# HIP FIX™

# LATERAL POSITIONING DEVICE

**Instructions for Use**

**NOT STERILE**

Explanation of symbols on labels and packaging

Manufacturer

Production date


LOT / Serial number


Cataloge / article number

Single use only

Attention, see instructions for use

Read instructions for use

Medical Device, class I (MDR)


Latex free product

**Manufacturer:**

Opitek International
Gøngehusvej 252
2950 Vedbæk
Danmark

Telephone: +45 39 66 16 44
Mail: info@opitek.dk

**For ordering replacement parts and maintenance:**

www.opitek-international.dk - info@opitek.dk



**Instructions for Use Lateral Positioning Device**

**Device name**

The device brand name is **Hip Fix.** The generic device name is **Lateral Positioning Device**

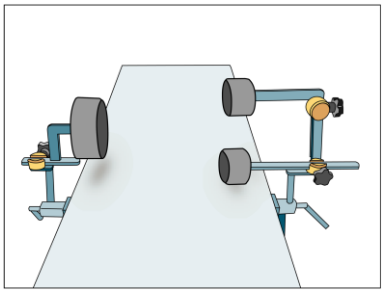
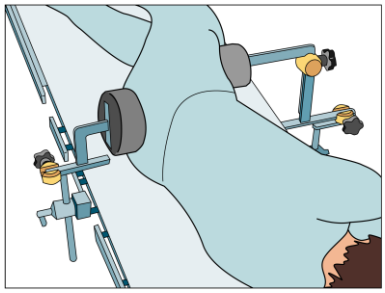
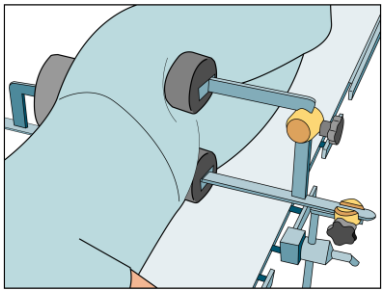
**Description**

Before and during surgery on the hip, Hip Fix provides the operating team with accurate and stable patient positioning on the operating table.
Total hip replacement (THA) is a demanding and exacting surgical technique. Advances in technologies, new materials, and biomechanics have made it increasingly important for the orthopaedic surgeon to be able to accurately orientate the implant components in a reproducible way. Hip Fix has more than 20 years of clinical history.
The newest Hip Fix models are all equipped for use with single use (one set per patient / procedure) pads for increased hygiene, comfort and patient safety.
Using this specific lateral positioning device should result in:

- Facilitation of accurate and reproducible positioning of implant components
- Accurate and reproducible patient and component orientation
- Stability of patient position throughout procedure
- Abdomen free from external pressure during procedure.

**THE PRINCIPLES OF 3 POINT FIXATION**

Hip Fix uses a unique 3-point fixation (crista iliaca and sacrum) to make the strong stability of the patient positioning match the surgeons need for space and manoeuvrability in the surgical field.

**Indication(s)**

The Hip Fix will be specifically useable for interventions on the hip joint (pelvis) were the patient is positioned laterally and were a strong fixation of the patient is desired.
General surgical procedures involving lateral positioning.
Lateral patient positioning where the positioned angle of the patient relative to the OR table surface is desired to be variable.
Lateral patient positioning where the anatomy of the patient is a challenge for the OR staff.
Were a hygienic consideration plays a role in the selection of the lateral positioning device.

**Contraindication(s)**

Patients where the iliacal crest cannot be felt / located through the skin
Patients with damaged skin in the area where the support touches the skin (necrosis, hypersensitivity, wounds, etc.)
Surgical procedures where the perioperative manipulation of the leg involves / demands an angle of more than 90 degrees relative to the median of the patient.

**Warning**

- Always support the legs of the patient when positioning or changing position of the Hip Fix, not supporting the legs may result in severe patient injury.
- After changing position, it must be checked if the positioning and stability of the patient and the fastening of the locks has been secured and verified by the surgeon before starting the draping procedure.
- Only to be used with specific single use pads (for fitted models). By multiple use of single use pads, a risk of cross contamination (patient-to-patient transfer of biological substances) cannot be excluded.
- 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 when scrubbing. Support the leg by hand or with a sling in a holding / lifting device.
- To reduce the potential for squeezing of (abdominal) skin, secure that all excessive or loose skin are not constructed or trapped between holders, pads, OR table-top mattress and stainless steel parts.
- Do not tighten the fixation handles too strongly.
- Do not lean on or against the support, leaning on the support may damage the inbuilt safety features of the lock mechanisms and result in sliding of pads. This may result in patient injury and skin damage.
- Do not submerge the device in a detergent or an antiseptic solution, this could damage the locking mechanisms and may lead to malfunction of the device resulting in severe injury of the patient.
- Always follow the described sequence when positioning the patient. This is important both for patient safety and accurate positioning.

**Precaution**

- When using rail clamps check whether they are usable for a 25 x 10 mm (1” x ¼”) table rail and will adapt the octagonal rods (4 flat sides) of the support. Country specific rail clamps are available upon request. The manufacturer is not responsible for events related to the use of rail clamps other than the provided.
- Using the support device should only be performed by staff being trained on assembling, mounting and adjusting the device.

