TST R. ve Tıbbi Aletler San. ve Tic. Ltd. Şti.
Sanayi Mah. Şehit Cevdet Çelenk Cad.
No:3 34912 Kurtköy-Pendik-İstanbul-Turkey

CE 1984
KIWA **CERTIFICATION INC.**

English

INSTRUCTIONS FOR USE OF THE HIP PROTHESIS (Femoral Components/Stems)

1. Product Description

Stem: The main body part of the prosthesis placed in the femoral medulla.
TST Ltd. has 4 different types of stems: Calcar Supported Hip Replacement, Supra Art-1 Hip Replacement, Arthrom Modular Hip Replacement and Volumed Modular Straight Stem:

•Calcar Supported Hip Replacement System; Designed to provide versatility in hip replacement surgeries to meet the stability requirement of unpredictable intraoperative trochanter fractures or pre-detected fractures. **The purpose of use** of the hip replacement is to replace the damaged parts of the hip joint with artificial parts so that the joint can continue to function. Calcar Supported Hip Replacement System products; It is produced from ISO 5832-4 CoCrMo alloy material. Porous coating, Hydroxyapatid coating and double (PC+HA) coating options are available.

•Supra Art-1 Hip Replacement is designed to meet the need for better stability by providing perfect attachment to the femur with no or minimal complications in hip replacement surgeries. The purpose of use of the Supra Art-1 stem; It is used to replace the damaged parts of the hip joint with artificial parts so that the joint can continue to function. Supra Art-1 Hip Prosthesis is produced from ISO 5832-4 CoCrMo alloy material. It can be applied with or without cement with coated and uncoated options.

•Arthrom Modular Hip Replacement; In hip replacement surgery, the femoral component is designed for use as a modular stem. **The purpose of use** is to support the natural functioning of the femur, replacing the removed part of the femur with minimal complications in the hip region. The Arthrom Modular Hip Prosthesis is designed to be wide in modules for narrow or large patients and patients with weak proximal femoral support. Arthrom hip prostheses are made of ISO 5832-3 Ti6Al4V alloy. Coated (PC (porous coating), HA (Hydroxylapatite) and PC+HA) femoral body and stem and uncoated options are available.

•**The purpose of use** the Volumed Modular Straight Hip Replacement is to replace the damaged parts of the hip joint with artificial parts so that the joint can continue to function. Volume Mod. Straight Stem's tapered and angular stem geometry supports axial load transfer and rotational stabilization. This design makes it easier to place the femoral stem. It is produced from wrought Stainless Steel material (ISO 5832-1) and used for Cementitious applications.

The use of Stainless Steel and Cobalt Chromium alloy materials with each other is limited on non-articular surfaces of hip implant systems. (In TST, the connections of Stem and Modular Head to A. Unipolar Ring implants are non-articular surfaces)
Never use the surfaces of the components made of the following metals in contact with each other:
Modular Head and A. Unipolar Ring produced from stainless steel ISO 5832-1 raw material and ISO 5832-4 Cobalt alloy Femoral Stems should not be used together. Femoral stems that are ISO 5832-1 Stainless Steel and Modular Heads these are ISO 5832-4, ISO 5832-12 Cobalt alloy should not be used with each other.

