DRAGONFLY
CORDLESS DRILL

USER MANUAL

Art. No. 199500
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veterinary technology for life
Eickemeyer®

INHALT

1. INTRODUCTION AND PRODUCT DESCRIPTION

1.1 General Information

Before any product use, carefully read this instruction for use (IFU), while keeping it easily available for the Operator or for appropriate service personnel.

Carefully read all the symbol-marked caution and warning texts. Incorrect use of the products may lead to serious injuries of the patient, the user or other persons.

This is an instruction for use for a battery-powered handpiece with different attachments including accessories. These can be purchased as a system or as separate units.

1.2 Intended Purpose

1.2.1 Handpiece, Battery (Drive Unit) and attachments

The powertool-system is intended for bone or hard tissue treatment by a professional surgeon, in a surgical procedure. The battery-powered system is intended to drill, ream, bolt, saw and sever of bones, as well as for mounting of KIRSCHNER wires and STEINMANN pins.

1.2.2 Cleaning and maintenance accessories

The cleaning and maintenance accessories are used for cleaning and processing of the powertool-system during transport and storage up to surgical application.

1.3 Indications

1.3.1 Handpiece, Battery (Drive Unit) and attachments

The DRAGONFLY-system is a handheld, battery operated, surgical machine used for treatment in small bone surgery for preparation of bone or hard tissue. The DRAGONFLY-system consists of a battery-operated power tool with a range of attachments and accessories for drilling, reaming and bolting operations, for mounting of KIRSCHNER wires and STEINMANN nails, as well as for cutting of bones, bone material or hard tissues in small bone surgery.

1.3.2 Cleaning and maintenance accessories

The cleaning and maintenance accessories are used for cleaning and processing of the powertool-system during transport and storage up to surgical applications. The maintenance kit is also used for storage and repair of appropriate components. A sterile funnel is used as accessory outside the immediate operating area to transfer the non-sterile Drive Unit into the sterile handpiece body.

1.4 Contraindications

1.4.1 Handpiece, Battery (Drive Unit) and attachments

The contraindications diabetes and osteoporosis must be observed when using the Drive Units and the accessories, with regard to mitigated bone stability.
The system should not be used in an area that has already been subjected to previous treatment (for example scarred tissue) in order not to negatively influence the healing process.
Any applications of the system, other than those, specified in intended purpose above, are neither intended by design nor tested and are therefore forbidden.

1.4.2 Cleaning and maintenance accessories

The cleaning kit shall exclusively be used for the purpose for which it has been intended in the medical fields and operated by educated and qualified personnel. The attending physician or an appropriate medical staff member shall be responsible for cleaning kit selection with accessories for defined applications, as well as for adequate training and correct management.

1.5 Application

1.5.1 Application duration

The products are intended for short application periods (< 60 min.)

1.5.2 Patient population

Apart from the contraindicated uses listed previously in 1.4, there are no restrictions on the patient population.

1.5.3 Intended users and field of operation

The DRAGONFLY-system (including the cleaning and maintenance accessories) shall be used exclusively by properly educated and qualified personnel at professional healthcare environment. It is an essential requirement that the user, as well as the appropriate medical staff, get familiar with the instruments before their practical handling.

1.5.4 Service life

EICKEMEYER® provides one-year inspection and maintenance by authorized service stations (e.g., EICKEMEYER®). EICKEMEYER® shall assume no responsibility for any defects/failures, arising either from improper handling of the devices or from their unauthorised maintenance. Assuming proper handling and authorised maintenance of the devices, their service life is, at least, 3 years (except wear & tear parts).

As the products are subject to normal wear and tear, they must be checked and maintained regularly. Corresponding recommendations are given in particular section of this user manual.

The date of manufacturing can be found out from the number behind the symbol on the devices.

1.6 Safety and Warning Instructions

The general safety and warning instructions are listed below. These are individually supplemented and specified in individual parts of this user manual.

1.6.1 General safety instructions

- It is recommended to always have a spare system ready for immediate use, since technical problems can never be entirely excluded. The same recommendation applies to lengthy and long-lasting procedures.
- Components with visible defects (for example after being dropped) must not be used.
- The system must not be used in the presence of oxygen, nitrous oxide or of flammable mixtures of volatile anaesthetic gases and the air.
- Regarding electromagnetic compatibility (EMC), it is imperative to learn the contents of the appropriate chapter of this user manual.
- The device contains Li-Ion batteries. Special handling and disposal are essential to consider (see user manual).

1.6.2 Cleaning and care

- Before the first and all subsequent applications, the handpieces, the attachments and the accessories shall undergo a complete reprocessing procedure.
- Protective covers and films must be fully removed before sterilisation.
- In order to assure proper performance of the system, EICKEMEYER® specifies cleaning and care after every use to be performed according to the instructions provided in the chapter “Care and Maintenance” of this Instruction for use.
- Moving parts must be maintained for their smooth operation with a special lubrication oil; EICKEMEYER® special oil/oil spray (Art. No. 563706) is recommended, suitable for sterilisation.

- In order to guarantee proper performance of the system, EICKEMEYER® specifies an annual maintenance and inspection to be carried out by one of their medical customer service stations.
- The Drive Unit and the charger must never be cleaned manually or automatically or sterilized/autoclaved.
- It is imperative that the sterile funnel is sterilised after each use in order to guarantee the system sterility, when a non-sterile Drive Unit is inserted into a sterile handpiece.

1.6.3 Combination products and tools

- New cutting tools must be used for each surgical procedure.
- For protection against heat necrosis of tissues, cutting tools shall always be flushed with a coolant.
- In order to guarantee proper performance of the system, only original cutting tools of EICKEMEYER® or of recommended manufacturers (also applies for battery-loading equipment).

1.6.4 The user/Application

- The user is responsible for proper intraoperative handling and use of the products.
- If the system is used in connection with an implant system, its use must be subordinate to the surgical technique of the procedure.
- The manufacturer accepts no responsibility for damages, which may arise from improper operation of the system or from its maintenance provided by unauthorised service stations.
- The machines get heated under continuous load. In order to avoid exceeding of permissible surface temperature of the device, appropriate cooling phases have to be implemented (see chapter in this user manual).

1.6.5 Users and/or patients

- Note to the user: All serious incidents relating 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 Bedienung und Akkubetrieb

- In order to avoid injuries, the locking mechanism of the device must be activated before the device is put aside, i.e., the selection switch have to be set at the LOCK position STOP. In addition, the device should always be handled in its lateral position in order to avoid possible tipping and falling down.
- The device has to be put in operation only with its fully charged Drive Unit It must be ensured that the Drive Unit has fully been charged. It is recommended that the Drive Unit is returned to the charging unit immediately after a given procedure is completed.
- In order to guarantee sterility, the Drive Unit can be replaced during surgical procedure only according to the instructions provided in the user manual.

1.7 Combination Products and Accessories

1.7.1 Accessories to be used/Scope of delivery

The DRAGONFLY-system comprises a universal handpiece with different exchangeable attachments (drilling, sawing, wire driver). The system also includes one Drive Unit (battery, motor, electronics) and other accessories.

The Drive Unit must be charged with the appropriate EICKEMEYER® charging cable (Art. No. 199504).

For proper functioning of the system, the cutting tool manufacturers specified by EICKEMEYER® must be used, otherwise EICKEMEYER® cannot guarantee responsibility for proper functioning.

Special agents are recommended for cleaning and maintaining the system, such as cleaning brushes (Art. No. 195011) and EICKEMEYER® special oil/oil spray (Art. No. 563706), suitable for sterilisation. No other oils may be used, otherwise medical bees GmbH cannot guarantee responsibility for proper functioning.

EICKEMEYER® recommends the use of a sterilisation tray, specifically designed for the system (Art. No. 199505) for sterilisation and storage of the system. Otherwise, EICKEMEYER® will not guarantee for flawless performance of the system.
The following components (at least) are necessary for the DRAGONFLY-system operation:

The Drive Unit must be inserted into the handpiece and an attachment must be selected and coupled. The Drive Unit is charged outside the device via a transportable charging cable.

- Handpiece (Art. No. 199520)
- Drive Unit (Art. No. 199502)
- Sterile funnel (Art. No. 199503)
- Charge cable with power supply (Art. No. 199504)
- At least one attachment, belonging to the system: e.g. Jacobs drill chuck attachment (Art. No. 195030)

An overview of the components belonging to the system can be found at the end of this user manual (see Chapter 6).

Recommended are the saw blades of EICKEMEYER® with the dimensional data and connections contained therein: Stryker® connection for oscillating saw attachment, crossed teeth (see Chapter 6).

1.7.2 Storage and transport

All products of DRAGONFLY-system market by EICKEMEYER® are delivered as non-sterile and must undergo reprocessing procedure before use (expect for Drive Unit and charging cable with power supply unit). EICKEMEYER® prescribes single use of corresponding drilling and cutting tool.

For reasons of product safety, only original packaging systems shall be used for shipment and transport. If this is no longer available, please contact EICKEMEYER®.

The environmental conditions for storage and transport are addressed in this user manual. Before disposal or return transport to the EICKEMEYER® Company, the devices/handpiece, as well as attachments, have to undergo the complete procedure of clinical processing for protection against infections. In addition, the products must be marked appropriately as either "hygienically safe" or "not decontaminated".

