Instructions for Use (IFU)

Separable Fastener

Manufacturer:

Smart Denture Conversions, LLC
1800 N. Salem St.
Suite 104
Apex NC, 27523
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:

The Smart Denture Conversions' Separable Fastener secures the TiBase to the multi-unit abutment the same way as a prosthetic screw, except the PEEK Cap (screw head) and the Threaded Post are designed to separate, allowing the denture to be removed from the mouth. The PEEK Cap will disengage and remain in the TiBase for the pickup while the Threaded Post remains in the multi-unit abutment. Smart Denture Conversions' Separable Fasteners are offered in two sizes across 6 styles. The table below summarizes the items:

Name	Part Number	Compatible TiBase	Material	# of Uses
Standard Separable Fastener, Unigrip	ASF-001	SF-003	300 Series Stainless Steel And Unfilled PEEK (Poly-Ether Ether Ketone)	Single
Tall Separable Fastener, Unigrip	ASF-001L	SF-004		
Standard Separable Fastener, Extended Thread	ASF-002	SF-003		
Tall Separable Fastener, Extended Thread	ASF-002L	SF-004		
Standard Separable Fastener, Tilobe	ASF-003	SF-003		
Tall Separable Fastener, TiLobe	ASF-003L	SF-004		
Standard Separable Fastener, Paltop	ASF-004	PT-003		
Tall Separable Fastener, Paltop	ASF-004L	PT-004		
Standard Separable Fastener, 0.05" Hex	ASF-005	SF-003/SF-012		
Tall Separable Fastener, 0.05" Hex	ASF-005L	SF-004/SF-012L		
Standard Separable Fastener, Omnibut	ASF-006	OA-003		
Tall Separable Fastener, Omnibut	ASF-006L	OA-003L		

Indications for Use:

Separable Fasteners are indicated for use with Smart Denture Conversions' TiBases and screw-retained multiple-unit Abutments in the maxilla and mandible. Standard Separable Fasteners should be used with Standard TiBases and Tall Separable Fasteners should be used with Tall TiBases. Separable Fasteners are designed to withstand enough torque to hold the TiBase to the multi-unit abutment, Lab Analog or Coating Mandrel, but not too much to prematurely separate the Separable Fastener. Smart Denture Conversions' Separable Fasteners 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 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 Separable Fastener 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 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 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 Press-On Caps are tools that are used in the operatory with transient patient contact, and do not remain in the body. These products 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 Press-On Caps in the MR environment is unknown.

Separable Fastener

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.

Separable Fastener

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 1-Pack	SF1PK	ASF-001	+D990SF1PK0
Separable Fastener 10-Pack	SF10PK	ASF-001	+D990SF10PK0
Tall Separable Fastener 1-Pack	TSF1PK	ASF-001L	+D990TSF1PK0
Tall Separable Fastener 10-Pack	TSF10PK	ASF-001L	+D990TSF10PK0
Separable Fastener 1PK, Ext. Thread	TFMV-SF1PK	ASF-002	+D990TFMVSF1PK0
Separable Fastener 10PK, Ext. Thread	TFMV-SF10PK	ASF-002	+D990TFMVSF10PK0
Tall Separable Fastener 1PK, Ext. Thread	TFMV-TSF1PK	ASF-002L	+D990TFMVTSF1PK0
Tall Separable Fastener 10PK, Ext. Thread	TFMV-TSF10PK	ASF-002L	+D990TFMVTSF10PK0
Tall Separable Fastener 10-Pack, w/ Cementation Aid, Ditron	DDUS-TSFCA10PK	ASF-001L	+D990DDUSTSFCA10PK0
Separable Fastener 10PK, TiLobe (Quad Drive)	KDTL-SF10PK	ASF-003	+D990KDTLSF10PK0
Separable Fastener, Tall 10PK, TiLobe (Quad Drive)	KDTL-TSF10PK	ASF-003L	+D990KDTLTSF10PK0
Separable Fastener 10PK, Paltop (IHex)	KDIH-SF10PK	ASF-004	+D990KDIHSF10PK0
Separable Fastener, Tall 10PK, Paltop (IHex)	KDIH-TSF10PK	ASF-004L	+D990KDIHTSF10PK0
Separable Fastener 10PK, 0.05" Hex	FZMF-SF10PK	ASF-005	+D990FZMFSF10PK0
Tall Separable Fastener 10PK, 0.05'' Hex	FZMF-TSF10PK	ASF-005L	+D990FZMFTSF10PK0
Tall Spare Parts Kit, 0.05” Hex	FZMF-TSP	ASF-005L	+D990FZMFTSP0
Premium Starter Kit, SDC	PSK	ASF-001/ASF-001L	+D990PSK0
Starter Kit, SDC	SK	ASF-001/ASF-001L	+D990SK0
Recharge Kit w/ Tall Spare Parts, SDC	RK	ASF-001/ASF-001L	+D990RK0
Recharge Kit w/ POC, SDC	RKPOC	ASF-001	+D990RKPOC0
Separable Fastener Assembly 10-pack with Drill kit	SFA10PKDK	ASF-001	+D990SFA10PKDK0
Tall Spare Parts Kit, SDC	TSP	ASF-001L	+D990TSP0
Premium Starter Kit, Straumann	PSK-ST	ASF-002/ASF-002L	+D990PSKST0
Starter Kit, Straumann	SK-ST	ASF-002/ASF-002L	+D990SKST0
Recharge Kit w/ Tall Spare Parts, Straumann	RK-ST	ASF-002/ASF-002L	+D990RKST0
Recharge Kit w/ POC, Straumann	RKPOC-ST	ASF-002	+D990RKPOCST0
Separable Fastener Assembly 10-pack with Drill kit, Straumann	SFA10PKDK-ST	ASF-002	+D990SFA10PKDKST0
Tall Spare Parts Kit, Straumann	TSP-ST	ASF-002L	+D990TSPST0
Premium Starter Kit, TiLobe	KDTL-PSK	ASF-003/ASF-003L	+D990KDTLPSK0
Starter Kit, TiLobe	KDTL-SK	ASF-003/ASF-003L	+D990KDTLSK0
Recharge Kit w/ Tall Spare Parts, TiLobe	KDTL-RK	ASF-003/ASF-003L	+D990KDTLRK0
Recharge Kit w/ POC, TiLobe	KDTL-RKPOC	ASF-003	+D990KDTLRKPOC
Separable Fastener Assembly 10-pack with Drill Kit, TiLobe	KDTL-SFA10PKDK	ASF-003	+D990KDTLSFA10PKDK0
Tall Spare Parts Kit, TiLobe	KDTL-TSP	ASF-003L	+D990KDTLTSP0
Premium Starter Kit, Paltop	KDIH-PSK	ASF-004/ASF-004L	+D990KDIHPSK0
Starter Kit, Paltop	KDIH-SK	ASF-004/ASF-004L	+D990KDIHSK0
Recharge Kit w/ Tall Spare Parts, Paltop	KDIH-RK	ASF-004/ASF-004L	+D990KDIHRK0
Recharge Kit w/ POC, Paltop	KDIH-RKPOC	ASF-004	+D990KDIHRKPOC0