**Adverse effects**

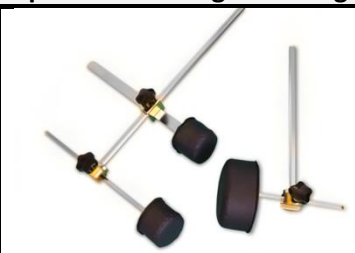
- There is a small risk of light pressure markings. These marking are often lightly red and will disappear within the first hours post operatively. This could also occur due to a hypersensitivity skin condition.
- In very rare cases there have been reports on severe (blueish) pressure markings, damaged skin (wounds) and blistering. In these cases it has been reported that the skin has been in contact with hard surfaces on the device (stainless steel, hard plastic) and at the same time been under pressure for an extended period of time (more than 1½ hours). No patients are reported to have permanent damage from being positioned in the device.
- There have been reports of patients sliding out of the device perioperatively and getting pressure marks from the incident. The event also disturbed the surgical procedure technically. The root cause have been found to be faulty positioning due to lack of training in positioning and / or a wish to use the device in contradiction to the instructions.

**Contents / Product parts to be used for a clinical event – 4 options (2 w/fixed pads + 2w/ single use pads)**

| **1. Hip Fix model with non-detachable fixed soft foam pads**<br>Fixed distance from the side of the OR-table rail to the patient (= always 90 degrees lateral positioning) | | |
|---|---|---|
|  |  | |
| Hip Fix # 2000-182 | Clamp # 10-305-P, 2 pcs. | |

| **2. To upgrade from fixed soft foam pads to exchangeable single use pads (single patient set)** | | |
|---|---|---|
|  |  |  |
| Hip Fix 2015 Upgrade set, # 2015-100 | + Hip Fix # 2000-182 | = Ready Hip Fix # 2015-200 |
|  |  |  |
| Hip Fix # 2015-200 | Clamp # 10-305-P, 2 pcs. | Single use pad set # 2015-50-1 |

| **3. Hip Fix model with non-detachable fixed soft foam pads**<br>Flexible distance from the side of the OR-table rail to the patient (= not always 90 degrees lateral positioning or individual use of supports (ie pubic support only)) | | |
|---|---|---|
|  |  | |
| Hip Fix # 1900-01 | Clamp # 10-305-P, 2 pcs. | |

| **4. To upgrade from fixed soft foam pads to exchangeable single use pads (single patient set)** | | |
|---|---|---|
|  |  |  |
| Hip Fix 1915 Upgrade set, # 1915-100 | + Hip Fix # 1900-01 | = Ready Hip Fix # 1915-200 |
|  |  |  |
| Hip Fix # 1915-200 | Clamp # 10-305-P, 2 pcs. | Single use pad set # 2015-50-1 |

**Preparation and inspection procedure**

**Note**: The Lateral Positioning Device is not a sterile device.

1- Inspect if the clamp fixation screws are working and not damaged.
2- Inspect if the rail clamps fit properly on the table rail.
3- Inspect if the rail clamp fits properly on the vertical stems of the Hip Fix.
4- Replace the rail clamp(s) if not working properly.
5- Inspect the Hip Fix components for damage.
6- Inspect the Hip Fix for proper function of the joints and clamps.
7- Repair / Maintain the Hip Fix if not working properly.
8- Inspect if the Hip Fix surfaces, including fixed foam pads (if equipped) and / or single use pad holders (if equipped), are clean.
9- Clean items if contaminated.
10- If damage is noticed judge whether device can be used or needs to be repaired.

# Assembly and mounting procedures (for clinical options # 1-4)

**Clinical Option # 1: HIP FIX 2000-182**

**Hip Fix model with non-detachable fixed soft foam pads**
Fixed distance from the side of the OR-table rail to the patient (= always 90 degrees lateral positioning)

| | | |
|---|---|---|
|  |  | |
| Hip Fix # 2000-182 | Clamp # 10-305-P, 2 pcs. | |

The Hip Fix 2000-182 consists of 5 parts. See the next page for details and product label identification. Please ensure that all parts are included in the package. Inspect that content is intact and without visible damage. If clamps/table mounts are ordered, these will be included together with the 5 Hip Fix parts. Any transport damage should be reported to the transport / shipping company.

First assemble the front support, lower (part # 20014) by sliding it into the front post (part # 20021) brass coupling. Tighten the lower Bakelite knob by hand. Slide the front support, upper (part # 200017) into the double brass coupling on the front support, lower (part # 200014) and lock the connection with the upper Bakelite knob by hand.

Mount the complete front support on the side of the operating table that will face the patient's anterior side (by means of the Hip Fix clamp (part # 10-305-P) so that the lower support cushion can easily be moved towards the patient.

Then mount the rear post (part # 200026) on the side of the operating table that will face the patient's posterior side (by means of the Hip Fix clamp (part # 10-305-P). Do not mount the back support (part # 200010) at this moment.

