Care/Maintenance
Maintenance of the device must be scheduled every 6 months and be performed by a healthcare professional. During this maintenance, particular attention must be given to the knee hinges wear pattern. If the healthcare professional notices any kind of early wear on the hinges, he must notify Thuasne and provide all required information (pictures etc.) to evaluate whether or not a repair is required.
Hinges:
The hinges on the brace are pre-lubricated in the factory.
If sand, dirt or water gets inside the hinges, they may require lubricating again.
If you notice the hinges not gliding smoothly, a few drops of a synthetic lubricant can be applied.
Wipe off any excess lubricant before wearing the brace to prevent stains on clothing.

Storage
Store at room temperature, preferably in the original packaging.

Disposal
Dispose of in accordance with local regulations.

Keep this instruction leaflet.

COMMERCIAL WARRANTY AGREEMENT AND WARRANTY LIMITATIONS
Thuasne offers a free, limited commercial warranty to the user, in the territory where the device was purchased, against defects in manufacturing and workmanship for a period of:
- six months for the textile components;
- two years for the rigid components.

The limited warranty is effective from the date of purchase of the product by the end-user.
The limited commercial warranty does not apply to any defects in manufacturing and workmanship in case of:
- misuse of the product or any damage occurred by a usage outside the normal and intended use of the product as mentioned in the instructions for use,
- damages occurred while user is squatting or kneeling,
- damages occurred as part of attempts to modify the product.

Any claim for this commercial warranty must be sent by the user or its legal representative (parents, guardian...) to the entity where the product was purchased, which will forward this claim to the corresponding Thuasne entity.
Any warranty claim will first be reviewed by Thuasne to determine if the conditions of the limited warranty are fulfilled and do not fall into one of the cases of exclusion of the commercial warranty.
To benefit from the warranty, the buyer must mandatorily provide:
- an original and dated proof of purchase of the product;
- an original and dated proof that the scheduled maintenance was performed every 6 months.

If the conditions of the limited warranty are fulfilled and the claim is made by the user or its legal representative (parents, guardian...) within the warranty delays indicated above, the buyer will get a new substitution product.
It is expressly agreed that this commercial warranty is in addition to the legal warranties binding the entity which sold the product to the user, in accordance with the applicable local legislation in the country of purchase of the product.

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THUASNE®

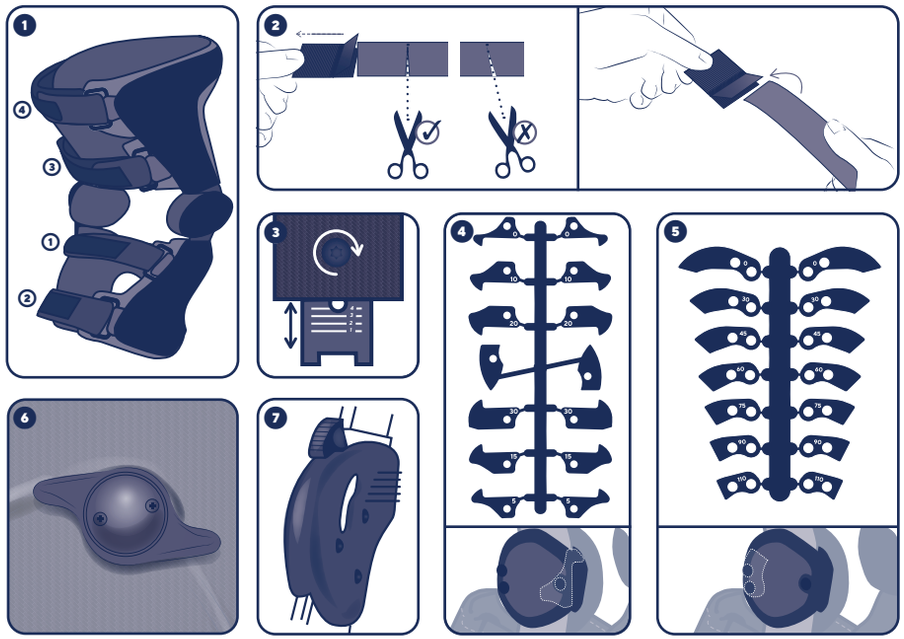
SpryStep® Knee

INSTRUCTIONS FOR USE
CUSTOM RIGID KNEE BRACE

Custom-made device.
Custom fabricated orthosis, made from a positive model of the patient's limb.

