Instructions for Use (IFU)

Lab Analog and Coating Mandrel

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:

Lab Analog

The Lab Analog is designed to simulate the prosthetic side of a multi-unit abutment and can be used in a quick set stone model to create a repair jig or stone model. It is also used in packaging to hold the Separable Fastener, TiBase and Prosthetic Screw in a single unit.

Prosthesis Scan Body

The Lab Analog is designed to simulate the prosthetic side of a multi-unit abutment and can be used in a quick set stone model to create a repair jig or stone model. It is also used in packaging to hold the Separable Fastener, TiBase and Prosthetic Screw in a single unit.

Coating Mandrel

The Coating Mandrel is used to hold the TiBase and Separable Fastener together, making it easier to precoat the two components together with acrylic. Precoating allows for an easier handle of the combined components, ensures acrylic fills all crevices for a better pickup and prevents the PEEK Cap from spinning when drilling through it later in the process. The Coating Mandrel can be held by hand or in a lab handpiece with a 2.35mm collet, run at the lowest speed setting. The table below summarizes the items:

Name	Part Number	Compatible Separable Fastener	Compatible TiBases	Compatible Prosthetic Screw	Material	# of Uses
Lab Analog, M1.4	SFT-003	ASF-001, ASF-001L, ASF-002, ASF-002L, ASF-003, ASF-003L, ASF-005, ASF-005L	SF-003/SF-004 SF-012/SF-012L	PS-001, PS-002, PS-003, PS-005, PS-006, PS-007, PS-008	300 Series Stainless Steel	Single
Coating Mandrel, M1.4	SFT-008					
Lab Analog, #1-72	PT-007	ASF-004, ASF-004L	PT-003/PT-004	PS-004		
Coating Mandrel, #1-72	PT-008					

Indications for Use:

Lab Analogs and Coating Mandrels are intended for use with the compatible Smart Denture Conversions' Separable Fastener, Prosthetic Screw and TiBases and are intended for use within the lab. Lab Analogs and Coating Mandrels are not for patient contact and 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.SmartDentureConversions.com.

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Note: The Prosthetic Screw/Separable Fastener must be properly aligned with the axis of the threaded hole in the Lab Analog or Coating Mandrel. Failure to properly align the axis' can cause damage to either or both components.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Pin Vise if:

- Operator or Patient shows signs of allergy or hypersensitivity to the chemical components of the materials listed in the chart above.

Warning:

- The supplied Lab Analog and Coating Mandrel are intended for laboratory use by a trained technician.
- 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.
- Overtightening may cause components to become deformed, broken or stuck resulting in damage to components.
- 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.

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.