Application Option	Hip Prothesis Option	Cement Application	Acetabular Components to be Used Together
Partial Hip Replacement System	Supra Art-1 Stem (CoCr alloy 5832-4)	CEMENTED (Used with Plug and Centraliser)	Used with Bipolar Head (CrNi (ISO 5832-1), CoCrMo (ISO 5832-4)- all sizes), Modular head (CoCrMo (ISO 5832-12) – all sizes) (Inner head).
		CEMENTLESS	Used with Bipolar Head (CrNi (ISO 5832-1), CoCrMo (ISO 5832-4)- all sizes), Modular Head (CoCrMo (ISO 5832-12) – all sizes) (Inner head).
	Calcar Stem (CoCr alloy 5832-4)	CEMENTED (Used with Plug and Centraliser)	Used with Bipolar- Head (CrNi (ISO 5832-1), CoCrMo (ISO 5832-4)- all sizes), Modular Head (CoCrMo (ISO 5832-12) – all sizes) (Inner Head).
		CEMENTLESS	Used with Bipolar Head (CrNi (ISO 5832-1), CoCrMo (ISO 5832-4)- all sizes), Modular Head (CoCrMo (ISO 5832-12) – all sizes) (Inner head).
	Volumed Stem (CrNi 5832-1)	CEMENTED (Used with Plug and Centraliser)	Used With Bipolar Head (CrNi (ISO 5832-1), CoCrMo (ISO 5832-4) – all sizes), Modular Head (Inner Head; CrNi (ISO 5832-1) – all sizes) and A. Unipolar Head (CrNi (ISO 5832-1) – all sizes), Ring (CrNi (ISO 5832-1) – all sizes)
	Arthrom Stem (Ti6Al4V alloy 5832-3) Arthrom Body (Used with Connecting Screw)	CEMENTED (Used with Plug and Centraliser)	Used with Bipolar Head (CoCrMo (ISO 5832-4), CrNi (ISO 5832-1)- all sizes), Modular Head (Inner head; CoCrMo (ISO 5832-12), CrNi (ISO 5832-1) all sizes) Used With A. Unipolar head (CrNi (ISO 5832-1) all sizes), Ring (CrNi (ISO 5832-1), all sizes)
		CEMENTLESS	Used with Bipolar Head (CoCrMo (ISO 5832-4), CrNi (ISO 5832-1)- all sizes) and Modular Head (Inner head; CoCrMo (ISO 5832-12), CrNi (ISO 5832-1)- all sizes) Used With A. Unipolar head (CrNi (ISO 5832-1) all sizes), Ring (CrNi (ISO 5832-1), all sizes).
Total Hip Replacement System	Supra Art-1 Stem (CoCr alloy 5832-4)	CEMENTLESS	Used With Press-fit Cup (Ti – all sizes), Insert (UHMWPE – all sizes) and Modular head (CoCrMo – all sizes) (inner head) and acetabular screws (Ti – all sizes)
	Calcar Stem (CoCr alloy 5832-4)	CEMENTLESS	Used with Press-fit Cup (Ti – all sizes), Insert (UHMWPE – all sizes) and Modular Head (CoCrMo – all sizes) (inner head) and acetabular screws (Ti – all sizes).
	Volumed Stem (CrNi 5832-1)	CEMENTLESS	Used with Press-fit Cup (Ti – all sizes), Insert (UHMWPE – all sizes) and Modular Head (CrNi– all sizes) (Inner Head) and acetabular screws (Ti – all sizes).
	Arthrom Stem (Ti6Al4V alloy 5832-3) Arthrom Body (Used with Connecting Screw)	CEMENTLESS	Used with Press-fit Cup (Ti – all sizes), Insert (UHMWPE – all sizes) and Modular Head (CrNi, CoCrMo – all sizes) (Inner head) and acetabular screws (Ti – all sizes).

2. Protecting the Product

Implants should always be stored unopened in their boxes. Before use, the package should be checked for any damage and sterilization. When opening the package, the information on the product label is verified. The relevant aseptic instructions should be observed when removing the implant from the package. The prosthesis should be kept separate from materials that will damage its surface. Each implant should be visually inspected prior to use. Damaged or poorly protected products should not be used.
Femoral and acetabular parts are designed for cemented and cementless use.
Applications of PC, HA, PC+HA coated products are carried out cementless; Applications of sandblasted and polished products are carried out with cement.
Caution: The head of the Femoral Stem should always match the interior of the modular femoral head.

3. Packaging and Sterilization

All products are individually wrapped in protective boxes after triple packaging and sterilized by Irradiation.

4. Sterilization and Resterilization

Products included in the Hip Prosthesis/Stem group are offered for use as "sterile". TST Hip Replacement products are sterilized by being subjected to radiation sterilization method. After the sterile products are taken out of their boxes, they are used by opening their sterile packages, which are packaged in three layers. In order to re-sterilize products with impaired sterility, they must be contacted with TST and returned to the company. All unpackaged products should not be re-sterilized by users. Opened or deformed products should be returned to the manufacturer.

