

# ottobock 17BK1 Multifunctional Correction System Instruction **Manual**

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ottobock 17BK1 Multifunctional Correction System



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#### **Foreword**

# **INFORMATION**

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- Please read this document carefully before using the product and observe the safety notices.
- Instruct the user in the safe use of the product.
- Please contact the manufacturer if you have questions about the product or in case of problems.
- Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- Please keep this document for your records.

These instructions for use provide important information for the processing of the 17BK1=\* multifunction correction orthotic joint.

## **Product description**

Article number	System width
17BK1=L4 17BK1=R4	12 mm
17BK1=L3 17BK1=R3	14 mm
17BK1=L2 17BK1=R2	16 mm
17BK1=L1 17BK1=R1	20 mm

## Size recommendation

User height	17BK1=*			
	Wrist joint	Elbow joint 1)	Knee joint	Ankle joint
Child up to 1 m	*= L4/R4	*= L4/R4	*= L4/R4	*= L4/R4
Child from 1 to 1.4 m	*= L4/R4	*= L3/R3	*= L3/R3	*= L3/R3
Adult up to 1.6 m	*= L4/R4	*= L3/R3	*= L2/R2	*= L2/R2
Adult from 1.6 to 1.9 m	*= L3/R3	*= L2/R2	*= L1/R1	*= L1/R1

<sup>1)</sup> For elbow applications: reverse the sides right to left and left to right.

## Scope of delivery (see fig. 1)

Item	Quant it	Designation	Reference number
1	1	Upper joint section	17X14=*
2	1	Countersunk screw	501T19=*
3	1	Gear wheel	30Y157=*
4	1	Joint nut	30Y156=*
5	1	Lower joint section	17U14=*
6	1	Hollow screw	30Y172=*
7		Angle scale	
8	1	Lock cover	30Y154=*
9	1	Adjustment lever	30Y212=*
10	4	Phillips head screw (not illustrated)	
11	1	Allen key (not illustrated)	
12	1	Washer set (not illustrated)	

## Intended use

#### Indications for use

The 17BK1=\* orthotic joint is intended exclusively for orthotic fittings of the upper or lower limbs (hand, elbow, knee or ankle joint). In the locked state, the joint may be used exclusively in positioning orthoses without supporting the load of the body weight.

## Orthotic joint combination possibilities

#### Hand and elbow

- 17BK1=\* bilateral 2)
- 17BK1=\* and 1x 17BK3=\* medial support
- 17BK1=\* unilateral 3)

#### Knee and ankle

- 17BK1=\* bilateral 2)
- 2) Medial and lateral on one limb
- 3) Medial or lateral on one limb

#### Indications

Functional joint contractures
Indications must be determined by the physician.

#### Contraindications

#### **Absolute Contraindications**

· Structural joint contractures

#### **Relative Contraindications**

The following accompanying symptoms require consultation with a physician: skin diseases and injuries, especially in case of inflammatory changes, prominent scars with swelling, reddening and hyperthermia in the area treated; lymphatic flow disorders, including unclear soft tissue swelling distal to the device; sensory and circulatory disorders.

#### Lifetime

The product is designed for a lifetime of two years given intended use and when professionally assembled.

#### Qualification

Patients may be fitted with the product only by trained qualified personnel.

The qualified personnel must be familiar with the handling of the various techniques, materials, machines and tools.

### **Combination possibilities**

The 17BK1\* orthotic joint can be combined with the 17BK2=\* dynamic unit.

### Safety

#### **Explanation of warning symbols**



Warning regarding possible risks of accident or injury.



Warning regarding possible technical damage.

#### Safety instructions



## Excessive strain on load-bearing components

Injuries due to changes in or loss of functionality

- Only use the product for the defined area of application.
- If the product has been exposed to extreme strain (e.g. due to falling), take any necessary measures (e.g. re pair, replacement, inspection by the manufacturer's customer service, etc.).

## **⚠** CAUTION

## Mechanical damage to the product

Injuries due to changes in or loss of functionality

- Use caution when working with the product.
- Check the product for proper function and readiness for use.
- In case of changes in or loss of functionality, discontinue use of the product and have it checked by authorised, qualified personnel.

## **⚠** CAUTION

## Incorrect alignment, assembly or adjustment

Risk of injury due to change in or loss of functionality

- Assembly, adjustment and maintenance operations may only be completed by qualified personnel.
- · Observe the alignment, assembly and adjustment instructions.



#### Excessive strain due to use on more than one patient

Risk of injury and loss of functionality as well as damage to the product

- Use the product on only one patient.
- Observe the maintenance recommendations.



