KeystoneDentalGroup

Prosthetic
Manual

EasyPro
A KeystoneDentalGroup Brand

Warning

The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry and are not intended to be a substitute for formal clinical or laboratory training. These devices should only be used by individuals with training and experience specific to their clinically accepted application.

CAUTION: US Federal law restricts the sale of this device to, or on the order of, a licensed dentist or physician.

1 Characteristics

1.1 Specifications

Introduction

This manual outlines the appropriate step-by-step procedures to convert a full or partial prosthesis using the EasyPro™ Kit.

Indications for Use

The EasyPro™ System facilitates the conversion of full dentures, full arch immediate bridges & partial immediate bridges (two units or more) to fixed screw retained provisional restoration.

Patient Population

Recommended only for patients who have completed jawbone growth, ranging from adolescents to the elderly population.

Description

The EasyPro™ System consists of a complete solution for the conversion of removable prostheses into temporary implant supported fixed screw retained prostheses. The system is designed to function on two or more Keystone Dental industry standard regular platform multi-unit abutments.

Warnings

As the clinical outcome of dental treatment is influenced by multiple variables, the residual risks described below can occur even if the product is used according to the instructions for use. These include allergy; aspiration; tissue, nerve or bone damage due to magnetic resonance imaging; swallowing; discomfort; pain; edema; treatment failure; local infection; inflammation; local irritation; loss of product function; pyrogenic reaction; and prosthetic, esthetic, or biomechanical issues.

Contraindications

Patients who show signs of allergy or hypersensitivity to chemical ingredients of the materials. These products are also contraindicated for customization, unitary and cemented prostheses. Refer to the EasyPro™ IFU.

1.2 Description and Design

TiTemp Copings

TiTemp Coping 4.0 mm H, 6.0 mm H are anodized yellow. They have a cylindrical shape with mechanical retention for acrylic or composite and varying cuff heights. The coping has a screw access channel on the occlusal surface that allows for:

1. The insertion of the anodized retaining screw
2. Access for the TiTemp Base Coping Screw and screwdriver
3. The TiTemp Coping is designed to have a friction fit over the TiTemp Base Coping.

TiTemp Base Coping

4.0 mm H Coping

6.0 mm H Coping

TiTemp Base Copings

TiTemp Base Coping has a conical shape with screw access hole for a TiTemp Base Coping Screw. The coping is designed to sit over the Regular Platform Multi-Unit abutment. The base coping has a unique feature of parallel walls above the collar that enables the base coping to have a friction fit inside the TiTemp Coping (both heights)

TiTemp Base Coping

Parallel Wall Friction Feature

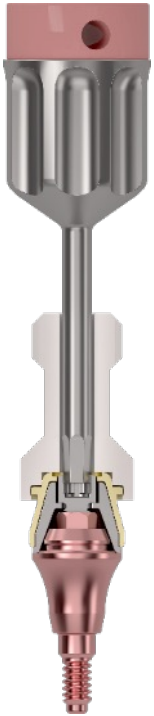
Correct seating of the TiTemp Coping over the TiTemp Base Coping

The TiTemp Base Coping Screw seats inside the TiTemp Base Coping securing it to the Multi-Unit Abutment. The screw may be tightened using the Ø1.25 Manual Hex Driver. It is recommended to tighten the screw by hand to a torque not exceeding 15 Ncm.

EasyPro™ Final Retaining Screw

EasyPro™ Final Retaining Screw is anodized yellow and is designed to attach the TiTemp Coping over the TiTemp Base Coping directly to the Multi-Unit Abutment. The screw may be tightened using the Ø1.25 Manual Hex Driver. It is recommended to tighten the screw by hand to a torque not exceeding 15 Ncm.

EasyPro™ Final Retaining Screw



EasyPro™ Retraction O-Rings

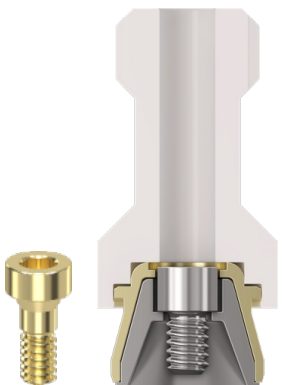
EasyPro™ O-Rings Wide and Narrow (profiles) are made of Viton and are designed to seat over the TiTemp Coping after assembly on the Multi-Unit Abutment.

