Electric Pen Drive

Compact Drive With Specific Attachments
For A Wide Spectrum Of Applications

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Introduction

General Information

Indications:
The Electric Pen Drive (EPD) System is indicated for screw insertion, pin and wire placement, cutting of bone and metal, drilling, reaming, decorticating, shaping and smoothing of bones and teeth in a wide variety of surgical procedures, including but not limited to general orthopedic trauma, foot, hand, maxillofacial, neurosurgical, oral, otolaryngological, reconstructive and spine surgery.

Safety Instructions
The surgeon has to evaluate if the machine is suitable for an application based on several key factors, such as:

- Power capability of the machine, attachment and cutting tool relative to the bone strength/anatomical situation
- Handling of the machine, attachment and cutting tool relative to bone size

In addition, contraindications of the implant must be considered and respected. If the Electric Pen Drive System is used in conjunction with an implant system make sure to consult the corresponding “Surgical Technique”.

The Electric Pen Drive System is only to be used for patient treatment after careful consultation of the instructions for use. It is recommended that a backup EPD System is available to use during application, as technical problems can never be completely ruled out.

The Electric Pen Drive System is designed for use by physicians and trained medical personnel.

DO NOT use any component if damage is apparent.

DO NOT use this equipment in presence of oxygen, nitrous oxide or a mixture consisting of flammable anesthetic and air.

Never place the Electric Pen Drive in a magnetic environment since the machine might start unintentionally.

To ensure proper operation of the tool, use only DePuy Synthes original accessories.

Before first and every use, power tools and their accessories/attachments have to run through the complete reprocessing procedure. Protective covers and foils must be fully removed before sterilization.

Check instruments for correct adjustment and functioning prior to every use.

Always wear personal protective equipment (PPE) including safety goggles when handling with the Electric Pen Drive.

To prevent overheating, always respect the duty cycles for each attachment listed on page 45.

For the tool to function properly, DePuy Synthes recommends that it is cleaned and serviced after each use in accordance with the process recommended in the Cleaning and Disinfection section of this manual. It is mandatory to check used cutting tools after every use for wear and/or damage and to replace them if necessary. We recommend using new DePuy Synthes cutting tools for every surgery.

Cutting tools must be cooled with irrigation liquid to prevent bone necrosis due to heat.

The user of the product is responsible for proper use of the equipment during surgery.

For important information regarding electromagnetic compatibility (EMC) please refer to the chapter “Electromagnetic Compatibility” in this manual.

The tool is classified as type B against electrical shock and leakage current. The tool is suitable for use on patients in accordance with IEC 60601-1.

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

Unusual Transmissible Pathogens
Surgical patients identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments. Dispose of instruments used or suspected of use on a patient with CJD after surgery and/or follow current national recommendations.
Precautions:

- To avoid injuries, the locking mechanism of the tool has to be activated before every manipulation and before placing the tool back down, i.e. the mode switch has to be in the LOCK position (\textcircled{1}).
- If the machine drops on the floor and has visible defects, do not use it anymore and send it to the DePuy Synthes service center.
- If a product drops on the floor, fragments may split off. This represents a danger for the patient and user as:
  - these fragments may be sharp
  - unsterile fragments may enter the sterile field or hit the patient

Accessories/Scope of Delivery

The main components of the Electric Pen Drive (EPD) System are the handpiece, hand switch, foot switch, console, electric cables as well as attachments and accessories. An overview of all components belonging to the Electric Pen Drive System can be found in the chapter “Ordering Information”.

For using the EPD System the following components are a must:

- Electric Pen Drive (05.001.010)
- Hand Switch (05.001.012) or Foot Switch (05.001.016) with the Cable Foot Switch-Console (05.001.022)
- Console (05.001.006 or 05.001.002)
- Cable Electric Pen Drive – Console (05.001.021 or 05.001.025)
- At least one attachment belonging to the system and a cutting tool fitting to the attachment.

For an optimal function of the system, use only DePuy Synthes cutting tools.

DePuy Synthes recommends the use of DePuy Synthes Graphic Cases and Washing Basket (68.001.800), which are designed specifically to sterilize and store the system.

For care and maintenance, special tools are available, such as cleaning brushes, DePuy Synthes Maintenance Oil for EPD and APD (05.001.095), Maintenance Spray (05.001.098), and a Maintenance Unit (05.001.099).

No oils from other manufacturers may be used. Only DePuy Synthes oil may be used. Lubricants with other compositions can 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.

Locating of the Instrument or Fragments of Instruments

DePuy Synthes instruments 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 instrument.

Storage and Transport

Only use the original packaging for dispatch and transport. If the packing material is no longer available, please contact the DePuy Synthes office. For storage and transport environmental conditions, see page 44.

Warranty/Liability

The warranty for the tools and accessories does not cover damage of any kind resulting from wear, improper use, improper reprocessing and maintenance, damaged seal, use of non-DePuy Synthes cutting tools and lubricants or improper storage and transport.

The manufacturer excludes liability for damage resulting from repairs or maintenance carried out by unauthorized sites.

For further information on the warranty please contact your local DePuy Synthes office.
Explanation of Symbols

Caution
Consult Instructions for Use
Indicates that the device complies with the classification type B against electrical shock and electrical leakage current. The device is suitable for use on patients as defined by IEC 60601-1
Do not immerse device in liquids
The marked device shall be re-calibrated

IP X4
Locked symbol. Drive Unit is off for safety

Manufacturer
Date of manufacture
Non-sterile
Temperature limit
Catalog Number
Lot number
Serial number
Packaging unit ISO 7000-2794 (2009-02)
Use-by-date
INMETRO Ord. 350 certified

Do not reuse
Products intended for single use must not be reused.

Reuse or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

DePuy Synthes does not recommend reprocessing contaminated products. Any DePuy Synthes product that has been contaminated by blood, tissue and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the products may have small defects and internal stress patterns that may cause material fatigue.

Ingress protection rating according to IEC 60529

The device meets the requirements of directive 93/42/EEC for medical devices. It is authorized by an independent notified body for which it bears the CE symbol.

The European directive 2012/19/EC on waste electrical and electronic equipment (WEEE) applies to this device. This device contains materials that should be disposed of in accordance with environment protection requirements. Please observe national and local regulations.

Indicates Environment Friendly Use Period of 10 years in China
Indicates Environment Friendly Use Period of 50 years in China
Humidity limitation
Atmospheric pressure limitation
Do not use if package is damaged
Consoles

Standard and Basic Consoles

The Electric Pen Drive (05.001.010) can be supplied with the Standard Console (05.001.006), or the Basic Console without irrigation (05.001.002).

**Standard Console with Irrigation, without Torque Limiting Function (05.001.006)**

1. Slide control for adjusting the maximum speed for 1 Electric Pen Drive  
2. Slide control for adjusting the maximum speed for a second Electric Pen Drive  
4. Selection switch for irrigation  
5. Connection for Adapter for Small Battery Drive*  
6. Connection for Electric Pen Drive and Small Electric Drive**  
7. Connection for Electric Pen Drive and Small Electric Drive**  
8. Connection for Foot Switch  
9. Twist lock for irrigation pump  
10. Adjustment knob for irrigation flow rate  
11. LED Irrigation Ready (Activation with Foot Switch)

**Basic Console (05.001.002)**

1. Slide control for adjustment of the maximum speed for  
5. Connection for Adapter for Small Battery Drive*  
6. Connection for Electric Pen Drive and Small Electric Drive**  
8. Connection for Foot Switch ( )

*This connection is not of use anymore since the Adapter for Small Battery Drive is no longer available.  
**The Small Electric Drive is no longer available for purchase.
Set-up of Consoles

Color Coding Set
A color coding set is supplied with every console. Each set contains 3 text stickers, 8 silicone rings in 3 colors (red, blue and white) and 8 stickers of the colored rings. The stickers and silicone rings can be used to indicate on the console and the cables how the system has to be assembled.

Set-up
Before the initial operation of the device, make sure that the power switch (12) is set to position 0 (OFF). Only connect the console to the power supply with the cable provided via the power plug socket (13) and set the power switch to position 1 (ON). The LED marked with on the front of the console signals the proper operation of the console. If the LED flashes, the console must be sent in for maintenance.

A potential equilization connector (14) for an equipotential earth plug is integrated in the console. Existing equipotential earth plugs can be connected there.

(15) Fuses: 2x3AF/250V, Breaking Capacity 1500A
Mounting Cables on Consoles

To mount the respective cables on the consoles, position the nose on the plugs flush with the groove on the plug sockets and insert the plugs. For improved orientation, red dots are provided on the plug and socket that must face upward when connecting the cable.

Removing Cables

To remove the plug, grasp the release sleeve, pull back and remove.

The connections 5–8 (page 8) are used to connect the following devices:

<table>
<thead>
<tr>
<th>Connection</th>
<th>Device Description</th>
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<tr>
<td>5</td>
<td>Connection for a Small Battery Drive handpiece*</td>
</tr>
<tr>
<td>6 &amp; 7</td>
<td>Connection for an Electric Pen Drive and Small Electric Drive**</td>
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<tr>
<td>8</td>
<td>Connection for the Foot Switch</td>
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Connections not used can be sealed off with the protective caps provided.

Precautions:

- Do not lay textiles or objects under the console. These can be sucked up and block the ventilation inlet.
- Do not block the ventilation opening on the back of the console with any object.
- Only place consoles on smooth and flat surfaces.
- Do not place the console in the sterile field.
- Do not hang the irrigation liquid directly above the console to prevent liquid from dripping on the console.
- Do not pull the cable! Always activate the release sleeve.
- The use of HF (= high frequency) equipment for tissue coagulation can cause electromagnetic interferences – in this case cables should be separated as far as possible.
- Ensure that the power cord can always be disconnected immediately from mains supply.

* This connection is not of use anymore since the Adapter for Small Battery Drive is no longer available.
** The Small Electric Drive is no longer available for purchase.
Speed Regulation

Functions of the Standard Console (05.001.006) and the Basic Console (05.001.002)

Adjustment of the maximum speed (1, 2)
Speed is automatically optimized and adjusted for each attachment; for certain attachments it is however recommended that you reduce the maximum speed of the connected handpiece. Adjustment can be performed in increments of 25% with the slide controls for adjustment of maximum speed. It is recommended using this feature for high speed burrs. A letter code on each burr indicates the maximum speed specified by DePuy Synthes.

