, nitrous oxide or flammable mixtures of volatile anesthetics and air.
- With regard to electromagnetic compatibility (EMC), the corresponding chapter in the instructions for use must be observed.
- The device contains Li-ion batteries. Special handling and disposal must be observed (see instructions for use).

### 1.6.2 Cleaning and care

- Handpieces, attachments and accessories must have undergone the complete reprocessing procedure before the first and all subsequent uses.
- The protective covers and films must be completely removed before sterilization.
- To ensure proper operation of the system, Dimeda Instrumente GmbH recommends cleaning and maintaining the system after each use in accordance with the instructions in the chapter "Care and maintenance".
- Moving parts must be kept lubricated with a special oil; the Hi-Tech Oil Pen (33.302.94) suitable for sterilization is recommended.
- To ensure correct operation of the system, Dimeda Instrumente GmbH prescribes annual maintenance and inspection by a Dimeda Instrumente service center.
- The power pack and charger must never be reprocessed (manual or mechanical cleaning) or sterilized.
- It is essential to sterilize the sterile funnel after each use to ensure sterility when inserting the non-sterile power pack into the sterile handpiece.

### 1.6.3 Combination products and tools

- New cutting tools must be used for each surgical procedure.
- To protect against heat necrosis, always rinse cutting tools with coolant.
- To ensure correct operation of the system, only original accessories from Dimeda Instrumente GmbH or the tools suggested by Dimeda Instrumente GmbH may be used (this also applies to the battery charging accessories to be used).


### 1.6.4 User / Application

- The user is responsible for the proper intraoperative handling and use of this product.
- If the system is used in conjunction with an implant system, the corresponding "Surgical technique" must be observed.
- The manufacturer accepts no responsibility for damage resulting from improper operation of the system or maintenance by unauthorized persons.
- The machines heat up under continuous load. To prevent the permissible surface temperature of the appliance from being exceeded, the corresponding cooling phases must be observed. A description of this can be found in the operating instructions.

### 1.6.5 Users and/or patients

- Notice to the user and/or patient: Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

### 1.6.6 Operation and battery operation

- To prevent injuries, the locking mechanism must be activated before putting the device down, i.e. the slider must be set to the LOCK position  . In addition, the diMAGNI- S system should be placed in a lateral position to prevent it from tipping over and falling.
- The device may only ever be put into operation with a fully charged power pack. Ensure that the power pack is charged in good time. We recommend plugging the power pack back into the charging cable immediately after completing an operation.
- To ensure sterility, the power pack may only be changed during the operation in accordance with the instructions described in the instructions for use.

## 1.7 Combination products and accessories

### 1.7.1 Accessories to be used/scope of delivery

The system consists of a universal handpiece with various attachments belonging to the system (drill attachment, saw attachment and wire chuck attachment), one or more power packs (battery, motor and electronics) and other accessories.

The corresponding Dimeda instruments charging cable with mains adapter (33.302.11) must be used to charge the Powerpacks.

For the system to function properly, the cutting tool manufacturers specified by Dimeda Instrumente GmbH must be used, otherwise Dimeda Instrumente GmbH cannot guarantee that it will function properly.

Special tools such as cleaning brushes and a Hi-Tech oil pen (33.302.94) are available for cleaning and maintaining the system. No oils from other manufacturers may be used, otherwise Dimeda Instrumente GmbH cannot guarantee proper function.

For sterilization and storage, use the Dimeda Instruments tray suitable for the system (e.g. 33.302.90), otherwise Dimeda Instrumente GmbH cannot guarantee proper function.

The following components are (at least) essential for operation:

The power pack must be inserted into the handpiece and an attachment selected and coupled. The power pack is charged outside the machine using a charging cable.

Handpiece (33.302.01)

Powerpack (33.302.10)

Sterile funnel (33.302.52)

Charging cable with mains

adapter (33.302.11)

At least one attachment belonging to the system: e.g. Jacobs small drilling attachment (33.302.40)

**REF**

An overview of the components belonging to the system can be found at the end of these instructions for use. See chapter 6.

Date 14.05.2024	<b>1001-2</b>	Revision 01	Page 7 of 50
--------------------	---------------	----------------	-----------------

### 1.7.2 Combinability of diMAGNI-S system with diMAGNI5 system components




Accessories	Name	33.302.01 Universal handpiece	33.302.11 Charging cable with mains adapter	33.302.90 Strainer basket with lid for 1 machine
33.301.15	Mains cable (EU standard)		X	
33.301.16	Mains cable (UK standard)		X	
33.301.17	Mains cable (US standard)		X	
33.301.18	Mains cable (AU standard)		X	
33.302.94	Hi-Tech Oil Pen	X		
33.301.60	Universal flushing adapter	X		
33.301.80	Flushing set			X
33.301.81	Rinse adapter washing machine Miele/ Steelco/ Webeco			X
33.301.82	Rinsing adapter washing machine Belimed			X
33.301.83	Rinse adapter washing machine Maquet/ MediKomp/ Getinge			X
28.316.00	Cleaning brush set	X		

### 1.7.3 Combinability of the individual diMAGNI-S system components

Third-party products (Recommendations of Dimeda Instrumente GmbH; not included in the product list)	Drilling attachment AO connection	Drilling attachment Jacobs small	Drilling attachment Jacobs large	Drilling attache nt Röhm	Drill attachment Quick-action chuck with locking	Drill attachment Quick-action chuck without locking	Oscillating saw attachment	Jigsaw attachment	Cribbed wire chuck
	33.302.30	33.302.40	33.302.41	33.302.42	33.302.43	33.302.44	33.302.50	33.302.51	33.302.20
Twist drill		X	X	X	X	X			
AO twist drill (small)	X								
Saw blades for oscillating Saw connection							X		
Saw blades for jigsaw connection								X	
Cribbing wire from 0.5 to 1.8 mm									X
Cribbing wire from 1.8 to 4.0 mm									X

Further information on suitable tools can be found in the product catalog.

We recommend the saw blades of the following manufacturers with the dimensions and connections specified therein.

	RISA GmbH
<b>Stryker® "Sabo Sagittal Saw" connection for oscillating saw attachment</b> 	Teeth set: 11.5 - 45 mm length, 5.5 - 20.0 mm width, 0.4 - 0.7 mm thickness
<b>MicroAire® "Smart Driver™" Connection for jigsaw</b> 	Teeth set 25.4 - 40.1 mm length, 0.4 - 0.5 mm thickness
<b>Linvatec Hall® "Micro Power™" Connection for jigsaw</b> 	Teeth set 25.4 - 37.5 mm length, 0.4 mm thickness

When using a saw blade from another manufacturer, the user must check that the dimensions and connections are compatible. If one of the two characteristics is not fulfilled, the saw blade must not be used.

#### 1.7.4 Storage and transportation

All diMAGNI-S-System products marketed by Dimeda Instrumente GmbH are supplied non-sterile and must be reprocessed before use (except for the power pack and loading unit). Dimeda Instrumente GmbH stipulates that the corresponding drilling and cutting tools are to be used only once.

For product safety reasons, only the original packaging may be used for shipping and transportation. If these are no longer available, please contact Dimeda Instrumente GmbH.

The environmental conditions for storage and transportation are listed in these instructions for use. The devices/handpieces and attachments must have undergone the complete clinical reprocessing process to protect them from infection before disposal or return transportation to Dimeda Instrumente GmbH.

In addition, the products must be labeled accordingly "*hygienically safe*" or "*not decontaminated*". For this purpose, a form can be requested from Dimeda Instrumente GmbH or downloaded from the website, which must be completed.

#### 1.7.5 Waste disposal

Defective devices can usually be repaired, see instructions for use. The devices contain lithium-ion batteries (Li-Ion = chemical symbol of the pollutant) and must be disposed of properly for environmental reasons. Disposal in accordance with national laws and the European Battery Directive 2006/66/EC and Waste Electrical and Electronic Equipment 2012/19/EU.

Special care must be taken with regard to the risk of fire, explosion and combustion. As a preventive measure, the battery cells must not be damaged, opened, dismantled, short-circuited, crushed or brought into contact with liquids.

The handpiece and the attachments must undergo the complete clinical reprocessing process before disposal to protect against infection. The device must not be disposed of with household waste.

#### 1.7.6 Warranty








The warranty for devices and accessories is excluded in the event of improper use, improper storage and transportation. The manufacturer also accepts no responsibility for damage resulting from repairs or maintenance carried out by unauthorized persons.

## 2 Operating the device

### 2.1 Description of the operating elements, information functions and symbols

#### 2.1.1 Universal handpiece (33.302.01)



	Press to unlock the attachments
	Slider in the middle position → LOCKING / SECURITY POSITION; Device cannot be started unintentionally
	Slider extended → Clockwise rotation
	Slider retracted → Counterclockwise rotation
	Oscillation mode switched on
	Oscillation mode switched off
	Hole for oiling the top clutch

- 1 Unlocking sleeve for attachments
- 2 Pusher for speed regulation
- 3 Slider for switching to clockwise rotation, locking (safety position), anticlockwise rotation
- 4 Closure buckles
- 5 Switch lever for oscillation mode ON or OFF
- 6 Sight glass for LED display

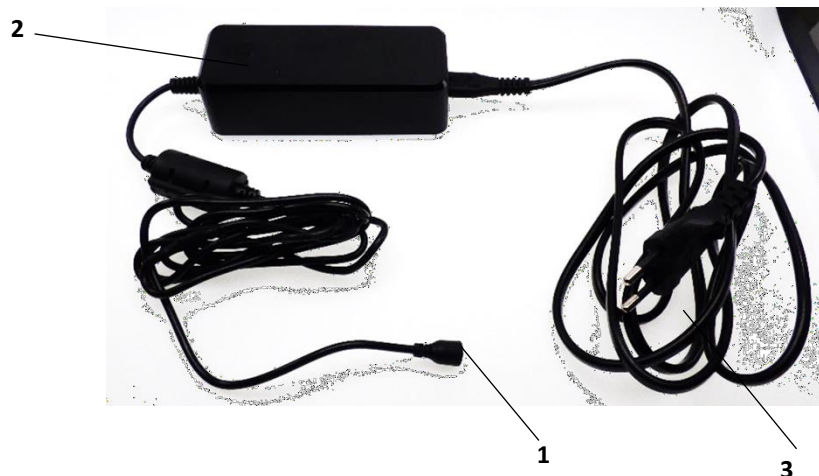
#### 2.1.2 Powerpack (33.302.10)

- 1 Finger recesses for removing power packs from the machine
- 2 LED display
- 3 Charging connector plug



### 2.1.3 Charging cable with mains adapter (33.302.11)

- 1 Charging plug
- 2 Charger information display (LED ring)
- 3 Device cable (replaceable)







## 2.2 Commissioning

### 2.2.1 Insert power pack

The following procedure must be followed for the handpiece.

