

Drill Bits

Manufacturer:



Smart Denture Conversions, LLC
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 855-550-8787
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Training:

The following descriptions are insufficient to allow immediate use of the Smart Denture Conversions’ system. Knowledge of implant-prosthetic treatment and instruction in the handling of the Smart Denture Conversions’ system provided by an operator with the relevant experience are necessary. It is strongly recommended that new and experienced users of Smart Denture Conversions’ products complete special training before using a new product for the first time. Smart Denture Conversions offers a variety of training options. Please go the www.SmartDentureConversions.com for more information.

Product Description:

Smart Denture Conversions offers three drills needed to create a pilot hole, a screw channel, and clear the PEEK cap and debris from the TiBase in an acrylic denture.

Pilot Drill with Adapter – Is used in a laboratory handpiece to create a pilot hole in the denture to the occlusal/cameo surface, by drilling through the screw hole in the TiBase.

Access Drill – Is used in a laboratory handpiece to chase the pilot hole and expand it to 3/32”. The tip of the bit will fit into the pilot hole from the occlusal/cameo surface and help guide it until it hits the top of the TiBase.

Cleanout Drill – Is used in the Pin Vise and manually rotated clockwise in the access drill channel following the 5x5 Technique. The Cleanout Drill is used to remove the Peek Cap from the TiBase and remove any residual debris left behind.

5x5 Cleanout Drill Technique:

- 5 turns clockwise with light pressure on Pin Vise
- 5 turns clockwise while wobbling bit in screw channel
- 5 turns clockwise with firm pressure on Pin Vise
- 5 turns clockwise with light pressure on Pin Vise
- 5 turns clockwise while retracting Cleanout Drill from screw channel

The table below summarizes the items:

Name	Part Number	For Use in	Material	Suggested RPM	Maximum Speed
Pilot Drill with Adapter	ADB-001	Lab Handpiece with 2.35mm Diameter Collar	High Speed Steel (M1, M2, M7, M42, M50)	10,000RPM	20,000RPM
Pilot Drill Bit, Manufactured	DB-004				
Access Drill	DB-001				
Cleanout Drill	DB-003	SDC Pin Vise		N/A, Hand Rotate	

Indications for Use:

These drill bits are rotary instruments used in conjunction with the Smart Denture Conversions’ Pin Vise and dental handpieces, intended to drill into dental acrylic materials. SDC drill bits are intended for use with SDC TiBases, SDC Separable Fasteners, laboratory handpiece with 2.35mm collet and the SDC Pin Vise. We recommend using a new Drill Kit for each conversion, to ensure you have sharp bits for quicker drilling and leaving cleaner holes. Dull bits can cause slow drilling, resulting in chipping of the acrylic and excess heat that can dislodge the TiBase.

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Reuse: As a guideline, drill bits can be used up to 5 times. The practical lifetime of any bit is a function of the wear sustained during the procedure. Reuse of the device is solely at the discretion of the user.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Drill Bits if:

- Operator or Patient shows signs of allergy or hypersensitivity to the chemical components of the materials listed in the chart above.

Warning:

- The supplied drill bits are intended for laboratory use by a trained technician.
- Before each use, inspect the bits for excessive wear. Discard worn bits.
- Before and during use, inspect the bits for debris and manually clear with a brush as needed.
- Never use drill bits above the manufacturer's recommended RPM.
- The drill bits are made of High Speed Steel and will rust if stored wet or in a moist environment.
- Drill bits should always be used to drill straight and force should never be loaded off axis, which could cause damage to the bit or drilling material.
- Ensure that the bit is fully seated and gripped in the hand piece collet.
- Do not extend the bit from the handpiece chuck. A loose or extended bit could eject from the chuck or break and cause injury.
- Eye protection must be worn to protect against ejected particles.
- Surgical masks must be worn to avoid inhalation of aerosol or dust generated.
- Maintain hand piece in good working order and correctly lubricated.
- Ensure the bit is continuously moving when in use, to help avoid localized heating and/or damage.
- If the indication or the nature of use is not clear, do not use until all points have been clarified.
- Do not use if package is damaged.
- Always inspect components before use. Do not use damaged, deformed, corroded, or discolored components.
- Smart Denture Conversions is not liable for damage resulting from use outside the intended use of the product.

Cautions/Precautions:

The following precautions are required before or during procedure:

- Do not use Smart Denture Conversion components after the expiration date indicated on the packaging.
- Before every procedure make sure that all required components, instruments, and auxiliary equipment are complete, in operating order and available in the required quantity.
- Always wear suitable personal protective equipment for your own safety.
- Position the patient such that the danger of aspiration of components is minimized.
- All components used in the patient's mouth must be secured to prevent aspiration and swallowing.

Cleaning and Sterilization Instructions:

Smart Denture Conversions' drill bits are made of high speed steel (HSS) and can corrode if cleaned with water or sterilized using saturated steam. Since these are laboratory tools and are not intended for patient contact, components are delivered non-sterile by Smart Denture Conversions and sterilization is not required, but regular cleaning is suggested.

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Suggested Cleaning Procedure

The bits can be sterilized using dry heat, following the sterilizer manufacturers' directions. A manual cleaning process is listed below.