The complete Hip Fix 2000-182 assembly at the operating table can be seen in fig. 1.

1. **Fixation anterior:**

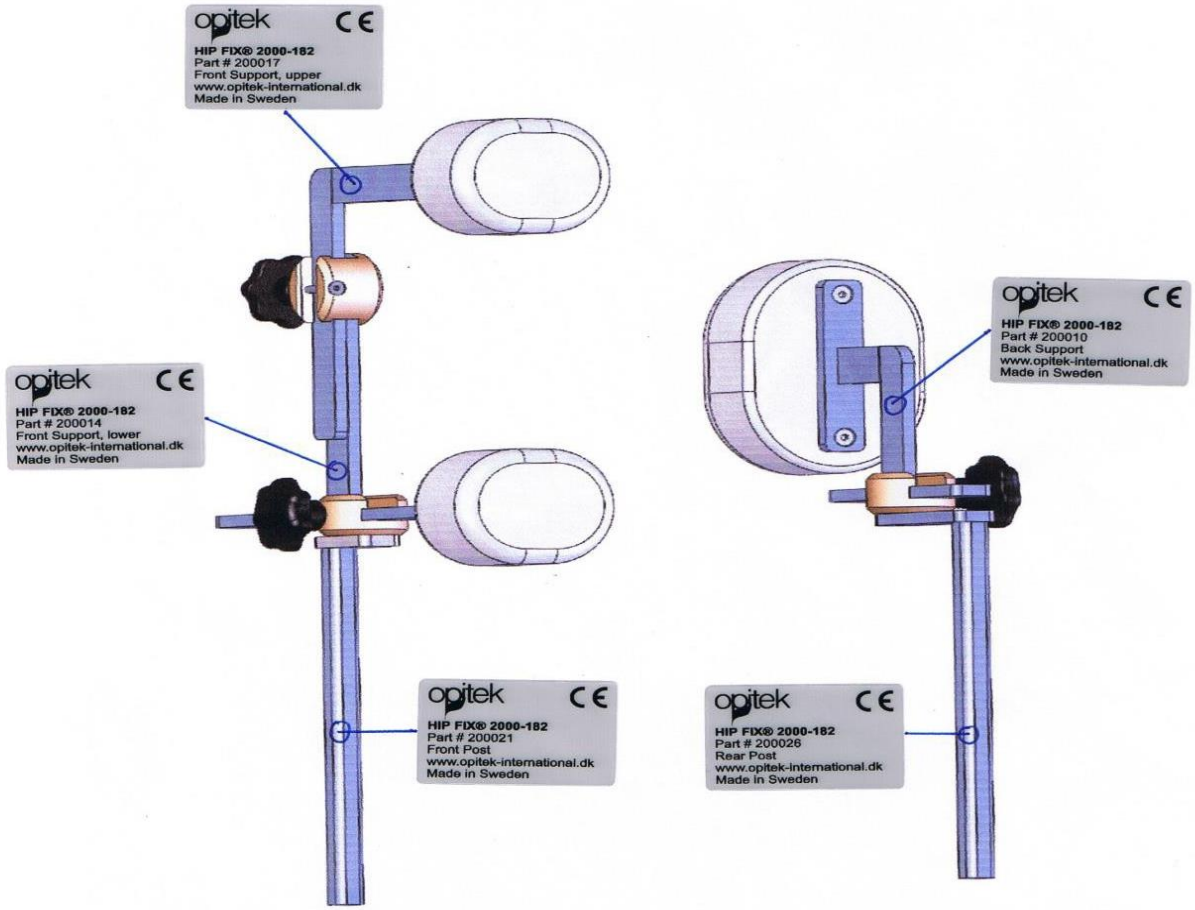
   Angle the patient slightly backwards and open the lower Bakelite knob so that the support cushion can be put against spina iliaca. Hands tighten the lower knob. Open the clamp/table mount so that you can push the complete front support down into the operating table mattress. Lock the clamp/table mount, and open the lower Bakelite knob and push the lower support cushion carefully against the patient. If you are using a soft type of operating mattress, with one hand push the mattress down under the support cushion to make it easier to put the cushion against the patient's lower spina iliaca. Tighten the lower

Bakelite knob. See fig. 2.

2.
Angle the patient against the upper support cushion, which will be placed against the upper spina iliaca, and at the same time adjust the right height and tighten the Bakelite knob. See fig. 3.

**3. Fixation posterior:**
Keep the patient in position against the front support. Mount the back support (part # 200010) with cushion. This part can be slid into the brass lock coupling from the outside. The back support assembly should be placed against the sacrum - the height will be adjustable with the clamp/table mount. See fig. 4.

4.
Verify that the patient lies stable fixed in 90 degrees against the table. If not, the position will have to be corrected by returning to step 1.