<table>
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<tr>
<th>Marking</th>
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<tr>
<td>A</td>
<td>100%</td>
</tr>
<tr>
<td>B</td>
<td>100%</td>
</tr>
<tr>
<td>C</td>
<td>75%</td>
</tr>
<tr>
<td>D</td>
<td>50%</td>
</tr>
<tr>
<td>E</td>
<td>25%</td>
</tr>
</tbody>
</table>

This is also explained by symbols on the supplied adhesive foil. The adhesive foil can be applied to the console as a reference aid.
Irrigation

Function of the Standard Console (05.001.006)

The function of the Standard Consoles described in the following is not available on the Basic Console.

Irrigation (4)

With the integrated irrigation system, tools can be cooled to prevent tissue necrosis affected by excess heat. Irrigation nozzles for the attachments and sterile irrigation tubes are available for the irrigation system. In addition to the OFF position (position 4.1), there are two operating positions for Pen 1 and Pen 2: constant and variable irrigation.

If constant irrigation for Pen 1/Pen 2 is chosen, a constant quantity of irrigation liquid will be released for Pen 1/Pen 2. A constant flow rate between 10 and 100 ml/min (0.34 and 3.4 oz/min) can be adjusted with the adjustment knob (10) for the irrigation flow rate (position 4.3/4.5).

If variable irrigation for Pen 1/Pen 2 is chosen, the flow rate will be directly proportional to the speed selected on the Hand or Foot Switch, i.e. the higher the selected speed, the higher is the irrigation flow rate. The maximum flow rate can be set between 10 and 100 ml/min (0.34 and 3.4 oz/min) with the adjustment knob (10) for the irrigation flow rate (position 4.2/4.4).

The LED lights up if the irrigation is activated (11) on the foot switch. Please refer to the chapter of the Foot Switch for a detailed explanation on how to activate or deactivate the irrigation.
Consoles

Irrigation Tube Set (05.001.178.01S) and Clips for Irrigation Tube Set (05.001.179.05S).

Inserting Irrigation Tube

1. Remove the sterile Irrigation Tube (Fig. 1) from the sterile package.
2. Secure the attachment-specific Irrigation Nozzle on the attachment (Fig. 2) used.
3. Fit the irrigation tube on the Irrigation Nozzle used first and then fix it with the clips (Fig 3) on the cable.
4. Route the Irrigation Tube end into the non-sterile area and open the twist lock for the irrigation pump in the direction of the arrow (see Fig. 4).
5. Insert the Irrigation Tube in the pump in accordance with the marking (see Fig. 4) and close the twist lock.
6. Remove the protective cap from the cannula and connect cannula to irrigation bag. When doing so, make sure that the connection nipple of the cannula is not touched by non-sterile persons while securing irrigation nozzle to the attachment. The vent of the spike has to be open when the irrigation is used.

Push the Irrigation Nozzles for the Burr Attachments and Reciprocating Saw Attachment as far as necessary over the attachment from the front.

Push the Irrigation Nozzle for the Sagittal Saw Attachment onto the attachment from the rear (from the attachment coupling side) before mounting the attachment on the handpiece.
Electric Pen Drive System

Electric Pen Drive 60,000 rpm (05.001.010)

1. Adjustment sleeve
2. Release sleeve for attachment
3. Cable IN/OUT position
4. LOCK position
5. Forward position (clockwise)
6. Reverse position counterclockwise
7. Lock slide for adjustment sleeve

Turning the Adjustment Sleeve
To avoid an unintentional change of the operating mode the lock slide for adjustment sleeve (7) locks the adjustment sleeve automatically. To be able to move the adjustment sleeve the lock slide has to be pushed in the direction indicated by the arrow. After having reached the desired position, release the lock slide (7) and the adjustment sleeve (1) is locked in the desired position.

Mounting Cable on Handpiece
Move the adjustment sleeve (1) on the handpiece into the position cable IN/OUT (3). Align the groove on the plug with the notch in the sleeve and insert the plug. Turn the adjustment sleeve into the LOCK (4) position. The cable is now firmly locked to the handpiece and the handpiece is in locked mode. To remove it again, move the adjustment sleeve (1) into the cable IN/OUT position (3) and remove the cable.

FWD/REV Switchover
By turning the adjustment sleeve into the forward position (5), the handpiece can be switched into a clockwise operating direction. In the reverse position (6) the handpiece can be operated in a counterclockwise direction.

In addition to locking the cable, the LOCK position (4) is used for safety switch-off when changing attachments and tools to prevent accidental start-up of the unit.

For instructions on mounting the attachments see page 18.

Either a Hand Switch (page 15) or a Foot Switch (pages 16/17) can be used for speed control.

Precautions:
• Do not place the handpiece on magnetic covers or in the immediate vicinity of other magnetic objects. This can activate the handpiece.
• When two Electric Pen Drive handpieces are connected and the speed is controlled with the Foot Switch, one handpiece must be switched to LOCK. Otherwise both handpieces will be blocked for safety reasons.
• In all other cases, the first activated device functions. As long as this device is activated, all others are deactivated.
• HF (= high frequency) equipment for tissue coagulation can cause electromagnetic interferences and inadvertently activate the Electric Pen Drive. Cables should be separated as far as possible.
Hand Switch (05.001.012)

1. Positioning arrow
2. Pull-out finger rest
3. Positioning arrow
4. Guide groove
5. Locking switch

Mounting the Hand Switch on the Handpiece 
(05.001.010)
Position the Hand Switch on the handpiece so that both positioning arrows (1) of the Hand Switch cover the positioning arrows (3) over the guide grooves (4) of the pen. Then press downward vertically until the Hand Switch clicks into position.

Removal
To remove the Hand Switch, grasp the lever and pull it upwards, away from the handpiece.

Operation
The length of the Hand Switch can be individually adjusted with the pull-out finger rest (2). The speed can be continuously adjusted by operating the Hand Switch. The Hand Switch can be deactivated (LOCK position) or activated (ON position) with the locking switch (5).
Foot Switch, 1 Pedal (05.001.016)

Connecting the Foot Switch to a Console

The Foot Switch can be connected to the console with the Foot Switch Cable (05.001.022). To insert the plugs, align the red dots on the plugs with those on the sockets and insert the plug. A second foot pedal can be connected using the second socket on the back of the foot pedal. Use a foot pedal cable (05.001.022) to connect the two foot pedals. Note: this cannot be done with the basic console.

The second socket is covered with a protective cap on delivery; the cap may be removed if necessary.

Disconnecting a Foot Switch

Grasp the respective plug by the release sleeve, pull back and remove.

Operation

The speed can be continuously adjusted with the pedal (2).

Briefly pressing the irrigation button (1) connects or disconnects the irrigation. In the ON position, the setting preselected with the irrigation selection switch on the console is activated. The LED lights up if the irrigation is activated on the foot switch. If the user holds this button down, the irrigation quantity set with the irrigation flow-rate adjustment knob (page 8) is supplied continuously until the button is released. This function is independent of the position selected on the irrigation selection switch (page 8) and of the activation of the pedal (2) or Hand Switch (page 15).

Precaution: When the cable is not connected properly to the foot switch, it is possible that the handpiece is activated without pressing the foot switch.
Foot Switch, 2 Pedals (05.001.017)

Connecting the Foot Switch to a Console
The Foot Switch can be connected to the console with the Foot Switch Cable (05.001.022). To insert the plugs, align the red dots on the plugs with those on the sockets and insert the plug. A second foot pedal can be connected using the second socket on the back of the foot pedal. Use a foot pedal cable (05.001.022) to connect the two foot pedals. Note: this cannot be done with the basic console.

The second socket is covered with a protective cap on delivery; the cap may be removed if necessary

Disconnecting the Foot Switch
Grasp the respective plug by the release sleeve, pull back and remove.

Operation
Operating mode is forward FWD (1) when activating the right pedal and reverse REV (2) for the left pedal.

The speed can be continuously adjusted with the pedals (1 and 2).

Briefly pressing the irrigation button (3) connects or disconnects the irrigation. In the ON position the setting preselected with the irrigation selection switch on the console is activated. The LED lights up if the irrigation is activated on the foot switch. If the user holds this button down, the irrigation quantity set with the irrigation flow-rate adjustment knob (page 8) is supplied continuously until the button is released. This function is independent of the position selected on the irrigation selection switch (page 8) and of the activation of the pedal (1 and 2).

Precautions:
• When operating the Electric Pen Drive with the Foot Switch, the operating mode is defined by the pedal used on the Foot Switch (i.e. right pedal for Forward mode and left pedal for Reverse mode) regardless of the operating mode (FWD or REV), defined by the adjustment sleeve of the handpiece.
• When the cable is not connected properly to the foot switch, it is possible that the handpiece is activated without pressing the foot switch.
Attachments

General Information

Mounting the Attachments on the Handpieces (05.001.010)
The attachments can be connected in 8 different positions (45° increments). To mount, turn the release sleeve for the attachments clockwise (see arrow on the release sleeve) until it engages. The release sleeve protrudes slightly from the black section of the handpiece towards the front. Insert the attachment into the attachment coupling from the front and press it lightly against the handpiece. The attachment automatically engages. If the release sleeve accidentally closes, turn the attachment clockwise while applying slight pressure against the handpiece until it engages without holding the release sleeve in place, or repeat the entire connection process. Check secure holding of the attachment on the handpiece by pulling on the attachment.

Removing the Attachments from the Handpiece
Turn the release sleeve for attachments clockwise until it disengages. Hold the attachment upward while doing so, then remove the attachment.

Attachments and Accessories
For easier change of burrs, without having the Burr Attachment or Craniotome Attachment connected to the handpiece, the Handle for Change of Instruments (05.001.074) can be used.