The O-Ring may assist with:

- Retraction of the soft tissue
- Protection of the soft tissue & adjacent sutures
- Protection of undercuts caused by exposure of the cuff portion of concave Multi-Unit Abutments
- The O-rings should be removed after fabrication and bonding of the TiTemp Coping

EasyPro™ Unit consisting of:

TiTemp Handle, TiTemp Coping either 4 mm H or 6 mm H, TiTemp Base Coping, TiTemp Coping Base Screw is pre-assembled ready for use and packed sterile in a pouch together with the EasyPro™ Retaining Screw.



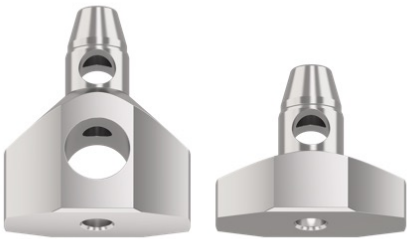
EasyPro™ 4.0 mm H unit shown

EasyPro™ Laboratory Kit

EasyPro™ Cassette, Empty
Drill Guide - Short
Drill Guide - Standard
Intaglio Drill
Occlusal Drill
EasyPro™ Laboratory Bur Ø6 mm
Ø1.25 mm Manual Hex Driver
EasyPro™ Manual Reamer
EasyPro™ IFU

EasyPro™ Kit Application

The EasyPro™ Kit houses the tools used to prepare and convert a removable prosthesis into fixed prosthesis.



The EasyPro™ Drill Guide comes in standard (17 mm in length) and short (12 mm in length) versions. The Drill Guide has a Ø2.1 mm hole to allow the free transition of the Intaglio Drill. It comes with the same friction feature as the TiTemp Base Coping and will seat inside the TiTemp Coping firmly allowing for easy drilling procedure from the intaglio surface out through the occlusal surface using the 30 mm length Ø2.0 mm Intaglio Drill. The Standard Drill Guide has two ventilation holes & the Short Drill Guide has one ventilation hole that facilitates venting for the acrylic or composite fragments and reduces heat transition. It is recommended to complete the drilling through the

drill guide using several short steps allowing the fragments to be released & preventing overheating of the drill or drill guide.

*NOTE: in cases where the prosthesis may have increased height and the drill fails to perforate the occlusal surface, the Standard Drill Guide may then be exchanged with the Short Drill Guide to allow for an additional drill depth of 5 mm. In extreme cases it may be necessary to remove the Short Drill Guide and to complete the drilling free hand. Free-hand drilling at this stage will follow the drilling access due to the pre-drilled channel of approximately 18 mm in depth.

*NOTE: the Drill Guide may be used to protect the inner surface of the TiTemp coping when adding small amounts of reline flow material.

The Intaglio Drill features an active cutting thread with a diameter of Ø2.0 mm. The drill shank will attach to a laboratory motor or a straight surgical handpiece. It has a stop at 30 mm in length. The drill length functionality may be increased by changing over from the Standard to the Short Drill Guide.

The Occlusal Drill has a smooth drill tip of Ø1.8 mm and is designed to enter the occlusal channel created by the Intaglio Drill. The occlusal drill then increases in diameter to Ø2.8 mm to create the required diameter of the screw access channel for the anodized EasyPro™ Retaining Screw. The Occlusal Drill should be used until the wider section meets the occlusal housing of the TiTemp Coping.

The Laboratory bur is used to grind a cavity in the intaglio surface to house the TiTemp Coping, take care not to perforate the occlusal surface of the teeth during this process. On completion of the EasyPro™ process, the bur is used to modify the flanges of the denture. For instructions for the EasyPro™ Laboratory bur, Ø6.0 mm, manufactured by Komet, refer to the Komet IFU 'Instructions for use and safety recommendations for the application of rotary and reciprocating instruments in the medical field' (refer to the most current version of Komet's IFU found on Komet's website - https://www.kometmedical.com).