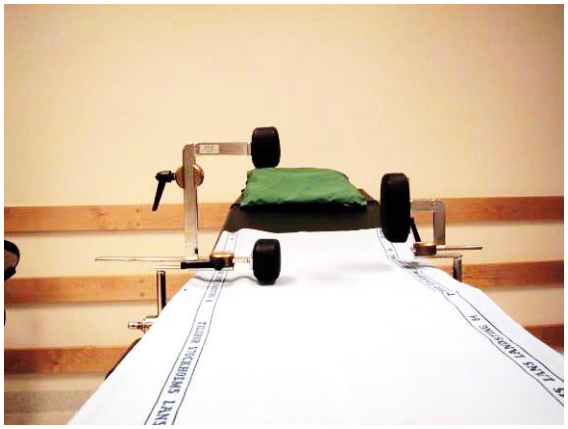


Fig. 1

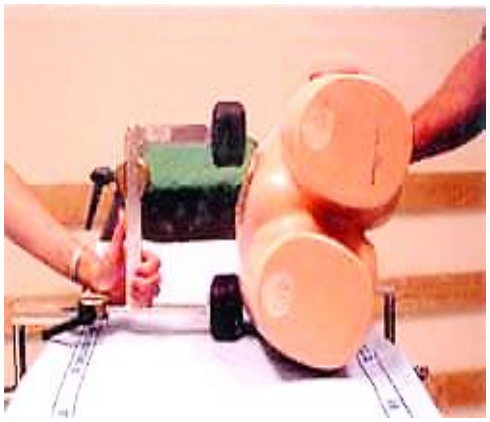


Fig. 2

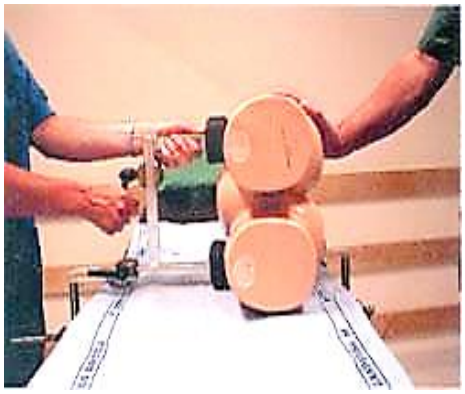


Fig. 3

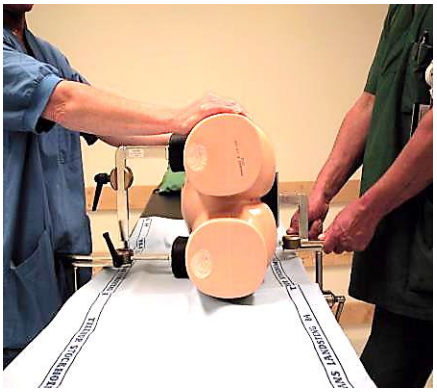


Fig. 4

**Notes:**

If there is a risk of skin necrosis, upholstering could / should be applied on the support cushions. Verify that all 3 support cushions and all 3 Bakelite knobs are fixed in the respective brass couplings.

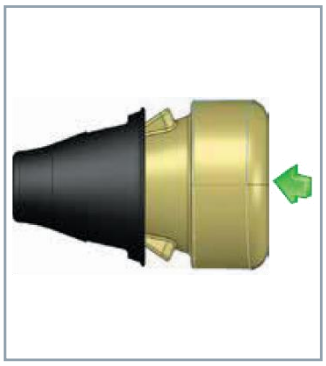
If any part of the Hip Fix shows signs of wear, it is essential for achieving the desired results and absolute stability that this or these parts are replaced. Cease use immediately if any parts appear faulty.

Check for any wear of the operating table attachments so that they do not negatively affect the use and mounting of Hip Fix. Handles need to be tightened by HAND force only.

**Clinical Option # 2: HIP FIX 2015-200**

| 1. To upgrade from fixed soft foam pads to exchangeable single use pads (single patient set) | | |
|---|---|---|
|  |  |  |
| Hip Fix 2015 Upgrade set, # 2015-100 | + Hip Fix # 2000-182 | = Ready Hip Fix # 2015-200 |
|  |  |  |
| Hip Fix # 2015-200 | Clamp # 10-305-P, 2 pcs. | Single use pad set # 2015-50-1 |





# HOLDER & CUSHION ASSEMBLY

## FRONT LOWER SUPPORT

REF 2015-10

HOLDER

REF 2015-01

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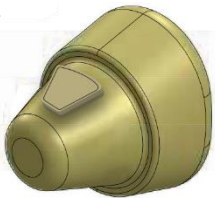


CUSHION

ASSEMBLY

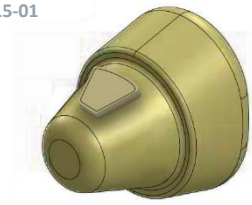
## FRONT UPPER SUPPORT

REF 2015-20

HOLDER

+

REF 2015-01



CUSHION

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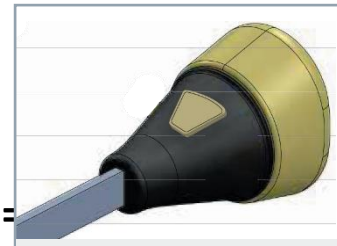


