

6-Bar Hydraulic Knee Joint NK-6 Symphony

User's Guide



Introduction

Thank you for using the NK-6 Symphony. This product is a prosthetic knee joint which ensures high stability of stance and excellent ability to respond to the walking speed through unique 6-bar linkage system and hydraulic cylinder. Before using the product, read this User's Guide, and understand the correct procedures for using. Keep it handy for future reference.


Important Information

- Intended purpose of NK-6 Symphony
NK-6 Symphony was designed and manufactured for use as an artificial knee joint by above-knee, knee disarticulation, and hip disarticulation. Do not use NK-6 Symphony for any other purposes.

For hip prostheses, it is recommended to use a torsion adapter to prevent application of large torsion to NK-6 Symphony.

This device is intended for single patient multiple use.

For the specifications for NK-6 Symphony, see 4. Outline of the Product.

 Do not use NK-6 Symphony outside of the specification range. Do not modify the main body or parts.
Doing so can cause injury or damage NK-6 Symphony.

- Cautions for handling NK-6 Symphony safely
Nabtesco Corporation (hereinafter, referred to as Nabtesco) cannot foresee all of potential residual risks of NK-6 Symphony and risks resulting from human errors and usage environment.

Although there are a lot of instructions and prohibitions for handling NK-6 Symphony (assembling, adjusting and maintaining the prosthesis), all these matters cannot be described in this document or on the warning labels on the body of NK-6 Symphony.

Therefore, when handling NK-6 Symphony, it is necessary not only to observe the precautions stated in this document, but also to take safety measures necessary for prosthesis knee joint.

Particularly important matters concerning the safe handling of NK-6 Symphony are described below.

If you have a serious incident related to NK-6 Symphony, please report it to the manufacturer (contact information on the back cover) and the competent authority in your country.

- Read this document thoroughly
Before handling NK-6 Symphony, thoroughly read this document, and sufficiently understand the contents. Strictly observe the safety precautions stated in the document.

About This Document

- Target of this document
This document is intended for the prosthetists to fit the product for prosthetic users.
It covers the following references:
NK-6, NK-6SH, NK-6+L and NK-6SH+L.
- Copy right
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When you have questions about the copyright of this document for copy or reference, contact Nabtesco.
- When this document is lost or damaged
If this document or any related document is lost or damaged, immediately ask the Local sales representative or Distributor (hereinafter, referred to as the Distributor) to reissue it.
Handling NK-6 Symphony without this document can cause accidents.
- Information
The information on this manual is subject to change without prior notice for product improvement.



Contents

1 Safety Precautions.....	P.4
1-1 Contraindications	P.4
1-2 Definition of Symbols.....	P.4
1-3 Mandatory Precautions	P.5
2 Basic Construction and Operational Principle.....	P.7
2-1 Basic Construction	P.7
2-2 Operational Principle.....	P.7
3 Before Use	P.8
3-1 How to Activate the "Stance-Flexion" Function	P.8
3-2 Procedures for Operating the Selective Lock (Optional Function)	P.9
3-3 Precautions for Operating the Selective Lock.....	P.10
3-4 Precautions When Sitting in and Standing up from a Chair	P.11
3-5 Precautions When Wiping Surface Dirt	P.11
4 Troubleshooting.....	P.12
5 Outline of the Product.....	P.13
6 Disposal	P.14
7 Symbols Used on Labels.....	P.15
7-1 UDI Label (Packing Box).....	P.15
7-2 Body Mass Limit Label (Knee Joint Body)	P.15
7-3 Product Type Label (Knee Joint Body).....	P.15

1. Safety Precautions

1-1 Contraindications

- Person who cannot understand how to use the knee and caution for use
- Person who has problem and pain on the residual limb
- Person who weighs over 125kg (if high-active user: over 100kg)
- Use for any sports which give high impact on the knee

1-2 Definition of Symbols

 WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or property damage.
	Indicates a general caution to be observed.
 PROHIBITION	Indicates prohibition of a specific action.
 MANDATORY ACTION	Indicates obligation of a specific action.

1-3 Mandatory Precautions



WARNING



MANDATORY ACTION

Hand the separate User's Guide to the user and explain the instructions for use.

Improper use can cause a fall or injury.



MANDATORY ACTION

Upon detecting any abnormal noise, play, or drop in hydraulic resistance, discontinue use and contact your local sales representative/dealer.

Continued use despite a detected abnormality may cause damage of parts, leading to a fall.



