

For Electric Pen Drive and Air Pen Drive

Maintenance Unit

Instructions for Use



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Introduction

General Information

Introduction

Associated device systems with these Instructions for Use are:

05.001.099, Maintenance Unit, for Electric Pen Drive (EPD) and Air Pen Drive (APD) (includes 05.001.094)

05.001.089 Adapter, for Maintenance Unit, for Air Pen Drive

05.001.064 Adapter, for Maintenance Unit, for Burr Attachment XL and XXL

Refer to section 'Ordering Information' for specific devices in scope.

For full user instructions and precautions please additionally consult the device IFU.

Intended Use

The Maintenance Unit is an electrically and compressed air powered device for maintaining handpieces and attachments for Electric Pen Drive (EPD) and Air Pen Drive (APD).

Intended User

The Maintenance Unit is intended to be used by health-care professionals in the reprocessing department in healthcare facilities.

Indications

There are no device specific indications associated with the Maintenance Unit as it is not patient contacting and is not used during a surgical procedure.

Contraindications

There are no device specific contraindications associated with the Maintenance Unit as it is not patient contacting and is not used during a surgical procedure.

Patient Target Group

There are no restrictions on patient population as the Maintenance Unit is not patient contacting and is not used during a surgical procedure

Expected Clinical Benefits

Not applicable. The device is an accessory and is used to support specific power tools (Electric Pen Drive and Air Pen Drive) to meet their intended function.

Potential Adverse Events, Undesirable Side Effects and Residual Risks

The Maintenance Unit is not patient contacting and is not used during a surgical procedure. Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the implants can be found in the respective Synthes implant instructions for use.

Combination of Medical Devices

Use the Maintenance Unit only in combination with the Electric Pen Drive/Air Pen Drive devices specified in the labeling. Please refer to the associated device information for details on its use, precautions, warnings and side effects. Depuy Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Treatment before the Device is Used

Warning: Before using the Maintenance Unit, please read the instructions for use.

Warnings and Precautions

Warnings:

- The device may only be used with authorized Depuy Synthes lubricants.
- Do not expose the device to direct sunlight or moisture.
- The device must not come into direct or indirect contact with the patient. The device is only allowed to be stored and used outside of the OR.
- Do not insert/ connect any objects other than EPD/ APD devices and adapters as the coupling may otherwise be damaged.
- Do not dismantle, open, short-circuit, manipulate the device.
- To ensure the proper operation of the Maintenance Unit, only use Depuy Synthes original accessories.
- Before operating the device, visually inspect the product for damage and wear (e.g. unrecognizable markings, missing or removed part numbers, corrosion, etc.). Do not use any component if damage is apparent.
- Always observe the temperature of the device to prevent overheating and possible injury to the user.
- The use of high frequency (HF) equipment for tissue coagulation can cause electromagnetic interferences – in this case the cables should be separated as far as possible.

Precautions:

- If the device is damaged, contact the Depuy Synthes representative. Do not use a damaged or faulty device. Send the device to the Depuy Synthes representative for repairs.
- Should the devices have corroded parts, do not use it anymore and send it to the Depuy Synthes Service Center.
- The device may only be operated on an even, dry surface that is sufficiently strong to hold its weight. Place the device on a non-slip, stable base.
- If the device drops on the floor, fragments may split off. This represents a danger for the user as these fragments may be sharp.
- Do not dismantle, open, short-circuit, manipulate the device. Risk of injury due to electric shock!

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 Synthes cutting tools and lubricants or improper storage and transport.

The manufacturer excludes liability for damage resulting from improper use, neglected or unauthorized maintenance or servicing of the tool.

Precaution: The manufacturer shall assume no responsibility for damage resulting from unauthorized service and repair.

Accessories/Scope of delivery

The Maintenance Unit consists of the unit itself, the pneumatic connection, the power supply, a country specific power cord as well a bottle of maintenance oil and the filter.

