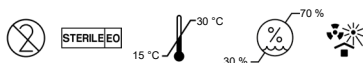


Information on handling, possible applications and potential restrictions for the product group:

TOTAL KNEE REPLACEMENT – CMS



Identification

CMS – Femoral component	CMS – Hinge
Size range: 2 – 5	Size range: 2 – 5
CMS – Rotary peg	CMS – Tibial plateau
Size range: 2 – 5	Size range: 2 – 5
CMS – Insert	CMS – Partial femoral repl.
Size range: 2 – 5	
CMS – Partial tibial repl.	CMS – Partial tibial repl. with clip
CMS – Partial femoral and tibial repl.	SVR – Cementless femoral stem
	Size range: D12 – D22
SVR – Cementless tibial stem	
Size range: D10 – D20	

Information about sterility

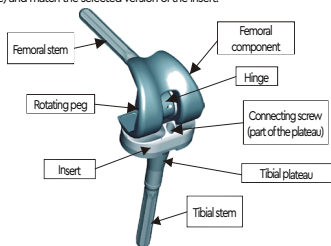
- The product is supplied by the manufacturer in a sterile pack
- Sterility of the implant in the protective sterile packaging is guaranteed for 5 years. Expiry dates are marked clearly on the protective sterile packaging
- Not to be used if the sterile packaging is damaged. The product cannot be re-sterilised

Intended use

The implants are designed as a total knee replacement using bone cement.

Product description

TNKK – CMS is intended for knee replacement using bone cement. It is indicated in patients with deformation changes and knee joint instability. When used in patients with bone tumours in the knee area, where resection of the tibia and femur contact parts is required, or in patients with major bone defects of a different origin, the replacement may be supplemented with a partial femur and tibia replacement (individual joint replacement). The replacement set comprises of a femoral component with a hinge and a rotating peg secured with a setting screw, tibial plateau, insert and connecting screw, as well as extension stems for the femoral component and the tibial plateau. The size of the femoral component and the tibial component must be identical. The tibial component in a specific size must be used with an insert in the same size (three insert thicknesses are available). The peg must be the same size as the femoral component and the size of the hinge must be identical (three versions are available) and match the selected version of the insert.



		CMS – Tibial plateau and CMS – Insert					Patella				CMS – Femoral component					
		2	3	4	5	1	2	3	4	2	3	4	5			
CMS – Femoral component	2	X				X	X	X								
	3		X			X	X	X	X							
	4			X		X	X	X	X							
	5				X	X	X	X								
SVR – Femoral stem (no differentiation)												X	X	X	X	
SVR – Tibial stem (no differentiation)		X	X	X	X											
Hinge (no differentiation)	2											X				
	3												X			
	4													X		
	5														X	
Rotating peg	2										X					
	3											X				
	4												X			
	5														X	

The table always applies to the R (right) or L (left) versions

CMS – Femoral component

The CMS type of the femoral component is designed for the hinge type of total knee replacement with internal rotation and is intended for application with bone cement. It is made in 4 sizes in left and right versions. The articulated part of the component comprises of two condyles joined by a front disc. The articulated surfaces of the condyles and the external surfaces are based on the anatomic conditions of a knee joint to ensure the total replacement functions optimally. Creating a limited intercondylar space is a major step to ensuring operation of the hanging type of TNKK with internal rotation. The intercondylar space houses the case where the hinge and the elevated insert tab for locking are fitted. The internal surfaces are structured with recesses so the component is securely fitted in the bone cement. The cylindrical countersinking on the inner sides of the condyles is designed for augmentation hinges. The augmentation size must be identical to the size of the femoral component, and the augmentation type and thickness (dorsal and distal) is selected according to the need for filling bone defects. The precisely manufactured profile of the internal surfaces and the intercondylar space ensures precise fitting and secure connection with the bone. The upper end of the case, with a thread for fitting the stem, is an important

structural part. The component is made of cobalt alloy (ISO 5832-4), the surface of the articulated surfaces is polished and the inner surfaces are finely blasted.

CMS – Tibial plateau

The cemented tibial plateau is designed for the hinge type of total knee replacement with internal rotation, type CMS and is intended for application with bone cement. It is made in 4 sizes. The component includes an upper plate designed for fitting on a precisely resected proximal part of the tibia and the stem. The plate has a symmetrical oval shape. An opening for the hinge, insert guiding and a threaded opening for the connecting screw are in the upper part of the plate. The lower part of the plate is structured with recesses designed for primary fixation of the component in bone cement. The plateau stem ensures stability of the implant. Therefore, its lower part has a threaded conical opening for the extended stem. The connecting screw is included in the tibial plateau pack. The component is made of wrought stainless steel (ISO 5832-1) and the connecting screw is made of wrought titanium alloy (ISO 5832-3). The surface of the tibial plateau and the connecting screw is finely blasted.

CMS – Insert

The CMS type of the insert is designed for the hinge type of total knee replacement with internal rotation. It is made in 4 sizes and 3 thicknesses (12, 15 and 20 mm). The insert has a symmetrical oval shape. The articulated surface of the implant comprises of two cylindrical surfaces divided by a bridge. The bridge with the tab on the hinge ensures the stability of the femoral component and limited rotation around the vertical axis by ± 7°. The bridge has an opening for the connecting screw to ensure secure connection with the tibial plateau. Oblique projections for inserting in the tibial plateau guide are on the lower surface. The PE plug included in the insert pack is designed for locking the opening in the bridge. The insert and the plug are made of cross-linked ultra-high molecular weight polyethylene (ISO 5834-2). The insert surface is finely machined.

