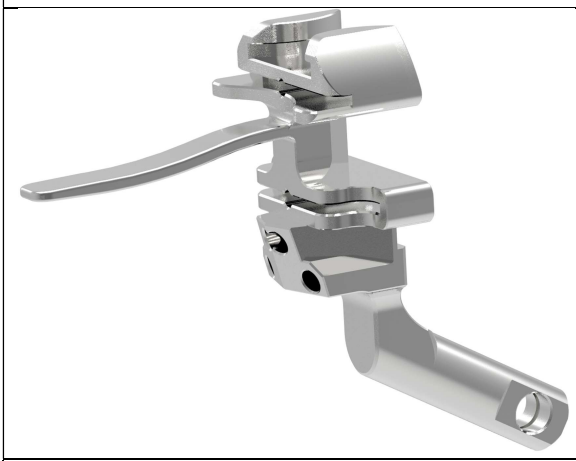
EFFECTUMMEDICAL
YOUR START-UP TO MARKET

Instructions for use

‘Joint Line Referencing and Resection Guide system for balanSys UNI’

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

Products	Item number and name
	02.001.012 Joint Line Referencing Resection Guide, Thickness 2
	02.001.017 Flexion Angle Referencing Drillguide

Product Description:
The ‘Joint Line Referencing and Resection Guide system for balanSys UNI’ is a small reusable surgical instrument set for use with the standard Mathys BalanSys UNI surgical procedure. It provides an alternative surgical technique for the bone defect referencing and the bone osteotomy order. The technique allows to perform the required bone resections to create room for the replacement of the native anatomy by an artificial unicompartmental knee implant.

Product Material:
The Joint Line Referencing and Resection Guide system for balanSys UNI is made out of stainless steel (1.4057) according to DIN EN ISO 7153 (2016-12).

Intended Use:
The ‘Joint Line Referencing and Resection Guide system for balanSys UNI’ is intended to provide guidance to the operating surgeon in performing the required bone resections to create room for the replacement of the native anatomy (bone and cartilage) by an artificial unicompartmental knee arthroplasty (UKA). This ensures appropriate restoration of the joint functionality for the knee of the patient.

The ‘Joint Line Referencing and Resection Guide system for balanSys UNI system’ in combination with other supporting instruments provides the surgeon with feedback on the cutting levels (angle, height, position in relation to the joint-line) before relevant bony resections are made.

The ‘Joint Line Referencing and Resection Guide System for balanSys UNI system’ facilitates the preparation of the implant seating by guiding the saw blade during femoral and tibial bone preparation.

Indications / Contraindications:
General indications and contraindications for balanSys UNI partial knee replacement:

Indications:
Painful and/or disabling unicompartmental joint disease in the femorotibial compartment resulting from osteoarthritis, avascular necrosis or post-traumatic arthritis.

Contraindications:
- Local or general infection
- Any soft tissue, ligament, nerve or vessel insufficiency that might lead to an unacceptable risk of prosthesis instability, prosthesis fixation failure and/or complications in post-operative care
- Insufficiency of the extensor mechanism
- Compromised bone stock due to bone loss or bone defects and/or insufficient bone substance, which cannot provide adequate support and/or fixation for the prosthesis
- Hypersensitivity to materials used • Insufficiency of the ACL and/or PCL
- Earlier valgus-producing osteotomy resulting in valgus >5°
- Extension deficiency of >10° • Varus or valgus deformity of > 10°
- Genu recurvatum
- Degenerative disease of other compartments
- Systemic inflammatory arthritis
- Progressive neoplastic disease
- Skeletal immaturity

Specific indications for the Joint line referencing resection guide system:

Indications:
The product may only be combined with instruments and implants belonging to the balanSys UNI knee system provided by Mathys AG, Bettlach, Switzerland.
Indication of balanSys implants can be found in the surgical technique of balanSys UNI system.

Contraindications:
Application of instrument with implant systems other than specified above.

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 use of the Effectum Medical joint line referencing resection technique.

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).
- The instruments are intended for intra-operative transient surgically invasive use.
- The instruments are intended to be combined solely with Mathys balanSys UNI instruments. Refer to the surgical technique for compatibility. Do not use with components of other systems.
- The 'Joint Line Referencing and Resection Guide for balanSys UNI system' must be used by specifically trained personnel only. The surgeon must be familiar with the balanSys UNI 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.
- MRI unsafe: The devices are made of hardened stainless steel. Hardened stainless steel is attractive to magnetism. Therefore, the devices will pose hazards in all MR environments.

Mathys balanSys UNI surgical technique compatibility:
The instruments are compatible with the following surgical techniques:

- balanSys® UNI, Surgical technique, Ligament tensor
- balanSys® UNI, Surgical technique, Spacer block

The use of the Joint line referencing resection system' obsoletes the use of specific instruments in these systems. The standard instruments which are not intended to be used during the surgical procedure are described in the surgical technique:

03.001.012 V2	**'Joint Line Referencing and Resection Guide for balanSys UNI system'**

Combination of Medical Devices:
The Effectum Medical Joint Line Referencing and Resection Guide system for balanSys UNI is not intended to be combined with instruments of systems, other than the Mathys balanSys UNI system. Effectum Medical has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

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:

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

Manufacturer:
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