UNIUM™

POWER TOOL FOR SMALL BONE TRAUMATOLOGY, ORTHOPEDIC SURGERY AND STERNOTOMIES

Instructions for Use

Table of Contents

Glossary

The following abbreviations are used in the UNIUM™ Instructions for Use:

Abbreviation	Description
W	Watt
rpm	Revolutions per minute
Nm	Newtonmeter
osc./min	Oscillations per minute
g	Gram
kg	Kilogram
lbs	Pound
mm	Millimeter
m	Meter
L × W × H	Length × Width × Height
sec	Second
min	Minute
h	Hour
° C	Degrees Celsius
° F	Degrees Fahrenheit
hPa	Hectopascal
V	Volt
Ah	Ampere hour
Wh	Watt hour

■ **Notes**
▲ **Precautions**
▲ **WARNINGS**

UNIUM™ Portfolio Overview

UNIUM™ Modular Handpiece (05.001.601)*

Speed (without attachment):	0–3,400 rpm
Torque (with reaming attachment):	0–6.0 Nm
Weight:	750 g/1.65 lbs (incl. Power Unit)
Size:	117 × 64 × 181 mm (L × W × H)
Cannulation:	∅ 3.2 mm
Protection against electric shock:	BF IEC 60601-1
Protection against water ingress:	IPX6 / IPX8 / IPX9

The handpiece is compatible with a full range of attachments and Small Bone Cutting Tools.

Attachments for UNIUM™ Modular Handpiece

To be used for drilling, reaming, screwing, wire setting, burring and sawing.

Cutting Tools

Detailed ordering information on the cutting tools can be found in the brochure “Small Bone Cutting Tools”.

* Technical data is subject to tolerances.

UNIUM™ Reciprocating Saw Handpiece (05.001.611)*

Speed:	0–12,400 osc./min
Size:	178 × 64 × 186 mm (L × W × H)
Stroke:	4 mm
Weight:	915 g/2.02 lbs (incl. Power Unit)
Protection against electric shock:	BF IEC 60601-1
Protection against water ingress:	IPX6 / IPX8 / IPX9

Size and weight figures do not include the Top for Sternum and Reciprocating Saw Blade.

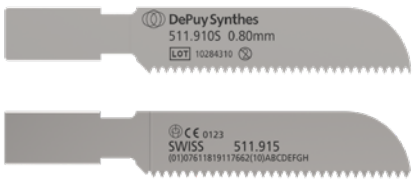
This image shows the Top for Sternum (05.001.612) and Reciprocating Saw Blade (511.910S) connected to the Reciprocating Saw Handpiece. Both articles are sold separately.

UNIUM™ Top for Sternum for Reciprocating Saw Handpiece (05.001.612)

Size:	91 × 35 × 29 mm (L × W × H)
Weight:	40 g/0.09 lbs

The Top for Sternum is compatible with the UNIUM Reciprocating Saw Handpiece and the following saw blades:

Reciprocating Saw Blades	
511.910S**	Reciprocating Saw Blade 41.5 × 10 × 0.80 mm
511.915S***	Reciprocating Saw Blade 41.5 × 10 × 1.10 mm



All other Reciprocating Saw Blades are compatible with the UNIUM Reciprocating Saw Handpiece (05.001.611), but can not be used with the Top for Sternum (05.001.612). A list of these saw blades can be found in the brochure “Small Bone Cutting Tools”.

* Technical data is subject to tolerances.
** Supplied exclusively in sterile packaging. The saw blade is single use only.
*** Supplied in either sterile or non-sterile packaging. The saw blade is reusable.

UNIUM™ Power Unit (05.001.602)*

Incorporates the Li-Ion battery and the electronic control unit.

Battery inside:	Li-Ion (Lithium Ion)
Operating voltage (rated):	10.8 V
Battery capacity:	2.0 Ah/21.6 Wh
Size:	84 × 54 × 145 mm (L × W × H)
Weight:	248 g/0.55 lbs
Charging Time:	typically <60 minutes
International Air Transport Association (IATA) regulation:	UN 3481 PI 967
Protection against water ingress:	IPX4

Battery level indicator can be found on the underside of the Power Unit.

UNIUM™ Sterile Cover (05.001.603)

To be used for the aseptic transfer technique of the Power Unit detailed on page 15.

UNIUM™ Adapter for UBC II (05.001.604)

To charge the Power Unit with the Universal Battery Charger II.

Universal Battery Charger II (05.001.204)

In order for the Power Unit to be recognized and charged by the UBC II, a minimum of firmware 16.0 is required. A label placed on the underside of the charger indicates which firmware it has (see page 13).

The image shows the UNIUM Adapter for UBC II inserted in the charger and the UNIUM Power Unit connected to it.

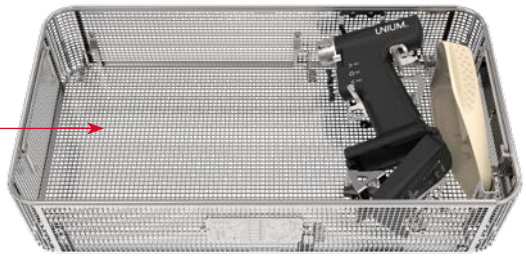
* Technical data is subject to tolerances.

Washing and Sterilization Basket for the UNIUM™ Modular Handpiece items 68.001.650 + 68.001.653 + 68.001.654

Insert Tray for Washing and Sterilization Basket, size 1/1, for UNIUM™ Modular Handpiece (68.001.654)

The insert tray is placed in the basket to hold the attachments during automated washing and sterilization procedure. It can also be taken out of the basket and placed on the operating room table to store the attachments and place the handpiece in an upright position.

Washing and Sterilization Basket, size 1/1, for UNIUM™ Modular Handpiece, without lid, without insert tray (68.001.650)



Lid for Washing and Sterilization Basket, size 1/1, for UNIUM™ Modular Handpiece (68.001.653)

All items 68.001.650, 68.001.653 and 68.001.654 need to be ordered separately.

Washing and Sterilization Basket for the UNIUM™ Reciprocating Saw Handpiece items 68.001.651 + 68.001.652

Lid for Washing and Sterilization Basket, size ½, for UNIUM™ (68.001.652)

Washing and Sterilization Basket, size ½, for UNIUM™ Reciprocating Saw Handpiece, without lid (68.001.651)

The images show the baskets fully loaded, all handpieces, attachments and accessories must be ordered separately.

General Information

Introduction

The UNIUM Portfolio consists of the following items:
- Modular handpiece
- Reciprocating Saw handpiece
- Power Unit
- A range of specially designed attachments and accessories.

Important note for medical professionals and operating room staff: These Instructions for Use do not include all of the information necessary for selection and use of the devices.

In addition, please read the following documents carefully before using UNIUM:
- Universal Battery Charger II Instructions for Use
- Cutting Tools Instructions for Use
- Care and Maintenance Poster UNIUM
- Brochure titled "Working with the Radiolucent Drive"

When working with implants, ensure you are familiar with the appropriate technique by referring to the Synthes Implant Instructions for Use. The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating.

Intended Use

UNIUM is a battery-driven Power Tool intended for use in traumatology and orthopedic surgery which may include drilling, reaming, burring, screwing, tapping, sawing and setting pins and wires.

Intended User

UNIUM is intended to be used by qualified health care professionals, e.g. surgeons, operating room staff, and individuals involved in preparation of the device.

Indications

UNIUM does not have any product specific indications. Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes Implants.
The indications are based upon the implant devices rather than the instruments. Specific indications for the implants can be found in the respective Synthes Implant Instructions for Use.

Contraindications

UNIUM does not have any product specific contraindications. Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes Implants. The contraindications are based upon the implant devices rather than the instruments. Specific contraindications for the implants can be found in the respective Synthes Implant Instructions for Use.

Patient Target Group

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes Implants. The patient target group is based upon the implant devices rather than the instruments. Specific patient target group for the implants can be found in the respective Synthes Implant Instructions for Use.

Expected Clinical Benefits

No direct clinical benefit is expected from these devices as this benefit is expected to be derived from the associated surgery or implants.
Indirect clinical benefits may be achieved by consistent torque and adjustable speeds by facilitating procedural steps and/or application of implants.

Potential Adverse Events

As with all major surgical procedures, risks, side effects and adverse events can occur. The following potential adverse events can occur:
- Infection
- Adverse Tissue Reaction
- Injury to Patient
- Injury to User

Unusual Transmissible Pathogens

▲ WARNING:

Surgical patients identified as at-risk of Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use devices. Dispose of instruments, Power Tools and attachments used or suspected of having been used on a patient with CJD after surgery by incineration and/or follow current national recommendations.

Required Reprocessing Before Device Is Used

▲ WARNINGS:

- Before first and every use, and prior to returning for service, Power Tools and their accessories/ attachments must be run through the complete reprocessing procedure. Protective covers and films must be fully removed prior to sterilization. Failure to follow the reprocessing instructions may lead to infection.
- Always follow the specified cleaning and disinfection steps for the Power Unit, Adapter for UBC II and UBC II as described in the Instructions for Use.

Safety Measures During Use

It is recommended to have a back-up UNIUM Handpiece readily available to use during surgery, as the potential for technical problems can never be completely avoided.
Do not use any visibly damaged devices.
Do not use this equipment in the presence of oxygen, nitrous oxide or a mixture consisting of flammable anesthetic and air. To ensure proper operation of the surgical medical device, only use original accessories.

For the surgical medical device to function properly, it is recommended that it is cleaned, disinfected and maintained after each use in accordance with the process defined in the "Care and Maintenance" section. Compliance with these specifications can considerably extend the service life of the device and reduce the risk of malfunction or harm to user and patient.

To reach the specified performance, only Synthes cutting tools must be used because they are optimized to meet the specific requirements of the device. Non-Synthes cutting tools' compatibility has not been tested and can reduce the lifetime of the device. The only exception are the saw blades with a DePuy Synthes saw coupling manufactured by Gebr. Brasseler GmbH & Co. KG. In this case, Gebr. Brasseler is the legal manufacturer and DePuy Synthes the exclusive distributor.

▲ WARNINGS:

- Cutting tools must be cooled with irrigation fluid to prevent heat necrosis. For this purpose, irrigate manually.
- Check used cutting tools after every use for wear and/or damage and replace them if necessary.

▲ Precaution:

It is recommended to use new cutting tools for every surgery to prevent the device from heating up as a result of reduced cutting performance.

Used cutting tools present the following risks:
- Necrosis due to excess heat.
- Longer cutting time due to reduced performance of the cutting tool.
- Infection caused by residue.

The user of the product is responsible for proper use of the equipment during surgery.
Check proper operation of the Power Tool before using it on the patient. To prevent overheating, always respect the specified Duty Cycles described in this manual.
For important information regarding electromagnetic compatibility (EMC) please refer to the corresponding "Electromagnetic Compatibility" section.
Both handpieces are classified as type BF against electrical shock and leakage current and are certified according to 60601-1 Medical Electrical Equipment.

Accessories Required

Please refer to the "Ordering Information" section for an overview of the articles of the UNIUM Portfolio.

Special accessories such as cleaning brushes (519.400, 519.40* and 532.024) and Synthes Special Oil (519.970, 519.97*) are available for cleaning and servicing device.

Only Synthes Special Oil (519.970, 519.97*) must be used to lubricate the Power Tools and attachments. Lubricants with other compositions may cause jamming, have a toxic effect or have a negative impact on the sterilization results. Only lubricate the Power Tool and the attachments when clean.
It is recommended to use the specifically designed UNIUM Washing and Sterilization Baskets (68.001.650, 68.001.651, 68.001.652, 68.001.653 and 68.001.654) for automated cleaning, sterilization and storage of the device. Further information can be found in the "Care and Maintenance" section of this document.

Latex Information

Not made with natural rubber latex.

Combination of Medical Devices

Use UNIUM Handpieces in combination with attachments, adapters, cutting tools and the Universal Battery Charger II as specified in this document.

Synthes has not tested the compatibility with devices produced by other manufacturers and assumes no liability when used with an unauthorized device.

Storage and Transport

Only use the original packaging for dispatch and transport as damage may occur otherwise. If the original packaging materials are no longer available, please contact your local DePuy Synthes Representative.

The Power Unit is classified as a "Li-Ion battery contained in equipment" according to the International Air Transport Association (IATA) regulation UN 3481 PI 967. Please ensure that the packaging and documentation requirements for shipping a Power Unit are followed.

* available in USA only.

Do not store or transport Power Units haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects. This can damage the Power Unit and generate heat, which can cause burns.

Please note that if the UNIUM Power Unit (05.001.602) is damaged, it cannot be transported by aircraft cargo. Please refer to the chapter "Repairs and Technical Service" to see when a Power Unit can be considered to be damaged.
Please refer to the chapter "Environmental Conditions" to see both transport and storage conditions.

Servicing

▲ WARNING:

- This device requires regular maintenance service, at least once a year, in order to maintain its safety and functionality. This service has to be performed by the original manufacturer or an authorized site.

Warranty and Liability

The warranty for the tools and accessories does not cover normal wear or damage of any kind resulting from improper use, improper reprocessing and maintenance, damaged seal, use of non-Synthes Cutting Tools and Lubricants or improper storage and transport. The manufacturer excludes liability for damage resulting from improper use, neglected or unauthorized maintenance or servicing of the tool. In such cases the product will no longer be accepted or repaired by DePuy Synthes. For further information on the servicing, warranty and return policy please contact your local DePuy Synthes Office.

General Warnings and Precautions

▲ WARNINGS:

- For safety reasons, please read the Instructions for Use carefully before using the device.
- Do not use any device if the packaging is damaged or if there is any apparent damage to the device.
- Always wear personal protective equipment (PPE) including safety goggles when handling with the device.
- To avoid injuries, always switch OFF the handpiece before every manipulation (e.g. inserting/removing the power unit, attachments and/or cutting tools) and before placing it back down.
- Should the handpiece fall on the floor and have visible damage, do not use and send it to the DePuy Synthes Service Center. Using a damaged device may cause harm to the user or patient.
- If a product falls on the floor, fragments may break off. This may cause harm to the patient or user due to:
  – loose or sharp fragments.
  – unsterile fragments potentially entering the sterile field or coming into contact with the patient.
- Synthes Devices are designed and manufactured to perform within the scope of their intended use. However, if a Power Tool or accessory/attachment breaks during use, a visual inspection or a medical imaging device (e.g. CT, Radiation Devices, etc.) can aid in locating the fragments and/or components of the device.

▲ Precautions:

- After inserting an attachment, a top for sternum or a cutting tool, always check that it is properly engaged by pulling on it gently.
- Avoid changing the position of the mode switch while the handpiece is operating. Should this happen, release the trigger, turn the mode switch to ON or FWD ONLY and press the trigger again to restart the device.
- Do not grasp or touch any rotating or moving component while the handpiece is operating.
- Do not apply excessive pressure with an accessory, such as bending or prying. Excessive pressure may bend or fracture the accessory and result in tissue damage, loss of tactile control, and/or the ejection of accessory fragments at a high velocity.
- The handpiece must only be operated with a fully charged Power Unit. Therefore, ensure that the Power Unit is fully charged prior to usage. We recommend installing the Power Unit just before use in order to prevent unwanted discharge if the handpiece is not in the OFF mode. Furthermore, it is recommended that the Power Unit is placed into the charger immediately after surgery.
- Should the device have corroded parts, discontinue use and send it to the DePuy Synthes Service Center.
- Only use the Universal Battery Charger II (05.001.204) to charge the UNIUM Power Unit. Using a charger that does not originate from Synthes can damage the UNIUM Power Unit.
- United States Federal law restricts this device to sale by or on order of a physician or other licensed healthcare provider.

UNIUM™ Modular Handpiece (05.001.601)

1 Mode Switch: ON (forward, reverse, oscillating drilling modes), OFF (lock mode), FWD ONLY (forward only mode)
2 Forward Trigger
3 Reverse Trigger
4 Attachment Coupling
5 Release Buttons for Attachment
6 Casing Opening Button on the Front Lid
7 Casing Cover with Battery Level Indicator

Forward Mode

Set the Mode Switch (1) in the ON or FWD ONLY position and press the Forward Trigger (2) to gradually increase and decrease the speed.