Location, storage and transport

The Synthes Maintenance Unit is only permitted for storage and operation outside the operating room (OR).

For operation and storage place the maintenance unit on a straight and solid surface.

Warnings:

- Do not store/use this equipment in the presence of oxygen, nitrous oxide or a mixture consisting of flammable anesthetics and air.
- The device is designed to be operated and stored in closed rooms. Do not use the product in the direct vicinity of radiators or other heat emitting products, as these can affect the product.

Empty the tank and use the original packaging for dispatch and transport. If the packaging material is no longer available, please contact the Depuy Synthes office. For storage and transport environmental conditions, see page 21.

The Lubrication Process

1. Installation

Install the provided Power Supply in the power supply connection, then connect the country specific Power Cord to the Power Supply and to a plug socket.



Plug the end of the Pneumatic Connection into the air connector on the back of the module; then connect the nipple for the Pneumatic Connection to the air supply. Set the air pressure of the air supply to 5–10 bars.



Fill the oil tank with Synthes Maintenance Oil, 40 ml for EPD and APD (05.001.095), as described in the chapter Care and Maintenance.


Warnings:


- Do not use oxygen, nitrous oxide or a mixture consisting of flammable anesthetics and air to run the Maintenance Unit. Only use compressed air or compressed nitrogen.
- The operating air pressure must be between 5 and 10 bar. Do not exceed the pressure.
- The air supply must be turned off prior to connecting or disconnecting the air hose from the Maintenance Unit.

Precaution:

- The device may only be used with the supplied power adapter and power cord. Only connect to a power supply with grounding, a rated voltage between 100 V and 240 V and a network frequency range of 50 or 60 Hz.
- Ensure that the power cord can always be disconnected immediately from mains supply.

2. Start the Maintenance Unit

Push the ON/OFF button  on the keypad to turn on the Maintenance Unit. The POWER ON LED should stay lit up.

If the ERROR  LED flashes or lights up, consult the chapter Troubleshooting.



3. Connect Handpiece and Attachment

Connect the Electric Pen Drive Handpiece (05.001.010)

The connector for handpieces is on the left side of the unit. To connect the Electric Pen Drive handpiece, open the release sleeve for attachments on the handpiece. Place it with the coupling for attachments pointing forward, then push the handpiece with light pressure towards the connector fitting until the handpiece locks in place.



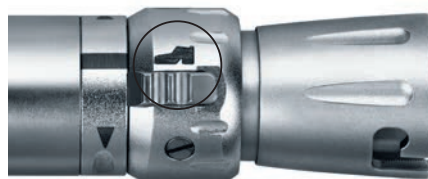
Connect the Air Pen Drive Handpiece (05.001.080)

To connect the Air Pen Drive handpiece, the Adapter for Maintenance Unit for Air Pen Drive (05.001.089) has to be used. Place the female side of the Adapter onto the connector on the left of the Maintenance Unit, making sure that the pins on the connector engage in the slotted link on the Adapter and then turn the Adapter clockwise. To apply the handpiece, set the adjustment sleeve to the foot switch position. Then mount the air hose coupling side of the handpiece to the connector by fitting the pins into the grooves of the Adapter and turn the handpiece clockwise.



Warnings:

- The Air Pen Drive (APD) must be lubricated through the air inlet / outlet, not through the attachment coupling. The Air Pen Drive must be set to foot switch position during the lubrication process. Otherwise the lubrication process is blocked.



Connect the Attachments

The remaining connectors can be used for attachments. To connect the attachments, carefully push the attachment with the cone coupling pointing towards the connector fitting and turn the attachment counterclockwise to lock it in place.

Connect the Burr Attachments XL and XXL 20°

To connect Burr Attachment XL 20° (05.001.063) and XXL 20° (05.001.055) the Adapter for Maintenance Unit for Burr Attachments XL and XXL (05.001.064) has to be used. Place the male side of the Adapter onto the second connector from the left, making sure that the pins on the Adapter engage in the slotted link on the connector and then turn the Adapter counterclockwise.