Indications

- Adult population 18+, men, women
- Patients with severe axial deformities (valgus, varus) in the knee area, bony ankylosis, bone tumours requiring major bone resection, major bone defects of a different origin, severe instabilities of various aetiology, including post-traumatic causes.

Contraindications

Infectious diseases or local infections, severe neurovascular or vascular diseases, tumour process generalization, internal contraindications, cachexia in the patient, osteoporosis, documented allergy to or intolerance of metals (ISO 5832-3, ISO 5832-4), UHMWPE (ISO 5834-2) and bone cement. Conditions of a rheumatic origin with an active inflammatory component are a relative contraindication.

Caution and warnings

Before surgery

Patient

- The patient consents to the surgery and associated risks
- The patient must be mentally capable of understanding the meaning of the surgery and observing the postoperative regimen
- The patient must be aware of the restrictions caused by the implant
- The patient must meet the requirement of the maximum BMI – body mass index (max. BMI=30)

Workplace performing surgery

- Ensures highly sterile operating conditions
- Checks sterility of the packaging (damage to the packaging and expiry dates)
- Tools for implantation must be complete and functional
- The implant is intended for single use only
- Ensures that damaged, non-sterile or reoperated implants are not used
- Patients receiving a knee joint replacement must be informed that the implant's lifetime depends on their weight and level of activity
- All necessary implantation components must be available

During surgery

- During application, the instruments supplied by the manufacturer must be used and the manufacturer's recommended surgical procedure provided in the manual must be followed
- Surgical gloves must be used when handling the product
- The precisely shaped articulated surface and the surfaces intended for fitting the insert must be protected when handling the insert. Any damage to the articulated surfaces adversely affects the lifetime of the implant
- Damaged tools must not be used to introduce the insert
- The CMS – Insert must not be used for testing the joint connection
- Do not use the CMS – Femoral component to test the joint connection
- The polished articulated surfaces, the surfaces designed for fitting the insert and the hanger and all threaded surfaces must be protected when handling the product
- Ensure all articulated surfaces are perfectly clean when testing or performing the final joint connection
- Remove any loose bone cement; pieces of bone cement may spread between the contact surfaces and cause abnormal wear and tear of the implant
- When performing final joint connection, all CMS parts must be perfectly clean and dry (the articulated surfaces, the upper surface and the opening for the tibial plateau hanger)
- The connecting screw must be tightened appropriately (2 to 2.5 Nm)
- The implant may only be combined with implants supplied by BEZNOSKA, s.r.o. or implants expressly recommended for use by BEZNOSKA, s.r.o.

After surgery

Patient

- The patient must be aware of the restrictions caused by the implant
- The patient must be warned that the new implant may only undergo limited stress until the bone has healed fully
- If there are any unexpected changes that may relate to the implant, a visit to a specialist is recommended
- The patient should avoid any long hikes, running, jumping, squatting, kneeling, contact sports, horse riding, skiing, hard physical labour and carrying heavy loads; on the other hand, swimming is highly recommended

Workplace performing surgery

- The load-bearing capacity of the implant is not comparable with that of a healthy bone
- Perform preventive checks of the artificial joint in a timely manner
- Based on the available information, magnetic resonance imaging with a static magnetic field up to 3T may be performed in patients with implants by BEZNOSKA, s.r.o., if at least 6 weeks have passed from the date of implantation and if the implant does not display any signs of being loose

Procedure during surgery

A detailed surgical procedure describing the complete implantation process is available for the total knee replacement – CMS type.

Adverse complications

During surgery

- Damage to vascular and nerve structures
- Iatrogenic damage to the bone, sometimes even occurrence of fractures
- Incorrect position of the components
- Incorrect resection

After surgery

- Cardiovascular defects, such as TEN, deep phlebothrombosis, MI, postoperative hematoma
- Wound healing disorders, infection
- Loosening of the entire total replacement or its components, deformation or breakage of a component, flexion contracture, limb shortening

Product disposal

After being used, the implant is classified as "dangerous waste" in health care. It is to be disposed of in accordance with the valid legislation of the country where the implant is being disposed of.

Manufacturer's recommendations:

The implant cannot be re-sterilised due to the risk of:

- Tibial component – damage to the conical and anchoring surfaces (cement and stem rubbing), damage to the plug opening, damage to the thread for the stem and the connecting screw
- Insert – damage to the articulated surface (loosening of rubbed parts), damage to insertion elements, material degradation (high risk of component destruction)
- Femoral component – damage to the articulation surface (loosening of rubbed parts), damage to the anchoring elements
- PE plug – damage to the connecting elements (difficulties during assembly), material degradation (high risk of component destruction)

Risks arising from repeated use from the patient's perspective:

- Failure of the implants due to damage to the articulated and conical surface, anchoring surfaces (risk of rubbing, effect of rubbed parts and subsequent loosening of the implant), pain or inadequate sterilization – risk of early need to reoperate
- Risk of infection in the patient (risk of infection and loosening of the implant) – risk of urgent need to reoperate
- Mistaken implant size or type or incomplete implant – risk of repeated surgery or need to reoperate early

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