Reverse Mode

Set the Mode Switch (1) in the ON position and press the Reverse Trigger (3) to gradually increase and decrease the speed.

Oscillating Drilling Mode

Set the Mode Switch (1) in the ON position and press the Forward and Reverse Triggers (2 and 3) at the same time. To gradually increase the oscillating drilling speed, press down both triggers simultaneously. To decrease the speed, simultaneously reduce the pressure on both triggers. The oscillating drilling mode helps protect against soft tissue damage when drilling and inserting Kirschner wires. The cutting tool inserted into the attachment oscillates both clockwise and counterclockwise.

Both triggers (2) and (3) allow control of the speed from 0 to the maximum rpm. Maximum torque and speed vary depending on the attachment. Ensure that the correct attachment is used for each operation in terms of speed and torque.

▲ WARNINGS:

- Only use the oscillating drilling mode with drill attachments (05.001.250, 05.001.252, 05.001.253, ~~532.011, 532.012~~) or the K-wire attachment (05.001.188). Never use the oscillating drilling mode with any other attachment to avoid injuries.
- Never use the saw attachments (532.021, 532.023 and 532.026) in oscillating drilling mode to avoid injuries.

UNIUM™ Reciprocating Saw Handpiece (05.001.611)

1 Mode Switch ON (reciprocating mode), OFF (lock mode)
2 Trigger
3 Release Knob for Reciprocating Saw Blade
4 Release Buttons for Top of Sternum
5 Insertion Point for Top of Sternum
6 Casing Opening Button on the Front Lid
7 Casing Cover with Battery Level Indicator

To operate the handpiece, turn the Mode Switch (1) to the ON position and press and release the Trigger (2) to gradually increase and decrease the reciprocating frequency, respectively.

▲ Precaution:

Insert a reciprocating saw blade into the coupling and push until it locks in place. Gently pull on the saw blade to ensure it is properly seated.

If using the Top for Sternum, mount it into the correct position on the handpiece until it clicks (5). The tip of the reciprocating saw blade (511.910S or 511.915S) must be inside the slot of the guard.
The Top for Sternum can be mounted in 4 different positions to accommodate the chosen surgical technique. To release the Top for Sternum, press both release buttons (4) simultaneously. Turn the Release Knob (3) in the direction of the arrow to eject the reciprocating saw blade.

Intraoperative Battery Level Check for Modular and Reciprocating Saw Handpieces

The battery level can be checked intraoperatively by pressing the trigger on the handpiece while the mode switch is in the ON position or FWD ONLY position (for the Modular Handpiece). The remaining capacity level is visible on the Battery Level Indicator (7) on the bottom of the handpiece.

■ Notes:

- Turn the Mode Switch (1) to OFF, wait approximately 2 seconds, and then turn it back to either ON or FWD ONLY before checking the battery level indicator (7) on the casing cover.
- The UNIUM Handpiece is automatically switched off after two hours of inactivity. To reactivate it, switch it OFF and ON again with the mode switch.

UNIUM Power Unit (05.001.602)

1 Battery Level Indicator
2 Service Indicator
3 Information Button
4 Handle to hold the Power Unit

The Power Unit (05.001.602) incorporates the Li-Ion battery and the electronic control unit.

Checking the Battery Level

By briefly pressing the Information Button (3), the battery level is shown by the Battery Level Indicator (1).

Power Unit Condition Self-Test

A self-test of the Power Unit can be performed by pressing the Information Button (3) for 8 seconds. The four battery level indicator LEDs (1) will flash and the red LED of the Service Indicator (2) will light up. The self-test is completed after a few seconds. If all the LEDs turn off, then the Power Unit is in good condition.

If the red LED of the Service Indicator (2) remains on alone for around 5 seconds, the Power Unit is blocked for further use and needs to be replaced. The red LED will then turn off. However, if the Information Button (3) is pressed down again, the red LED will light up again for a few seconds.

Charging and Storage of the UNIUM Power Unit with the Universal Battery Charger II (05.001.204)

In order for the Power Unit to be recognized and charged by the Universal Battery Charger II (UBC II), a minimum of firmware 16.0 is required. A label placed on the underside of the charger indicates which firmware it has. If necessary, send the charger to a DePuy Synthes Representative for a firmware update.

The UBC II includes four independent charging bays. Insert the UNIUM Adapter for UBC II (05.001.604) into one of the bays and the Power Unit into the adapter as shown in the picture. Up to four Power Units can be charged simultaneously in separate bays, each equipped with an adapter.

Store the Power Unit in the UBC II and turn the charging station on. This will prevent the Power Unit from discharging and ensures it will be fully charged and ready to use.

To ensure that both UNIUM Handpieces can operate safely and reliably, the Power Unit has to be checked at periodical intervals. The UBC II will indicate when a check is necessary. After the check has been completed the UBC II will indicate if the Power Unit performance is sufficient or if it needs to be replaced.

For further information on the UBC II and the UNIUM Adapter for UBC II, consult the Instructions for Use of UBC II or contact your local DePuy Synthes Office.

Battery Level Indicator (1):
– All four LEDs illuminate when fully charged.
– Three or fer LEDs illuminate when not fully charged. The state of charge may suffice depending on the intended application.
– Bottom LED flashes orange when discharged.

SW-Rev. 16.0
2019/10/16

Example label found on the underside of the charger with firmware 16.0

Charging, Storage and Use

Charging

To ensure the longest possible service life, the manufacturer has partially charged the Power Unit for transport and storage purposes. The Power Unit must be fully charged before first use. This standard, initial charging operation must only be carried out by the end user (hospital). The Power Unit should be charged before every use.

Upon completing the surgery, follow the cleaning and disinfection instructions for the Power Unit as stated on page 29. Then, place it immediately into the charger.

Storage

Do not store an empty Power Unit as this will shorten the lifetime and void warranty coverage.

When the Power Unit is not in use, store it in the UBC II (05.001.204). This will guarantee that the Power Unit is always fully charged and ready to use.
The UBC II should always be switched on when a Power Unit is in the charging bay. This ensures availability of charged Power Units.

Never store the Power Unit in the handpieces as this will discharge it if the handpiece is not in the OFF mode.

Keep the Power Unit and the UBC II clean and in a cool and dry place. Avoid storage in direct sunlight.

Use

Do not remove a Power Unit from its original packaging until required for use.

Do not drop or apply force to the Power Unit as this will destroy it.

Only use the Power Unit for its intended use. Do not use any Power Unit or battery that is not designed for use with the equipment.

Do not use a damaged Power Unit (e.g. one that has been dropped). To check the condition of the Power Unit run the self-test. If the self-test has been run and the Service Indicator does not illuminate, the Power Unit can be used. However, if the Power Unit still does not function properly, it should not be further used and needs to be replaced.

In the case of an unintended short-circuit, the fuse in the Power Unit will blow. This prevents excessive overheating and fire. If this happens, the Power Unit cannot be used anymore.

UNIUM Power Units perform best when they are operated at normal ambient temperature (20 °C +/- 5 °C; 68 °F +/-9 °F).

▲ WARNINGS:

- A fully charged Power Unit can normally deliver sufficient power to perform an entire surgery. Never open a handpiece intraoperatively to insert a new Power Unit as this may lead to infection. Always have a second fully charged UNIUM Handpiece ready before the start of the surgery.
- In case of cell leakage, do not allow the leaking fluid to come into contact with skin or eyes. In case of contact, wash the affected area with sufficient amounts of water and seek medical attention.
- Risk of fire and burns. Do not disassemble, crush, heat above 60°C/140 °F or incinerate the battery cells.
- Never expose the Power Unit to temperatures over 60 °C/140 °F. The maximum exposure time at 60 °C/140 °F is 72 hours.
- Do not dismantle, open, short-circuit or shred the Power Unit.

▲ Precautions:

- Only use an original UNIUM Power Unit manufactured by Synthes with a UNIUM Handpiece. Using a non original UNIUM Power Unit can damage the UNIUM Handpiece.
- Do not leave the Power Unit empty of charge as this will reduce its lifetime or damage the Power Unit.

Aseptic Transfer Technique

The aseptic transfer technique allows a non-sterile Power Unit to be inserted into UNIUM Handpieces whilst preserving the sterile barrier in the operating room.

Not submitting a power unit or a battery to a steam sterilization process after each use will maximize its lifespan and shorten the turnaround time.

Before using the aseptic transfer technique follow the cleaning and disinfection instructions of the Power Unit on page 29. This procedure should be done directly after surgery.

Inserting the Power Unit

To ensure sterility of the UNIUM Modular Handpiece (05.001.601) and UNIUM Reciprocating Saw Handpiece (05.001.611), the non-sterile Power Unit (05.001.602) is inserted into the casing of the handpiece by two people, the scrubbed person and the circulating person:

1. The scrubbed person holds the sterile handpiece. If the casing cover of the handpiece is not opened, the same person presses the opening button to unlock it, turns the “front lid” 180° until it clicks and then pulls the “front lid” up to open it (Fig. 1–2). This step is marked on the “front lid” by an arrow and the words “Press” and “Open”. Ensure that the casing cover is fully opened (Fig. 3).
2. The scrubbed person places the sterile cover (05.001.603) on top of the open casing of the handpiece (Fig. 4). Check that it is seated correctly. The scrubbed person must not touch the inside of the handpiece. The sterile cover helps to guide the Power Unit into the handpiece and prevents contamination of the sterile casing by the non-sterile Power Unit.
3. The circulating person carefully guides the non-sterile Power Unit through the sterile cover (Fig. 5 and Fig. 6). It is important that the circulating person picks up the non-sterile Power Unit by the handle as shown in Fig. 5. The same person then presses the Power Unit completely into the casing to ensure that it is fully seated (Fig. 6). The circulating person grips the flanges on the sterile cover and removes it from the casing (Fig. 7).

▲ WARNING:

Avoid all contact with the outer surface of the handpiece so that it does not get contaminated. Should the non-sterile Power Unit or the circulating person’s hand come into contact with the outer surface of the handpiece, it must be cleaned and resterilized before being used in the operating room.

Figure 1

Figure 2

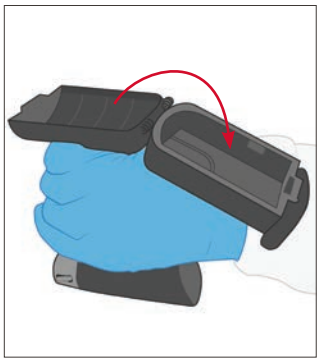


Figure 3

Figure 4

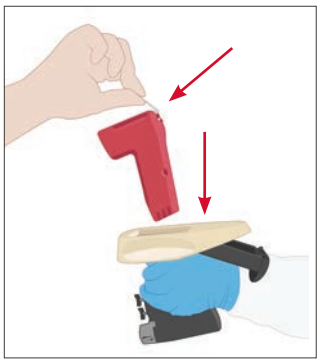


Figure 5

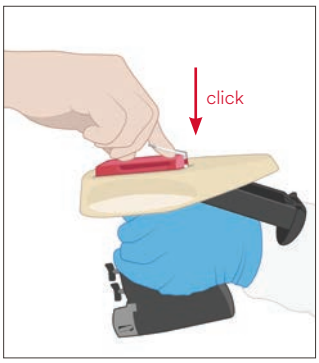


Figure 6

Figure 7

4. The scrubbed person closes the casing cover from the outside without contacting the Power Unit or the inside of the casing (Fig. 8–11). The scrubbed person releases the “front lid” by pressing on the “Press” button (Fig. 8). The scrubbed person places one hand under the casing cover (Fig. 9) and closes it. They then turn the “front lid” 180° until it clicks (Fig. 10). Always ensure that the casing cover and front lid are totally closed before using the handpiece (Fig. 11).

▲ WARNING:

The scrubbed person must not touch the non-sterile Power Unit or the inside of the handpiece in order to avoid contamination. Should this happen, the scrubbed nurse must be scrubbed again. Should the handpiece be contaminated, it must be cleaned and resterilized before being used in the operating room.

Removing the Power Unit

1. The scrubbed person opens the casing as described in step 1. The circulating person removes the Power Unit by holding the handle while the scrubbed person holds the handpiece firmly (Fig. 12). Ensure that the Power Unit does not touch the outer surface of the handpiece to avoid contaminating the Power Unit.
   If this occurs follow the information in the section “Cleaning and Disinfection of the Power Unit (05.001.602) Directly After the Surgery”. Store the Power Unit by using the Adapter for UBC II (05.001.604) in the Universal Battery Charger II (05.001.204) when not in use. The Universal Battery Charger II should always be turned on (Fig. 13).

▲ WARNINGS:

- To ensure aseptic conditions, the Power Unit must not be removed from the handpiece until the end of surgery.
- To avoid injuries, always switch OFF the handpiece before every manipulation (e.g. inserting/removing the power unit, attachments and/or cutting tools) and before placing it back down.

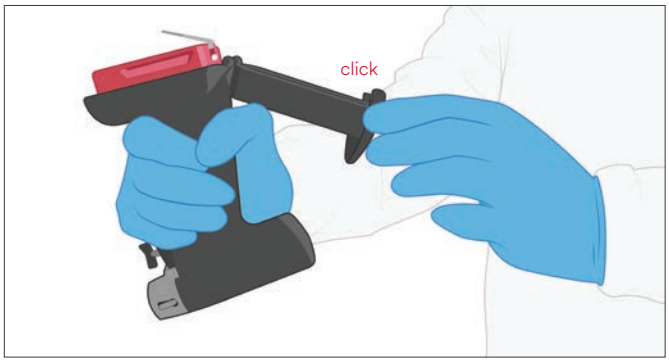


Figure 8


Figure 9

Figure 10


Figure 11

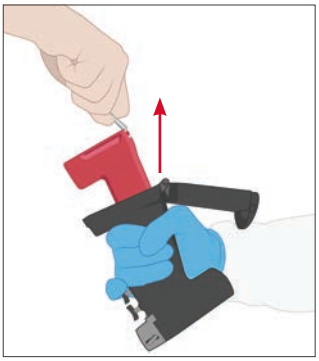


Figure 12

Figure 13

Attachments for UNIUM™ Modular Handpiece

Introduction

The UNIUM Portfolio offers a broad range of attachments which are described in the following pages. Some of the attachments have been color coded between drill (blue) and ream (red) speed.

Inserting and Removing the Attachments

Insert the attachment into the attachment coupling (Fig. 1). If the positioning pins do not lock into place right away, rotate the attachment a bit to the right or left until it locks into the correct position.

▲ Precaution:

Once inserted, check to make sure the attachment is seated correctly by gently pulling on it.

Press the attachment release buttons simultaneously and pull to remove the attachment from the coupling head of the handpiece.

Figure 1

▲ WARNINGS:

- To avoid injuries, always switch OFF the handpiece before every manipulation (e.g. inserting/removing the power unit, attachments and/or cutting tools) and before placing it back down.
- Please observe the safety instructions and warnings stated in the instructions when working with attachments and cutting tools. Only use original attachments and cutting tools. Damage resulting from the use of attachments from other manufacturers is not covered by the warranty.
- Never use an attachment in reverse mode (e.g. 05.001.254, 05.001.257, 05.001.258, 05.001.259 and 05.001.260, 532.015) with a legacy series flexible reamer shaft, as this may lead to serious injury to the patient.
- Only place the handpiece in an upright position when changing attachments or cutting tools intraoperatively. The handpiece must be laid on its side when not in use in order to avoid the risk of being dropped or contaminating other devices. Alternatively, only when using the insert tray (68.001.654) the handpiece can be left in an upright position.

▲ Precautions:

During reaming procedures, high torque values are generated by the Power Tool and delivered to the reaming head to allow efficient bone removal. In cases where the reaming head is suddenly blocked, these high torque values can be transferred onto the user's hand, wrist and/or the patient's body. In order to prevent injuries it is therefore essential that:

- the Power Tool is held in an ergonomic position with a firm grip.
- if the reamer head gets blocked, the speed trigger is immediately released.
- the correct function of the speed trigger (immediate stop of the handpiece when the trigger is released) is checked before the reaming process.