EasyPro™ Manual Reamer: In cases where fragments of material remain in the screw access channel it may be necessary to exchange the occlusal drill with the manual reamer to create the base of the screw access channel. After use it is recommended to use compressed air to remove all fragments.

The EasyPro™ System is compatible with all industry standard multi-unit regular platform abutments & implant systems.
In the case of EasyPro™, a minimum of two implants are required together with chosen industry standard multi-unit regular platform abutments of the desired height and angulation.

Applications:
Laboratory instruments and components used to perform the procedure of converting removable prostheses into fixed screw retained prostheses.

2 Planning and Preparation

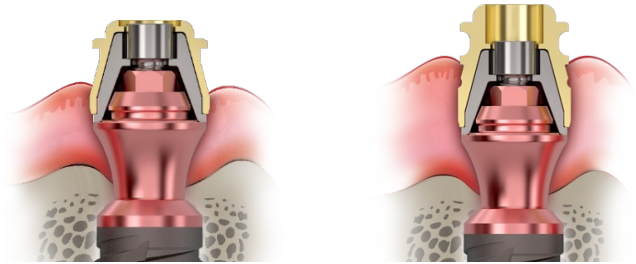
1.2 Description and Design

Directions for Use

The EasyPro™ procedure begins following the placement of Multi-Unit Abutments (regular platform). A minimum of two Multi-Unit Abutments are required.

STEP 1
Verify the Multi-Unit Abutments are fully seated (x-ray verification is recommended) and the abutments have been torqued down to their required torque.

STEP 2
Measure the soft tissue depth from the Multi-Unit Abutment platform to the height of the surrounding soft tissue. Choose the appropriate height of EasyPro™ Unit in accordance with the soft tissue depth. The EasyPro™ Units come sterilized by gamma irradiation packaged in a pouch. Refrain from opening the package until you have measured all tissue heights and have chosen the required height of TiTemp Coping.



Illustrating different soft tissue heights showing TiTemp Copings of 4 mm and 6 mm in height.

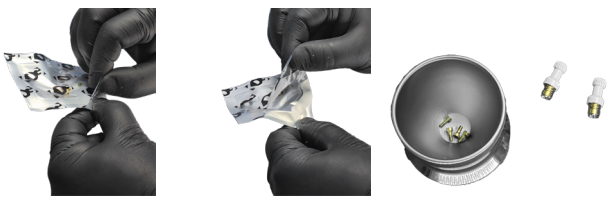
Caution

These products are intended for single use before the "use by" date printed on the product label. The sterile packaging must not be opened until immediately prior to insertion. Do not use it if packaging is damaged.

Resterilization can cause risk or harm to the patient. Keystone Dental does not accept any responsibility for resterilized EasyPro™ components.

STEP 3

The dental assistant should open the EasyPro™ pouch and carefully deliver the assembled components, dropping them onto the sterile tray.



STEP 4

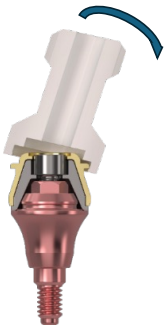
Using the conveniently attached PEEK handle to hold the components, install the EasyPro™ Unit over the Multi-Unit Abutment. The TiTemp Base Coping Screw is captured inside the EasyPro™ unit with the help of the PEEK handle. Use the Ø1.25 mm Manual Hex Driver in a clockwise direction through the access channel in the PEEK handle to close the TiTemp Base Coping Screw. Tighten by hand not exceeding 15 Ncm. Check carefully that the EasyPro™ Unit is seated correctly and there is no interference with the surrounding soft tissue or possible sutures. For your convenience the TiTemp Coping is anodized yellow, this will help to verify the TiTemp Coping is fully seated on the TiTemp Base Coping.

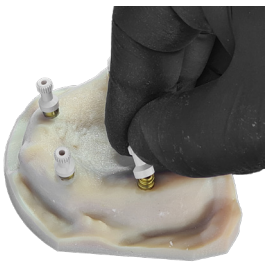
Convenient PEEK Handle

Ø1.25 mm Manual Hex Driver

Once connected remove the TiTemp Handle by using a gentle tilting motion.

