TIPSAN TIBBİ ALETLER SAN. VE TİC. A.Ş.
Kemalpaşa Cad.7404/1 Sk.No:3 Pınarbaşı- Izmir- Turkey
Tel: +90 232 479 5654 www.tipsan.com.tr

CE 2975

TIPSAN PENTA MERS TUMOR SYSTEMS

TPS-IFU-04 TUMOR

Rev.00, Issue Date:10.10.2022

The following languages are included in this packet:

The following languages are included in this packet:

English (EN)

For additional information and translations please contact the manufacturer or local distributor.

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

TUMOR SYSTEM

A.DEFINITIONS:

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition	Symbol	Definition
	Batch code		Date of manufacture
	Catalog number		Manufacturer
	Do not re-use		Sterilized using radiation
	Caution, consult accompanying documents		Do not use if package is damaged
	Consult operating instructions		Unique Device Identifier Number
	Use by		Medical Device
	Keep dry		Double sterile barrier system
	Keep away from sunlight		Contains hazardous substances
	Do not resterilise		

B.DESCRIPTION:

The PENTA-MERS Tumor System is comprised of a wide variety of components designed to reconstruct irrepairable defects involving hip, knee, shoulder and elbow joints as well as defects associated with neighboring femur, tibia, humerus and ulna bones caused by tumor resection, These components can be utilized in a variety of configurations to assemble the final construct. Only components from Tıpnsa should be used to prevent mismatch or misalignment of components.

The implants are single use only devices.

Materials:

The Components are manufactured from a variety of materials which include cobalt-chromium-molybdenum alloy, titanium alloy and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards, or internal standards. The component material is provided on the outside carton label

Table-2 : Tumor System

Device Description
PENTA-MERS Tumor System

Implantation of the devices will expose patients to the following materials:

Material Description	Elements in Material	% Composition
Titanium alloy - Ti-6Al-4V (ISO 5832-3)	Aluminium	5,5 to 6,75
	Vanadium	3,5 to 4,5
	Iron	0,3 max.
	Oxygen	0,2 max.
	Carbon	0,08 max.
	Nitrogen	0,05 max.
	Hydrogen	0,015 max.
	Titanium	Balance

Material Description	Elements in Material	% Composition
Casting Co.Cr Alloy Alloy (ISO 5832-4)	Chromium	26,5 to 30,0
	Molybdenum	4,5 to 7,0
	Nickel	1,0 max.
	Iron	1,0 max.
	Carbon	0,35 max.
	Manganese	1,0 max.
	Silicon	1,0 max.
	Cobalt	Balance

Material Description	Elements in Material	% Composition
UHMWPE (ISO 5834-2) (ISO 5834-1)	Ultra high molecular weight polyethylene	%100

Components manufactured by Cobalt Alloy material contain the following substances defined as CMR 1B in a concentration above 0.1% weight by weight:
-Cobalt; CAS No. 7440-48-4; EC No. 231-158-0.

Some preclinical and clinical evidence suggests that Co CA (cobalt-containing alloys) in medical devices are unlikely carcinogenic or reproductive hazards to patients.

C.INTENDED PURPOSE & INDICATIONS

Intended Purpose:

The PENTA-MERS Tumor System is intended for use in Oncology cases to reconstruct irrepairable defects involving hip, knee, shoulder and elbow joints as well as defects associated with neighboring femur, tibia, humerus and ulna bones caused by tumor resection in skeletally mature patients. The system's main objectives are pain reduction and the restoration of physiological functions

Indications:
Hip, knee, shoulder and elbow joints replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of bone is required.

Intended Clinical Performance:
Intended Clinical performance of device is:

- Pain reduction;
- The restoration of the functioning of the joint and the improvement of the mobility compared to the preoperative state;

Intended Patient populations:
The PENTA-MERS Tumor System is designed to be used for skeletally mature patients. No limitations in regard to gender

Intended user :
Tıpsan Knee Systems are designated to be used only by Health care professional – Orthopaedic Surgeon,

D.CONTRAINDICATIONS

1- Pathological fracture;
2- Overt infection;
3- Inopportune placement of biopsy incision; and,
4- Rapid disease progression beyond a respectable margin.
5-skeletally immature patients

E.GENERAL PRECAUTIONS &WARNINGS

The manufacturer is not liable for complications that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice or handling of material and/or surgical instruments.

Preoperative

- The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments and surgical procedure prior to performing surgery. The surgeon should contact Tıpsan for product-specific surgical techniques.
- Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Any joint replacement system, including the implant/bone interface, cannot be expected to withstand activity levels and loads as would normal healthy bone and will not be as strong, reliable, or durable as a natural human joint/bone. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.
- Additional conditions presenting increased risk of failure include:

  1-uncooperative patient or patient with mental or neurologic conditions which can affect patient's ability or willingness to follow instructions;

  2-marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;

  3-metabolic disorders that may impair bone formation;

  4-osteomalacia;

  5-conditions that could impair or impede healing (e.g., alcohol or drug abuse, decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition);

  6-pre-existing conditions commonly considered with any surgery including bleeding disorders, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.
- The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.
- Patients should be warned that the longevity of the implant may depend on their weight and level of activity
- Patient sensitivities or allergies to the materials of the implants, particularly to metal ions are possible. The type of materials for each implant is provided on the box label. The attending physician should include possible risks concerning sensitivities to implant materials as part of the preoperative planning.

