

INSTRUCTIONS FOR USE





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HOPPER® BLADES

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Intended for healthcare professionals and patients, the purpose of this manual is to help users choose the suitable category and to optimize the blade settings.

The Audacieuse and Intrépide blades by Hopper® were designed in France by engineers with the help of users and healthcare professionals to facilitate access to sport for people with limb differences.

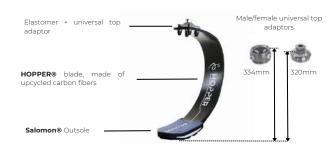


INTENDED USE

These products are medical devices designed to replace ankle and foot function in children, teenagers and adults with limb differences who wish to practice running activities. They must be installed by a healthcare professional, and a clinical assessment must be carried out with the patient beforehand.

AUDACIEUSE BY HOPPER®

A comfortable, lightweight (840g) and versatile blade that allows access to various sports (Running, trail running, etc.) for athletes and for beginners. It is suitable for people with a minimum clearance of **24cm** (distance between floor and the socket on the walking prosthesis with a shoe).



Suitable for above-knee and below-knee amputations





Different categories from XS to XI

Suitable for the weight of each person from 45kg to 110kg





Suitable for any level of activity thanks to its flexibility and comfort

INTRÉPIDE BY HOPPER®

A comfortable, lightweight (740g) and versatile blade that allows access to various sports (Running, trail running, etc.) for athletes and for beginners. It is suitable for people with a minimum clearance of **19cm** (distance between floor and the socket on the walking prosthesis with a shoe).



Suitable for above-knee and below-knee amputations





Different categories from PXS to PXL

Suitable for the weight of each person from 35kg to 110kg





Suitable for any level of activity thanks to its flexibility and comfort

WHICH CATEGORY TO CHOOSE?

These recommendations complement the expertise of the prosthetist.

ACCORDING TO THE TYPE OF GROUND

- ▶To use on fairly hard surfaces such as roads, we recommend using the range shown in the table below.
- ▶To use on soft ground, it is advisable to choose a lower range than the one indicated in the table below.

ACCORDING TO THE TYPE OF ACTIVITY

▶ For fitness walking or weight-bearing sports, we recommend initial an trial with a softer blade. Flexibility improves stability and comfort.

ACCORDING TO THE FEELING OF THE USER

- ▶ If the user has a feeling of not controlling or having too much restitution, it is advised to use a lower range than the one indicated.
- ▶ If the user has the feeling of too high flexibility and lacking restitution, it is recommended to use a higher range than the one indicated.
- ▶ Improved stability and comfort for bilateral amputees has been observed with stiffer blades. We therefore recommend the following ranges.

Weight		77-100 lbs 35-45 kg		101-121 lbs 46-55 kg		122-148 lbs 56-67 kg		149-172 lbs 68-78 kg		173-199 lbs 79-90 kg		200-242 lbs 91-110 kg	
Activity	level	1/2	3	1/2	3	1/2	3	1/2	3	1/2	3	1/2	3
Audacieuse	> 24 cm*			XS	s	s	М	М	L	L	XL	XL	XL
Intrepide	> 19 cm*	PXS	PXS	PXS	PS	PS	РМ	РМ	PL	PL	PXL	PXL	PXL

Activity level: 1 = Low / 2 = Medium / 3 = High

FOR BILATERAL PATIENTS: Increase by one category for added stability.



*Minimum clearance: distance between the ground and the bottom of the socket on the walking prosthesis with shoe.

ASSEMBLING

-MOUNTING THE UNIVERSAL TOP ADAPTOR -

Place the elastomer against the upper part of the blade in front of the 4 holes and set the adaptor with the 4 holes and the 4 screws provided (ref. HAV100) (torque: 9 N.m). The 4 screws of the plate are initially loosened to allow you to position the pyramid (male or female). Once the correct setting of the transverse rotation is found with the user you must tighten the 4 screws (torque: 9 N.m) and the clamping screw (torque: 8 N.m). If you wish to change the pyramid, remember to loosen the 4 screws upstream.



MOUNTING THE OUTSOLE







STEP 1: Fold the base of the outsole and insert the blade so that the Velcro® on the base does not touch the Velcro® on the blade yet. Push the outsole onto the blade, making sure to push it in as far as possible.

STEP 2: Attach the two parts of the Velcro® together and make sure they are at the exact same level.

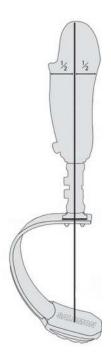
STEP 3: To check that the outsole is perfectly assembled, bend the front end of the sole (the outsole should not move).

MOUNTING

Alignments are identical for our two products: L'Audacieuse and L'Intrépide.