1.7.3 Disposal


Li-Ion

Defective devices can mostly be repaired, see the instruction for use for this issue. The devices contain lithium-ion batteries (Li-ion = chem. Symbol of harmful substance) and, for reasons relating to the protection of the environment, have to be properly disposed. Battery disposal must comply with national laws or with the European battery directive: 2006/66/EC, as well as with the Waste of Electrical and Electronic Equipment (WEEE) directive – 2012/19/EU.

A special care must be taken with regards to fire, explosion and burn hazards. It must be kept in mind that battery cells must not be damaged, opened, torn, shorted, crushed or allowed to come into contact with fluids.

Before disposal, the devices/handpieces, as well as the attachments, must undergo the complete procedure of clinical processing for protection against infections. The devices are not allowed to be disposed of with the household waste.

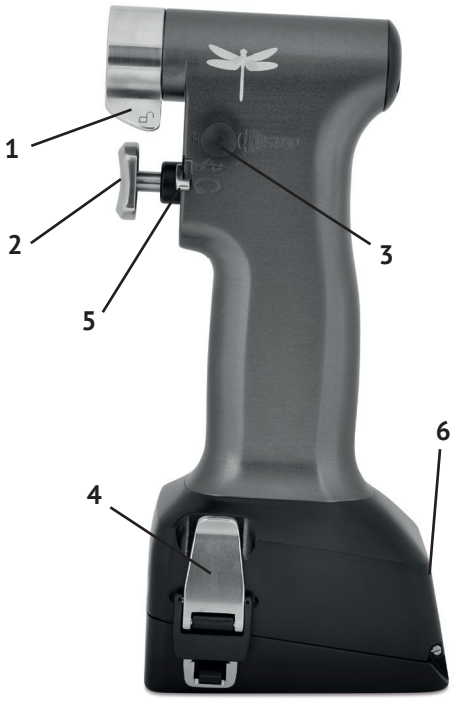
1.7.4 Guarantee

The guarantee for the devices and accessories expires in case of their unintended use and/or inappropriate operation, storage or transport. The manufacturer accepts no responsibility for damages, which may arise from improper operation of the system or its maintenance provided by unauthorised service stations.

2. OPERATION OF THE DEVICE

2.1 Description of the Controls, Indication Functions and Symbols

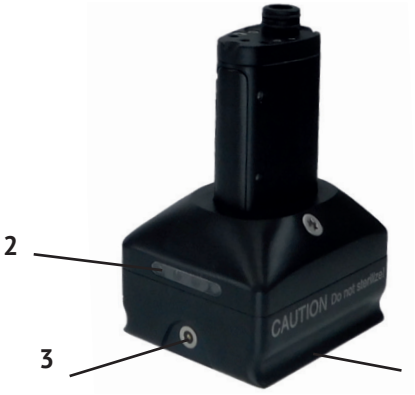
2.1.1 Handpiece (Art. No. 199520)



	Press to unlock the attachments
	Slider in the middle position → LOCKING/SAFETY POSITION the device cannot be unintentionally started
	Slide extended → Clockwise rotation
	Slide retracted → Counterclockwise rotation
	Oscillating mode is on
	Oscillating mode is off
	Bore hole for oiling the attachment coupling

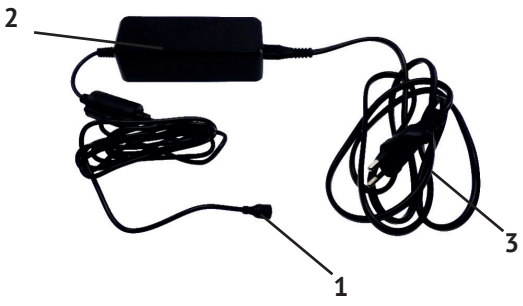
1. Release sleeve for attachments
2. Trigger for speed regulation
3. Slider for switching in the clockwise direction, locking (safety position), counterclockwise rotation
4. Locking latches
5. Switch lever to switch oscillating mode ON or OFF
6. Sight glass for LED display

2.1.2 Drive Unit (Art. No. 199502)



1. Finger recesses for Drive Unit removal from the handpiece
2. LED display
3. Charging connector

2.1.3 Charging cable with power supply (Art. No. 199504)



1. Charging plug
2. Charger information display (LED ring)
3. Power cable (exchangeable)

2.2 Initial Operation

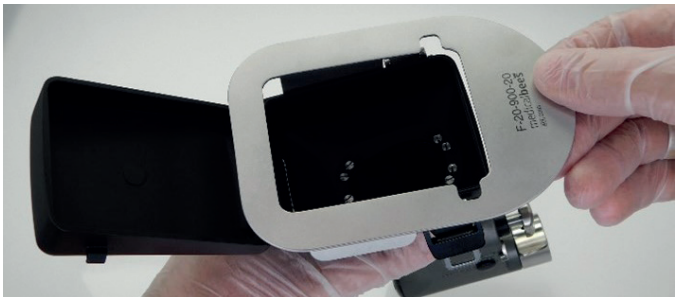
2.2.1 Drive Unit insertion

Apply the following procedures for all handpieces.
In order to ensure sterility, the Drive Unit insertion into the sterile housing of the handpiece must be done by two persons, out of whom, one must be dressed in sterile clothing:

1. The "sterile" person holds an open, sterile handpiece with the opened side upwards

2. The "sterile" person puts the sterile funnel on the handpiece and ensures its correct positioning.

   Remark:
   The sterile funnel ensures that the unsterile Drive Unit does not come in direct contact with the outer side of the sterile handpiece.



3. The "non-sterile" person carefully pushes the non-sterile Drive Unit through the sterile funnel into the handpiece using the recesses.
   Apply firm pressure to the Drive Unit to ensure that it sits correctly in the handpiece.
   During insertion, take care that the Drive Unit is correctly seated and that the "unsterile" person does not touch the outer side of the sterile handpiece.

4. The "unsterile" person takes the sterile funnel away from the handpiece

5. The person in sterile clothes closes the lid.

6. Hold the handpiece, as shown on the picture and close the latches.

2.2.2 Drive Unit removal

The following procedure must be followed for the handpiece.
After the operation, remove the Drive Unit from the handpiece and connect it to the charging cable with power supply.
The handpiece must be reprocessed (cleaning/sterilisation).

Hold the handpiece as shown in the picture and open the two latches.
Do not turn the handpiece till the removal of the Drive Unit.
Caution: Destruction of the Drive Unit with possible consequential damages!

7. Grip the lid with the fingers and open.

8. Remove the Drive Unit from the handpiece by pulling at the recesses.

Remark:
When the Drive Unit is replaced during surgery, it must be removed by the "unsterile" person.
In addition, the Drive Unit shall then be connected to the charging cable with power supply.
The handpiece, the attachments and accessories must then be submitted to reprocessing.

Attention:
The Drive Unit must under no circumstances be immersed, washed in a fluid or sterilised.

Caution:
Destruction of the Drive Unit with possible consequential damages!

2.3 Battery Capacity

2.3.1 Available battery capacity

The capacity of a fully charged Drive Unit is sufficient to carry out long and complex operations without any need of new charging (for technical data, see 5.2 Device specification).
The charging status of the Drive Unit is indicated during surgical operations by LED lights (see 2.5.1)
Before any operation, the Drive Unit must be connected to the charging cable with power supply unit 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 Drive Unit is not in use to provide full battery capacity.

Attention:

- The device must be put in operation only with its fully charged Drive Unit. It must be ensured that the Drive Unit has been charged in time. It is recommended that the Drive Unit is returned to the charging unit immediately after a given procedure is completed.
  Warning: Extension of surgical operation time!
- In case of doubt, check the charge status before inserting the Drive Unit by connecting it to the charging cable with power supply unit.
  Warning: Extension of surgical operation time!
- In order to guarantee sterility, the Drive Unit can be replaced during surgical procedure only according to the instructions provided in the IFU. (see 2.2.1 Drive Unit insertion and 2.2.2 Drive Unit removal)
  Warning: Danger for the patient!
- It is imperative that the sterile funnel is sterilised after each use in order to guarantee the system sterility, when a non-sterile Drive Unit is inserted into the sterile handpiece.
  Warning: Danger for the patient!
- If the Drive Unit was affected by a light mechanic impact or drop, it must be checked for mechanic damage, cracks, etc. Damaged Drive Units have to be withdrawn from use and sent for repair. If no visible damages are identified, check the functionality of the Drive Unit in the handpiece. Therefore, insert the Drive Unit into the handpiece and close the lid. Activate the trigger for rotation speed control. When the machine is running and all the functions can be activated, Drive Unit can further be used. In case of functional failure or no function, send the powerpack for repair.
  Warning: Danger for the patient!

2.3.2 Drive Unit overheating

The machines get heated under continuous load. In order to avoid exceeding of permissible surface temperature of the device, appropriate cooling phases have to be followed (see 5.1 Operating cycle).
Warning: Danger for the patient and for the user!
A safety system protects the battery and the motor against overheating damages.

- If the cooling phases are not followed and either the battery or the motor are too hot, the device automatically switches off. The machine can only be started again after the Drive Unit has cooled down.

Attention:
In case of long-lasting surgical procedures, another device has to be kept ready and ready for use or the necessary cooling time have to be taken into account in the course of surgery.

2.3.3 Energy saving function

No standby function needs to be selected on the system, as an integrated unit control automatically disconnects the machine from the power supply.