Drill Attachments

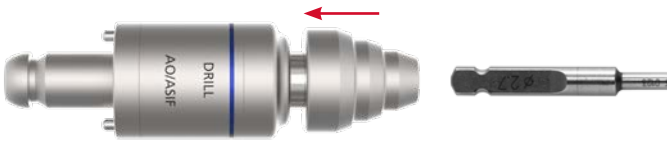
AO/ASIF Quick Coupling Drill Attachment, 1,255 rpm

Inserting and Removing the Cutting Tools

To connect the cutting tool, insert it into the attachment by applying a light pressure while rotating it slightly until it locks in place.
To disconnect, pull the coupling sleeve back and remove the cutting tool.

■ Note:

Adapters (310.930, 310.93K*, 338.490, 338.49*, 511.300 and 511.30* and 532.031) can be used in connection with the AO/ASIF Quick Coupling (05.001.250).



AO/ASIF Quick Coupling (05.001.250)
for cutting tools with an AO/ASIF coupling shaft.

Drill Chuck Attachments, 1,255 rpm

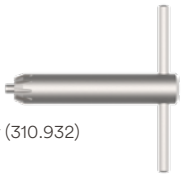
Inserting and Removing the Cutting Tools

Open the jaws of the chuck using the appropriate key or by hand. Insert the shaft of the cutting tool into the open drill chuck and close it by twisting the chuck. Make sure that the shaft lies central to the three jaws. Tighten the drill chuck with the key. Make sure that the teeth of the key engage correctly in the toothed rim of the chuck.
To remove the cutting tool open the chuck with the key.

▲ WARNINGS:

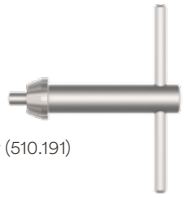
- To ensure secure insertion of the cutting tool, make sure the toothed rims on the chuck and key are not worn. Replace damaged or worn components. Only use an original key.
- Remove the original key from the drill chuck before operating the handpiece.

Chuck, clamping range up to ∅ 4.0 mm
(05.001.252)



Key (310.932)

Chuck, clamping range up to ∅ 7.3 mm
(05.001.253).



Key (510.191)

Mini Quick and J-Latch Quick Couplings Drill Attachments, 3,400 rpm

Inserting and Removing the Cutting Tools

To connect the cutting tool, pull the coupling sleeve back and then insert the cutting tool while rotating slightly until it locks in place.

To disconnect, pull the coupling sleeve back and remove the cutting tool.

*available in USA only

Mini Quick Coupling (532.011)

J-Latch Coupling (532.012)

Ream Attachments

All UNIUM Reaming attachments provide a maximum torque of approximately 6.0 Nm at maximum load and a maximum speed of 340 rpm with no load.

Quick Coupling Ream Attachments

Inserting and Removing the Cutting Tools

To connect the cutting tool, pull the coupling sleeve back and then insert the cutting tool while rotating slightly until it locks in place.

To disconnect, pull the coupling sleeve back and remove the cutting tool.

■ Note:

Adapters for Kuentscher (511.787) and Harris (511.788) can be used in connection with the AO/ASIF Quick Coupling (05.001.257).

The four attachments shown on the right replace the legacy Colibri II/Small Battery Drive II attachments (532.017, 532.018, 532.019 and 532.020) They are designed to enable the use of reverse function.

AO/ASIF Quick Coupling (05.001.257)

Hudson Quick Coupling (05.001.258)

Trinkle Quick Coupling (05.001.259)

Trinkle Quick Coupling, modified (05.001.260)

Quick Coupling for DHS/DCS Triple Reamers

Inserting and Removing the Cutting Tools

To connect the cutting tool, push the coupling sleeve forward and then insert the cutting tool while rotating slightly until it locks in place.
To disconnect, push the coupling sleeve forward and remove the cutting tool.

The DHS/DCS attachment can be used with the reverse function.

DHS/DCS Quick Coupling (532.015)

Ream Chuck Attachment

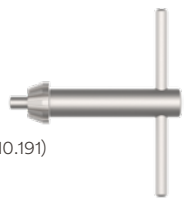
Inserting and Removing the Cutting Tools

Open the jaws of the chuck using the appropriate key or by hand. Insert the shaft of the cutting tool into the open drill chuck and close it by twisting the chuck. Make sure that the shaft lies central to the three jaws. Tighten the drill chuck with the key. Make sure that the teeth of the key engage correctly in the toothed rim of the chuck.

To remove the cutting tool open the chuck with the key.

The warnings for the Drill Chuck Attachment also apply to the Ream Chuck Attachment. See page above.

Chuck, clamping range up to ∅ 7.3 mm (05.001.254)



Key (510.191)

Screw Attachment and Quick Coupling for Kirschner Wires

Screw Attachment, 340 rpm

AO/ASIF Quick Coupling (05.001.251)

Inserting and Removing the Cutting Tools

To connect the cutting tool, insert it into the attachment by applying a light pressure while rotating it slightly until it locks in place.

To disconnect, pull the coupling sleeve back and remove the cutting tool.

▲ WARNINGS:

- Never fully insert screws with the handpiece. The last turns or locking should always be done manually.
- Always use an appropriate torque limiting attachment when putting locking screws into a locking plate.

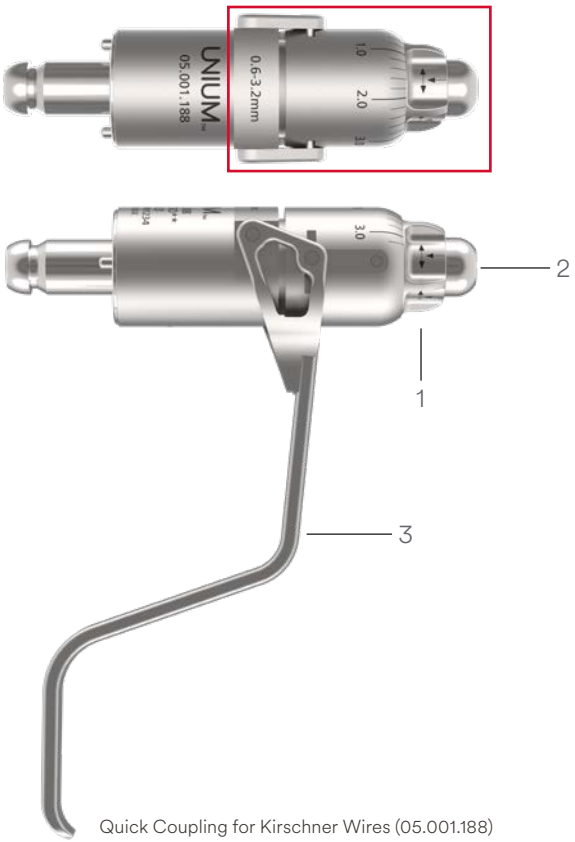
▲ Precaution:

It is also possible to use the AO/ASIF Quick Coupling drill attachment (05.001.250) to insert screws. However, the Screw Attachment (05.001.251) has a lower speed and a higher torque and is therefore more suitable. Screws with a large diameter may not be able to be inserted with the AO/ASIF Quick Coupling drill attachment as the torque may not be sufficient.

Quick Coupling for Kirschner Wires, 1,700 rpm

Kirschner Wires of any length with a diameter of 0.6–3.2 mm can be used with the quick coupling for Kirschner Wires.

1. Adjust the Kirschner Wire diameter according to the markings on the adjusting sleeve (1). Slightly press the adjusting sleeve axially against the handpiece and rotate the sleeve.
2. Apply a slight amount of pressure to insert the Kirschner Wire from the front into the cannulation (2). The wire is then held in place.
3. Adjust the working length by pulling or pushing on the wire.
4. To clamp the wire in place, pull the tension lever (3) towards the handpiece with your little finger and ring finger. The clamping force can be changed by pulling and releasing the tension lever.
5. Insert the wire into the bone.
6. To adjust the grip on the wire, reduce the clamping force and slide the attachment along the wire to the desired length. Reclamp the wire by pulling on the tension lever.



Quick Coupling for Kirschner Wires (05.001.188)

Burr Attachment

Burr Attachment, 17,000 rpm

The burr attachment for UNIUM is compatible with Small Bone Small Torx coupling burrs, sizes Medium (M) and Long (L).

Burr Attachment
(05.001.187)

1

Changing Burrs

Turn the release sleeve for burrs (1) until it engages in the UNLOCK position and remove the burr.
Insert the new burr as far as possible, rotate it slightly until it locks in place and then turn the release sleeve for burrs (1) into the LOCK position until it engages.

▲ WARNING:

Cutting tools must be cooled with irrigation fluid to prevent heat necrosis. For this purpose, irrigate manually.

Saw Attachments

Oscillating Saw Attachment (532.021), 17,000 osc./min

Positioning the Oscillating Saw Attachment

The oscillating saw attachment can be inserted in eight different positions (45° increments).
Slide the sleeve (1) toward the attachment coupling and rotate it into the desired position (Fig. 1).

Figure 1

▲ Precaution:

To prevent injury, always hold the saw attachment with the saw blade facing away from the user.

Changing the Saw Blade

1. Pull the locking knob (2) down and turn it counterclockwise.
2. Lift and remove the saw blade.
3. Insert a new saw blade into the saw blade coupling (3) and move it into the desired position (Fig. 2).
   The desired positions can be offset from each other at 45° angles (Fig. 3).
4. Place your thumb on the saw blade coupling (3) to hold the saw blade and turn the locking knob (2) clockwise until the saw blade is secured.
5. Put the mode switch of the handpiece in the ON or FWD ONLY position.

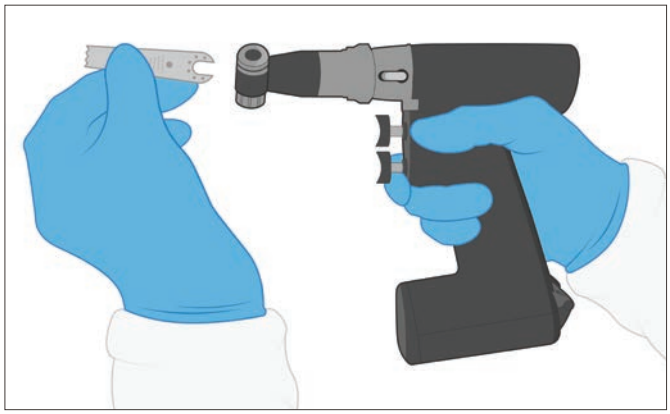


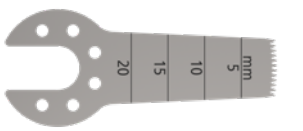
Figure 2

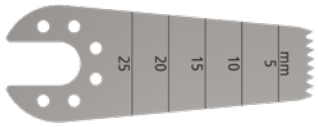
▲ Precautions:

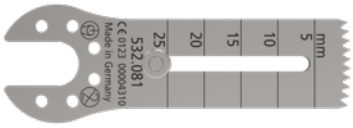
Saw blades labeled “Single Use” should not be reused.

Using the Oscillating Saw Attachment

The saw blade must already be oscillating when the saw is applied to the bone. Do not apply strong pressure to the saw blade as this will delay the cutting process and the saw teeth will catch in the bone. Optimal saw performance is achieved by moving the Power Tool slightly back and forth in the plane of the saw blade so that the blade oscillates beyond the bone on both sides. Very precise cuts can be made when the saw blade is guided steadily. Imprecise cuts arise due to used saw blades, excess pressure or the saw blade jamming on the bone.


Fine tooth saw blades


Coarse tooth saw blades



Parallel saw blades

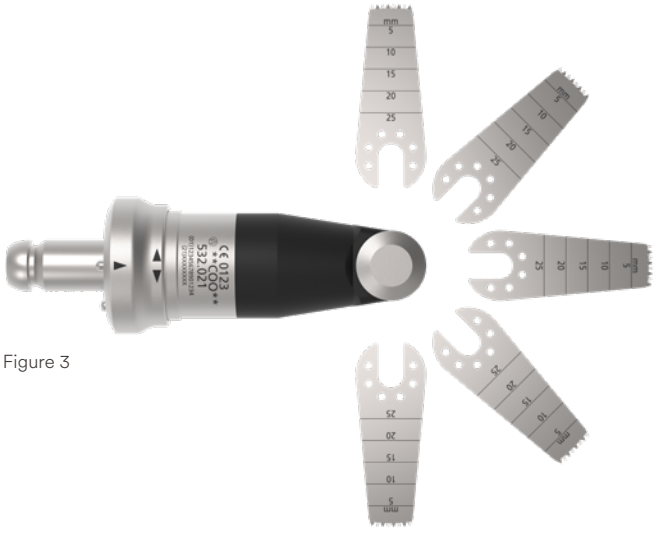


Figure 3

Oscillating Saw Attachment II (Crescentic Technique) (532.023), 17,000 osc./min

The Oscillating Saw Attachment II is designed for use with crescentic saw blades guided by a 1.6 mm Kirschner Wire. It can also be used with saw blades that have a shaft extension of 105° for reaching difficult-to-access sites.

Figure 1: Oscillating Saw Attachment II (Crescentic Technique)

Inserting and Removing the Saw Blades

Pull the sliding sleeve (2) back and then insert the saw blade until it locks into the saw blade coupling (1). Release the sliding sleeve (2) and check that the saw blade is correctly fixed by gently pulling on it.

Pull the sliding sleeve (2) back and remove the saw blade.

Figure 2: Crescentic Saw Blades e.g. (03.000.313S)

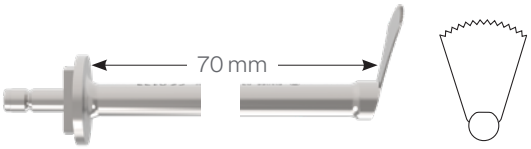


Figure 3: 105° Angled Saw Blades e.g. (03.000.341S)

Large Oscillating Saw Attachment (532.026), 17,000 osc./min

The Large Oscillating Saw Attachment is designed for performing a crescentic saw cut (Fig. 1).

Figure 1

Inserting the Saw Blade

Insert the saw blade in the saw blade coupling (1) and tighten the screw in the saw blade with the key (532.027) that was delivered with the attachment (Fig. 2) or use a T15 StarDrive screwdriver (e.g. 314.115).

Check that the saw blade is correctly in place and properly tightened.

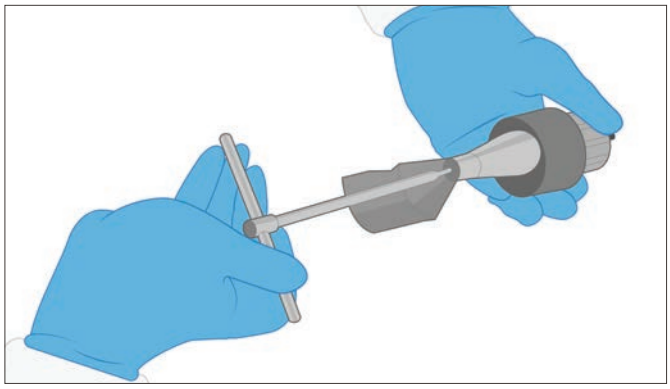


Figure 2

Mounting the Saw Attachment

Make sure that the locking sleeve (2) on the saw attachment is set to the unlock position 🔓 (Fig. 3). Insert the saw attachment in any position into the attachment coupling of the handpiece until it locks into place. To prevent vibrations during operation and to increase the sawing capacity, additional manual tightening of the attachment onto the handpiece is required. To achieve this, turn the locking sleeve (2) into the lock position until you feel that the coupling pins engage into the handpiece (approx. half a revolution).