5. Pre-Operation Planning

Preoperative planning provides important information about the appropriate prosthesis and possible combinations of components. Keep other ready-to-use implants with you when other sizes are requested or if the selected implant cannot be used.

6. Operation Sequence Planning

Hip replacement surgeries can be performed with general or epidural (waist numbing) anesthesia. Epidural or intravenous pain pumps can be used to prevent post-operative pain. The solidification time of the cement should be taken into consideration in the application with cement. The duration of the anesthesia should be considered in hip replacement surgeries using epidural anesthesia.

7. Post-Operation Planning

Activities such as running, jumping and heavy work after the prosthesis will cause the premature wear of the prosthesis and reduces its attachment to the bone. It is not appropriate to sit in low chairs and cross your legs, especially in the first 6 months after the surgery. Such extreme movements can cause dislocation of the hip joint and repetitive surgeries. 6-8 weeks after the prosthesis surgery, the period of healing in bone and muscle tissue begins. In addition, leg shortness between 2-3 cm can be eliminated after hip replacement surgery.

8. Implant Materials

Stem of the femoral head is made of one of the following materials; CrNi (ISO 5832-1), Titanium alloy (Ti6Al4V) (ISO 5832-3) or casting CoCrMo alloy (ISO 5832-4).
Coatings; Hydroxyapatite (ISO 13779-2; ASTM F1185, ASTM F1609) or Porous coating (ASTM F1580) or Porous & Hydroxyapatite coating.
Cable/Swage is manufactured from CoCrWNi (ISO 5832-5), Ti6Al4V (ISO 5832-3) Titanium alloy or CrNi Steel (ISO 5832-1).

9. Magnetic Resonance Environment

TST Products have not been evaluated for safety and compatibility in the MR environment. TST products have not been tested in the MR environment.

10. Indications

- Advanced joint destruction from traumatic, posttraumatic, rheumatoid or degenerative arthritis
- Femoral head fracture or avascular necrosis
- Failure of a previous operation, eg osteosynthesis, joint reconstruction and artodesis.
- Hemi-arthroplasty and total hip replacement, Osteoarthrosis, Osteodystrophy.

11. Contraindications

- Infection (or a history of infection); acute or chronic, local or systemic
- Severe muscular, neurological, and vascular deficiencies consistent with the affected exterminated state
- Destruction of the bone or poor bone quality that may affect the stability of the implant
- Obesity
- Charcot joint disease
- Osteomalacia
- Multiple Organ Failure
- Sepsis condition
- Inflammatory Degenerative Joint Disease
- Immature skeletal structure
- Slipped femoral head epiphysis

12. Conditions That May Affect the Success of the Procedure

- Severe osteoporosis
- Severe deformation, congenital dislocation
- Regional tumors in the bone
- Systemic and metabolic disorders
- Past Infectious disease
- Pill and/or drug addiction
- Obesity
- An overweight or obese patient may produce loads on the prosthesis that may impede fixation of the implant or cause fracture of the prosthesis itself

Caution: If this total hip system is determined to be the best for the patient and the patient has one or more of the above-mentioned conditions, it is necessary to inform the patient about how these conditions will affect the operation and product life. It is recommended that the patient be advised of any activities that can reduce the problems that these conditions may present.
These implants should be used by specialist physicians with appropriate training and experience in hip arthroplasty.

13. Side Effects

The following effects are known as the most typical and common side effects encountered in hip arthroplasty.

- Changes in positioning and loosening of the prosthesis
- Incorrect positioning of the prosthesis
- Infection
- Hemotama, venous thrombosis and pulmonary embolism
- Induration
- Discharge in the operation area
- Pain
- Swelling

14. Warnings and Precautions Before Use

- The patient should be informed about the use of the product after the surgery and it should be ensured that the patient follows the care instructions.
- Although it is very rare, necessary allergy tests should be performed before surgery in patients with sensitivity to the material.
- The product is suitable for use in primary and revision cases.
- There is no harm in its use in immunocompromised patients (AIDS, etc.).
- TST instruments should be used with TST products to maintain patient health and product reliability, and to prevent damage to component relationships. The use of TST instruments with products of other brands is not recommended.
- Important note for medical professionals and operating room personnel: These operating instructions do not contain all the information necessary for the selection and use of a device. For all necessary information, please refer to the relevant labels (relevant Surgical Techniques, Important Information).
- **Do not use opened products and return them to the manufacturer.**
- Implants are for single use only, used implants should not be reused.
- Products should be protected from direct sunlight.
- Products should be stored at room temperature.
- All attempts and instruments must be removed from the field prior to closure of the surgical incision. It should not be left in the body.
- **Patients with hip joint replacement should be advised that the longevity of the implant may depend on the patient's weight and activity levels.**

