EasyPro IFU
Instructions for Use

1 Indications for Use:

1.1 The EasyPro System is indicated to facilitate the conversion of full dentures, full arch immediate bridges and partial immediate bridges (two units or more) to fixed screw retained provisional restoration.

2 Patient Population:

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

3 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.

4 The EasyPro Solution comprises of the following components:

Component	Material
TiTemp Handle	PEEK Classix
TiTemp Coping 4.0 mm H	Titanium 6Al-4V ELI per ASTM F136
TiTemp Coping 6.0 mm H	
TiTemp Base Coping	
TiTemp Base Coping - Screw	
EasyPro Final Retaining Screw	
EasyPro, Retract ORing,12Pk,Wide (Round, ID Ø4.7 mm OD Ø7.7 mm)	FLUORINATED HYDROCARBON (Viton)
EasyPro, Retract ORing,12Pk,Narrow (Round, ID Ø4.5 mm OD Ø6.5 mm)	
EasyPro Units	
EasyPro Unit 4.0 mm H	PEEK Classix and Titanium 6Al-4V ELI per ASTM F136
EasyPro Unit 6.0 mm H	
EasyPro Laboratory Kit	
EasyPro Cassette, Empty	N/A
EasyPro Kit	N/A
Drill Guide - Short	Titanium 6Al-4V ELI per ASTM F136
Drill Guide - Standard	
Intaglio Drill	Stainless Steel 630
Occlusal Drill (Straight Irrigated Step Drill 1.8 /2.8)	Stainless Steel 420F
EasyPro Laboratory Bur, Ø6	Stainless Steel 440B
Manual Driver	Stainless Steel 420C
EasyPro Manual Reamer	Titanium 6Al-4V ELI per ASTM F136

5 Components Description & Use:

5.1 TiTemp Coping 4.0 mm H, 6.0 mm H are made of Titanium 6Al-4V ELI per ASTM F136 and 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:
- The insertion of the anodized retaining screw
- Access for the TiTemp Base Coping Screw and screwdriver
- The TiTemp Coping is designed to have a friction fit over the TiTemp Base Coping

5.2 TiTemp Base Coping is made of Titanium 6Al-4V ELI per ASTM F136 and has a conical shape with screw access hole for a TiTemp Base Coping Screw. The coping is designed to sit over the Keystone Dental Industry Standard 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).

5.3 The TiTemp Base Coping Screw is made of Titanium 6Al-4V ELI per ASTM F136 and will seat inside the TiTemp Base Coping to secure it to the Multi-Unit Abutment. The screw may be tightened using the Ø1.25mm Manual Hex Driver. It is recommended to tighten the screw by hand to a torque not exceeding 15 Ncm.

5.4 EasyPro Retaining Screw, is made of Titanium 6Al-4V ELI per ASTM F136 and is anodized yellow. It is designed to secure the TiTemp Coping over the TiTemp Base Coping directly to the Multi-Unit Abutment. The screw may be tightened using the Ø1.25mm Manual Hex Driver. It is recommended to tighten the screw by hand to a torque not exceeding 15 Ncm.

5.5 Round Retraction O- Ring – Wide and Narrow (profile) are made of ViTon and is 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 concave profile of the cuff portion of the Multi-Unit Abutments
- The O-rings should be removed after fabrication and bonding of the TiTemp Coping

5.6 EasyPro Unit: The EasyPro Unit is a complete system consisting of:
TiTemp Handle, TiTemp Coping either 4.0 mm H or 6.0 mm H, TiTemp Base Coping, TiTemp Base Coping Screw pre-assembled ready for use and packed sterile in a pouch together with the EasyPro retaining screw.

5.7 EasyPro Laboratory Kit. The laboratory kit contains the following components.
- EasyPro Cassette, Empty
- Drill Guide - Short
- Drill Guide - Standard
- Intaglio Drill
- Occlusal Drill
- EasyPro Laboratory Bur Ø6
- Manual Driver
- EasyPro Manual Reamer
- EasyPro IFU

5.8 Drill Guide comes in regular (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 anodized 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. It is recommended to stabilize the drill guide with one hand when in use.

