



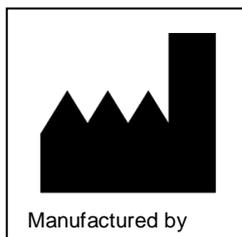
*Pedi*Stirrup

PAEDIATRIC LEG SUPPORT

Instructions for Use
Paediatric Leg Support

NOT STERILE

Explanation of symbols on labels and packaging



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Instructions for Use for Paediatric Leg Support

Device name

The device brand name is **IMDS PediStirrup**.
 The generic device name is **Leg Support**.

Description

Many children face surgery every year. Some operations are elective procedures, others are emergency response to an urgent medical condition.

To be able to perform, e.g. a surgical procedure, among others, on abdomen/perineum (including laparoscopy) on children the child's legs need to be fixated for optimal surgery position and optimal sight. This is currently done by taping the child's feet to the operating table or holding position by an assistant when no fixation is used. This because there are no convenient surgery leg supports available in the market that can specifically be used for child surgery. Operative/Interventional specialists do have concerns about the current used tape fixation:

- Tape fixation of the legs is instable and can be unsafe if the tape releases during the procedure,
- Tape fixation limits the possibility for an optimal surgery position in all phases of the procedure,
- Tape fixation limits sight of the surgeon on the operation field and therefore increases the risk of complications,
- Limited sight and potential re-tape fixation during complex procedures increases the surgery time.

Using the specific paediatric leg support should result in:

- More stable and safer positioning of the child's legs during the procedure,
- Possibility to position the child's buttock at the far edge of the operating table,
- Better sight of the surgeon on the operation field and therefore less risk of complications,
- Excellent view is possible for the first assistant,
- Better sight and gaining time during combined abdominal/perineal operations because the position of the legs can be simply and safely changed during operation under sterile conditions. Therefore always the best position can be used.

Indication

The leg support will be specifically useable for interventions on babies, infants and children up to a physical length of 1.40 meters with a maximum weight of 45 kg, requiring Lithotomy Positioning, especially where intra-operative re-positioning may be required.

Contra indication

Children and adults with a length over 1.40 m.
 Patients of weight over 45 kg.

Warning

- Always support the leg of the patient when positioning or changing position of the leg support, not supporting the leg may result in severe patient injury.
- After changing position, it must be checked if the lock has been secured before releasing the support of the leg.
- Only to be used with shoes with specific quick release system and fixation straps.
- Do not sterilize, the device has not been tested for sterilization procedures. Sterilization may lead to malfunction of the fixation and adjusting means which in turn, may result in severe patient injury.
- To reduce the potential for knee joint damage, do not position the leg in a stretched position.
- To reduce the potential for squeezing the foot, do not tighten the fixation straps too strong.
- Do not lean on or against the leg support, leaning on the leg support may damage the inbuilt safety features of the lock mechanisms.
- Do not submerge the device in a soapy bath or cleaning alcohol, this could damage the locking mechanisms and may lead to malfunction of the device resulting in severe injury of the patient.

Precaution

- When using rail clamps check whether they are usable for a 25 x 10 mm (1" x 1/4") table rail and will adapt the 25 x 6 mm bar of the leg support.
- Using the leg support should only be performed by staff being trained on assembling, mounting and adjusting the device.

Adverse effects

None known.

Contents/Product parts to be used for a clinical event

Rail clamp	2
Left Leg Support with telescopic arm and shoe mounting plate	1
Right Leg Support with telescopic arm and shoe mounting plate	1
Pair of shoes (selected size)	1
Velcro Straps (depending on shoe size)	4 or 6
Nut and bolt for joining rail clamp and Leg Support bar	2
Laser pointer	2

Instructions for use

I. Preparation and inspection procedure

Note: The Leg Support is not a sterile device.

- 1- Inspect if the clamp fixation screw is working and not damaged.
- 2- Inspect if the rail clamp fits properly on the table rail.
- 3- Inspect if the rail clamp fits properly on the bar of the leg support.
- 4- Replace the rail clamp when it is not working properly.
- 5- Inspect the leg support for damage.
- 6- Inspect the leg support for proper function of the joints and clamps.
- 7- Inspect if the telescopic tubes can be extended / shortened.
- 8- Maintain the leg support when it is not working properly.
- 9- Inspect if the leg support, including quick release plate and shoes, is clean.
- 10- Clean items when contaminated.
- 11- If damage is noticed judge whether device can be used or has to be repaired.
- 12- Inspect shoes for damage.
- 13- Replace shoes when damage restricts proper functioning.
- 14- Inspect fixation straps for damage and contamination.
- 15- Replace straps if damaged or contaminated.
- 16- Check the function of the laser pointer to be used for adjustment of the primary joint.
- 17- Replace batteries of laser pointer or replace laser pointer if necessary.

II. Assembly and mounting procedure

The assembly and mounting procedure can start before or after the patient is positioned at the appropriate position on the operating table.