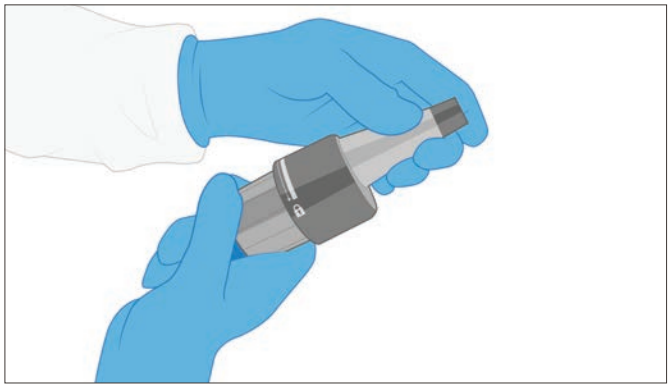


Figure 3

▲ Precaution:

Avoid applying high pressure onto the saw blade.

Removing the Saw Attachment

Turn the locking sleeve (2) to the unlock position 🔓 and then push both release buttons on the handpiece.

Radiolucent Drive

Radiolucent Drive (511.300, 511.30*), 1,255 rpm

The Radiolucent Drive can be used with the UNIUM Modular Handpiece in combination with the AO/ASIF Quick Coupling (05.001.250) and the Adapter for the Radiolucent Drive (532.031).

Figure 1

Coupling the Radiolucent Drive

Connect the AO/ASIF Quick Coupling to the UNIUM Modular Handpiece and the adapter to the Quick Coupling. Position the Radiolucent Drive as far as it will go over the Quick Coupling and the adapter and rotate it into the desired working position. Support the drive with your free hand.

Inserting the Drill Bit

To insert the drill bit, push the release sleeve ring (1) on the attachment and position the drill bit inside the coupling as far as it can go while rotating it slightly. Pull back the ring on the attachment to fix the drill. Check if the drill bit is seated correctly by gently pulling on it (Fig. 2).

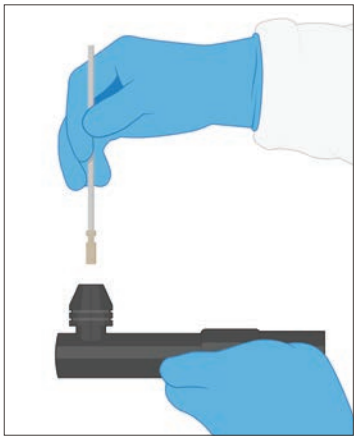


Figure 2

Removing the Drill Bit

Follow the same procedure in reverse order.

Using the Radiolucent Drive

Before positioning the Radiolucent Drive, align the image intensifier until the distal locking hole of the medullary nail is round and easily visible (Fig. 3).

After the incision, position the Radiolucent Drive and center the drill bit tip over the locking hole. On the monitor of the image intensifier, you can see both the drill bit and the target rings of the drive (Fig. 4).

Swing the drive up and center it precisely so that the drill bit appears as a round point and the locking hole is visible around it. The target ring also assists the centering. The locking hole can now be drilled directly (Fig. 5).

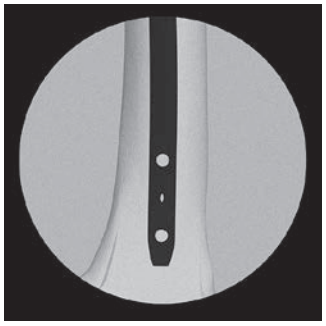


Figure 3

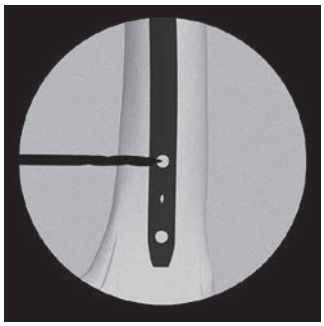


Figure 4

Figure 5

* available in USA only

▲ WARNINGS:

Grip the coupled Radiolucent Drive tightly when switching on the Power Tool, particularly if the Power Tool is held face down.

Additionally, refer to the brochure titled “Working with the Radiolucent Drive” for an overview of the available Drill Bits.

▲ Precautions:

- To protect the gears, the Radiolucent Drive is equipped with a slip clutch that disengages in case of an overload and emits an audible rattling noise.
- The following procedures can cause an overload:
  – Correcting the drilling angle when the cutting edges of the drill bit are completely in the bone.
  – Hitting the medullary nail with the drill bit.
- If overload occurs, drilling can be continued after having made the following corrections:
  – Correcting the drilling angle: remove the drill bit until the flutes are visible and then restart the drilling.
  – Hitting a medullary nail: remove the drill bit until the flutes are visible and re-aim the drill bit or exchange the drill bit if necessary.
- Handle the Radiolucent Drive with great care. Do not allow contact between the drill bit and the medullary nail.
- Depending on the setting of the image intensifier, a zone may appear in the rear of the Radiolucent Drive that is not radiolucent. However, this does not inhibit aiming and working with the device.

General Information

Power Tools and attachments are frequently exposed to high mechanical loads and shocks during use and should not be expected to last indefinitely. Proper handling and maintenance help extend the useful life of surgical devices and reduce the risk of malfunction or harm to the user and patient.

Power Tools must be serviced and inspected at least once a year by the original manufacturer or an authorized site. Yearly maintenance will ensure that the equipment maintains the highest standard of performance and will prolong the life of the device. The manufacturer assumes no warranty for damages arising from improper use, neglected or unauthorized servicing of the tool. In such cases the product will no longer be accepted or repaired by DePuy Synthes.

A visual overview of the Care and Maintenance procedures can be found on the UNIUM Care and Maintenance Poster.

▲ WARNINGS:

- Before first and every use, and prior to returning for service, Power Tools and their accessories/attachments must be run through the complete reprocessing procedure. Protective covers and films must be fully removed prior to sterilization. Failure to follow the reprocessing instructions may lead to infection.
- Cannulations, unlocking sleeves and other narrow sites require special attention during cleaning.
- The UNIUM device is designed to be adequately protected against water intrusion when exposed to water jets in automated washers. Do not use excessive water pressure when cleaning the cannulations. Follow the instructions of the manufacturers' automated washers. Never immerse the handpieces, power units and attachments in aqueous solutions or in an ultrasonic bath.
- The Power Unit and Adapter for UBC II must never be autoclaved, washed, rinsed, immersed or dropped. This will destroy them with possible secondary damage.
- Cleaning agents with a pH of within 7–9.5 are recommended. Highly alkaline conditions (pH >10) can damage components and devices made of materials such as aluminum, titanium and its alloys, plastics and compound materials. The use of such cleaners should be subject to the data regarding material compatibility in the corresponding data sheet.
  Do not use a cleaning aid that can damage the surface of devices such as steel wool, abrasive cleaners or wire brushes.
- Follow the neutral pH enzymatic or mild alkaline detergent Instructions for Use for correct dilution/concentration, temperature and water quality. The chemical quality of the water used during reprocessing can impact device safety. Facilities should meet the recommended water quality requirements for device reprocessing in accordance with local guidance (such as AAMI TIR 34 “Water for the reprocessing of medical devices”) and this Instructions for Use. Devices should be cleaned in a fresh, newly-made solution.
- Do not use saline, environmental disinfection (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-containing products).
- Detergents used on the products will be in contact with the following materials: stainless steel, aluminum, plastic, and rubber seals.

Unusual Transmissible Pathogens

▲ WARNING:

Surgical patients identified as at-risk of Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use devices. Dispose of instruments, Power Tools and attachments used or suspected of having been used on a patient with CJD after surgery by incineration and/or follow current national recommendations.

▲ Precautions:

- Clean and lubricate the triggers on the handpiece by following the care and maintenance instructions in the UNIUM Instructions for Use.
- Do not use sharp or pointed objects for cleaning.
- The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with standards such as the ISO 15883 and ISO 17665 series.
- Consult national regulations and guidelines for additional information. Furthermore, compliance with internal hospital policies and procedures and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment is required.

Notes:

- The clinical processing instructions provided have been validated by Synthes for preparing a non-sterile Synthes medical device; these instructions are provided in accordance with ISO 17664 and ANSI/AAMI ST81.
- Cleaning Agent Information: Examples of detergents that were used by Synthes during the cleaning validations include ProlysticaTM 2X Concentrate Enzymatic Cleaner, ProlysticaTM 2X Neutral Detergent, Neodisher® MediZym.
  These cleaning agents are not listed in preference to other available neutral pH enzymatic or mild alkaline cleaning agents which may perform equally satisfactorily.
- Non-single use brushes and other cleaning tools should be decontaminated at least once a day using a solution as detailed in step “3, Spray and Wipe” on page 31.
- The temperature of the cleaning agent should be ≤ 40°C (104°F) for manual cleaning.
- Residual organic matter and/or a large number of microorganisms may reduce the effectiveness of the sterilization process.
- Soiled devices should be transported separately from non-contaminated devices to avoid contamination when being moved from the operation room to the reprocessing department.
- It remains the responsibility of the processor to ensure that the processing performed achieves the desired result using the appropriate, properly installed, maintained and validated equipment, materials and personnel in the processing unit. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.
- Both UNIUM Handpieces have an IPX6/IPX8/IPX9 rating against water ingress in accordance with IEC 60528:
  – IPX6: protected against powerful water jets
  – IPX8: protected against the effects of continuous immersion in water (handpiece immersed 1 meter deep in water for 35 minutes)
  – IPX9: protected against high pressure and temperature water jets
  All three tests were performed with the handpiece casing cover and front lid fully closed.
- The UNIUM Power Unit has an IPX4 rating against water ingress in accordance with IEC 60528:
  – IPX4: protected against splashing water.
  Please note that for both the UNIUM Handpieces and the Power Unit only the clinical processing instructions provided in this Instructions for Use (see care and maintenance section) have been validated by Synthes.
- For all UNIUM compatible items without a designated place inside the UNIUM Washing and Sterilization basket, the reprocessing can be done in accordance with the steps outlined in this Instructions for Use. However, it remains the responsibility of the processor to ensure that the processing performed achieves the desired result.
- Consult the Synthes brochure titled “Important Information (with Cleaning and Sterilization Instructions)” for general information on reprocessing.

Cleaning and Disinfection

Preparation Prior to Reprocessing

Disassembly

Before cleaning, remove all attachments and cutting tools from the Power Tool. Remove the Power Unit from the UNIUM Modular Handpiece and Reciprocating Saw Handpiece.

Cleaning and Disinfection of the Power Unit, Adapter for UBC II and UBC II Directly After the Surgery:

1. To clean the Power Unit, Adapter for UBC II and the UBC II, wipe them off with a clean, soft and lint-free cloth dampened with deionized water until no visible soil remains on the devices. If any visible soil remains, repeat the step with a new damped cloth. Dry them off using a clean, soft, lint-free single-use cloth prior to disinfection (Fig. 1 and 2).
2. To disinfect the Power Unit, Adapter for UBC II and the UBC II, wipe them off with a new, clean, soft and lint-free cloth dampened with a minimum of 70% alcohol-based disinfectant for thirty (30) seconds. A disinfectant that is VAH (Verbund für Angewandte Hygiene) listed, EPA (Environmental Protection Agency) registered or locally recognized is recommended. This step has to be repeated two (2) additional times using a new, clean, soft and lint-free cloth dampened with a minimum 70% alcohol-based disinfectant each time.

Figure 1

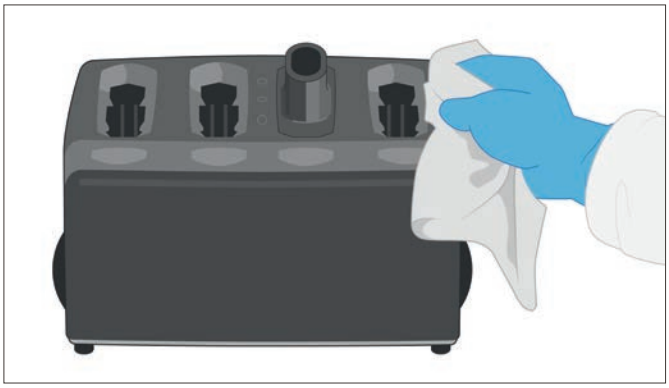


Figure 2

▲ Precautions:

- Do not use solvents to disinfect the Power Unit. Sockets must not contact water or solvents as there is a danger of short-circuiting.
- Do not spray the contacts. When using a damp cloth to wipe off the contacts, ensure that they are completely dry before inserting the Power Unit into the handpiece. Residual moisture could cause a short-circuit.
- Inspect the Power Unit and Adapter for UBC II for cracks and damage.

Place the Power Unit by using the Adapter for UBC II in the UBC II after each use (Fig. 3).
Once the Power Unit is completely charged (indicated by the green LED illuminating), remove it from the Adapter and wipe it with a minimum 70% alcohol-based disinfectant prior to returning to use.

Figure 3

Reprocessing of the UNIUM Handpieces, Sterile Cover, Attachments and Accessories Directly After the Surgery

- All devices must be reprocessed using:
- manual cleaning, or
- automated cleaning with manual pre-cleaning

■ Note:

Clean all movable parts in opened or unlocked position.

Manual Cleaning Instructions

■ Notes:

- The manual cleaning steps should also be followed to clean the inside of the UNIUM Modular or Reciprocating Saw Handpiece and the UNIUM Washing and Sterilization Baskets, Insert Tray and Lids.
- It is recommended to hold the UNIUM Modular Handpiece and Reciprocating Saw Handpiece in an upright position (Fig. 1) whenever possible and to drain the inside of the Handpiece from excess water after each step.
- Handle the handpieces' front lid, casing cover, edges, seals and hinges with care.

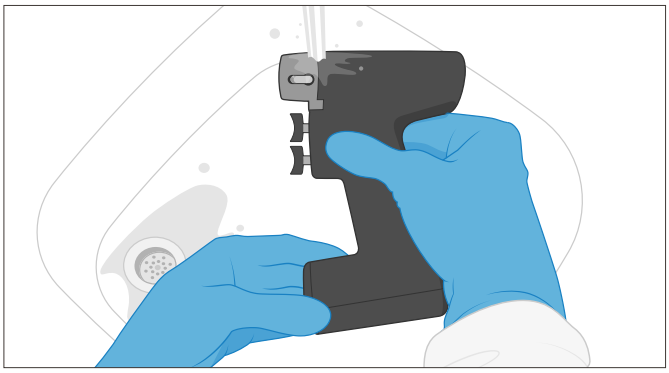


Figure 1

1. Remove Debris

Rinse the device under cold, running tap water for a minimum of 2 minutes (Fig. 1). Use a soft lint-free cloth or soft-bristled brush to assist in removing gross soil (Fig. 2 and Fig. 3).
For cannulations of the handpiece and attachments, the cleaning brushes (519.40, 519.40* and 532.024) below should be used.

Figure 2

2. Manipulate Moving Parts

Manipulate all moving parts such as triggers, sliding sleeves, attachment release rings, saw blade coupling and switches, etc. under running tap water to loosen and remove gross debris.