Stabilisation | Biomechanical correction | Motion control

MD | 1 | LATEX



Description/Destination
The device is intended only for the treatment of the indications listed.
This device is a rigid knee brace (KO) that supports and/or stabilizes the knee while walking.
Available in 3 versions: Sprystep® Ligament Knee, Sprystep® OA Knee, Sprystep® Neuro Knee.
A kit with 2 addtional condylar pads, extension limitations ❹ (except for Neuro version) is included in the brace's box.

Composition
Rigid components: carbon fibre - high density polyethylene - stainless steel - aluminium - polyoxymethylene - vinyl - polypropylene - polyamide - epoxy resin - brass - acetal - natural latex (in extension assist option only).
Textile components: polyamide - elastane - polyurethane - ethylene vinyl acetate - silicone - polyethylene.

Properties/Mode of action
The knee brace is composed of two parts (rigid and soft) already assembled.
The rigid part, made of composite materials and polyamide, is positioned around the knee to provide stabilisation and/or biomechanical correction.

Indications
These indications are biomechanical deficits of neurological, traumatic, muscular or degenerative origin.
Conservative treatment of knee ligament injuries and/or ruptures (cruciate and/or lateral ligaments).
Joint instability/laxity (including for knee osteoarthritis).
Specific to offloading knee braces (OA version):
Symptomatic unicompartimental femorotibial osteoarthritis (moderate to severe).
Knee off-loading for post-traumatic, post-operative or degenerative conditions.
Alternative to osteotomy or leg misalignment surgery.

Specific to locking joint knee braces (Neuro version):
Post-operative immobilisation or/and rehabilitation.
Post-traumatic immobilisation.
Weakness of the knee flexor muscles ≤ 3.
Knee instability during stance phase.
Quadriceps weakness.
Knee hyperextension.

Contraindications
Do not use the product if the diagnosis has not been confirmed.
Do not apply the product in direct contact with broken skin.
Do not use in the event of known allergy to any of the components.
Do not use for patients weighing > 180 kg (400 lbs).
Open ulcers of the foot, ankle or lower leg.
Severe loss of sensation in the lower limb.

Precautions
Verify the product's integrity before every use.
Do not use the product if it is damaged.
The initial fitting and adjustment must be done by a healthcare professional.
Strictly comply with your healthcare professional's prescription and recommendations for use.
Check the condition of the affected limb and the state of the skin daily (with particular attention for patients with sensory deficit).
In the event of discomfort, significant hindrance, pain, variation in limb volume, abnormal sensations or change in colour of the extremities, remove the device and consult a healthcare professional.
For hygiene, security and performance reasons, do not re-use the product for another patient.
Do not use the device in case of application of certain products on the skin (creams, ointments, oils, gels, patches...).
Do not wear the product in a medical imaging machine.
The ability to drive a vehicle with the device must be assessed by a healthcare professional and according to local regulations.
It is recommended to adequately tighten the device to achieve a good fit on the limb without restricting blood circulation.
Do not expose the product to extreme temperatures.
In the event of any modification in the product's performance, remove it and consult a healthcare professional.
Before any sports activity, check the compatibility of the use of this medical device with your healthcare professional.
In pediatric applications:
It is recommended that an adult supervises the application and use of the product by a child.
Could contain natural latex with the option extension assist.

Undesirable side-effect
This device can cause skin reactions (redness, itching, burns, blisters,etc.) or wounds of various degrees of severity.
Possible risk of venous thrombosis.
Any serious incidents occurring related to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is resident.

Instructions for use/Application
Preparation of the orthosis performed by the healthcare professional:
The healthcare professional must supervise the fitting of the product and the specific walking conditions of the patient when using the device for the first time.
It is recommended to wear the device directly on the skin, unless contraindicated.
Please read these instructions with the patient when fitting the brace for the first time and make sure that he/she understands how to position the knee brace.
How to fit the knee brace:
- Loosen all the straps of the knee brace, and to ease application, fold the self-fastening straps back.
- Have the patient sit on the edge of a chair, and have the patient bend his/her knee to a position of approximately 30-60° of flexion.
- Place the knee brace on the bare leg.