Warranty: Only use DePuy Synthes saw blades, burrs and rasps while working with the Electric Pen Drive attachments. The use of other tools voids the device warranty.
Drill Attachments

Speed Drill Attachments (05.001.030-05.001.032, 05.001.044): approx. 1,800 rpm

The system includes straight Drill Attachments with Mini Quick Coupling, J-Latch Coupling and AO/ASIF Coupling, as well as a 45° Drill Attachment with AO/ASIF Coupling (see pg. 52).

The 45° Drill Attachment with AO/ASIF Coupling has a cannulation of 1.6 mm, which permits the use of this attachment for drilling and reaming over Kirschner Wire (e.g. for cannulated screws and for cup and cone technique).*

Mounting and Removing Tools
Lock unit. Pull back the release sleeve (1) and insert/remove the tool.

Drill Attachment 45°, Cannulated, with Jacobs Chuck (05.001.120)
Speed drill attachments: approx. 1,800 rpm

Clamping area: 0.5 mm–4.7 mm

The cannulation of 1.6 mm permits the use of this attachment for drilling and reaming over Kirschner Wire (e.g. for cannulated screws and for cup and cone technique).

Mounting and Removing Tools
Lock unit. Open the chuck with the key provided (310.93K) or by hand by turning the two moving parts clockwise with respect to each other. Insert/remove the tool. Close the chuck by turning the moving parts counterclockwise and tighten it by turning the key clockwise.

* The cannulation was implemented from batch number 9232779.
Drill Attachment 90°, Short (05.001.035) and Long (05.001.036) with Mini Quick Coupling

Speed: approx. 1,800 rpm

Due to their very small angled head the 90° Drill Attachments enable good visibility during operations with narrow access (e.g. intra-oral, shoulder, etc.).

Mounting and Removing Tools

Lock unit. Move the slide (1) to the side following the arrow on the slide and insert/remove the tool. To secure the tool, push the slide back again.

Oscillating Drill Attachment (05.001.033)

Frequency: approx. 3,200 osc/min

The oscillating drilling movement of the Oscillating Drill Attachment prevents tissue and nerves from wrapping around the drill. This can considerably improve the operating results.

Mounting and Removing Tools

Tools with a Mini Quick Coupling can be clamped with the Oscillating Drill Attachment. To do this, lock the unit, pull back the release sleeve and insert/remove the tool.

Precaution: The handpiece must be in FWD position to use the oscillating drill attachment.
Screw Attachments

Screw Attachments (05.001.028, 05.001.029, 05.001.034)

Speed: approx. 400 rpm

The system includes screw attachments with AO Coupling, Hexagonal and Mini Quick Coupling.

Mounting and Removing Tools

Lock unit. Pull back the release sleeve and insert/remove the tool.

Precaution: Always use an appropriate Torque Limiting Device while inserting locking screws into a locking plate.

Kirschner Wire Attachment

Kirschner Wire Attachment (05.001.037)

Speed: approx. 2,700 rpm

With the Kirschner Wire Attachment, Kirschner Wires of any length with a diameter of 0.6 mm–1.6 mm can be tensioned. The tensioning lever (1) can be rotated by 300°, permitting individual adjustment (suitable for left and right-handed users).

Mounting and Removing Kirschner Wires

Lock unit. To insert and remove Kirschner Wires, press the tensioning lever (1). After the lever is released, the Kirschner Wire is automatically tensioned. To re-grasp, press the tensioning lever, pull back the unit along the Kirschner Wire and then release the tensioning lever again.
Saw Attachments

Working with Saw Attachments
Allow the unit to start up before placing it on the bone. Avoid heavy pressure on the saw blade so that the cutting process is not slowed and the saw teeth do not bind up in the bone. The best sawing performance is achieved by moving the unit slightly back and forth in the plane of the saw blade. Imprecise cuts indicate worn saw blades, excessive pressure or jamming of the saw blade due to tilting.

Information on Handling Saw Blades
DePuy Synthes recommends using a new, sterile saw blade for each surgery. This prevents health risks to the patient.

Used saw blades present the following risks:
- Necrosis due to excess heat
- Longer cutting time due to reduced sawing performance

Sagittal Saw Attachment (05.001.039)
Frequency: approx. 22,000 osc./min

Sagittal Saw Attachment, Centered (05.001.183)
Frequency: approx. 22,000 osc./min

Sagittal Saw Attachment, 90° (05.001.182)
Frequency: approx. 16,000 osc./min

Changing Saw Blades
1. Lock unit.
2. Press the clamping button (1), lift the saw blade and remove it.
3. Push a new saw blade into the saw blade coupling and move it into the desired position. The saw blade can be locked in 5 different positions (05.001.039 and 05.001.183) and in 8 different positions (05.001.182) for optimum positioning (45° increments).
4. Release the clamping button.
Oscillating Saw Attachment (05.001.038)

Frequency: approx. 16,000 osc./min

The Oscillating Saw Attachment is used with DePuy Synthes crescentic and 105° angled saw blades.

Changing Saw Blades
1. Lock unit.
2. Pull back the release sleeve for saw blades (1) and remove the saw blades from the mounting opening (2).
3. Push a new saw blade into the mounting opening (2) and move it into the desired position.
4. Release the release sleeve for saw blades.

Mounting and Removing the Guide for Kirschner Wires (05.001.121)

Secure the guide for Kirschner Wires on the Oscillating Saw Attachment, by pushing the guide as far as possible over the attachment from the front, so that it engages in the shape of the oscillating saw.

Then, mount the attachment on the handpiece.

Note: No irrigation nozzle is available for the oscillating saw attachment.

Reciprocating Saw Attachment (05.001.040)

Frequency: approx. 18,000 osc./min
Stroke: 2.5 mm

Both DePuy Synthes reciprocating saw blades and DePuy Synthes rasps can be used with the Reciprocating Saw Attachment.

Replacing saw blades
- Lock unit.
- Turn the release sleeve for saw blades (1) clockwise until it engages and remove the saw blade.
- Insert a new saw blade until slight resistance can be felt. Turn the saw blade with slight pressure until it automatically engages.
Burr Attachments

Burr Attachments

(05.001.045–05.001.050, 05.001.055, 05.001.063)

Gear ratio: 1:1.

The system includes straight and angled Burr Attachments in 3 lengths each (S, M, L). The related burrs are also marked with S, M and L. Angled XL and XXL Burr Attachments are also available; for these attachments the L burrs shall be used.

Changing Burrs

1. Lock unit.
2. Turn the release sleeve for burrs (1) until it engages in the UNLOCK position and remove the tool.
3. Insert the new tool as far as possible, turn it slightly until it locks in place and then turn the release sleeve for burrs into the LOCK position until it engages. The burr is correctly clamped when the marking S, M or L on the burr shank is no longer visible.

Information on Handling Burrs

DePuy Synthes recommends using a new sterile burr for each operation. This prevents health risks to the patient. Used burrs present the following risks:

- Necrosis due to excess heat
- Longer cutting time due to reduced performance of the burr

Precautions:

- Burrs must be cooled with irrigation liquid to prevent heat necrosis. For this purpose, use either the integrated irrigation function or irrigate manually.
- The size of the burr attachment must correspond to the size of the burr (e.g. attachment size S with burr size S) or one burr size bigger (e.g. attachment size S with burr size M).
- Respect the optimal speed for each burr indicated by the speed letters A to D (see chapter Speed Regulation on page 11) in order to avoid jamming, kick-back or jumping of the burr.
- User and OR personnel must wear safety goggles when working with burrs.
- When the Burr Attachments are not attached to the handpiece during tool change, use the handle (05.001.074) for easier change of burr.
Drill/Burr Attachment, Straight, for Round Shafts Ø 2.35 mm (05.001.123)
Gear ratio 1:1

Drill/Burr Attachment, Straight, for Round Shafts Ø 2.35 mm (05.001.128)
Gear ratio 16:1

Friction fit attachment for 2.35 mm diameter shafts with round shaft, J-latch and Mini Quick Coupling.

Changing Cutting Tools
1. Lock the handpiece.
2. Turn the release sleeve (1) until it engages in the UNLOCK position and remove the tool.
3. Insert the new tool and turn the release sleeve into the LOCK position until it engages.

Precautions:

- The user is liable for the safety and correct application of the DePuy Synthes Power Tool, including the attachment and the cutting tools.
In particular, consider the following points:
  - Maximum speed of the Drill/Burr Attachment for Round shafts with 2.35 mm diameter is 60,000 rpm for 05.001.123 and 3,750 rpm for 05.001.128
  - Use of the appropriate cutting tools (specifically length and speed)
  - Secure fixation of the cutting tool, i.e. the tool must be fully inserted
  - The instrument must be rotating before contact is made with the workpiece
  - Avoid jamming and using the instrument as a lever as this leads to an increased risk of breakage
  - Check the vibration and the stability of the used cutting tool before every usage on the patient. If vibration or instability occur, reduce the speed until the vibration stops or do not use the burr.
Adapter for Intra Coupling

Adapter for Intra Coupling (05.001.103)
Gear ratio 1:1

The Adapter for Intra Coupling (05.001.103) enables the use of dental handpieces, mucotomes and dermatomes designed according to ISO 3964 (EN 23 964) in combination with the Electric Pen Drive (05.001.010) and Air Pen Drive (05.001.080).

Warranty/Liability: The user is responsible for ensuring only compatible products are used in combination with the Electric and Air Pen Drive System and the Adapter for Intra Coupling.
Perforators

Perforator with Hudson Coupling (05.001.177)
Gear reduction: 97:1

The Perforator with Hudson Coupling is used with a trepan burr/protection sleeve combination – usually referred to as a cranial perforator – with a Hudson end to open the cranium. The operational mode of the handpiece has to be FWD ⏮️. Hold the perforator perpendicular to the skull at the point of penetration and always apply constant pressure when the trepan burr is engaged in the bone.

Changing the Cranial Perforator

1. Attaching the cranial perforator:
   First move the coupling sleeve (1) on the adapter toward the rear, and then completely insert the tool.
   After the tool has been fully inserted, release the coupling sleeve. Check that the tool is properly locked in the attachment by gently pulling on it.

2. Removing the cranial perforator:
   First move the coupling sleeve (1) towards the rear, and then remove the tool.

Precautions:

• For the use of the trepan burrs or cranial perforators, the respective instructions for use with warnings and restrictions from the manufacturer apply.