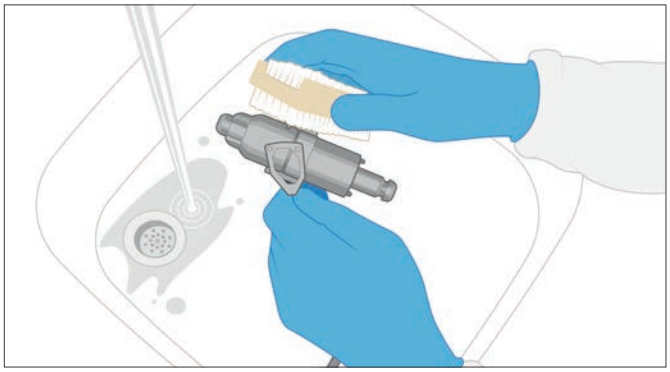
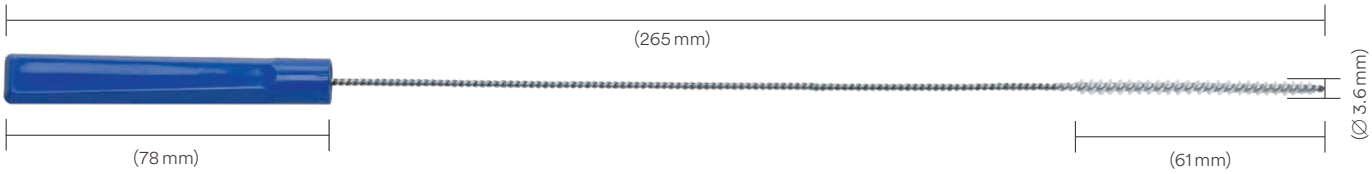
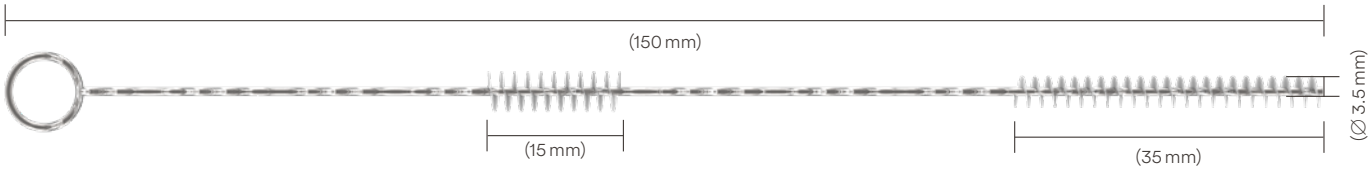


Figure 3



Cleaning brush (519.400, 519.40*) for the cannulation of UNIUM Modular handpiece and attachments



Cleaning Brush (532.024) for Oscillating saw attachment (532.023)

*available in USA only

3. Spray and Wipe

Spray the device with newly prepared neutral pH enzymatic or mild alkaline detergent solution in accordance to the detergent manufacturer's instructions. The temperature of the solution should be ≤ 40 °C (≤ 104 °F) for manual cleaning. Leave the solution to interact with the surface of the device for a minimum of 2 minutes (Figs. 4, 5 and 6) and then wipe it off.

4. Rinse with Tap Water

Rinse device with cold tap water for a minimum of 2 minutes (Fig. 7). Use a syringe or pipette to flush lumens and channels.

5. Clean with Detergent

Manually clean device under running warm water for a minimum of 5 minutes. From time to time (during the 5 minutes cleaning period) use a soft-bristled brush and/or soft lint-free cloth that is soaked with the newly prepared neutral pH enzymatic or mild alkaline detergent solution to remove soil and debris (Fig. 8 and Fig.9). Manipulate all moving parts such as triggers, sliding sleeves, attachment release rings, saw blade coupling, switches, etc. under running water (Fig. 10).

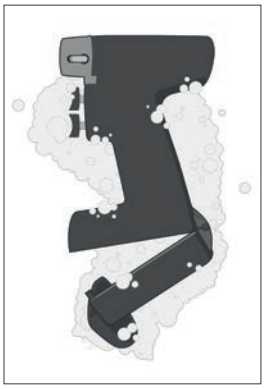


Figure 4

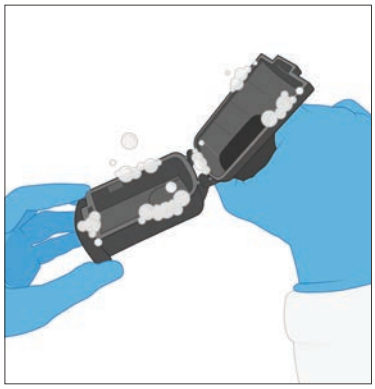


Figure 5

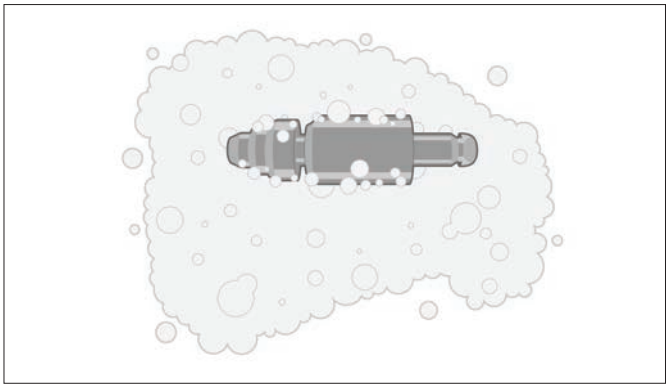


Figure 6

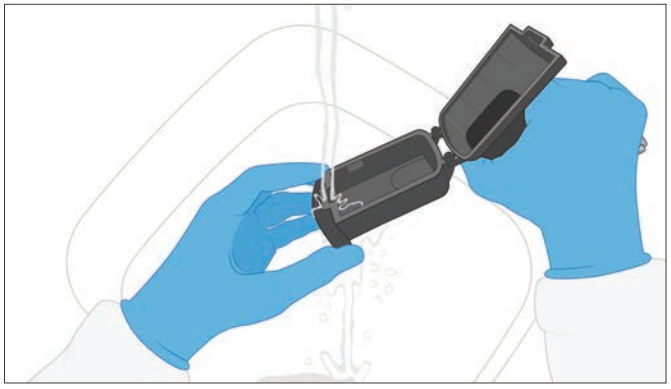


Figure 7

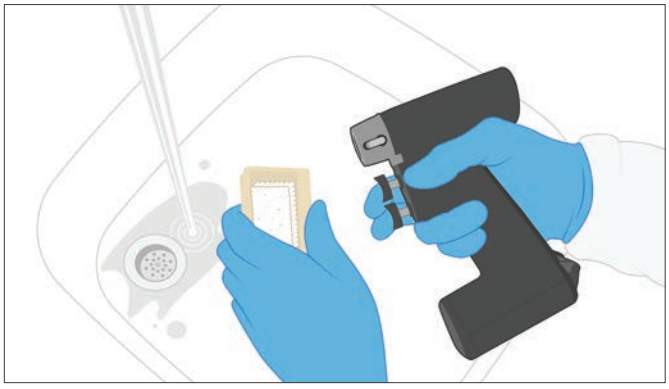


Figure 8

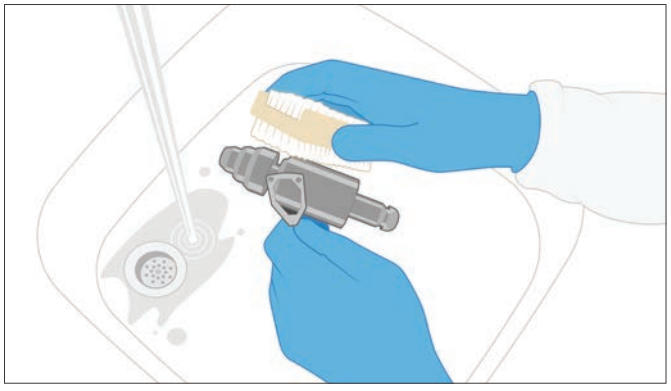


Figure 9

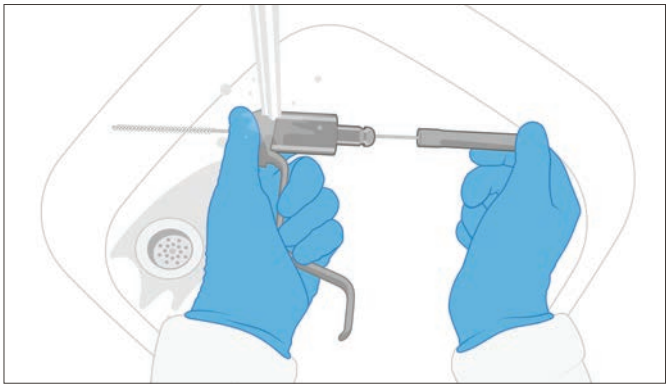


Figure 10: Quick Coupling for Kirschner Wires ∅ 0.6 to 3.2 mm for UNIUM™ (05.001.188)

6. Rinse with Tap Water

Rinse the device thoroughly using cool to lukewarm running water for a minimum of 2 minutes (Fig. 11). Use a syringe, pipette or water jet to flush lumens and channels. Move joints, handles and other movable device features in order to rinse thoroughly under running water. After completing this step, drain any excess water.

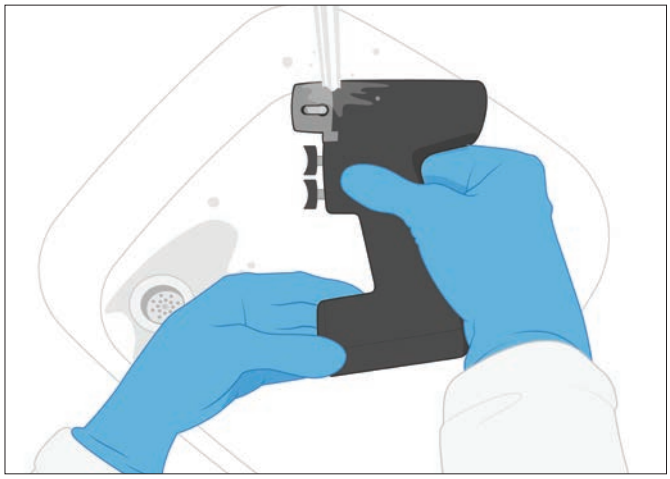


Figure 11

7. Wipe/Spray Disinfection

Wipe off or spray the surfaces of the devices with a minimum of 70% alcohol-based disinfectant for thirty seconds. This step has to be repeated two (2) additional times using a new, clean, soft and lint-free cloth dampened with a minimum 70% alcohol-based disinfectant each time.

8. Visually Inspect Device

Inspect the device including cannulations, sliding sleeves, attachment release rings, etc. for visible soil. Repeat the process if visible soil remains.

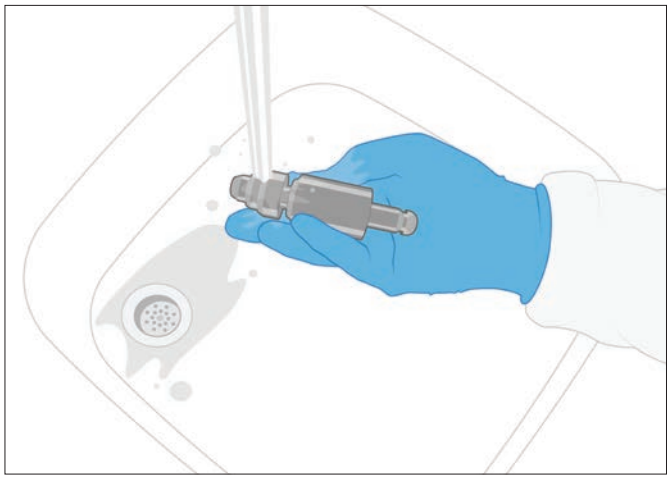


Figure 12

9. Final Rinse with De-ionized/Purified Water

Final rinse with de-ionized or purified water for a minimum of 2 minutes (Fig. 12).

10. Dry

Dry device using a clean, soft lint-free cloth (Fig. 13) or medical grade compressed air. If smaller devices or cannulations contain residual water, blow them dry with medical grade compressed air. Ensure that all parts are dry including the inside of the handpiece.

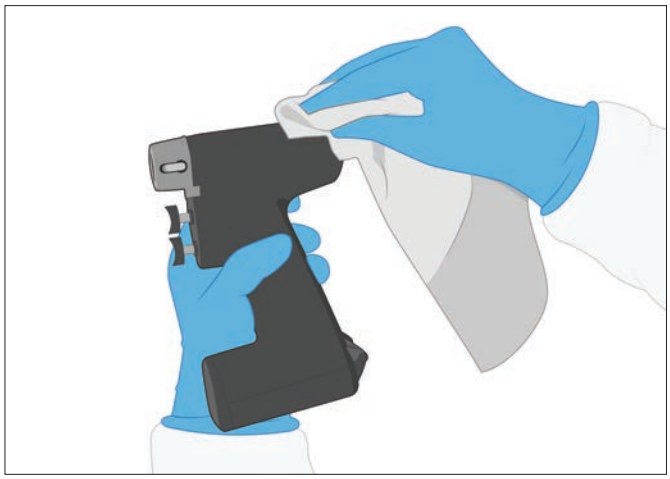


Figure 13

Cleaning and Disinfection

Automated Cleaning Instructions with Manual Pre-Cleaning

1. Manual Pre-Cleaning

For the manual pre-cleaning please follow steps 1–6 and 8 of the Manual Cleaning Instructions on pages 30–32. Once completed, place the articles in the washing basket for the automated cleaning procedure.

■ Notes:

- Manual pre-cleaning prior to automated cleaning is important to ensure cannulations and other difficult to access areas are clean.
- Alternative cleaning procedures other than the one described (including manual pre-cleaning) have not been validated.
- The automated cleaning instructions with manual pre-cleaning are valid for the UNIUM Washing and Sterilization Baskets, Insert Tray and Lids.

2. Load Washing Basket

Use the specially designed baskets for automated washing (68.001.650, 68.001.651 and 68.001.654).

▲ WARNING:

Always carefully follow the washing basket loading plans. If the devices are incorrectly placed this could affect the outcome of the reprocessing.

Ensure that the items are placed in the basket as indicated by the markings (Fig. 1). Make sure that all items are fully pushed into the silicon place holders. The attachments must be fully opened, so that the water can flow off any surfaces. Ensure that the casing cover of the handpiece is open and the front lid is turned 180° until it clicks. Place it in the position specified in the loading plans on page 35. For further reference, see loading plan diagram on the basket (Figs. 2 and 3).

■ Note:

Lids (68.001.652, 68.001.653) are available for the baskets.

Overview of Washing and Sterilization Basket, size 1/1, for UNIUM Modular Handpiece

Basket (68.001.650) with
Insert Tray (68.001.654) and Lid (68.001.653)

Dimensions (Length × Width × Height):

Basket without Lid: 480 × 250 × 100 mm
Basket with Lid: 480 × 250 × 108 mm

Weight

Basket (68.001.650):	1.46 kg/3.22 lbs
Insert Tray (68.001.654):	0.94 kg/2.07 lbs
Lid (68.001.653):	0.73 kg/1.61 lbs
Total weight when empty:	3.13 kg/6.90 lbs

Overview of Washing and Sterilization Basket, size 1/2, for UNIUM Reciprocating Saw Handpiece

Basket (68.001.651) with Lid (68.001.652)

Dimensions (Length × Width × Height):

Basket without Lid: 240 × 250 × 100 mm
Basket with Lid: 240 × 250 × 108 mm

Weight

Washing Basket (68.001.651):	1.08 kg/2.38 lbs
Lid (68.001.652):	0.4 kg/0.88 lbs
Total weight when empty:	1.48 kg/3.26 lbs

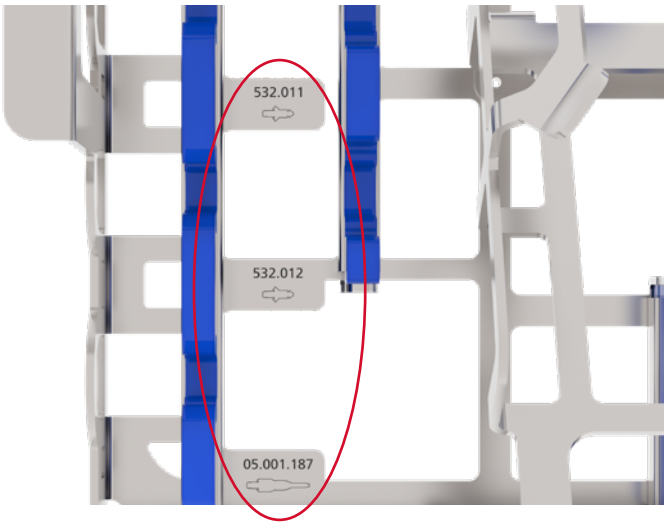


Figure 1: Detailed view of the markings inside the basket

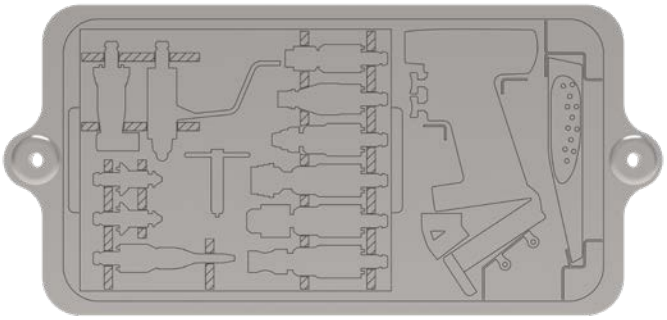


Figure 2: Loading plan diagram on the Washing and Sterilization Basket, size 1/1, for UNIUM Modular Handpiece