1. Clean bits thoroughly to remove excess organic debris with a soft dry brush.
2. Liberally spray bits with 91% or higher Isopropyl Alcohol.
3. Immediately dry the bits thoroughly with dry heat or an absorbent towel. Use caution to not run fingers down the sharp face of the bit, as this can break the skin.
4. Inspect and discard any devices that show signs of damage or corrosion.
5. Lubricate bits with food safe anticorrosive lubricant, like Barrier Milk, to prevent corrosion during storage.

Storage, Handling and Transportation:

The devices must be stored in a dry place in their original packaging at room temperature and protected from direct sunlight. Improper storage may compromise essential material and design characteristics, leading to device failure.

Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy. Separation, recycling, or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable. If there is no current legislation, pack them in a perforating waste/sharps disposal container and dispose of them in hospital waste.

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Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Catalog Number	Included Parts	Basic UDI-DI Number
Pilot Drill and Adapter 1PK	PDA	ADB-001	+D990PDA0
Access Drill 1PK	AD	DB-001	+D990AD0
Clean Out Drill 1PK	COD	DB-003	+D990COD0
Pilot Drill 1PK	PD1PK	DB-004	+D990PD1PK0
Drill Kit 1PK	DK	DB-001, DB-003, DB-004	+D990DK0
Premium Starter Kit, SDC	PSK		+D990PSK0
Starter Kit, SDC	SK		+D990SK0
Recharge Kit w/ Tall Spare Parts, SDC	RK		+D990RK0
Recharge Kit w/ POC, SDC	RKPOC		+D990RKPOC0
Separable Fastener Assembly 10-pack with Drill kit	SFA10PKDK		+D990SFA10PKDK0
Premium Starter Kit, Straumann	PSK-ST		+D990PSK-ST0
Starter Kit, Straumann	SK-ST		+D990SK-ST0
Recharge Kit w/ Tall Spare Parts, Straumann	RK-ST		+D990RK-ST0
Recharge Kit w/ POC, Straumann	RKPOC-ST		+D990RKPOC-ST0
Separable Fastener Assembly 10-pack with Drill kit, Straumann	SFA10PKDK-ST		+D990SFA10PKDK-ST0
Premium Starter Kit, TiLobe	KDTL-PSK		+D990KDTL-PSK0
Starter Kit, TiLobe	KDTL-SK		+D990KDTL-SK0
Recharge Kit w/ Tall Spare Parts, TiLobe	KDTL-RK		+D990KDTL-RK0
Recharge Kit w/ POC, TiLobe	KDTL-RKPOC		+D990KDTL-RKPOC0
Separable Fastener Assembly 10-pack with Drill Kit, TiLobe	KDTL-SFA10PKDK		+D990KDTL-SFA10PKDK0
Premium Starter Kit, Paltop	KDIH-PSK		+D990KDIH-PSK0
Starter Kit, Paltop	KDIH-SK		+D990KDIH-SK0
Recharge Kit w/ Tall Spare Parts, Paltop	KDIH-RK		+D990KDIH-RK0
Recharge Kit w/ POC, Paltop	KDIH-RKPOC		+D990KDIH-RKPOC0
Separable Fastener Assembly 10-pack with Drill kit, Paltop	KDIH-SFA10PKDK		+D990KDIH-SFA10PKDK0
Premium Starter Kit, BioHorizons	BHHD-PSK		+D990BHHD-PSK0
Starter Kit, BioHorizons	BHHD-SK		+D990BHHD-SK0
Recharge Kit w/ Tall Spare Parts, BioHorizons	BHHD-RK		+D990BHHD-RK0
Recharge Kit w/ POC, BioHorizons	BHHD-RKPOC		+D990BHHD-RKPOC0
Separable Fastener Assembly 10-pack with Drill kit, BioHorizons	BHHD-SFA10PKDK		+D990BHHD-SFA10PKDK0
Drill Kit 1PK, ZimVie	ZV-DK		+D990ZV-DK0
Pilot Drill 1 Pack, ZimVie	ZV-PD1PK	DB-004	+D990ZV-PD1PK0
Access Drill 1PK, ZimVie	ZV-AD	DB-001	+D990ZV-AD0
Clean Out Drill 1PK, ZimVie	ZV-COD	DB-003	+D990ZV-COD0

Validity:

Upon publication of these instructions for use, all previous versions are superseded.

Availability:

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Some items of Smart Denture Conversions are not available in all countries.

Warranty:













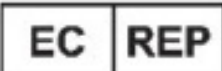












Please visit www.SmartDentureConversions.com for the most up to date warranty information.

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Symbols Glossary:

The following Symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

	Manufacturer		Date of Manufacture
	Use By Date		Serial Number
	Batch Code		Catalog Number
	Unique Device Identifier		Medical Device
	CE Mark		UK Representative
	United Kingdom Conformity Assessment Mark		United Kingdom Conformity Assessment Mark with Approved Body Number
	European Representative		Non-Sterile
	Comes Sterilized		Comes Sterilized using Aseptic Processing
	Comes Sterilized using Ethylene Oxide Processing		Comes Sterilized using Irradiation Processing
	Comes Sterilized using Dry Heat Processing		Do Not Resterilize
	Do Not Reuse		Consult Instructions for Use
	Keep Dry		Keep Away from Sunlight
RX Only	For Prescription Use Only		Caution, Consult Accompanying Documents