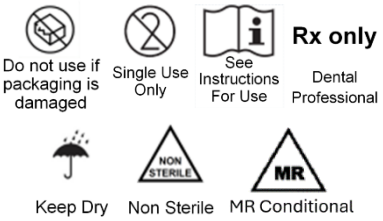
Omnidirectional Multi-Unit Abutments

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:

Omnidirectional Multi-Unit Abutments (Omnibuts) are premanufactured dental implant abutments to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation. Omnibuts are made of titanium alloy. Omnibuts are single patient, single-use devices. See the chart below for implant system compatibility.

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)	Description	Material
NobelActive®	3.5	NP (3.5)	Omnibut, Nobel NP	Titanium alloy - Ti-6Al-4V ELI (90% Ti, 6% Al, 4% V ELI)
	4.3, 5.0	RP (3.9)	Omnibut, Nobel RP	
Neodent Grand Morse Helix	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM (3.0)	Omnibut, Neodent	
Straumann BLX	3.5, 3.75, 4.0, 4.5	RB	Omnibut, Straumann BLX	
	4.5, 5.0, 5.5, 6.5	WB		
Zimmer Tapered Screw-Vent	3.7, 4.1	3.5	Omnibut, Zimmer TSV 3.5	
	4.7	4.5	Omnibut, Zimmer TSV 4.5	
	6.0	5.7	Omnibut, Zimmer TSV 5.7	

Intended Use:

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Omnibuts, in combination with four or more endosseous implants, are indicated for multiple unit reconstructions when screw retained prosthetics is preferred.

Indications for Use:

The Omnibut is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Omnidirectional Multi-Unit Abutments 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.
- Cases with less than four endosseous dental implants in a single arch.

Warning:

- Abutments are to be used by dental health care professionals and are to be used in patients subject to dental implant treatment.
- Do not exceed 30° correction angle or apply excessive force with the swivel at the maximum rotation pivot angle.
- 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 abutment or other components to become deformed, broken or stuck, resulting in damage to components.
- Ensure products are secured against aspiration when handled intraorally. Use of a cotton gauze throat shield is advised. 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 by the patient, follow-up treatment, incorrect impression resulting in incompatible restorations.
- As the clinical outcome of dental treatment is influenced by multiple variables, the residual patient risks described below can occur even if the product is used according to the instructions for use.
    - anaphylaxis (severe allergic reaction); aspiration or swallowing of components; pain; local infection; inflammation; local irritation; loss of product function; need for follow-up treatment.
- Smart Denture Conversions is not liable for damage resulting from use outside the intended use of the product.
- Small diameter implants and Omnibuts are not recommended for the posterior or molar regions.

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.
- Ensure that the abutment surface is clean before placing Temporary Cylinders.
- 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 for the patient.
- Always wear suitable personal protective equipment for your own safety and to minimize potential for patient infection and cross-contamination.
- Position the patient such that the danger of aspiration of components is minimized. Use of a cotton gauze throat shield is advised.
- 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:

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	Omnibut
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

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 of abutments prior to use.

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.

Directions for Use:

Clinical procedure:

1. Place abutment using the Omnibut Driver (Fig. 1)
2. Ensuring that the driver is fully seated in the Omnibut, tighten the abutment according to Table 1, using the Omnibut Driver with a torque wrench. (Fig. 2)
   Caution: Never exceed recommended maximum tightening torque for the Omnibut. Overtightening of abutment may lead to damage.
3. Using the Orientation Post included with the Omnibut, move the Omnibut Swivel Base to the desired angulation (Fig. 3).
4. Tighten each Orientation Screw to 25 Ncm using the Orientation Driver (Fig. 4).
5. Provisionalize the patient using Smart Denture Conversions techniques. For step-by-step instructions, go to SmartOnX.com/Technique-Manual
6. Secure the provisional prosthesis with Omnibut Prosthetic Screws (Fig. 5) and tighten to 15 Ncm using the Orientation Driver with a torque wrench (Fig. 6).

