Nabtesco

HybridKnee

User's Guide

(NI-C3 Series)

Language: English

Introduction

Thank you for purchasing Nabtesco's Hybrid Knee.
Hybrid Knee is a totally new intelligent prosthetic knee joint that integrates hydraulic and pneumatic control with computer control to provide safe and pleasant walking.
This user's guide (hereinafter referred to as this document) was produced by Nabtesco Corporation to ensure safe and comfortable use of Hybrid Knee.
This document describes matters concerning typical usage such as fitting and walking, maintenance, and cautionary notes that anyone utilizing Hybrid Knee needs to know.

Important Information

Intended purpose of Hybrid Knee

Hybrid Knee was designed and is manufactured for use as a prosthetic knee joint by above-knee amputated, knee disarticulated, and hip disarticulated patients. Do not use Hybrid Knee for any other purposes. For hip prostheses, it is recommended to use a torsion adapter to prevent significant torsion from being applied to Hybrid Knee. This device is intended for single patient multiple use.
For the specifications for Hybrid Knee, see 9. Product Overview.

■ **Do not use Hybrid Knee outside of the specification range. Do not modify the main body or parts.**
Doing so can cause injury or damage Hybrid Knee.

Cautions for handling Hybrid Knee safely

Nabtesco Corporation (hereinafter referred to as "Nabtesco") cannot foresee all potential residual risks of Hybrid Knee and risks resulting from human errors and the usage environment. Although there are many instructions and prohibitions for handling Hybrid Knee (assembling, adjusting, and maintaining the prosthesis), all these matters cannot be described in this document or on the warning labels on the body of Hybrid Knee.
Therefore, when handling Hybrid Knee, it is necessary not only to observe the precautions stated in this document, but also to take the safety measures necessary for a prosthesis knee joint. Particularly important matters concerning the safe handling of Hybrid Knee are described below.

Read this document thoroughly

Before handling Hybrid Knee, thoroughly read this document, and sufficiently understand the contents. Strictly observe the safety precautions stated in the document.

Qualification of assemblers and adjusters

Anyone assembling or adjusting Hybrid Knee must have attended Hybrid Knee license seminars and be a licensed prosthetist. Outsourcing to anyone else is strictly prohibited.

About This Document

Target of this document

This document is intended for patients who are fitted with a Hybrid Knee.
It covers the following references: NI-C311, NI-C311s, NI-C313, NI-C313s.

Copyright

If 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 Hybrid Knee without this document can cause accidents.

Information

The information in this manual is subject to change without prior notice for product improvement.

Table of Contents

1 Safety Precautions

1-1 Contraindications

The following users cannot use Hybrid Knee.

- Persons who cannot understand how to use the knee and the precautions for use
- Persons experiencing pain in the amputated limb
- Persons who weigh over 125 kg (or over 100 kg for highly-active users)
- Persons who engage in sports that put a significant burden on the knee

1-2 Definition of Symbols

 WARNING	**Indicates a potentially hazardous situation which, if this symbol is not observed, could result in serious injury.**
 CAUTION	**Indicates a potentially hazardous situation which, if this symbol is not observed, could 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 to perform a specific action.**

1-3 Mandatory Precautions

WARNING

Mandatory Action

Upon detecting any abnormal noise, looseness, 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 falling.

Prohibition

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

If used for a person who weighs over **125** kg, damage of parts may occur, leading to falling. This, however, does not preclude loading and unloading of baggage, etc. occurring in daily life.

***For K4 individuals, the weight limit is 100 kg.**

Prohibition

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

The hand can be caught, causing injury.

Prohibition

Never attempt to disassemble or modify Hybrid Knee.

Failure to observe this warning can cause breakage of parts, leading to falling.

Prohibition

DO NOT attempt to charge, disassemble, heat, or short-circuit the battery, and DO NOT dispose of it in a fire.

Failure to observe this warning can cause an explosion or fire.

CAUTION

Mandatory Action

Be sure to attend the operation training course offered by your local sales representative/dealer.

Incorrect adjustment can prevent pleasant walking.

Mandatory Action

Be sure to undergo periodic inspection every two years.

If Hybrid Knee is used without inspection, parts can become worn down more quickly.

Prohibition

A socket should be formed and aligned so that neither the socket nor any other part contacts the pneumatic cylinder at the maximum flexion angle.

It will damage the pneumatic cylinder, impeding normal walking.