Warnings:

- The adapter may only be used for the authorized Depuy Synthes lubricants.
- Make sure before you start the lubrication process that the adapter, attachments and handpieces are properly engaged and in the correct position for lubrication.
- Burr Attachments (05.001.045–05.001.050, 05.001.063, 05.001.055, 05.001.123 and 05.001.128) and Craniotome Attachment (05.001.059) must be lubricated in lock position. Otherwise the lubrication procedure stops.



4. Start the Lubrication Process

Before starting the lubrication process the Lid must be closed. After closing the Lid, push the START button to start the lubrication procedure. The lubrication procedure will take approximately three minutes when all connectors are loaded.

If the ERROR  LED flashes or lights up, consult the chapter Troubleshooting.

Warnings:

- The lubrication loop is successfully completed when the READY LED will flash up.
- Make sure before you start the lubrication process that the oil tank is filled up, the cap is closed properly and that the lid of the Maintenance Unit is closed.



5. Remove the Handpieces and Attachments

To remove the Electric Pen Drive handpiece, turn the release sleeve as indicated by the arrow and remove the handpiece.


To remove the Air Pen Drive handpiece, simply turn the handpiece anticlockwise and remove from the Adapter. When the Maintenance Unit is only used for maintaining the Air Pen Drive it is possible to keep the Adapter in the Maintenance Unit.

The attachments can be removed by turning them clockwise in the connector and carefully pulling them out.

After the sterilizing process the handpiece and the attachments will be ready to use.

Care and Maintenance

1. Fill the Oil Tank

If the oil tank is empty, the ERROR  LED will stay lit up; oil should then be refilled. Open the oil tank by turning the cap counterclockwise and refill only with Synthes Maintenance Oil, 40 ml, for EPD and APD, 05.001.095.

Warning: Only use Synthes Maintenance Oil, for EPD and APD, 05.001.095 until the expiration date printed on the label. Lubricants with other compositions can cause jamming, can have a toxic effect or can have a negative impact on the sterilization results.

Precaution: As soon as the tank is empty refill one maximal bottle of Maintenance Oil, 40 ml for EPD and APD, 05.001.095. Do not overfill the tank.



2. Change the Filter

If oil can be detected in the filter in the inspection window (1), the filter has to be changed. We recommend changing the filter every time the oil has to be filled up.

To change the filter, open the lid, remove the old filter and fit the new filter into the bottom of the Maintenance Unit.

Precaution: The old filter and the empty bottle of Synthes Maintenance Oil, for EPD and APD, should be disposed of according to national regulations.

Note: The Maintenance Kit 05.001.094 contains 1 bottle of Synthes Maintenance Oil 05.001.095 and 1 spare filter.



3. Cleaning

By unscrewing the fixing bolts on both sides of the unit, it is possible to remove the lid in order to get easier access for cleaning. When mounting the lid again, make sure that both fixing bolts are properly inserted and tightened.

The device must be unplugged before it is cleaned. To clean the Maintenance Unit and the Adapters, wipe them off with a clean, soft and lintfree cloth dampened with ph-neutral detergent or with an alcohol based disinfectant that is either VAH (Verbund für Angewandte Hygiene) listed, EPA (Environmental Protection Agency) registered or locally recognized. Follow the instructions provided by the manufacturer. Dry well.

Warning: Do not sterilize, wash, rinse, drop or apply force to the Device. This will destroy it with possible secondary damage.

Precaution: Danger of electric shock! Unplug before cleaning.

Repairs and Technical Service

If the Maintenance Unit malfunctions, do not use it anymore and send it back to Depuy Synthes for repair.

If it is no longer possible or feasible to repair the tool it should be disposed off (refer to the following section "Disposal").

Other than the above-mentioned care and maintenance procedures, no further maintenance must be carried out by the user or by third parties.

