Burs

Manufacturer:

Smart Denture Conversions, LLC
1800 N. Salem St.
Suite 104
Apex NC, 27523
855-550-0707
www.SmartDentureConversions.com

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 burs that can assist in preparing the prosthesis. The table below summarizes the items:

Name	For Use in	Suggested RPM	Maximum Speed
Polishing Mushroom	Lab Handpiece with 2.35mm Diameter Collar	10,000	15,000
Polishing Disk		10,000	15,000
Bur, Pointed Cutter		15,000	100,000
Bur, Carbide Bur		15,000	100,000
Bur, Mushroom Cutter		15,000	50,000
Bur, Toothing Cutter		15,000	30,000
Polishing Disk Shaft		N/A	10,000
Bur, Abrasive Buff		6,000	10,000
Bur, Horse Hair Bristles		6,000	15,000

Indications for Use:

Burs are for lab use only.

Warning:

- The supplied burs are intended for laboratory use by a trained technician.
- Before each use, inspect the burs for excessive wear. Discard worn burs.
- Never use burs above the manufacturer's recommended RPM.
- Ensure that the bur 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.

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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.

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.

Basic UDI-DI Information:

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

Product	Catalog Number	Basic UDI-DI Number
Polishing Mushroom 10PK	BPM10PK	+D990BPM10PK0
Polishing Disk 10PK	BPD10PK	+D990BPD10PK0
Pointed Cutter 10PK	BPC10PK	+D990BPC10PK0
Pointed Cutter 5PK	BPC5PK	+D990BPC5PK0
Pointed Cutter 1PK	BPC1PK	+D990BPC1PK0
Round Carbide 10PK	BRC10PK	+D990BRC10PK0
Mushroom Cutter 10PK	BMC10PK	+D990BMC10PK0
Mushroom Cutter 5PK	BMC5PK	+D990BMC5PK0
Mushroom Cutter 1PK	BMC1PK	+D990BMC1PK0
Toothing Cutter 10PK	BTC10PK	+D990BTC10PK0
Toothing Cutter 5PK	BTC5PK	+D990BTC5PK0
Toothing Cutter 1PK	BTC1PK	+D990BTC1PK0
Disk Mandrel 10PK	BDM10PK	+D990BDM10PK0
Multifunction Polisher 10PK	BMP10PK	+D990BMP10PK0
Disc Brush 10PK	BDB10PK	+D990BDB10PK0
Bur Block Kit	BBK	+D990BBK0
Bur Block Kit, ZimVie	ZV-BBK	+D990BBKZV0

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.

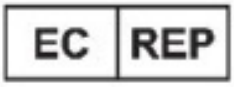
Warranty:

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
	Do Not Use if Packaging is Damaged		