Prohibition

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

Continued use after any part is dropped will damage the pneumatic cylinder, impeding normal walking.

Prohibition

DO NOT allow contact with liquids such as water, salt water, chlorinated water, soapy water, gel soap, bodily fluids, and exudations. DO NOT use any detergent or solvent (thinner) for cleaning.

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

Prohibition

DO NOT leave or store in an environment with a temperature of less than -20°C/-4°F or more than +60°C/140°F

Doing so could result in a malfunction.

1-4 Compatible Medical Devices (Prosthesis Components)

Hybrid Knee reference	NI-C311, NI-C311s	NI-C313, NI-C313s
Proximal connectors	Female pyramidal connectors	M36 screw connectors
Distal connectors	φ34 tube adapter	φ34 tube adapter

2 Certification of International Standard

Structural durability

Hybrid Knee was tested for 3 million walking cycles with a load of 125 kg which corresponds to the average walking distance for 3 years. We will not assume liability for ageing or damage of the product due to long-term usage.

*For products with an extended warranty, the replacement of structural parts during periodic inspections is covered by the warranty.

ISO10328-P6-125kg*) 

***) The body mass limit is not to be exceeded. For specific conditions and limitations of use, see the manufacturer's written instructions on intended use.**

K Level (MOB)

K2 Level (MOB2): User can handle small environmental barriers such as curbs, steps, or uneven ground, both indoors and around the home.

K3 Level (MOB3): 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 (MOB4): User has physical abilities higher than basic walking. This includes children and athletes.

EMC Information

Hybrid Knee belongs to Group 1 and Class A equipment in accordance with IEC/EN60601-1-2. Hybrid Knee requires special precautions regarding EMC (Electromagnetic Compatibility) and need to be installed, put into service, and used according to the following information.

CAUTION

- **Do not use any cables other than the cables that are provided or specified by the manufacturer, Nabtesco Corporation.**
- **Do not use any chargers, accessories, or peripheral devices except those sold by Nabtesco Corporation.**
  Doing so may increase the emission of, or decrease the resistance to, electromagnetic waves of Hybrid Knee.
- **Do not use Hybrid Knee near other electronic equipment. Portable and mobile RF communications equipment can affect Hybrid Knee. If you must use Hybrid Knee near such equipment, be sure to ensure safety.**
- **Please carefully read this instruction manual to avoid the risk of ignition or electric shock.**

Declaration of Conformity

Nabtesco Corporation hereby declares that the following Class I medical device complies with the essential health and safety requirements of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

3 Basic Construction and Operational Principle

3-1 Basic Construction

Hybrid Knee has accomplished sophisticated integration of the hydraulic rotary damper to control the stance phase, the MRS system, and the microprocessor-controlled pneumatic cylinder for the swing phase.

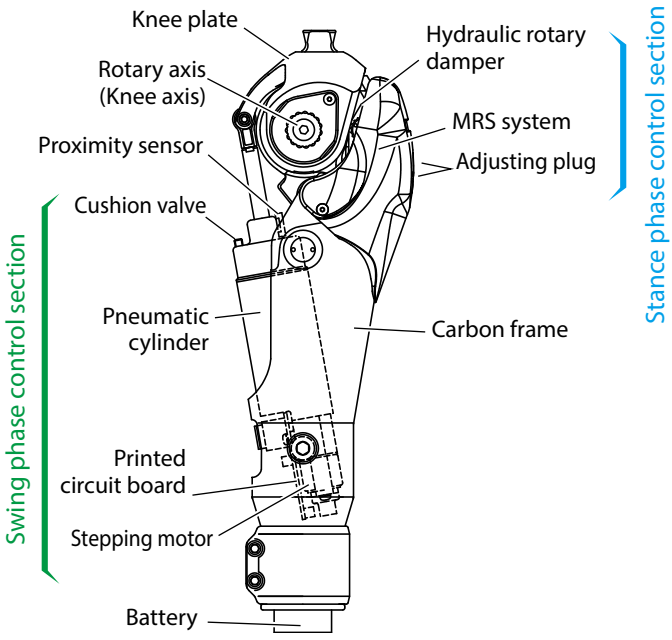


Fig. 1 Main Components

3-2 Operational Principle

The hydraulic rotary damper reliably functions while the prosthesis is in contact with the floor, thus preventing abrupt buckling. When the prosthesis leaves the floor, the microprocessor-controlled pneumatic cylinder functions, providing swing control that responds to cadence.