Precautions:

- **This device requires regular maintenance service, at least every 5 years, in order to maintain its functionality. This service has to be performed by the original manufacturer or an authorized site.**
- **Users or third parties should not carry out repairs themselves.**
- **The device should be sent to the Depuy Synthes representative for repair if it is faulty or malfunctions.**



Disposal

In most cases faulty chargers can be repaired (see section "Repair 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.

Please send devices that are no longer used to the local Synthes representative. This ensures that they are disposed of in accordance with the national application of the respective directive.

Warning: Do not dispose of contaminated products with household waste.

Precautions:

- **The device should be disposed of in an environmentally friendly manner and in accordance with national regulations.**
- **The old filter and the empty bottle of Synthes Maintenance Oil, for EPD and APD, should be disposed of according to national regulations.**



Troubleshooting

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

Problem	Possible Causes	Remedy
After pushing the start button the ERROR  LED lights up.	The START button only works when the Lid is closed.	Close the Lid and push the START button again.
	A Burr Attachment (05.001.045–05.001.050, 05.001.063, 05.001.055, 05.001.123 and 05.001.128) or Craniotome Attachment (05.001.059) is placed on the connectors, but the release sleeve is in the unlock position. This blocks the lubrication procedure.	Turn the release sleeve of the attachment (05.001.045–05.001.050, 05.001.063, 05.001.055, 05.001.123, 05.001.128 or 05.001.059) into lock position and push the START button again.
	The fixing bolts are not properly inserted or tightened into the housing of the Maintenance Unit.	Insert both fixing bolts proper and tighten them.
The Maintenance Unit stops during the lubrication procedure and the ERROR  LED lights up.	The Lid has been opened during the lubrication procedure.	Close the Lid and repeat the lubrication procedure.
	The air pressure falls (< 5 bar) during the lubrication procedure.	Open the Lid, set the pressure to 5–10 bars and close the Lid. Push the START button again.
ERROR  LED stays lit.	The oil level is too low.	Fill up oil.
	The air pressure is too low (< 5 bar).	Set the air pressure to 5–10 bars.
	The Air Pen Drive is being lubricated through the attachment coupling.	The Air Pen Drive has to be lubricated with the Adapter for Maintenance Unit for Air Pen Drive (05.001.089) and through the air inlet/outlet.
	The Air Pen Drive is not set to the foot switch position during lubrication.	Set the Air Pen Drive to the foot switch position during lubrication.
ERROR  LED flashes.	The Maintenance Unit is faulty.	Send the Maintenance Unit to your Depuy Synthes Service Centre.
Lubrication procedure does not start, despite pushing the start button. The POWER ON LED lights up.	No handpiece or attachment is plugged to the Maintenance Unit or is detected.	Reconnect the handpiece or attachments (entirely). Push the start button again.
The adapter coupling is worn out or damaged and the device cannot be attached.	Coupling is mechanical damaged.	Send Maintenance Unit or Adapter to Depuy Synthes Service Centre.
	Coupling is blocked by residue.	Clean the Maintenance Unit and the Adapters according to care and maintenance guidelines.
The Power Tools device coupling is worn out or damaged and the device cannot be attached.	Coupling is mechanical damaged.	Send Maintenance Unit or Adapter to the Depuy Synthes Service Centre.
	Coupling is blocked by residue.	Clean the Maintenance Unit and the Adapters according to care and maintenance guidelines.
Visible physical damage of Maintenance Unit and Adapter.	Maintenance Unit and Adapter were sterilized, washed or rinsed.	Replace Maintenance Unit and Adapter or send Maintenance Unit or Adapter to Depuy Synthes Service Centre.
	Maintenance Unit and Adapter were exposed to excessive heat.	Replace Maintenance Unit and Adapter or send Maintenance Unit or Adapter to Depuy Synthes Service Centre.
	Maintenance Unit and Adapter drop on the floor.	Replace Maintenance Unit and Adapter or send Maintenance Unit or Adapter to Depuy Synthes Service Centre.

