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Nabtesco

For Prosthetists

6-Bar Hydraulic Knee Joint NK-6 Symphony

Instruction Manual

6-Bar Hydraulic Knee NK-6 Symphony™

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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 response to the walking speed through unique 6-bar linkage system and hydraulic cylinder.

Before using the product, read this Instruction Manual, and understand the correct procedures for using. Keep it handy for future reference. Hand the separate User's Guide to the user, and explain the instructions for use.

Contents

MEMO

1-1 Definition of Symbols

	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	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.
	Indicates prohibition of a specific action.
	Indicates obligation of a specific action.

1-2 Mandatory Precautions

WARNING

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

Improper use can cause a fall or injury.

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.

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.

MEMO

8. Outline of the Product

● Specifications

Model No.	NK-6	NK-6+L	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	920g	970g	960g	1010g
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)			
Mobility Grade	Low ~ Mid Active (K-Level 2+3. Mobility Class 2+3)			

* These specifications are subject to changes without prior notice.

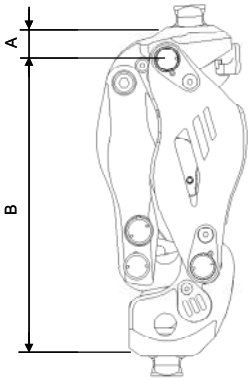

Fig.23 Installation Height

● 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.

PROHIBITION

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

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 manufacture'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.

CAUTION

Make adjustments in accordance with the adjustment procedures stated in the Instruction Manual.

Improper adjustments may result in poor performance.

When making a socket, ensure that the socket or the buttock is in contact with the foot part at the maximum flexion angle.

If the socket or the buttock is not in contact with the foot part, excessive load may be applied to the knee joint, thereby causing damage of parts.

DO NOT drop parts such as a screw in the frame.

Continued use after any part is dropped may cause damage of a pneumatic cylinder, impending normal walking.

DO NOT immerse the product in any liquid such as water and seawater.

Parts may rust, thereby causing failure.

7-3 Removing the Base bracket cover

Remove the Base bracket cover by following procedures when replacing the extension stopper rubbers or the stance-flexion rubber as described in 7-1 or 7-2.

1. Spread the Base bracket cover sideling
2. Remove the whole of the cover toward the anterior direction.

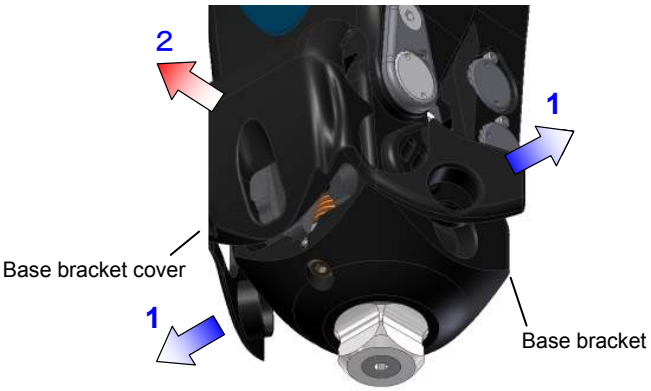

Fig.22 Detaching the Base bracket cover

7-2 Replacing the Stance-Flexion Rubber

If looseness or abnormal noise occurs when the self-lock is activated, replace the stance-flexion rubber*2.

*2 The stance-flexion rubber is an expendable. The rubber may deteriorate earlier under some use conditions. When replacing it, purchase the stance-flexion rubber replacement kit (N-G011(NORMAL)or N-G012(HARD)).

1. Push out the rubber inserting a slotted screwdriver to the side hole as shown in Fig. 20. Working from the holes in both sides can facilitate removal of the rubber.
2. As shown in Fig. 21, push the new stance-flexion rubber with the chamfered side on the knee joint side. The rubber is so hard that it cannot be inserted smoothly. To fit it easily, clamp the body with a vise or the like.

CAUTION

Make sure that the chamfered side of the stance-flexion rubber is correctly located. If it is fitted in the opposite direction, it may be damaged, or it may come off during use.