Fitting the orthosis
The hinges and uprights should be aligned with the midline of the sides of the leg, or just posterior to midline (2nd third of the leg in the sagittal plane).
NOTE: It is always better to put your brace on a little too high than too low.
Secure the straps ❶:
Feed the strap(s) through the corresponding buckles. ①②③④
Strap chafes can be angled to ensure the straps fit flat against the back side of the leg.
If one or more of the knee brace straps is too long, each strap can be cut to the desired length.
To do this, remove the self-fastening hook tab from the end of the strap, cut the strap to the desired length, and reattach the self-fastening hook tab to the end of the strap. ❷
Take care to not cut any strap too short.
The comfort pads fixed inside the straps may need to be removed for this operation and repositioned after the strap is cut to avoid any interference when the strap is tightened.
If the device provided has a Loadshifter Mechanism ❸:
Check the fit, suspension and pain level prior to adjusting the corrective force.
Confirm the Loadshifter Mechanism above each knee joint are in the factory-set neutral position (same height on both sides of the thigh shell).
Ask the patient to stand and walk, taking normal steps and looking straight ahead.
Confirm the brace fits and suspends properly on the leg.
Adjusting the corrective force:
The dual Loadshifter Mechanism ❸ enables you to change the angle of the femoral shell of the brace to increase the corrective 3-point force and offload the compromised (degenerated, compressed) medial or lateral compartment of the knee.
Both uprights are set during fabrication in a neutral position at mid-height.
The best way to adjust the correction is to increase the length of the upright on the affected side. This produces more leverage force. If the patient is short, you can also increase correction by shortening the length of the upright on the unaffected side.
For severe OA and/or severe varus or valgus deformities, you may need to adjust both uprights.
To adjust the Loadshifter Mechanism ❸, unlock the screw located on the upright above the hinge, on the side requiring adjustment, lengthen or shorten the upright and tighten the screw. ❸
Case of Medial Compartment Femoro-Tibial Osteoarthritis of the Knee:
A thicker condylar pad should be positioned on the external/lateral hinge (on the side opposite the affected compartment).
To increase corrective force, the internal/medial upright (affected side) can be lengthened compared with the external/lateral upright, or the external/lateral upright can be shortened compared to the internal/medial upright.
Case of Lateral Compartment Femoro-Tibial Osteoarthritis of the Knee:
The thicker condylar pad should be positioned on the internal/medial hinge (on the side opposite the affected compartment).
Evaluation of pain after adjusting the corrective force.
After adjusting the offloading of the brace:
- Ask the patient to walk again and assess his/her pain level.
- Repeat the operation, increasing or reducing the correction until the proper amount of offloading is achieved for the patient.
- If the patient feels any discomfort, reduce the angle of the thigh shell which will reduce the corrective force.

For conservative treatment, start with a small amount of correction and let the patient wear the knee brace for one or two weeks. If it is necessary to increase the correction, see the patient again.
A bag containing an additional set of condylar pads is provided in the box with the brace. If necessary, use the set of thicker pads to increase the compression on the sides of the knee.
Lines and numbers are printed on the uprights of the knee brace. There is no correlation between these graduations and specific degrees of correction. You can record in the patient's chart the initial setting of the Loadshifter.
If the device provided has flexion/extension limitations:
The brace's default extension setting is 0°. To change this setting, please follow the following instructions, to be repeated **with the same limitation on both hinges**.
The extension and flexion limitations are situated on plastic pieces contained in the box. ❹ ❺
Extension can be limited to 0°, 5°, 10°, 15°, 20° and 30°.
Flexion can be limited to 0°, 30°, 45°, 60°, 75°, 90° and 110°.
Adjusting the extension limitation:
1. Choose the desired extension limitation on the corresponding plastic piece . ❹
2. Remove the screw located on the side of each hinge.
3. Flex the hinge slightly and remove the existing extension limitation. Take care to note the direction this limitation is facing.
4. Insert the desired limitations, hole end first, with the hook end at the top and facing forward. Straighten the hinge to full extension to confirm the extension limitations are correctly positioned. The small hole in each limitation must be aligned and visible through the screw hole so the screw will thread into the limitation.
5. Reinsert and tighten the screw.