To ensure sterility, the power pack is inserted into the sterile housing of the handpiece by two people, one of whom must be dressed in sterile clothing:

1.	The "sterile" person holds the open, sterile handpiece with the open side facing upwards.	
2.	The "sterile" person places the sterile sterile funnel on the handpiece and checks that it is correctly seated.  <b>Note:</b> The sterile funnel ensures that the non-sterile power pack does not come into contact with the outside of the sterile handpiece.	

<p>3.</p>	<p>The "non-sterile" person carefully pushes the non-sterile power pack through the sterile funnel into the handpiece using the trays.</p> <p>Press firmly on the power pack to ensure that it is correctly seated in the handpiece.</p> <p>When inserting, ensure that the power pack is correctly aligned and that the "non-sterile" person does not touch the outside of the sterile handpiece.</p>	
<p>4.</p>	<p>The "non-sterile" person removes the sterile funnel from the handpiece.</p>	
<p>5.</p>	<p>The person wearing sterile clothing closes the lid.</p>	
<p>6.</p>	<p>Hold the handpiece as shown in the illustration and close the two fasteners.</p>	

## 2.2.2 Remove power pack

The following procedure must be followed for the handpiece.

After the operation, remove the power pack from the handpiece and connect it to the charging cable with power supply unit. The handpiece must be reprocessed (cleaning/sterilization).

<p>1.</p> <p>Hold the handpiece as shown in the illustration and open the two fasteners.</p> <p>Do not turn the handpiece over until after the power pack has been removed.</p> <p><b>Caution:</b> Destruction of the power pack with possible consequential damage!</p>	
<p>2.</p> <p>Grasp the lid with your fingers and open it.</p>	
<p>3.</p> <p>Pull the power pack out of the handpiece using the finger recesses.</p> <p><b>Note:</b> When changing during surgery, the power pack must be removed from the "unsterile" person.</p> <p>Then reconnect the power pack to the charging cable with power adapter.</p> <p>handpiece, attachments and accessories for reprocessing.</p>	



**Attention:**

**Under no circumstances should the Powerpack be immersed in liquid, washed or sterilized.**

**Caution: Destruction of the power pack with possible consequential damage!**

## 2.3 Battery capacity

### 2.3.1 Available battery capacity

The capacity of a fully charged Powerpack is sufficient to carry out even lengthy and complex operations without recharging the Powerpack. (For technical data, see 5.2 Device specification)

The charge status of the Powerpack can be seen from the LED indicators during operation. (see 2.5.1)

Before an operation, the Powerpack must be connected to the charging cable with mains adapter until it is fully charged to ensure that it is ready for use. It is recommended to charge at least every 6 months when the Powerpack is not in use to ensure full battery capacity.

Date 14.05.2024	<b>1001-2</b>	Revision 01	Page 13 of 50
--------------------	---------------	----------------	------------------

 **Attention:**

- Only ever operate the device with a fully charged power pack. Therefore, always ensure that the power pack is charged in good time and that the power pack is reconnected to the charging cable with power supply unit immediately after an operation has been completed.

**Warning:** Extension of the operating time!

- If in doubt, check the charge status before inserting the Powerpack by connecting it to the charging cable with mains adapter.

**Warning:** Extension of the operating time!

- To ensure sterility, the power pack may only be changed during the operation in accordance with the instructions above. (See 2.2.1 Inserting the power pack and 2.2.2 Removing the power pack) **Warning:** Danger to patient!

- Sterilize the sterile funnel after each use to ensure sterility when inserting the non-sterile power pack into the sterile handpiece.

**Warning:** Danger to patient!

- If the Powerpack has been subjected to a slight mechanical shock or impact, it must be checked for mechanical damage, cracks or similar. Damaged Powerpacks must not be used and must be returned for repair. If there is no visible damage, check the functionality of the Powerpack with a handpiece. To do this, insert the Powerpack into a handpiece and close the lid. Operate the pusher for speed regulation. If the machine is running and all functions are working, the Powerpack can be used again. In the event of a malfunction or no function, return the Powerpack for repair.

**Warning:** Danger to patient!

### 2.3.2 Overheating protection of the Powerpack

The machines heat up under continuous load. To prevent the permissible surface temperature of the appliance from being exceeded, the corresponding cooling phases must be observed, see 5.1 Operating cycle.

**Warning:** Danger to patient and user!

A safety system protects the battery and motor from overheating damage:

- If the cooling phases are not observed and the battery or motor become too hot, the appliance switches off automatically. The machine cannot be restarted until the power pack has cooled down.

 **Attention:**

For lengthy operations, a second device must be kept ready or the time required for the device to cool down must be taken into account.

### 2.3.3 Energy saving function

There is no need to select a standby function on the system, as an integrated appliance controller automatically disconnects the machine from the power supply.

## 2.4 Charging, shipping and storing the Powerpack

The Powerpack contains the motor, battery and electronics and must be handled with care.

The following points must be observed to ensure that the appliance functions properly:

### **Loading**

- Fully charge the Powerpack before use. (See chapter 2.6.3)
- Charge the Powerpack at an ambient temperature of +10°C to +40°C.

### **Storage**

- Do not expose the Powerpack to temperatures above +55°C under any circumstances (chapter 5.3)

**Caution:** Device defect!

- The battery cells of the Powerpack discharge minimally even when not in use (physical effect). Connect the Powerpack to the charging cable for a sufficiently long time before an operation and charge it at least every 6 months when not in use.

Before using the Powerpack, always check that it is fully charged.

### **Shipping**

- The Powerpack may only be shipped by air freight with a maximum load capacity of 30%. The shipped Powerpacks are loaded to 30% at the factory.

If a newly delivered Powerpack is inserted into a machine, the orange LEDs become visible. On site, the Powerpack can be charged to 100% as normal.

**Note:** If an empty/discharged Powerpack is charged for approx. 20 minutes, a charging capacity of 30% is achieved.

### **Attention:**

- Only use the power pack (33.302.10) in the handpieces (33.302.01) intended for this purpose.

**Caution:** Device defect!

- Only use a Dimeda instruments charging cable (33.302.11) to charge the Powerpack.

**Caution:** Device defect!

- Do not wash, rinse, sterilize, drop or apply pressure or force to the Powerpack. This would destroy the Powerpack and cause possible consequential damage.

**Caution:** Device defect!

- Do not use defective Powerpacks, but return them to the responsible Dimeda Instruments service center.

**Warning:** Danger to patient and user!

- The Powerpack may only be opened by the original manufacturer or an authorized service centre. Unauthorized opening voids the warranty.

## 2.5 LED light indicator

### 2.5.1 LED display Powerpack during operation

Condition	Motor condition	LED 1	LED 2
50% < battery charge < 100%	Ready for operation	Green permanently illuminated	Green permanently illuminated
10% < battery charge < 50%	Ready for operation	Green permanently illuminated	Orange permanently illuminated
0% < battery charge < 10%	Ready for operation	Orange permanently illuminated	Orange permanently illuminated
Temperature warning	Ready for operation	Flashing green or orange	Flashing green or orange
Exceeded temperature	Not ready for operation	Red and green or orange flashing alternately	Red and green or orange flashing alternately
Overload	Not ready for operation	Permanently illuminated red	Permanently illuminated red
Battery empty	Not ready for operation	Flashing red	Flashing red
Error, defective	Not ready for operation	Permanently illuminated red	Permanently illuminated red

In the event of a temperature warning, the LEDs flash in the color corresponding to the current battery status (green or orange). If the temperature is exceeded, the color of the LEDs changes between red and the color of the current battery status (green or orange). In the event of an overload, the motor switches off during operation and the LEDs light up red. As soon as the overload is removed, the Powerpack can be restarted.

### 2.5.2 LED display Powerpack during charging process

Condition	Charging status	LED 1	LED 2
Battery full	Does not load	Green permanently illuminated	Green permanently illuminated
Battery charge > 50%	Loads	Flashing green	Flashing green
Battery charge < 50%	Loads	Flashing orange	Flashing orange
Exceeded temperature	Does not load	Flashing red	Flashing red
Error, defective	Does not load	Permanently illuminated red	Permanently illuminated red

Once the charging process is complete, the LEDs remain green for 2 hours.

At the start of the charging process, the Powerpack initially flashes orange for 2-5 seconds. Only after this time is the current charge status determined and correctly displayed via the LED colors.

### 2.5.3 Power supply indicator light during charging

Condition	Charging status	Display power supply unit
Power supply unit connected to mains via device cable	Loads	Blue LED ring permanently illuminated
Power supply unit <u>not</u> connected to power supply via device cable	Does not load	No display

## 2.6 Charger

Only use the charging cable with mains adapter 33.302.11 to charge the Powerpack!

No other chargers may be used. This may damage the Powerpack. The warranty is no longer valid if a different charger is used.

**Caution:** Device defect!

Only use the charger in a dry environment and outside the operating environment (with patient contact).

**Caution:** Device defect!

### 2.6.1 Putting the charging cable into operation


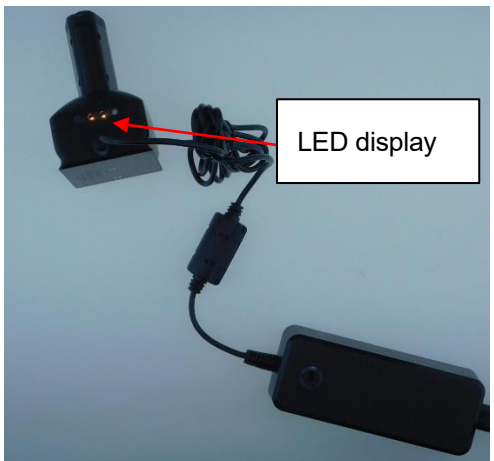
Before using the charging cable, make sure that no power pack is connected to the charging cable. Only connect the charging cable to the mains supply using the power adapter supplied.

The charging cable is ready for use as soon as it is connected to the mains supply with the power supply unit. The blue LED ring on the top of the power supply unit lights up.