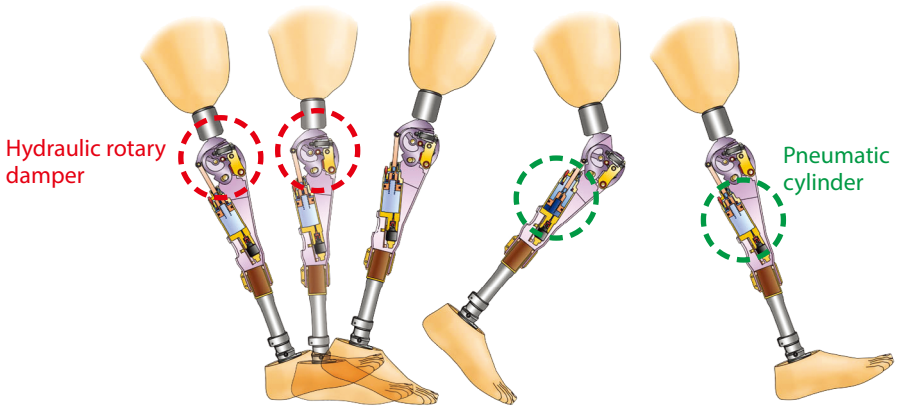


Fig. 2 Level Floor

3-3 Stance Phase Control

When the knee is flexed, the hydraulic rotary damper produces hydraulic resistance, thus preventing abrupt buckling. The **MRS** (**M**echanism of **R**eaction Force **S**ensing) system mechanically detects floor reaction force and sets hydraulic resistance to be ON or OFF. When floor reaction force exists at the heel side from the sensing point, hydraulic resistance is turned on. When it exists at the toe side, the hydraulic resistance is turned off.

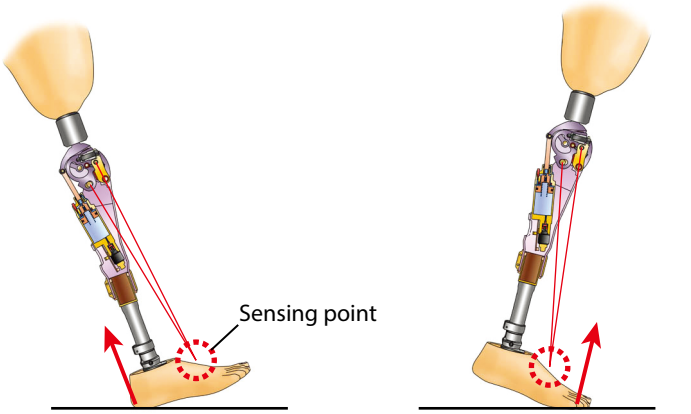


Fig. 3 MRS System

● Yielding function

By having the heel land first, the patient can slowly flex the knee while applying body weight to the knee. After getting familiar with the yielding function, he/she can perform various acts such as descending a slope or stairs.

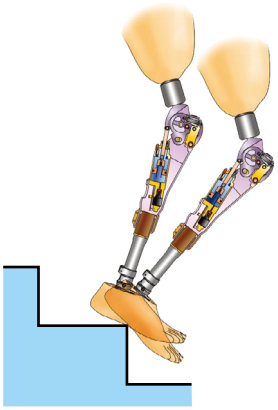


Fig. 4 Stairs

WARNING

In order to make the yielding function effective, be sure to strike the floor with the heel first. Striking the floor with the toe first will turn off hydraulic resistance, meaning the body weight cannot be supported.
There is a risk that knee buckling may occur, causing falling-down. For safe use, fully understand the operational principle and proper walking method, and provide the patient with instructions.

Note: **Hybrid Knee** is intended to assist the capability of a person who uses a prosthesis. Nobody can descend a steep slope or stairs without proper gait training.

3-4 Swing Phase Control

The microprocessor calculates the time for one walking cycle by using data on knee joint flexion as detected by the proximity sensor. Also, this microprocessor stores a maximum of 10 stages of adjustment data, which consists of the cadence and reaction force of the pneumatic cylinder, for each patient. When cadence changes, the microprocessor commands the stepping motor to activate the needle valve immediately to select a swing speed for the prosthesis.