• Cooling the cutting tool during trepanation is recommended to avoid heat necrosis. Use the irrigation nozzle (05.001.180) and make sure that it is positioned to allow the cooling liquid to reach the tool.

• Check function before each use of the perforator.

• The user is liable for ensuring the compatibility of the Perforator with Hudson Coupling, the Irrigation Nozzle and the cutting tool used.
Craniotome Attachment

Craniotome Attachment (05.001.059) and Dura Guards (05.001.051–05.001.053)

Gear ratio: 1:1

The system includes a Craniotome Attachment and Dura Guards in 3 lengths (S, M, L). The related burrs are also marked with S, M and L.

Changing Cranial Burrs

1. Lock the handpiece.
2. Turn the release sleeve for burrs (1) until it engages in the UNLOCK position.
3. Pull off the Dura Guard over the burr and remove the burr.
4. Insert the new burr as far as possible turning it slightly. The burr is correctly inserted when the Dura Guard can be properly fitted.
5. Push the Dura Guard over the burr and mount the Dura Guard on the Craniotome Attachment (pay attention to the arrows for the correct inserting position (2)). Then turn the release sleeve of the Craniotome Attachment into the LOCK position until it engages to clamp the burr and the Dura Guard.
6. Check that the Cranial Burr can be turned freely and that the Dura Guard is well engaged by pulling on it slightly.

Precautions:

- Only use the Craniotomes with the related Cranial Burrs.
- Cranial Burrs must be cooled with irrigation liquid to avoid heat necrosis. For this purpose, attach the Irrigation Tube (05.001.178.01S) to the nozzle built into the Dura Guard.
- Avoid side load on the burr and Dura Guard in order to prevent breakage of the Dura Guard.
- When the Craniotome Attachment is not attached to the handpiece during tool change, use the Handhold (05.001.074) for easier change of the burr and Dura Guard.
Cutting Tools

General Information

Intended use

Saw Blades
The saw blades are designed for use in traumatology and orthopaedic surgery of the skeleton, e.g. cutting bone.

Stainless Steel Burrs
Stainless Steel Burrs (Small Torx Cutting Tools) are designed for use in surgery of the skeleton, i.e. cutting, shaping, smoothing, drilling, reaming or burring of bones.

Diamond Coated or Carbide Burrs
Diamond coated or carbide burrs (Small Torx Cutting Tools) are designed for use in surgery of the skeleton, i.e. cutting, shaping, smoothing of bones, teeth and metal.

Single Use/Reprocessing
For best results DePuy Synthes recommends using a new cutting tool for each operation. Performing cuts with a new and sharp cutting tool is faster, more precise and generates less heat. This results in a shorter surgery time, a reduction of risk of bone necrosis and a better, more reproducible result.

All diamond coated or carbide cutting tools are single use only.

Packaging and Sterility
All cutting tools are available sterile packed.

The manufacturer cannot guarantee sterility if the package seal is broken or if the package is improperly opened, and assumes no liability in such instances.

Dimension and Speed Letter Code
Cutting tool dimensions are specified on the packaging label.

The speed letter codes on the cutting tools are described on page 11.

Cooling of Cutting Tools
DePuy Synthes strongly recommends the use of an irrigation nozzle, the irrigation tube set (see page 13) and cooling fluid to cool cutting tools.

Implant Removal with Cutting Tools
Implant removal with cutting tools should only be conducted if no other solution for implant removal exists. Only use diamond coated or carbide cutting tools. Remove all particles by continuous flushing and vacuuming. Soft tissue must be covered well. Observe the material composition of the implant.

User Safety
User and OR personnel must wear safety goggles.

Disposal of Cutting Tools
Only dispose of contaminated cutting tools within contaminated hospital waste or decontaminate it.

Note: For an overview and the ordering information of all cutting tools available, refer to the brochure “Small Bone Cutting Tools”.

Cleaning and Disinfection

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 instruments. Frequent reprocessing does not have a big impact on the life of the unit and attachments.

Gentle care and maintenance with proper lubrication can substantially increase the reliability and life of the system components.

DePuy Synthes Power Tools must be serviced and inspected annually by the original manufacturer or an authorized site. The manufacturer assumes no warranty for damages arising from improper use, neglect or unauthorized servicing of the tool.

Precautions:

- Reprocessing must be performed immediately after each use.
- Cannulations, unlocking sleeves and other narrow sites require special attention during cleaning.
- Cleaners with a pH 7– 9.5 are recommended. The use of cleaners with higher pH-values can – depending on the cleaner – cause a dissolution of the surface of aluminum and its alloys, plastics or compound materials. High pH cleaners should only be used after considering the data regarding material compatibility according to the data sheet. At pH values higher than 11, the stainless steel surfaces can also be affected.
- Follow the enzymatic cleaner or detergent manufacturer’s instructions for use for correct dilution concentration, temperature, exposure time and water quality. If temperature and time are not provided, follow DePuy Synthes recommendations. Devices should be cleaned in a fresh, newlymade solution.
- Detergents used on the products will contact the following materials: stainless steel, aluminum, plastic, and rubber seals.
- Do not immerse any system component in aqueous solutions or in an ultrasonic bath. Do not use pressurized water as this will cause damage to the system.
- DePuy Synthes recommends using new, sterile cutting tools for each operation.
- Lubricating regularly with DePuy Synthes Maintenance Unit (05.001.099), the Maintenance Spray (05.001.098) or DePuy Synthes Maintenance Oil (05.001.095), especially when mechanical cleaning is performed, will reduce wear and can substantially extend the service life of the product.

Unusual Transmissible Pathogens

Surgical patients identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments. Dispose of instruments used or suspected of use on a patient with CJD after surgery and/or follow current national recommendations.

Notes:

- The clinical processing instructions provided have been validated by DePuy Synthes for preparing a non-sterile DePuy Synthes medical device; this instruction is provided in accordance with ISO 17664:2004 and ANSI/AAMI ST81:2004.
- Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures, and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment.
- Cleaning Agent Information: DePuy Synthes used the following cleaning agents during validation of these reprocessing recommendations: neutral pH enzymatic detergents (e.g. Prolystica 2X Concentrate Enzymatic Cleaner). These cleaning agents are not listed in preference to other available cleaning agents which may perform satisfactorily.
- 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.
Preparation Prior to Cleaning

Disassembly
Before cleaning, remove all the instruments, cutting tools, attachments and cables from the power tool.

Important:
- Reprocessing must be carried out immediately after each use in order to prevent corrosion of the instruments and the drying of blood.
- Never immerse handpieces, attachments, consoles or foot switches in aqueous solutions or in an ultrasonic bath, as this could decrease the service life of the system.
- Clean all movable parts in opened or unlocked position.
- Do not clean or sterilize the console, foot switches or cables for the foot switches with an automated system - manual only.
- The silicone rings fixed to the cables have to be removed (moved backwards on the cable) before washing and then fixed again before sterilization.

Cleaning and Disinfection of Consoles and Foot Switches
1. To clean the console, foot switches and cables for the foot switches, wipe them off with a clean, soft and lint-free cloth dampened with deionized water and then dry it.

2. To disinfect the consoles, foot switches and the cable of the foot switches, wipe them off with a clean, soft and lint-free cloth dampened with a minimum of 70% alcohol-based disinfectant for thirty (30) seconds. A disinfectant that is VAH listed, EPA 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 damped with a minimum 70% alcohol-based disinfectant each time. Follow the instruction provided by the manufacturer of the disinfectant.

Handpieces and attachments may be processed using
- a. manual cleaning
- and/or
- b. automated cleaning with manual pre-cleaning

The foot switch may be cleaned under running water if necessary. Make sure that the ventilation holes on the bottom plate face downward during cleaning so that no water enters the ventilation hole, and that the protective cap (delivered with the product) is used to cover the female plug in the back of the foot switch. Do not immerse. Allow to dry after cleaning.

Cleaning and Disinfection of Handpieces, Attachments and Cables Connecting the Handpieces
Assembly prior to mechanical/automated cleaning:

Make sure the surfaces, which the Seal Nipple will cover, are disinfected. To do this, first wipe off these surfaces with a clean, soft and lint-free cloth dampened with a minimum of 70% alcohol-based disinfectant. Make sure that no disinfectant enters the cable.

Connect both sides of the cables connecting the handpieces with the Seal Nipple.

* For details on mechanical/automated cleaning, please see Maintenance and Cleaning Chart for Pen Drive Systems.
Manual Cleaning Instructions

Important: Do not clean consoles, foot switches and cable for the foot switches using the following Manual Cleaning Instructions.

1. Remove Debris:
   Rinse the device under running cold tap water for a minimum of 2 minutes. Use a sponge, soft, lint-free cloth or soft-bristled brush to assist in removing gross soil. For cannulations of attachments, the cleaning brush shown below should be used.

   Note: Do not use pointed objects for cleaning. Brushes shall be inspected before daily use and discarded if they have degraded to the point where they may scratch instrument surfaces or be ineffective due to worn or missing bristles.

2. Manipulate Moving Parts:
   Manipulate all moving parts, such as the triggers, sleeves and switches, under running tap water to loosen and remove gross debris.

3. Spray and Wipe:
   Spray and wipe the device using a neutral pH enzymatic solution for a minimum of 2 minutes. Follow the enzymatic detergent manufacturer’s directions for correct temperature, water quality (i.e. pH, hardness) and concentration/dilution.

4. Rinse with Tap Water:
   Rinse device with cold tap water for a minimum of 2 minutes, then use a syringe or pipette to flush lumens & channels.

5. Clean with Detergent:
   Clean the device manually under warm, running water using an enzymatic cleaner or detergent for a minimum of 5 minutes. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft, lint-free cloth to remove all visible soil and debris. Follow the enzymatic cleaner or detergent manufacturer’s instructions for use for correct temperature, water quality and concentration/dilution.
6. **Rinse with Tap Water:**
Rinse the device thoroughly using cool to lukewarm running water for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other movable device features in order to rinse thoroughly under running water.

![Image of rinsing device](image1.png)

7. **Wipe/Spray with Disinfectant:**
Wipe off or spray the surfaces of the devices with a minimum of 70% alcohol-based disinfectant.