IN THE SAGITTAL PLANE

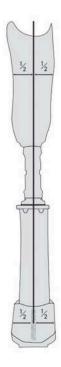
The mounting line (vertical laser) passes through the middle of the socket, the middle of the adaptor and the first "O" of Salomon® on the outsole.



MOUNTING

IN THE FRONTAL PLANE

The mounting line passes through the middle / outer edge of the patella and the middle of the outsole (cutting the Salomon® word in half lengthwise).



OTHER SETTINGS

HEIGHT ADJUSTMENTS BEFORE STATIC TESTS

Sports activities require the blade to move vertically. To ensure user comfort, it is essential to provide an additional offset to the walking prosthesis.

Fitness walking	+2 cm compared to the walking prosthesis for below-knee amputees. +0 cm for above-knee amputees.			
Moderate running	+3 cm compared to the walking prosthesis for below-knee amputees. +0 cm for beginners above-knee amputees.			
High intensity running	+5 cm compared to the walking prosthesis (no difference between AK and BK amputees)			

DYNAMIC FITTING

The transverse rotation must be adjusted in dynamic fitting and the rear clambing screw tightened to $8\,\mathrm{N.m.}$

The physical capabilities and length of the residual limb will affect the alignment. Each user will have an individual and specific optimal alignment, depending on their practice. The adjustments are to be modified according to the sensations and the feedback from the user during the run.

The length of the step can be affected by the anteroposterior positioning of the socket in relation to the blade

For sport knee assembly, please refer to the instructions of the manufacturer.



OUR ADVICE

MAINTENANCE AND SAFETY

- Observe the maximum weight of the product.
- ► Assemble only with approved prosthetic components according to the instructions.
- Do not re-cut or drill the blade
- ► Check the tightness of the screws. The prosthetist should also regularly check the prosthesis to ensure that the tightening has not changed.
- If the product is not used in accordance with your supplier's recommendations, it may cause damage to the blade components (carrying heavy loads, jumping from a great height, etc.).
- ► The presence of sand, particles or foreign bodies inside the outsole could modify its behavior and damage it.

USE IN WATER OR DIRTY ENVIRONMENT

- ▶ The device may be used in the following environments: salt water, chlorinated water, mud, sand or other dirty environments and will require systematic rinsing with clear water.
- ▶ Remove the outsole and thoroughly rinse the blade and other parts with clear water to remove particles (mud, sand etc.).
- ▶ Dry the various components and reassemble the outsole.
- As the outsole is a consumable item, it is necessary to visually inspect it before each use. If damage or wear is detected, the outsole must be replaced.

END OF LIFE OF THE DEVICE

It is advisable to return the device to the manufacturer at the end of its life cycle so that it can be recycled or reused.

LIABILITY

The manufacturer recommends using the device only under the specified conditions and for the intended purpose. The device must be maintained in accordance with the instructions for use.

The manufacturer cannot be held responsible for damage caused by combinations of components not authorized by the manufacturer.

COMPLIANCE

These products meet European Certification (CE) standards.

The composite blade and top adaptor have been subjected to tests to failure and two million load cycles under conditions that best reflect actual use. This corresponds to two to three years of use depending on the user's activity.

However, it is recommended carry out safety checks on an annual basis.

Any serious incident related to the device should be reported to Hopper SAS as well as to the competent authority of the country where the user is established.

Instructions for use about the Hopper® sports blades, English version 5.

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Manufacturer: HOPPER SAS, 8 avenue Pierre Gilles de Gennes 81000 Albi,

France





IUD-ID IDENTIFICATION AND MAXIMAL WEIGHT

AUDACIEUSE BY HOPPER®

Audacieuse by Hopper® XS	HLOIXS	03770027689003	65kg
Audacieuse by Hopper® S	HLOIS	03770027689010	75kg
Audacieuse by Hopper® M	HLOIM	03770027689027	90kg
Audacieuse by Hopper® L	HLOIL	03770027689034	100kg
Audacieuse by Hopper® XL	HLOIXL	03770027689058	110kg



IUD-ID IDENTIFICATION AND MAXIMAL WEIGHT

INTRÉPIDE BY HOPPER®

Intrépide by Hopper® PXS	HL02PXS	03770027689065	65kg
Intrépide by Hopper® PS	HL02PS	03770027689072	75kg
Intrépide by Hopper® PM	HL02PM	03770027689089	90kg
Intrépide by Hopper® PL	HL02PL	03770027689096	100kg
Intrépide by Hopper® PXL	HL02PXL	03770027689102	110kg

WARRANTY

The supplier commits to accepting returns from the customers and to refunding the goods as indicated in the signed general conditions of sale.







CONTACT-US

+33 (0)7 81 94 34 27 contact@hopper-accessibility.com hopper-accessibility.com

@hopper_community