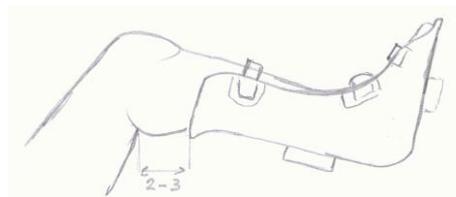
Note: The physician may decide to follow another procedure.

Warning: Always support the patient until he/she is fixated in the leg support

Note: A rail clamp can be permanently connected to the leg support bar by placing a rail clamp over the bar (watch right position) and inserting the supplied nut and bolt in the hole at the bottom end of the bar.

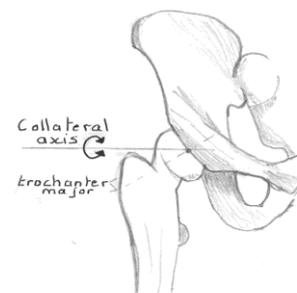
III. Selection of the appropriate size of the shoes

1. The selection of the appropriate size of the shoes is of fundamental importance.
2. The length of the dorsal side of the shoe has to be 2-3 cm smaller than the length of the dorsal side of the lower leg. There must be at least 2-3 cm free between the upper end of the shoe and the hollow of the knee. On the other hand the maximum amount of the calf has to be supported.



IV. Starting the procedure

1. Mount an appropriate rail clamp on each side of the table.
2. Place the bar of the leg support in the rail clamp.
3. Position the primary joint approximately at the position of the hip joint.
4. Secure the rail clamp and bar to the table rail.
5. Insert a laser pointer, or other light source, in the hole of the primary joint.
6. Release the rail clamp for adjusting.
7. Adjust the center of the primary joint with assistance of the light source beam in horizontal plain at the center of the hip joint and vertical just cranial/above of the Greater Trochanter (Collateral axis).
Warning: Do not point the laser to persons' eyes or equipment. This may bring severe damage to eyes or inadvertently effect use of equipment with infra red controls.
8. Firmly secure the rail clamp to the table.
9. Repeat steps 1 to 8 for the other leg support.



V. Mounting the shoe and pre-positioning the support arm and mounting the shoe

Note: Always support the leg support when locking mechanisms are unlocked.

1. Mount the selected appropriate size shoe on the quick release mounting plate.
2. Secure the quick release mechanism.
3. Release the vertical lock mechanism.
4. Turn the telescopic arm in a horizontal position.
5. Secure the lock mechanism.
6. Extend the telescopic arm to an appropriate length for the patient by releasing the clamps and extend the telescopic arm.

Note: the leg has to be positioned with a slightly bended leg (about 20°) to avoid overstretching.

7. Secure the clamps on the telescopic arm.
8. Repeat step 1 to 7 for the other leg support arm.

VI. Adjusting the leg support to the patient

Note: Positioning the patient's leg in the leg support has to be done by two persons, one is supporting the leg, and the other is adjusting the leg support.

Note: Always support the leg support when locking mechanisms are unlocked.

Warning: Always support the leg while positioning the leg support for the procedure.

- 1- Unlock the clamps of the telescopic arm.
- 2- Unlock the ball joint mechanism.

- 3- Gently place a leg in the leg support.
 Remark: Replace shoe for larger or smaller size if foot does not fit properly in shoe.
- 4- Use the Velcro straps to fixate the foot and calf in the shoe.
Warning: Check whether the leg is sufficiently secured.
Warning: Do not tighten the straps too much to avoid affecting the blood flow.
- 5- While supporting the leg adjust/extend the telescopic arm to the appropriate length.
Note: The leg has to be fixated with the knee in an approximately 20° angle position.
- 6- Secure the clamps of the telescopic arm.
- 7- Position the foot and calf in the appropriate position.
Note: The more in abduction (straddle) the upper leg is placed the more the foot (shoe) has to be fixed in exorotation (outwards rotation).
Note: The leg of the shoe should not press extremely on the calf.
 If the leg of the shoe merges in to the hollow of the knee, change the shoe for a smaller and shorter size.
 Release the straps on the foot and calf and remove the shoe by unlocking the lock mechanism. Replace the shoe. Repeat step V-6 to 7 and VI-1 to 7.
Warning: Always support the leg and foot while changing a shoe.
- 8- Secure the lock of the ball joint.
- 9- Repeat steps 1 to 8 for the other leg and leg support arm.

VII. Control of correct positioning if during intervention change of position is needed

Warning: Always support the Leg Support when positioning or changing position.

1. If during the operation change of position of the legs is needed always check the requested change without sterile sheets before covering the legs.
2. Special attention has to be paid to check that the hip is not moving in relation to the operating table during change of position.

VIII. Preparing for sterile covering

1. Cover the legs according to the local procedures with sterile sheets.

IX. Sterile position Change procedure

Warning: Always support the leg while re-positioning the leg support during the procedure.

Warning: If large vertical changes are needed both the legs will have to be changed at the same time by two persons, in this way large forces on the hip joint can be avoided.

Note: Changing position does not need removing the sterile sheets. Lock mechanisms can be used through the sterile sheets.