Do a few flexions/extensions to make sure that the limitation is properly locked at the desired angle.
Adjusting the flexion limitation:
1. Choose the desired flexion limitation on the corresponding metallic piece. ❺
2. Remove the two screws from the posterior aspect of each hinge cover and take out the spacer that was installed at the factory.
3. Insert the limitation with the flat end facing up and position it so that both holes in the limitation are visible through the screw holes in the cap.
4. Thread and tighten the screws through the cap and into both holes in the limitation.

Do a few flexions/extensions to make sure that the limitation is properly locked at the desired angle.
Warning:
The adjustment of the flexion/extension must be decided and performed by the healthcare professional, not by the patient.
Both hinges MUST be adjusted to the same angle. There can be damage to the hinges, and compromises (including injury) to the patient, if the settings are not the same on both hinges.
If the device provided has a locking joint Twist ❻:
To achieve continuous free motion, twist the lever clockwise until it clicks (the lever should not return to a neutral position). This allows patients to ambulate without having the joints fixated at extension.
To disengage the free motion override, push the center button on the twist release until the lever returns to a neutral position.
The system will lock once the patient returns to terminal extension.
If the device provided has a locking joint Trigger ❼:
To release the locking mechanism to allow to bend the knee, press UP on the Trigger at the top of both hinges.
When the patient straightens the leg, the locks automatically re-engage.
Ensure comfort of leg with no impingements prior to use.
It may take several weeks to feel comfortable with the brace on your leg.
Thuasne cannot be held responsible for undesirable effects or injuries resulting from any unsupervised or inadapted adjustments.
Depending on country of sale, additional accessories/spare parts could be available.
Fitting the spare parts (by a healthcare professional or by the patient):
The spare parts kit contains the following components: foam pads, straps with self-fastenings tabs, adhesive self-fastening tabs and hinges caps (Ligament and OA versions only).
Remove the textile parts and the adhesive self-fastening tabs (if damaged) sticked on the rigid part.
Clean the area where the self-fastening tabs were applied.
Replace the self-fastening tabs by new ones and then position the new foam pad.
To replace the straps, open the self-fastening tabs fixed on the structure, remove the straps and position the news ones.
If needed, shorten the strap(s): remove the self-fastening tab, trim the strap(s) and replace the tab.
To replace the hinge cap, remove the 3 screws on the cap, remove the cap, position the new one and fix it thanks to the 3 screws.
Alterations that can be done to the brace during fitting:
- Femoral shell: if needed a portion of the thigh shell can be removed to improve patient comfort or ease of use.
  Do not remove material within 2 cm of the knee joint insert.
  Make sure the surface of the shell is sufficient to support the force pattern of the brace and contain soft tissue without discomfort.
- Tibial shell: some minimal trimming of the shell can be done (max. 2 cm).
  Do not remove material within 2 cm of the knee joint insert.

The following actions would waive the warranty:
- Over trimming of the femoral or tibial shell.
- Any attempt to heat-mold the composites materials.

Care/Maintenance
Cleaning
Product can be washed in accordance with the instructions shown on this leaflet and on the label. If the device comes into contact with water, dry the textile part and wipe the rigid part well with a dry cloth. If the device is exposed to seawater or chlorinated water, make sure to rinse it in clear water and dry it.
Rigid components: wash the rigid part with a moist cloth.
Textile components: the soft part can be fully removed for washing. Replace in the original location before next use. Hand wash. Remove the self-fastening tabs before washing. Do not use detergents, fabric softeners or aggressive products (products containing chlorine). Do not dry clean. Do not tumble-dry. Do not iron. Squeeze out excess water. Dry flat. Dry away from any direct heat source (radiator, sun, etc.). After prolonged use, if the fibers on your strap do not adhere as well to the self-fastening tab, cut the strap shorter so the self-fastening tab adheres to a section of the strap that has fresher fibers. If this is not possible, you should contact the medical provider who fit your brace.