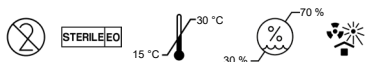




Information on handling, possible applications and potential restrictions for the product group:

**TOTAL KNEE REPLACEMENT – SVL**



**Identifikation**

SVL/N – Femoral component	SVL – Tibial plateau
Size range: 1 – 6	Size range: 1 – 6
SVL – Insert	SVL/RP – Tibial plateau
Size range: 1 – 6	Size range: 2 – 6
SVL/RP – Insert	SVL – Modular tibial plateau
Size range: 1 – 6	Size range: 1 – 6
SVL – Tibial cemented stem	SVL – Stem plug for tibial plateau
Size range: D12 – D15	
Patella	
Size range: D25 – D34	

**Information about sterility**

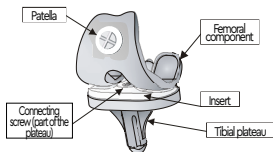
- The product is supplied by the manufacturer in a sterile pack
- Sterility of the implant in the protective sterile packaging is guaranteed for 5 years. Expiry dates are marked clearly on the protective sterile packaging
- Not to be used if the sterile packaging is damaged. The product cannot be resterilised

**Intended use**

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

**Product description**

The standard type SVL/N cemented knee joint replacement is designed for primary knee joint replacement using bone cement during surgeries with the anterior cruciate ligament maintained. The joint replacement set comprises of a femoral component, a tibial plateau, an insert and a connecting screw, and stems may be used for additional securing.



		SVL – Tibial plateau / modular and insert						Patella			
		1	2	3	4	5	6	1	2	3	4
SVL/N – Femoral component	1	1								X	
	2	2	X					X	X	X	
	3	3		X				X	X	X	X
	4	4			X			X	X	X	X
	5	5					X	X	X	X	X
	6	6						X	X	X	X
Tibial stem (the entire size range)		X	X	X	X	X	X				
Stem plug (Ti or PMMA)		X	X	X	X	X	X				

		SVL/RP – Tibial plateau and SVL/RP – Insert						Patella			
		1	2	3	4	5	6	1	2	3	4
SVL/N – Femoral component	2	2								X	
	3	3	X					X	X	X	
	4	4/3		X				X	X	X	X
	4	4			X			X	X	X	X
	5	5					X	X	X	X	X
	6	6						X	X	X	X

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

**SVL/N – Femoral component**

The standard femoral component is designed for total knee joint replacement with the option of maintaining the anterior cruciate ligament and is intended for application using bone cement. It is made in 6 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 the knee joint to ensure optimal functioning of the total replacement. The internal surfaces are structured with recesses to securely fit the component in bone cement. The components are fitted with a pair of pins for precise fitting and a strong connection. The component is made of wrought cobalt alloy (ISO 5832-4). The articulated surfaces are polished, and the internal surfaces are finely blasted.

**SVL – Tibial plateau**

The standard tibial plateau is designed for total knee joint replacement with the option of maintaining the anterior cruciate ligament and is intended for application using bone cement. It is made in 6 sizes in left and right versions. The component includes an upper plate designed for fitting on a precisely resected proximal part of the tibia and a stem with ribs. The plate has an oval, asymmetric shape (left and right) and has an opening for the anterior cruciate ligament. The plate has an oval depression for the insert on the upper side and an opening for the screw. The opening is designed for the connecting screw that secures the insert. The lower part of the plate is structured with recesses designed for the primary fixation of the component in bone cement. The component is anchored in the tibia in particular with a conical stem and a pair of anti-rotational ribs. The component is made of wrought titanium alloy (ISO 5832-3). The surface of the implant is finely blasted.

**SVL – Modular tibial plateau**

The modular tibial plateau is designed for total knee joint replacement with the option of maintaining the anterior cruciate ligament and is intended for application using bone cement. It is made in 6 sizes in L/R versions. The plateau includes an upper plate designed for fitting on a resected proximal part of the tibia and an anchoring stem with anti-rotational ribs. The plate has an oval, asymmetric shape (L/R) and has an opening for the anterior cruciate ligament. The plate has a depression for the insert on the upper side and an opening for the screw. A threaded hole for connecting an extended stem or a stem plug is in the lower part of the stem. The lower part of

the plate is structured with recesses designed for primary fixation of the component in bone cement. The plateau is made of wrought titanium alloy (ISO 5832-3). The surface of the implant is finely blasted.

**SVL/RP – Tibial plateau**

The standard tibial plateau is designed for total knee joint replacement with the option of maintaining the anterior cruciate ligament and is intended for application using bone cement. It is made in 5 sizes. The component includes an upper plate designed for fitting on a precisely resected proximal part of the tibia and the stem with ribs. The plate has an oval, symmetric shape and has an opening for the anterior cruciate ligament. The plate has an opening for the PE insert hinge on its top side. The lower part of the plate is structured with recesses designed for primary fixation of the component in bone cement. The component is anchored in the tibia in particular with a conical stem and a pair of anti-rotational ribs. The component is made of cobalt – chrome – molybdenum alloy (ISO 5832-4). The surface of the implant is finely blasted. The contact surface with the PE insert and the opening for the insert hinge are polished to a mirror-like shine.