### 2.6.2 Cleaning the charging cable with power supply unit

Only clean with the mains plugs disconnected. Wipe the charging cable from time to time with a dry or slightly damp cloth (do not use solvents).

### 2.6.3 Charging the power pack

<p>1. Connect the power pack to be charged to the charging cable.</p> <p>It is a magnetic contact, which means that the plug on the charging cable and the plug on the power pack connect automatically a few millimeters before contact.</p> <p>As soon as it is connected, the LED on the power pack lights up.</p>	
<p>2. As soon as the Powerpack is fully charged, the charging cable with mains adapter switches to trickle charging (Powerpack indicator lights up green).</p> <p>The charging cable can be disconnected from the Powerpack at any time. However, the full battery capacity is only available when the green indicator on the Powerpack is permanently lit.</p>	

### 2.6.4 Charging a new or unused Powerpack

New Powerpacks and Powerpacks that have not been used for more than one month and have not been stored on the charging cable with mains adapter will only reach their maximum capacity again after three to five full charging cycles.

### 2.6.5 Storing the Powerpack

Remove the power pack from the handpiece after each use and then recharge it. Never store used Powerpacks uncharged. Always recharge unused Powerpacks within 6 months to retain the full battery capacity.

Do not use Powerpacks that have not been taken directly from the charging cable and for which the indicator on the Powerpack has not lit up green (fully charged). Otherwise the charge level may be too low for the application.

**Warning:** Extension of the operating time!

### 2.6.6 Display on the Powerpack after removing the charging cable

If the charging cable is removed from the Powerpack before it is fully charged, no indicators will light up on the Powerpack.

Once the power pack has been fully charged and removed from the charging cable, the indicator lights up green. The indicator goes out automatically after two hours or after commissioning with a handpiece. The indicator is intended to signal to the OR staff that the power pack is fully charged and can be used.

### 2.6.7 Disconnect the charging cable from the mains supply

Before disconnecting the charging cable from the mains supply, make sure that there is no power pack connected to it.



**Attention:**

- After power failures or switching to the emergency power supply, the power supply unit switches back on automatically.

- Only Powerpacks (33.302.10) may be charged with the power supply unit.

There is a risk of fire and explosion when charging other batteries or rechargeable batteries.

**Warning:** Danger to users!


## 2.7 General use of the various attachments



**Attention:**

-If the diMAGNI-S machine is not required during the operation, lay it down to ensure that it is stable and cannot tip over.

**Caution:** Device defect!

To protect against injury each time a cutting tool is fitted/dismantled and before the appliance is put down, set the slider to the center position at  LOCKING / SAFETY POSITION.

**Warning:** Danger for users!

### 2.7.1 Commissioning

Depending on the application, set the slider to clockwise or counter-clockwise rotation.

The speed can be set using the speed control handle. The appliance stops when the button is released.

### 2.7.2 Switching oscillation mode on and off

Oscillation mode can be switched on or off using the switch lever. If the switch lever is in the lower position (symbol

, oscillation mode is deactivated. In the upper position

(symbol , oscillation mode is activated.

### 2.7.3 Mounting/dismounting the attachments

**Note:** The following instructions apply to all attachments.

**⚠ Attention:**

– When mounting/dismounting attachments and cutting tools, always secure the appliance against unintentional start-up (slide to **STOP** LOCKING / SAFETY POSITION).

**Warning:** Danger for users!

– After fitting an attachment or cutting tool, check that it is properly seated by pulling on the attachment or tool.

**Warning:** Danger to user and patient!

– Only original attachments and tools from Dimeda Instrumente GmbH or from Dimeda Instrumente GmbH suggested manufacturers.

**Caution:** Device defect!

– Damage caused by the use of attachments and cutting tools from other manufacturers is not covered by the warranty.

– Cooling the cutting tools with coolant is recommended to protect against heat necrosis.

**Warning:** Danger to patient!



– Only use cutting tools once.

**Warning:** Danger to patient!

### 2.7.4 Fitting attachments

Secure the appliance against unintentional start-up (slide to **STOP** LOCKING / SAFETY POSITION).

**Warning:** Danger for users!

1.	Push the attachment in from the front until you feel it stop.	
2.	Then check the correct fit by gently pulling on the attachment.	

Before using the device on a patient, ensure that the correct operating mode is set, e.g. trigger the device briefly in the air.

### 2.7.5 Insert cutting tools into attachments and remove them again


See detailed description of all essays (from chapter 2.8)

### 2.7.6 Remove attachments

Secure the appliance against unintentional start-up (slide to **STOP** LOCKING / SAFETY POSITION).

**Warning:** Danger for users!

It is recommended to hold the appliance in the position shown. The attachment should be pointing slightly upwards to prevent it from falling.

<p>Press and hold the release sleeve as far as it will go. Grasp the attachment with the other hand and remove it.</p> <p>Release the release sleeve again. Put the removed attachment to one side.</p>	
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## 2.8 Application of rotating attachments

When mounting/dismounting attachments and cutting tools, always secure the appliance against unintentional start-up (**STOP** LOCKING / SAFETY POSITION).

**Warning:** Danger for users!




**Attention:**

Never switch on the drive unit to close the drilling attachments.

**Warning:** Danger for users!

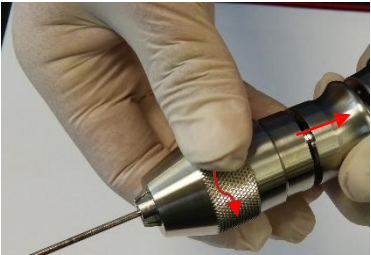
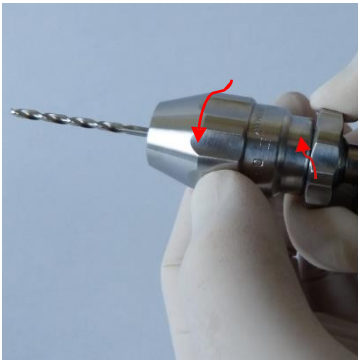
### 2.8.1 Drill attachment with key (33.302.40, 33.302.41, 33.302.42)

#### 2.8.1.1 Assembly and disassembly of the cutting tools

<p>Open the drill chuck by turning it anticlockwise using the key supplied. Insert or remove the cutting tool. To close, turn the key clockwise.</p>	
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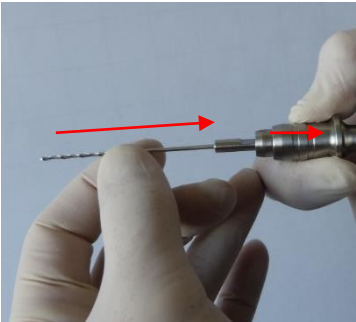
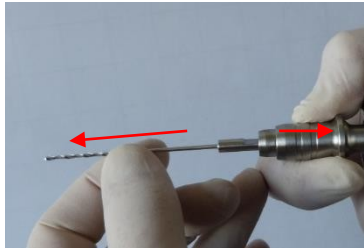
## 2.8.2 Keyless drilling attachment (33.302.43, 33.302.44)

### 2.8.2.1 Assembly and disassembly of the cutting tools

<p>33.302.43: To open the drill chuck, pull back and hold the locking sleeve and then turn the front ring clockwise.</p> <p>It is not necessary to pull back the locking sleeve to close it, turn the front ring counterclockwise.</p>	
<p>33.302.44: To open, hold the rear ring of the drill chuck and turn the front ring clockwise.</p> <p>Insert / remove the cutting tool. To close, hold the rear ring of the drill chuck and turn the front ring counterclockwise.</p>	

## 2.8.3 AO connection small (33.302.30)

### 2.8.3.1 Assembly and disassembly of the cutting tools

<p><b>Assembly:</b> Insert the cutting tool into the front of the attachment with light pressure and a slight twisting movement. In doing so, push the coupling sleeve of the attachment backwards. Once the cutting tool has been pushed in as far as it will go, release the coupling sleeve. Check that the tool is firmly seated by pulling gently.</p>	
<p><b>Disassembly:</b> To remove the cutting tool, slide the coupling sleeve of the attachment backwards and remove the tool.</p>	

## 2.9 Application Cribbed wire chuck (33.302.20)

For inserting/removing cribbing wires/ Kirschner wires/pins of any length with a diameter of Ø0.5-4.0.

When mounting/dismounting attachments and cutting tools, always secure the appliance against unintentional start-up (STOP LOCKING / SAFETY POSITION).

**Warning:** Danger for users!



**Attention:**

Never switch on the drive unit to close the cribbing wire attachments.

**Warning:** Danger for users!

### 2.9.1 Insert and position the cob wire chuck attachment

See section 2.7.3.

When fitting the cramp wire chuck, ensure that the cramp wire chuck is aligned so that the lever for clamping is axial to the housing.

1.	<p>Make sure that your fingers do not enclose the handle when inserting the attachment, otherwise your fingers may become trapped for a short time if you press on the adjustment sleeve at the same time.</p> <p><b>Warning:</b> Danger for users!</p>	
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### 2.9.2 Insert the cribbing wire into the attachment

1.	<p>Set the adjusting sleeve at the front end of the attachment to the diameter of the cribbing wire. To do this, turn the adjusting sleeve while applying slight pressure.</p>	
2.	<p>Insert the cribbing wire into the front of the attachment. The cribbing wire is lightly clamped and remains in the selected position.</p>	

### 2.9.3 Inserting the cribwire into the bone

Pull the lever towards the handpiece to clamp the cribbing wire securely and press the trigger. If necessary, release the lever to readjust the position of the cribbing wire in the attachment.



### 2.9.4 Remove the cribbing wire from the bone

Set the required diameter on the adjusting sleeve of the attachment. Slide the adjusting sleeve and the attachment over the cribbing wire. Pull the lever towards the handpiece to grip the Kirschner wire and press the pusher (slide to counterclockwise rotation) to pull the wire out of the bone.

### 2.9.5 Extension sleeve for crib wires (33.301.29)

The extension sleeve (33.301.29) must always be used for long cribbing wires that exceed the dimensions of the appliance and protrude from the back of the cover of the appliance barrel.

**Warning:** Danger for users!

Screw the extension sleeve into the cover of the appliance barrel.



#### **⚠ Attention:**

The following processes can lead to an overload:

-Correction of the drilling angle while the cutting grooves of the drill are completely in the bone.