MANDATORY ACTION

This product shall be used as a prosthetic knee joint. Never use it for other purposes.

We do not warrant the product against damage caused by use for any unintended purpose.



MANDATORY ACTION

DO NOT undertake any.

maintenance actions on the device. Maintenance must be carried out by a professional at least every 2 years.



PROHIBITION

DO NOT use for a person who weighs over 125 kg.

NK-6 Symphony was tested for 3 million walking cycles with load of 125kg which corresponds to the average working distance within about 3 years. We will not assume liability for ageing or damage of the product. If used to a person who weighs over 125 kg, damage of parts may occur, leading to a fall. This, however, does not preclude loading and unloading of baggage, etc. occurring in daily life.

ISO 10328-P6-125kg ^{*)}



^{*)} Body mass limit not be exceeded!
For specific conditions and limitations of use see manufacturer's written instructions on intended use!

Specific condition: For persons on a high activity level and persons wearing a hip prosthesis, the weight limit shall be 100 kg.



PROHIBITION

DO NOT place the hand behind the knee when flexing the knee.
DO NOT touch the knee when extending it.

Your hand can be caught, thereby causing injury.



PROHIBITION

Never attempt to disassemble or modify the knee joint.

Parts may be damaged, thereby causing a fall.



PROHIBITION

Never attempt to heat or put in a fire

Risk of fire or explosion.



CAUTION

◆Instructions for storage◆



DO NOT put the product in a high place. DO NOT place it against something in an unstable state.

The product may drop or fall down, thereby causing damage to parts.



DO NOT put anything on the product. DO NOT step on it.

Parts may be damaged.



DO NOT store the product where the temperature may exceed the range of -20 to 50°C.

Parts may be deteriorated or deformed, thereby causing failure.



DO NOT leave the product in a place where it may be exposed to water or moisture.

Parts may rust, thereby causing failure.

◆Instructions for use◆



Do not use the product where the outdoor temperature is lower than -20°C.

The lubricant and rubber parts may harden, thereby causing failure.



Do not use the product near open flame or where the temperature exceeds 50°C.

The plastic parts may be deformed, thereby causing failure.



DO NOT jump down from a high place nor play active sports to intentionally give strong impact to the product.

Parts may be damaged, thereby causing a fall.



DO NOT contact liquids such as water, salt water, chlorinated water, soapy water, gel soap, body fluids and exudates. DO NOT use any detergent or solvent (thinner) for cleaning it.

Could result in rusting, discoloration, desiccation of the grease, could result in a malfunction and abnormal noises.

2. Basic Construction and Operational Principle

2-1 Basic Construction

The NK-6 Symphony consists of a 6-bar linkage which controls the stance phase and a hydraulic cylinder which controls the swing phase. The selective lock with which the user can lock the knee by himself/herself can be chosen at the user's option.

(Model : NK-6+L, NK-6SH+L)

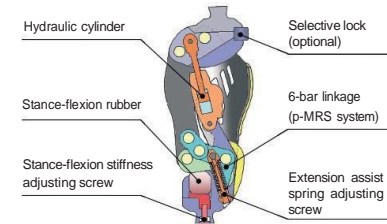


Fig. 1 Main Components

2-2 Operational Principle

The geometric self-locking system reliably functions while the prosthesis is in contact with the floor, thus preventing abrupt buckling. When the prosthesis leaves the floor, the hydraulic cylinder functions, providing cadence responsive swing control.



Fig. 2 Walking on a Level Floor

3. Before Use

3-1 How to Activate the “Stance-Flexion” Function

Fig. 3 shows how to load the prosthesis equipped with this knee joint. When the weight is placed on the heel as shown in the left figure while the knee is completely extended, the knee is automatically locked (self-locked) and slightly flexed (stance-flexion). The maximum flexion angle is 10° depending on the loading method and the setting of the adjustment. If the weight is placed on the toe as shown in the right figure, the lock is released.

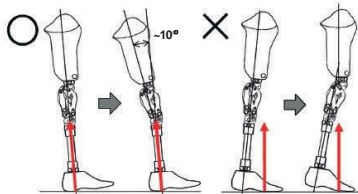


Fig. 3 Differences in self-lock function depending on loading method



Until getting used to use the product, place your weight on the prosthesis while holding on the parallel bars, and confirm the self-locking function. Thoroughly understand the mechanism and the function prior to use.