2.4 Drive Unit Charging, Transportation and Storage

The Drive Unit contains a motor, a battery and an electronic system and therefore must be handled with care.
To ensure that the device is functioning properly, the following points must be observed:

Charging

- Fully charge the Drive Unit before use (see Chapter 2.6.3).
- Charge the Drive Unit in ambient temperature between +10 °C and +40 °C.

Storage

- Under no circumstances expose the Drive Unit to temperatures above +55 °C (see Chapter 5.3).
  Caution: Device defect!
- The battery cells of the Drive Unit discharge also minimally when not in use (a physical effect). The Drive Unit shall always be kept connected to the charger for sufficient time before an operation and charged at least every 6 months, when not in use.

Always check the Drive Unit before use if it is fully charged.

Transport

- The Drive Unit may be sent by air freight with charge capacity of 30 % max. The delivered Drive Units are sent with factory charging of 30 %. If such a delivered Drive Unit is inserted into a machine, the orange LED indicator will be visible. The Drive Unit can be charged on site to 100 % regular.

Remark: If a discharged Drive Unit is charged for approximately 20 minutes, it will achieve the charge capacity level of 30 %.

Attention:

- Only use the Drive Unit (Art. No. 199502) in the handpiece (Art. No. 199520) intended for this purpose.
  Caution: Device defect!
- Only use a EICKEMEYER® charging cable (Art. No. 199504) to charge the Drive Unit.
  Caution: Device defect!
- Do not wash, rinse, sterilise, drop or apply pressure or force to the Drive Unit. This would destroy the Drive Unit and cause possible consequential damage.
  Caution: Equipment defect!
- Do not use defective Drive Unit but send them to the responsible EICKEMEYER® service station.
  Warning: Danger for patient and user!
- The Drive Unit may only be opened by the original manufacturer or an authorised service station. Unauthorised opening expires the warranty.

2.5 LED Light Indication

2.5.1 LED display Drive Unit during operation

Status	Motor status	LED 1	LED 2
50 % < battery charge < 100 %	Ready for use	Light green permanently	Light green permanently
10 % < battery charge < 50 %	Ready for use	Light green permanently	Light orange permanently
0 % < battery charge < 10 %	Ready for use	Light orange permanently	Light orange permanently
Temperature warning	Ready for use	Flashing green or orange	Flashing green or orange
Temperature exceeded	Not ready for use	Flashing red and green or orange alternately	Flashing red and green or orange alternately
Battery empty	Not ready for use	Flashing red	Flashing red
Error, defective	Not ready for use	Light red permanently	Light red permanently

In case of a temperature warning, the LED's flash in the corresponding colour of the current battery status (green or orange). If the temperature is exceeded, the colour of the LED's changes between red and the colour of the current battery state (green or orange).

2.5.2 LED display Drive Unit during charging process

Status	Charging status	LED 1	LED 2
Battery full	Not charging	Light green permanently	Light green permanently
Battery charge > 50 %	Charging	Flashing green	Flashing green
Battery charge < 50 %	Charging	Flashing orange	Flashing orange
Temperature exceeded	Not charging	Flashing red	Flashing red
Error, defective	Not charging	Light red permanently	Light red permanently

After the charging process is complete, the LED's light up green for 2 hours.
At the beginning of the charging process, the Drive Unit initially flashes orange for 2 – 5 seconds. Only after this time the current charging status is determined and correctly displayed via the LED colours.

2.5.3 Power supply indicator light during charging

Status	Charging status	Power supply unit display
Power supply unit connected to supply mains via power cable	Charging	Blue LED ring lights permanently
Power supply unit not connected to supply mains via power cable	Not charging	No display

2.6 Charging Unit

Only use the charging cable with power supply (Art. No. 199504) to charge the Drive Unit!
No other chargers may be used. This may damage the Drive Unit. The warranty is no longer valid if another charger is used.
Caution: Device defect!

Use the charger only in a dry environment and outside the surgical environment (with patient contact).
Caution: Device defect!

2.6.1 Charging cable initial operation

Before using the charging cable, make sure that no Drive Unit is connected to the charging cable.
Only connect the charging cable to the mains supply using the power supply supplied.
The charging cable is ready for use as soon as it is connected to the mains supply with the power supply. 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

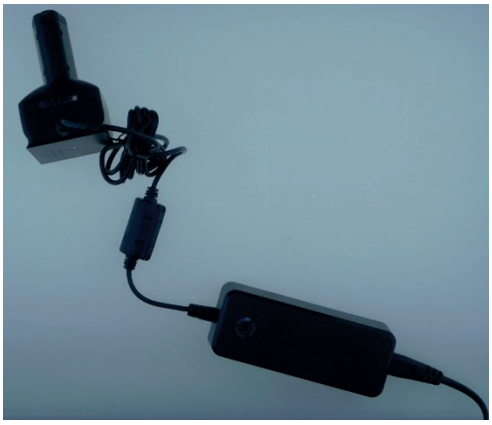
Clean only when the mains plug is disconnected. Wipe the charging cable with a dry or slightly damp cloth from time to time (do not use solvents).

2.6.3 Drive Unit charging

Connect the Drive Unit to be charged to the charging cable.

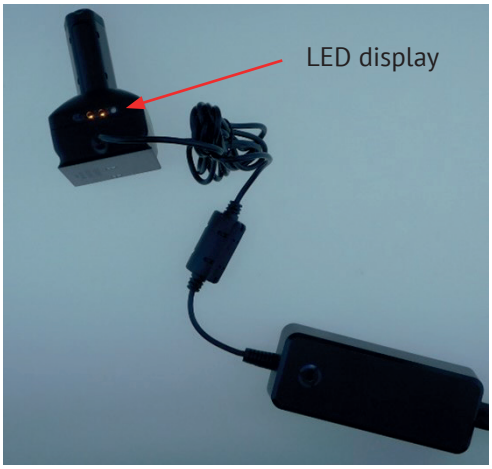
This is a magnetic contact, which means that the plug on the charging cable and the plug on the Drive Unit automatically connect a few millimetres before contact is made.

As soon as they are connected, the Drive Unit's LED lights up.



9. As soon as the Drive Unit is fully charged, the charger switches to trickle charge (Drive Unit indicator lights up green).

   The charging cable can be disconnected from the Drive Unit at any time. However, the full battery capacity is only available when the green indicator on the Drive Unit lights permanently.



2.6.4 Charge new or longer unused Drive Units

New Drive Unit and those which were not used longer than one month and were then not placed in a charger, obtain their maximum capacity only after initial three to five full charging cycles.

2.6.5 Drive Unit storage

After each use, remove the Drive Unit from the handpiece and then recharge it. Never store used Drive Units uncharged. Always recharge unused Drive Units within 6 months to retain full battery capacity.
Do not use Drive Units that have not been taken directly from the charging cable and for which the indicator on the Drive Unit has not light up green (fully charged). The charge level could otherwise possibly be too low for the application.
Warning: Extension of surgical operating time!

2.6.6 Indication on the Drive Unit after removing the charging cable

If the Drive Unit is removed from the charger before full charging, then no indicators lights on the Drive Unit.
When the Drive Unit is fully charged, its indicator light green after removal from the charger. The LED display will automatically disappear after two hours or after start in a handpiece. The LED display is provided to inform the surgical team that the Drive Unit is fully charged and ready for use.

2.6.7 Disconnect the charging cable from the mains supply

Before the mains cable is unplugged from the mains, it must be ensured there is no Drive Unit connected.

Attention:

- After supply failure or a change onto emergency power supply, the charger automatically switches on.
- Charge only (Art. No. 199502) Drive Units with the charger.
  Charging other batteries may pose a fire or explosion hazard.
  Warning: Hazard to users!

2.7 Application of the Different Attachments in General

Attention:

- If a DRAGONFLY-machine is not used during a surgical procedure, put it aside and ensure that it is stored in stable condition and cannot be tilted.
  Caution: Device defect!
- For protection against injuries, set the slider in its middle position on STOP LOCKING/SAFETY POSITION before any mounting/dismantling of cutting tools, as well as before placing the tool back down.
  Warning: Danger for the user!

2.7.1 Initial operation

Depending on application, set the slider to the clockwise or to the counterclockwise direction of the machine.
Speed control is possible with the trigger. Release of the trigger stops the machine.

2.7.2 Oszillationsmodus ein- und ausschalten

The oscillating mode can be switched on and off with the switch lever. If the switch lever is in the bottom position (symbol), then the oscillating mode is deactivated. If the switch lever is in the upper position (symbol), then the oscillating mode is activated.

2.7.3 Assembly/disassembly of the attachments

Remarks: The following instructions apply for all attachments.

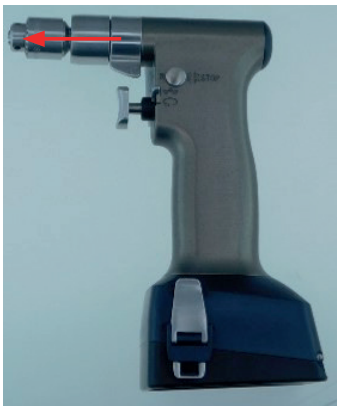
Attention:

- When attachments/cutting tools are mounted/removed, ensure against any unintentional start of the machine (STOP LOCKING/SAFETY POSITION).
  Warning: Danger for the user!
- After an attachment or a cutting tool is mounted, check its proper seat by pulling.
  Warning: Danger for the user!
- Use exclusively original attachments and tools from EICKEMEYER® or from manufacturers recommended by EICKEMEYER®.
  Caution: Device defect!
- Damages, resulting from the use of attachments or cutting tools of other manufacturers, are not covered by warranty.
- Cutting tools shall be cooled with irrigation liquid to prevent heat necrosis.
  Warning: Danger for the patient!
- Cutting tools may only be used once.
  Warning: Danger for the patient!