Explanation of Symbols

	Caution		This is a recognised component by UL.
	Read the Instructions for Use before operating the device		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.
	Legal Manufacturer		
	Manufacturing Date		Non sterile
	Do not immerse device in liquids		Range of temperature
	The product is double insulated		Range of relative humidity
	Indoor use only		Range of atmospheric pressure
	Air intake		Reference number
	Polarity of the supply voltage connector		Serial number
	Product is UL classified to the requirements of both the United States and Canada		Lot number
	The device meets the requirements of the Medical Device Regulation (EU) 2017/745		Packaging unit ISO 7000-27/94 (2009-02)
			Medical Device in the European Community
			INMETRO Ord. 350 certified

System Specifications

Performance Characteristics of the Device

Depuy Synthes has established the performance and safety of the Maintenance Unit and that it represents a state of the art medical surgical power tool and performs as intended for the function according to its instructions for use and labeling.

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:
IEC 60601-1-6 (2010) (Ed. 3.0) + A1 (2013)



UL classified with respect to electrical shock, fire and mechanical hazard only in accordance with ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1

Technical Data*

Maintenance Unit







Weight:	~ 4700 g
Dimensions:	342 mm/205 mm/162 mm
Operating voltage:	24 VDC
Degree of protection against the penetration of water:	IP X0
Intake air pressure:	5 – 10 bar/70 – 145 psi
Intake air quality:	Filtered air 5 µm, unoiled
Noise level in the operating position:	approx. 65 dB(A)

Power Supply

Weight:	~130 g (including cable)
Dimensions:	92 mm/40 mm/28 mm
Operating voltage:	100 VAC – 240 VAC, 50/60 Hz
Output voltage:	24 VDC
Output current:	500 mA
Degree of protection:	IP X0

*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.

Environmental Conditions

	Operation	Storage
Temperature	10 °C 50 °F  40 °C 104 °F	10 °C 50 °F  40 °C 104 °F
Relative humidity	30 %  90 %	30 %  90 %
Atmospheric pressure	700 hPa 0.7 bar  1060 hPa 1.06 bar	700 hPa 0.7 bar  1060 hPa 1.06 bar
Altitude	0–3000 m	0–3000 m

Transportation*

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

*products have been tested according to ISTA 2A

Electromagnetic Compatibility

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

Emissions

Guidance and manufacturer's declaration – electromagnetic emissions

The Maintenance Unit 05.001.099 is intended for use in the electromagnetic environment specified below.
The customer or the user of the Maintenance Unit 05.001.099 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Maintenance Unit 05.001.099 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.
RF emissions CISPR 11	Class B	The Maintenance Unit is suitable for use in professional healthcare facility environment but not in home healthcare or special environment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Immunity (all devices)**Guidance and manufacturer's declaration – electromagnetic immunity**

The Maintenance Unit 05.001.099 is intended for use in the electromagnetic environment specified below. The customer or the user of Maintenance Unit 05.001.099 should assure that it is used in such an environment.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 3 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1.5 kV line to line not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply lines	< 5% UT (0,5 cycle)	< 5% UT (0.5 cycle)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Maintenance Unit 05.001.099 requires continued operation during power mains interruptions, it is recommended that the Maintenance Unit 05.001.099 is powered from an UPS.
IEC 61000-4-11	40% UT (5 cycles)	40% UT (5 cycles)	
	70% UT (25 cycles)	70% UT (25 cycles)	
	< 5% UT for 5s	< 5% UT for 5 s	
Note: UT is the a.c.mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field	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.
IEC 61000-4-8			

Immunity (not life-supporting devices)**Guidance and manufacturer's declaration – electromagnetic immunity**

The Maintenance Unit 05.001.099 is intended for use in the electromagnetic environment specified below. The customer or the user of the Maintenance Unit 05.001.099 should assure that it is used in such an environment.