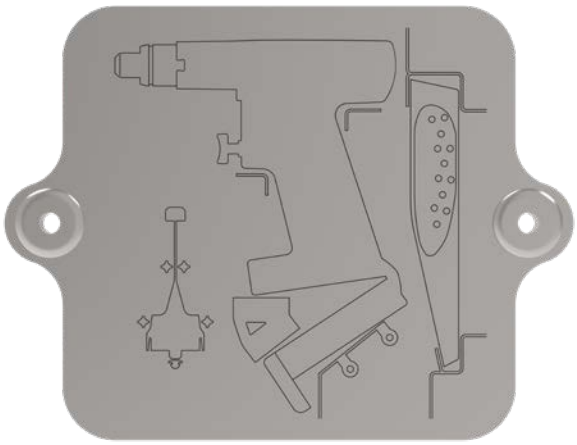
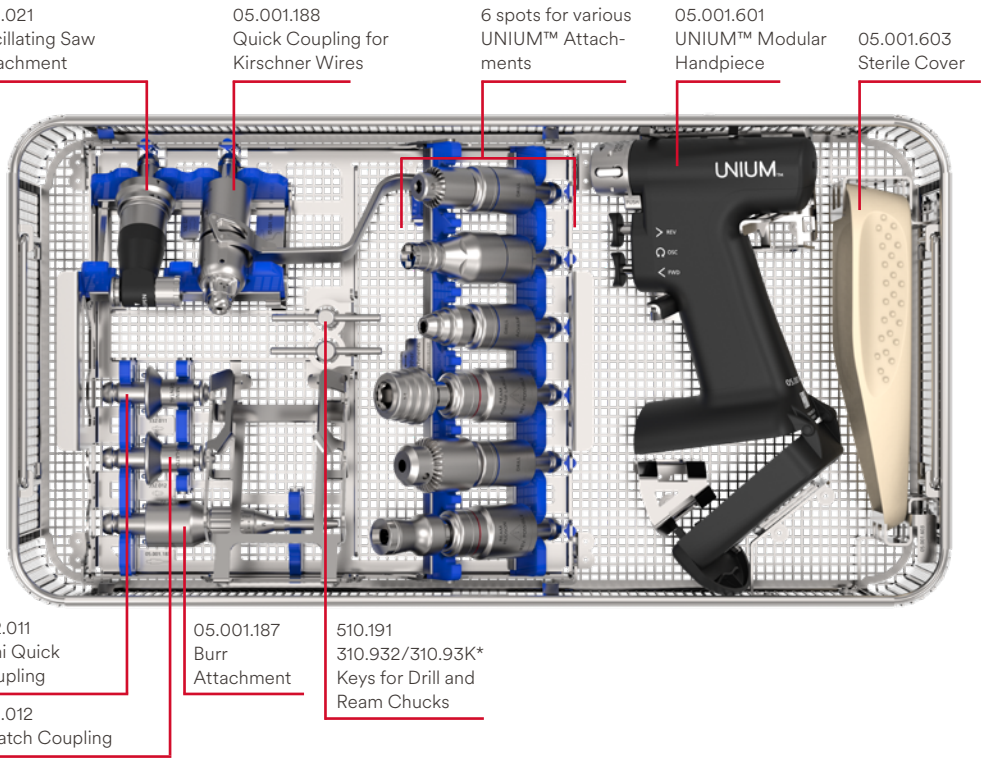


Figure 3: Loading plan diagram on the Washing and Sterilization Basket, size 1/2, for UNIUM Reciprocating Saw Handpiece

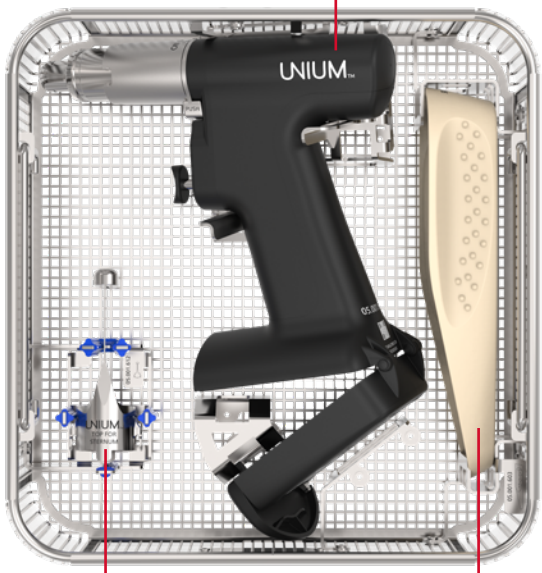
Loading Plan of Washing and Sterilization Basket, size 1/1, for UNIUM™ Modular Handpiece (68.001.650) with Insert Tray (68.001.654)



The insert tray should be kept inside the basket during the automated washing and sterilization procedure.

*available in USA only

Loading Plan of Washing and Sterilization Basket, size ½, for UNIUM™ Reciprocating Saw Handpiece (68.001.651)



Notes:

- Ensure that the casing cover of the UNIUM Modular or Reciprocating Saw Handpiece is open and the front lid is turned 180° until it clicks. Handle the front lid, casing cover, edges, seals and hinges with care.
- Alternatively, the UNIUM Modular Handpiece 05.001.601 can also be placed in the Washing and Sterilization Basket, size ½ (68.001.651).

Loading plans are available as separate documents. The images show the basket fully loaded, all items must be ordered separately.

3. Automated Cleaning Cycle Parameters

■ Note:

Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and -2, or to an equivalent standard. Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens can drain freely. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer's instructions.

Cycle	Minimum Time (minutes)	Water Type & Minimum Temperature	Type of Detergent
Pre-wash	2	Cold tap water	N/A
Wash I	2	Cold tap water (< 40 °C/104 °F)	Cleaning agent
Wash II	5	Warm tap water (> 40 °C/104 °F)	Cleaning agent
Rinse	2	Warm deionized water or purified water (> 40 °C/104 °F)	N/A
Thermal disinfection	5	≥ 93 °C/199 °F)	N/A
Dry	40	≥ 90 °C/194 °F	N/A

4. Inspect Device

Remove all devices from the washing basket.

Inspect the cannulations, sliding sleeves, etc. for visible soil. If necessary, repeat the manual pre-cleaning/automated cleaning cycle. Confirm that all parts are free of moisture both inside and outside. A reduction of the dry time may lead to damage to the device due to the presence of moisture. Such damage will not be covered by warranty.

▲ Precaution:

- Automated cleaning is an additional stress for devices, especially for seals and bearings. Therefore, devices must be properly lubricated after automated cleaning as indicated on page 37.

Maintenance and Lubrication

The handpieces and attachments must be lubricated after each use to:

- Increase their lifetime by reducing the wear between moving parts.
- Reduce heat generation by reducing the friction between moving parts.

Failing to lubricate the parts will lead to damage and malfunction, increasing the risk of harm to the user and patient.

For further information, please refer to the UNIUM Care and Maintenance Poster and the Instruction for Use of Synthes Special Oil (519.970, 519.97*).

Accessible moving parts of the handpiece and attachments must be lubricated after each use with one (1) drop of Synthes Special Oil (Fig. 1). Once the oil has been applied, move (e.g. press, open/close) the moving parts several times to properly spread the oil. Wipe off excess oil with a cloth. This applies to the following components:

Lubricating the Handpieces (Figs. 2 and 3)

- Trigger shafts (05.001.601 and 05.001.611).
- Attachment release buttons (only 05.001.601).
- Mode switch (05.001.601 and 05.001.611).
- Attachment coupling (05.001.601), reciprocating saw blade coupling and release knob (05.001.611).

Lubricating the Casing Cover and Front Lid

- Casing opening button (Fig. 4).
- Shaft on the inside of the casing cover lid (Fig. 5).
- The entire length of the sealing evenly (Fig. 6). Wipe off excess oil with a cloth.

Figure 1

Figure 2

Figure 3

Figure 5

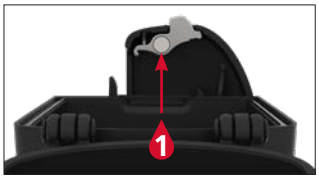


Figure 4

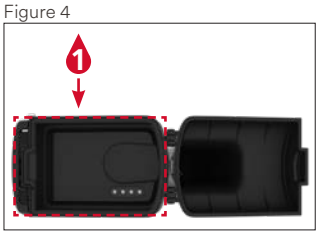


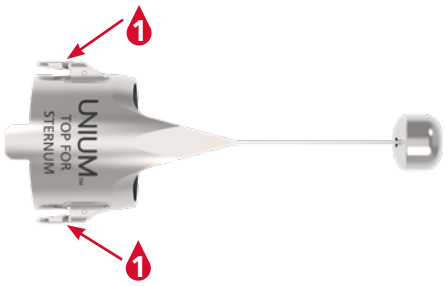
Figure 6

*available in USA only.

Lubricating the Attachments

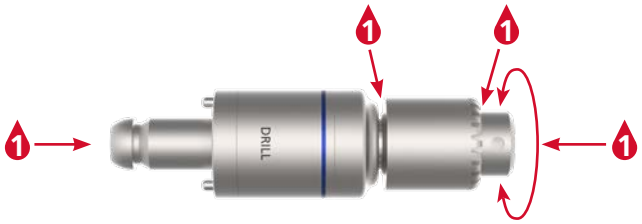
Top for Sternum (05.001.612)

- Two moving parts.



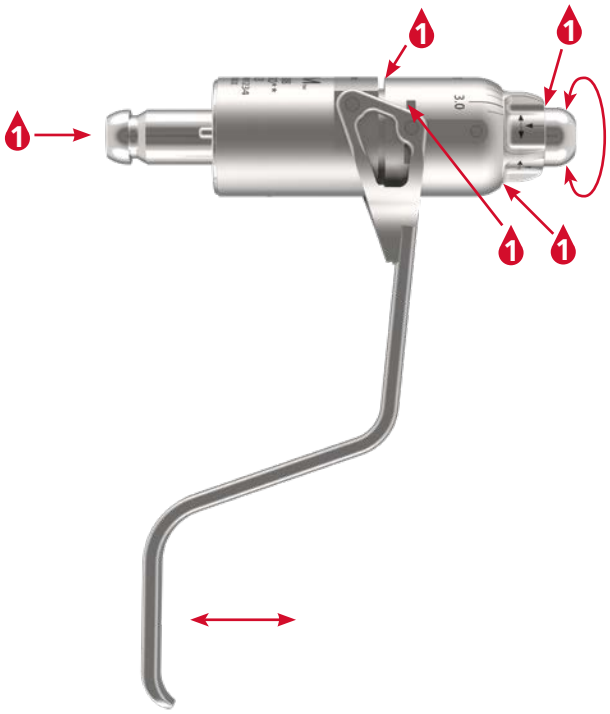
Drill and Ream Chuck (05.001.252–05.001.254)

- Opening of the attachment coupling, jaws and the toothed rim.



Quick Coupling for Kirschner Wires (05.001.188)

- Opening of the attachment coupling, the tension lever and the clamping mechanism. Hold the Quick Coupling up and add one drop of oil into the attachment hole and on the holder of the lever. Move the tension lever several times.



AO/ASIF Quick Coupling (05.001.250, 05.001.251)
Quick Coupling for DHS/DCS Triple Reamers (532.015)
Quick Coupling for Medullary Reaming (05.001.257, 05.001.258, 05.001.259, 05.001.260)

- Opening of the attachment coupling and the unlocking ring.

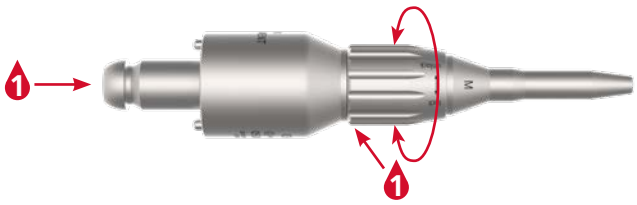
Mini Quick Coupling (532.011)
J-Latch Coupling (532.012)
Adapters (511.787, 511.788, 310.930, 338.490 and 310.93K* and 338.49*)

- Opening of the attachment coupling and the unlocking ring.

* available in USA only.

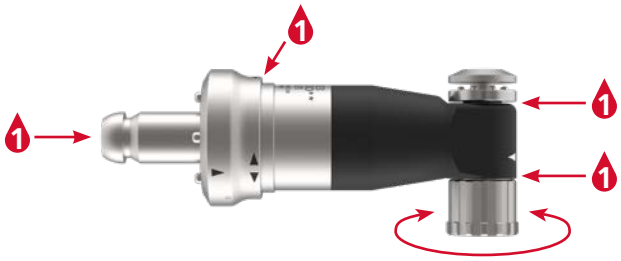
Burr Attachment (05.001.187)

- Opening of the attachment coupling and the release sleeve.



Oscillating Saw Attachment (532.021)

- Opening of the attachment coupling, the locking mechanism and the saw blade coupling.

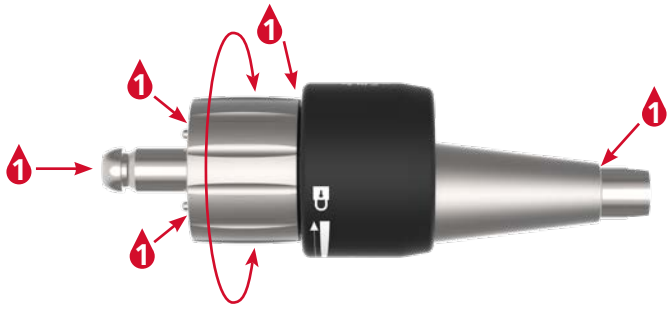


Oscillating Saw Attachment II (532.023)

- Opening of the attachment coupling, the sliding sleeve and the attachment coupling.

Large Oscillating Saw Attachment (532.026)

- Saw blade coupling (slot between the saw blade coupling and attachment), the sliding sleeve of the attachment coupling (slots on both sides), the coupling pins and the opening of the attachment coupling.



▲ WARNINGS:

- This device requires regular maintenance service, at least once a year, in order to maintain its safety and functionality. This service has to be performed by the original manufacturer or an authorized site.
- Do not use excessive oil when lubricating the parts as this may affect the reprocessing. Wipe off any excess oil with a cloth.

▲ Precautions:

- To ensure a long service life and reduce repairs, the handpieces and attachments must be lubricated after each use. Only lubricate the devices when they are clean to ensure the best possible outcome.
- Exception: The Radiolucent Drive (511.300, 511.30*) and the Adapter for Radiolucent Drive (532.031) do not require lubrication.
- The Power Tools and attachments must only be lubricated with Synthes Special Oil (519.970, 519.97*). Oil from another manufacturer must not be used. Lubricants with different compositions may cause jamming, have a toxic effect or have a negative impact on the sterilization results.

* available in USA only.

Inspection and Function Test

All movable parts should be moving smoothly. Check that no residuals parts prevent this.

Check the triggers in the handpiece and mode switch for smooth operation and function. Confirm that the triggers in the handpiece are not blocked and move freely when pressing on them.

Check the all devices (e.g. sterile cover, washing basket, etc.) for cracks, broken off parts and deformations.

Perform function tests using a fully operational device, i.e. the Power Unit connected to the handpiece.

Do not use damaged, worn or corroded devices but return them to the DePuy Synthes Service Center.

Failing to follow these instructions may lead to damage and malfunction, increasing the risk of harm to the user and patient.

For further information on the inspection and function test, please refer to the UNIUM Care and Maintenance Poster.

▲ WARNINGS:

- Visually inspect for damage and wear (e.g. un-recognizable markings, missing or removed part numbers, corrosion, etc.) to ensure the device has not reached its end of life.
- Check the coupling head of the handpiece and the locking sleeves of the attachments for smooth operation, and check for proper function with cutting tools.
- Check attachments and cuttings tools for correct adjustment and functionality prior to every use.

