Instructions for Use (IFU)

Horizontal Scan Gauges

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:

Horizontal Scan Gauges are designed to facilitate the acquisition of accurate implant position readings in scans taken with intraoral scanners for full arch prosthetic restorations. The scan gauges are to be mounted directly on the implant abutment embedded in the mandible or maxilla. Horizontal scan gauges have three locations to cut to optimize placement. The table below summarizes information on the devices:

Name	Approx. Height	Material	Use
Horizontal Scan Gauge	7.5mm	Polymethyl Methacrylate (PMMA)	Single Use

Intended Use:

Horizontal Scan Gauges are intended to be mounted to an implant abutment and scanned with intraoral scanners. Horizontal Scan Gauges are intended to be cut to the proper length to provide optimal placement. They are intended to serve a secondary function as a verification jig to fabricate a stone model, accurately representing the 3-dimentional inter-abutment positions. Horizontal Scan Gauges 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.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Horizontal Scan Gauge 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 Horizontal Scan Gauge 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.

Horizontal Scan Gauges

- 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.
- Ensure that the abutment surface is clean before placing a Horizontal Scan Gauge.
- 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 Horizontal Scan Gauges 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 Horizontal Scan Gauges in the MR environment is unknown.

Disinfection Instructions:

Components are delivered non-sterile by Smart Denture Conversions and are intended for single use. Devices should be disinfected prior to use on a patient to ensure safety and prevent the risk of infection. An intermediate disinfectant, such as Chlorhexidine gluconate (0.12%), should be used. Follow the manufacturer’s instructions for the correct application, ensuring adequate contact time to achieve effective disinfection. Ensure that the device is clean and free from any contaminants before applying the disinfectant to maximize efficacy.

Note: This device should not be steam sterilized, as exposure to high temperatures and moisture may cause the part to deform and compromise its functionality.

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.

Horizontal Scan Gauges

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.

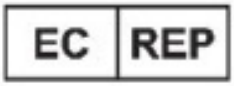
Warranty:

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

Horizontal Scan Gauges

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