Warning: Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device 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 Maintenance Unit 05.001.099, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance c
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 10 Vrms 150 kHz to 230 MHz	$d = 0.35 \sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	E1 = 10 V/m 80 MHz to 800 MHz	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 800 MHz to 2.7 GHz	E2 = 10 V/m 800 MHz to 6.2 GHz	$d = 0.7 \sqrt{P}$ 800 MHz to 2.7 GHz

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

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

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



Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance c
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Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 Maintenance Unit 05.001.099 is used exceeds the applicable RF compliance level above, the Maintenance Unit 05.001.099 or the device, which contains it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device containing the Maintenance Unit 05.001.099.

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 (not life-supporting devices)**Recommended Separation Distances between portable and mobile RF Communications Equipment and the Maintenance Unit 05.001.099**

The Maintenance Unit 05.001.099 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Maintenance Unit 05.001.099 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Maintenance Unit 05.001.099 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	m		
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 6.2 GHz
	$d = 0.35 \sqrt{P}$	$d = 0.35 \sqrt{P}$	$d = 0.7 \sqrt{P}$
0,01	3.5 cm	3.5 cm	7 cm
0,1	11 cm	11 cm	23 cm
1	35 cm	35 cm	70 cm
10	1.1 m	1.1 m	2.3 m
100	3.5 m	3.5 m	7 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Ordering Information

Maintenance Unit and Adapters

05.001.099	Maintenance Unit, for EPD and APD (includes 05.001.094)
05.001.095	Synthes Maintenance Oil, 40 ml, for EPD and APD
05.001.089	Adapter, for Maintenance Unit, for APD
05.001.064	Adapter, for Maintenance Unit, for Burr Attachment XL and XXL

Spare parts

05.001.094	Maintenance kit with oil and filter, for EPD and APD
60032599	Lid, for Maintenance Unit 05.001.099
50160470	Fixing bolt, for Maintenance Unit 05.001.099
50160473	Pneumatic connection, for Maintenance Unit 05.001.099
50160471	Oil cap, for Maintenance Unit 05.001.099
50161414	Power Supply
05.001.130	Power Cord, two-pole (AT, BE, BG, CH, CN, CZ, DE, DK, ES, FI, FR, GR, HU, ID, IT, NL, NO, PL, PR, PT, RO, RU, SE, SK, TR)
05.001.131	Power Cord, two-pole (Argentina, Brazil, Canada, Colombia, Korea, Mexico, Taiwan, USA)
05.001.132	Power Cord, two-pole (Great Britain, Ireland, Hong Kong, Malaysia, Singapore)
05.001.133	Power Cord, two-pole (Australia, New Zealand, Uruguay)
05.001.134	Power Cord, two-pole (Japan)
05.001.135	Power Cord, two-pole (India, South Africa)

Materials Device(s)

Material(s)	Standard(s)
Maintenance Unit	Stainless Steel ISO 7153-1 Aluminum DIN EN 573 ABS n/a CR n/a FPM n/a NBR n/a PA n/a PC n/a PE n/a PUR n/a TPE n/a
Spare Parts	Stainless Steel ISO 7153-1 Aluminum DIN EN 573 Copper-zinc (nickel-plated) n/a ABS n/a PA n/a PBTP n/a PC n/a PP n/a PUR n/a PVC n/a TPE n/a Synthetic Oil n/a

Precaution: The device may only be used with the supplied power adapter and power cord. Only connect to a power supply with grounding, a rated voltage between 100 V and 240 V and a network frequency range of 50 or 60 Hz.



Not all products are currently available in all markets.
Please contact your Depuy Synthes sales representative for
more information.

This publication is not intended for distribution in the USA.

All Synthes Implant Instructions for Use as well as general
instructions for use are available as PDF files at www.e-ifu.com