2.7.4 Attachment mounting
Secure the device against unintentional start (set the slider on STOP LOCKING/SAFETY POSITION).
Warning: Danger for the user!

1. Push in the attachment from the front until perceptible stop.


2. Then check if it is fit correctly by pulling gently on the attachment.




Before application of the tool in a patient, ensure that the correct mode is set, therefore activate the device shortly in the air.

2.7.5 Mount and remove cutting tools into the attachments
See the detailed description of all attachments (from chapter 2.8).

2.7.6 Attachment removal
Secure the device against unintentional start (set the slider on STOP LOCKING/SAFETY POSITION).
Warning: Danger for the user!

It is recommended to hold the device in the indicated position. The tool shall be slightly oriented upwards to avoid its drop.

Retract the release sleeve till the stop and hold the attachment with the other hand and remove it.
Release the release sleeve.
Lay aside the removed attachment.

2.8 Application of Rotating Attachments

When attachments and cutting tools are mounted/removed, ensure protection against any unintentional start of the machine (STOP LOCKING/SAFETY POSITION).
Warning: Danger for the user!

Attention:
Under no circumstances Drive Units shall be switched on to close the drill attachments.
Warning: Danger for the user!

2.8.1 Drill attachment with a key (Art. No. 199530, E19952001)

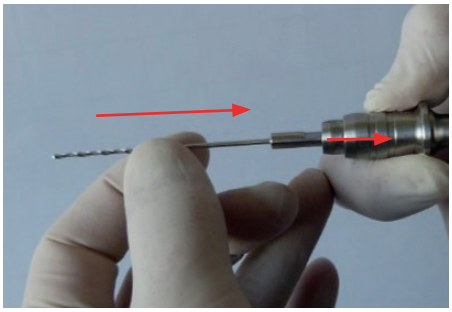
2.8.1.1 Assembly and disassembly of cutting tools

Open the drill chuck with the key included in the scope of delivery by turning it counterclockwise. Insert or remove the cutting tool. Turn the key clockwise, for closing.

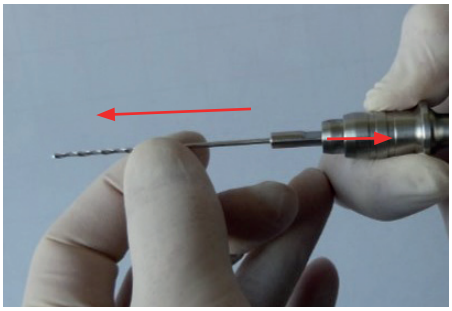
2.8.2 Quick-action chuck for AO-Attachments (Art. No. 199560)

2.8.2.1 Assembly and disassembly of cutting tools

Mounting: Insert the cutting tool with a light pressure and rotation forwards in the chuck. Simultaneously, move the coupling sleeve of the chuck backwards. When the cutting tool reaches the stop, release the coupling sleeve. Confirm the firm seat of the tool by pulling it slightly.



Dismantling: In order to remove the cutting tool, move the coupling sleeve of the chuck backwards and take out the tool.



2.9 Application of Quick-action Chuck for KIRSCHNER Wires (Art. No. 199530)

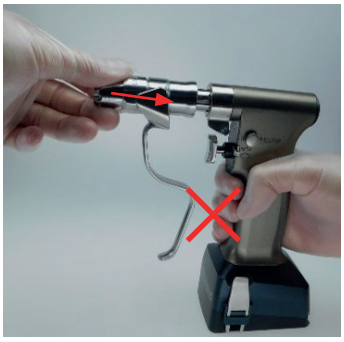
For inserting/removing of (KIRSCHNER) wires/pins of any length with a diameter of Ø 0.5 – 4.0 mm.
When attachments and cutting tools are mounted/removed, ensure protection against any unintentional start of the machine (STOP LOCKING/SAFETY POSITION).
Warning: Danger for the user!

Attention:
Under no circumstances Drive Units shall be switched on to close the KIRSCHNER wire attachments.
Warning: Danger for the user!

2.9.1 Inserting and positioning of Quick-action chuck for KIRSCHNER wires

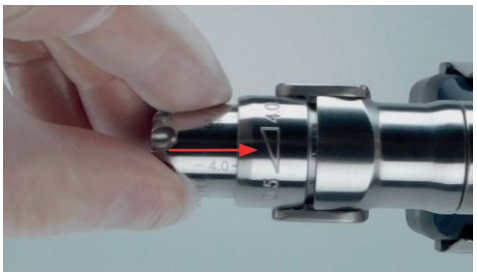
See chapter 2.7.3.
When mounting the Quick-action chuck for KIRSCHNER wires, it is necessary to ensure, that the Quick-action chuck for KIRSCHNER wires is aligned with axial lever for tensioning to the housing.

Consider that the fingers do not enclose the handle when inserting the attachment, otherwise the fingers may become slightly trapped for a short time if the adjustment sleeve is pressed at the same time.
Warning: Danger for the user!



2.9.2 KIRSCHNER wire insertion into the attachment

1. Set the adjusting sleeve on the front end of the attachment to the diameter of the KIRSCHNER wire to be inserted. For this, turn the adjusting sleeve while applying slight pressure.



2. Insert the KIRSCHNER wire into the attachment. The KIRSCHNER wire will be slightly clamped and held in the selected position.

2.9.3 KIRSCHNER wire insertion into bones

Pull the lever to the handpiece in order to clamp the KIRSCHNER wire and activate the trigger. If needed, release the lever in order to adjust the position of the KIRSCHNER wire in the attachment.

2.9.4 KIRSCHNER wire from bones

Set the required diameter on the adjustment sleeve of the attachment. Move the adjustment sleeve and the attachment above the KIRSCHNER wire. Pull the lever to the handpiece in order to clamp the KIRSCHNER wire and activate the trigger (with the slider moved for counterclockwise run) in order to pull the wire from the bone.

Attention:
The following procedures may lead to overloads:

- Correction of drilling angle, when the cutting grooves of the drill are fully inserted into the bone.
  Warning: Danger for the patient and for the user!
  Caution: Device defect!
- Drill jamming by drilling of of a KIRSCHNER wire or STEINMANN nail.
  Warning: Danger for the patient!
  Caution: Device defect!

It is mostly possible to continue operation after the following correction measures:

- Drill/Boring angle correction: Pull out the drill till the cutting grooves are visible and start the drilling procedure again.
- Drill/Boring of a KIRSCHNER wire or STEINMANN nail: Pull out the drill till the cutting grooves are visible, start drilling again or, if necessary, replace the drill.

2.10 Application Attachment Oscillating Saw (Art. No. 199540)

Attention:

- If the saw is not used during a surgical procedure, put it aside and ensure that it is stored in stable condition and cannot be tilted.
  Caution: Device defect!
- For protection against injuries, set the slider in its middle position on STOP LOCKING/SAFETY POSITION before any mounting/dismantling of cutting tools, as well as before placing the tool back down.
  Warning: Danger for the user!
- The oscillation mode must NOT be used as the operating mode when using the saw attachment. This mode has no function with a connected saw attachment.
  Warning: Extension of OP duration!

2.10.1 Inserting and positioning the saw attachment

See chapter 2.7.3.
When mounting the saw attachment, please note that the alignment of the saw attachment can be done in 90° steps (in axial direction) on the housing, depending on the insertion direction of the grooves on the attachment coupling.

2.10.2 Replacement of saw blades

Saw blades with the Stryker „EICKEMEYER® Saw“ connection shall exclusively be used.
Warning: Danger for the patient and for the user!
Caution: Device defect!

1. Open the clamping screw with key (Art. No. E199503001) 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. Lock the saw blade by turning the clamping screw clockwise with key (Art. No. E199503001).

   If using he key (Art. No. E199503001), tighten hand-tight.

Attention:
The saw blade must be correctly inserted into the holder via the contour in the saw blade. To ensure correct mounting of the saw blade, check that there is no gap between the saw blade and the cover, but that the saw blade lies flat.
Warning: Danger for the patient and for the user!

2.10.3 Working with the oscillating saw attachment
The device shall be started and run in the air before contact on bones. Do not apply any excessive pressure on the saw blade to avoid jamming. For optimal sawing performance, move the device slightly back and forth along the plane of the saw, so that the blade swings a little above the bone. Smooth and steady guidance of the saw ensures very precise cutting. Inaccurate cuts result from worn saw blades, excessive pressure or tilting of the blade.
Warning: Danger for the patient!

2.10.4 Recommendations for handling of saw blades
In order to obtain optimal results, EICKEMEYER® recomments that a new saw blade is used for every surgical procedure. In this way, it is assured that saw blades are always sharp and clean. Worn saw blades pose the following risks:

- Necrosis by strong heat development
- Infections by deposits
- Longer cutting time because of reduced saw performance

Warning: Danger for the patient!

Under the following conditions, noises and vibrations can deviate from normal values:

- The use of untypical saw blades
- Vertical saws
- The use of tools in poor condition
- The use of saw blades of other manufacturers

Saw blades shall always be cooled with a coolant to avoid heat necrosis.
Warning: Danger for the patient!