In a standing posture, put the prosthesis slightly forward, and weight on the heel while fully extending the knee. If the weight is placed when the knee is not fully extended or prior to toe-off, knee buckling may occur, and the user may fall down. Particularly users who have a habit of standing with their prostheses slightly backward shall keep this in mind.

3-2 Procedures for Operating the Selective Lock (Optional Function)

The selective lock is to be operated by the user. The user shall thoroughly understand the operating procedures.

The selective lock mechanism has a switch above the knee joint to switch the lock mode on or off. However, the lock switch cannot be operated while the knee is flexed. The joint can be locked when the knee is fully extended.

[Locking procedure]

As shown in Fig. 4, slide the lock switch in front of the knee plate in the arrow direction.

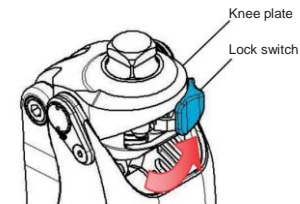


Fig. 4 Locking Procedure

[Unlocking procedure]

As shown in Fig. 5, slide the lock switch in front of the knee plate in the arrow direction.

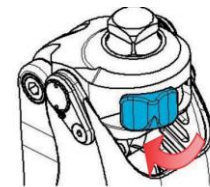



Fig. 5 Unlocking Procedure


3-3 Precautions for Operating the Selective Lock


[Precautions for locking operation]

 Before starting to walk, make sure that the selective lock is securely activated.

To operate the selective lock, slide the switch surely to the position shown in Fig.4 (A click will sound.) Although the lock can be activated before the position shown in Fig.4, the lock parts may be damaged if the product is used in such a state.

[Precautions for unlocking operation]

 After releasing the selective lock, make sure that the knee can be normally flexed before starting to walk.

To release the selective lock, slide the switch surely to the position shown in Fig.5 (A click will sound.)
 The lock cannot be released if the switch is stopped before the position shown in Fig.5 Slide it correctly.

[Cosmetic foam cover]

Note that the cosmetic foam cover may be broken depending on the way of operating the selective lock if the lock is used with the cover fitted.

3-4 Precautions When Sitting in and Standing up from a Chair

- When sitting in a chair, never place the hand behind the knee. The hand can be caught in the swaying part of the hydraulic cylinder, causing serious injury.

- When standing up from a chair, never place the hand on the knee. Fingers can be caught between the knee plate and the front link, causing serious injury. For ease of standing up from a chair, placing hands on the armrests or on the seating face* is recommended.



- * In addition to the above, placing a hand on the socket or placing both hands on the sound leg also facilitate standing up from a chair. Provide instructions on the safe method according to the user's circumstances.

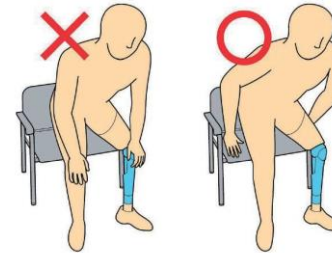


Fig. 6 Recommended Posture When Standing up from a Chair

3-5 Precautions When Wiping Surface Dirt

If necessary, wipe the surface with a soft cloth moistened with fresh water.

Make sure that no moisture or lint from the cloth remains after wiping. Rust and lint caught in the knee may cause abnormalities in the rotating part and affect the bending and stretching of the knee.




4. Troubleshooting

Status	Items to be checked	Countermeasures
The self-lock cannot be activated.	Check if body weight is applied properly.	Practice how to fully apply body weight to the heel.
	Check for proper alignment.	Adjust the alignment so that body weight can be fully applied to the heel (See 3-2-1).
	Check if the foot is appropriate.	Select a foot with which body weight can be fully applied to the heel.
	The above measures cannot resolve the problem.	Contact your prosthetist.
The joint does not fully extend before the heel contacts to the ground.	Check if the adjusting valve (E) on the extension side of the hydraulic cylinder is not tightened excessively.	Contact your prosthetist.
The self-lock is not released unintentionally, thereby causing sticking.	Check if smooth heel-to-toe weight shift is achieved while walking.	Practice how to walk to place sufficient load on the toe when pushing off the prosthesis.
	The above measures cannot resolve the problem.	Contact your prosthetist.
The selective lock cannot be activated.	Check if the knee joint is fully extended.	When operating the switch, fully extend the knee.
	Check if the cosmetic foam cover is not involved.	Take care that the cosmetic foam cover is not caught.
	The above measures cannot resolve the problem.	Contact your prosthetist.
Abnormal noise or rattling occurred.	Check if a foreign object is caught in the moving part.	Remove it if possible.
	The above measures cannot resolve the problem.	Contact your prosthetist.