![Image of wiping device](image2.png)

8. **Visually Inspect Device:**
Inspect the cannulations, coupling sleeves, etc., for visible soil. Repeat steps 1–8 until no visible soil remains.

![Image of inspecting device](image3.png)

9. **Final Rinse with De-ionized/Purified Water:**
Rinse with de-ionized or purified water for a minimum of 2 minutes.

![Image of final rinsing device](image4.png)

10. **Dry:**
Dry device using a soft, lint-free cloth or medical grade compressed air. If smaller devices or cannulations contain residual water, blow dry with medical grade compressed air.

![Image of drying device](image5.png)
Automated Cleaning Instructions with Manual Pre-Cleaning

Important:

- Manual pre-cleaning prior to automated cleaning/disinfection is important to ensure that cannulations and other difficult to access areas are clean.

- Alternative cleaning/disinfection procedures other than in the procedure described below (including manual precleaning) have not been validated by DePuy Synthes.

- Before the manual pre-cleaning, ensure that both sides of the cable (05.001.021, 05.001.025) are connected with the Seal Nipple (05.001.027).

Important: Do not clean consoles, foot switches and cable for the foot switches using the following Manual Cleaning Instructions.

1. **Remove Debris:**
   Rinse the device under running cold tap water for a minimum of 2 minutes. Use a sponge, soft lint-free cloth or soft-bristled brush to assist in removing gross soil. For cannulations of the handpiece and attachments, the cleaning brush (05.001.075 shown below) should be used.

   **Note:** Do not use pointed objects for cleaning. Brushes shall be inspected before daily use and discarded if they have degraded to the point where they may scratch instrument surfaces or be ineffective due to worn or missing bristles.

2. **Manipulate Moving Parts:**
   Manipulate all moving parts such as the triggers, sleeves and switches under running tap water to loosen and remove gross debris.

3. **Spray and Wipe:**
   Spray and wipe the device using a neutral pH enzymatic solution for a minimum of 2 minutes. Follow the enzymatic detergent manufacturer’s directions for correct temperature, water quality (i.e. pH, hardness) and concentration/dilution.
4. **Rinse with Tap Water:**
Rinse device with cold tap water for a minimum of 2 minutes. Use a syringe or pipette to flush lumens and channels.

5. **Clean with Detergent:**
Clean the device manually under running warm water using an enzymatic cleaner or detergent for a minimum of 5 minutes. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth to remove all visible soil and debris. Follow the enzymatic cleaner or detergent manufacturer’s instructions for use for the correct temperature, water quality and concentration/dilution.

6. **Rinse with Tap Water:**
Rinse the device thoroughly using cool to lukewarm running water for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other movable device features in order to rinse thoroughly under running water.

7. **Visually Inspect Device:**
Inspect the cannulations, coupling sleeves, etc., for visible soil. Repeat steps 1–7 until no visible soil remains.

8. **Load Washing Basket:**
Place devices into the specially designed tray for machine washing supplied by DePuy Synthes if available, or refer to the loading plan.
9. **Automated Cleaning Cycle Parameters**

   **Note:** The washer/disinfector should fulfill the requirements as specified in ISO 15883.

<table>
<thead>
<tr>
<th>Step</th>
<th>Duration (minimum)</th>
<th>Cleaning instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rinse</td>
<td>2 minutes</td>
<td>Cold tap water</td>
</tr>
<tr>
<td>Pre-wash</td>
<td>1 minute</td>
<td>Warm water (≥ 40 °C); use detergent</td>
</tr>
<tr>
<td>Cleaning</td>
<td>2 minutes</td>
<td>Warm water (≥ 45 °C); use detergent</td>
</tr>
<tr>
<td>Rinse</td>
<td>5 minutes</td>
<td>Rinse with de-ionized (DI) or purified water (PURW)</td>
</tr>
<tr>
<td>Thermal disinfection</td>
<td>5 minutes</td>
<td>Hot DI water, ≥ 90 °C</td>
</tr>
<tr>
<td>Dry</td>
<td>40 minutes</td>
<td>≥ 90 °C</td>
</tr>
</tbody>
</table>

10. **Inspect the Device:**

   Remove all the devices from the washing basket. Inspect the cannulations, coupling sleeves, etc., for visible soil. If necessary, repeat the manual pre-clean/automated cleaning cycle. Confirm that all parts are completely dry. If smaller devices or cannulations contain residual water, blow dry with medical grade compressed air.

   Automated cleaning/disinfection is an additional stress for power equipment, especially for seals and bearings. Therefore, systems must be properly lubricated and regularly sent to be serviced (at least once per year).
Care and Maintenance

Maintenance and Lubrication

To ensure long service life and reduce the need for repairs, it is necessary that the accessible moving parts of the handpiece and attachment are lubricated after each use. Lubrication helps prevent damage and malfunction of the devices.

For further information on lubrication, please refer to the Instructions for Use of the DePuy Synthes Maintenance Oil (05.001.095), DePuy Synthes Maintenance Spray (05.001.098) and the EPD Cleaning Chart.

**Maintenance – with the DePuy Synthes Maintenance Unit**

DePuy Synthes recommends using the DePuy Synthes Maintenance Unit (05.001.099) developed for oiling the handpiece and attachments. With the Maintenance Unit, an optimal maintenance of the system over the entire service life can be ensured. The operation of the Maintenance Unit is explained in the Maintenance Station User’s Manual.

It is recommended that DePuy Synthes Maintenance Oil for the Electric and Air Pen Drives is being applied after each use, or as needed. Apply the oil to the movable parts of the handpiece, as described in the following chapter entitled “Maintenance – Manual.”
Maintenance – Manual

Oiling the Handpiece – with Maintenance Spray

1. Perform maintenance on the handpiece following every use with the DePuy Synthes Maintenance Spray (05.001.098) and Oiling Adapter for Electric Pen Drives (05.001.101).

2. Push the spray in the attachment coupling of the handpiece and briefly actuate it once (approx. 1 sec.). When doing so, wrap the pen with a cloth to catch excess oil, or hold it over a washbasin. Always spray away from the body.

3. Remove the excess oil with a cloth after spraying.

It is also recommended that DePuy Synthes Maintenance Oil (05.001.095) for Electric and Air Pen Drives is applied to movable handpiece parts after each use, or as needed. Apply the oil as described below.

Oiling Movable Parts of the Handpiece with DePuy Synthes Maintenance Oil 05.001.095

Apply one drop of DePuy Synthes Maintenance Oil in the slots between the adjustment sleeve (1) and the basic body, one drop of oil in the slots behind the release sleeve (2) and then move the sleeves.

Oiling the Attachments

Perform maintenance on the attachments following every use with the DePuy Synthes Maintenance Spray and Oiling Adapter for Attachments for Maintenance Spray (05.001.102).

Push the spray over the attachment coupling and briefly actuate it once (approx. 1 sec.). When doing so, wrap the attachments with a cloth to catch excess oil, or hold over a sink. Always spray away from the body. Remove the excess oil with a cloth after spraying.

Oiling Movable Parts of Attachments

Apply one drop of DePuy Synthes Maintenance Oil (05.001.095) to all movable parts of the attachments.

Precaution: Only use the DePuy Synthes Maintenance Spray (05.001.098) and/or DePuy Synthes Maintenance Oil (05.001.095). Their biocompatible composition matches the requirements for power tools in the operating room. Lubricants with other compositions may lead to sticking and could have a toxic effect.
Function Control

- Visually inspect for damage and wear.
- Should the system have corroded parts, do not use it anymore and send it to the DePuy Synthes service center.
- Check the handpiece controls for smooth operation and function.
- Check the coupling sleeves of the handpiece and attachments for smooth operation and check for function together with instruments such as cutting tools.
- Check instruments for correct adjustment and functioning prior to every use.
Packaging, Sterilization and Storage

Packaging

Put cleaned, dry products into their respective places in the DePuy Synthes Graphic Cases or Washing Basket. Additionally, use an appropriate sterilization wrap or re-usable rigid container system for sterilization, such as a Sterile Barrier System according to ISO 11607. Care should be taken to protect implants, and pointed and sharp instruments from contact with other objects that may damage the surface or the Sterile Barrier System.

Sterilization

**Important:** Remove the Seal Nipple for Cable (05.001.027) prior to sterilization.

DePuy Synthes Electric Pen Drive System may be resterilized using validated steam sterilization methods (ISO 17665 or national standards). DePuy Synthes’ recommendations for packed devices and cases are as follows.

<table>
<thead>
<tr>
<th>Cycle type</th>
<th>Sterilization exposure time</th>
<th>Sterilization exposure temperature</th>
<th>Drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturated steam-forced air removal (pre-vacuum, minimum 3 pulses)</td>
<td>Minimum 4 minutes</td>
<td>Minimum 132 °C</td>
<td>20–60 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maximum 138 °C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Minimum 3 minutes</td>
<td>Minimum 134 °C</td>
<td>20–60 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maximum 138 °C</td>
<td></td>
</tr>
</tbody>
</table>

Dry times generally range from 20 to 60 minutes due to differences in packaging materials (Sterile Barrier System, e.g., wraps or re-usable rigid container systems), steam quality, device materials, total mass, sterilizer performance and varying cool-down time.

Precautions:

- The consoles and the foot switches should not be sterilized.
- The following maximum values may not be exceeded: 138 °C for a maximum of 18 minutes. Higher values can damage the sterilized products.
- After sterilization, the handpiece should only be used again when it has cooled down to room temperature.
- Do not accelerate the cooling process.
- Hot air, ethylene oxide, plasma and formaldehyde sterilization are not recommended.

Storage

Storage conditions for products labeled “STERILE” are printed on the packaging label. 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.

Precautions:

- The consoles and the foot switches should not be sterilized.
- The following maximum values may not be exceeded: 138 °C for a maximum of 18 minutes. Higher values can damage the sterilized products.
- After sterilization, the handpiece should only be used again when it has cooled down to room temperature.
- Do not accelerate the cooling process.
- Hot air, ethylene oxide, plasma and formaldehyde sterilization are not recommended.

