Extractors

Manufacturer:

Smart Denture Conversions, LLC
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855-550-0707
www.SmartOnX.com



Training:

It is strongly recommended that clinicians, new as well as experienced implant and abutment users, always go through special training before undertaking a new treatment method. Smart Denture Conversions offers a wide range of courses for various levels of knowledge and experience. For more information, please visit www.SmartOnX.com.

Product Description:

Extractors are tools used for removal of abutment fragments.

Description	Instrument
Extractor Bur The Extractor Bur is used for creating an indentation in the abutment fragment.	
Tap Drill The Tap Drill is to drill a pilot hole into the abutment body to aid in retrieval.	
Remover Drill The Remover Drill is used for the removal of abutment fragments. The instrument is for **manual use only**.	

The table below summarizes the different types:

Name	Connection Type	System Compatibility	Material	RPM	# of Uses
Extractor Bur	Latch Type (ISO 1797)	Omnibut	Stainless Steel	3000	Single
Tap Drill				3000	
Remover Drill	4mm Square			N/A	

Intended Use/Indications for Use:

Extractors are intended to be used to remove broken Omnibut fragments from an implant. Extractors are intended for single use. Re-use of single use devices creates a potential risk of patient or user infection and misfitting components. For more specific information on process steps, please refer to the Technique manual located on the website www.SmartOnX.com.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Extractors in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who show signs of allergy or hypersensitivity to the chemical components of the materials listed in the chart above.

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Warning:

- Components are to be used by dental health care professionals and are to be used in patients subject to dental implant treatment.
- 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.
- Using Extractors at higher RPMs may cause the Extractors or other components to become deformed, broken or stuck on the implant analog or abutment, resulting in damage to components.
- The preparation of the abutment may not be possible and therefore the prosthetic restoration cannot be preserved.
- Ensure products are secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.
- Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications: Aspiration or swallowing of components, follow-up treatment, incorrect impression resulting in incompatible restorations.
- Even if the product is used according to the instructions for use, the clinical outcome of dental treatment is influenced by multiple variables and may lead to any or all of the following complications: anaphylaxis (severe allergic reaction); aspiration or swallowing of components; pain; local infection; inflammation; local irritation; loss of product function; follow-up treatment.
- 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 treatment:

- Do not use Smart Denture Conversion components after the expiration date on packaging (if applicable).
- During preparation with drills the recommended speed, which is in the range of the maximum speed, must be used. The maximum speed must not be exceeded and also the speed must not be reduced to an excessively slow level.
- Products intended for manual use shall not be used together with a contra-angle handpiece.
- Adequate space should be ensured around the implant to be repaired.
- Where the repair is not successful (e.g. breakage of an instrument), a trephine drill adjusted to the diameter of the implant should be kept ready for explantation of the implant.
- All products intended for single use must not be reused. Re-use of single use devices creates a potential risk of patient or user infection and misfitting components.
- Before every procedure make sure that all required components, instruments, and auxiliary equipment are complete, in operating order and available in the required quantity.
- If, due to unfavorable anatomical conditions, instruments do not fit or cannot be used for other reasons, the course of treatment planned with them must not be continued and alternatives must be sought.
- 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.

Magnetic Resonance Imaging (MRI) Safety Information:

Smart Denture Conversion Extractor within the scope of this IFU are used in the operatory with transient patient contact, and do not remain in the body. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Smart Denture Conversion Extractors in the MR environment is unknown. Scanning a patient who has such a product may result in patient injury.

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Directions for Use:

In the event that the neck of the Omnibut breaks, follow the protocol outlined below:

1. Use the Bur to create a shallow recess in the fractured surface to facilitate centering of the Tap Drill.
2. Using the Tap Drill in a counter clockwise drill, center the drill in the recess parallel to the axis of the implant.
3. Drill 2-3mm deep at 3000RPM.
4. Insert the Remover Drill parallel to hole/implant axis.
5. Apply vertical force to Remover Drill and rotate counter clockwise to extract the abutment from the implant.

Sterilization Instructions:

Components are delivered non-sterile by Smart Denture Conversions and are intended for single use. Prior to use, the devices must be sterilized by the user. Smart Denture Conversions recommends the following procedure for sterilization prior to use. Sterilization is recommended to be performed corresponding to the following scheme:

1. **Preparation for sterilization:** Place components (up to 6 devices) in a sterilization pouch which is FDA-cleared for the intended cycle.
2. **Sterilization:**

Method	Cycle	Temperature	Exposure Time*	Dry Time
Steam	Dynamic Air Removal (Prevacuum)	132°C (270°F)	4min	20min
Steam	Gravity Displacement	121°C (250°F)	30min	30min

*Minimum exposure times, the operating times are longer and may vary depending on the device.

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.

Assembly and UDI Information:

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

Product	Catalog Number	Basic UDI-DI Number
Omnibut Extractor Bur, Latch Type 5PK	OEB5PK-LT	+D990OEB5PKLT0
Omnibut Extractor Bur, Latch Type 10PK	OEB10PK-LT	+D990OEB10PKLT0
Omnibut Remover Drill, Square Type 1PK	ORD1PK-SQ	+D990ORD1PKSQ0
Omnibut Tap Drill, Latch Type 1PK	OTD1PK-LT	+D990OTD1PKLT0
Omnibut Extractor Kit	OEK	+D990OEK0

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.

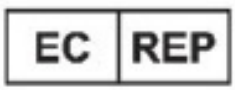
Warranty:

Please visit www.SmartOnX.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
	Do Not Use if Packaging is Damaged		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