5. Outline of the Product

• Specifications



Model No.	NK-6	NK-6L	NK-6SH	NK-6SH+L
Proximal Connection	Male Pyramid Adapter		Screw Head	
Selective Lock	—	O	—	O
Total Length	197mm		191mm	
A ref. measurement	14mm		14.5mm	
B ref. measurement	156mm		156mm	
Weight	920 g	970 g	960 g	1010 g
Max. Knee Flexion Angle	170°			
Material	Titanium & Aluminum			
Max. Body Weight	125kg (100kg For Hip Prosthesis & High Active User) Compliance with ISO 10328 P6 (A-125kg)			
Applicable activity level for user	K 2 ~ K 4			

* These specifications are subject to changes without prior notice.

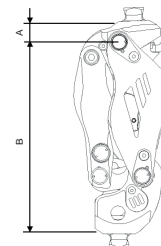


Fig. 7 Installation Height

• Lifetime: 6 years

• Features

1 Smooth walking

The product is named "Symphony" because the knee smoothly harmonizes between the stance phase and swing phase control. The p-MRS system controls shifting from the stance phase to the swing phase seamlessly.

2 High stability of stance and Stance-Flexion function

The 6-bar linkage using the p-MRS system identifies floor reaction force positions and controls the knee stability. The Stance-Flexion feature will reduce an impact at the heel strike and also reduce bobbing of center-of-mass.

3 Locking of knee by selective lock (optional)

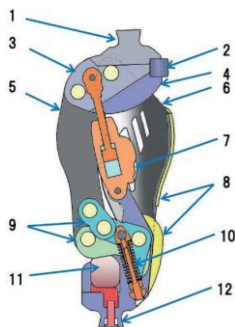
The user can lock the knee by himself/herself. Whenever the user needs stability, for example, while working at standing posture, walking on snowy road, in strong winds or on irregular ground, he/she can lock his/her knee to completely prevent knee buckling.

6. Disposal

The table below shows the materials of the NK-6 Symphony knee unit in each component. When disposing of the knee joint, comply with the rules stipulated in the local community. If you return it to Nabtesco after giving such a notification, we will dispose of it for you.



	Part name	Classification of material	Remarks
1	Alignment block	Metal	Pyramid type: titanium alloy Screw head type: iron alloy
2	Lever	Metal	Aluminum alloy
3	Knee plate	Metal	Aluminum alloy
4	Knee cover	Plastic	Refer to each material symbol on each.
5	Rear link	Metal	Aluminum alloy
6	Front link	Metal	Titanium alloy
7	Hydraulic cylinder	Metal	Body: aluminum alloy Piston: iron alloy O-ring: rubber
8	Front link cover Base bracket cover	Plastic	Refer to each material symbol on each.
9	Base link Supplementary link	Metal	Titanium alloy
10	Spring	Metal	Iron alloy
11	Stance-flexion rubber	Rubber	
12	Alignment block	Metal	Titanium alloy



7. Symbols Used

7-1 UDI Label (Packing Box)



- Legal manufacturer
- Made date
- Medical device
- Item number
- Serial number
- Global Trade Item Number
- Authorized representative for EU countries
- The maximum and minimum temperatures for storing, transporting, and using the product.
- Declaration of conformity according to the European Regulation 2017/745
- Single patient multiple use

7-2 Body Mass Limit Label (Knee Joint Body)

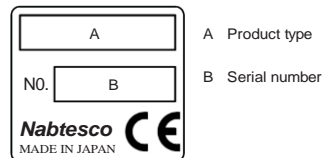
MAX. WEIGHT
~K3 (MOB3): 125kg
K4 (MOB4): 100kg

Body mass limit not to be exceeded.

■ K Level

- K1 Level : User can move to a bed or chair, and can walk on a flat surface indoors at a constant speed.
- K2 Level : User can handle small environmental barriers such as curbs, steps, or irregular ground both indoors and around the home.
- K3 Level : User can handle most environmental barriers and can walk at different speeds. In addition to simple walking, he/she can do light work and exercise as well.
- K4 Level : User has physical abilities higher than basic walking; children, athletes, etc.

7-3 Product Type Label (Knee Joint Body)



Declaration of conformity according to the European Regulation 2017/745

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