3. CARE AND MAINTENANCE (after validated cleaning and sterilisation procedures)

3.1 General Information

Handpieces and attachments are exposed to frequent mechanical loads and shocks during use and should not be expected to last indefinitely. Proper use and regular maintenance extend service life of surgical tools and instruments.
Repeated clinical reprocessing has a minimal effect on the service life of the Drive Units and attachments. Careful care and maintenance, as well as thorough oiling can significantly increase the reliability and durability of the system components.
EICKEMEYER® recommends annual inspections and maintenance, either by the original manufacturer or a selected authorised service station. The manufacturer accepts no responsibility for any defects/failures, arising either from improper handling of the devices or from their unauthorised maintenance. Assuming proper handling and authorised maintenance of the device, its service life is, at least, 3 years.

Attention:

- Clinical processing (includes cleaning and subsequent steam sterilisation/autoclaving) should always be done immediately after use.
  Caution: Device defect!
- Cannulations, release sleeves and other hard accessible sites require particularly diligent cleaning.
  Caution: Device defect!
- Drive Units and chargers shall 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 avoid contact of liquid with Drive Unit during use.
  Caution: Device defect!
- The cleaning agent may have a pH value between 7 – 9.5. Cleaners with pH above 11 may, depending on their cleaning agent, affect surfaces made of aluminium, aluminium alloys, plastic or composite materials, and shall be used only with consideration of data of material compatibility of used cleaner acc. to its data sheet. With pH values above 11, also stainless steel surfaces may be affected. For proper dilution, temperature, exposure time and water quality, follow the instructions of enzymatic cleaner or cleaning agent manufacturers in order to achieve an optimal cleaning effect. If there are no manufacturer's recommendations, regarding temperature and exposure duration, then follow the instructions of EICKEMEYER® (see from 3.2).
  Instruments should be cleaned in a freshly set up solution.
  Caution: Device defect!
- The used cleaning agents come in contact with the following materials: Stainless steel, aluminium, plastic and rubber seals.

The instruction, specified herein for the clinical processing, has been proven by the EICKEMEYER® Company. It meets the requirements of ISO 17664-1:2021 international standard and is intended for processing of non-sterile medical devices of the EICKEMEYER®Company.
Additional information is available from national laws and directives. The internal guidelines and procedural instructions of a hospital have to be considered too, as well as the recommendations and instructions of the manufacturers of cleaning and disinfection agents and of the systems for clinical processing.
The supplier is obligated to take responsibility for ensuring that the processing is carried out by properly trained personnel and with the use of appropriate, properly installed, maintained and checked systems and materials, in order to achieve the desired results. Any deviations from the above presented instructions have to be verified and assessed with regards to their possible, harmful impacts.

3.2 Preparation for Cleaning

3.2.1 Dismantling

Ensure that all the mounted parts are dismantled, the bottom cap is opened and the Drive Unit is removed from the machine/handpiece.
Caution: Device defect!
Powerpacks and chargers can be wiped with a dry or slightly damp cloth (do not use solvents).

Attention:
The Drive Units must not be washed, rinsed, disinfected or sterilised.
Caution: Device defect!

Clinical processing of handpieces and attachments can be done by machine/automatic cleaning cycle with manual pre-cleaning (see the following chapters).

3.3 Automatic Cleaning After Manual Pre-cleaning

Attention:

- The manual cleaning before the mechanic/automatic cleaning/disinfection is important because it ensures that cannulations and other hard accessible areas are clean.
  Warning: Danger for the patient!
  Caution: Device defect!
- No cleaning/disinfection procedure, alternative to the procedures, which are described below (including manual pre-cleaning) has been validated by EICKEMEYER®.
  Warning: Danger for the patient and for the user!
  Caution: Device defect!

3.3.1 Manual pre-cleaning of the handpiece

1. **Remove residues**
   Rinse handpiece under running, cold tap water for, a least, 2 minutes. Coarse impurities and deposits shall be removed with a sponge, a lint-free cloths and/or a soft brush. All cannulations shall be cleaned with a specially designed cleaning brush (Art. No. 195011). Triggers, release sleeves for attachments, mode-selection switches and other moving parts shall be moved at least 5 times in their entire mobility range under running cold water in order to lose and remove bigger deposits.

Attention:
Neither pointed nor sharp objects shall be used for cleaning.
Caution: Device defect!

2. **Spray with a cleaning agent**
   Spray all components with an enzymatic cleaner, a cleaning solution or a cleaning foam (0.5 % Neodisher Mediclean). Leave the agent on the components for, at least, 2 minutes and then wipe it down.
   For proper dilution, temperature, exposure time and water quality, follow the instructions of enzymatic cleaner or cleaning agent manufacturers in order to achieve an optimal cleaning effect.
3. **Clean with a cleaning solution**
   Clean with an enzymatic cleaner or a cleaning agent (0,5 % Neodisher Mediclean) under running water for, at least, 5 minutes. Move the moving parts at least 5 times in their entire mobility range under running cold water. Remove visible soiling and deposits with the aid of a soft brush and/or a lint-free cloth.
   For proper dilution, temperature, exposure time and water quality, follow the instructions of enzymatic cleaner or cleaning agent manufacturers in order to achieve an optimal cleaning effect.
4. **Rinse with tap water**
   Rinse the components thoroughly under cold to lukewarm, running water for, at least, 2 minutes. Use a syringe, pipette or water pistol to flush lumens and channels. Move the joints, handles and other moving parts at least 5 times in their entire mobility range in order to flush the mobility ranges thoroughly under running water.

5. **Check the components visually**
   Repeat steps 1 through 5 till all the components are free from any visual contamination.
   Subsequently to the above described manual cleaning, mechanic/automatic cleaning shall follow.
   Further see item 3.3.3 Automatic cleaning.

3.3.2 Manual pre-cleaning of the attachments

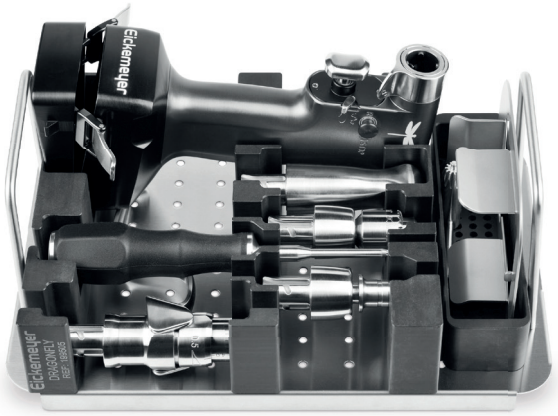
1. **Remove residues**
   Place the attachments (e.g. drill attachment/saw attachment) in cold tap water for 5 minutes.
   In addition, move all the moving parts at least 5 times in their entire mobility range under running water in order to loose and remove bigger deposits.
   Remove coarse impurities and deposits with a sponge, a lint-free cloths and/or a soft brush till no contaminations are visible. All cannulations shall be cleaned with a specially designed cleaning brush (Art. No. 195011).

   Attention:
   Neither pointed nor sharp objects shall be used for cleaning.
   Caution: Device defect!

2. **Cleaning in ultrasonic bath**
   Handle the attachments for 5 minutes in ultrasonic bath (0.5 % cleaning solution of Neodisher MediClean [Dr. Weigert, Hamburg], 40 °C).
3. **Cleaning with a water pistol**
   Flush all the gaps, joints and cavities with a water pistol for a minimum of 20 minutes.
4. **Check the components visually**
   Repeat steps 1 through 4 till all the components are free from any visual contamination.
   Subsequently to the above described manual cleaning, mechanic/automatic cleaning shall follow.
   Further see item 3.3.3 Automatic cleaning

3.3.3 Automatic cleaning

1. **Load a washing machine tray**
   Place all articles in the EICKEMEYER® tray (Art. No. 199505) specially designed for the system.



Cleaning programme
Remark: The cleaning/disinfection device shall meet the requirements of ISO 15883 international standard.
Cleaning agent: e.g neodisher MediClean (Dr. Weigert, Hamburg).

- 2-minute pre-cleaning with cold potable water
- Empty
- 5-minute cleaning with a 0.5 % cleaning solution at 55 °C
- Empty
- 2-minute neutralisation (Neodisher® Z)
- Empty
- 3-minute rinsing with cold, completely desalinated water
- Empty
- 2-minute final rinsing with cold, completely desalinated water
- Empty
- 5-minute thermal disinfection with hot completely desalinated water (≥ 93 °C)
- 40-minute drying (≥ 90 °C)

2. **Checking of components**
   Remove all components from the wash machine tray. Check all the cannulas, coupling sleeves, etc. for visible contamination/soiling.
   If necessary, repeat the automatic cleaning cycle with manual pre-cleaning.
   Devices/handpieces, especially seals and bearings, are particularly affected by automatic cleaning/disinfection.
   Especially, check carefully the circumferential gasket in the lid after cleaning for any damages.
   The components shall properly be oiled and regularly maintained.

