



# Instructions For Use: Try-in 3D Printed - US

ART-017, Version 2.0 (Effective from 20/01/2023)

## Indication for use:

3D Printed Try-Ins are transient devices intended for the clinician to check the accuracy of final prosthesis parameters during the appointment.

## Description:

Each 3D Printed Try-in is made for an individual patient as prescribed by the health professional, digitally designed using advanced dental CAD (Computer Aided Design) Systems, and 3D printed in biocompatible materials.

The 3D Printed Try-ins are either designed and manufactured by Osteon and provided to clinicians, or the clinicians may order a 3D printed Try-in's Design only and self-manufacture the 3D Printed Try-in. Please note: For the latter the below information may not be applicable, and it is up to the Clinician to provide all the necessary information to the patient.

## Material:

The Osteon Manufactured 3D Printed Try-ins are made of light-curable polymerizable biocompatible Photopolymer Resin, which are composed of Acrylic Oligomers and Photoinitiators.

## Contraindications:

The material used for the 3D Printed Try-ins are classified as Sensitizer, which means that exposure over time can cause the body to have a mild allergic reaction. The material may cause skin irritation, skin allergic reaction, eye irritation and respiratory irritation. If any irritation occurs, please seek medical attention.

## Warnings and Precautions:

Proper surgical procedures are the responsibility of the dental professional. Each clinician must evaluate the appropriateness of the procedure used based on personal medical training and experience as applied to the patient case at hand. The Osteon Manufactured 3D Printed Try-ins are meant to be inserted and retained in the patient's mouth only for the duration of the appointment (approx. 1 hour). The patient should not wear the 3D Printed Try-ins for prolonged period. It is the responsibility of the Clinicians to remove the 3D Printed Try-ins prior to the end of the appointment to ensure no adverse reactions are caused.

Small components dropped/chipped in the patient's mouth could be swallowed or aspirated and therefore should be handled with care. If any part of Osteon manufactured 3D Printed Try-ins is swallowed, please seek medical attention.

These products are made specifically for a patient. Re-use of the product for another patient should not be attempted. Osteon assumes no responsibility for attempted re-use of the device on another patient.

## Disinfection:

Osteon products are supplied NON-STERILE and must be disinfected prior to their placement in the mouth. It is the responsibility of the clinician to disinfect the 3D Printed Try-ins. Disinfection can be carried out by using any medical grade disinfectant. Please follow instructions provided by the disinfectant manufacturer to adequately disinfect the 3D Printed Try-ins.

## Specific Instruction For Use:

3D Printed Try-ins are always made with straight screw channels. It is the responsibility of the clinician to use the compatible screwdriver for the case in hand. Screws should

only be hand torqued without exceeding 10Ncm to check the fitting of the 3D Printed Try-in.

## Safety information:

Osteon products have not been evaluated for safety when exposed to electric, radiation, vibration, and thermal energy and compatibility is unknown. Exposure to these energies may result in patient injury and adequate precautions should be taken.

**Note:** Any serious incident(s) that has occurred in relation to the device shall be reported to Osteon and the competent authority having jurisdiction in the locale where the incident occurred.

## MRI Safety Information:

The RF safety of the 3D Printed Try-ins has not been tested in the MR environment. It has not been tested for heating, unwanted movement (vibration) or image artifact in the MR environment. The safety of the 3D Printed Try-ins is unknown. Performing an MR Exam on a person who has this medical device may result in injury or device malfunction.

## Labelling Symbols:

Labelling Symbols according to ISO 15223-1:2021	
Symbol	Description
	Manufacturer
	Date of manufacture
	Non-Sterile
	Consult electronic Instructions for Use (E-IFU)
	Fragile, handle with care
	Medical Device
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
	MR Unsafe
	Catalogue number
	Serial Number
	Do not use if package is damaged




Product of Australia

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	Keep dry (before opening)
	Single patient (multiple use)
	Unique Device Identifier

## Disposal:

For disposing of the product and packaging, comply with the applicable waste disposal regulations in your local jurisdiction / country.

## Contact Details:



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