STEP 5
Repeat the above procedure on all Multi-Unit Abutments.

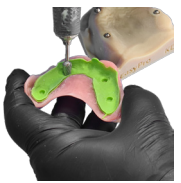


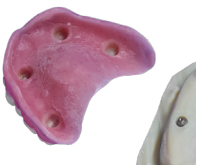


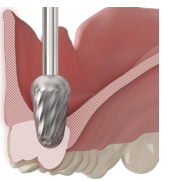
STEP 6
Prosthesis/denture preparation

EasyPro™ conversion may be used on all types of prostheses, partial or full, for the purpose of this IFU the procedure will be described for a full arch denture. The same

steps may be conducted for partial dentures, full arch or partial immediate bridges. Mark the position of the EasyPro™ unit on the intaglio surface of the denture using either a marking paste or silicone wash material. Use the provided laboratory bur in the EasyPro™ kit (Ø6 mm) to grind a cavity in the intaglio surface large enough to house the TiTemp Copings. Take care not to grind away too much material that may then weaken the prosthesis. Avoid perforating the occlusal surface. Verify the correct seating of the full denture, evaluating the occlusal relationship will assist in ensuring the denture is seated correctly and will minimize occlusal adjustments following the conversion. If in doubt use marking paste an additional time and remove all areas of premature contact to the EasyPro™ Unit components.

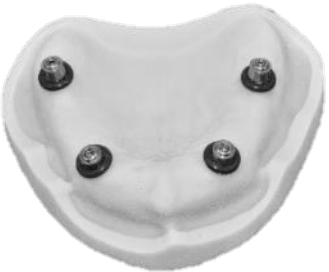


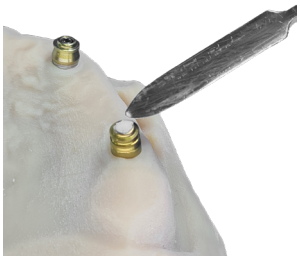




STEP 7

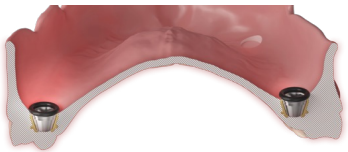
The Retraction O-Rings may be seated over the TiTemp Coping to protect the surrounding mobile soft tissue and to assist in retracting soft tissue. In some cases, the Retraction O-Ring may be needed to protect the exposed concave collar of a Multi-Unit Abutment to ensure the reline material does not catch the undercut area of the gingival cuff. Cover the head of the TiTemp Base Coping Screw with an appropriate block out material (Silicone body putty/wax).

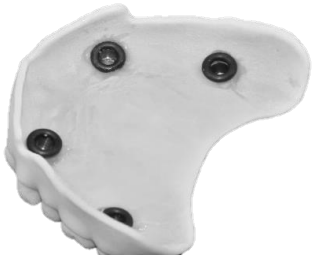




STEP 8
Reline the denture over the TiTemp Copings. We recommend the use of a material that may be injected into the denture "TiTemp" cavities. Using a material that functions with a simple injection handgun will simplify the procedure. In the absence of such a material conventional self-curing acrylic may be used. Follow the IFU of the material used. It may be necessary to paint a layer of bonding agent prior to adding material. Use light cure when recommended by the IFU. It is recommended to place a small amount of material inside the cavity in the intaglio surface of the denture and cover the retentive portion of the TiTemp Coping equally with the reline material. This will ensure an efficient pick-up process.

Validate the patient is in a closed centric bite relationship during the curing procedure when possible, this will ensure minimum occlusal adjustments at the finishing stage. After the material has cured, remove the denture by applying moderate force in the posterior segment first and then towards the anterior segment to leverage its removal in an easy manner. Review the pick-up of the TiTemp Copings inside the denture, ensure they have been captured and are stable in the prosthesis. In some cases, the Retraction O-Rings may be captured in the reline. The Retraction O-Rings should be removed using a dental probe or any suitable pointed instrument.