3.4 Oiling/Maintenance

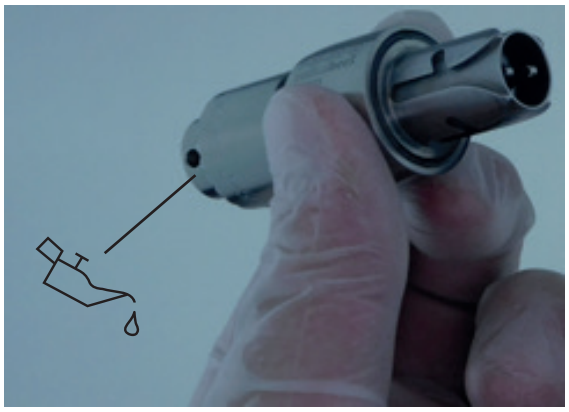
Regular oiling of the devices/handpieces and of the attachments guarantees their long service life and trouble-free operation. All the approachable moving parts of the devices/handpieces, the enclosure cover and the attachments, have to be oiled with a spray oil or a sterilisable oil (Art. No. 563706) prior to sterilisation. The component have to be moved afterwards several times to distribute the oil. Wipe excessive oil with a cloth.

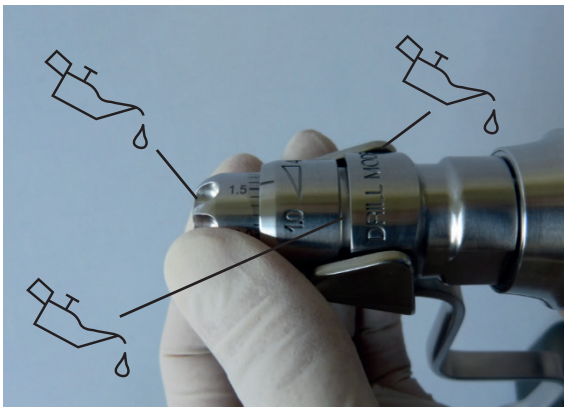
3.4.1 Handpiece

- Oil the pusher plunger, right/left-handed slider, switch lever and operate them several times.
- Oil the release sleeve via the drill hole and operate it several times without inserting the attachment.

3.4.2 Attachments

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





3.5 Packaging for Sterilisation Process

Cleaned and dry products shall be placed into a tray (Art. No. 199505) in intended positions. The screen basket shall additionally be wrapped in a sterile barrier material, acc. to ISO 11607 standard, e.g. in an appropriate sterilisation wrap or in a multi-use sterilisation container (Art. No. 185555).

Protect pointed or sharp instruments from damage by mutual contact.
Caution: Device defect!

Take care, that sharp or pointed objects do not damage the sterile barrier material.
Warning: Danger for the patient!

3.6 Sterilisation

Attention:
Never sterilise the powerpack, as the sterilisation process can damage it. The Drive Unit has to be removed before sterilisation from the device/handpiece.
Warning: Danger for the user!
Caution: Device defect!

The systems may be resterilised in a validated steam sterilisation process (acc. to ISO 17665 or national standards). EICKEMEYER® recommends the following parameters for instruments and the tray:

Sterilisation procedure (cycle)	Territory	Sterilisation duration	Sterilisation temperature	Drying time
Steam sterilisation (fractionated pre-vacuum) (at least 3 intervals)	US	at least 4 minutes	at least 132 °C maximum 138 °C	20 –60 minutes
	EU	at least 5 minutes	at least 134 °C maximum 138 °C	20 –60 minutes

The drying times vary between 20 and 60 minutes, depending on various packaging materials (sterile barrier systems consisting of a sterilisation wrap or a multi-use sterilisation container), steam quality, the materials of the products to be sterilised, the total weight, the performance characteristics of the steriliser and various cooling times.

Attention:

- The following maximum values shall not be exceeded: 143 °C above maximum 22 minutes.
- Do not accelerate the cooling process.
- Sterilisation in hot air, ethylene oxide, radiation, plasma and formaldehyde shall not be applied.

Caution: Device defect!

3.7 Repairs and Technical Service

In case of any defect or malfunction of the device, send it for repair to EICKEMEYER® or to any authorised service station.
Caution: Device defect!

A dropped device must be sent for inspection and repair.
Caution: Device defect!

Defective device must not be used further.
Warning: Danger for the patient and for the user!

If repair is neither possible nor justified, put the device to disposal. See the instructions in the chapter disposal.

Except the above-mentioned care and maintenance measures, no maintenance steps may be undertaken, either by the user or any third person.
Warning: Danger for the patient and for the user!
Caution: Device defect!

EICKEMEYER® recommends that the device and its accessories, as well as the attachments are regularly (at least once a year) maintained by the manufacturers or an authorised service station to ensure safe and proper operation on an ongoing basis.

No battery cells may be replaced. In case of any defect of the Drive Unit, send it to the EICKEMEYER® company or to any authorised service station.
Warning: Danger for the patient and for the user!
Caution: Device defect!

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

- Batteries with a defect that impairs safety,
- Batteries with damaged or significantly deformed cases,
- Leaking batteries or batteries with gas leakage, or
- Batteries with defects that cannot be diagnosed before transport to the place of analysis.

If the batteries are merely inoperable, no special conditions apply.
Warning: Danger for the user!

Attention:
Do not make any modifications to this unit without the approval of the manufacturer. If this unit is modified, appropriate inspections and tests must be carried out to ensure safe use of the unit.

Attention:
The manufacturer accepts no responsibility for damages, which may arise from improper operation of the system or from its maintenance provided by unauthorised service stations.
Warning: Danger for the patient and for the user!
Caution: Device defect!

4. TROUBLESHOOTING

4.1 Device / Handpiece and Enclosure Cover

Problem	Possible cause	Remedy / corrective action
Machine does not start	No Drive Unit in the handpiece	Insert a charged Drive Unit
	Drive Unit is unloaded	Charge the Drive Unit
	Safety system is activated (slide in safety position)	Set the slider to clockwise or counter-clockwise rotation
	Drive Unit is defective	Send the Drive Unit the EICKEMEYER® service station
	Overheating protection is activated; LED's flash alternately red and green or red and orange	Let the machine cool down
Machine has insufficient power	Drive Unit is discharged; indicator on Drive Unit already red	Antriebseinheit aufladen
	Machine and/or attachments are poorly maintained	Send the machine and attachments to the EICKEMEYER® service station
Machine stops suddenly	Drive Unit is discharged; indicator on the Drive Unit lights up red	Charge the Drive Unit
	Machine is overheating; the LED's have already alternately flashed green or orange. Indicator on the Drive Unit alternately red and green or red and orange	Cool down the machine
	Machine or Drive Unit is defective	Insert a fully charged Drive Unit into the machine. If this does not help, send the machine to the EICKEMEYER® service station
Machine continues to run after the pusher is released	Pusher is blocked by deposits (e.g. blood)	Press the button several times, clean and maintain the machine according to instructions.
	Drive Unit is defective	Remove the Drive Unit and let it run until it stops. Then send the Drive Unit to the EICKEMEYER® service station
Machine becomes noticeably warm/hot	Machine has been subjected to heavy use	Let the machine cool down
Machine runs too slowly	Pusher blocked and cannot be operated to the intended stop	Clean and oil the pusher, remove any deposits or blockages underneath the pusher
	Speed transmission from machine to attachment is defective	Operate the machine without the attachment and check whether the drive shaft rotates fast enough, if not, send the machine to the EICKEMEYER® service station

Problem	Possible cause	Remedy/corrective action
Machine saws too slowly	Pusher blocked and cannot be operated to the intended stop	Clean and oil the pusher, remove any deposits or blockages below the pusher
	Speed transmission from machine to attachment is defective	Operate the machine without the attachment and check whether the drive shaft rotates fast enough, if not, return the machine to the EICKEMEYER® service station
	Saw blade is not tightened	Tighten the saw blade tensioning screw
Oscillating saw vibrates too much	Saw blade fastening is not tightened or has come loose	Tighten the saw blade tensioning screw
Attachments cannot be fitted to the machine	Machine clutch is clogged with deposits	Remove deposits by cleaning thoroughly and then oiling
	Locking mechanism defective	Oil the mechanism and move it, if it still does not work, send the machine to the EICKEMEYER® service station
Attachments cannot be removed from the machine	Unlocking sleeve for attachments is blocked/clogged with debris	Check the release sleeve, clean and oil if necessary
	Locking mechanism defective	Return the machine to the EICKEMEYER® service station
Pusher is difficult to move	Pusher is blocked by deposits	Clean and oil the pusher
	Mechanism defective	Return the machine to the EICKEMEYER® service station

4.2 Drive Unit

Problem	Possible cause	Remedy / corrective action
Drive Unit cannot be inserted into the handpiece	Drive Unit is deformed, possibly due to a fall	Send the Drive Unit to the service station of EICKEMEYER®, follow point 3.7 Repair and technical service
Drive Unit cannot be removed from the handpiece	Drive Unit has a tight fit due to the rubber buffers	Pull the Drive Unit a little harder to loosen it
	Drive Unit is blocked in the handpiece	Return the machine to the EICKEMEYER® service station
Fully charged Drive Unit does not work	Safety system is activated (slider in safety position)	Set the slider to clockwise or counter-clockwise rotation
	The Drive Unit is defective, e.g. because it has been dropped after being disconnected from the charging cable or has come into contact with liquids	Send the Drive Unit to the service station of EICKEMEYER®, follow point 3.7 Repair and technical service
LED indicator lights up continuously	The Drive Unit is connected to the charger	No defect. The LED's in the connected charger light up continuously
	The fully charged Drive Unit has been disconnected from the charger and has not yet been used in the handpiece	No defect. After disconnecting a fully charged Drive Unit from the charger, the LED's light up green for 2 hours
LED indicator does not light up Drive Unit connected to charging cable	Charging cable is not plugged in	Connect the charging cable to the mains supply using the device cable supplied
	Charging cable has a fault	Let the charging cable be checked by a EICKEMEYER® service station and repaired if necessary
	Drive Unit has a fault	Send the Drive Unit to the service station of EICKEMEYER®, follow point 3.7 Repair and technical service
Light indicator of the Drive Unit does not light up	Charging cable is not plugged in	Connect the charging cable to the mains supply using the device cable supplied
Drive Unit was accidentally washed, immersed in liquids or sterilised and is defective	Inadvertence of the personnel	There is a small dot next to the LED's. If this is coloured grey, the Drive Unit has been sterilised
Drive Unit housing has visible damages	The Drive Unit has been exposed to excessive heat	Send the Drive Unit to the service station of EICKEMEYER®, follow point 3.7 Repair and technical service
	The Drive Unit was dropped	Send the Drive Unit to the service station of EICKEMEYER®, follow point 3.7 Repair and technical service
Drive Unit is not powerful enough	Drive Unit has been stored separately from the charging cable for longer than 1 month and has not been used	3 – 5 charge / discharge cycles are necessary to restore the Drive Unit to its optimum capacity
LED indicator flashes red or is continuously red, although the charger's indicator light is on and the Drive Unit is plugged in	The Drive Unit has a malfunction	Send the Drive Unit to the service station of EICKEMEYER®, follow point 3.7 Repair and technical service

