Instructions for Use (IFU)

Direct Separable Fastener

Manufacturer:

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

Direct Separable Fasteners secure Temporary Abutments to the implant the same way as an abutment screw, but temporary. The PEEK Cap (screw head) and the Threaded Post are designed to separate, allowing the crown or bridge to be removed from the mouth. The PEEK Cap will disengage and remain in the Temporary Abutment, while the Threaded Post remains in the implant. Separable Fasteners are offered multiple sizes to accommodate for multiple implant system compatibilities. The table below summarizes the different types:

Name	Drive Feature	Temporary Cylinder Platform Compatibility	Material	# of Uses
Direct Separable Fastener, M1.6	T5	Biomet Certain 3i Non-Engaging, Nobel CC NP	300 Series Stainless Steel and Unfilled PEEK (Poly-Ether Ether Ketone)	Single
Direct Separable Fastener, M1.6, Narrow		Biomet Certain 3i Engaging, Straumann BLX		
Direct Separable Fastener, M1.8		Zimmer TSV, Biohorizons		
Direct Separable Fastener, M2		Nobel CC RP		

Indications for Use:

Direct Separable Fasteners are indicated for use with Temporary Abutments in the maxilla and mandible. Separable Fasteners are designed to withstand enough torque to hold the Temporary Abutment to the implant or Lab Analog, but not too much to prematurely separate the Direct Separable Fastener. Direct 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 Temporary Abutment screw seat. 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' Direct 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.
- Overtightening may cause the Direct Separable Fastener or other components to become deformed, broken or stuck on the implant analog or abutment, resulting in damage to 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.
- 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).
- 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.
- Observe specified torques.

Magnetic Resonance Imaging (MRI) Safety Information:

Smart Denture Conversion LLC Separable Fasteners 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 Separable Fasteners in the MR environment is unknown.

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:

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1. **Preparation for sterilization:** Place components (up to 6 devices) in a sterilization pouch which is approved 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.

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.

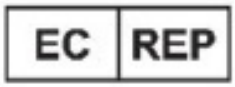
Warranty:

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
	Do Not Use if Packaging is Damaged		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