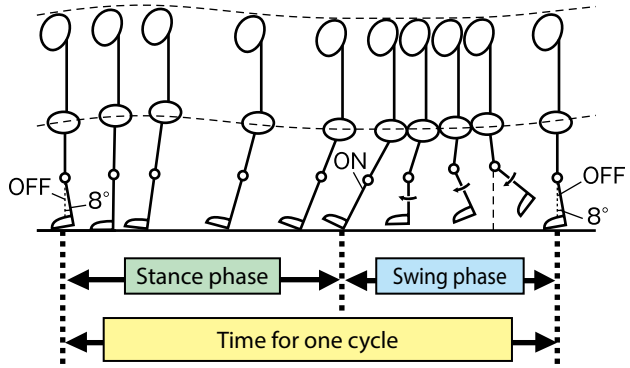


Fig. 5

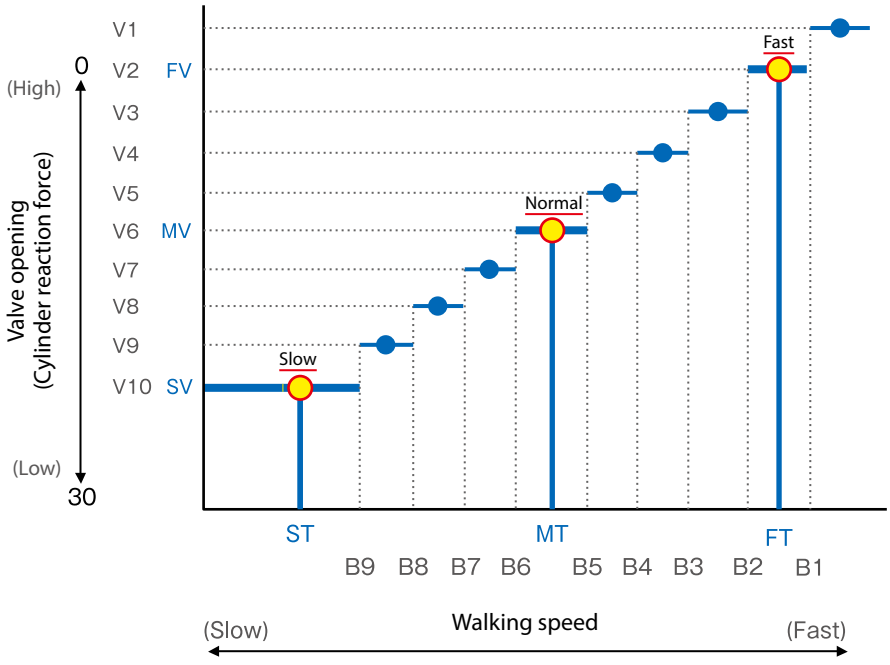


Fig. 6 10-Stage Setting

● When walking stops

When the patient stops walking for 8 seconds or more, the needle valve is automatically set to his/her normal cadence.

● When the battery is running low

When the remaining battery power is low, the needle valve is automatically set to the normal cadence of the patient. After that, it can not respond to a cadence change but the patient can walk at a constant speed.

● Data storage

As adjustment data is stored in the memory, it will not be deleted even if the battery connector is pulled out. In other words, readjustment is not required even when the battery is replaced.

4 Precautions for Handling

Follow the precautions below when using or removing the Intelligent Prosthesis Knee Joint:

4-1 When the IP Is in Place

Prohibition

DO NOT immerse the IP in liquids like water or salt water.

This could cause the device to rust and subsequently malfunction.

Prohibition

DO NOT use the IP in places where the temperature exceeds 50°C (122°F), such as near a fire.

This could cause deformation of the plastic and subsequent trouble.

Prohibition

DO NOT use the IP for more than 2 hours where the air temperature is -10°C (14°F) or lower.

The device may not respond to changes in walking speed; however, walking at a constant speed is possible even in such conditions.

Prohibition

Never insert your hand into the IP when bending to sit down, and never put your hand into the device when stretching it to stand up.

Your hand could be caught or pinched in the device.

Prohibition

DO NOT jump from a high place or use the IP in any manner in which it receives a strong intentional shock.

This could cause damage to the parts and a subsequent fall.

DO NOT use the IP in any place with especially strong magnetic emissions, radio waves, or radiation.

These could cause malfunctions. However, it is not necessary to worry about this in normal environments.

Use the IP with the foam cover.

If not, direct water splashes or the entry of foreign matter could cause a malfunction.

4-2 When the IP Is Not in Use

DO NOT leave the IP in a humid place or where water could splash on it.