**Warning:** Danger to patient and user!

**Caution:** Device defect!

-Blocking the drill bit by drilling into the nail.

**Warning:** Danger to patient!

**Caution:** Device defect!

Work can continue after the following corrective measures have been taken:

-Drilling angle correction: Pull out the drill bit until the cutting grooves are visible and start the drilling process again.

-Drilling the nail: Pull out the drill bit until the cutting grooves are visible, retarget or, if necessary, replace the drill bit.


The cobweb chuck must not be dismantled during reprocessing. Only operate all moving elements several times during manual pre-cleaning (see 3.3.2).

## 2.10 Use of the oscillating saw attachment 33.302.50

### **Attention:**

-If the saw is not required during the operation, lay it down to ensure that it is stable and cannot tip over.

**Caution:** Device defect!

To protect against injury each time a cutting tool is fitted / removed, the saw head is positioned and before the appliance is put down, set the slider to  LOCKING / SAFETY POSITION.

**Warning:** Danger for users!

-Oscillation mode must **NOT** be used as the operating mode when using the saw attachment. This mode has no function when a saw attachment is connected.

**Warning:** Prolongation of surgery duration!

### 2.10.1 Insert and position the saw attachment

See section 2.7.3.




When fitting the saw attachment, please note that the saw attachment can be aligned on the housing in 90° increments (in the axial direction) depending on the direction in which the grooves on the attachment coupling are inserted.

### 2.10.2 Replacing saw blades

Only saw blades with the Stryker "Sabo Sagittal Saw" connection may be used.

**Warning:** Danger to patient and user!

**Caution:** Device defect!

1.	Open the clamping screw with wrench 33.302.85/- 86 by turning it counterclockwise.	
2.	Insert the new saw blade and bring it into the desired position. The saw blade can be locked in five different positions.	
3.	Tighten the saw blade by turning the clamping screw clockwise with a wrench. 33.302.85/- 86 tighten/close.  When using 33.302.85, tighten hand-tight. When using 33.302.86, turn the screw until the torque wrench clicks noticeably. Operate the machine before each use and check that the saw blade is sufficiently tensioned.	

 **Attention:**

-The saw blade must be correctly inserted into the holder using the contour in the saw blade. To ensure that the saw blade is fitted correctly, check that there is no gap between the saw blade and the cover and that the saw blade lies flat.

**Warning:** Danger to patient and user!

### 2.10.3 Working with the oscillating saw attachment

Allow the device to start up before placing it on the bone. Do not exert excessive pressure on the saw blade to prevent it from jamming. To achieve optimum sawing performance, move the appliance slightly back and forth in the plane of the saw blade so that the blade swings slightly over the bone on both sides. If the saw is guided smoothly, very precise cuts can be made. Inaccurate cuts indicate worn saw blades, excessive pressure or tilting of the saw blade.

**Warning:** Danger to patient!

### 2.10.4 Instructions for handling saw blades

To achieve optimum results, Dimeda Instrumente prescribes the use of a new saw blade for each operation. This ensures that the saw blade is always optimally sharpened and clean. Used saw blades entail the following risks:

- Necrosis due to strong heat development
- Infections due to residues
- Longer cutting time due to reduced sawing performance

**Warning:** Danger to patient!

Under the following conditions, noise and vibrations can deviate significantly from the standard values:

- Use of atypical saw blades
- Vertical sawing
- Working with tools in poor condition
- Use of saw blades from non-explicitly recommended manufacturers

Always cool saw blades with coolant to prevent heat necrosis.


**Warning:** Danger to patient!

## 2.11 Using the jigsaw attachment (33.302.51)

 **Attention:**

-If the saw is not required during the operation, lay it down to ensure that it is stable and cannot tip over.

**Caution:** Device defect!

To protect against injury each time a cutting tool is fitted / removed, the saw head is positioned and before the appliance is put down, set the slider to  LOCKING / SAFETY POSITION.

**Warning:** Danger for users!

-Oscillation mode must **NOT** be used as the operating mode when using the saw attachment. This has no function when a saw attachment is connected.

**Warning:** Prolongation of surgery duration!

### 2.11.1 Insert and position the saw attachment

See section 2.7.3.




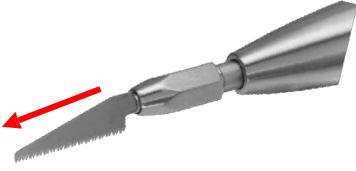
When fitting the saw attachment, please note that the saw attachment can be aligned on the housing in 90° steps (in the axial direction) depending on the direction in which the grooves on the attachment coupling are inserted.

### 2.11.2 Replacing saw blades

Only use saw blades with the connection described in section 1.7.3.

**Warning:** Danger to patient and user!

**Caution:** Device defect!

1.	Open the saw blade release by hand or with key 33.302.87 by turning it clockwise.	
2.	Insert or remove the new saw blade.	
3.	Tighten the saw blade by turning the clamping sleeve counterclockwise and clamp it in place with key 33.302.87.	
4.	Check that the saw blade is firmly seated by pulling it lengthwise. Activate the attachment for 3-5 seconds and check whether the saw blade is still stuck. If not, tighten again with the wrench.	

The saw blade must be properly clamped and checked before each use to prevent the saw blade from loosening. If the saw blade is to be used for a longer period of time, retighten the saw blade clamp from time to time.

**Warning:** Danger to patient and user!

### 2.11.3 Working with the jigsaw attachment

Allow the device to start up before placing it on the bone. Do not exert excessive pressure on the saw blade to prevent it from jamming. Very precise cuts can be made if the saw is guided smoothly. Inaccurate cuts indicate worn saw blades, excessive pressure or tilting of the saw blade.

**Warning:** Danger to patient!

### 2.11.4 Instructions for handling saw blades

To achieve optimum results, Dimeda Instrumente GmbH prescribes the use of a new saw blade for each operation. This ensures that the saw blade is always optimally sharpened and clean. Used saw blades entail the following risks:

- Necrosis due to strong heat development
- Infections due to residues
- Longer cutting time due to reduced sawing performance

**Warning:** Danger to patient!

Under the following conditions, noise and vibrations can deviate significantly from the standard values:

- Use of atypical saw blades
- Working with tools in poor condition
- Use of saw blades from non-explicitly recommended manufacturers

Always cool saw blades with coolant to prevent heat necrosis.

**Warning:** Danger to patient!

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

### 3.1 General information

Handpieces and attachments do not have an unlimited service life due to the frequent mechanical stress they are subjected to during use. Proper use and regular maintenance extend the service life of surgical tools and instruments.

Repeated clinical reprocessing has little effect on the service life of the drive unit and attachments. Careful care and maintenance as well as thorough oiling can significantly increase the reliability and service life of the system components.

Dimeda Instrumente GmbH prescribes annual inspection and maintenance by the original manufacturer or selected authorized service points. The manufacturer accepts no responsibility for damage caused by improper operation or unauthorized maintenance. With proper handling and prescribed maintenance, the device has a service life of at least 3 years.



**Attention:**

-Clinical reprocessing (including cleaning and subsequent sterilization) should always be carried out immediately after use.

**Caution:** Device defect!

Through-holes, release sleeves and other hard-to-reach areas require particularly careful cleaning.

**Caution:** Device defect!

-The power pack and charger can be wiped with a cloth, but must not be washed, rinsed, disinfected or sterilized.

**Caution:** Device defect!

-Only completely dried products may be used to prevent liquid from coming into contact with the power pack during use.

**Caution:** Device defect!

-The cleaning agents may have a pH value of 7 - 9.5. Cleaners with a pH value higher than 11 can attack the surfaces of aluminum, aluminum alloys, plastics or composite materials, depending on the cleaning agent in question, and should only be used taking into account the data on material compatibility of the cleaner according to its data sheet. At pH values above 11, the surface of stainless steel may also be affected. Follow the enzyme cleaner or detergent manufacturer's instructions to achieve the correct dilution, temperature, contact time and water quality. If there are no manufacturer's instructions regarding temperature and contact time, follow the Dimeda Instrumente GmbH recommendations (see from 3.2). Instruments should be cleaned in a fresh, newly prepared solution.

**Caution:** Device defect!

-The cleaning agents used come into contact with the following materials: Stainless steel, aluminum, plastic and rubber seals.

The instructions for clinical reprocessing listed here have been reviewed by Dimeda Instrumente GmbH. It complies with the requirements of the international standard ISO 17664-1:2021 and is suitable for the reprocessing of non-sterile Dimeda Instrumente GmbH medical devices.

For additional information, please refer to the national laws and guidelines. The clinic's internal guidelines and procedural instructions as well as the recommendations and instructions of the manufacturers of cleaning agents, disinfectants and clinical reprocessing systems must also be followed.

It is the responsibility of the user to ensure that reprocessing is carried out by appropriately trained personnel and using the appropriate, properly installed, maintained and inspected systems and materials to achieve the desired result. Any deviation from the above instructions must be properly reviewed and evaluated for effectiveness and potential adverse effects.

#### 3.1.1 Exceptional transmissible pathogens

Always operate with disposable instruments on patients who are considered to be at risk of Creutzfeldt-Jakob disease (CJD) and the associated infections.

Dispose of instruments used to operate on a patient with suspected or confirmed CJD after surgery and/or follow current national recommendations.

## 3.2 Preparation for cleaning

### 3.2.1 Dismantling

Ensure that all attachments have been removed, the lower housing cover is open and the power pack has been removed from the machine/handpiece.

**Caution:** Device defect!

Powerpacks and charging cables with mains adapter can be wiped with a dry or slightly damp cloth. (Do not use solvents).



**Attention:**

The Powerpacks must not be washed, rinsed, disinfected or sterilized.

**Caution:** Device defect!

The clinical reprocessing of handpieces and attachments can be performed by:

- a) machine/automated cleaning with manual pre-cleaning. (see the following points)

## 3.3 Machine cleaning after manual pre-cleaning



**Attention:**

– Manual cleaning before machine/automated cleaning/disinfection is important to ensure that cannulations and other hard-to-reach areas are clean.

**Warning:** Danger to patient!

**Caution:** Device defect!

– Alternative cleaning/disinfection procedures to the procedure described below (including manual pre-cleaning) have not been validated by Dimeda Instrumente GmbH.