15. Possible Risks

As with all major surgical procedures, risks, side effects, and adverse events can occur. There are many possible reactions, the most common include: Problems arising from anesthesia and patient positioning (nausea, vomiting, dental injury, neurological disorders, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, soft tissue damage including swelling, abnormal scar formation, musculoskeletal side effects associated with weakening of the system, Sudeck's disease, allergy/hypersensitivity reactions and hardware prominence, faulty union or nonunion.

16. Meanings of Symbols Used with Product Label

Neither the manufacturer nor the dealers take any responsibility for the resterilization of the implants by the customer. The recommendations provided are for informational purposes only.
TST implants should not be used in conjunction with implants from other manufacturers.
All implants are single use. The label of the product should be attached to the patient's file and the file should be kept for at least 15 (fifteen) years.
See the hip group product catalog (TST.K.05.0). for the surgical technique and application of the product.

WARNING: CAN ONLY BE USED BY SPECIAL PHYSICIANS!

CE 1984	Notified Body Number 93/42/EEC compliance		Do not use if package is damaged.
LOT	Product LOT Number	REF	Product Catalog Number
	User Guide		Expire Date
	Do not use a second time	2 STERILIZE	Do not Resterilize
	Production Date		Manufacturer Information
STERILE R	Sterilized by Radiation		

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INSTRUCTIONS FOR USE OF THE PLUG X-RAY RING AND CENTRALIZER GROUP

1. **Product Description:** TST Plug and Centralizer group products are used in cemented hip prosthesis applications. Products are produced from Ultra High Molecular Weight Polyethylene (UHMWPE) ISO 5834-2 material.
Plug: For cemented femoral fixation during hip arthroplasty. They are used to occlude the intramedullary canal. The plug remains inside the patient with the prosthesis until the revision prosthesis is made. There are different sizes of plugs. TST Plugs are manufactured from UHMWPE (Very High Molecular Weight Polyethylene) (according to ISO 5834-2). The ring around the plug is for the plug to be visible under X-Ray. Rings made of implant stainless steel (according to DIN 1.4441 or ISO 5832-1).
Centralizer: For cemented femoral fixation during hip arthroplasty. They are used to center cemented stems (centering the prosthesis in the femoral canal) and to prevent direct bone-to-metal contact. Centralizers help to form a homogeneous cement cover. Different sizes are available. TST Centralizers are manufactured from UHMWPE (Very High Molecular Weight Polyethylene) (according to ISO 5834-2).

Auxiliary Product Option	Hip Prosthesis Option	Cemented Option
Plug X-Ray Ring (all sizes) Centralizer (all sizes)	Supra Art-1 Stem Arthrom Moduler Stem	Cemented
Plug X-Ray Ring (all sizes) Centralizer for Calcar (all sizes)	Calcar Stem	

2. **Protecting the Product**
Implants should always be stored unopened in their protective boxes. Before use, the package should be checked for any damage that may endanger the function or sterility of the product. When you open the package of the implant, it should be verified that the product code, lot number and size information on the product and the label are the same. Relevant aseptic instructions should be followed when taking out the implant from the package. Contact of the implant with materials that may damage its surface should be avoided. Inspect each implant for visual damage prior to use. Discard damaged and poorly preserved implants.

3. **Packaging and Sterilization**
All products are individually wrapped in protective boxes after triple packaging and sterilized by Irradiation.

4. **Sterilization and Resterilization**
Plug and Centraliser group products are released as "sterile". TST Plug and Centralisers group products are sterilized by being subjected to radiation sterilization method. All products are individually packed in their protective boxes in sterile condition (min 25 kGy gamma irradiation). After the sterile products are taken out of their boxes, they are used by opening their sterile packages, which are packaged in three layers. All unpackaged products should not be re-sterilized by users. Opened or deformed products should be returned to the manufacturer.