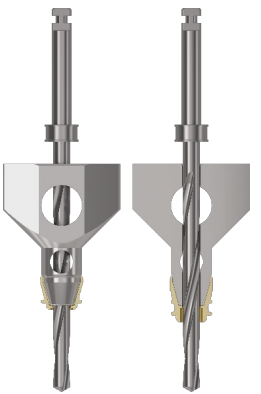


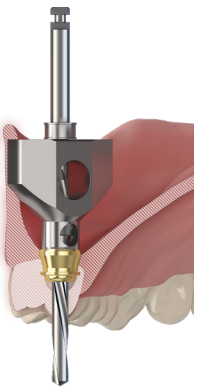


If there are small voids around the TiTemp Copings we recommend filling them with a convenient flowable material. To avoid accidental flow of material inside the TiTemp Coping we recommend seating the Drill Guide, Standard during this procedure to function as a protection cap.

STEP 9

Prepare the screw access channel. Position the Drill Guide, Standard inside the TiTemp Coping. Use light pressure to ensure it is seated correctly. Use the Intaglio Drill on a laboratory motor or straight handpiece and drill the hole with moderate pressure (while stabilizing the drill guide with your hand) until the Intaglio Drill exits the occlusal surface. If the drill does not exit the occlusal surface swap out the Drill Guide, Standard for the Drill Guide, Short and repeat the process. Now that you have completed the preliminary screw access channel, it is recommended to complete the drilling through the drill guide using several short steps allowing the fragments to be released & preventing overheating of the drill or drill guide.





Remove the Intaglio Drill. The occlusal drill has a smooth drill tip of Ø1.8 mm and is designed to enter the occlusal channel created by the Intaglio Drill. Utilizing the occlusal drill through the hole created by the Intaglio increase in diameter to Ø2.8 mm to create the required diameter of the screw access channel for the anodized Retaining Screw. The Occlusal Drill should be used until the wider section meets the occlusal housing of the TiTemp Coping.

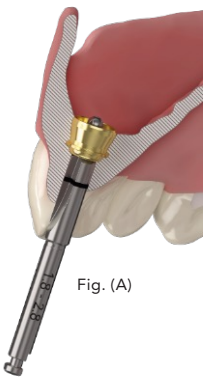


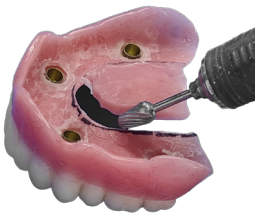
Fig. (A)

*NOTE: Evaluate that the occlusal drill tip is protruding the TiTemp Coping as shown in Fig. (A). It may be necessary to repeat the drilling procedure to achieve the desired result.

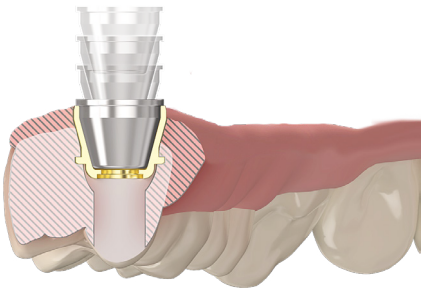
*NOTE: Use the EasyPro™ Manual Reamer in cases where fragments of material remain in the screw access channel it may be necessary to exchange the Occlusal Drill with the Manual Reamer to create the base of the screw access channel. After use it is recommended to use compressed air to remove all fragments.

STEP 10

Using conventional laboratory techniques grind away the flanges and palate (in case of maxilla) of the denture to attain the correct intaglio profile of the provisional screw retained bridge. This final shaping of the prosthesis is carried out while the TiTemp Base Copings are still attached to the Multi-Unit Abutments.

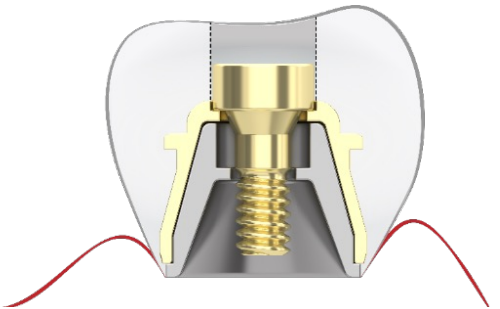


On completion of the final shaping and polishing, remove the TiTemp Base Copings from the Multi-Unit Abutments, and with moderate pressure insert the TiTemp Base Coping into the TiTemp Coping. Ensure all Base Copings are seated correctly.