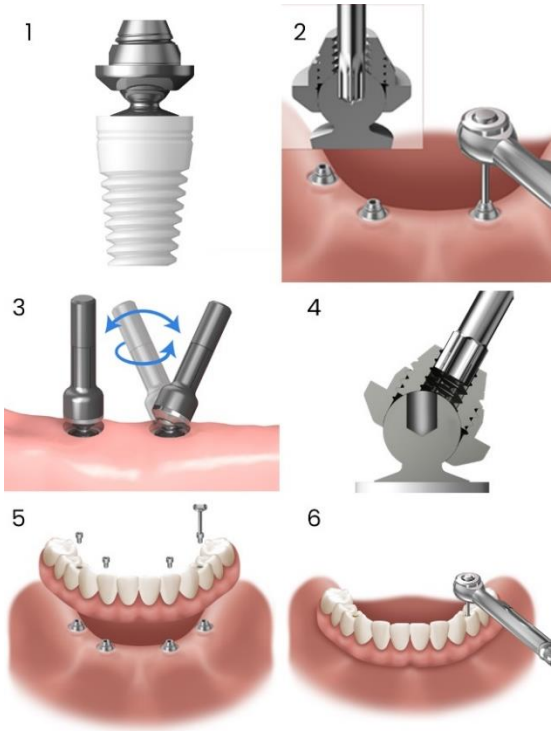


Table 1

Implant System	Recommended OEM Torque
NobelActive	35 Ncm
Neodent Grand Morse	32 Ncm
Straumann BLX	35 Ncm
Zimmer Tapered Screw-Vent	30 Ncm

Note: Always refer to the original implant manufacturer's instructions for use with regards to the implant indications and contraindications, as well as tooling and tightening torque.

We strongly recommend a radiograph to verify the final abutment seating. For more specific information on process steps, please refer to the Omnibut Technique manual located on the website www.SmartOnX.com.

It is recommended to establish a tailored prosthetic maintenance plan for each patient, considering their capability to maintain cleanliness of their prosthesis. This plan may include periodic removal and replacement of prosthetic screws every 6, 12, or 18 months. It is expected that clinicians instruct their patients on the proper maintenance of full-arch implant restorations following the American College of Prosthodontists Position Statement *Maintenance of Full-Arch Implant Restorations.*

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, re-cycling 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	Basic UDI-DI Number
Omnibut, Nobel NP	23NANP-OA	+D99023NANPOA0
Omnibut, Nobel RP	23NARP-OA	+D99023NARPOA0
Omnibut, Neodent GM	23NEOGM-OA	+D99023NEOGMOA0
Omnibut, Straumann BLX	23BLX-OA	+D99023BLXOA0
Omnibut, Zimmer Internal Hex 3.5	23ZIH35-OA	+D99023ZIH35OA0
Omnibut, Zimmer Internal Hex 4.5	23ZIH45-OA	+D99023ZIH45OA0
Omnibut, Zimmer Internal Hex 5.7	23ZIH57-OA	+D99023ZIH57OA0
Orientation Screw 1PK	OS1PK	+D990OS1PK0
Orientation Screw 10PK	OS10PK	+D990OS10PK0

Validity:

Upon publication of these instructions for use, all previous versions are superseded.

Availability:

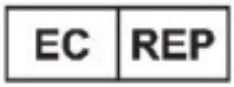
Some items of Smart Denture Conversions are not available in all countries.

Warranty:

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

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		European Representative
	Batch Code		Catalog Number
	CE Mark		UK Representative
	United Kingdom Conformity Assessment Mark		United Kingdom Conformity Assessment Mark with Approved Body Number
	Serial Number		Non-Sterile
	Do Not Resterilize		Do Not Reuse
	Do Not Use if Packaging is Damaged		Consult Instructions for Use
	Keep Dry		Keep Away from Sunlight
	Unique Device Identifier		Medical Device
RX Only	For Prescription Use Only		Caution, Consult Accompanying Documents
 MR Conditional	MR Conditional		