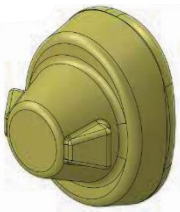
ASSEMBLY

## BACK SUPPORT

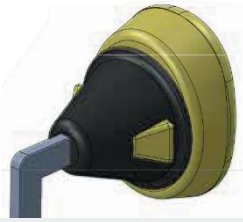
REF 2015-30

HOLDER

REF 2015-02

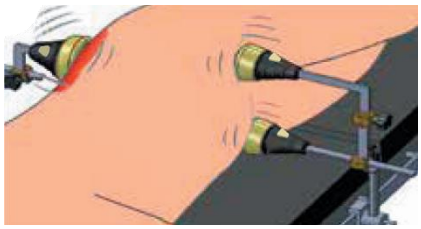


CUSHION

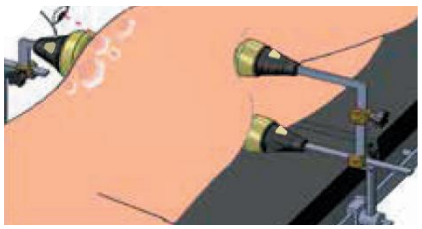


ASSEMBLY

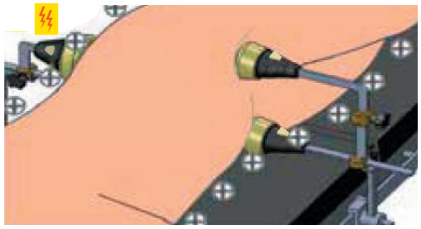
## PRE-OPERATION



Avoid friction

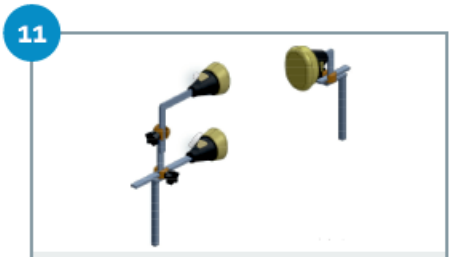


Do not apply to damaged skin

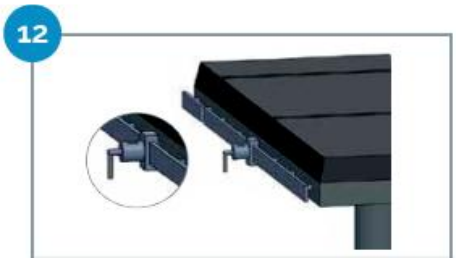


Avoid conditions of electro discharge

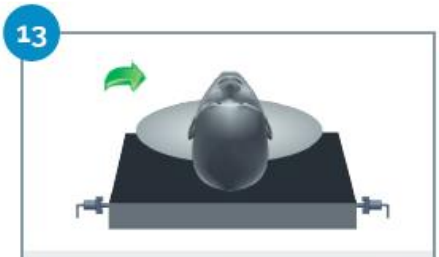
## HIP FIX ASSEMBLY



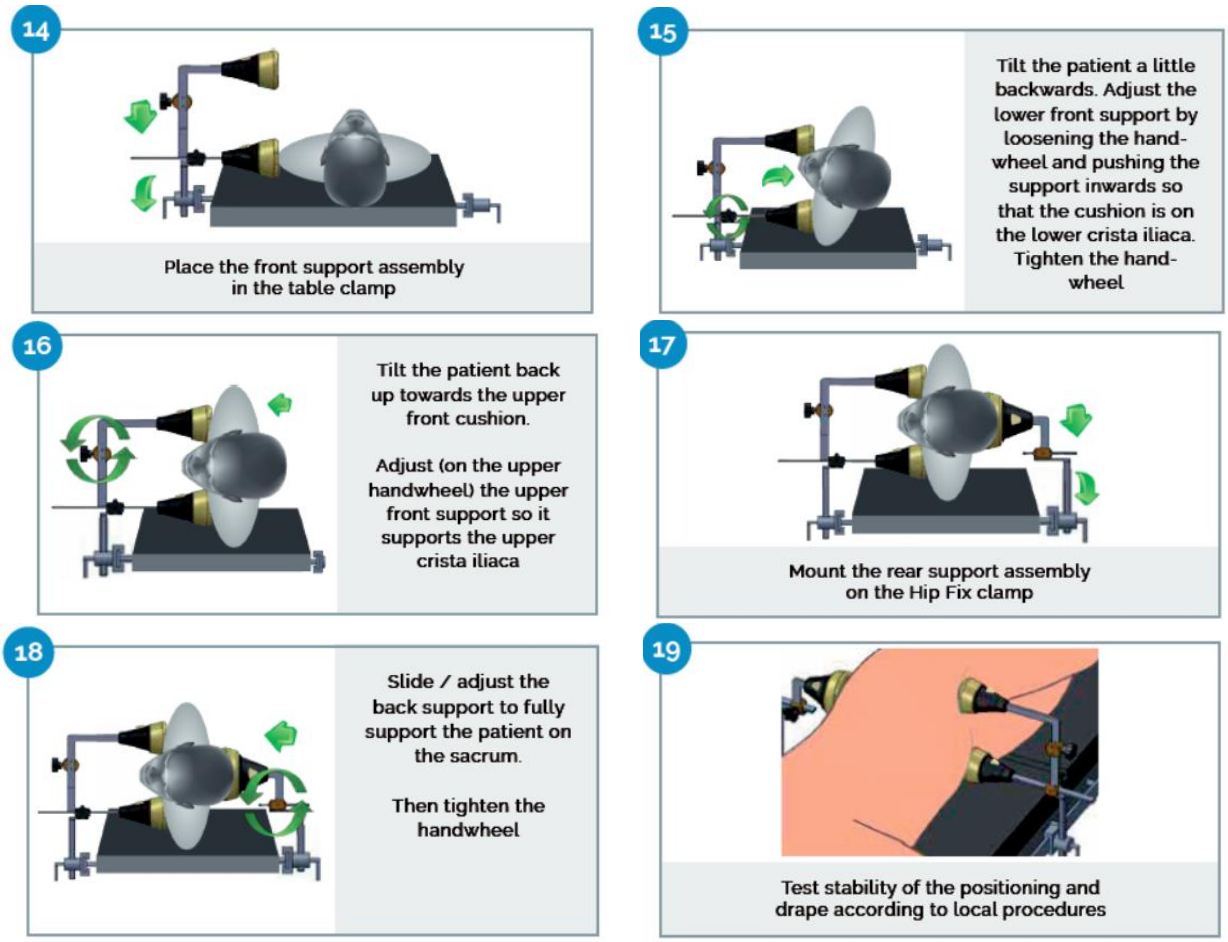

Begin by assembling the front support and back support




Apply the 2 clamps (10-305-P) on each side, centrally




Place the patient in horizontal position on the operating table




**Note:**

It might be useful to suppress the table mattress manually while pushing the lower support against the patient's ilical crest (lower).

If you are using a soft type of operating mattress, with one hand push the mattress down under the support cushion to make it easier to put the cushion against the patient's lower spina iliaca.

## POST-OPERATION

20

Cushion disassembly for cleaning and inspection of holders

21

Use normal hospital equipment cleaning / disinfection procedure

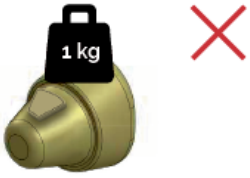
22

23

Non-Conductive

24


25




Storage

26

Single use only

27

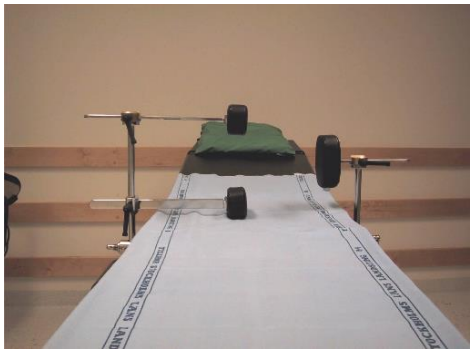