5. **Pre-Operation Planning**
Preoperative planning provides important information about the appropriate prosthesis and possible combinations of components. Keep other ready-to-use implants with you when other sizes are requested or if the selected implant cannot be used.

6. **Operation Sequence Planning**
Hip replacement surgeries can be performed with general or epidural (waist numbing) anesthesia. Epidural or intravenous pain pumps can be used to prevent post-operative pain. The operation is performed by specialist doctors who have the appropriate training and experience in their field, with the appropriate instruments. These devices are only used in applications using bone cement.

7. **Post-Operation Planning**
Activities such as running, jumping and heavy work after the prosthesis will cause the premature wear of the prosthesis and reduces its attachment to the bone. It is not appropriate to sit in low chairs and cross your legs, especially in the first 6 months after the surgery. Such extreme movements can cause dislocation of the hip joint and repetitive surgeries. 6-8 weeks after the prosthesis surgery, the period of healing in bone and muscle tissue begins. In addition, leg shortness between 2-3 cm can be eliminated after hip replacement surgery.

8. **İmplant Materials**
Centralizers and Plug group products; They are produced from Ultra High Molecular Weight Polyethylene (UHMWPE) ISO 5834-2 material.

9. **Magnetic Resonance Environment**
TST Products have not been evaluated for safety and compatibility in the MR environment. TST products have not been tested in the MR environment.

10. **Indications**
For Centraliser, Cement Plugs;
Cemented hip arthroplasty is indicated when a cement Centraliser, restrictor, and/or plug is considered beneficial.

11. **Contraindications**
- Infection (or history of infection); acute or chronic, local or systemic)
- Severe muscular, neurological or vascular (vascular) deficiencies that may endanger the sick leg
- Destruction of bone or poor bone quality that may affect the stability of the prosthesis
- Any concomitant disease that may compromise the function of the prosthesis

12. **Conditions that may adversely affect the success of the procedure**
- Severe osteoporosis
- Severe deformities, congenital dislocation
- Regional tumors in the bone
- Systemic and metabolic disorders
- Past infectious disease and failures
- Drug addiction and/or abuse
- Obesity
- An overweight or obese patient may produce loads on the prosthesis that may impede fixation of the implant or cause fracture of the prosthesis itself.
- High levels of physical activity (eg, heavy physical labor, competitive sports, marathon running, etc.)

13. **Side Effects**
- The following effects are known as the most typical and common side effects in total hip arthroplasty.
- Changes in position and loosening of the prosthesis,
- Dislocation of the prosthesis,
- Infection
- Vein thrombosis (blood clot that causes a blockage in a vein) and pulmonary embolism (pulmonary vascular obstruction).

14. **Warnings and Precautions Before Use**
- The patient should be informed about the use of the product after the surgery and it should be ensured that the patient follows the care instructions.
- Although it is very rare, necessary allergy tests should be performed before surgery in patients with sensitivity to the material.
- The product is suitable for use in primary and revision cases.
- There is no harm in its use in immunocompromised patients (AIDS, etc.).
- TST instruments should be used with TST products to maintain patient health and product reliability, and to prevent damage to component relationships. The use of TST instruments with products of other brands is not recommended.
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- All attempts and instruments must be removed from the field prior to closure of the surgical incision. It should not be left in the body.

15. **Possible Risks**
As with all major surgical procedures, risks, side effects, and adverse events can occur. There are many possible reactions, the most common include: Problems arising from anesthesia and patient positioning (nausea, vomiting, dental injury, neurological disorders, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, soft tissue damage including swelling, abnormal scar formation, musculoskeletal side effects associated with weakening of the system, Sudeck's disease, allergy/hypersensitivity reactions and hardware prominence, faulty union or nonunion.

16. **Meanings of Symbols Used with Product Labels**

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	User guide		Expire Date
	Do not use a second time.	STERILIZE	Do not resterilize
	Production date		Manufacturer Information
STERILE R	Sterilized by Radiation.		

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