











## 2. Intended Purpose and Patient

### 2.a. Intended Purpose of the Device

ADLER ORTHO implants are intended for use in total knee arthroplasty.

### 2.b. Patient Whom the Device is Intended to Be Used

Treatment selection for the patient is the surgeon's responsibility. When a surgeon has selected total knee arthroplasty as the preferred treatment for the patient, the devices are indicated for:

- Primary and secondary arthrosis
- Rheumatoid arthritis
- Bone necrosis
- Revisions, where other devices or treatments have failed

Total knee arthroplasty is contraindicated in the following conditions:

- infection, septicemia, and osteomyelitis constitute cases of absolute contraindication;
- serious metabolic, cardiovascular, respiratory or neurological pathologies;
- serious osteoporosis;
- rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- obesity;
- skeletally immature patients;
- female patients of childbearing age, for whom a negative pregnancy test is not obtained;
- high patient activity which could lead to overloading of the implant.

## 3. Special Operating Instructions

Not applicable. There is no such information for the patient. The instructions for use of the device are only applicable to the surgeon.

## 4. Intended Performance and Side Effects

### 4.a. Intended Performance of the Device

Provide increased patient mobility and reduce where there is evidence of sufficient sound bone to seat and support the components.

### 4.b. Potential Undesirable Side Effects

#### GENERAL

- Loosening, displacement, or migration of the implant
- Component dislocation or disassembly
- Change in position of the implant
- Implant breakage
- Fatigue fracture of the implant
- Wear of the polyethylene component
- Incomplete cement mantle
- Infection
- Peripheral neuropathies
- Subclinical nerve damage as a result of surgical trauma
- Tissue reactions, osteolysis

#### INTRAOPERATIVE OR EARLY POSTOPERATIVE

- Damage to blood vessels
- Temporary or permanent nerve damage
- Lengthening or shortening of the affected extremity
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, and myocardial infarction
- Haematoma
- Delayed wound healing

- Infection

#### LATE POSTOPERATIVE

- Bone resorption which may lead to loosening of the implant
- Instability as a result of subluxation or dislocation
- Comprised ambulation (patient limping)

## 5. Residual Risks

- Weight and physical activity can still have an impact on the implant lifetime an allergic reaction to the implant material is possible, although extremely rare.
- Implantation of a foreign material inside the body can cause a cellular reaction.

## 6. Warnings and Precautions

### 6.a. Warnings

Adler Ortho Australia does not recommend magnetic resonance imaging (MRI) for any patients implanted with metallic knee components without prior consultation with an expert radiologist. The safety of the devices in the MR environment has not been tested and scanning of patients who have the device may result in patient injuries. The device should be considered MRI not tested.

### 6.b. Precautions

In the event of having an MRI or equivalent intervention, the patient needs to inform qualified health professionals prior to having this examination

## 7. Postoperative

### 7.a. Examination

Post-operative follow-up and examination should be scheduled on a regular basis by the health professional

### 7.b. Symptoms or signs that could indicate the device is malfunctioning

- Pain
- Discomfort
- Inflammation
- Infection
- Persisting haematoma
- Joint dislocation
- Subluxation
- Abnormal joint noise
- Lengthening or shortening of the affected extremity

### 7.c. Precautions that should be taken if the performance of the device changes or the patient experiences any of the symptoms mentioned in section 7.b.

Inform the health professional without delay then follow their instruction. In the meantime, reduce physical activity and limit weight bearing of the affected extremity.

### 7.d. Expected device lifetime

Approx. 95% survivorship at 10 years for total knee replacement

Approx. 70% survivorship at 10 years for unicompartmental knee replacement

### 7.e. Factors that could shorten device lifetime

- Increased patient weight may shorten device lifetime
- Physical activity may shorten device lifetime

### 7.f. Precautions to be taken at or near the end of the expected device lifetime

No particular precautions should be taken at or near the end of the expected device lifetime as long as:

- No symptoms or sign that could indicate that the device is malfunctioning are observed (See section 7.b.)

- Radiographic examination (if recommended) by a specialist health professional is performed and shows no sign of undesirable effects

### 7.g. Other circumstances

If in doubt regarding the operation of the device, the patient should contact their health professional.

## 8. Materials and Residues

### 8.a. Materials

1. Femoral Component, Total Knee, Cemented: Cobalt-Chrome-Molybdenum
2. Femoral Component, Total Knee, Cementless: Cobalt-Chrome-Molybdenum with Cobalt-Chrome-Molybdenum Alloy Beads + HA Coating
3. Tibial Tray, Total Knee, Cemented: Cobalt-Chrome-Molybdenum
4. Tibial Tray, Total Knee, Cementless: Cobalt-Chrome-Molybdenum with Cobalt-Chrome-Molybdenum Alloy Beads + HA Coating
5. Femoral Component, Uni Knee, Cemented: Titanium Alloy
6. Femoral Component, Uni Knee, Cementless: Titanium Alloy with Porous Titanium + HA Coating
7. Tibial Tray, Uni Knee, Cemented: Titanium Alloy
8. Tibial Tray, Uni Knee, Cementless: Titanium Alloy with Porous Titanium + HA Coating
9. Tibial Insert: Ultra-High-Molecular-Weight-Polyethylene
10. Patella: Ultra-High-Molecular-Weight-Polyethylene
11. Screw: Titanium Alloy

### 8.b. Manufacturing Residuals

There is no known patient risk associated with potential residual manufacturing residues

## 9. Therapeutic Goods Administration

### 9.a. Incident Reporting

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the appropriate regulatory body.

### 9.b. Address

*Therapeutic Goods Administration website:*

<https://www.tga.gov.au/>

*Name & address of manufacturer:*

**Adler Ortho SpA**

Via dell'Innovazione 9, 20032 Cormano – (MI), Italy

*Adler Ortho Australia contact details:*

<http://www.adlerortho.com.au/contact-us>