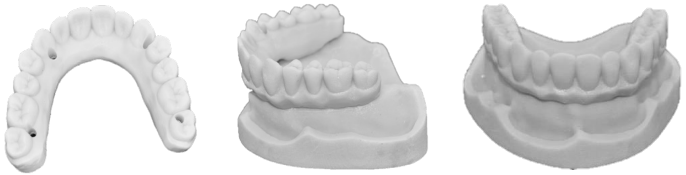


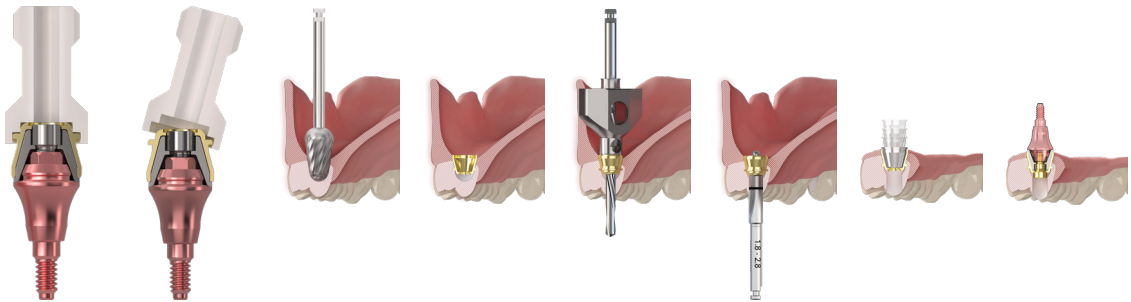
Now insert the EasyPro™ Retaining Screw one by one into the screw access channel to ensure that it is seated correctly and has travelled through the Base Coping.

*NOTE: Note the level of the tip of the retaining screw when assembled correctly in the image below.



Now that you have shaped, polished and verified the correct seating of TiTemp Base Copings and TiTemp EasyPro™ Final Retaining Screws, the prosthesis may be attached to the Multi-Unit Abutments using the Final Retaining Screws and the Ø1.25 mm Manual Hex Driver. We recommend hand tightening to 15 Ncm. Protect the chimney of the screw access channel using conventional techniques, check for correct occlusion and make minor adjustments as needed.



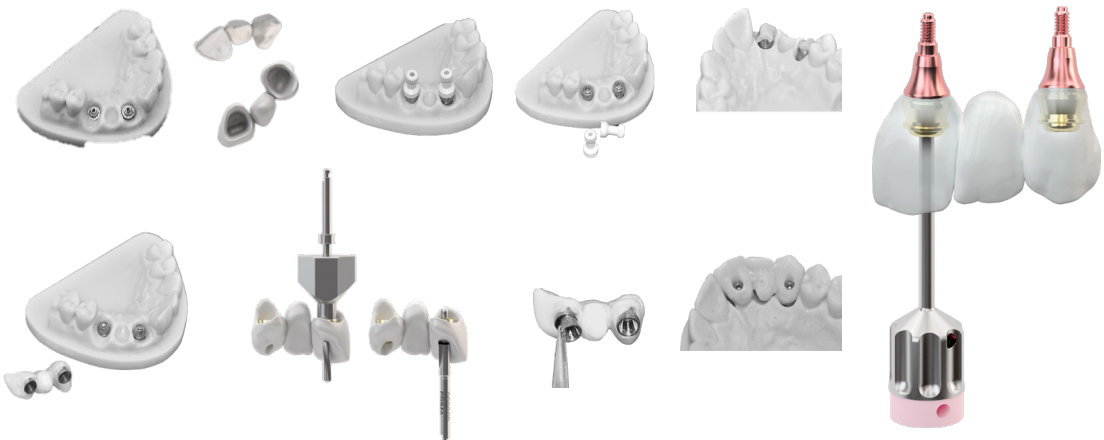


1. Attach EasyPro™ Unit
2. Remove Handle
3. Denture preparation
4. Pick up of TiTemp Coping
5. Intaglio drill
6. Occlusal drill
7. Insertion of TiTemp Base Coping
8. Conversion Complete

2.2 Directions for Use - Partially Edentulous

Directions for Use

*NOTE:. The workflow for partial cases follows the same procedure, see illustration below.