## Thermal overloading of the orthosis joint

Damage to the bearing washers due to improper thermal treatment, loss of orthosis joint movement

- Do not carry out any heat treatment.
- · Check the function of the orthosis joint.
- · Replace damaged bearing washers.



**Exposure of the product to unsuitable environmental conditions** Damage, brittleness or destruction due to improper handling

- Avoid storage in condensing ambient humidity.
- Avoid contact with abrasive substances (e.g. sand, dust).
- Do not expose the product to temperatures below -10 °C or above +40 °C (e.g. sauna, excessive sunlight, dr ying on a radiator).



Contact with saltwater or water containing chlorine/soap, fresh water or abrasive substances (e.g. sand)

Damage and premature product wear

• Following any contact with the substances identified above, promptly clean the product in accordance with the section "Cleaning".

## Preparing the product for use

#### **Processing**



#### Reaching into the area of the joint mechanism

Pinching of limbs (e.g. fingers) and the skin due to uncontrolled joint movement

- Do not reach into the joint mechanism during daily use.
- Close attention is required during assembly and adjustment tasks.

# **INFORMATION**

## Delivery of finished orthosis to the patient

Prior to delivery of the orthosis to the patient, the fit, support and all functions must be tested.

## Pay attention to the parallel alignment of the orthotic joints.

Instruct the patient in handling the product.

Prerequisite: The patient-specific plaster model has been fabricated.

**Selecting bars** 

· Select compatible bars.

17BK1=*	Article number	Width [mm]	Thickness [mm]	Length [mm]
*=L1/R1	605P8=20	20	5	Approx. 2000
*=L2/R2	605P8=16	16	5	Approx. 2000
*=L3/R3	17F52=14x3x220	14	3	220
*=L4/R4	17F52=12x3x220	12	3	220

## Fabricating the orthosis

- 1. Fabricate the orthosis shells using the chosen procedure.
- 2. For stability reasons, adapt the edges of the bars to the curves of the insertion zone for the orthotic joints.
- 3. Screw the bars to the orthotic joint.
- 4. Adapt the bars to the model.
- 5. INFORMATION: Align the orthotic joint with the anatomical compromise pivot point. When using two

## joints, make sure the joints are aligned parallel to one another.

- 6. Remove the shells and the bars from the plaster.
- 7. Finish the shells and bars.

#### Adjusting the orthosis joint

#### NOTICE Adjusting the orthosis joint on the patient under full load

Damage to the orthosis joint due to overloading of the material, breakage of load-bearing components

- Do not perform any angle adjustments on the patient under full load (e.g. in case of spasticity).
- Insert the hexagon wrench into the hollow screw of the lower joint section and set the desired joint angle (see fig. 1, item 6, see fig. 2).

The adjustment lever marks colours to indicate the functional state of the orthotic joint

Col ou	Illustration	Functional state
Red	see fig. <u>3</u>	The orthotic joint is locked.
Yel low	see fig. 4	The orthotic joint can be moved in the flexion direc tion and is limited by the ext ension stop.
Gre en	see fig. <u>5</u>	The orthotic joint is unlocked in flexion and exten sion.

## Finishing the orthosis

**Required materials:** 636W28\* special adhesive, degreasing cleaner The bars must be glued in the insertion zones to ensure stability.

- 1. Clean the connecting surfaces with a degreasing cleaner.
- 2. Apply the special adhesive to the connecting surfaces.
- 3. Insert the bars.
- 4. Secure with the enclosed screws.

5. Allow to cure for at least 4 hours.

INFORMATION: Final bonding strength will be reached after 16 hours.

## Cleaning

Promptly clean the joint after contact with water containing salt, chlorine or soap, or if it gets dirty.

- 1. Rinse the orthotic joints with clean fresh water.
- 2. Dry the orthotic joints with a cloth or allow them to air dry. Avoid exposure to direct heat (e.g. from an oven or radiator).

#### **Maintenance**

## **INFORMATION**

The product may be exposed to increased loads by the patient.

• Shorten the maintenance intervals according to the expected loads.

The manufacturer recommends a semi-annual inspection to verify functionality and check for wear and tear to the orthotic joints.

Spare parts are listed in the section "Components/design".

Only use 633F7 special lubricant.

## **Disposal**

Dispose of the product in accordance with national regulations.

#### Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

#### Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. Themanufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

## **CE** conformity

The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE declaration of conformity can be downloaded from the manufacturer's website.



## **Documents / Resources**



ottobock 17BK1 Multifunctional Correction System [pdf] Instruction Manual 17BK1, Multifunctional Correction System, 17BK1 Multifunctional Correction System, Correction System, System

#### References

• Welcome to Ottobock

Manuals+,