The Drill Guide Standard has two ventilation holes & the Short drill guide has one ventilation hole that facilitates venting for the acrylic or composite fragments and reduce heat transition

*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 5mm. 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.

5.9 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 30mm in length. The drill length functionality may be increased by changing over from the Standard to the Short Drill Guide.

5.10 Occlusal Drill has a smooth drill tip of Ø1.8mm 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.

5.11 EasyPro Laboratory Bur- For 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).

5.12 EasyPro Manual Reamer: In cases where the prosthesis material reaches a high coefficient of hardness or 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.

5.13 The EasyPro System is compatible with all Keystone Dental Group Industry Standard Multi-Unit Regular Platform Abutments & Implant systems.
In the case of EasyPro, a minimum of two implants are required together with chosen Keystone Industry standard Multi-Unit (Regular Platform) abutments of the desired height and angulation.

6 Applications:

6.1 Laboratory instruments and components used to perform the procedure of converting removable prostheses into fixed screw retained prostheses on Keystone Dental Multi-Unit Abutments.

7 Warnings:

7.1 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.

8 Contraindications:

8.1 The EasyPro components are contraindicated for patients who show signs of allergy or

hypersensitivity to any of the materials mentioned in section 3. These products are also contraindicated for customization, unitary and cemented prostheses.

9 Directions for Use:

For detailed information on the specific product system you are using, please consult the EasyPro Manual.

9.1 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 prosthetic 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 EasyPro until you have measured all tissue heights and have chosen the required height of TiTemp Coping.

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 by pealing away the transparent packaging.

*Note one corner of the packaging is pre-released for this purpose. Take care when removing the EasyPro Unit to place the anodized retaining screw into a sterile dappen dish. and carefully deliver the assembled components, dropping them onto the sterile tray.

Step 4. Use the convenient 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 Ø1.25mm Manual Hex Driver in a clockwise direction through the access channel in the PEEK Handle to tighten the TiTemp Base Coping Screw. Tighten by hand, do not exceed 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. Once connected remove the TiTemp Handle by using a gentle tilting motion.

Step 5. Repeat the above procedure for 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 Units 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 (Ø6.0mm) 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.

The retraction O-Rings may be seated over the TiTemp Coping to protect the surrounding soft tissue and to assist in retracting mobile soft tissue. In some cases, the Viton 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. Cover the head of the TiTemp Base Coping Screw with an appropriate block out material.

Step 7. 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. It is recommended to place a small amount of material inside the cavity in the denture intaglio surface and to cover the retentive portion of the TiTemp Coping equally with the reline material. This will ensure an efficient pick-up process.

Ensure the patient is in a closed centric bite relationship during the curing procedure when possible. After the material has been 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 way. Review the pick-up of the TiTemp Copings inside the denture.

Ensure they have been captured and are stable. In some cases, the Viton O-Rings may be captured in the reline. The O-Rings should be removed using a dental probe or any suitable instrument.

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

Step 8. Preparation of the screw access channel. Position the Standard Drill Guide 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 until the Intaglio Drill exits the occlusal surface. If the drill does not exit the occlusal surface swap out the Drill Guide for the short Drill Guide and repeat the process. . 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.

Now that you have completed the preliminary screw access from the intaglio surface remove the intaglio drill and replace with the Occlusal Drill into the handpiece. The Occlusal Drill has a smooth drill tip of Ø1.8mm and is designed to enter the occlusal channel created by the Intaglio Drill. The Occlusal Drill then increases in diameter to Ø2.8mm 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.

*Note: in cases where the prosthesis material reaches a high coefficient of hardness or 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 9. Denture conversion finishing. 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 anodized Coping. Ensure all Base Copings are seated correctly. Now insert the EasyPro Retaining Screw one by one into the screw access channels to ensure that they are seated correctly and have travelled through the Base Copings.

