EFFECTUM MEDICAL
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# Instructions for use
# Femoral Trial Component

Please read these instructions for use and the processing instructions carefully prior to use.

**Products**

| Article number | Product |
|---|---|
| 02.001.001 | Femoral Trial Component PS, BalanSys knee system compatible, Size B, Left, extra oblique trochlear groove |
| 02.001.002 | Femoral Trial Component PS, BalanSys knee system compatible, Size B, Right, extra oblique trochlear groove |
| 02.001.003 | Femoral Trial Component PS, BalanSys knee system compatible, Size C, Left, extra oblique trochlear groove |
| 02.001.004 | Femoral Trial Component PS, BalanSys knee system compatible, Size C, Right, extra oblique trochlear groove |
| 02.001.005 | Femoral Trial Component PS, BalanSys knee system compatible, Size D, Left, extra oblique trochlear groove |
| 02.001.006 | Femoral Trial Component PS, BalanSys knee system compatible, Size D, Right, extra oblique trochlear groove |

**Product Description**
The femoral trial component is a reusable surgical instrument for use during the trial reduction evaluation according to the Mathys BalanSys PS surgical procedure. The additional trial reduction steps with the new femoral trial component must take place **after** the trial reduction with the standard BalanSys PS components, in cases where a maltracking of the patella is observed. The femoral trial component is intended to be combined solely with the BalanSys PS trial meniscal bearings and trial tibia plateaus, to evaluate the patella tracking.

**Product Material**
The femoral trial component is made out of stainless steel (1.4301) according to DIN EN ISO 7153.

**Intended Use**
The femoral trial component with extra oblique trochlear groove is combined with a Mathys BalanSys PS trial tibia plateau and meniscal component, to provide an intra operative analysis of the patella tracking (before placement of the final prosthesis components) in cases where a compromised patella tracking is observed using the standard BalanSys trial components.

Before use of the femoral trial component with extra oblique trochlear groove, all bony resections are made according to the BalanSys PS surgical technique and guidelines, and an initial trialing with the standard BalanSys PS components has been executed.

Always use a femoral trial component for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration size as the corresponding components intended to be permanently implanted.

The femoral trial component shall only be used **after** trial testing with the Mathys BalanSys femoral trial components.

**Indications / Contraindications**
**Indications:**
The femoral trial component with oblique trochlear groove is indicated to be used with a trial tibia plateau and meniscal component of the Mathys BalanSys PS system, to provide an intra operative analysis of the patella tracking in cases where a compromised patella tracking is observed using the standard Mathys BalanSys PS femoral trial component.

**Contraindications:**
- The femoral trial component is not intended to be combined trial meniscal bearings, trial tibia plateaus and instruments of systems other than the Mathys BalanSys PS system.
- The femoral trial component is not intended to be used when no compromised patella tracking is observed using the standard Mathys BalanSys PS femoral trial component.
- The femoral trial component is not intended to be used with permanent implants.

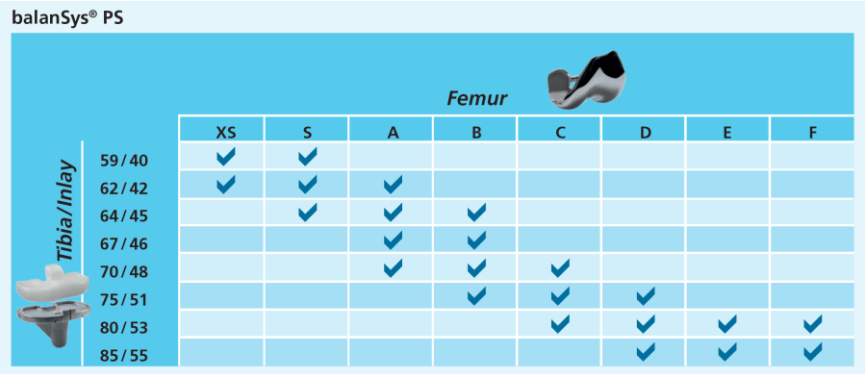
**Patient Information**
Preoperative instruction of the patient is essential. The patient is to be informed by his/her physician of all surgical risks, including those associated with the additional trialling with the Effectum Medical trial component.

**Potential Side Effects and Adverse Events**
Besides the known potential side effects and adverse events of a total knee replacement there are no additional side effects and adverse events expected, specifically related to the intended use of the Effectum Medical trial component.

