Retrieval Tool

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 Retrieval Tool is used to recover the Threaded Post from a multi-unit abutment, if the Press-On Caps will not engage the threaded post, meaning the Threaded Post has been over-driven. The Retrieval Tool is designed to allow recovery of the Threaded Post even when it is fully in the multi-unit abutment. The Retrieval Tool is designed to be used in an implant handpiece or latch-lock slow speed and applying light pressure until the tip slips over the non-threaded portion of the Threaded Post. It can then be run slowly in reverse to remove the Threaded Post from the MUA. The table below summarizes the items:

Name	Part Number	Compatible Separable Fastener	Driver	Material	# of Uses
Retrieval Tool	SFT-001	All	Implant Handpiece or Latch-Lock Slow Speed	304 Stainless Steel	Single

Indications for Use:

The supplied Retrieval Tool is indicated for use with Smart Denture Conversions' Threaded Posts (threaded portion of the Separable Fastener) in screw-retained multi-unit abutments in the maxilla and mandible.

Retrieval Tools are intended to be reprocessed until they do not work as intended. For more specific information on process steps, please refer to the Technique manual located on the website www.SmartDentureConversions.com.

Note: The Retrieval Tool must be properly aligned with the axis of the Threaded Post prior to the press fit. Failure to properly align the axis' can cause damage to the Retrieval Tool and/or Threaded Post.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Retrieval Tool 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:

- When extracting the Threaded Post from the MUA, ensure it is securely attached to the Retrieval Tool to reduce the risk of dropping parts into the patient's mouth.
- 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.
- 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 a component, follow-up treatment, incorrect impression resulting in incompatible restorations.
- As the clinical outcome of dental treatment is influenced by multiple variables, even if the product is used according to the instructions for use the residual risks described below can. 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 indicated on the packaging.
- 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:

All Smart Denture Conversion LLC products which remain in the patient's body have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Smart Denture Conversion LLC products in the MR environment is unknown. Scanning a patient who has such a product may result in patient injury.

Reuse Instructions:

Components are delivered non-sterile by Smart Denture Conversions and are intended for reuse. Prior to use, clean and sterilize the product follow the instructions in the Cleaning and Sterilization Instructions section.

Impression copings shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Impression copings shall be discarded if any of the following criteria are met:

- If any wear, abrasion of the anodization, deformations or corrosion is visible on the component.
- If the Retrieval Tool does not seat accurately or has a loose fit in the Threaded Post.

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Cleaning Instructions:

Components are delivered non-sterile by Smart Denture Conversions and are intended for reuse. Prior to use, the devices must be cleaned and sterilized by the user.

Smart Denture Conversions recommends the following procedure for cleaning and sterilization of the devices prior to use.

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe for soil and debris in cavities.

   Caution: All dental debris adhering to the impression copings (such as impression material) must be cleaned away after use. It may not be possible to remove the dried debris later in the process. Impression copings shall be discarded if dental debris cannot be removed.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

4. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
5. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

   Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.
6. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Manual Cleaning and Drying:

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 mL lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP or Neodisher Medizym; maximum 45°C (113°F)) using an irrigation needle connected to a 20 mL syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solutions.
6. Immerse the device in an ultrasonic bath containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP or Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45° (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 mL lukewarm tap water using an irrigation needle connected to a 20 mL syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting or cracked seals, or if dental debris remains on the device. Properly discard any devices that fail the inspection.

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Sterilization Instructions:

Components are delivered non-sterile by Smart Denture Conversions. 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.

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
Retrieval Tool 1PK	RT	SFT-001	+D990RT0
Premium Starter Kit, SDC	PSK	SFT-001	+D990PSK0
Starter Kit, SDC	SK	SFT-001	+D990SK0
Premium Starter Kit, Straumann	PSK-ST	SFT-001	+D990PSK-ST0
Starter Kit, Straumann	SK-ST	SFT-001	+D990SK-ST0
Premium Starter Kit, Tilobe	KDTL-PSK	SFT-001	+D990KDTL-PSK0
Starter Kit, Tilobe	KDTL-SK	SFT-001	+D990KDTL-SK0
Premium Starter Kit, Paltop	KDIH-PSK	SFT-001	+D990KDIH-PSK0
Starter Kit, Paltop	KDIH-SK	SFT-001	+D990KDIH-SK0
Premium Starter Kit, Biohorizons	BHHD-PSK	SFT-001	+D990BHHD-PSK0
Starter Kit, Biohorizons	BHHD-SK	SFT-001	+D990BHHD-SK0
Premium Starter Kit, TSV	ZVTS-PSK	SFT-001	+D990ZVTS-PSK0
Premium Starter Kit, Low Profile	ZVLP-PSK	SFT-001	+D990ZVLP-PSK0
Retrieval Tool 1PK, ZimVie	ZV-RT	SFT-001	+D990ZV-RT0

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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.

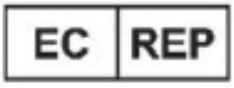
Warranty:

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		