Note: For additional information, please refer to the package insert or www.e-ifu.com. For detailed cleaning and sterilization instructions, please refer to www.depuysynthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.
Repairs and Technical Service

The tool should be sent to the DePuy Synthes office for repair if it is faulty or malfunctions.

If a device is dropped, it has to be sent in for service.

Faulty devices may not be used. If it is no longer possible or feasible to repair the device, then it should be disposed per the following chapter called “Disposal”.

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

The Electric Pen Drive System requires regular maintenance service, at least once a year, in order to maintain its functionality. This service has to be performed by the original manufacturer or an authorized site.

Please use the original packaging to send devices back to DePuy Synthes facilities or an authorized site.

When returning the console for repair or maintenance, always send back the power cord.

**Warranty/Liability:** The manufacturer shall assume no responsibility for damage resulting from unauthorized maintenance.

**Replacing Fuses**
1. Before replacing the fuse make sure that the power cable is disconnected from the plug socket (13).
2. Remove the fuse drawer (15) and replace the fuses. Use only fuses of 3 AF/250 V with a breaking capacity of 1500 A. Make sure that both fuses are of same type and rating.
3. Insert fuse drawer (15) into console.
Disposal

In most cases faulty tools can be repaired (see previous chapter “Repairs and Technical Service”).

The European directive 2012/19/EC on waste electrical and electronic equipment (WEEE) applies to this device. This device contains materials that should be disposed of in accordance with environment protection requirements. Please observe national and local regulations.

**Precaution:** Contaminated products have to run through the complete reprocessing procedure, so that there is no danger of infection during disposal.

At end of life, recycle or dispose of device in accordance with local and national regulations.
<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible causes</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece (pen) does not start up.</td>
<td>Console is not switched on or connected.</td>
<td>Connect and/or switch on console.</td>
</tr>
<tr>
<td>Handpiece is not connected to console.</td>
<td></td>
<td>Connect handpiece to console.</td>
</tr>
<tr>
<td>Adjustment sleeve on handpiece is set to LOCK position.</td>
<td></td>
<td>Set adjustment sleeve to FWD or REV position.</td>
</tr>
<tr>
<td>Release sleeve for burr on burr attachment set to UNLOCK position.</td>
<td></td>
<td>Set release sleeve on burr attachment to LOCK position.</td>
</tr>
<tr>
<td>Two handpieces and one Foot Switch are connected and adjustment sleeves of both handpieces are set to FWD/REV.</td>
<td></td>
<td>With Foot Switch connected, release sleeve of one handpiece must be switched to LOCK.</td>
</tr>
<tr>
<td>Handpiece has not cooled down sufficiently following sterilization (over-heating protection is activated).</td>
<td></td>
<td>Wait until Handpiece has cooled down.</td>
</tr>
<tr>
<td>Hand Switch turned by 180°.</td>
<td></td>
<td>Turn Hand Switch by 180° and fit as described in the chapter entitled “Hand Switch”.</td>
</tr>
<tr>
<td>Safety switch on Hand Switch is in LOCK position.</td>
<td></td>
<td>Set safety switch to ON position.</td>
</tr>
<tr>
<td>Handpiece suddenly stops.</td>
<td>Handpiece has overheated (overload protection is activated).</td>
<td>Wait until Handpiece has cooled down.</td>
</tr>
<tr>
<td>Attachments cannot be coupled to unit.</td>
<td>Attachment Coupling is blocked by deposits.</td>
<td>Remove solid objects with a pair of tweezers.</td>
</tr>
</tbody>
</table>

**Precaution:** When removing objects, set unit to LOCK.
### Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible causes</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tool (saw blade, drill, burr etc.), cannot be coupled or only with difficulty.</td>
<td>Shaft geometry of tool damaged.</td>
<td>Replace tool or send to your DePuy Synthes service center.</td>
</tr>
<tr>
<td>Bones and tool heat up due to working process.</td>
<td>Cutting edges of tool are blunt.</td>
<td>Replace tool.</td>
</tr>
<tr>
<td>Irrigation fluid does not flow to Drive Unit when pump is operating.</td>
<td>Irrigation tube inserted in wrong direction.</td>
<td>Insert irrigation tube as described on page 13.</td>
</tr>
<tr>
<td>Hand Switch does not function.</td>
<td>Hand Switch has been dropped on floor. Magnet is de-magnetized.</td>
<td>Send in Hand Switch to your DePuy Synthes service center.</td>
</tr>
<tr>
<td>LED £ on console flashes.</td>
<td>Console defective.</td>
<td>Send in console to your DePuy Synthes service center.</td>
</tr>
</tbody>
</table>

If the recommended remedies are unsuccessful, please contact your DePuy Synthes service center.
## System Specifications

**Technical data**

**Pen: 05.001.010**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of protection</td>
<td>IP 54</td>
</tr>
<tr>
<td>Clockwise and counterclockwise running</td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>183 g</td>
</tr>
<tr>
<td>Length</td>
<td>130 mm</td>
</tr>
<tr>
<td>Continuously variable speed</td>
<td>0–60,000 rpm</td>
</tr>
</tbody>
</table>

**Consoles: 05.001.006 and 05.001.002**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating voltage</td>
<td>100 VAC–240 VAC, 50/60 Hz</td>
</tr>
<tr>
<td>Operating current</td>
<td>2.0–0.7 A</td>
</tr>
<tr>
<td>Degree of protection</td>
<td>IP X0</td>
</tr>
<tr>
<td>Fuse</td>
<td>2X3 AF/250 V Breaking capacity 1500 A</td>
</tr>
</tbody>
</table>

**Console: 05.001.006**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>5.25 kg (±10 %)</td>
</tr>
<tr>
<td>Dimensions</td>
<td>245 mm X 192 mm X 181 mm</td>
</tr>
</tbody>
</table>

**Console: 05.001.002**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>4.1 kg (±10 %)</td>
</tr>
<tr>
<td>Dimensions</td>
<td>245 mm X 170 mm X 118 mm</td>
</tr>
</tbody>
</table>

**Foot Switches: 05.001.016 and 05.001.017**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of protection</td>
<td>IP X8</td>
</tr>
</tbody>
</table>

**Foot Switch: 1 pedal – 05.001.016**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>1.6 kg</td>
</tr>
<tr>
<td>Dimensions</td>
<td>220 mm X 160 mm X 154 mm</td>
</tr>
</tbody>
</table>

**Foot Switch: 2 pedals – 05.001.017**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>3 kg</td>
</tr>
<tr>
<td>Dimensions</td>
<td>350 mm X 210 mm X 160 mm</td>
</tr>
</tbody>
</table>

*Technical data is subject to tolerances. Specifications are approximate and may vary from one device to another or as a result of power supply fluctuations.
The Device Meets the Following Standards

Medical electrical equipment – Part 1:
General requirements for basic safety and essential performance:
IEC 60601-1 (2012) (Ed.3.1),
EN 60601-1 (2006) +A11+A1+A12,
ANSI/AAMI ES60601-1:2005/(R)2012,
CAN/CSA-C22.2 NO. 60601–1:14

Medical electrical equipment – Part 1–2:
Collateral Standard: Electromagnetic disturbances –Requirements and tests:
IEC 60601-1-2 (2014) (Ed. 4.0),
EN 60601-1-2 (2015)

Medical electrical equipment - Part 1-6:
Collateral Standard: Usability:
### System specifications

#### Environmental Conditions

<table>
<thead>
<tr>
<th></th>
<th>Operation</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature</strong></td>
<td>40 °C / 104 °F</td>
<td>40 °C / 104 °F</td>
</tr>
<tr>
<td></td>
<td>10 °C / 50 °F</td>
<td>10 °C / 50 °F</td>
</tr>
<tr>
<td><strong>Relative humidity</strong></td>
<td>90 %</td>
<td>90 %</td>
</tr>
<tr>
<td></td>
<td>30 %</td>
<td>30 %</td>
</tr>
<tr>
<td><strong>Atmospheric pressure</strong></td>
<td>1060 hPa / 1.06 bar</td>
<td>1060 hPa / 1.06 bar</td>
</tr>
<tr>
<td></td>
<td>700 hPa / 0.5 bar</td>
<td>700 hPa / 0.5 bar</td>
</tr>
<tr>
<td><strong>Altitude</strong></td>
<td>0 – 3000 m</td>
<td>0 – 3000 m</td>
</tr>
</tbody>
</table>

#### Transportation*

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Duration</th>
<th>Humidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>–29 °C; –20 °F</td>
<td>72 h</td>
<td>uncontrolled</td>
</tr>
<tr>
<td>38 °C; 100 °F</td>
<td>72 h</td>
<td>85 %</td>
</tr>
<tr>
<td>60 °C; 140 °F</td>
<td>6 h</td>
<td>30 %</td>
</tr>
</tbody>
</table>

*products have been tested according to ISTA 2A
## Duty Cycles

To prevent overheating, always respect the duty cycles for each attachment listed below.

<table>
<thead>
<tr>
<th>Intermittent operation</th>
<th>( X_{\text{min on}} )</th>
<th>( Y_{\text{min off}} )</th>
<th>Cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drill/Burr Attachments</td>
<td>30 s</td>
<td>30 s</td>
<td>10</td>
</tr>
<tr>
<td>Craniotome Attachment</td>
<td>30 s</td>
<td>30 s</td>
<td>5</td>
</tr>
<tr>
<td>Perforator</td>
<td>1 min</td>
<td>3 min</td>
<td>3</td>
</tr>
<tr>
<td>Reciprocating Saw</td>
<td>30 s</td>
<td>60 s</td>
<td>5</td>
</tr>
<tr>
<td>Oscillating Saw</td>
<td>25 s</td>
<td>60 s</td>
<td>5</td>
</tr>
<tr>
<td>Sagittal Saw Attachment</td>
<td>30 s</td>
<td>60 s</td>
<td>5</td>
</tr>
</tbody>
</table>

These recommendations for times of use for the Electric Pen Drive attachments have been determined under average load with an ambient air temperature of 20 °C (68 °F).

Above mentioned duty cycles might need to be reduced due to higher loads applied and due to ambient air temperatures above 20 °C (68 °F). This needs to be taken into consideration during the planning of the surgical intervention.