Fig. 20 Removing the Stance-Flexion Rubber

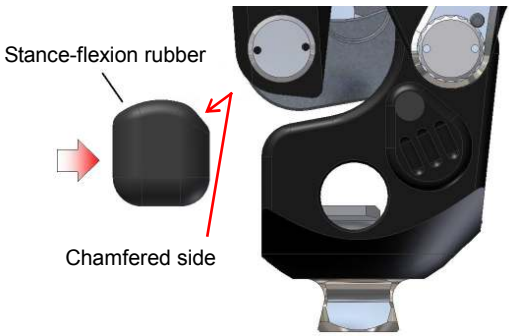

Fig. 21 Inserting the Stance-Flexion Rubber

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: NK6+L, NK-6SH+L)

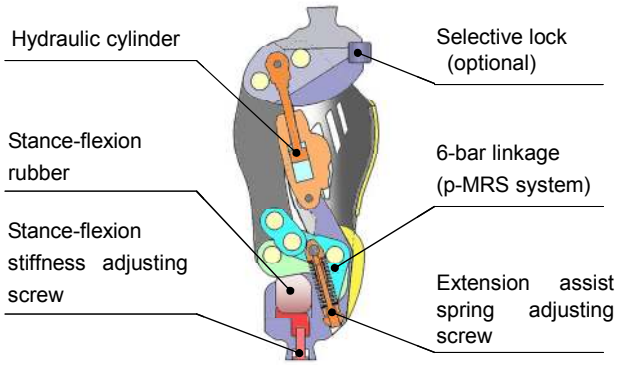

Fig. 1 Main Components

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

2-3 Stance Phase Control

- p-MRS system (Polycentric-Mechanism of Stance-Flexion Stiffness Sensing)

  The 6-bar linkage detects the floor reaction force position and controls the stance phase. The center of rotation of this linkage system, the sensing point is located around the toe break. If the floor reaction force is applied on the heel side from the sensing point, the knee joint geometrically locks the knee flexion, and if it is applied on the toe side from the sensing point, the lock is released. Since the stance phase is controlled according to the position of the floor reaction force, the stance phase control works reliably at a low heel contact load and is released smoothly at the push-off stage. This leads to the user's relief and smooth shifting to the swing phase.

Fig. 3 p-MRS System

- Stance-Flexion

  The knee joint provides a stance flexion during from the heel-contact to the mid-stance. This feature results in absorbing shocks at the heel-strike and reducing bobbing of center-of-mass.

  The amount of the stance flexion can be easily adjusted to maximum 10 degrees.

Fig. 4 Stance-Flexion

7. Maintenance

7-1 Replacing the Extension Stopper Rubber

Replace the extension stopper rubber*1 when terminal impact occurs in the swing phase (if the impact cannot be eliminated by adjusting the valve (E) on the extension side of the hydraulic cylinder).

*1 The extension stopper rubber is an expendable. The rubber may deteriorate earlier under some use conditions. When replacing it, purchase the extension stopper rubber replacement kit (N-G010).

1. Remove the hexagon socket head machine screw (M3) using a 2 mm hexagonal wrench, and remove the rubber cover.
2. Remove the extension stopper rubber. It can be removed easily if the knee joint is in the stance-flexion state.
3. Insert the new extension stopper rubber in the direction shown in Fig. 19. It can be inserted easily if the knee joint is in the stance-flexion state.

CAUTION

Insert the rubber with the front oval protrusion pointing toward the rear of the knee joint. If it is fitted in a wrong direction, it cannot be inserted correctly.

4. Fit the rubber cover, and tighten the hexagon socket head machine screw after applying an appropriate amount of LOCTITE 243 (or its equivalent) to the threaded portion of the screw.
   [Tightening torque: 1.0 N·m]
5. Perform the same on the opposite side.
   (2 places on the right and left sides)

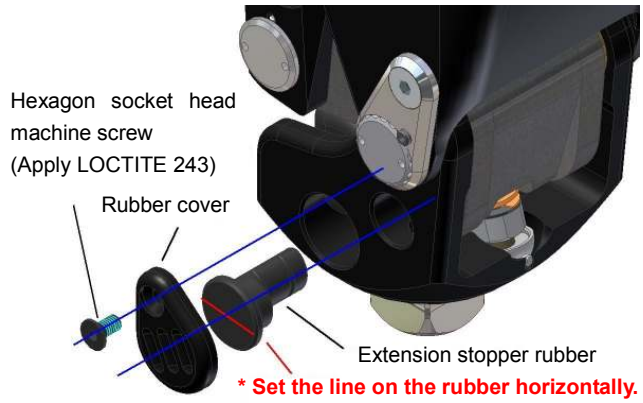

Fig. 19 Replacing the Extension Stopper Rubber

Status	Items to be checked	Countermeasures
The self-lock cannot be activated even if the stance-flexion rubber is adjusted.	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 local sales representative/dealer.
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.	Loosen the adjusting valve (E) on the extension side.
	The above measures cannot resolve the problem.	Contact your local sales representative/dealer.
The self-lock is not released unintentionally, thereby causing sticking.	Check if smooth heel-to-toe weight shift is achieved while walking.	Teach the user how to walk to place sufficient load on the toe when pushing off the prosthesis.
	Check for proper alignment.	Adjust the alignment so that body weight can be fully applied to the toe(See 3-2-1).
	Check if the stance-flexion rubber is stiff.	Tighten the stance-flexion stiffness adjusting screw.
	The above measures cannot resolve the problem.	Contact your local sales representative/dealer.
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 local sales representative/dealer.