This could cause the device to rust and subsequently malfunction.

DO NOT leave the IP in a place where the temperature exceeds 50°C(122°F), such as in a car in direct sunlight or near a fire.

This could cause deformation of the plastic and subsequent trouble.

DO NOT leave the IP in a place where the temperature is 0°C (32°F) or below.

This could cause malfunction or trouble.

DO NOT put the IP in a high place or lean it against something in an unstable manner.

It could fall and be damaged.

DO NOT put anything on the IP or step on it.

This could cause damage to the parts.

When the IP has been left unused for one month or more, bend and stretch it two or three times before use.

5 Precautions When Sitting in and Standing up from a Chair

WARNING

- When sitting in a chair, never place the hand behind the knee. The hand can be caught in the swaying part of the pneumatic 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 hydraulic unit, causing serious injury. If the patient needs assistance in standing up from a chair, we recommend placing hands on the armrests or on the seat*.

* In addition to the above, placing a hand on the socket or placing both hands on the sound leg can also help the patient stand up from a chair. Provide instructions on the safe method according to the patient's circumstances.

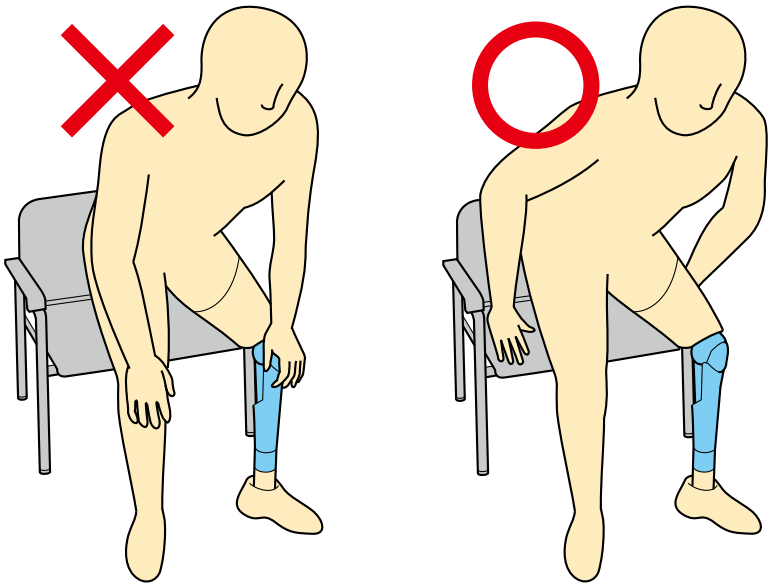


Fig. 7 Recommended Posture When Standing up from a Chair

6 Troubleshooting

Status	Items to be checked	Countermeasures
Even if hydraulic resistance is adjusted to a higher level, yielding strength is not increased.	Check if body weight is being applied properly.	Practice how to sufficiently apply body weight to the heel.
	Check if alignment is proper.	Make adjustments so that body weight can be sufficiently applied to the heel.
	Check if the foot is appropriate.	Select a foot with which body weight can be sufficiently applied to the heel.
	The above measures can not resolve the problem.	Contact your local sales representative/dealer.
In the stance phase when walking on a level floor, minor wobbling motions occur on the knee joint.	Check if alignment is proper.	Adjust alignment to the stable side.
	Check if the knee joint is flexed when the heel makes floor contact.	Practice how to walk with the knee fully extended in the stance phase.
	Check if the pneumatic cylinder cushion is adjusted too strongly.	Loosen the cushion valve.
Hydraulic resistance becomes effective when it is not supposed to. (Sticking occurs during transition from stance to swing phase.)	Check if hydraulic sensitivity is adjusted too strongly.	Loosen the sensitivity adjusting plug. (DO NOT make 3 turns or more from the fully closed position.)
	Check if the pneumatic cylinder cushion is adjusted too strongly.	Loosen the cushion valve.
	Check if smooth heel-to-toe weight shifting is achieved while walking.	Provide gait training so that body weight is sufficiently applied to the toe of the prosthetic foot at time of toeing off.
	The above measures can not resolve the problem.	It is possible that the load on the toes at the time of push-off is insufficient. Proper alignment, foot selection, adjustment, and gait training are essential to take full advantage of this knee joint.
Yielding function is not sustained when the patient descends a slope.	Check if body weight is being applied properly.	Practice how to sufficiently apply body weight to the heel. *
	Check if alignment is proper.	Make adjustments so that body weight can be sufficiently applied to the heel.
	Check if the prosthetic foot has adequate heel stiffness (not too soft).	Select a prosthetic foot with medium heel stiffness.
	The above measures can not resolve the problem.	Contact your local sales representative/dealer.