Generally, electrical systems can heat up if in constant use. For this reason the handpiece and the attachment should be allowed to cool down for the above recommended periods of constant use. If this is observed the system will be prevented from overheating and possibly harming the patient or user. After the above indicated number of cycles, the respective attachments must be allowed to cool down for 30 minutes. The user is responsible for the application and for turning off the system as prescribed. If longer periods of constant use are required, an additional handpiece and/or attachment should be used. For oral surgery it is recommended to prevent any contact of warm components with soft tissues as temperatures around 45 °C may damage the lips and oral mucosa.

### Precautions:

- Carefully observe the recommended duty cycles.
- Always use new cutting tools to prevent heating up of the system due to reduced cutting performance.
- Careful maintenance of the system will reduce heat development in the handpiece and the attachments. The use of the Maintenance Unit (05.001.099) is strongly recommended.

**Warning:** The Electric Pen Drive must not be stored or operated in an explosive environment.
## Declaration of the Emission Sound Pressure Level and the Sound Power Level According to the EU Directive 2006/42/EC Annex I

Sound pressure level \([L_{pA}]\) in accordance with the norm EN ISO 11202  
Sound power level \([L_{wA}]\) in accordance with the norm EN ISO 3746

<table>
<thead>
<tr>
<th>Handpiece</th>
<th>Attachment</th>
<th>Cutting tool</th>
<th>Sound Level ((L_{pA})) in ([\text{dB(A)}])</th>
<th>Sound Power Level ((L_{wA})) in ([\text{dB(A)}])</th>
<th>Max. Daily Exposure Time Without Hearing Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPD 05.001.010</td>
<td>–</td>
<td>–</td>
<td>58</td>
<td>–</td>
<td>no limitation</td>
</tr>
<tr>
<td></td>
<td>Drill Attachment AO/ASIF</td>
<td>–</td>
<td>61</td>
<td>–</td>
<td>no limitation</td>
</tr>
<tr>
<td></td>
<td>05.001.032</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oscillating Saw Attachment 05.001.038</td>
<td>Saw blade 03.000.313</td>
<td>81</td>
<td>90</td>
<td>19 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Saw blade</td>
<td>81</td>
<td>94</td>
<td>19 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>03.000.316</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sagittal Saw Attachments 05.001.039</td>
<td>Saw blade 03.000.303</td>
<td>73</td>
<td>79</td>
<td>no limitation</td>
</tr>
<tr>
<td></td>
<td>05.001.182</td>
<td>Saw blade</td>
<td>83</td>
<td>90</td>
<td>12 h</td>
</tr>
<tr>
<td></td>
<td>05.001.183</td>
<td>03.000.315</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reciprocating Saw Attachment 05.001.040</td>
<td>Saw blade 03.000.321</td>
<td>71</td>
<td>–</td>
<td>no limitation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Saw blade</td>
<td>71</td>
<td>–</td>
<td>no limitation</td>
</tr>
<tr>
<td></td>
<td>03.000.330</td>
<td>03.000.321</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Burr Attachment 05.001.055</td>
<td>Burr 03.000.017</td>
<td>63</td>
<td>78</td>
<td>no limitation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Burr</td>
<td>64</td>
<td>77</td>
<td>no limitation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>03.000.108</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Declaration of Vibration Emissions According to EU Directive 2002/44/EC

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

<table>
<thead>
<tr>
<th>Handpiece</th>
<th>Attachment</th>
<th>Cutting tool</th>
<th>Declaration [m/s²]</th>
<th>Max. Daily Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPD 05.001.010</td>
<td>–</td>
<td>–</td>
<td>&lt; 2.5</td>
<td>8 h</td>
</tr>
<tr>
<td>Drill Attachment AO/ASIF 05.001.032</td>
<td>–</td>
<td>–</td>
<td>&lt; 2.5</td>
<td>8 h</td>
</tr>
<tr>
<td>Oscillating Saw Attachment 05.001.038</td>
<td>Saw blade 03.000.313</td>
<td>24.8</td>
<td>4 min 50 s</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Saw blade 03.000.316</td>
<td>33.6</td>
<td>2 min 30 s</td>
<td></td>
</tr>
<tr>
<td>Sagittal Saw Attachments 05.001.039</td>
<td>Saw blade 03.000.303</td>
<td>5.14</td>
<td>1 h 53 min</td>
<td></td>
</tr>
<tr>
<td>05.001.182</td>
<td>Saw blade 03.000.315</td>
<td>24.98</td>
<td>4 min 40 s</td>
<td></td>
</tr>
<tr>
<td>05.001.183</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reciprocating Saw Attachment 05.001.040</td>
<td>Saw blade 03.000.321</td>
<td>5.9</td>
<td>1 h 26 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Saw blade 03.000.330</td>
<td>6.3</td>
<td>1 h 15 min</td>
<td></td>
</tr>
<tr>
<td>Burr Attachment 05.001.055</td>
<td>Burr 03.000.017</td>
<td>0.91</td>
<td>8 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Burr 03.000.108</td>
<td>0.74</td>
<td>8 h</td>
<td></td>
</tr>
</tbody>
</table>
Electromagnetic Compatibility

Accompanying Documents According to IEC 60601-1-2, 2014, ED. 4.0

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The DePuy Synthes EPD System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>The emissions characteristic of this equipment make it suitable for use in a professional environment in industrial areas and hospitals. If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Electromagnetic Compatibility

**Immunity (all devices)**

**Guidance and Manufacturer's Declaration - Electromagnetic Immunity**

The DePuy Synthes EPD System is intended for use in the electromagnetic environment specified below. The customer or the user of the DePuy Synthes EPD System should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test standard</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±8 kV contact</td>
<td>±8 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>±15 kV air</td>
<td>±15 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±4 kV for power supply lines</td>
<td>±4 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±4 kV for signal lines</td>
<td>±4 kV for signal lines</td>
<td></td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV line to line</td>
<td>±1 kV line to line</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±2 kV line to earth</td>
<td>±2 kV line to earth</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11</td>
<td>&lt; 5% $U_T$ (0.5 cycle)</td>
<td>&lt; 5% $U_T$ (0.5 cycle)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the DePuy Synthes EPD System requires continued operation during power mains interruptions, it is recommended that the DePuy Synthes EPD System is powered from an UPS.</td>
</tr>
<tr>
<td></td>
<td>40% $U_T$ (5 cycles)</td>
<td>40% $U_T$ (5 cycles)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% $U_T$ (25 cycles)</td>
<td>70% $U_T$ (25 cycles)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5% $U_T$ for 5 s</td>
<td>&lt; 5% $U_T$ for 5 s</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** $U_T$ is the a.c. mains voltage prior to 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. |
Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The DePuy Synthes EPD System is intended for use in the electromagnetic environment specified below. The customer or the user of the DePuy Synthes EPD System should ensure that it is used in such an environment.

**Precaution:** 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 DePuy Synthes EPD System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

<table>
<thead>
<tr>
<th>Immunity Test Standard</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Recommended Separation Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>V1 = 10 Vrms</td>
<td>d = 0.35 \sqrt{P}</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 kHz to 80 MHz</td>
<td>150 kHz to 230 MHz</td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td>E1 = 10 V/m</td>
<td>d = 0.35 \sqrt{P}</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>80 MHz to 800 MHz</td>
<td>80 MHz to 800 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td>E2 = 10 V/m</td>
<td>d = 0.7 \sqrt{P}</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>800 MHz to 2.7 GHz</td>
<td>800 MHz to 6.2 GHz</td>
<td>800 MHz to 2.7 GHz</td>
</tr>
</tbody>
</table>

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

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

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

**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.

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\( a \) 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 the DePuy Synthes EPD System is used exceeds the applicable RF compliance level above, the DePuy Synthes EPD System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DePuy Synthes EPD System.

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

\( c \) Possible shorter distances outside ISM bands are not considered to have a better applicability of this table.
Recommended Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter</th>
<th>Separation distance according to frequency of transmitter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>800 MHz to 6.2 GHz</td>
</tr>
<tr>
<td>0.01</td>
<td>d = 0.35 √P</td>
</tr>
<tr>
<td></td>
<td>3.5 cm</td>
</tr>
<tr>
<td></td>
<td>3.5 cm</td>
</tr>
<tr>
<td></td>
<td>7 cm</td>
</tr>
<tr>
<td>0.1</td>
<td>11 cm</td>
</tr>
<tr>
<td></td>
<td>11 cm</td>
</tr>
<tr>
<td></td>
<td>23 cm</td>
</tr>
<tr>
<td>1</td>
<td>35 cm</td>
</tr>
<tr>
<td></td>
<td>35 cm</td>
</tr>
<tr>
<td></td>
<td>70 cm</td>
</tr>
<tr>
<td>10</td>
<td>1.1 m</td>
</tr>
<tr>
<td></td>
<td>1.1 m</td>
</tr>
<tr>
<td></td>
<td>2.3 m</td>
</tr>
<tr>
<td>100</td>
<td>3.5 m</td>
</tr>
<tr>
<td></td>
<td>3.5 m</td>
</tr>
<tr>
<td></td>
<td>7 m</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metric units (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.
## Ordering Information

### Consoles
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.006</td>
<td>Standard Console, with Irrigation, without Torque Limiting for Electric Pen Drive</td>
</tr>
<tr>
<td>05.001.002</td>
<td>Basic Console, for Electric Pen Drive</td>
</tr>
</tbody>
</table>

### Handpieces
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.010</td>
<td>Electric Pen Drive 60,000 rpm</td>
</tr>
</tbody>
</table>

### Hand Switch
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.012</td>
<td>Hand Switch, for Electric Pen Drive</td>
</tr>
</tbody>
</table>

### Foot Switch
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.016</td>
<td>Foot Switch (1 pedal), for Electric Pen Drive</td>
</tr>
<tr>
<td>05.001.017</td>
<td>Foot Switch (2 pedals), for Electric Pen Drive</td>
</tr>
</tbody>
</table>