2-4 Swing Phase Control

A hydraulic cylinder is used for swing phase control. The swing phase is controlled based on the hydraulic resistance generated when the knee is flexed and extended. The resistance at the initial swing phase is kept at a low level so that the user can initiate the swing phase easily, and the resistance is increased when the flexion angle is 40˚ or more. This provides the user a comfortable walking and less fatigue as if wearing a pneumatic knee joint, and also powerfully response to various walking speeds.

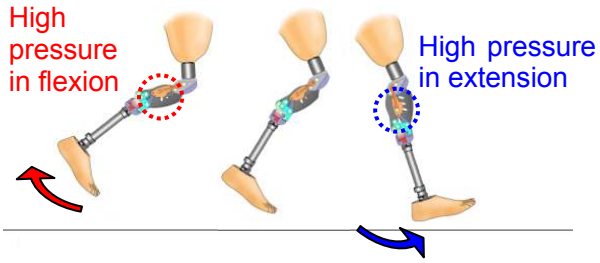

Fig. 5 Swing Phase

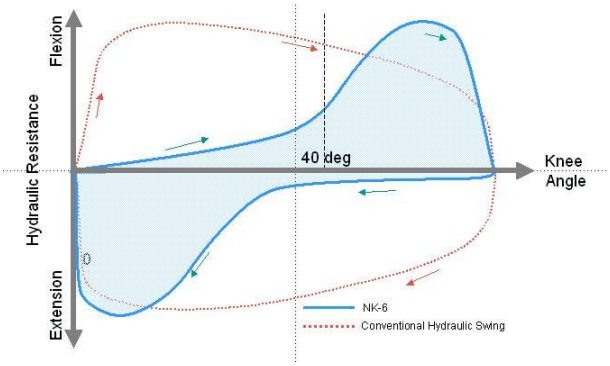

Fig. 6 Hydraulic Resistance

3. Before Use

3-1 Scope of Delivery

Please confirm that the following items are included.

- NK-6 Symphony ·····1
- User's Guide ·····1

(After explaining the instructions for use, hand it to the user.)

- Instruction Manual (this document) ·····1

3-2 Assembly Procedure

3-2-1 Static Alignment

Perform static alignment according to the following procedure.

● Alignment of frontal plane

Complete alignment so that the load line passes through the center of the knee joint and falls in the heel center of the foot section.

● Alignment of sagittal plane

As shown in Fig. 7, complete alignment so that the weight load line passes through the center of the knee axis of the knee joint within a deviation of ±5 mm (0 mm recommended).

Improper alignment may result in poor self-lock performance. Excess load applied to the parts may accelerate wear.

CAUTION

For users who wear hip prostheses and play any sports such as golf, use of a torsion adapter is recommended. If the adapter is not used, large torsion force will be applied to the prosthesis, and wear of parts may be accelerated.

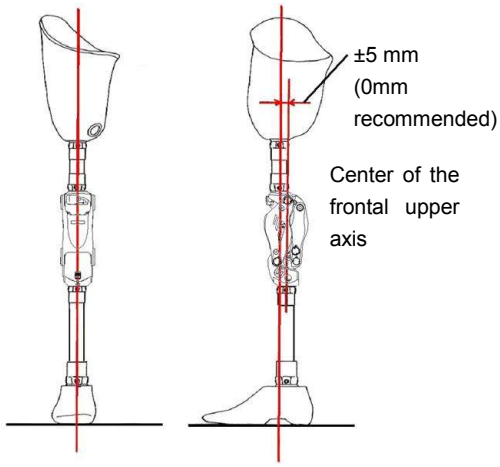

Fig. 7 Statistic Alignment

5-4 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 linkages, causing serious injury. For ease of standing up from a chair, placing hands on the armrests or on the seating face* is recommended.

WARNING

* 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 way according to the user's circumstances.