Status	Items to be checked	Countermeasures
When the patient descends stairs, yielding does not function.	Check if the floor contact position of the foot is appropriate.	Put the mid-foot on the edge of the stairs. *
	Check if the toe touches the floor first due to insufficient knee extension.	Swing the prosthesis to fully extend the knee joint. Be sure to put the mid-foot on the edge of the stairs. *
	Even if the knee is fully extended, it is flexed due to its own weight before the foot contacts the floor.	Repeat gait training of how to shift the body weight forward and to obtain the best timing of swing and landing. *
	Even after gait training, the patient cannot fully extend the knee joint.	Select a pneumatic cylinder with a strong spring to assist extension. During its use, however, the patient may feel heaviness during swing motion in the swing phase.
	The above measures can not resolve the problem.	Use of yielding for stairs should be prohibited.

*

WARNING

Make sure that the patient always holds a handrail during gait training. There is a risk that the patient might lose balance and fall down.

7 Battery

Function

- The battery powers the microcomputer and the motor built into the pneumatic cylinder that controls the swing of the below knee-portion according to the walking speed.

Effects of Power Depletion

- The patient can walk at a constant speed, but there will be no flexion adjustment for actual walking speed.
- When the battery is replaced, the patient can walk just as before. (Settings do not need to be readjusted.)

Approximate Battery Replacement Interval

- The battery life is approximately two years, depending on the conditions of use.
- You will be informed of the date for battery replacement by the prosthesis manufacturer. If necessary, please ask the prosthesis manufacturer.

Battery Replacement

- When replacing the battery, consult the prosthetist, since lithium batteries are used exclusively in the IP.

8 Maintenance

For comfortable use of the Intelligent Prosthesis Knee Joint, please read and understand the following:

- When cleaning the inside of the IP, do not use water or paint thinner; wiping the inside is sufficient.
  * Even if there is dust on the inside parts, it will not affect functionality.
- Replace the battery and the rubber for the extension stopper approximately one year after installation. Replacement should be done by the prosthetist. DO NOT undertake any maintenance actions on the device.

If you have any of the following problems using the IP, consult the prosthetist.

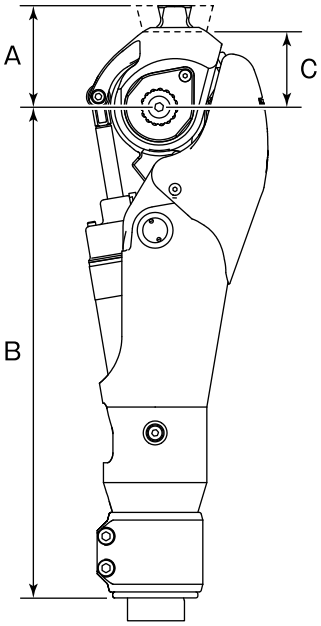
- The swing of the below knee portion does not match you walking speed.
  * In the following cases, the IP will not correspond to your walking speed:
    1. The battery is dead.
    2. The IP has been used more than two hours in a place where the temperature is -10°C (14°F) or below.
    3. The IP is used where it is exposed to strong electromagnetic waves.
- The swing of the below-knee portion becomes too slow for your walking speed.
  * When you get used to using the device and are able to walk faster, you may not be satisfied with the speed. In this case, you will be able to walk faster with a simple adjustment.
- There is some looseness or noise in the device.
- Water has gotten into the IP.
- You feel something is wrong with the device.

9 Outline of the Product

● Specifications

Type		NI-C311/NI-C311s	NI-C313/NI-C313s
Dimensions	Overall length	296 mm	292 mm
	A	51 mm	45 mm
	B	247 mm	247 mm
	C	38 mm	38 mm
Weight		1,375 g	1,385 g
Knee flexion angle		Max. 140°	
Patient's body weight limit		125 kg (100 kg for highly-active users) Compliant with ISO 10328 P6 (A-125 kg)	
Battery life time		Approx. 2 years	

* These specifications are subject to changes without prior notice.



● Lifetime: 6 years

● Features

1 Excellent stance phase stability and yielding function

The hydraulic rotary damper and the unique MRS system serve to accurately create hydraulic resistance and to avoid knee buckling. In addition, the yielding function helps achieve safe descending on a slope and stairs.