Keep stock of REF 2015-50-1

28

Keep on file

**Clinical Option # 3: HIP FIX 1900-01**

| **Hip Fix model with non-detachable fixed soft foam pads**<br>Flexible distance from the side of the OR-table rail to the patient (= not always 90 degrees lateral positioning or individual use of supports (ie pubic support only)) | | |
|---|---|---|
| | | |
|  |  | |
| Hip Fix # 1900-01 | Clamp # 10-305-P, 2 pcs. | |



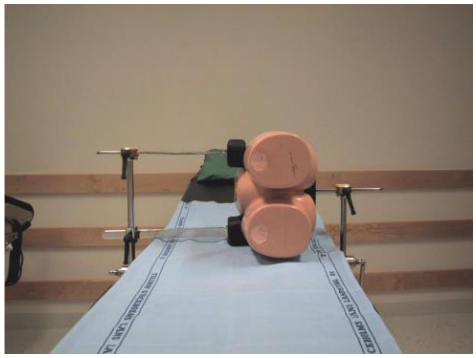
The complete system mounted on the OR- table
(variations on details on locking devices (hand wheels) may apply depending of model year)

**Hip Fix 1900-01 - Directions for Use**

1. Place the patient laterally on the operating table with the affected hip upwards.

**2. Posterior:**
Mount the vertical posterior support on the operating table. Adjust the support bars so the pad is against the patient's sacrum.

Lock the vertical support bar to the operating table.



**3. Anterior:**

Mount the vertical anterior support on the operating table.
Adjust both anterior supports so they are positioned against the patient's iliac crest.
Lock the vertical support bar to the operating table.

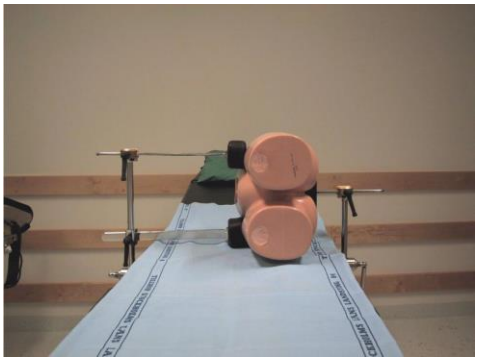
Push the lower horizontal support lightly against the operating table. It might be useful to suppress the table mattress manually while pushing the lower support against the patients ilical crest (lower). Secure the locking screw.