### Cable
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>05.001.021</td>
<td>Cable Electric Pen Drive – Console, length 4 m</td>
</tr>
<tr>
<td>05.001.022</td>
<td>Cable Foot Switch – Console, for Electric Pen Drive, length 4 m</td>
</tr>
<tr>
<td>05.001.025</td>
<td>Cable Electric Pen Drive – Console, length 3 m</td>
</tr>
<tr>
<td>05.001.027</td>
<td>Seal Nipple for Cable, for Electric Pen Drive</td>
</tr>
</tbody>
</table>

### Graphic Cases
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>690.586</td>
<td>Three Level Modular Graphic Case (Includes Lid)</td>
</tr>
<tr>
<td>690.596</td>
<td>Single Level Modular Graphic Case (Includes Lid)</td>
</tr>
<tr>
<td>690.597</td>
<td>Two Level Modular Graphic Case (Includes Lid)</td>
</tr>
<tr>
<td>690.580</td>
<td>Graphic Case for Electric Pen Drive</td>
</tr>
</tbody>
</table>

### Graphic Case Accessories and Replacement Parts
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>690.578</td>
<td>Module Insert, 4 compartments (includes dividers and screws)</td>
</tr>
<tr>
<td>690.578.04</td>
<td>Divider Kit for Module Insert (for extra divider inserts and screws)</td>
</tr>
<tr>
<td>690.579</td>
<td>Module Insert, 2 Compartments (includes dividers and screws)</td>
</tr>
<tr>
<td>690.581</td>
<td>Lid, for Graphic Case</td>
</tr>
<tr>
<td>690.582</td>
<td>Attachment Rack, for Graphic Case</td>
</tr>
<tr>
<td>690.585</td>
<td>Graphic Case Base</td>
</tr>
<tr>
<td>690.587</td>
<td>Insert Tray for 60,000 rpm Drive Unit</td>
</tr>
<tr>
<td>690.588</td>
<td>Attachment Tray Assembly</td>
</tr>
<tr>
<td>690.589</td>
<td>Lid for Modular Graphic Case</td>
</tr>
</tbody>
</table>

### Screw Attachments
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.028</td>
<td>Screw Attachment, with AO/ASIF Quick Coupling, for EPD and APD</td>
</tr>
<tr>
<td>05.001.029</td>
<td>Screw Attachment with Hexagonal Coupling, for EPD and APD</td>
</tr>
<tr>
<td>05.001.034</td>
<td>Screw Attachment with Mini Quick Coupling, for EPD and APD</td>
</tr>
</tbody>
</table>

### Drill Attachments
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.030</td>
<td>Drill Attachment with Mini Quick Coupling, for EPD and APD</td>
</tr>
<tr>
<td>05.001.031</td>
<td>Drill Attachment with J-Latch Coupling, for EPD and APD</td>
</tr>
<tr>
<td>05.001.032</td>
<td>AO/ASIF Drill Attachment, for EPD and APD</td>
</tr>
<tr>
<td>05.001.033</td>
<td>Oscillating Drill Attachment 45°, with Mini Quick Coupling, for EPD and APD</td>
</tr>
<tr>
<td>05.001.035</td>
<td>Drill Attachment 90°, short, with Mini Quick Coupling, for EPD and APD</td>
</tr>
<tr>
<td>05.001.036</td>
<td>Drill Attachment 90°, long, with Mini Quick Coupling, for EPD and APD</td>
</tr>
<tr>
<td>05.001.037</td>
<td>Kirschner Wire Attachment, for EPD and APD</td>
</tr>
<tr>
<td>05.001.044</td>
<td>AO/ASIF Drill Attachment 45°, for EPD and APD</td>
</tr>
<tr>
<td>05.001.120</td>
<td>Drill Attachment 45°, cannulated, with Jacobs Chuck, for EPD and APD</td>
</tr>
<tr>
<td>05.001.123</td>
<td>Drill/Burr Attachment, straight, for Round Shafts ø 2.35 mm, for EPD and APD</td>
</tr>
<tr>
<td>05.001.103</td>
<td>Adapter for Intra Coupling, for EPD and APD</td>
</tr>
<tr>
<td>05.001.128</td>
<td>Drill/Burr Attachment, straight, for round shafts ø 2.35 mm, for EPD and APD</td>
</tr>
</tbody>
</table>

### Saw Attachments
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.038</td>
<td>Oscillating Saw Attachment, for EPD and APD</td>
</tr>
<tr>
<td>05.001.039</td>
<td>Sagittal Saw Attachment, for EPD and APD</td>
</tr>
<tr>
<td>05.001.183</td>
<td>Sagittal Saw Attachment, centered, for EPD and APD</td>
</tr>
<tr>
<td>05.001.182</td>
<td>Sagittal Saw Attachment, 90°, for EPD and APD</td>
</tr>
<tr>
<td>05.001.040</td>
<td>Reciprocating Saw Attachment, for EPD and APD</td>
</tr>
</tbody>
</table>
### Burr Attachments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.045</td>
<td>Burr Attachment, S, for EPD and APD</td>
</tr>
<tr>
<td>05.001.046</td>
<td>Burr Attachment, M, for EPD and APD</td>
</tr>
<tr>
<td>05.001.047</td>
<td>Burr Attachment, L, for EPD and APD</td>
</tr>
<tr>
<td>05.001.048</td>
<td>Burr Attachment, S, angled, for EPD and APD</td>
</tr>
<tr>
<td>05.001.049</td>
<td>Burr Attachment, M, angled, for EPD and APD</td>
</tr>
<tr>
<td>05.001.050</td>
<td>Burr Attachment, L, angled, for EPD and APD</td>
</tr>
<tr>
<td>05.001.055</td>
<td>Burr Attachment XXL, 20°, for EPD and APD</td>
</tr>
<tr>
<td>05.001.059</td>
<td>Craniotome Attachment, for EPD and APD</td>
</tr>
<tr>
<td>05.001.051</td>
<td>Dura Guard, S, for Craniotome Attachment No. 05.001.059, for EPD and APD</td>
</tr>
<tr>
<td>05.001.052</td>
<td>Dura Guard, M, for Craniotome Attachment No. 05.001.059, for EPD and APD</td>
</tr>
<tr>
<td>05.001.053</td>
<td>Dura Guard, L, for Craniotome Attachment No. 05.001.059, for EPD and APD</td>
</tr>
<tr>
<td>05.001.177</td>
<td>Perforator, with Hudson coupling, for EPD and APD</td>
</tr>
</tbody>
</table>

### Accessories

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.001.121</td>
<td>Guide for Kirschner Wire, for Oscillating Saw, for EPD and APD</td>
</tr>
<tr>
<td>05.001.066</td>
<td>Irrigation Nozzle, short, for EPD and APD, for Nos. 05.001.045 and 05.001.048</td>
</tr>
<tr>
<td>05.001.067</td>
<td>Irrigation Nozzle, medium, for EPD and APD, for Nos. 05.001.046 and 05.001.049</td>
</tr>
<tr>
<td>05.001.068</td>
<td>Irrigation Nozzle, long, for EPD and APD, for Nos. 05.001.047 and 05.001.050</td>
</tr>
<tr>
<td>05.001.065</td>
<td>Irrigation Nozzle, for EPD and APD, for No. 05.001.063</td>
</tr>
<tr>
<td>05.001.122</td>
<td>Irrigation Nozzle, for EPD and APD, for angled Burr Attachment XXL No. 05.001.055</td>
</tr>
<tr>
<td>05.001.111</td>
<td>Irrigation Nozzle, for EPD and APD, for Drill Attachments Nos. 05.001.030, 05.001.031, 05.001.032 and 05.001.110</td>
</tr>
<tr>
<td>05.001.070</td>
<td>Irrigation Nozzle, for EPD and APD, for Sagittal Saw Attachment No. 05.001.039</td>
</tr>
<tr>
<td>05.001.185</td>
<td>Irrigation Nozzle, for EPD and APD, for Sagittal Saw Attachment, centered No. 05.001.039</td>
</tr>
<tr>
<td>05.001.184</td>
<td>Irrigation Nozzle, for EPD and APD, for Sagittal Saw Attachment, 90°</td>
</tr>
<tr>
<td>05.001.071</td>
<td>Irrigation Nozzle, for EPD and APD, for Reciprocating Saw Attachment No. 05.001.040</td>
</tr>
<tr>
<td>05.001.180</td>
<td>Irrigation Nozzle, for Perforator with Hudson Coupling 05.001.177, for EPD and APD</td>
</tr>
<tr>
<td>05.001.178.015</td>
<td>Irrigation Tube Set, for EPD and APD, sterile, single pack</td>
</tr>
<tr>
<td>05.001.179.055</td>
<td>Clips for Irrigation Tube Set, sterile, pack of 5 units</td>
</tr>
<tr>
<td>05.001.098</td>
<td>DePuy Synthes Maintenance Spray, 400 ml</td>
</tr>
<tr>
<td>05.001.099</td>
<td>Maintenance Unit, for EPD and APD</td>
</tr>
<tr>
<td>05.001.094</td>
<td>Refill Set for Maintenance Unit, for EPD and APD</td>
</tr>
<tr>
<td>05.001.095</td>
<td>DePuy Synthes Maintenance Oil, 40 ml, for EPD and APD</td>
</tr>
<tr>
<td>05.001.101</td>
<td>Adapter for EPD Handpiece, for Maintenance Spray No. 05.001.098</td>
</tr>
<tr>
<td>05.001.102</td>
<td>Adapter for EPD/APD Attachments, for Maintenance Spray No. 05.001.098</td>
</tr>
<tr>
<td>05.001.074</td>
<td>Handle for Change of Instruments, for EPD and APD Attachments</td>
</tr>
<tr>
<td>05.001.075</td>
<td>Cleaning Brush for No. 05.001.037</td>
</tr>
<tr>
<td>310.93K</td>
<td>Spare Key, for Nos. 310.930, 532.016 and 05.001.120</td>
</tr>
</tbody>
</table>

### Cutting Tools

For ordering informations for the Electric Pen Drive Cutting Tools refer to the brochure “Small Bone Cutting Tools”.
Please see the package insert(s) or other product labeling associated with the devices contained in this manual for additional information.

Some devices listed in this technique guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products are currently available in all markets.

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Please contact your DePuy Synthes Sales Representative for more information.