4.3 Attachments and Tools

Problem	Possible cause	Remedy/corrective action
Attachments cannot be mounted on the machine	Attachment coupling is blocked by deposits	Remove deposits by cleaning thoroughly and oiling
Attachments cannot be dismantled from the machine	Release sleeve for attachments is blocked/clogged by deposits	Check the release sleeve, clean and oil if necessary. If necessary, send the machine to the EICKEMEYER® service station
Cutting tool cannot be mounted on an attachment or can only be mounted with difficulty	Locking mechanism is blocked by deposits	Remove deposits by cleaning thoroughly and then oiling
	Attachment or tool is deformed due to improper use (e.g. falling), wear and tear	Replace the attachment or tool or send it to the EICKEMEYER® service station
Attachment becomes noticeably warm/hot	Attachment has been subjected to heavy wear	Cool down the attachment and oil it before the next use
The KIRSCHNER wire/pin cannot be inserted into the KIRSCHNER wire attachment	The KIRSCHNER wire attachment is not open	Set the adjustment sleeve of the attachment to the correct wire diameter
The KIRSCHNER wire/pin cannot be gripped even though the tensioning lever is actuated	The KIRSCHNER wire attachment is not open wide enough	Set the adjustment sleeve of the attachment 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	Return the KIRSCHNER wire attachment to the EICMEMEYER® service station
Bone and tool heat up due to the working process	The cutting tool is blunt	Replace tool

4.4 Charging Cable with Power Supply

Problem	Possible cause	Remedy / corrective action
No indicator light on the Drive Unit	Power cable is not plugged in	Connect the charging cable to the mains supply using the device cable supplied
	Charging cable has a fault	Let the charging cable be checked by an EICKEMEYER® service station and repaired if necessary
Drive Unit connected to charging cable, no indicator on Drive Unit	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 of the Drive Unit	Disconnect the charging cable from the Drive Unit, disconnect the charging cable from the mains supply, wipe the charging contact of the cable and Drive Unit with a cloth and reconnect
	Charging cable has a fault	Let the charging cable be checked by an EICKEMEYER® service station and repaired if necessary
	Drive Unit has a fault	Let the charging cable be checked by an EICKEMEYER® service station and repaired if necessary
Drive Unit with red flashing display	Drive Unit temperature is too high	Connect the powerpack to the charging cable, after cooling down the charging process starts automatically
	Drive Unit is deeply discharged	Fully discharged Drive Unit was not recharged immediately after use and was not used for several weeks. several charging / discharging cycles are necessary to restore the optimum capacity of the Drive Unit

Remark: If the above steps fail to remedy the problem, please contact your EICKEMEYER® service station.

5. TECHNICAL DATA

5.1 Operating Cycle

Device (each with 199520 handpiece together with the subsequent attachment:)	**Switch-on time**	**Switch-off time**	**Cycles**
199530 Jacobs drill chuck attachment at oscillating mode	20 seconds	40 seconds	5
199560 Quick-action chuck for AO-Attachments	60 seconds	120 seconds	5
199530 Jacobs drill chuck attachment	60 seconds	120 seconds	5
199540 Attachment oscillating saw	30 seconds	60 seconds	5
199550 Quick-action chuck for KIRSCHNER wires	20 seconds	40 seconds	5

When oscillating mode and sawing attachments are used, the operator should not work longer than 30 minutes per day.
Warning: Danger for the user!

The recommended application durations of the devices have been calculated at their average load and for ambient temperature of +20 °C.
The machines get heated under continuous load.

After the above-mentioned active period, both the handpiece and the used accessories must cool down at least for turn-off time duration. After five cycles, both the handpiece and the accessories must cool down for at least 30 minutes. Compliance with these regulations prevents overheating of the system. In this way, patient's or user's injuries can be excluded. The user is responsible for the application and adherence to cooling phases. For longer constant load periods it is recommended to have an additional device, as well as additional attachments at hand.
Warning: Danger for the patient and for the user!
Caution: Device defect!

Attention:

- Always adhere to recommended operation cycles. Device is not suitable for permanent operation.
  Caution: Device defect!
- Only new cutting tools shall be used in order to avoid overheating of the system from reduced cutting performance.
  Caution: Device defect!
- In order to avoid heat necrosis, always flush the cutting tools with cooling fluid. Manual flushing.
  Warning: Danger for the patient!
- Careful care and maintenance of the system reduces development of heat in the handpiece and in attachments.
  Caution: Device defect!

5.2 Device Specification

Handpiece (Art. No. 199520)	
Handpiece dimensions (without attachment) (W x H x D)	100 x 190 x 68 mm
Mass of handpiece without powerpack	590 g
Continuously adjustable rotation speed	0 – 1.350 rpm
Cannulation	Ø 4,3 mm cannulation
Protection class	B, EN 60601-1
Application parts	Whole operational handpiece with attachment (type B)
IP protection	IPX0
Power supply	Internal battery

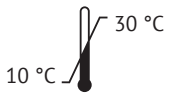
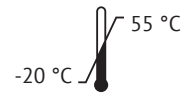
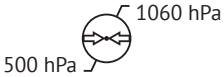
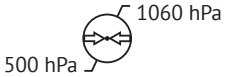
Art. No.	Attachment	Continuously adjustable speed	Mode-DRILL	Mode-OSCI	Cannulation
199560	Quick-action chuck for AO-Attachments	0 – 1.350 rpm	X	X	Ø 4,3 mm
199530	Jacobs drill chuck attachment	0 – 1.350 rpm	X	X	Ø 4,0 mm
199540	Attachment oscillating saw	0 – 14.000 cpm	X	(not permissible)	
199550	Quick-action chuck for KIRSCHNER wires	0 – 1.350 rpm	X	X	Ø 4,0 mm

Note: Performance data is subject to technical fluctuations.

Drive Unit / battery (Art. No. 199502)	
Dimensions (W x H x D)	73 x 102 x 54 mm
Mass	450 g
Type	Li-Ion
Max. voltage	8,4 V
Operating voltage (rated voltage)	7,2 V
Capacity	2,5 Ah
Typical charging time	< 90 min

Charging cable with power supply (Art. No. 199504)	
Dimensions	124 x 50 x 37 mm
Mass	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 Environmental Conditions

	Operation	Transport and storage
Temperature		
Relative air humidity		
Air pressure		

Attention:
The devices must not be stored or operated in an explosive atmosphere.

5.4 Applicable Standards

The devices complies with the following standards and directives:

- Regulation (EU) 2017/745 of 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: Supplementary standard: Electromagnetic disturbances

5.5 Electromagnetic Compliance

Attention:

In general, mutual disturbances of electric devices cannot be fully excluded. We strongly advise compliance with the following recommendations (distances) and observance of the instructions of other used electrical equipment.

The DRAGONFLY-system is intended to be used in professional healthcare facility environment, expect near active HF surgical equipment and outside the RF shielded room with high intensity EM disturbances.

In case of exposure to electromagnetic disturbances, unwanted speed fluctuations or even drop out may occur on DRAGONFLY-system machines. Thus any operation may be conducted only conditionally. No essential performance is defined for DRAGONFLY-system, that can be affected and lead to an unacceptable risk due to electromagnetic disturbances.

Use of this unit immediately adjacent to other units or in stacked form to other units should be avoided as this may result in incorrect operation. If use in the prescribed manner is nevertheless necessary, this unit and the other units should be observed to ensure that they are operating properly.

The use of accessories other than those specified or provided by EICKEMEYER® may result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and may lead to incorrect operation.

Portable and mobile RF communications equipment (radio equipment) (including their accessories, like, for example, aerial cables or external aerials) shall be used no closer to the DRAGONFLY-system equipment than 30 cm (or 12 in.). Any non-observance of this recommendation may lead to reduced performance of the devices.

