

CombiSet[®], sterile

Schulterarthroskopie-Set APK, 2641713

Intended Purpose

Intended Use:

Orthopedics

The CombiSets for orthopedics are single-use, sterile component sets, customized for various interventions on humans in the field of orthopedics such as

- Hallux valgus - correction of a deformity of the big toe
- Hand surgery - all interventions of the hand including wrist, e.g., carpal tunnel surgery
- Hip TEP - insert an implant on the hip (hip total endoprosthesis)
- Knee arthroscopy - arthroscopic operation on the knee, e.g., arthroscopic meniscus resection
- Knee total endoprosthesis (TEP) - insert an implant on the knee
- Shoulder arthroscopy - arthroscopic operation on the shoulder
- Surgery lower arm - all surgical procedures on the forearm (radius and ulna), e.g., osteosynthese techniques
- Surgery lower leg - all interventions of the foot and lower leg, e.g., achilles tendon rupture
- Surgery upper arm - all interventions on the collarbone, shoulder, upper arm, elbow, e.g., rotator cuff shoulder surgery
- Surgery upper leg - All surgical procedures on the hip, thigh and knee , e.g., proximal femoral nail (PFN) performed by healthcare professionals within an operating theater; the single components might get in contact with skin, mucosal membranes, injured skin, circulatory system, bone and blood, and it is intended for long term use.

Target user/group: Healthcare professionals

Medical device class of the set (based on component with the highest classification): II a

“The product is an assembly of medical devices and processes for set configuration (combination, packaging, sterilization, transport) are supervised by TÜV – 0123.”

Application/Indication

The medical indication results from the necessity to perform an operation in the field of orthopedics by , e.g., hallux valgus (to treat painful joint range of motion (ROM) deformity of the joint complex), hand surgery (to deal with , e.g., hand and wrist injuries, nerve compression disorder, rheumatoid arthritis) , hip total endoprosthesis (e.g., to treat osteoarthritis, inflammatory arthritis, both seropositive and seronegative) , knee arthroscopy (to relieve painful symptoms of many problems that damage the cartilage surfaces and other soft tissues surrounding the joint), knee total endoprosthesis (a treatment for pain and disability in the knee) , shoulder arthroscopy (used as treatment of majority of shoulder problems, as well as for diagnosis of some patients with shoulder pain) , surgery lower arm (e.g., fixation of radial shaft fractures, radial osteotomy or tumour biopsy and excision), surgery lower leg (e.g., for severe lower extremity injuries) , surgery upper arm or surgery upper leg.

Reference Number

2641713

Quantity	Component description	Included substances
1	Cannula 20 = 0,90 Gauge=mm 70 = 2 3/4" mm=Inch yellow	See set label
1	Instrument Table Cover 80 cm 145 cm telescopic folding	See set label
2	OR tape adhesive 10 cm 50 cm	See set label
1	Basin plastic 500 ml 11,5 cm	See set label
1	Drape adh Prot 175 cm 150 cm 171 cm	See set label
1	Foliodress Gown Protect standard XL 140 cm not reinforced	See set label
1	Scalpel Blade Fig. 11 stainless steel	See set label
1	Table Cover Wrapping reinf 160 cm 150 cm	See set label
1	Skin Marker ruler printed on marker	See set label
1	Stockinet rolled up 25 cm 80 cm rolled	See set label

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1	Shoulder Arthroscopy Drape ProtPlus 420 cm 245 cm 13 cm	See set label
1	Camera Cable Cover 13 cm 250 cm perforation	See set label
1	Scalpel Blade Fig. 15 stainless steel	See set label
1	Scalpel Blade Fig. 10 stainless steel	See set label
1	Syringe 20 ml Luer 2-parts	See set label
1	Foliodress gown Comfort Extra reinforced XXL 155 cm reinforced	See set label
1	Sharps Pad 16 cm 12 cm 0,3 cm	See set label
1	Suction Set Pinpoint 12/4,00 CH/mm no V.C	See set label
1	Ideal bandage 10 cm 5 m white	See set label
1	Velcro fastener 2 cm 23 cm Standard	See set label

Instruction for use, Contra-Indications and Undesirable Side Effects, Warnings:



Consult instructions for use



Caution

For possible contraindications please follow the instructions/warning hints of the individual set items listed in the instructions for use enclosed within the set.

Sterile Device:



Sterilized using ethylene oxide



Do not use if package is damaged



Do not re-sterilize

Single Use Device:



Do not re-use

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.



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year month day

Shelf Life: Maximum 5 years, or the shelf life of the component with the shortest shelf-life

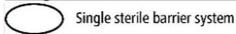
Medical Devices in the set are indicated by following symbol



Unique Device Identification (UDI) for the set:



Single Sterile Barrier System



Packaging: Ventbag

Primary packaging /transport carton	Primary packaging /dispenser	transport carton/pallet	Primary packaging dimension	Dispenser dimension	Transport carton dimension	Pallet dimension
3	n.a.	16	Ventbag L	n.a.	570 x 367 x 426 mm	1200 x 800 x 1950 mm

Latest Date of Revision: 2020-11-12