Separable Fastener Reference Bases

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.SmartOnX.com for more information.

Product Description:

The Separable Fastener Reference Bases are attachments for multi-unit abutments that allow for fabrication of reference arches to effectively communicate midline incisal edge position and occlusal plane to a laboratory. The Reference PEEK Cap and the Threaded Post are designed to separate during the pickup of a reference arch. The Separable Fastener Reference Bases are available in three sizes. The table below summarizes the items:

Name	Part Number	Material	# of Uses
Separable Fastener Reference Base, Unigrip	ARB-001	300 Series Stainless Steel and Unfilled PEEK	Single
Separable Fastener Reference Base, Extended Thread	ARB-002		
Separable Fastener Reference Base, Omnibut	ARB-003		

Indications for Use:

Separable Fastener Reference Bases are intended to assist in fabricating reference arches that assist in communicating intraoral positioning to laboratories.

Separable Fasteners Reference Bases 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.

Note: It is suggested to use the Torque Driver to properly tighten the Separable Fastener Reference Base and the axis' must be properly aligned to ensure the proper amount of torque is transferred while tightening. Applying too much torque when tightening the Reference Base can cause the Threaded Post to continue to screw into the mating component and cause the PEEK Cap to separate. To correct this, ensure the top of the threaded section of the Threaded Post is flush with the top of the MUA. This can be done either by hand or by using the Retrieval Tool in a contra angle. With the Threaded Post at the proper height, the Peek Cap can simply be pressed back on, then turned clockwise slightly to ensure a snug fit.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Separable Fasteners Reference Bases 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.
- 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 on packaging (if applicable).
- 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 LLC products within this IFU 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.

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.

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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.

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
Separable Fastener Reference Base 10PK	SFRB10PK	ARB-001	+D990SFRB10PK0
Separable Fastener Reference Base 10PK, Extended Thread	SFRB10PK-EX	ARB-002	+D990SFRB10PKEX0
Separable Fastener Reference Base 10PK, Omnibut	SFRB10PK-OA	ARB-003	+D990SFRB10PKOA0

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.

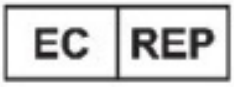
Warranty:

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
	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		