Separable Fastener

Separable Fastener Assembly 10-pack with Drill kit, Paltop	KDIH-SFA10PKDK	ASF-004	+D990KDIHSFA10PKDK0
Tall Spare Parts Kit, Paltop	KDIH-TSP	ASF-004L	+D990KDIHTSP0
Premium Starter Kit, BioHorizons	BHHD-PSK	ASF-005/ASF-005L	+D990BHHDPSK0
Starter Kit, BioHorizons	BHHD-SK	ASF-005/ASF-005L	+D990BHHDSK0
Recharge Kit w/ Tall Spare Parts, BioHorizons	BHHD-RK	ASF-005/ASF-005L	+D990BHHDRK0
Recharge Kit w/ POC, BioHorizons	BHHD-RKPOC	ASF-005	+D990BHHDRKPOC0
Separable Fastener Assembly 10-pack with Drill kit, BioHorizons	BHHD-SFA10PKDK	ASF-005	+D990BHHDSFA10PKDK0
Premium Starter Kit, TSV	ZVTS-PSK	ASF-005/ASF-005L	+D990ZVTSPSK0
Premium Starter Kit, Low Profile	ZVLP-PSK	ASF-005/ASF-005L	+D990ZVLPPSK0
Recharge Kit w/ Tall Spare Parts, TSV	ZVTS-RK	ASF-005/ASF-005L	+D990ZVTSRK0
Recharge Kit w/ Tall Spare Parts, Low Profile	ZVLP-RK	ASF-005/ASF-005L	+D990ZVLPRK0
Recharge Kit w/ POC, TSV	ZVTS-RKPOC	ASF-005	+D990ZVTSRKPOC0
Recharge Kit w/ POC, Low Profile	ZVLP-RKPOC	ASF-005	+D990ZVLPRKPOC0
Separable Fastener 10PK, ZimVie	ZV-SF10PK	ASF-005	+D990ZVSF10PK0
Tall Separable Fastener 10PK, ZimVie	ZV-TSF10PK	ASF-005L	+D990ZVTSF10PK0
Separable Fastener Assembly 10PK - Drill Kit Included, TSV	ZVTS-SFA10PKDK	ASF-005	+D990ZVTSSFA10PKDK0
Separable Fastener Assembly 10PK - Drill Kit Included, Low Profile	ZVLP-SFA10PKDK	ASF-005	+D990ZVLPSFA10PKDK0
Separable Fastener 1-Pack, Omnibut	SF1PK-OA	ASF-006	+D990SF1PKOA0
Separable Fastener 10-Pack, Omnibut	SF10PK-OA	ASF-006	+D990SF10PKOA0
Tall Separable Fastener 1-Pack, Omnibut	TSF1PK-OA	ASF-006L	+D990TSF1PKOA0
Tall Separable Fastener 10-Pack, Omnibut	TSF10PK-OA	ASF-006L	+D990TSF10PKOA0
Premium Starter Kit, Omnibut	PSK-OA	ASF-006/ASF-006L	+D990PSKOA0
Recharge Kit w/ Tall Spare Parts, Omnibut	RK-OA	ASF-006/ASF-006L	+D990RKOA0
Recharge Kit w/ POC, Omnibut	RKPOC-OA	ASF-006	+D990RKPOCOA0
Separable Fastener Assembly 10-pack with Drill kit, Omnibut	SFA10PKDK-OA	ASF-006	+D990SFA10PKDKOA0
Tall Spare Parts Kit, Omnibut	TSP-OA	ASF-006L	+D990TSPOA0

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.

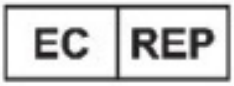
Warranty:

Please visit www.SmartOnX.com for the most up to date warranty information.

Separable Fastener

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 Reuse		Do Not Resterilize
	Keep Dry		Consult Instructions for Use
RX Only	For Prescription Use Only		Keep Away from Sunlight
	Do Not Use if Packaging is Damaged		Caution, Consult Accompanying Documents
 MR Conditional	MR Conditional		