Adjust the patient so the pelvis is perpendicular to the table. Lock the upper horizontal support with the locking screw.

**4. Posterior**

Press the posterior horizontal support against the patient to get stable fixation.

Lock the horizontal posterior support.



**Notes:**
If there is a risk of skin necrosis, upholstering could / should be applied on the support cushions. Verify that all 3 support cushions and all 3 Bakelite knobs are fixed in the respective brass couplings.
If any part of the Hip Fix shows signs of wear, it is essential for achieving the desired results and absolute stability that this or these parts are replaced. Cease use immediately if any parts appear faulty.
Check for any wear of the operating table attachments so that they do not negatively affect the use and mounting of Hip Fix. Handles need to be tightened by HAND force only.

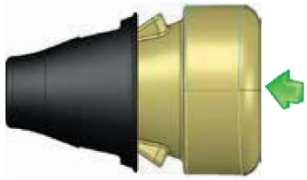
**Clinical Option # 4: HIP FIX 1915-200**

| To upgrade from fixed soft foam pads to exchangeable single use pads (single patient set) | | |
|---|---|---|
|  |  |  |
| Hip Fix 1915 Upgrade set, # 1915-100 | + Hip Fix # 1900-01 | = Ready Hip Fix # 1915-200 |
|  |  |  |
| Hip Fix # 1915-200 | Clamp # 10-305-P, 2 pcs. | Single use pad set # 2015-50-1 |

Read instructions

REF 2015-50-1

3 support cushions, single use



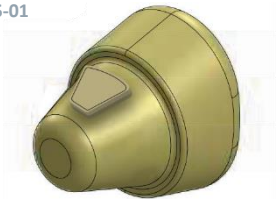
## HOLDER & CUSHION ASSEMBLY

### FRONT UPPER SUPPORT

REF 2015-10

HOLDER

REF 2015-01



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CUSHION

ASSEMBLY

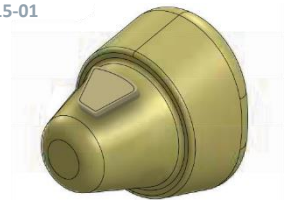
## FRONT LOWER SUPPORT

REF 2015-20

HOLDER

+

REF 2015-01



CUSHION

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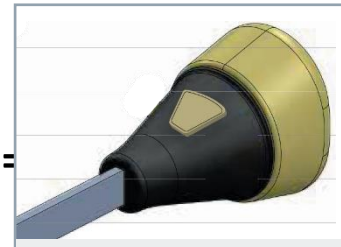


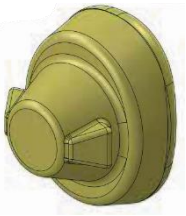
ASSEMBLY

## BACK SUPPORT

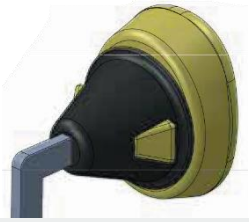
REF 2015-30

HOLDER

REF 2015-02

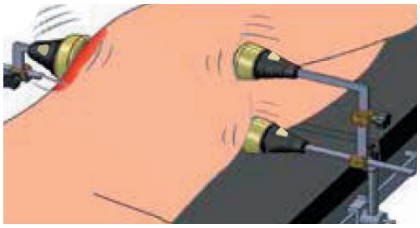


CUSHION

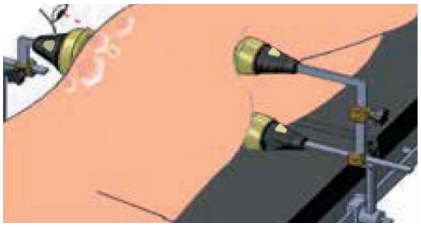


ASSEMBLY

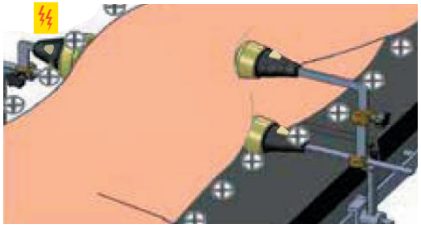
## PRE-OPERATION



Avoid friction



Do not apply to damaged skin



Avoid conditions of electro discharge

**Proceed with patient positioning as described in clinical Clinical Option # 3: HIP FIX 1900-01**
**Design of metal parts may vary depending on model**

## POST-OPERATION

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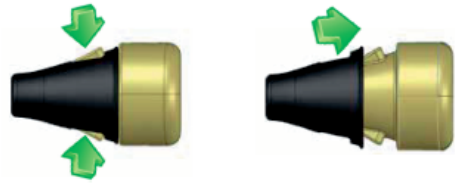

Cushion disassembly for cleaning and inspection of holders

21

Use normal hospital equipment cleaning / disinfection procedure

22

23

Non-Conductive

24


25


Storage

26

Single use only

27

Keep stock of REF 2015-50-1

28

Keep on file

## Completing the procedure

**Warning**: Always support the patient while positioning the lateral support for the procedure.
**Note**: Removing the lateral support has to be done by two persons. One has to support the patient, and the other one is releasing the locking knobs and rail clamps.