Now that you have shaped, polished and verified the correct seating of TiTemp Base Copings and Final Retaining Screws the prosthesis may be attached to the Multi-Unit Abutments using the retaining screws and the 1.25 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.

10 Sterility:

10.1 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.

10.2 The intact sterile packaging protects the gamma-sterilized devices from outside influences, if stored correctly ensures sterility up to the expiration date.

10.3 When removing the devices from the sterile packaging, the rules of asepsis must be observed.

10.4 The sterile packaging must not be opened until immediately prior to use.

10.5 Devices with damaged sterile packaging must not be used due to the risk of contamination.

10.6 Keystone Dental does not accept any responsibility for re-sterilization of products supplied sterile.

10.7 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.

11 Cleaning and Sterilization:

11.1 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).

11.2 For all other EasyPro components, follow the cleaning and sterilization instructions below:

11.2.1 Tools/Instruments which are not supplied sterile must be cleaned and sterilized prior to first use 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.

11.2.2 All tools/instruments were developed for sterilization by autoclave.

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

11.2.4 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.

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

11.2.6 Tools/Instruments inside a kit should be removed from the tray using dental tweezers.

11.2.7 Used tools/instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva, and tissue residue.

11.2.8 Multiple-part tools/instruments must be disassembled prior to cleaning and sterilization.

11.2.9 Internal debris/residue on devices must be removed with a soft brush.

11.2.10 Devices should be inspected, cleaned separately, and discarded if damaged.

11.2.11 Devices should be placed in an ultrasonic bath with an enzymatic solution, approved and appropriate for dental use (for example, Powerzume, Deconex).

11.2.12 Wash the devices in an ultrasonic device according to the device's instructions, for 15 minutes.

11.2.13 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.

11.2.14 Remove the devices from the ultrasonic bath at the end of the cycle and wash with running water.

11.2.15 Use a soft brush to remove any residue from the devices and wash again with running water and thoroughly dry.

11.2.16 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.

11.2.17 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.

11.12.18 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.

11.12.19 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.

12 Precautions

12.1 Drills must not be resharpened.

12.2 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.

12.3 Excessive wear of the prosthesis can compromise the mechanical properties and/or render it unusable.

12.4 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.

12.5 Patients who show signs of allergy or hypersensitivity to chemical ingredients of the materials listed in table in section 4.

12.6 These 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.

12.7 Ensure that the parts are not swallowed or aspirated by the patient.

12.8 Make sure you have all the necessary instruments to perform the procedure according to the planning.

12.9 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.

12.10 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.

12.11 It is the responsibility of the clinician/dental technician to use EasyPro products in accordance with the instructions for use.

12.12 If any accident involving the device occurs, carefully remove the parts from the patients' mouth and inform Keystone Dental, Inc.

12.13 Too much force can cause unwanted effects and render the product useless.

12.14 Do not apply lateral force on the drill bit over the risk of fracture.

12.15 Follow the acrylic resin manufacturers' handling guidelines.

12.16 Check and perform the occlusal adjustment after the installation of the prosthesis, avoiding the compromise of the system.

12.17 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.

12.18 Make sure to protect the abutment access channel.

12.19 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.

12.20 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.

12.21 For immediate loading application, check the torque indication for the installed implant.

13 Traceability:

The EasyPro items are traceable through identification of the REF and LOT numerical codes.

14 MR Safety Information – MR Conditional:

Warning: MR Conditional Labeling has not been reviewed or approved by Health Canada. 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 an EasyPro device can be scanned safely in an MR system under the following conditions:

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

15 Storage and Handling

15.1 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.

16 Disposal

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

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

REF	Catalog number
LOT	Batch Code
MD	Medical Device
	Do not reuse
NON STERILE	Non-Sterile
	Do not use if package is damaged and Consult instructions for use
STERILE R	Sterilized using irradiation
Rx only	By Prescription Only
	Use by date
	Manufacturer
MR	MR Conditional
	Keep away from sunlight
	Consult instructions for use

Keystone Dental, Inc.
154 Middlesex Turnpike
Burlington, MA 01803

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