**Warning:** Danger for patient and user!

**Caution:** Device defect!

### 3.3.1 Manual pre-cleaning of the handpiece

#### 1.) Remove residues

Rinse the handpiece under cold running tap water for at least 2 minutes. Remove coarse soiling and residues with a sponge, a lint-free cloth and/or a soft brush. Clean all cannulations with the cleaning brush provided (28.316.00). Move the handle, release sleeves for attachments, operating selector switch and other moving parts under cold running water at least 5 times over the entire range of movement to loosen and remove coarse residues.



**Attention:**

Do not use sharp or pointed objects for cleaning.

**Caution:** Device defect!

#### 2.) Spray with cleaning agent

Spray all components with an enzyme cleaner, a cleaning solution or a cleaning foam (0.5% Neodisher Mediclean), leave to act for at least 2 minutes and then wipe off.

For the correct dilution, temperature, contact time and water quality, follow the instructions of the enzyme cleaner or detergent manufacturer to achieve the optimum cleaning effect.

Date 14.05.2024	1001-2	Revision 01	Page 28 of 50
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**3.) Clean with cleaning solution**

Clean under running water for at least 5 minutes with an enzyme cleaner or a cleaning solution (0.5% Neodisher Mediclean). Move moving parts under running water at least 5 times over the entire movement range. Use a soft brush and/or a lint-free cloth to remove visible dirt and residues.

For the correct dilution, temperature, contact time and water quality, follow the instructions of the enzyme cleaner or detergent manufacturer to achieve the optimum cleaning effect.

**4.) Rinse with tap water**

Rinse the components thoroughly under cold to lukewarm running tap water for at least 2 minutes. Rinse out the cannulations and channels using a syringe, pipette or water pressure gun. Move joints, handles and other moving parts at least 5 times over the entire range of movement to rinse these areas thoroughly under running water.

**5.) Check components visually**

Repeat steps 1 to 5 until all components are free of any visible dirt.

The manual pre-cleaning described above must be followed by mechanical/automated cleaning. See also point 3.3.3 Mechanical cleaning.

### **3.3.2 Manual pre-cleaning of the attachments**

**1.) Remove residues**

Place attachments (e.g. drill chuck/saw attachment) in cold tap water for 5 minutes.

Then move all moving parts under water at least 5 times over the entire movement and operating range to loosen and remove coarse residues.

Remove coarse soiling and residues with a sponge, a lint-free cloth and/or a soft brush until no more soiling is visible. Clean all cannulations with the cleaning brushes provided for this purpose (28.316.00).



**Attention:**

Do not use sharp or pointed objects for cleaning.

**Caution:** Device defect!

**2.) Cleaning in an ultrasonic bath**

Treat the attachments for 5 minutes in an ultrasonic bath (0.5% cleaning solution Neodisher MediClean (Dr. Weigert, Hamburg), 40°C).

**3.) Cleaning with a water gun**

Rinse all gaps, joints and cavities with the water gun for at least 20 seconds.

**4.) Check components visually**

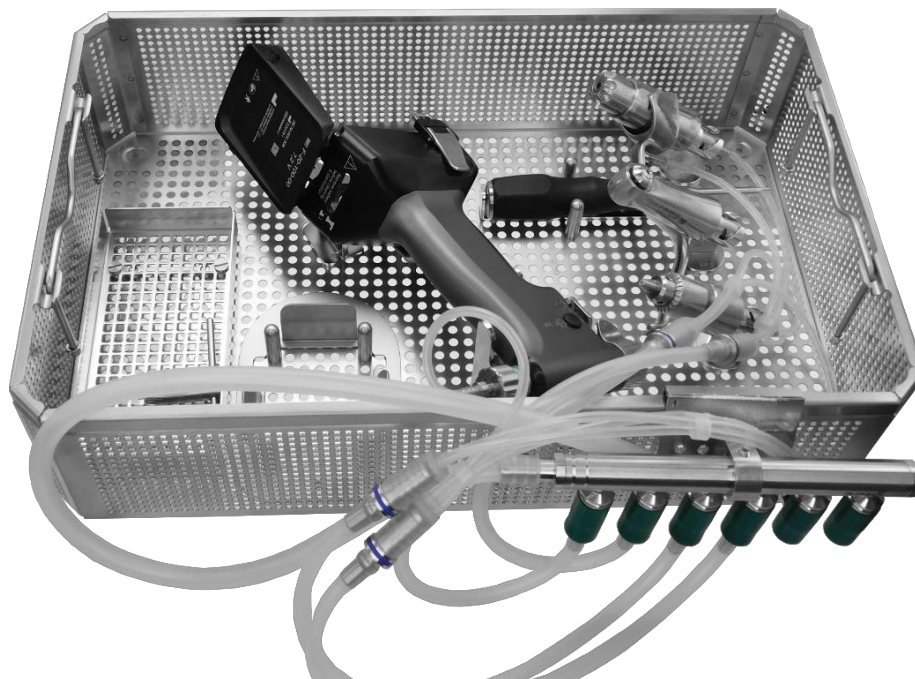
Repeat steps 1 to 4 until all components are free of any visible dirt.

The manual pre-cleaning described above must be followed by mechanical/automated cleaning. See also point 3.3.3 Mechanical cleaning.

### 3.3.3 Machine cleaning

#### 1.) Loading the washing machine basket

Place all items in the sieve basket specially developed for the system (e.g. 33.302.90) from Dimeda Instrumente. Ensure that all cannulations (attachments) are stored vertically, i.e. in an upright position. Attach the irrigation adapters (33.301.xx) to the handpieces. Connect the rinsing adapters, placed on the washing machine basket, to the rinsing medium system (for internal rinsing of the handpieces and attachments).



#### Cleaning program

**Note:** The washer-disinfector must meet the requirements of the international standard ISO 15883.

Cleaning agent: neodisher MediClean (Dr. Weigert, Hamburg)

- 2-minute pre-cleaning with cold drinking water
- Empty
- 5-minute cleaning with a 0.5% cleaning solution at 55°C
- Empty
- 2-minute neutralization (Neodisher® Z)
- Empty
- 3-minute rinse with cold, fully demineralized water
- Empty
- 2-minute final rinse with cold, demineralized water
- Empty
- 5-minute thermal disinfection with hot demineralized water ( $\geq 93^{\circ}\text{C}$ )
- 40-minute drying ( $\geq 90^{\circ}\text{C}$ )

#### 2.) Checking the components

Remove all components from the washing machine basket. Check all cannulas, coupling sleeves etc. for visible soiling.

If necessary, repeat the automatic cleaning cycle with manual pre-cleaning. Devices/handpieces, especially seals and bearings, are particularly affected by machine cleaning/disinfection. In particular, carefully check the circumferential seal in the lid for any damage after cleaning. The components must be properly oiled and regularly maintained.

### 3.4 Lubrication/ maintenance

Regular oiling of the devices/handpieces and attachments ensures a long service life and trouble-free operation. All accessible moving parts of the devices/handpieces, lids and attachments must be lubricated with a sterilizable spray oil (88.268.40) before sterilization. Then move the components several times to distribute the oil. Wipe off excess oil with a cloth.

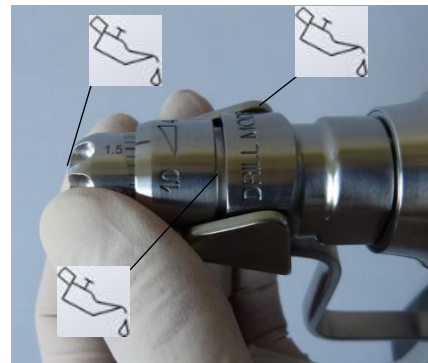
#### 3.4.1 Handpiece

- Lubricate pusher plunger, slide right/left, changeover lever and operate several times
- Lubricate the unlocking sleeve via the drill hole and actuate several times without the attachment inserted



#### 3.4.2 Essays

- Moisten moving jaws, rotating rings and levers with drops of oil and operate/open and close several times



### 3.5 Packaging for sterilization process

Place the cleaned and dry products in the designated positions of the basket. Additionally pack the basket in a sterile barrier system in accordance with ISO 11607, e.g. in a sterilization fleece provided for this purpose or a reusable sterilization container.

Protect tips or sharp instruments from damage due to mutual contact.

**Caution:** Device defect!

Ensure that pointed or sharp objects do not damage the sterile barrier system.

**Warning:** Danger to patient!

### 3.6 Steam sterilization



**Attention:**

Never sterilize power packs, otherwise they will be damaged. The power pack must be removed from the device/handpiece before sterilization.

**Warning:** Danger for users!

**Caution:** Device defect!

The systems can be resterilized by validated steam sterilization (ISO 17665 or national standards).

Dimeda Instrumente recommends the following parameters for instruments and trays packaged in the sterile barrier system:

Sterilization procedure (cycle)	Area	Sterilization time	Sterilization temperature	Drying time
Steam sterilization (fractionated fore-vacuum) (at least 3 intervals)	USA	at least 4 minutes	at least 132°C maximum 138°C	20 -60 minutes
	EU	at least 5 minutes	minimum 134°C maximum 138°C	20 -60 minutes

Drying times vary between 20 and 60 minutes due to different packaging materials (sterile barrier system consisting of sterilization fleece or a reusable sterilization container), steam quality, materials, products to be sterilized, total weight, performance characteristics of the sterilizer and variable cooling times.

**Attention:**

- The following maximum values must not be exceeded: 143°C for a maximum of 22 minutes.
- Do not accelerate the cooling process.
- Hot air, ethylene oxide, sterile wheel, plasma and formaldehyde sterilization must not be used.

**Caution:** Device defect!

## 3.7 Repair and technical service

In the event of a defect or malfunction, send the device to Dimeda Instrumente GmbH or an authorized service centre for repair.

**Caution:** Device defect!

A dropped appliance must be sent in for inspection and repair.

**Caution:** Device defect!

Do not continue to use defective devices.

**Warning:** Danger to patient and user!

If repair is no longer possible or does not make sense, the appliance must be disposed of. See instructions in the Disposal chapter below.

With the exception of the care and maintenance measures described above, no maintenance work may be carried out by the user or by third parties.

**Warning:** Danger to patient and user!


**Caution:** Device defect!

Dimeda Instrumente prescribes that the device and accessories such as attachments be serviced regularly (once a year) by the original manufacturer or an authorized service centre in order to ensure safe and proper operation on an ongoing basis.

Battery cells must not be replaced. If defective, send the power pack to Dimeda Instruments for repair GmbH or an authorized representative.