3 Sterility

3.1 Cleaning and Sterilization

Sterility

Sterile EasyPro™ components are sterilized using gamma sterilization. These products are intended for single use before the "use by" date printed on the product label. The sterile packaging must not be opened until immediately prior to insertion. The intact sterile packaging protects the gamma-sterilized devices from outside influences, if stored correctly ensures sterility up to the expiration date. When removing the devices from the sterile packaging, the rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to use. Devices with damaged sterile packaging must not be used due to the risk of contamination. Keystone Dental does not accept any responsibility for resterilization of products supplied sterile.

Some EasyPro™ components are supplied non-sterile. Refer to individual product labels for sterilization information. Products provided non-sterile for use in a clinical environment must be cleaned and sterilized prior to use.

Cleaning and Sterilization

For cleaning and sterilization instructions for the EasyPro™ Laboratory bur, Ø6, manufactured by Komet, refer to the Komet IFU 'Instructions for use and safety recommendations for the application of rotary and reciprocating instruments in the medical field' (refer to the most current version of Komet's IFU found on Komet's website - https://www.kometmedical.com).

For all other EasyPro™ components, use the following cleaning and sterilization instructions:
Tools/Instruments which are not supplied sterile must be cleaned and sterilized prior to first and after each use based on established procedures. Proper instrument care is an important part of successful implant dentistry. Automated washers should not be used, as it may reduce the life of the instruments. All tools/instruments were developed for sterilization by autoclave.

Prosthetic Devices provided non-sterile should be cleaned and sterilized prior to use.

Prosthetic Devices which are provided sterile and are modified by the end-user, must be

cleaned after any modifications are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.

Cleaning of the devices is performed in the dental clinic according to the following parameters:

- Tools/Instruments inside a kit should be removed from the tray using dental tweezers.
- Used tools/instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva, and tissue residue.
- Multiple-part tools/instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue on devices must be removed with a soft brush.
- Devices should be inspected, cleaned separately, and discarded if damaged.
- Devices should be placed in an ultrasonic bath with an enzymatic solution, approved and appropriate for dental use (for example, Powerzume, Deconex).
- Wash the devices in an ultrasonic device according to the device's instructions, for 15 minutes.
- Clean the plastic parts, the kit, the tray, including the grommets, with soap (for example, 18%, St-Moritz) and water and wash well with running water and dry.
- Remove the devices from the ultrasonic bath at the end of the cycle and wash with running water.
- Use a soft brush to remove any residue from the devices and wash again with running water and thoroughly dry.

- Devices may be delivered sterile or non-sterile. Please see indication on device package prior to use. Devices placed in the patient's mouth must be sterile prior to use.
- Sterilization of non-sterile packaged devices or prosthetic devices which are provided sterile and are modified by the end-user or laboratory, must be re-sterilized after any modifications are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.
- Sterilization of these non-sterile devices is performed in the dental clinic setting by steam autoclave sterilization according to the following parameters.

Sterilization Method	**Steam, Gravity Displacement**	**Steam, Pre-vacuum method (Dynamic Air Removal)**
Temperature	275°F (135°C)	275°F (135°C)
Cycle Time	10 minutes	3 minutes
Dry Time	30 minutes	16 minutes
Packaging	510(k)-cleared sterilization pouch	510(k)-cleared sterilization pouch
Sterility Assurance Level	≤ 10^{-6}	≤ 10^{-6}
Chamber Pressure	up to 2.3 bars (34 psi)	~296 KPa
Load Configuration	Coldest spot in the chamber, near the door. The autoclave may be loaded up to the maximal load, as determined by the autoclave manufacturer.	Coldest spot in the chamber, near the door. The autoclave may be loaded up to the maximal load, as determined by the autoclave manufacturer.