Note: Hybrid Knee is intended to assist the capability of an patient who uses a prosthesis. Please note that no one can easily descend a steep slope or stairs without gait training.

2 Wide range of speed follow-up performance and tireless walking

The microprocessor-controlled intelligent mechanism enables walking in a wide range of cadence. In addition, air pressure control can provide easy prosthesis swinging and can reduce fatigue.

3 User friendliness

Stance phase control can be easily adjusted with a hex wrench. The adjustment method for the stance phase control is the same as that for the conventional intelligent knee joint. Battery life time is approximately 2 years*.

Note: Battery life time varies according to the walking pattern of each patient. The battery life time of 2 years is based on a general walking pattern.

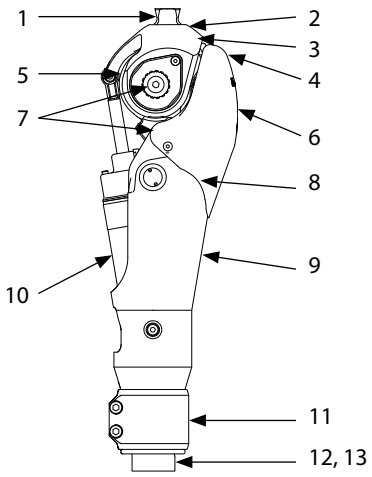
10 Disposal

The table below shows the materials of the Hybrid 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 notifying us, we will dispose of it for you.

CAUTION

Do not discard the lithium battery with general household garbage. If thrown away, the battery could short-circuit and ignite or release harmful fumes.

	Part name	Classification of material	Remarks
1	Joint parts	Metal	Titanium alloy
2	Knee plate	Metal	Aluminum alloy
3	Extension stopper	Rubber	Nitrile rubber
4	Front link	Metal	Aluminum alloy
5	Hydraulic unit	Metal	Body: Aluminum alloy Shaft: Iron alloy O-ring: Rubber
6	Knee cover	Plastic	Nylon 6
7	Fastening / supporting	Metal	Iron alloy
8	Base bracket	Metal	Aluminum alloy
9	CFRP frame	Plastic	Carbon fiber reinforced composite material
10	Pneumatic cylinder	Metal	Body: Aluminum alloy Fastening: Iron alloy O-ring: Rubber
11	Clamp	Metal	Aluminum alloy
12	Battery	Lithium battery	Primary battery
13	Battery holder and cap	Plastic	POM



11 Periodic Inspection and Warranty

● Periodic inspection

- Undergo a periodic inspection every 2 years.
  Inspections for the 2nd year are free of charge, and inspections for the 3rd year and following years are offered on a charged basis.

- Consumable parts (extension stopper rubber, battery) are available for purchase.

CAUTION

Be sure to undergo a periodic inspection every 2 years.
Failure to undergo a periodic inspection can nullify the warranty period.
Should the Hybrid Knee be used without a periodic inspection, parts can become worn down more quickly.

● Warranty

For the warranty, please refer to the separate warranty document.

12 Symbols Used

12-1 UDI Label (Packing Box)

Legal manufacturer

Date of manufacture

MD Medical Device

REF Item number

SN Serial number

GTIN Global Trade Item Number

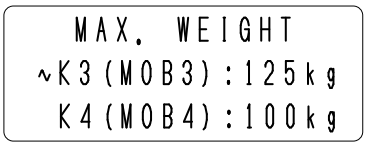
EC REP Authorized representative for EU countries

The maximum and minimum temperatures for storing, transporting, and using the product.

CE Declaration of conformity according to the European Regulation 2017/745

Single patient multiple use

12-2 Body Mass Limit Label (Knee Joint Body)



Body mass limit not to be exceeded.
See page 7.

12-3 Product Type Label (Knee Joint Body)

NO. Serial number

CE Declaration of conformity according to the European Regulation 2017/745

12-4 Tightening Torque Label (Knee Joint Body)

Tighten the clamp within this torque range.

12-5 Lithium Battery Label (Battery)

It certifies that this product complies with UL safety standards.

The EU requires recycling without disposal in a landfill. When disposing of this product, follow the rules of the local government.

MEMO

MEMO

Document Number: 81-SS00167 (ver.1)
Related prosthetist IFU: 81-SS00076 (ver.4)
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