**Warning:** Danger to patient and user!

**Caution:** Device defect!

 **Attention:** "SV 376 in ADR 2021" applies to the transportation of damaged lithium batteries. Damaged lithium batteries include in particular

- Batteries with a defect that impairs safety,
- Batteries with damaged or significantly deformed casings,
- leaking batteries or batteries with gas leakage or
- Batteries with defects that cannot be diagnosed before transportation to the place of analysis. If the batteries are merely inoperable, no special conditions apply.

**Warning:** Danger for users!

 **Caution:** Do not make any modifications to this appliance without the manufacturer's permission. If this appliance is modified, appropriate inspections and tests must be carried out to ensure the safe use of the appliance.

 **Attention:**

The manufacturer accepts no responsibility for damage resulting from repair or maintenance by unauthorized persons.

**Warning:** Danger to patient and user!

**Caution:** Device defect!

## 4 Troubleshooting

### 4.1 Device/handpiece and cover

Problem	Possible cause	Remedy
Machine does not start	No power pack in the handpiece	Insert a charged power pack
	Powerpack is discharged	Charging the power pack
	Safety system is activated (slider in safety position)	Position the slider for clockwise or anticlockwise rotation
	Powerpack is defective	Powerpack to the Dimeda instruments Submit service center
	Overheating protection is activated; LEDs flash alternately red and green or red and orange	Allow the machine to cool down
Machine has too little power	Powerpack is discharged; indicator on the Powerpack is already red	Charging the power pack
	Machine and/or attachments are poorly maintained	Send the machine and attachments to the Dimeda Instruments Service Center
Machine stops suddenly	Powerpack is discharged; indicator on the Powerpack lights up red	Charging the power pack
	Machine overheating, the LEDs have already been flashing alternately green or orange. Display on the Powerpack alternates between red and green or red and orange	Allow the machine to cool down
	Machine or power pack is defective	Insert a fully charged power pack into the machine. If this does not help, send the machine to the Dimeda Instruments Service Center
Machine continues to run after the pusher is released	Pusher is blocked by deposits (e.g. blood)	Press the trigger several times, clean and maintain the machine according to the instructions
	Powerpack is defective	Remove the Powerpack and let it run until it stops. Then send the Powerpack to the Dimeda Instruments Service Center
Machine gets noticeably warm/hot	Machine was heavily used	Allow the machine to cool down

Problem	Possible cause	Remedy
Machine runs too slowly	Handle is blocked and cannot be actuated to the intended stop	Clean and oil the lever handle, remove deposits or blockages underneath the lever handle
	Speed transmission from machine to attachment is defective	Operate machine without attachment and check whether drive shaft rotates fast enough, if not send machine to Dimeda Instrumente service center
Machine saws too slowly	Handle is blocked and cannot be actuated to the intended stop	Clean and oil the lever handle, remove deposits or blockages underneath the lever handle
	Speed transmission from machine to attachment is defective	Operate machine without attachment and check whether drive shaft rotates fast enough, if not send machine to Dimeda Instrumente service center
	Saw blade is not tightened	Tighten the saw blade tensioning screw firmly
Oscillating saw vibrates too much	Saw blade fastening is not tightened or has come loose	Tighten the saw blade tensioning screw firmly
Attachments cannot be fitted to the machine	Machine coupling is clogged with deposits	Remove deposits by thoroughly cleaning and then oiling.
	Locking mechanism defective	Oil and move the mechanism, if it still does not work, send the machine to the Dimeda Instruments Service Center
Attachments cannot be removed from the machine	Release sleeve for attachments is blocked / clogged with deposits	Check the unlocking sleeve, clean and oil if necessary.
	Locking mechanism defective	Machine to the Dimeda instruments Submit service center
Handle is difficult to move	Pusher is blocked by deposits	Clean and oil the lever handle
	Mechanics defective	Machine to the Dimeda instruments Submit service center

## 4.2 Powerpack

Problem	Possible cause	Remedy
Powerpack cannot be inserted into the handpiece	Powerpack is deformed, possibly due to a fall.	Send the Powerpack to the Dimeda Instruments Service Center, observe point 3.7 Repair and Technical Service.
Powerpack cannot be removed from the handpiece	Powerpack has a firm fit thanks to the rubber buffers	Pull a little harder on the power pack to release it.
	Powerpack is blocked in the handpiece	Machine to the Dimeda instruments Submit service center
Fully charged power pack does not work	Safety system is activated (slider in safety position)	Position the slider to clockwise or counterclockwise rotation.
	The power pack is defective because it e.g. was dropped after unplugging from the charging cable or came into contact with liquids. has come.	Send the Powerpack to the Dimeda Instruments Service Center, observe point 3.7 Repair and Technical Service.
LED indicator lights up continuously	The Powerpack is connected to the charger	No defect. The LEDs in the connected charger light up permanently.
	The fully charged Powerpack has been disconnected from the charger and has not yet been used in the handpiece	No defect. After disconnecting a fully charged Powerpack from the charger, the LEDs light up green for 2 hours.
LED indicator does not light up. Powerpack connected to charging cable	Device cable of the charging cable is not plugged in	Connect the charging cable to the mains supply using the device cable supplied.
	Charging cable has a fault	Charging cable to the Dimeda instruments Service Center.
	Powerpack has a fault	Send the Powerpack to the Dimeda Instruments Service Center, observe point 3.7 Repair and Technical Service.
Power supply indicator does not light up.	Device cable of the charging cable is not plugged in	Connect the charging cable to the mains supply using the device cable supplied.
Powerpack was accidentally washed, in immersed in liquids or sterilized and is defective	Carelessness of the staff	There is a small dot next to the LEDs; if it is gray, the power pack has been sterilized.
Housing of the Powerpack has visible damage	The power pack has been exposed to excessive heat	Send the Powerpack to the Dimeda Instruments Service Center, point 3.7 Repair and Technical Service note.
	The power pack has been dropped	Send the Powerpack to the Dimeda Instruments Service Center, point 3.7 Repair and Technical Service note.

<b>Problem</b>	<b>Possible cause</b>	<b>Remedy</b>
The Powerpack is not powerful enough	Powerpack has been stored separately from the charging cable for more than 1 month and has not been used.	3-5 charge/discharge cycles are necessary to restore the Powerpack's optimum capacity.
LED indicator flashes red or is permanently red, even though the charger indicator is lit and the Powerpack is plugged in	Powerpack has a fault	Send the Powerpack to the Dimeda Instruments Service Center, observe point 3.7 Repair and Technical Service.

### 4.3 Attachments and tools

<b>Problem</b>	<b>Possible cause</b>	<b>Remedy</b>
Attachments cannot be fitted to the machine	Top coupling is clogged with deposits	Remove deposits by thoroughly cleaning and then oiling.
Attachments cannot be removed from the machine	Release sleeve for attachments is blocked / clogged with deposits	Check the unlocking sleeve, clean and oil if necessary. If necessary, send the machine to the Dimeda Instruments Service Center
Cutting tool cannot be fitted to an attachment or can only be fitted with difficulty	Locking mechanism is clogged with deposits	Remove deposits by thoroughly cleaning and then oiling.
	Attachment or tool is deformed due to improper use (e.g. fall) or wear and tear	Replace the attachment or tool or send it to the Dimeda Instruments Service Center
Attachment becomes noticeably warm / hot	Attachment was heavily used	Allow the attachment to cool down and oil it before the next use.
Cribbing wire (Kirschner wire) cannot be inserted into the cribbing wire attachment	Kirschner wire attachment is not open	Set the adjusting sleeve to the correct wire diameter.
I cannot grip the cribbing wire despite operating the tensioning lever	Kirschner wire attachment is too wide open	Set the adjusting sleeve to the correct wire diameter.
Cribbing wire is stuck in the attachment and can no longer be moved	Kirschner wire was inserted at an angle and has jammed in the attachment	Send the Kirschner wire attachment to the Dimeda Instruments Service Center
Bones and tools heat up during the work process	The cutting tool is blunt	Replace tool

## 4.4 Charging cable with mains adapter

Problem	Possible cause	Remedy
No indicator light on the power supply unit	Device cable is not plugged in	Connect the charging cable to the mains supply using the device cable supplied.
	Charging cable has a fault	Have the charging cable checked by Dimeda Instruments Service Center and repaired if necessary.
Powerpack connected to charging cable, no display on powerpack	Charging cable is not plugged into the mains supply	Connect the charging cable to the mains supply using the device cable supplied.
	Charging cable plug is not correctly connected to the charging connector plug of the Powerpack	Disconnect the charging cable from the Powerpack, disconnect the charging cable from the mains supply and wipe the charging contact of the cable and Powerpack with a cloth and reconnect.
	Charging cable has a fault	Have the charging cable checked by Dimeda Instruments Service Center and repaired if necessary.
	Powerpack has a fault	Have the Powerpack checked by Dimeda Instruments Service Center and repaired if necessary.
Powerpack with red flashing display	Powerpack temperature too high	Plug the Powerpack into the charging cable, the charging process starts automatically once it has cooled down
	Deeply discharged power pack	Fully discharged Powerpack has not been recharged immediately after use and has not been used for several weeks. Several charge/discharge cycles are necessary to restore the Powerpack to its optimum capacity.

Note: If the solutions suggested above are not successful, please contact your local Dimeda Instruments Service Center.

## 5 Technical data

### 5.1 Operating cycle

Device (each 33.302.01 Universal handpiece together with the following attachment:)	Switch-on time	Switch-off time	Cycles
33.302.XX Drilling attachments <u>in oscillation mode</u>	20 seconds	40 seconds	5
33.302.30 Drill attachment AO connection small	60 seconds	120 seconds	5
33.302.40 Drilling attachment Jacobs small	60 seconds	120 seconds	5
33.302.41 Drilling attachment Jacobs large	60 seconds	120 seconds	5
33.302.42 Drill attachment Röhm drill chuck	60 seconds	120 seconds	5
33.302.43 Drill attachment quick-action chuck with locking device	60 seconds	120 seconds	5
33.302.44 Drill attachment quick-action chuck without locking device	60 seconds	120 seconds	5
33.302.50 Oscillating saw attachment	30 seconds	60 seconds	5
33.302.51 Jigsaw attachment	30 seconds	60 seconds	5
33.302.20 Cribbed wire chuck	20 seconds	40 seconds	5

In oscillation mode and with saw attachments, an operator must not work longer than 30 minutes per day.