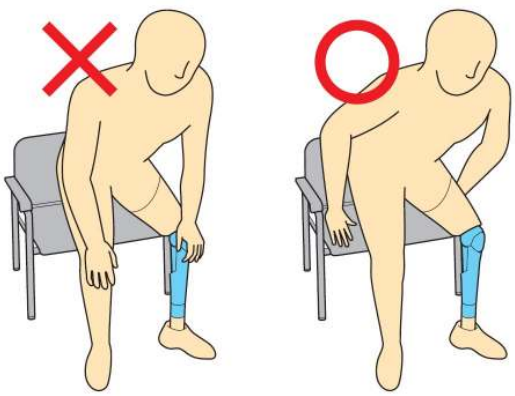

Fig.18 Recommended Posture When Standing up from a Chair

5-3 Precautions for Operating the Selective Lock

[Precautions for locking operation]

CAUTION

Instruct the user to make sure that the selective lock is securely activated before starting to walk.

CAUTION

To operate the selective lock, slide the switch surely to the position shown in Fig. 16. (A click will sound.) Although the lock can be activated before the position shown in Fig. 16, the lock parts may be damaged if the product is used in such a state.

[Precautions for unlocking operation]

CAUTION

Instruct the user to make sure that the knee can be normally flexed after releasing the selective lock before starting to walk.

CAUTION

To release the selective lock, slide the switch surely to the position shown in Fig. 17. (It will click.) The lock cannot be released if the switch is stopped before the position shown in Fig. 17. Slide it correctly.

[Cosmetic foam cover]

The cosmetic foam cover may be broken depending on the way of operating the selective lock if the foam cover is fitted over the prosthesis. Give a sufficient explanation to the user.

3-2-2 Precautions on socket fabrication

Make the socket in such a way that the socket or the buttock is in contact with the foot part when the knee joint is flexed at the maximum flexion angle.

If the socket or the buttock is not in contact with the foot part, excessive load may be applied to the knee joint, thereby causing damage of parts.

CAUTION

While making a prosthesis, do not touch the knee joint when the knee is flexed and extended. Your hand can be caught, thereby causing injury.

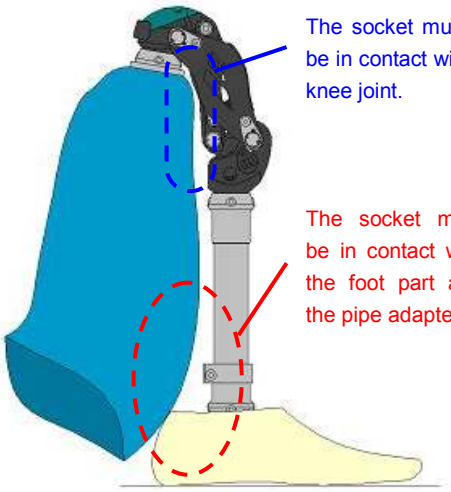

Fig. 8 Contact of socket at the maximum flexion angle

4-1 Adjusting the Stance Phase Control

4-1-1 Adjusting the stance-flexion rubber

For adjustment of the stance phase control, adjust the stiffness of the stance-flexion rubber.

- Adjust the adjusting screw (marked B) shown in Fig. 9 with a 3 mm hexagonal wrench.
- Turning the screw clockwise increases the stiffness and decreases the degree of bouncing. Turning it counterclockwise decreases the stiffness and increases the degree of bouncing.

CAUTION

If the stiffness of the stance-flexion rubber is too high, the self-lock may not work properly. Adjust the stiffness appropriately to the body weight and/or the impact at the heel strike.

CAUTION

Do not loosen the adjusting screw until its head is lower than the bottom of the pyramid (sealing surface). Doing so may drop the screw.

* When the head of the adjusting screw is set on the same level as the pyramid bottom, the stiffness of the stance-flexion rubber is lowest.

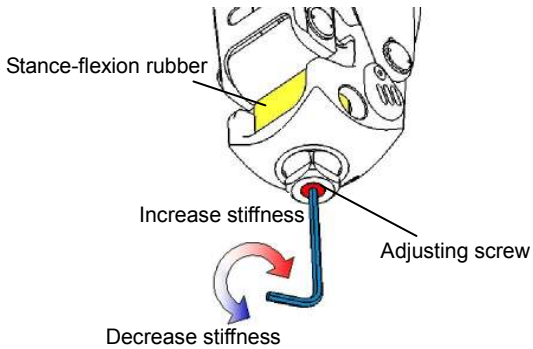

Fig. 9 How to Adjust Stance-Flexion Stiffness

IMPORTANT

The adjusting screw has been set to a position which is common to most people in the factory default setting. When you are unable to find a suitable position, turn the screw to its original position.
Standard setting: A position obtained by turning the screw fully clockwise to tighten and loosening it four turns

5-2 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. 16, slide the lock switch in front of the knee plate in the arrow direction.