Accompanying documents acc. to IEC 60601-1-2, item 5.2

Table 1:

Guidance and manufacturer's declaration – electromagnetic disturbance emissions		
The DRAGONFLY-system is intended for use in the electromagnetic environment specified below. The customer of the user of the system must ensure that the system is used in such environment.		
Interference emissions-measurements	**Compliance**	**Electromagnetic environment – guidelines**
RF emissions acc. to CISPR 11	Group 1	The system uses RF energy exclusively for its internal functions. Therefore, its RF emissions are very small and improbable to affect operation of adjacent/closely located electronic equipment
RF emissions acc. to CISPR 11	Class A	The system is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Emission of harmonic oscillations acc. to IEC 61000-3-2	Class A	Not applicable. Rated power of charger is less than 75 W
Emissions of voltage fluctuations/ flicker emissions acc. to IEC 1000-3-3	In compliance	

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

Table 2:

Guidance and manufacturer's declaration – electromagnetic immunity			
The DRAGONFLY-system is intended for use in the electromagnetic environment specified below. The customer of the user of the system must ensure that the system is used in such environment.			
Interference immunity-tests	**IEC 60601-1-2 testing level**	**Compliance level**	**Electromagnetic environment – guidelines**
Static electricity discharge (ESD) according to IEC 61000-4-2 standard	Contact discharge ± 8 kV Air discharge ± 15 kV	Contact discharge ± 8 kV Air discharge ± 15 kV	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity shall be at least 30 %
Electrical fast transient disturbances/bursts acc. to IEC 61000-4-4	± 2 kV for network lines ± 1 kV for input and output lines	± 2 kV for network lines ± 1 kV for input and output lines	The quality of the supply voltage should be to the standard of a typical business or hospital environment
Surge voltages acc. to IEC 61000-4-5	Line to Line: ±1.0 kV	Line to Line: ±1.0 kV	The quality of the supply voltage should be to the standard of a typical business or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines acc. to IEC 61000-4-11	0 % U_T für 0.5 cycle (1 phase) 0 % U_T für 1 cycle 70 % U_T für 25/30 cycles (50/60 Hz)	0 % U_T für 0.5 cycle (1 phase) 0 % U_T für 1 cycle 70 % U_T für 25/30 cycles (50/60 Hz)	The quality of the supply voltage should be to the standard of a typical business or hospital environment. If the user of the system needs to continue the undertaken procedure also when energy supply is broken, it is advised to supply the system either from an interruption-free mains or from a battery

Guidance and manufacturer's declaration – electromagnetic immunity							
The DRAGONFLY-system is intended for use in the electromagnetic environment specified below. The customer of the user of the system must ensure that the system is used in such environment.							
Interference immunity-tests	**IEC 60601-1-2 testing level**			**Compliance level**			**Electromagnetic environment – guidelines**
Magnetic field with the supply voltage frequency of 50/60 Hz shall conform to IEC 61000-4-8	30 A/m			30 A/m			Power frequency magnetic fields should correspond to their standard values at typical business or hospital environment
Immunity to proximity field from RF wireless communication equipment as defined in Table 9 of IEC 60601-1-2	Band (MHz)	Frequency (MHz)	Immunity test level (V/m)	Band (MHz)	Frequen-cy(MHz)	Immunity test level (V/m)	
	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 proximity magnetic fields acc. to 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			
Remark: U_T is the a.c. mains voltage prior to application of the test level							

Table 3:

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer of the user of the system shall ensure that the system shall be used in such environment.			
Interference immunity-tests	**IEC 60601-testing level**	**Compliance level**	**Electromagnetic environment – guidelines**
Conducted RF disturbances acc. to IEC 61000-4-6 Radiated RF disturbances acc. to IEC 61000-4-3	3 V effective value 150 kHz to 80 MHz 6 V effective value ISM-frequencies between 150 kHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 V effective value 150 kHz to 80 MHz 6 V effective value ISM-frequencies between 150 kHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz	Portable and mobile communication devices shall not be used in closer proximity of the system or its cables than the recommended safety distance, calculated from the equation applicable to the frequency of the transmitter. Recommended safety distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.5 GHz whereby *P* is the nominal power output of the transmitters in Watts (W), according to the transmitter manufacturer and d is the recommended safety distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol. 
Remark 1	Bei 80 MHz und 800 MHz gilt der höhere Frequenzbereich.		
Remark 2	Diese Leitlinien mögen nicht in allen Fällen anwendbar sein. Die Ausbreitung elektromagnetischer Größen wird durch Absorptionen und Reflexionen der Gebäude, Gegenstände und Menschen beeinflusst.		

a Field strengths from fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot, theoretically, be accurately predetermined. In order to assess the electromagnetic environment, due to fixed RF transmitters, an electromagnetic site survey shall be carried out. If the measured field strength in the location in which the system is used exceeds the above-mentioned level, then the system shall be monitored to verify normal operation If abnormal performance is observed, additional measures may be necessary, such as, for example, re-orienting or relocating of the system.

b Above the frequency range from 150 kHz to 80 MHz, the field strength shall be lower than 3 V/m.

Table 4:

Recommended safety distances between portable and mobile RF telecommunications equipment and the system			
The system is intended for use in the electromagnetic environment in which RF disturbances shall be controlled. The customer or user of the system can thus help avoid electromagnetic interference by maintaining the minimum safe distance between portable and mobile RF telecommunication devices (transmitters) and the system - depending on the maximum output power of the communications equipment, as specified below.			
Rated power of the transmitter W	**Safety distance, depending on 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 nominal power output is not covered by the above table, the recommended working clearance d in meters (m) can be determined, using the equation in the corresponding column, where P is the maximum nominal output of the transmitter in watts (W) specified by the transmitter manufacturer.			
Remark 1	The higher frequency range applies at 80 MHz and 800 MHz.		
Remark 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.		

6. ORDERING INFORMATION

The below listed products are an integral part of the present instruction for use. An appropriate QR card with information on how to access the electronic instructions for use is enclosed with every product delivery.

Art. No.	Description	Quantity
199500	DRAGONFLY Cordless Drill System, consisting of:	
199501	DRAGONFLY Transport Case, dimensions (in mm): L 400 x H 320 x D 100	1
199520	DRAGONFLY Handpieces, without adapters and battery/Drive Unit	1
199530	DRAGONFLY Jacobs Chuck, cannulated with key Ø 0.0 – 4.0 mm	1
199540	DRAGONFLY Oscillating Saw Attachment	1
199550	DRAGONFLY Quick Action Chuck for KIRSCHNER Wires Ø 0.5 – 4.0 mm	1
199560	DRAGONFLY Quick gction Chuck for AO-attachments	1
199502	DRAGONFLY Drive Unit with Battery	1
199503	DRAGONFLY Sterile-funnel for Handpiece	1
199504	DRAGONFLY Charging cable with Power Supply	1
199541	DRAGONFLY Saw Blade with STRYKER Connection, dimensions (in mm): L 18.5 x W 5.5 x H 0.5	1
199542	DRAGONFLY Saw Blade with STRYKER Connection, dimensions (in mm): L 29.5 x W 7 x H 0.5	1
199543	DRAGONFLY Saw Blade with STRYKER Connection, dimensions (in mm): L 34.5 x W 12 x H 0.4	1
199544	DRAGONFLY Saw Blade with STRYKER Connection, dimensions (in mm): L 35.5 x W 9.5 x H 0.4	1

Art. No.	Description – Recommended Accessories	Quantity
199505	DRAGONFLY Sterilisation tray, empty	1
195011	Cleaning brushes Ø 4 mm, L 350 mm, Pack of 3 pieces	1
563706	AESCULAP Oil Spray STERILIT, 300 ml	1

Art. No.	Description – Optional Accessories	Quantity
199545	DRAGONFLY Saw Blade with STRYKER Connection, dimensions (in mm): L 18,5 x B 7 x H 0,5	1
199546	DRAGONFLY Saw Blade with STRYKER Connection, dimensions (in mm): L 25,5 x B 5,5 x H 0,5	1
199547	DRAGONFLY Saw Blade with STRYKER Connection, dimensions (in mm): L 45 x B 13 x H 0,6	1
E19952001	DRAGONFLY Key for Jacobs Chuck	1
E19953001	DRAGONFLY Key for Oscillating Saw Attachment	1

7. USED SYMBOLS

The following symbols are applied on the device or on individual components:

	Attention: Read the delivered IFU before device operation.	CE 0483	Mark of conformity with European Directive 2017/745 and number of the notified body by EICKEMEYER®
	Read the delivered IFU before device operation.		The device is classified as type B, regarding protection against electric shock and electric leakage currents. The device is suitable for use on patients in conformity with IEC 60601-1 standard.
	Date of manufacturing		Store dry
LOT	Batch designation		The slider in the middle position → LOCKING/SAFETY POSITION The device cannot be unintentionally started
REF	Order number	R	Slide extended → Clockwise rotation
SN	Serial number	L	Slide retracted → Counterclockwise rotation
	Temperature limit		The oscillating mode is off
	Manufacturer		The oscillating mode is on
	Non-sterile		Release sleeve for the attachments
	Air humidity, limit		Bore hole for oiling the attachment coupling
	Air pressure, limit		Charger ready for use
 Li-Ion	The device contains batteries (Li-Ion = chem. symbol of harmful substance) Batteries shall properly be disposed, taking into account environment protection. Battery disposal must comply with national laws or with the european battery directive: 2006/66/EC and Waste Electrical and Electronic Equipment 2012/19/EU. **Attention:** Fire, explosion and burn hazard. The battery cells (batteries) must not be segmented or taken apart, shorted or crushed, or heated over +60 °C or burned.		

8. ADDRESS / REPORT

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For repairs / complaints:
repair@eickemeyer.de

CE 0483

NOTES

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