**SVL – Insert**

The standard insert is designed for total knee joint replacement with the option of maintaining the anterior cruciate ligament. It is made in 6 sizes and 5 thicknesses (8, 10, 12, 15 and 18 mm) and in left and right versions. The insert has an oval, asymmetric shape (left and right) and has an opening and a lighter section for the anterior cruciate ligament. The articulated surface of the implant comprises of two cylindrical surfaces divided by an elevated bridge to ensure the frontal stability of the femoral component and limited rotation around the vertical axis. The bridge has an opening for the connecting screw to ensure a secure connection with the tibial plateau. The implant is made of ultra-high molecular weight polyethylene and o of ultra-high molecular weight polyethylene with vit. E (ISO 5834-2). The surface of the implant has a uniform finish.

**SVL/RP – Insert and Insert 4/3**

The SVL/RP insert is designed for total knee joint replacement with the option of maintaining the anterior cruciate ligament. It is made in 6 conventional sizes and one version as a transition type 4/3, and all inserts are made in four thicknesses (8, 10, 12 and 15 mm) and in left and right versions. The insert has an oval, symmetric shape (left and right) with asymmetric articulation surfaces for the condyles) and has an opening and a lighter section for the anterior cruciate ligament. The articulated surface of the insert is identical to the articulated surfaces divided by an elevated bridge that ensures frontal stability of the femoral component. A conical stem ensuring rotation around the vertical axis on the tibial plateau is located on the bottom surface of the insert. The implant is made of ultra-high molecular weight polyethylene (ISO 5834-2). The surface of the implant is very finely machined.

**Patella**

The patella replacement is designed for total knee joint replacement with the option of maintaining the anterior cruciate ligament and for replacement with anterior stabilization. It is made in four sizes identical for left and right versions. The component is rotationally symmetric with a concave articulated surface. The anchoring part comprises of a cylindrical fitting with crosswise grooves preventing rotation in the mounting. All sizes are made with identical anchoring. The component is made of ultra-high molecular weight polyethylene (ISO 5834-2). The surface of the implant on the articulated surface is very finely machined.

**Indications**

- Adult population 18+, men, women
- Cases of severe arthropathy based on rheumatoid arthritis or osteoarthritis, severe post-traumatic conditions and certain systemic diseases. The patellar replacement is indicated for major degenerative changes in the patellar cartilage and patella tracking disorders. The patellar replacement should be performed preferentially in the event of TEP primary implantation.

**Contraindications**

Infectious diseases or local infections, severe neuromuscular or vascular diseases. Poor quality of bone structures, severe knee instability in the area of collateral ligaments. The implant is not to be used in patients with a documented allergy to or intolerance of metals (ISO 5832-3, ISO 5832-4), UHMWPE (ISO 5834-2) and bone cement. The patellar replacement is contraindicated in cases of patellar osteoporosis and small patella thickness and size.

**Caution and warnings**

**Before surgery**

**Patient**

- The patient consents to the surgery and associated risks
- The patient must be mentally capable of understanding the significance of prevention, as well as observing prevention.
- The patient must be aware of the restrictions caused by the implant

**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 lifetime of the implant 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 must be protected while handling the insert
- The polished articulated surfaces of all components (insert, femoral and tibial component) must be protected. Any damage to the articulated surfaces adversely affects the lifetime of the implant
- The SVL, SVL/RP insert must not be used for testing the joint connection
- The SVL/N – Femoral component can be used for testing the joint connection
- Damaged tools must not be used to introduce the insert
- The SVL, SVL/RP – Tibial/modular plateau can be used for testing the joint connection after cementing (in a set with a test articulation insert)
- Remove any loose bone cement; pieces of bone cement may spread between the contact surfaces and cause abnormal wear and tear of the implant
- Ensure all articulation surfaces are perfectly clean when testing or performing the final joint connection
- The Patella must not be used for testing the joint connection
- The upper surface of the SVL – Tibial plateau must be perfectly clean and dry before implantation of the insert
- Rinse and dry the surfaces thoroughly before placing the insert
- The connecting screw must be tightened appropriately (2 to 2.5 Nm)
- The implant may only be combined with implants supplied from BEZDOSKA, s.r.o. or implants expressly recommended for use by BEZDOSKA, 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

**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 BEZDOSKA, 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 – SVL type.

**Adverse complications**

**During surgery**

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

**After surgery**

- Cardiovascular defects, such as TEN, deep phlebotrombosis, 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 resterilised due to the risk of:

- Tibial component – damage to the conical and anchoring surfaces (rubbing of the cement and stem)
- Insert – damage to the articulated surface (release of rubbed parts), damage to insertion elements, material degradation (high risk of component destruction)
- Femoral component – damage to the articulated surface (release of rubbed parts), damage to the anchoring elements

**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 premature 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 premature need to reoperate

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