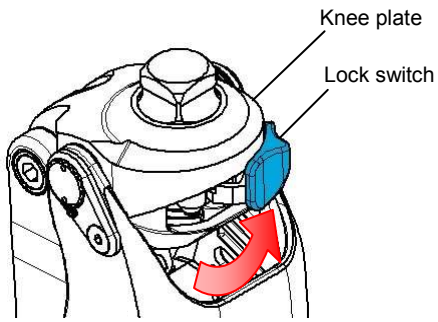

Fig. 16 Locking Procedure

[Unlocking procedure]

As shown in Fig. 17, slide the lock switch in front of the Knee-Plate in the arrow direction.

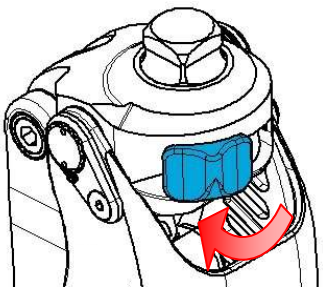

Fig. 17 Unlocking Procedure

5. Operation Procedures and Precautions

5-1 How to Activate the "Stance-Flexion" Function

Fig. 15 shows how to apply the body weight to the prosthesis. When the weight is placed on the heel as shown in the left figure while the knee is fully extended, the knee is automatically locked (self-locked) and slightly flexed (stance-flexion). The maximum flexion angle is 10˚ depending on the load and the setting of the adjustment. If the weight is placed on the toe as shown in the right figure, the lock is released.

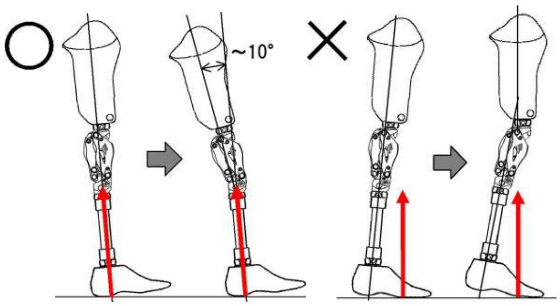

Fig. 15 Differences in the Self-Lock function depending on floor reaction force

CAUTION

Until the user gets used the knee joint, confirm that he/she understands the self-locking function while holding on the parallel bars and placing weight on the prosthesis. He/she should be thoroughly familiarized with the function prior to use.

In a standing posture, put the prosthesis slightly forward, and weight on the heel side while fully extending the knee. If the weight is placed when the knee is not fully extended or the toe side is in contact with the floor, 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.

CAUTION

Instruct the user to put the prosthesis slightly forward in a standing posture and place weight on the heel side while fully extending the knee. If the weight is placed when the knee is not fully extended or the toe side is in contact with the floor, knee buckling may occur, and the user may fall down. Give a sufficient explanation particularly to users who have a habit of standing with their prostheses slightly backward.

4-1-2 Adjusting the extension assist spring

The extension assist spring keeps the knee joint in the full extension when the prosthesis is lifted from the floor.

- Adjust the adjusting bolt shown in Fig. 10 with a 2.5 mm hexagonal wrench.
- To increase the extension assist force, turn the bolt clockwise. To reduce the force, turn it counterclockwise.

CAUTION

If the extension assist force is too low for the prosthesis, there is a possibility of landing with the knee flexed, and the user may fall down due to knee buckling.

Adjust the spring so that the foot can contact to the ground with the knee fully extended.
The adjusting screw has stoppers between the maximum and minimum positions. It can be adjusted in the range of about four turns.

CAUTION

If the adjusting bolt is turned to an excessively high torque, it may be damaged.

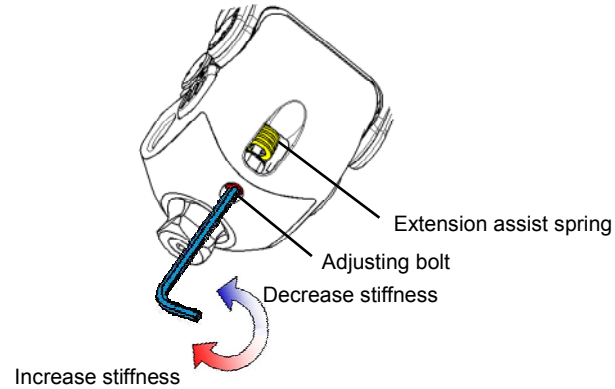

Fig. 10 How to Adjust the Extension Assist Spring

IMPORTANT

The adjusting screw has been set to a position which is common to most people in the factory default setting. When you are unable to find a suitable position, turn the screw to its original position.