1. Remove the sterile sheets / draping.
2. Hold the patient in a secured position laterally.
3. Release the complete back support (including the rail clamp) and gently remove it with the patient still in the lateral position.
4. Visually inspect the patient's skin relative to the back support cushion / pad application, and report any pressure marks that are not acceptable (slightly red markings are normal).
5. Support / tilt the patient into a safe and appropriate position on the back (supine).
6. Remove the single use back pad from the holder if fitted and discharge.
7. Remove the two single use pads on the front support if fitted and discharge.
8. Release the complete front support (including the rail clamp) by the rail clamp and gently remove.
9. Visually inspect the patient's skin relative to the front support cushion / pad application, and report any pressure marks that are not acceptable (slightly red markings are normal)

## De-assembling procedure

**Note**: Always support the lateral support when locking mechanisms are unlocked.

1. Remove the single use pads (if fitted) by depressing the tabs in the cut-outs of the holders. Then pull the pad out of the holder and discharge. The pads are single use products.
2. Back support: Release the rail clamp from the support. By means of a quarter turn on the black handwheel, open the brass coupling and slide the support out of the coupling. Store the parts in an appropriate place.
3. Front support: Release the rail clamp from the support. By means of a quarter turn on the two black handwheels, open the brass couplings and slide the two support parts out of the couplings. Store the parts in an appropriate place.

## Cleaning, disinfection and storage of the device

Instructions for Care, Cleaning and Disinfection Hip Fix™ Lateral positioners (applies to all models).
The frequency of routine cleaning will depend on the use of the device.
Cleaning / Disinfection:
Please observe the following before starting cleaning / disinfection procedures:
Use suitable personal protective measures to protect yourself from stains. Place the device on a suitable and stable surface.

1. Remove single use pads (if mounted) from their holders and discharge – do not remove fixed pads (if mounted).
2. Disassemble the device(s) into the main parts (each main part has a label with an article identification). This is done mainly by loosening (do not remove) the black hand wheels mounted on the brass couplings. No further disassembly is possible. Do not use tools or manual force to disassemble.
3. Ensure that all surfaces are visually inspected properly.

**Cleaning**

a) Use a clean soft cloth with warm (max. 65º C) water and a mild, neutral soap solution and wipe / wash the parts gently – avoid excessive fluid in the areas around the screws, threads and fixed pads (if mounted).
b) Wipe the parts thoroughly with a soft cloth and clean water.
c) Wipe the parts dry thoroughly with a soft cloth or paper napkins
d) Assemble the device (do not mount any single use pads until just before a surgical procedure)

**Disinfection**

If disinfection is needed repeat steps a) to d) while using a solution of Sodium Hypochlorite (dilution 1/100 – 10.000 ppm) or a standard disinfectant product (suited for OR equipment) including products containing benzalkonium chloride.
On the plastic parts (black single use pad holders), a 70% isopropyl alcohol solution should be used to avoid discoloration and material fatigue due to Sodium Hypochlorite.

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

**Warning:** Do not submerge the device in the detergent or an antiseptic solution, this could damage the locking mechanisms and may lead to malfunction of the device resulting in severe injury of the patient.
**Warning:** Do not autoclave.
**Note:** Only clean the surface. Avoid spilling of detergent or an antiseptic solution in the joint mechanisms. Spilling of soft soap and/or alcohol in the mechanisms may lead to malfunction of the system.

**Note**: Store in a dry place and preferably kept apart from other positioning devices similar to this support, in order to avoid mixing of components.

**WARNING**
**Do not use alkali or acidic substances for routine cleaning purposes. Substances used should be pH neutral (6-8). Always disinfect after cleaning if a biological contamination of the device is visible or suspected.**

**Maintenance of the lateral support**

The lateral 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. If parts show signs of extreme wear they can be replaced by either the technical service department or by sending the device to your local distributor. There is no fixed service interval. Contact your local distributor for service information and for ordering of spare parts.

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# DECLARATION OF CONFORMITY

**We, the manufacturer**

Opitek International ApS, Gøngehusvej 252, 2950 Vedbæk, Denmark
(Org. number: 30554582)

**declare that the following product(s):**

| Name of product / article | Article number(s) |
|---|---|
| Hip Fix, all models | *1900-01, 2000-182, 2015-200, 1915-200, 2015-200+8 & upgrades hereof (x-100)* |
| Hip Fix pads, multiple use | 2000-01, 2000-02 |
| Hip Fix Pads, single use | 2015-01, 2015-02 |
| | |

**Is (are) in conformity with the provisions of the following:**

**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**

**Classification according to Annex VIII, Chapter III, 4.1**
**Medical Device Class I: Non-invasive devices**

**Issued under the sole responsibility of the manufacturer**

**Place:** Vedbæk, **Date: April 1, 2019**

*Peter Christensen*
*CEO, Managing Director*
*Opitek International ApS*

**Notes:**

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