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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
Lab Analog 10PK	LA10PK	SFT-003	+D990LA10PK0
Coating Mandrel 6PK	CM6PK	SFT-008	+D990CM6PK0
Coating Mandrel 10PK	CM10PK	SFT-008	+D990CM10PK0
Lab Analog 10PK, Paltop	KDIH-LA10PK	PT-007	+D990KDIH-LA10PK0
Coating Mandrel 6PK, Paltop (IHex)	KDIH-CM6PK	PT-008	+D990KDIH-CM6PK0
Coating Mandrel 10PK, Paltop (IHex)	KDIH-CM10PK	PT-008	+D990KDIH-CM10PK0
Premium Starter Kit, SDC	PSK	SFT-003/SFT-008	+D990PSK0
Starter Kit, SDC	SK	SFT-003	+D990SK0
Recharge Kit w/ Tall Spare Parts, SDC	RK	SFT-003	+D990RK0
Recharge Kit w/ POC, SDC	RKPOC	SFT-003	+D990RKPOC0
Separable Fastener Assembly 10-pack with Drill kit	SFA10PKDK	SFT-003	+D990SFA10PKDK0
Premium Starter Kit, Straumann	PSK-ST	SFT-003/SFT-008	+D990PSK-ST0
Starter Kit, Straumann	SK-ST	SFT-003	+D990SK-ST0
Recharge Kit w/ Tall Spare Parts, Straumann	RK-ST	SFT-003	+D990RK-ST0
Recharge Kit w/ POC, Straumann	RKPOC-ST	SFT-003	+D990RKPOC-ST0
Separable Fastener Assembly 10-pack with Drill kit, Straumann	SFA10PKDK-ST	SFT-003	+D990SFA10PKDK-ST0
Premium Starter Kit, TiLobe	KDTL-PSK	SFT-003/SFT-008	+D990KDTL-PSK0
Starter Kit, TiLobe	KDTL-SK	SFT-003	+D990KDTL-SK0
Recharge Kit w/ Tall Spare Parts, TiLobe	KDTL-RK	SFT-003	+D990KDTL-RK0
Recharge Kit w/ POC, TiLobe	KDTL-RKPOC	SFT-003	+D990KDTL-RKPOC0
Separable Fastener Assembly 10-pack with Drill Kit, TiLobe	KDTL-SFA10PKDK	SFT-003	+D990KDTL-SFA10PKDK0
Premium Starter Kit, Paltop	KDIH-PSK	PT-007/PT-008	+D990KDIH-PSK0
Starter Kit, Paltop	KDIH-SK	PT-007	+D990KDIH-SK0
Recharge Kit w/ Tall Spare Parts, Paltop	KDIH-RK	PT-007	+D990KDIH-RK0
Recharge Kit w/ POC, Paltop	KDIH-RKPOC	PT-007	+D990KDIH-RKPOC0
Separable Fastener Assembly 10-pack with Drill kit, Paltop	KDIH-SFA10PKDK	PT-007	+D990KDIH-SFA10PKDK0
Premium Starter Kit, BioHorizons	BHHD-PSK	SFT-003/SFT-008	+D990BHHD-PSK0
Starter Kit, BioHorizons	BHHD-SK	SFT-003	+D990BHHD-SK0
Recharge Kit w/ Tall Spare Parts, BioHorizons	BHHD-RK	SFT-003	+D990BHHD-RK0
Recharge Kit w/ POC, BioHorizons	BHHD-RKPOC	SFT-003	+D990BHHD-RKPOC0
Separable Fastener Assembly 10-pack with Drill kit, BioHorizons	BHHD-SFA10PKDK	SFT-003	+D990BHHD-SFA10PKDK0
Premium Starter Kit, TSV	ZVTS-PSK	SFT-003/SFT-008	+D990ZVTS-PSK0
Premium Starter Kit, Low Profile	ZVLP-PSK	SFT-003/SFT-008	+D990ZVLP-PSK0
Recharge Kit w/ Tall Spare Parts, TSV	ZVTS-RK	SFT-003	+D990ZVTS-RK0
Recharge Kit w/ Tall Spare Parts, Low Profile	ZVLP-RK	SFT-003	+D990ZVLP-RK0
Recharge Kit w/ POC, TSV	ZVTS-RKPOC	SFT-003	+D990ZVTS-RKPOC0
Recharge Kit w/ POC, Low Profile	ZVLP-RKPOC	SFT-003	+D990ZVLP-RKPOC0

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Separable Fastener Assembly 10PK - Drill Kit Included, TSV	ZVTS-SFA10PKDK	SFT-003	+D990ZVTS-SFA10PKDK0
Separable Fastener Assembly 10PK - Drill Kit Included, Low Profile	ZVLP-SFA10PKDK	SFT-003	+D990ZVLP-SFA10PKDK0
Lab Analog 10PK, ZimVie	ZV-LA10PK	SFT-003	+D990ZV-LA10PK0
Coating Mandrel 10PK, ZimVie	ZV-CM10PK	SFT-008	+D990ZV-CM10PK0

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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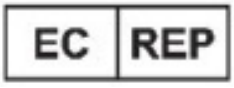
Symbols Glossary:

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		