Packaging, Sterilization and Storage

Packaging

Put clean, dry products into their proper places in the baskets (68.001.650, 68.001.654 and 68.001.651). Additionally, use an appropriate sterilization wrap or reusable rigid container system for sterilization, such as a Sterile Barrier System according to ISO 11607. Care should be taken in order to protect implants as well as pointed or sharp instruments from contact with other objects that may damage the surface or the Sterile Barrier System.

■ Notes:

- If baskets (68.001.650, 68.001.654 or 68.001.651) are used for sterilization in a sterilization wrap, then use the appropriate lid (68.001.653 or 68.001.652).
- If baskets (68.001.650, 68.001.654 or 68.001.651) are used for sterilization in a rigid container, then a lid (68.001.653 or 68.001.652) is not required.

Sterilization

Steam (moist heat) sterilization shall be performed in a locally approved, cleared pre-vacuum (forced air removal) cycle. The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ANSI ST8, including compliance to the requirements of ISO 17665. The steam sterilizer should be installed and maintained in compliance to manufacturer's instructions and local requirements. Ensure that a steam sterilizer cycle is chosen that is designed to remove air from porous or lumened device loads in accordance to manufacturer's instructions and does not exceed the maximal sterilizer load.

Cycle Type Prevacum	Sterilization Exposure Time (minutes)	Sterilization Exposure Temperature	Dry Time (minutes)
Saturated steam-forced air removal (pre-vacuum)	4	132 °C/270 °F	30–60
	3	134 °C/274 °F	30–60

Dry times may be highly variable due to differences in packaging materials (Sterile Barrier System, e.g., wraps or reusable rigid container), environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

▲ WARNINGS:

- Hot air, ethylene oxide, plasma and formaldehyde sterilization are not allowed. Using these methods could destroy the device with possible secondary damage.
- Never steam sterilize the handpiece with the casing cover and front lid closed. Follow the basket loading plan to ensure correct positioning of the device in order to avoid damage to it and prevent infection.

▲ Precautions:

- UNIUM Devices must be resterilized using either ISO 17665 methods or national standards.
  DePuy Synthes recommendations for packed devices are as shown in the table above.
- Remove the Power Unit from the handpiece to avoid damage.
- The sterilization parameters are only valid for devices that are adequately cleaned.
- The following maximum values must not be exceeded: 138 °C/280 °F over a maximum of 18 minutes. Higher values can damage the sterilized products.
- Inspect the packages prior to storage for visual moisture or dampness and if found on or within the pack, the product should be repackaged and sterilized with an increased drying time.
- Do not accelerate the cooling process as it will damage the Power Tool and could result in harm to the user and patient.
- Do not sterilize the Universal Battery Charger II and UNIUM Adapter for UBC II.

Storage

Packaged and sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests and extremes of temperature and humidity.
Use products in the order in which they are received ("first-in, first-out principle"), taking note of any expiration date on the label. Storage conditions for products labeled "STERILE" are printed on the packaging label.

Repairs and Technical Service

The Power Tool needs to be sent to the DePuy Synthes Service Center for repair if it is faulty or malfunctions or at least once a year for regular maintenance.

▲ WARNINGS:

- Prior to returning for repair or technical service, Power Tools and their accessories/attachments must be run through the complete reprocessing procedure. Failure to follow the reprocessing instructions may lead to infection.
- This device requires a regular maintenance service, at least once a year, in order to maintain its safety and functionality. This service has to be performed by the original manufacturer or an authorized site.
- The manufacturer excludes liability for damage resulting from improper use, neglected or unauthorized maintenance or servicing of the device. In such cases the product will no longer be accepted or repaired by DePuy Synthes.
- To prevent damage during shipping use the original packaging to return devices back to DePuy Synthes. Inadequate packaging could result in device damage and possible secondary damage. If the packaging material is no longer available, please contact the DePuy Synthes Representative.

Faulty devices must not be used. A device may have reached its end of life if there is evidence of damage and wear. This may include but is not limited to corrosion, discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed part numbers, damaged and excessively worn devices should not be used. If it is no longer possible or feasible to repair the device, then it should be disposed of according to the section “Disposal of Waste”. Failing to carry out a regular maintenance service, at least once a year, could cause end of life indicators to occur.

Other than the above-mentioned care and maintenance, no further maintenance work is to be carried out independently or by third parties.

Transporting UNIUM™ Power Unit

The Power Unit is classified as a “Li-Ion battery contained in equipment” according to the International Air Transport Association (IATA) regulation UN 3481 PI 967. Please ensure that the packaging and documentation requirements for shipping a Power Unit are followed.
Do not store or transport Power Units haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects. This can damage the Power Unit and generate heat, which can cause burns. Please refer to the chapter “Environmental Conditions” to see both transport and storage conditions. UN 38.3 Test Report available upon request from the DePuy Synthes Service Center.

Please note that if the Power Unit is damaged it cannot be transported by aircraft cargo.
The Power Unit can be considered to be damaged if any of the following apply:

- Decreased battery life, e.g. no longer enough to perform a procedure. A further Power Unit is needed to complete the operation. This could occur when the battery is at the end of its expected life.
- The Power Tool no longer performs as intended e.g. running too slow. This could be caused by a short circuit of the battery cells.
- The Power Unit does not work and cannot be charged in charger. No LED lights up when pressing the Information Button of the Power Unit. This could be caused by damage to the battery cells.
- The red Service Indicator LED lights up and remains on for a few seconds on the Power Unit. Either after the user running the self-test by pressing the Information Button on the Power Unit as described on page 13 or lighting up without the user having started the self-test. This means that the Power Unit is damaged and can no longer be further used.
- Whilst charging the Power Unit in the charger, the red Service Indicator LED lights up on the Power Unit. In parallel the red LED on the charger lights up as well. In this case the battery has a failure.
- The Power Unit is visibly damaged e.g. was mistakenly steam sterilized by the user and the excessive heat has melted the Power Unit.

Disposal of Waste and Materials

The devices must not be disposed of with household waste.
Please send devices that are no longer used to your local DePuy Synthes Representative. This ensures that they are disposed of in accordance with the national application of the following European Directives:

- European Battery Directive 2006/66/EC. This device contains Lithium-Ion batteries that should be disposed of in accordance with environment protection requirements. Please observe local or national regulations.
- European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). This device contains materials that should be disposed of in accordance with environment protection requirements. Please observe local or national regulations.

▲ WARNINGS:

- Contaminated products have to run through the complete reprocessing procedure in order to rule out any risk of infection in case of disposal.
- Risk of fire and burns. Do not disassemble, crush, heat above 60 °C/140 °F or incinerate the battery cells.
- Never expose the Power Unit to temperatures over 60 °C/140 °F. The maximum exposure time at 60 °C/140 °F is 72 hours.
- Do not dismantle, open, short-circuit or shred the Power Unit.

▲ Precaution:

Faulty devices must not be reused and should be disposed of in an environmentally friendly manner and in accordance with national regulations.

Materials

Device(s)	Material(s)	Abbreviation(s)	Standard(s)
Handpieces	Stainless Steel	SSt	ISO 7153-1
	Polyphenylsulfon	PPSU	n/a
	Elastomer	Elastomer	n/a
	Polyetheretherketon	PEEK	n/a
	Copper zinc with gold plating	CuZn gold plated	n/a
Power Unit	Acrylnitril-Butadien-Styrol-Copolymere	ABS	n/a
	Copper zinc with gold plating	CuZn gold plated	n/a
	Stainless Steel	SSt	n/a
	Polyester	PVS-G	n/a
Sterile Cover	Polyphenylsulfon	PPSU	n/a
Attachments and Adapters	Stainless Steel	SSt	ISO 7153-1
	Aluminium	Aluminium	DIN EN 573
	Polyetheretherketon	PEEK	n/a
	Elastomer	Elastomer	n/a
Keys for Drill and Ream Chuck Attachments	Stainless Steel	SSt	ISO 7153-1
Top for Sternum for Reciprocating Saw Handpiece	Stainless Steel	SSt	ISO 7153-1
Washing and Sterilization Baskets	Stainless Steel	SSt	ISO 7153-1
	Silicon Rubber	Silicon Rubber	n/a
	Polytetrafluorethylen	PTFE	n/a
Accessories	Stainless Steel	SSt	ISO 7153-1
	Polyamid	PA	n/a
	Polyethylen	PE	n/a
	Synthetic Oil	Synthetic Oil	n/a

Specifications
Duty Cycles

Intermittent operation type S9, according to IEC 60034-1. This data was measured at an ambient temperature of 20 °C / 68 °F.

UNIUM Modular Handpiece (05.001.601)

		⚠ Xs on	Ys off	Cycles
Drilling Speed Attachments		30 sec	45 sec	10
Reaming Speed Attachments		45 sec	45 sec	5
Burring Speed Attachments		30 sec	45 sec	5
Kirschner Wire setting		15 sec	45 sec	5
Sawing	532.021	15 sec	45 sec	4
	532.023	15 sec	45 sec	3
	532.026	15 sec	45 sec	3

UNIUM Reciprocating Saw Handpiece (05.001.611)

	⚠ Xs on	Ys off	Cycles
Sawing	30 sec	60 sec	5

Generally, electrical devices will heat up if in constant use. For this reason, the handpiece and the attachments should be allowed to cool for at least 60 seconds (Ys off) following the time of constant use (Xs on) as outlined in the table above. After a certain amount of cycles (defined in the above table under “Cycles”) the handpiece and attachment should be allowed to cool down. Observing this instruction prevents the device from overheating and possibly harming the patien or user. The user is responsible for the application and for turning off the device as prescribed. If longer periods of constant use are required, an additional handpiece and/or attachment should be used.

Depending on the cutting tool used and the load applied, the heat generated by the handpiece, attachment and/or cutting tool can vary.
The UNIUM Handpiece is equipped with a thermal overload safety system that shuts off the device if it becomes too hot during use. After cooling, the device can be used again. This will take a significant amount of time.

▲ Precautions:

- Carefully observe the duty cycles recommended in both charts.
- Follow the recommended duty cycle to prevent the equipment from overheating.
- Always control the temperature of the device to prevent overheating and possibly harming the patient or user.
- The duty cycles recommended in both charts must be reduced when a longer period of constant use (Xs on) is applied or the ambient temperature is above 20 °C/68 °F.
- The amount of duty cycles should be taken into consideration when planning a surgical procedure.
- It is recommended to use new cutting tools for every surgery to prevent the device from heating up as a result of reduced cutting performance.
- Careful maintenance of the device will reduce heat build-up in the handpiece and the attachments.

Applicable Standards, Environmental Conditions and Transportation

The device meets the following standards

Medical electrical equipment – Part 1: General requirements for basic safety and essential performance:
IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
EN 60601-1:2006, A1:2013 (Ed.3.1)
ANSI/AAMI ES60601-1:2005 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
CAN/CSA-C22.2 NO. 60601-1:14

Medical electrical equipment – Part 1-2:
General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests:
IEC 60601-1-2:2014
EN 60601-1-2:2015

Medical electrical equipment – Part 1-6:
General requirements for basic safety and essential performance – Collateral Standard: Usability:
IEC 60601-1-6:2010 (Third Edition), AMD1:2013
CAN/CSA-C22.2 NO. 60601-1-6:11, AMD1
EN 60601-1-6:2010 (Third Edition), A1:2015

Medical devices – Part 1: Application of usability engineering to medical devices:
IEC 62366-1:2015, AMD:2020
EN 62366-1:2015, A1:2020

E352266

Medical General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with:
ANSI/AAMI ES60601-1:2005 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
CAN/CSA-C22.2 NO. 60601-1:14
IEC 60601-1-6:2010 (Third Edition), AMD1:2013
CAN/CSA-C22.2 NO. 60601-1-6:11, AMD1

Environmental Conditions	Operation	Storage
Temperature	10 °C / 50 °F – 40 °C / 104 °F	10 °C / 50 °F – 40 °C / 104 °F
Relative humidity	10 % – 95 % No condensation	10 % – 95 % No condensation
Atmospheric pressure	500 hPa / 0.5 bar – 1060 hPa / 1.06 bar	500 hPa / 0.5 bar – 1060 hPa / 1.06 bar
Altitude	0 – 5000 m	0 – 5000 m

Transportation*

Temperature	Duration	Humidity
–29 °C; –20 °F	72 h	uncontrolled
38 °C; 100 °F	72 h	85 %
60 °C; 140 °F	6 h	30 %

*products have been tested according to ISTA 2A or ISTA 3A.

▲ WARNING:

UNIUM Devices must not be stored or operated in an explosive atmosphere.

Emission Sound Pressure, Sound Power, Vibration

Declaration of the Emission Sound Pressure Level and the Sound Power Level according to EU Directive 2006/42/EC

Measurements of the sound pressure level [LpA] are carried out in accordance with standard EN ISO 11202.
Measurements of the sound power level [LwA] are carried out in accordance with standard EN ISO 3746.

Handpiece	Attachment	Cutting Tool	Sound Pressure Level (LpA) in [dB(A)]	Sound Power Level (LwA) in [dB(A)]	Max. daily exposure time without hearing protection
UNIUM Modular Handpiece* (05.001.601)	–	–	59.67	74.10	No limitation
	AO/ASIF Quick Coupling (05.001.250)	–	76.70	75.81	No limitation
	Oscillating Saw Attachment (532.021)	Saw Blade (532.045)	74.46	89.41	No limitation
		Saw Blade (532.067)	83.17	98.05	11 h 34 min
	Oscillating Saw Attachment (532.023)	Saw Blade (03.000.313)	84.45	99.48	8 h 36 min
		Saw Blade (03.000.316)	90.13	105.43	2 h 19 min
	Large Oscillating Saw Attachment (532.026)	Saw Blade (03.000.394)	86.33	102.12	5 h 34 min
		Saw Blade (03.000.396)	82.53	100.23	13 h 25 min
UNIUM Recipro-cating Saw** (05.001.611)	–	–	83.31	96.89	11 h 11 min
		Saw Blade (511.920S)	92.40	98.72	1 h 22 min

▲ Precaution:

Carefully observe the above recommended maximum daily exposure times.

Operation condition:
* Handpiece 05.001.601 with 05.001.250 at idle speed (1,255 rpm)
* Handpiece 05.001.601 with 532.021, 532.023, 532.026 at idle speed (17,000 rpm)
** Handpiece 05.001.611 at idle speed (12,400 Osc./min)
Technical data is subject to tolerances.
The values were determined with Synthes Saw Blades with the exception of 511.920S which is manufactured by Gebr. Brasseler GmbH & Co. KG with Synthes acting as the exclusive distributor.

Declaration of Vibration Emission According to EU Directive 2002/44/EC

Vibration emissions [m/s²] tested according to EN ISO 5349-1.

Handpiece	Attachment	Tool	Vibration emission [m/s²]	Max. daily exposure
UNIUM Modular Handpiece* (05.001.601)	–	–	<2.5	8 h
	AO/ASIF Quick Coupling (05.001.250)	–	<2.5	8 h
	Oscillating Saw Attachment (532.021)	Saw Blade (532.045)	<2.5	8 h
		Saw Blade (532.067)	8.25	44 min
	Oscillating Saw Attachment (532.023)	Saw Blade (03.000.313)	5.16	1 h 52 min
		Saw Blade (03.000.316)	7.23	57 min
	Large Oscillating Saw Attachment (532.026)	Saw Blade (03.000.394)	12.20	20 min
		Saw Blade (03.000.396)	34.20	2 min
UNIUM Reciprocating Saw** (05.001.611)	–	–	11.59	22 min
		Saw Blade (511.920S)	14.28	14 min

▲ Precaution:

Carefully observe the above recommended maximum daily exposure times.

Operation condition:
* Handpiece 05.001.601 with 05.001.250 at idle speed (1,255 rpm)
* Handpiece 05.001.601 with 532.021, 532.023, 532.026 at idle speed (17,000 rpm)
** Handpiece 05.001.611 at idle speed (12,400 Osc./min)
Technical data is subject to tolerances.
The values were determined with Synthes Saw Blades with the exception of 511.920S which is manufactured by Gebr. Brasseler GmbH & Co. KG with Synthes acting as the exclusive distributor.

