Cementation Aid

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 Cementation Aid is a polymer rod that is used for cementing Cementable TiBases into temporary prostheses. It also has a secondary use of retrieving Separable Fastener Threaded Posts left in multi-unit abutments. The table below summarizes the device:

Name	Part Number	Length	Material	# of Uses
Cementation Aid	SFT-009	27.6mm	Delrin	Lab Use – Single Use Patient Use – Multi-Use

Intended Use:

The Cementation Aid is intended to cement Cementable TiBases into temporary prostheses. The Cementation Aid has a secondary use to retrieve Separable Fastener Threaded Posts left in multi-unit abutments. The Cementation Aid can be reprocessed for multi-use.

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' Cementation Aid 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.

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.
- 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.

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- 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).
- 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.
- Observe specified torques.

Magnetic Resonance Imaging (MRI) Safety Information:

All Smart Denture Conversion 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 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.

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

- If any wear, abrasion, deformations or corrosion is visible on the component.
- If the Cementation Aid does not interface accurately or has a loose fit on the Threaded Post.

Cleaning and Sterilization 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.

<u>Initial Treatment at Point of Use Prior to Reprocessing:</u>

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.

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Containment and Transportation/Shipping to Reprocessing Area:

1. 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.
2. 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.
3. 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.

Sterilization is recommended to be performed corresponding to the following scheme:

1. **Preparation for sterilization:** Place components in a sterilization pouch which is FDA-cleared for the intended cycle.

   Note: It is recommended to perform sterilization with a maximum load of six devices individually sealed in sterilization pouches.
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.

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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	Included Parts	Basic UDI-DI Number
Cementation Aid 10PK	CA10PK	SFT-009	+D990CA10PK0
Tall Separable Fastener 10-Pack, w/ Cementation Aid, Ditron	DDUS-TSFCA10PK	SFT-009	+D990DDUS-TSFCA10PK0

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.

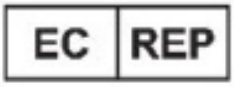
Warranty:

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		