Standard setting: A position obtained by 3 turning counterclockwise from fully tightened position.

4-2 Adjusting the Swing Phase Control

To adjust the swing phase control, select appropriate flexion and extension resistances using the two adjusting valves of the hydraulic cylinder.

4-2-1 Adjusting the flexion resistance of hydraulic cylinder

At first, adjust the flexion resistance.

As shown in Fig. 11, the flexion adjusting valve (F) is located on the right when viewed from the user. As shown in Fig. 12, the scale is graduated from “1” to “8”. “1” corresponds to the highest hydraulic resistance, and “8” corresponds to the lowest.

(Reference) Factory default: “8”

To adjust the valve, use a 2mm hexagonal wrench. Insert the wrench from the lowest hole in the front link side face.

CAUTION

This hydraulic cylinder is intended for swing phase control. Do not use it for any other purpose. If the prosthesis is used under overload, for example, by applying the body weight at a high flexion resistance, it may be damaged.

4-2-2 Adjusting the extension resistance of hydraulic cylinder

If terminal impact occurs at the end of the swing phase, adjust the extension resistance. As shown in Fig. 13, the extension adjusting valve (E) is located on the left when viewed from the user. As shown in Fig. 14, the scale is graduated from “1” to “8”. “1” corresponds to the highest hydraulic resistance, and “8” corresponds to the lowest.

(Reference) Factory default: “8”

To adjust the valve, use a 2mm hexagonal wrench. Insert the wrench from the center hole in the front link side face.

CAUTION

If the extension resistance is set too high, the knee does not extend fully, thereby causing falling.

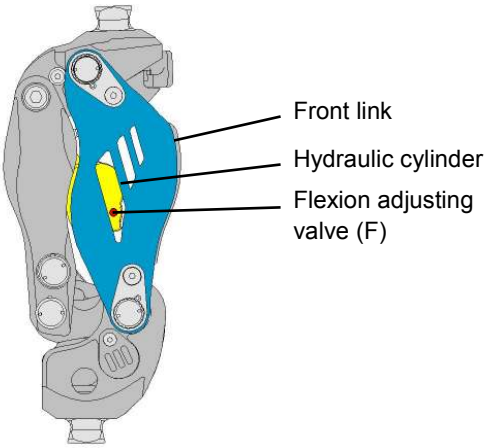

Fig. 11 Location of the Flexion Adjusting Valve

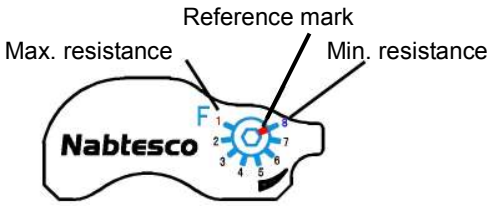

Fig. 12 Graduated Scale of the Flexion Adjusting Valve

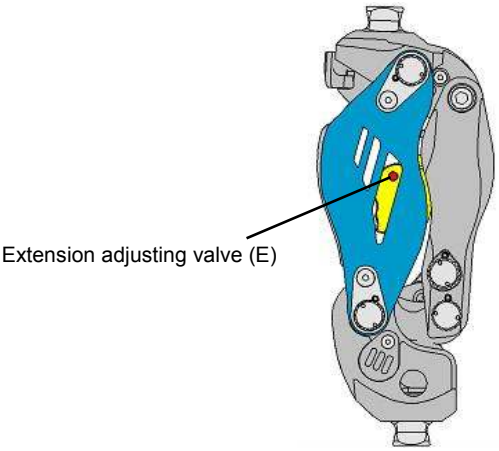

Fig. 13 Location of the Extension Adjusting Valve

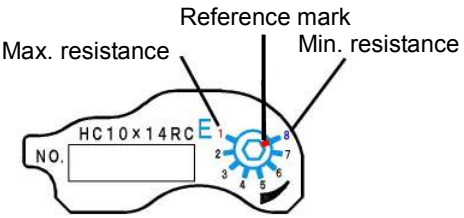

Fig. 14 Graduated Scale of the Extension Adjusting Valve