Note: Change position of leg in vertical direction only. Horizontal re-positioning without full vision may result in patient injury.

Note: Always support the leg support when locking mechanisms are unlocked.

- 1- Support the leg while changing position.
- 2- Unlock the vertical lock mechanism on the primary joint.
- 3- Position the leg in the appropriate position.
- 4- Lock the vertical lock mechanism.
- 5- Repeat step 1 to 4 for the other leg.
- 6- If necessary, re-cover the legs with sterile sheets according to the local procedures.

X. Completing the procedure

Warning: Always support the leg while positioning the leg support for the procedure.

Note: Removing the leg from the leg support has to be done by two persons. One has to support the leg. The other one is releasing the straps.

- 1- Remove the sterile sheets.
- 2- Hold the leg in a secured position.
- 3- Release the Velcro straps on one side of the shoe.
- 4- Repeat step 1 to 4 for the other leg.
- 5- Place the patient in an appropriate and safe position.

XI. De-assembling procedure

Note: Always support the leg support when locking mechanisms are unlocked.

Note: Store in a dry place.

- 1- Remove the shoe by unlocking the quick release mechanism.
- 2- Store the shoe in an appropriate place.
- 3- Open the lock mechanisms on the telescopic arm.
- 4- Shorten the telescopic arm to the minimum length.
- 5- Secure the lock mechanisms.
- 6- Unlock the vertical and horizontal lock mechanism.
- 7- Turn/rotate the arms in vertical downwards position for storage.
- 8- Secure the vertical and horizontal lock mechanisms.
- 9- Hold the support and release the rail clamp.
Note: If the rail clamp is permanently connected to the bar, steps 10 through 12 can be jumped over.
- 10- Remove the leg support from the rail clamp.
- 11- Remove the rail clamp from the table rail.
- 12- Store the rail clamp in an appropriate place.
- 13- Store the leg support arm in an appropriate place.
- 14- Repeat step 1 to 13 for the other leg support arm.

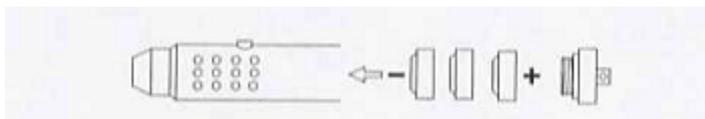
XII. Instruction for Use for Laser Pointer

Class 2 Laser, Laser Diode

Warning: Please note laser radiation is harmful to the eyes, do not look directly into the laser diode or collimated beam along its optical axis when the diode is activated; and also do not point the laser beam at anyone.

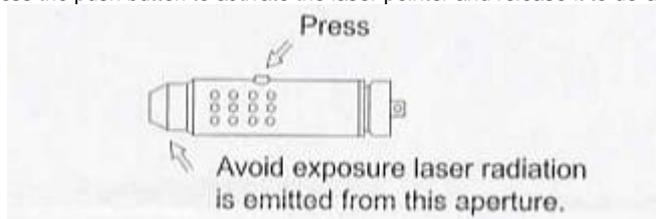
Replacing the Batteries

- Remove the battery cover.
- Remove the used batteries and replace with three new LR44 / AG13 coin-cell batteries.
- Insert cells with the positive (+) side facing out toward the end cap.
- Replace the end cap.



Operating the Laser Pointer

Simply press the push button to activate the laser pointer and release it to de-activate.



Warning: Laser pointers are not for children. If not used properly they can be hazardous for the eyes. Do not manipulate the output of the laser pointer.

No responsibility will be accepted for any damages caused should this security advice be disregarded.

Disposal of Batteries

- Batteries must not belong to domestic waste
- Dispose the batteries according to the local disposal rules.

XIII. Cleaning and storage of the device

Note: Handle the device with care. The lock mechanisms include safety mechanisms that can be damaged by unprofessional handling.

- 1- After use, clean the surface of the device, with maximum extended tube, with soft soap or cleaning alcohol according to local cleaning procedures.

Warning: Do not submerge the device in a soapy bath, this could damage the locking mechanisms and may lead to malfunction of the device resulting in severe injury of the patient.

Note: Do not use chlorous cleaning agents.

Note: Only clean the surface. Avoid spilling of soft soap and/or alcohol in the joint mechanisms. The mechanisms are semi-closed and provided with grease. Spilling of soft soap and/or alcohol in the mechanisms may lead to malfunction of the system.

- 2- Store the device and its accessories in a dry place.

XIV. Replacing the straps

Replace straps showing malfunction or if they are contaminated.

Unlock the Velcro on both sides and remove the strap.

Guide a new strap through a hole in the side of the shoe and loop back to secure one side of the strap.

Only use original approved and supplied straps.

XV. Maintenance of the leg support

The leg support is a mechanical device that needs maintenance as result of wear.

If locking mechanisms do not lock or need extra force to lock, do not use the device until it has been serviced.

The service interval is every two years. Contact your local distributor for service information.

XVI. Disclaimer of Warranty and Limitation of Remedy

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