Follow the autoclave manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the tools/instruments being sterilized including the internal surface and tubes channels. Allow tool/instrument to air cool to room temperature before use.

Products labeled as sterile should be considered sterile until the indicated "use by" date on the label unless the package has been opened or damaged. Never use products if the "use by" date has expired.

3.2 Sterility

Sterility

- Drills must not be resharpened.
- A converted prosthesis utilizing the EasyPro™ Unit is recommended for use up to 180 days.
- To perform the procedure, make sure that the patient has enough interocclusal space to handle the instruments in the desired region.
- Excessive wear of the prosthesis can compromise the mechanical properties and/or render it unusable.
- Inadequate planning may jeopardize the performance of the implant/prosthesis assembly, resulting in failure of the system, such as loss or fracture of the implant and loosening or fracture of the components and/or prosthetic screws.
- Patients who show signs of allergy or hypersensitivity to chemical ingredients of the materials listed in table in section EasyPro™ IFU Section 4.
- EasyPro™ products must be used sterile. Do not use the product if its packaging is damaged. Do not use the product if it is expired. Before each procedure, make sure that the parts fit together perfectly.
- Ensure that the parts are not swallowed or aspirated by the patient.
- Make sure you have all the necessary instruments to perform the procedure according

to the planning.

- Before each procedure, check the conditions of the instruments, always observing their life cycle. Replace the instruments in case of damage, erased markings, compromised sharpening, deformation, or wear.
- Always follow the EasyPro™ recommended product sequence. The use of instruments and/or prosthetic components from other manufacturers does not guarantee the proper function between the implant system and EasyPro™ conversion unit and will void any product warranty.
- It is the responsibility of the clinician/dental technician to use EasyPro™ products in accordance with the instructions for use.
- If any accident involving the device occurs, carefully remove the parts from the patients' mouth and inform your local distributor/Keystone Dental Inc.
- Too much force can cause unwanted effects and render the product useless.
- Do not apply lateral force on the drill bit due to the risk of fracture.
- Follow the acrylic resin manufacturers' handling guidelines.
- Check and perform the occlusal adjustment after the installation of the prosthesis, avoiding the compromise of the system.
- Refer to the torque to be given on the prosthetic component to be used. Too much or too little torque can lead to undesirable results.
- Make sure to protect the abutment access channel.
- During installation, be sure to align the EasyPro™ Unit to the multi-unit abutment, making sure it is seated to the component. For this, periapical radiographs with the

parallelism technique are recommended.

- Above 5 implants, the force to remove the prosthesis during the capture process in the clinical flow may be excessive. In these situations, and in situations where there is a great divergence in the orientation of the positioning of the multi-unit abutments it is recommended to complete a staged approached, attaching a selection of the EasyPro™ units in the first step followed by a second step to include the remaining EasyPro™ Units.
- For immediate loading application, check the torque indication for the installed implant.

4 References

4.1 MR Safety - MR Conditional

MR Safety Information - MR Conditional:
WARNING: MR Conditional Labeling has not been reviewed or approved by Health Canada. The RF safety of the EasyPro™ 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 a EasyPro™ device can be scanned safely in an MR system under the following conditions found on the next page.

For MR patient safety card please visit KeystoneDental.com/pages/mr

MRI Safety Information - MR Conditional

Device Name	EasyPro™ Device
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 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.

4.2 Storage and Handling

Storage and Handling

Product must be stored in its original, sterile (if applicable) packaging under dry, room temperature conditions, out of direct sunlight. There are no additional storage and handling conditions for EasyPro™ components.

Disposal

After use, devices may be disinfected and thrown in a designated bin for biohazard waste (follow local regulations and environmental requirements).

4.3 Symbol Definitions

	Catalog number
	Batch Code
	Medical Device
	Do not reuse
	Non-Sterile
	Do not use if package is damaged and consult instructions for use
	Sterilized using irradiation

	By Prescription Only
	Use by date
	Manufacturer
	MR Conditional
	Keep away from sunlight
	Consult instructions for use

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