Electromagnetic Compatibility Accompanying Documents According to IEC 60601-1-2, 2014, ed. 4.0

Table 1: Emission

Guidance and manufacturer's declaration – electromagnetic emissions

UNIUM Devices are intended for use in the electromagnetic environment of surgery rooms of hospitals except for near active HF surgical equipment. The customer or user of UNIUM Devices should ensure that they are used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions, CISPR 11	Group 1	UNIUM Devices only use RF energy for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	UNIUM Devices are suitable for use in a professional healthcare facility environment but not in a home healthcare environment.
Harmonic emissions, IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Not applicable	

▲ Precautions:

- Using UNIUM outside the specified electromagnetic environment may lead to malfunction (e.g. unintended start or stop of the device).
- Do not place the handpiece on a magnetic surface since the Power Tool might start unintentionally.
- Keep distance to magnets and equipment with magnets.

Table 2: Immunity (all devices)

Guidance and manufacturer's declaration – electromagnetic immunity

UNIUM Devices are intended for use in the electromagnetic environment of surgery rooms of hospitals except for near active HF surgical equipment. The customer or user of UNIUM Devices should ensure that they are used in such an environment.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines, IEC 61000-4-11	<5% U_T (0.5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

■ Note:

U_T is the AC mains voltage prior to the application of the test level.

Power frequency, 50/60 Hz magnetic field, IEC 61000-4-8	30 A/m	200 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Immunity (not life-supporting devices)

Guidance and manufacturer's declaration – electromagnetic immunity

UNIUM Devices are intended for use in the electromagnetic environment specified below.
The customer or user of the UNIUM Devices should ensure that they are used in such an environment.

▲ WARNING:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Electromagnetic environment – guidance

Portable and mobile RF communications equipment should be used no closer to any part of the UNIUM Devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance[a]
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d = 0.35\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	E1 = 10 V/m (measured 20 V/m) 80 MHz to 800 MHz	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 800 MHz to 2.5 GHz	E2 = 10 V/m (measured 20 V/m) 800 MHz to 2.7 GHz	$d = 0.7\sqrt{P}$ 800 MHz to 6.2 GHz

Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[b] should be less than the compliance level in each frequency range.[c]

Interference may occur in the vicinity of equipment marked with the following symbol:

■ Notes:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

▲ WARNINGS:

- Do not use device together with HF surgical equipment.
- Keep distance to mobile HF communication equipment as defined in tables 3 and 4, but at least 30 cm (12 inches).
- Keep distance to 5G mobile phones.

a Possible shorter distances of outside ISM bands are not considered to have a better applicability of this table.

b Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) 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 RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which UNIUM Devices are used exceeds the applicable RF compliance level above, the UNIUM Devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the UNIUM Devices.

c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table 4: Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and UNIUM Devices

UNIUM Devices are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the UNIUM Devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UNIUM Devices as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
	m		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 6.2 GHz $d = 0.7\sqrt{P}$
0.01	4 mm	4 cm	7 cm
0.1	11 cm	11 cm	22 cm
1	35 cm	35 cm	70 cm
10	1.11 m	1.11 m	2.22 m
100	3.5 m	3.5 m	7 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

■ Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- An additional factor of 10 / 3 is used in calculating the recommended separation distance to decrease the likelihood that mobile / portable communications equipment could cause interference if it is inadvertently brought into patient areas.

UNIUM Devices have the following essential performances for EMC: No change of motor rotation direction, oscillation angle not bigger than 360°. In case of degradation due to EMC disturbances a wrong direction of the motor or an oscillation angle bigger than 360° could occur.

Explanation of Symbols Used

Symbols for Operating the Device

ON	Indicates the ON position of the Mode Switch
FWD ONLY **FWD**	Indicates the Forward Only (FWD ONLY) and Forward (FWD) position of the Mode Switch
OFF	Indicates the OFF position of the Mode Switch
PUSH	Indicates that the Mode Switch can be PUSHED to change between modes
FWD >	Indicates the Forward Trigger
REV <	Indicates the Reverse Trigger
OSC	Indicates to press the Forward and Reverse Triggers at the same time for Oscillating Drilling Mode
◀PRESS▶	Indicates that the release buttons can be PRESSED to remove attachments
← PRESS	Indicates that the casing cover can be opened by PRESSING the casing opening button
OPEN	Indicates which direction the front lid should be rotated to open the casing cover
	Indicates how the sterile cover is placed on top of the handpiece and removed from it during the aseptic transfer
	
REV. POSSIBLE	Reverse Function is possible with the Attachment
M	Size of the Burr Attachment
	Lock and Unlock the tool in the Attachment
	Indicates where the Oscillating Saw Attachment can be inserted in the handpiece
	Indicates that the sleeve can be adjusted to fit a suitable Kirschner Wire by simultaneously pressing and turning it axially against the handpiece
	Battery Level Indicator
	Service Indicator on Power Unit. If the red LED lights up do not use the Power Unit further as it must be replaced
	Information Button on Power Unit. By pressing it briefly the battery level is shown on the Battery Level Indicator. By pressing it for 8 seconds the self-test of the Power Power Unit is run

General Symbols

Caution (Ref. 5.4.4 ISO 15223-1)

Consult Instructions For Use
(Ref. 5.4.3 ISO 15223-1)

Manufacturer and Date of Manufacture
(Ref. 5.1.1 ISO 15223-1)

Date of Manufacture (Ref. 5.1.3 ISO 15223-1)

Reference or Catalogue Number
(Ref. 5.1.6 ISO 15223-1)

Serial Number (Ref. 5.1.7 ISO 15223-1)

Lot or Batch Number (Ref. 5.1.5 ISO 15223-1)

Packaging unit, indicates the number of pieces in the package (Ref. 2794 ISO 7000)

Non-sterile (Ref. 5.2.7 ISO 15223-1)

Materials

Medical Device in the European Community/ Union

Authorized Representative in the European Community (Ref. 5.1.2 ISO 15223-1)

CE marking of conformity in European Community with identification of notified body (Regulation (EU) 2017/745)

CE marking of conformity in European Community (Regulation (EU) 2017/745)

Use-by Date (Ref. 5.1.4 ISO 15223-1)

Keep away from sunlight
(Ref. 5.3.2 ISO 15223-1)

Keep dry
(Ref. 5.3.4 ISO 15223-1)

Sterilized using irradiation
(Ref. 5.2.4 ISO 15223-1)

Do not use if package is damaged
(Ref. 5.2.8 ISO 15223-1)

Do not re-use (Ref. 5.4.2 ISO 15223-1)

Caution: United States Federal law restricts this device to sale by or on the order of a physician or other licensed healthcare provider (21 CFR 801.109)

Made in

Quantity, indicates the number of pieces in the package

Type BF applied part complying with IEC 60601-1 (Ref. 5.333 IEC 60417)

Do not immerse device in liquids

Duty Cycle type according IEC 60034-1

Water ingress protection rating according IEC 60529

Product is UL Classified to the requirements of both the United States and Canada

Separate collection (EN 50419)

Indicates Environment-Friendly Use Period of 10 years in China (SJ/T 11364)

Temperature Limit
(Ref. ISO 5.3.7 ISO 15223-1)

Humidity Limitation
(Ref. ISO 5.3.8 ISO 15223-1)

Atmospheric Pressure Limitation
(Ref. ISO 5.3.9 ISO 15223-1)

Non-ionizing electromagnetic radiation (Ref. 5.140 IEC TR 60878): Interference may occur in the vicinity of equipment marked with the following symbol (IEC 60601-1-2, clause 5.1.1)

Troubleshooting

For a patient/user/third party in the European Union and in countries with identical regulatory framework (Regulation (EU) 2017/745 on Medical Devices): if during the use of this device or as a result of its use, a serious incident has occurred, please report to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Problem	Possible Causes	Solution
Handpiece does not start up.	Power Unit is empty.	Charge the Power Unit or replace it with a charged Power Unit.
	The handpiece was not cooled off after sterilization.	Let the handpiece cool to room temperature.
	Mode switch is on OFF.	Turn the mode switch to ON or FWD ONLY mode.
	Handpiece switched off after two hours of no use.	Turn the mode switch to OFF and ON again.
Handpiece does not have enough power.	Power Unit is empty.	Charge the Power Unit or replace it with a charged Power Unit.
Handpiece stops suddenly.	The handpiece has overheated (overheating protection is activated).	Wait until the handpiece has cooled down.
	Power Unit has reached its end of use.	Replace with a new Power Unit and dispose off the old one.
Attachments cannot be coupled to or removed from the handpiece.	The attachment coupling is blocked by deposits or the coupling sleeve is damaged.	Remove solid objects with a pair of tweezers. **▲ WARNING:** Immediately turn mode switch to OFF position to avoid injuries. Remove solid particles with a pair of tweezers. Check the coupling sleeve; clean and lubricate if necessary. Send handpiece to DePuy Synthes Service Center if necessary.
Cutting tool (saw blade, drill, burr etc.) cannot be coupled or only with difficulty.	Shaft geometry of the attachment or handpiece is damaged.	Replace the attachment or handpiece or send it to your DePuy Synthes Service Center.
Oscillating saw attachment vibrates too much.	The saw blade locking mechanism is not tight.	Tighten the locking knob of the saw blade coupling.
	Both triggers being pressed simultaneously whilst the mode switch is in the ON position.	Keep the mode switch on ON but press forward trigger only or turn the mode switch to FWD ONLY mode.
Bone and cutting tool heat up during surgery.	Cutting edges of the cutting tool are blunt.	Replace the cutting tool.
The casing opening button is stuck.	The casing opening button needs to be lubricated.	Lubricate the casing opening button as described on page 37.
Handpiece continues to run after releasing trigger.	Trigger is jammed by deposits or handpiece is defective.	Immediately turn mode switch to OFF position. Ensure that the trigger is cleaned and lubricated correctly. If necessary send handpiece to DePuy Synthes Service Center.
Device is visibly damaged.	Device was for example: exposed to excessive heat, was incorrectly washed, disinfected, steam sterilized or fell on the floor, etc.	Do not further use the device as it must be replaced.

Ordering Information

Handpieces	
05.001.601	UNIUM™ Modular Handpiece
05.001.611	UNIUM™ Reciprocating Saw Handpiece

Power Unit, Sterile Cover, Adapter and Charger	
05.001.602	UNIUM™ Power Unit
05.001.603	UNIUM™ Sterile Cover
05.001.604	UNIUM™ Adapter for UBC II
05.001.204	Universal Battery Charger II

Attachments for UNIUM™ Modular Handpiece (05.001.601) Drill	
532.011	Mini Quick Coupling, for Colibri II / Small Battery Drive II and UNIUM™
532.012	J-Latch Coupling, for Colibri II / Small Battery Drive II and UNIUM™
05.001.250	AO/ASIF Quick Coupling for Colibri II / Small Battery Drive II and UNIUM™
05.001.252	Chuck (Drilling Speed), with Key, clamping range up to ∅ 4.0 mm, for Colibri II / Small Battery Drive II and UNIUM™
05.001.253	Chuck (Drilling Speed), with Key, clamping range up to ∅ 7.3 mm, for Colibri II / Small Battery Drive II and UNIUM™
532.031	Adapter for Radiolucent Drive, for Colibri II / Small Battery Drive II and UNIUM™
511.300	Radiolucent Drive
511.30	Radiolucent Drive (available in USA only)

Ream attachments with a reverse function	
05.001.254	Chuck (Reaming Speed), with Key, clamping range up to ∅ 7.3 mm, with reverse motion, for Colibri II / Small Battery Drive II and UNIUM™
05.001.257	AO/ASIF Quick Coupling for Medullary Reaming, for Colibri II / Small Battery Drive II and UNIUM™
05.001.258	Hudson Quick Coupling for Medullary Reaming, for Colibri II / Small Battery Drive II and UNIUM™
05.001.259	Trinkle Quick Coupling, for Colibri II / Small Battery Drive II and UNIUM™
05.001.260	Trinkle Quick Coupling, modified, for Colibri II / Small Battery Drive II and UNIUM™
532.015	Quick Coupling for DHS/DCS® Triple Reamers, for Colibri II / Small Battery Drive II and UNIUM™

Ream attachments without a reverse function	
532.017	AO/ASIF Quick Coupling for Medullary Reaming, for Colibri II / Small Battery Drive II and UNIUM™
532.018	Hudson Quick Coupling for Medullary Reaming, for Colibri II / Small Battery Drive II and UNIUM™
532.019	Trinkle Quick Coupling, for Colibri II / Small Battery Drive II and UNIUM™
532.020	Trinkle Quick Coupling, modified, for Colibri II / Small Battery Drive II and UNIUM™

Screw	
05.001.251	Screw Attachment with AO/ASIF Quick Coupling, for Colibri II / Small Battery Drive II and UNIUM™

■ Note:

The UNIUM Modular Handpiece is compatible with all legacy Colibri II/Small Battery Drive II attachments and Small Bone Cutting Tools. The only exception is the Quick Coupling for Kirschner Wires (532.022) which is only for use with Colibri II/Small Battery Drive II. The product description shows with which handpiece the article can be used.

K-Wire	
05.001.188	Quick Coupling for Kirschner Wires ∅ 0.6 to 3.2 mm, for UNIUM™

Burr	
05.001.187	Burr Attachment, for Colibri II / Small Battery Drive II and UNIUM™

Saw	
532.021	Oscillating Saw Attachment, for Colibri II / Small Battery Drive II and UNIUM™
532.023	Oscillating Saw Attachment II (Crescentic Technique), for Colibri II / Small Battery Drive II and UNIUM™
532.026	Large Oscillating Saw Attachment, for Colibri II / Small Battery Drive II and UNIUM™

Adapters	
511.787	Kuentscher Adapter
511.788	Harris Adapter
310.930	Drill Chuck, small, with Key, for Small Air Drill
338.490	Quick Coupling for Small Air Drill
338.49	Large Quick Coupling (available in USA only)

Keys for Drill and Ream Chuck Attachments	
310.932	Key for Drill Chuck, clamping range up to ∅ 4.0 mm
510.191	Key for Drill Chuck, clamping range up to ∅ 7.3 mm
532.027	Key, for No. 532.026 and 511.802
310.93K	Replacement Key for Small Chuck with Key (available in USA only)

Accessories for UNIUM™ Reciprocating Saw Handpiece (05.001.611)	
05.001.612	UNIUM™ Top for Sternum for Reciprocating Saw Handpiece
511.910S*	Reciprocating Saw Blade 41.5 × 10 × 0.80 mm
511.915S	Reciprocating Saw Blade 41.5 × 10 × 1.10 mm

Washing and Sterilization Baskets	
68.001.650	Washing and Sterilization Basket, size ½, for UNIUM™ Modular Handpiece, without lid, without insert tray
68.001.654	Insert Tray for Washing and Sterilization Basket, size ½, for UNIUM™ Modular Handpiece
68.001.653	Lid for Washing and Sterilization Basket, size ½, for UNIUM™ Modular Handpiece
68.001.651	Washing and Sterilization Basket, size ½, for UNIUM™, Reciprocating Saw Handpiece, without lid
68.001.652	Lid for Washing and Sterilization Basket, size ½, for UNIUM™

Accessories	
519.970	Synthes Special Oil, 40 ml
519.400	Cleaning Brush for Compact Air Drive II, Colibri II/Small Battery Drive II and UNIUM™
519.97	DePuy Synthes Special Oil, 40 ml (available in USA only)
519.40	Cleaning Brush for Handpiece and Attachment Cannulations (available in USA only)
532.024	Cleaning Brush for Oscillating Saw Attachment II (532.023)

Cutting Tools
Detailed ordering information on the cutting tools can be found in the brochure "Small Bone Cutting Tools".

Detailed ordering information on the special 3-flute drill bits for the Radiolucent Drive can be found in the brochure "Working with the Radiolucent Drive".

* The legal manufacturer is Gebr. Brasseler GmbH & Co. KG Germany. The blades are exclusively distributed by Synthes GmbH and The Anspach Effort, Inc.

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