**Warnings and Precautions**

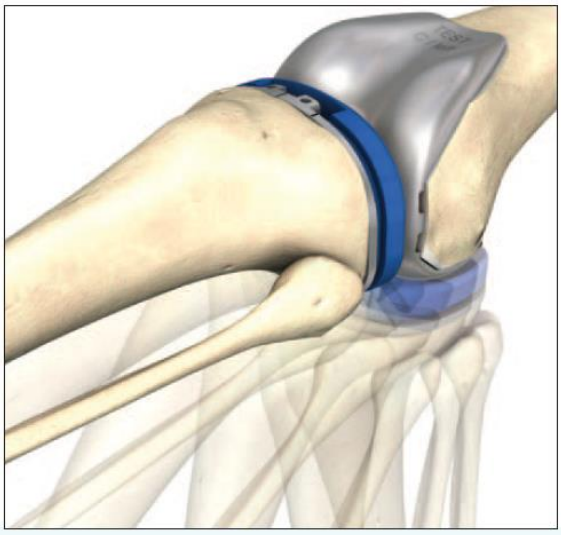
- Only use the device for its intended purpose (intended use).
- A trial component is an instrument intended for intra-operative transient surgically invasive use. Do **not** permanently implant trial components.
- The Effectum Medical femoral trial component shall only be used **after** trial testing with the Mathys BalanSys femoral trial components.
- The femoral trial component is intended to be combined solely with Mathys BalanSys trial meniscal bearings and trial tibia plateaus, to evaluate the patella tracking. **Refer to the compatibility chart to check for compatibility (see below).**
- The femoral trial component may only be combined with instruments belonging to the BalanSys PS knee system. Do not use with components of other systems.
- The femoral trial component shall not be combined with any components intended for permanent implantation.
- The femoral trial component must have the same configuration size as the corresponding components intended to be permanently implanted (e.g. B, C or D).
- The femoral trial component must be used by specifically trained personnel only. The surgeon must be familiar with the BalanSys PS knee system, surgical technique and surgical procedure prior to performing surgery. The surgeon is responsible for ensuring that the operation is carried out properly.
- Effectum Medical is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and / or operating techniques.
- Effectum Medical recommends that all instruments be regularly inspected for wear and disfigurement prior to use.
- Unless otherwise indicated, instruments are defined and provided as NOT STERILE. Before use they must be thoroughly cleaned and sterilized according to the Processing Instructions. Instruments that are not clean may not be effectively sterilized.

**Compatibility chart:**



**Combination of Medical Devices**
The Effectum Medical femoral trial component is not intended to be combined trial meniscal bearings, trial tibia plateaus and instruments of systems, other than the Mathys BalanSys PS system. Effectum Medical has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

**Application / Surgical Procedure**



1) Follow the standard Mathys balanSys surgical technique (refer to list of surgical techniques below) until trial with provisional Mathys PS components.
2) With all the provisional Mathys PS components in place, the knee is tested with respect to range of motion, stability, kinematics and mobility.
3) In case patella maltracking is observed, remove the BalanSys PS femoral trial component and replace by the corresponding size (B, C, D) and side (left/right) of the extra oblique femoral trial component.
4) Observe patella tracking and decide on corrective measures, e.g. ligament release.
5) Remove extra oblique femoral trial and replace again with the corresponding Mathys BalanSys PS femoral trial component to establish final position. Any designed adjustments should be made before the final position is marked.
   Resume with standard Mathys balanSys surgical technique (refer to list of surgical techniques below) for determination of final placement.

**<u>Surgical techniques Mathys BalanSys as listed below</u>**
- balanSys®, Surgical technique, Bone orientated 4in1 SMarT Instruments
- balanSys®, Surgical technique, Combination 4in1
- balanSys®, Surgical technique, LIS 4in1
- balanSys®, Surgical technique, Ligament orientated 4in1
- balanSys®, Surgical technique, Bone orientated 4in1
- Surgical technique, balanSys®, bone oriented leggera instruments

**Cleaning and Sterilization of Instruments**
All instruments are provided non-sterile and must be sterilized before use. Please refer to the processing instructions.

**Key to Symbols**

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|---|---|---|---|
| CE | „Conformité Européenne“ | REF | Catalogue number |
|  | Date of Manufacture | LOT | Lot Number |
|  | Manufacturer |  | Consult instructions for use |

**Manufacturer**
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