

Pin Vise

Manufacturer:



Smart Denture Conversions, LLC

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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:

The Pin Vise is used to hold the Cleanout Drill to remove the Peek Cap from the TiBase, while also removing any residual debris left in the screw channel. The Pin Vise is equipped with a swivel head for comfortable operation, while the octagonal shape helps prevent rolling. The two double-ended collets are conveniently stored in the barrel to prevent being damaged, lost or misplaced. The table below summarizes the items:

Name	Part Number	Intended Bit	Material
Pin Vise	PV-001	Cleanout Drill	Nickel Plated Steel and Spring Steel

Indications for Use:

The Pin Vise is intended to be used in conjunction with the Smart Denture Conversions' Cleanout Drill on an acrylic denture. Use of the proper collet should be verified to ensure proper fit of the bit. If the improper collet is used, it could prevent the insertion of the bit into the collet, or not allow the Pin Vise to be properly tightened onto the bit. Avoid putting off axis pressure onto the Pin Vise, as this can cause the bit to become damaged or fracture.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Pin Vise 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 Pin vise is 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.
- Ensure proper collet is selected for bit being used.
- Ensure that the bit is fully seated and gripped in the Pin Vise collet.
- Do not extend the bit from the Pin Vise collet. 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.
- 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.

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- 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' Pin Vise is made of nickel-plated steel and spring steel, and can corrode if cleaned with water or sterilized using saturated steam. Since this is a laboratory tool and is not intended for patient contact, components are delivered non-sterile by Smart Denture Conversions and sterilization is not required, but regular cleaning is suggested.

Suggested Cleaning Procedure

The Pin Vise 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
Pin Vise 1PK	PV	PV-001	+D990PV0
Premium Starter Kit, SDC	PSK		+D990PSK0
Starter Kit, SDC	SK		+D990SK0
Premium Starter Kit, Straumann	PSK-ST		+D990PSK-ST0
Starter Kit, Straumann	SK-ST		+D990SK-ST0
Premium Starter Kit, Tilobe	KDTL-PSK		+D990KDTL-PSK0
Starter Kit, Tilobe	KDTL-SK		+D990KDTL-SK0
Premium Starter Kit, Paltop	KDIH-PSK		+D990KDIH-PSK0
Starter Kit, Paltop	KDIH-SK		+D990KDIH-SK0
Premium Starter Kit, Biohorizons	BHHD-PSK		+D990BHHD-PSK0
Starter Kit, Biohorizons	BHHD-SK		+D990BHHD-SK0
Premium Starter Kit, TSV	ZVTS-PSK		+D990ZVTS-PSK0
Premium Starter Kit, Low Profile	ZVLP-PSK		+D990ZVLP-PSK0
Pin Vise 1PK, ZimVie	ZV-PV		+D990ZV-PV0

Validity:

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

Availability:

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













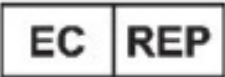












Warranty:

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