**Warning:** Danger for users!

The recommendations for the duration of use of the devices have been determined at an average load and at an ambient temperature of +20°C.

Electrical appliances heat up under continuous load.

After the above-mentioned switch-on time, the handpiece and attachments used should therefore cool down for at least the duration of the switch-off time. After five cycles, the handpiece and attachments should cool down for at least 30 minutes. Compliance with these specifications prevents the system from overheating. This prevents injury to patients or users. The user is responsible for the application and compliance with the cooling phases. It is recommended to have an additional device and additional attachments ready for longer continuous use.

**Warning:** Danger to patient and user!

**Caution:** Device defect!



**Attention:**

- Always adhere to the recommended operating cycles. The appliance is not suitable for continuous operation.

**Caution:** Device defect!

- Only use new cutting tools to prevent the system from heating up due to reduced cutting performance.

**Caution:** Device defect!

- To prevent heat corrosion, always rinse cutting tools with coolant. Rinse manually.

**Warning:** Danger to patient!


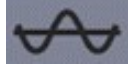
- Careful care and maintenance of the system reduces heat build-up in the handpiece and attachments.

**Caution:** Device defect!

## 5.2 Device specification

<b>33.302.01 Universal handpiece</b>	
Handpiece dimensions (without attachment) (WxHxD)	100 x 190 x 68 mm
Handpiece weight without power pack	590 g
Infinitely variable speed	0 - 1,350 rpm
Cannulation	Ø4.3mm through-hole
Protection class	B, EN 60601-1
Application parts	Complete ready-to-use handpiece with attachment (type B)
IP protection	IPX0
Power supply	Internal battery

Essay		Infinitely variable speed	Handpiece mode-DRILL	Handpiece mode-OSCI	Cannulation
<b>33.302.30</b>	Drilling attachment AO connection small	0 - 1,350 rpm	X	X	Ø 4.3 mm
<b>33.302.40</b>	Drilling attachment Jacobs small	0 - 1,350 rpm	X	X	Ø 4.0 mm
<b>33.302.41</b>	Drilling attachment Jacobs large	0 - 1,350 rpm	X	X	Ø 4.3 mm
<b>33.302.42</b>	Drilling attachment Röhm	0 - 1,350 rpm	X	X	Ø 4.3 mm
<b>33.302.43</b>	Drill attachment Quick-action chuck with locking device	0 - 1,350 rpm	X	X	Ø 4.3 mm
<b>33.302.44</b>	Drill attachment Quick-action chuck without locking device	0 - 1,350 rpm	X	X	Ø 4.3 mm
<b>33.302.20</b>	Cribbed wire chuck	0 - 1,350 rpm	X	X	Ø 4.0 mm

Essay		Infinitely variable stroke rate	Handpiece 	Handpiece 	Cannulation
<b>33.302.50</b>	Oscillating saw attachment	0 - 14,000 cpm	X	(not permitted)	/
<b>33.302.51</b>	Jigsaw attachment	0 - 14,000 cpm	X	(not permitted)	/

Note: Performance data is subject to technical fluctuations.

### 33.302.10 Powerpack (rechargeable battery)

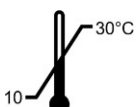
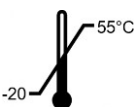
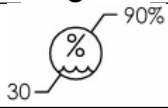
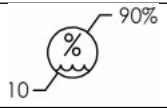
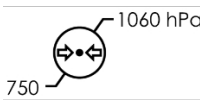
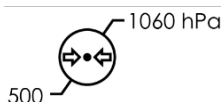
Dimensions (WxHxD)	73 x 102 x 54 mm
Weight	450g
Type	Li-ion
Max. Voltage	8,4 V
Operating voltage (nominal voltage)	7,2 V
Capacity	2.5 Ah
Typical charging time	< 90 min

### 33.302.11 Charging cable with mains adapter

Dimensions	124 x 50 x 37 mm
Weight	370 g
Type	Li-Ion battery charger
Input	100-240 VAC 50-60 Hz Max. 1.0 A
Output	12 VDC 3,5 A

## 5.3 Ambient conditions

The following conditions apply to the operation, transportation and storage of the Powerpack (33.302.10) and the charging cable (33.302.11), which must be observed for proper use:

	Operation	Transportation and storage
Temperature		
Relative humidity		
Air pressure		

 **Attention: The devices must not be stored or operated in explosive atmospheres.**

## 5.4 Applicable standards

The devices comply with the following standards and directives:

- Regulation (EU) 2017/745 on medical devices
- IEC 60601-1 Medical electrical equipment Part 1: General requirements for safety and essential performance
- IEC 60601-1-2 Medical electrical equipment Part 1-2: Collateral standard: Electromagnetic disturbances

Date 14.05.2024	<b>1001-2</b>	Revision 01	Page 41 of 50
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## 5.5 Electromagnetic compatibility

 **Attention:**

In principle, mutual interference between electrical devices can never be completely ruled out. We strongly recommend that you observe the following instructions (distances) and follow the instructions for the other electrical devices used.

The diMAGNI-S system is intended for use in professional healthcare facilities, except in the vicinity of active HF surgical equipment and outside the HF-protected room with strong EM interference.

Exposure to electromagnetic interference can lead to unwanted speed fluctuations or even dropouts in the machines of the diMAGNI-S system. This means that operations can only be carried out to a limited extent. No essential performance characteristics have been defined for the diMAGNI-S system that could be impaired or lead to an unacceptable risk due to electromagnetic interference.

Use of this appliance adjacent to other appliances or stacked with other appliances should be avoided as this may result in improper operation. However, if use in the manner described above is necessary, this appliance and the other appliances should be observed to verify that they are operating normally.

The use of accessories other than those specified or provided by Dimeda Instrumente may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.

Portable RF communications equipment (radios), including accessories such as antenna cables and external antennas, should be used no closer than 30 cm (12 inches) to the diMAGNI-S system. Failure to do so may result in a reduction in the performance characteristics of the devices.

Accompanying documents in accordance with IEC 60601-1-2 as per 5. 2Table 1:

<b>Guidelines and manufacturer's declaration - Electromagnetic emissions</b>		
The diMAGNI-S system is intended for use in the electromagnetic environment specified below. The customer or the user of the system must ensure that it is operated in such an environment.		
<b>Interference emission measurements</b>	<b>Compliance</b>	<b>Electromagnetic environment - Guideline</b>
HF emission according to CISPR 11	Group I	The system uses RF energy exclusively for its internal function. Therefore, its RF emissions are very low and it is unlikely that neighboring electronic devices will be disturbed.
HF emission according to CISPR 11	Class A	The system is suitable for use in all facilities with the exception of residential buildings and those directly connected to the public supply network, which also supplies buildings used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	Class A	Not applicable. The rated power of the charger is less than 75 W.
Emissions of voltage fluctuations / flicker according to IEC 61000-3-3	In accordance	

Note: The characteristics of this device, as determined by OUTPUTS, permit its use in industrial and hospital environments (CISPR 11, Class A). When used in a residential environment (for which CISPR 11 typically requires Class B), this device may not provide adequate protection of radio services. The user may need to take remedial action such as relocation or reorientation of the device.

Table 2:

<b>Guidelines and manufacturer's declaration - Electromagnetic immunity</b>						
The diMAGNI-S system is intended for use in the electromagnetic environment specified below. The customer or the user of the system must ensure that it is used in such an environment.						
<b>Interference immunity tests</b>	<b>IEC 60601-1-2 Test level</b>		<b>Match level</b>		<b>Electromagnetic environment - Guidelines</b>	
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 8 kV Contact discharge ± 15 kV Air discharge		± 8 kV Contact discharge ± 15 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%.	
Fast transient electrical disturbances / bursts according to IEC 61000-4-4	± 2 kV for mains cables ± 1 kV for input and output lines		± 2 kV for mains cables ± 1 kV for input and output lines		The quality of the supply voltage should correspond to that of a typical business or hospital environment.	
Surges according to IEC 61000-4-5	± 1 kV Voltage outer conductor-outer conductor		± 1 kV Voltage outer conductor-outer conductor		The quality of the supply voltage should correspond to that of a typical business or hospital environment.	
Voltage dips Short-term interruptions and fluctuations in the supply voltage in accordance with IEC 61000-4-11	0 % $U_T$ for 0.5 cycle (1 phase) 0 % $U_T$ for 1 cycle 70 % $U_T$ for 25/30 cycles (50/60 Hz)		0 % $U_T$ for 0.5 cycle (1 phase) 0 % $U_T$ for 1 cycle 70 % $U_T$ for 25/30 cycles (50/60 Hz)		The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the system requires continued operation even in the event of interruptions to the power supply, it is recommended that the system be powered from an uninterruptible power supply or a battery.	
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m		30 A/m		Magnetic fields at the mains frequency should correspond to the typical values found in business and hospital environments.	
Immunity to interference from high-frequency wireless communication devices as shown in Table 9 in IEC 60601-1-2	<b>Band (MHz)</b>	<b>Test frequency (MHz)</b>	<b>Interference immunity test level (V/m)</b>	<b>Band (MHz)</b>	<b>Test frequency (MHz)</b>	<b>Interference immunity test level (V/m)</b>
	380-390	385	27	380-390	385	27
	430-470	450	28	430-470	450	28
	704-787	710	9	704-787	710	9
		745			745	
		780			780	
	800-960	810	28	800-960	810	28
		870			870	
		930			930	
	1700-1990	1720	28	1700-1990	1720	28
1845		1845				
1970		1970				
2400-2570	2450	28	2400-2570	2450	28	
5100-5800	5240	9	5100-5800	5240	9	
	5500			5500		
	5785			5785		
Immunity to magnetic fields at close range in accordance with IEC 61000-4-39	134.2 kHz at 65 A/m 13.56 MHz at 7.5 A/m		134.2 kHz at 65 A/m 13.56 MHz at 7.5 A/m			

Note:  $U_T$  is the AC mains voltage before the test levels are applied

Table 3:

**Guidelines and manufacturer's declaration - Electromagnetic immunity**

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system must ensure that it is used in such an environment.