Intraoperative

- Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.
- Do not mix components from different manufacturers. Failure to comply may result in implant failure and revision surgery
- Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Cemented Application. Care is to be taken to ensure complete support of all components of the prosthesis embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete cleaning including complete removal of bone chips, bone cement fragments, and metallic debris, prior to closure of the prosthetic site is critical to prevent accelerated wear of the articular surfaces of the prosthesis.

Postoperative

- While expected life time of devices is difficult to estimate, Device life time is Finite. Functional device life time depends on variable factors such as patient weight, activity, patient bone quality therefore It not possible to state the exact functional life time. According to the literature review about the performance and security of Joint replacement Implant devices at long term follow-up, Estimated functional life time of the devices is Approximately 10 to 15 years. This estimated lifetime may change depends on variable factors such as patient weight, activity, patient bone quality and surgeon experience.
- The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses and possible loosening, fracture and/or wear, and follow the instructions of the physician with respect to follow-up care and treatment. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components.
- The patient should be advised to report any pain, decrease in range of motion, swelling, fever, squeaking, clicking, popping, grating, or grinding noises, and unusual incidences. Patient reports of squeaking, clicking, popping, grating, or grinding should be carefully evaluated as they may indicate position changes in the components which may compromise the durability of the implants.

F.ADVERSE EFFECTS

1) osteolysis (progressive bone resorption). Osteolysis can be asymptomatic, and therefore, routine periodic radiographic examination is vital to prevent any serious future complication;
2) particulate generation leading to increased wear rates necessitating early revision. Soft tissue imbalance leading to excessive wear;

3) Allergic reactions to materials; metal sensitivity; or reactions to wear debris that may lead to histological reactions, pseudotumor and aseptic lymphocytic vasculitis-associated lesions (ALVAL).

4) delayed wound healing; deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required;

5) a sudden drop in blood pressure intra-operatively

6) damage to blood vessels or hematoma;

7) temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;

8) cardiovascular disorders

including venous thrombosis, pulmonary embolism, or myocardial infarction;

9) dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;

10) periarticular calcification or ossification, with or without impediment to joint mobility;

11) pain.

G.HANDLING AND STERILIZATION

Implants are sterilized by gamma radiation. The immediate package label should be consulted for specific method of sterilization. Irradiated implants have been exposed to a minimum 25 and a maximum 40 kiloGrays of gamma radiation.

The products are supplied as sterile and should be considered sterile unless the inner package is opened or damaged. If the inner package integrity is compromised, contact the manufacturer for instructions. Remove from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product.

Devices labelled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

A prosthesis should never be resterilised or reused after contact with body tissues or fluids, but rather should be discarded. Tıpsan does not take any responsibility for the use of implants resterilised after contact with body tissues or fluids.

WARNINGS:

- All packaging materials MUST be removed from the implant prior to implantation.
- Inspect packages for punctures or other damage prior to surgery, If the sterile barrier has been broken, return the component to Tıpsan

H.STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

I.MAGNATIC RESONANCE IMAGING (MRI) SAFETY

There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

Tıpsan Tumor System has not been evaluated for safety and compatibility in the MR environment. Tıpsan Tumor System has not been tested for heating or migration in the MR environment. Since these devices have not been tested, Tıpsan cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

J.SUBSTANCES CONTAINED BY THE DEVICE

the devices do not contain or incorporate:
— a medicinal substance, including a human blood or plasma derivative, or
— tissues or cells, or their derivatives, of human origin, or
— tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012; or

K.REMOVAL AND DISPOSAL

Tıpsan Implants are intended for permanent implantation. Should a implant removal be necessary,
the appropriate instrument should be used. Removed implants should be handled as bio-hazard products and be discarded in accordance with all local and national regulations for infection prevention and control.

L.IMPLANT CARD

A physical implant card is delivered with Device, Health facilities / Hospitals should fill in this implant card and give it to Patients.

M.REPORTING OF SERIOUS INCIDENTS

Surgeons/Health Facilities must report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the serious incident has occurred;

N. OTHER INFORMATION

Access to "Summary of safety and clinical performance Report" :

Tıpsan has drawn up a "Summary of Safety and Clinical Performance" report in compliance with Article 32 of 2017/745 Medical Device Regulation. The Summary of Safety and Clinical Performance (SSCP) can be accessed on the Eudamed public website (https://ec.europa.eu/tools/eudamed) or can be requested directly from Tıpsan