Interference immunity tests	IEC 60601-Test level	Match level	Electromagnetic environment - Guidelines
<p>Conducted RF disturbances according to IEC 61000-4-6</p> <p>Radiated RF disturbances according to IEC 61000-4-3</p>	<p>3 V effective value 150 kHz to 80 MHz ISM frequencies 6V</p> <p>3 V/m 80 MHz to 2.7GHz</p>	<p>3 V effective value 150 kHz to 80 MHz ISM frequencies 6V</p> <p>3 V/m 80 MHz to 2.7GHz</p>	<p>Portable and mobile radio equipment should be used at no closer to the system, including cables, than the recommended safety distance calculated from the equation applicable to the transmitting frequency.</p> <p><b>Recommended safety distance:</b></p> $d = 1.2\sqrt{P}$ <p><math>d = 1.2\sqrt{P}</math> for 80 MHz to 800 MHz</p> $d = 2.3\sqrt{P}$ <p>for 800 MHz to 2.5 GHz</p> <p>with P as the rated power of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d as the recommended safety distance in meters (m).</p> <p>The field strength of stationary radio transmitters should be lower than the compliance level at all frequencies according to an on-site investigation<sup>a</sup> .<sup>b</sup></p> <p>Interference may occur in the vicinity of devices bearing the following symbol.</p> 
<p>Note 1</p>	<p>The higher frequency range applies at 80 MHz and 800 MHz.</p>		
<p>Note 2</p>	<p>These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections of buildings, objects and people.</p>		
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.</p> <p><sup>b</sup> Over the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.</p>			

Table 4:

<b>Recommended safety distances between portable and mobile HF telecommunications devices and the system</b>			
The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the output power of the communications equipment.			
Rated power of the transmitter  W	Protective distance, depending on 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 is not specified in the table above, the recommended safety distance $d$ in meters (m) can be determined using the equation belonging to the respective column, where $P$ is the maximum rated power of the transmitter in watts (W) as specified by the transmitter manufacturer.			
Note 1	The higher frequency range applies at 80 MHz and 800 MHz.		
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections of buildings, objects and people.		

## 6 **REF** Order information

The products listed below are part of these instructions for use. Each product delivery includes a "General Safety Instruction" with the most important safety instructions and information on how to access the electronic instructions for use.

### 6.1 Handpieces

<b>REF</b> Item number	Article description	Basic UDI-DI
33.302.01	Universal handpiece	042515541TD02PTHANDPIECHT

### 6.2 Powerpack (battery, motor, electronics) with accessories

<b>REF</b> Item number	Article description	Basic UDI-DI
33.302.10	Powerpack small, drive unit	042515541TD02PTPOWERPAC39
33.302.11	Charging cable with mains adapter	042515541TD02PTCHARGEFT
33.301.15	Mains cable (EU standard)	N/A
33.301.16	Mains cable (UK standard)	N/A
33.301.17	Mains cable (US standard)	N/A
33.301.18	Mains cable (AU standard)	N/A

### 6.3 Essays

<b>REF</b> Item number	Article description	Basic UDI-DI
33.302.30	Drill attachment AO connection small	042515541TD02PTATTACHML7
33.302.40	Drilling attachment Jacobs small	042515541TD02PTATTACHML7
33.302.41	Drilling attachment Jacobs large	042515541TD02PTATTACHML7
33.302.42	Drilling attachment Röhm	042515541TD02PTATTACHML7
33.302.43	Drill attachment Quick-action chuck with locking device	042515541TD02PTATTACHML7
33.302.44	Drill attachment Quick-action chuck without locking device	042515541TD02PTATTACHML7
33.302.50	Oscillating saw attachment	042515541TD02PTATTACHML7
33.302.51	Jigsaw attachment	042515541TD02PTATTACHML7
33.302.20	Cribbed wire chuck	042515541TD02PTATTACHML7
33.301.29	Extension for cribbed wire chuck	042515541TD02PTATTACHML7

## 6.4 Cleaning and care of the diMAGNI-S system

























REF	Item number	Article description	Basic UDI-DI
	33.302.52	Sterile funnel small	042515541TD02CMACCESSORVS
	33.302.90	Strainer basket with lid for 1 machine	042515541TD02CMACCESSORVS
	33.302.93	Lid for strainer basket	042515541TD02CMACCESSORVS
	33.302.94	Hi-Tech Oil Pen	N/A
	33.301.60	Universal flushing adapter	042515541TD02CMACCESSORVS
	33.301.80	Flushing set	N/A
	33.302.95	Rinse adapter washing machine Miele/ Steelco/ Webeco	N/A
	33.301.82	Rinsing adapter washing machine Belimed	N/A
	33.301.83	Rinse adapter washing machine Maquet/ MediKomp/ Getinge	N/A
	28.316.00	Cleaning brush set	N/A

## 6.5 Accessories

REF	Item number	Article description	Basic UDI-DI
	33.302.85	Key for saw attachment ("Standard")	N/A
	33.302.86	Wrench Saw attachment Torque limiter	N/A
	33.302.87	Key for jigsaw attachment	N/A
	33.302.60	Key for Jacobs drill chuck small	N/A
	33.302.61	Key for Jacobs drill chuck large	N/A
	33.302.62	Key for Roehm drill chuck	N/A

## 7 Symbols used

The following symbols are attached to the device or individual components:

	Attention: Take care when handling the device, pay particular attention to the conditions and use in order to avoid undesirable consequences.		Mark of conformity with European Directive 2017/745 and number of the notified body
	Follow the instructions for use Before using the device, read the Read the operating instructions supplied.		Device complies with classification type B against electric shock and electric leakage currents. For use on patients, the Device suitable according to the IEC 60601-1 standard.
	Reference to existing instructions for use, as these contain useful information.		Store in a dry place
	Date of manufacture		Slider in the middle position → LOCKING / SECURITY POSITION; Device cannot be started unintentionally
	Batch designation		
	Order number		Slider extended → Clockwise rotation
	Serial number		Slider retracted → Counterclockwise rotation
	Temperature limitation		Oscillation mode switched off
	Manufacturer		Oscillation mode switched on
	Non-sterile		Release sleeve for the attachments
	Humidity, limitation		Hole for oiling the top clutch
	Air pressure, limitation		Charger ready for use
	Device contains batteries (Li-Ion = chemical symbol of the pollutant). For environmental reasons, batteries must be disposed of properly.  Disposal in accordance with national laws and the European Battery Directive 2006/66/EC and Waste Electrical and Electronic Equipment 2012/19/EU.  <b>Caution:</b> Risk of fire, explosion and combustion.  Do not disassemble, short-circuit, crush, heat to over +60°C or incinerate the battery cells (batteries).		

## 8 Address / Message



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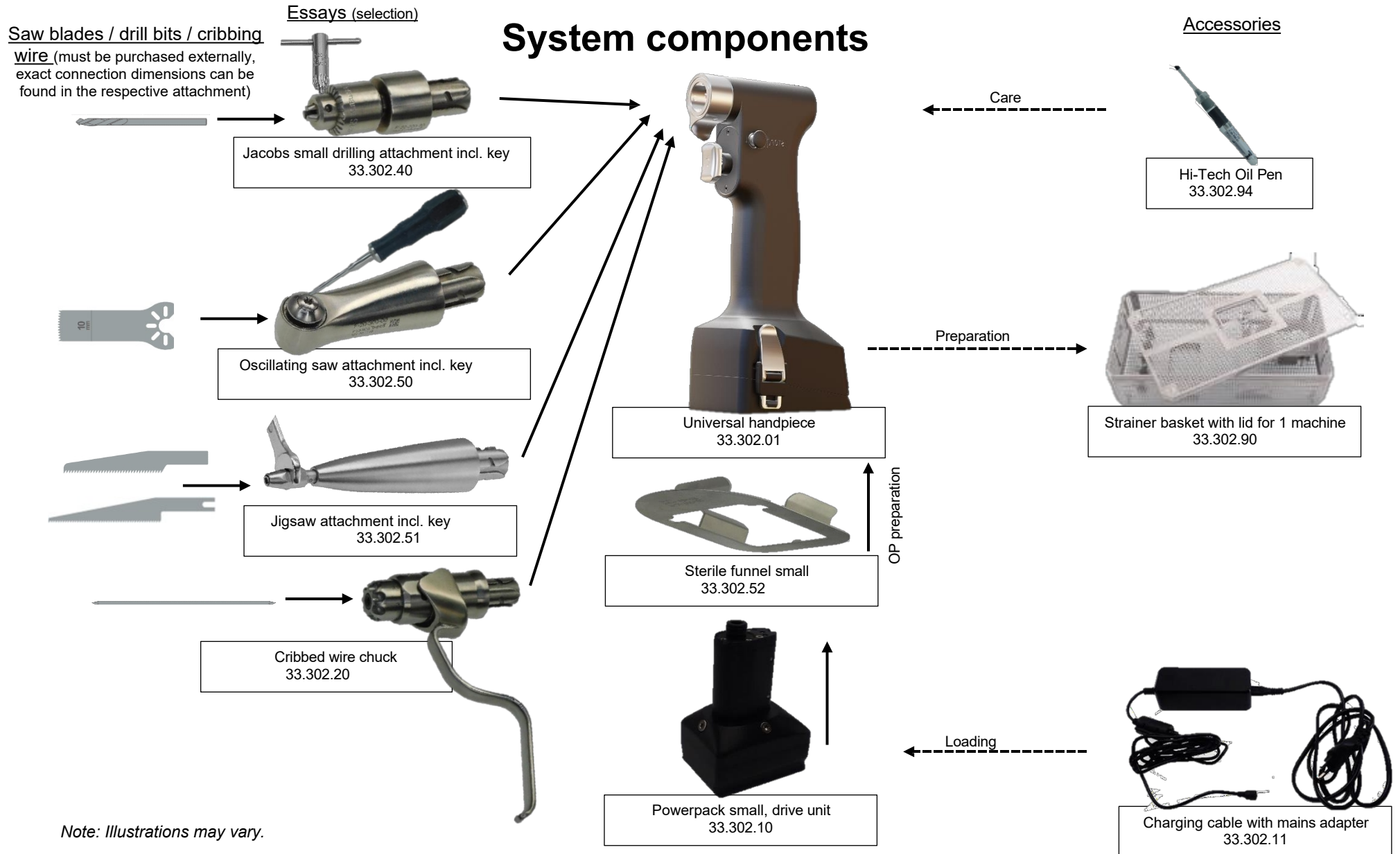
E-Mail: [info@medical-bees.de](mailto:info@medical-bees.de)

If you cannot reach us directly for reportable events, please send an e-mail to: [meldung@medical-bees.de](mailto:meldung@medical-bees.de)

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Note: Illustrations may vary.