

# OPRA™ AXOR™ II

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Patient Information

 Integrum

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## FUNCTIONS OF THE AXOR™ II

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The OPRA™ Axor™ II™ has two functions:

- The Axor™ II connects the OPRA™ Implant System to the external prosthesis.
- The Axor™ II protects the OPRA™ Implant System from overload in rotation and bending/flexion.

## USE AND RESET

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Your prosthetist will help you with the installation of the Axor™ II and show you the proper procedure for use, reset after release and cleaning.

If the release level is exceeded, the OPRA™ Axor™ II will release in bend or rotation by twisting the foot or releasing the foot. You can avoid overloading the OPRA™ Axor™ II by following and completing the training plan and discussing your post-operative activities with your physician.

If OPRA™ Axor™ II has released by twisting your foot or stumbling, you may reset it yourself. Your prosthetist (prosthesis specialist) will show you the proper procedure. It is important to reset the prosthetic foot back to its exact original position. After you reset the OPRA™ Axor™ II, you should not continue performing the same activity that caused the device to release.

The OPRA™ Axor™ II should be removed before laying down on a couch, bed or other flat surface.

## ATTACHING THE AXOR™ II TO THE ABUTMENT (DONNING)

The top part of the Axor™ II has four conical jaws with a square opening for the Abutment. The jaws are tightened with a screw mechanism that is managed by hand.

The Axor™ II is attached to the Abutment through the following procedure:

1. Sit down while attaching the Axor™ II.
2. Open the jaws by turning the grip counter-clockwise by hand until it stops and the Abutment can enter the Axor™ II (see Figure 1).
3. Insert the Abutment while keeping the Axor™ II open. Make sure that the Abutment contacts the bottom of the jaws (see Figure 2).
4. Release the grip and let it rotate freely. Tighten the grip clockwise by hand.
5. Move the leg side to side and tighten the grip further by hand to make sure it is firmly attached to the Abutment.
6. Try to pull off the Axor™ II to confirm that it is properly attached.

**CAUTION!** You should not use the Axor if a stable attachment cannot be achieved. Contact your prosthetist if there is any problem with the attachment.

**CAUTION!** Incorrect attachment (see Figure 3) may cause the Axor™ II to fall off the Abutment.

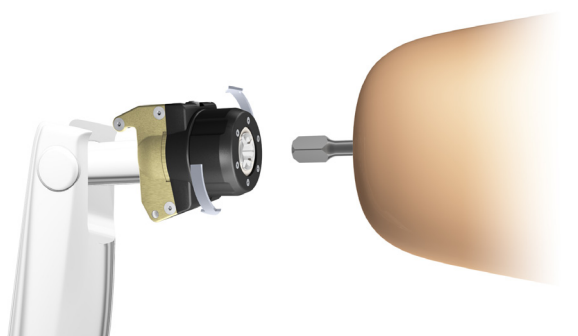


Figure 1. Turn the grip counter-clockwise until it stops.

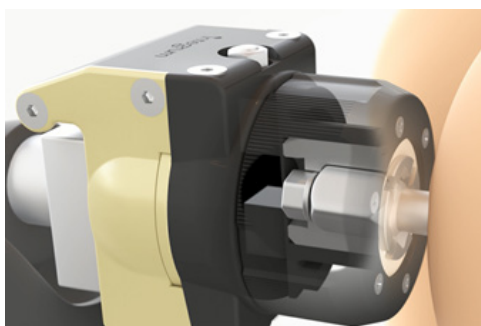


Figure 2. Fully inserted Abutment.



Figure 3. Incorrect attachment to the Abutment.

## DETACHING THE AXOR™ II FROM THE ABUTMENT (DOFFING)

The Axor™ II is removed from the Abutment through the following procedure:

1. Sit down to remove the Axor™ II.
2. Open the jaws by turning the grip counter-clockwise by hand.
3. It may take a higher initial amount of force to get the Axor™ II to release from the Abutment and in some instances an audible popping noise can be heard when the Axor™ II starts to release from the Abutment and the jaws begin to open.
4. Open the jaws wide enough so the Axor™ II can easily be removed from the Abutment.
5. Pull the Axor™ II off the Abutment.

## RELEASE FEATURES

The Axor™ II releases when subjected to high bending and/or rotational moments in order to protect the OPRA™ Implant System from excessive loads.

The Axor™ II releases according to the Figures below.

- In the *bending/flexion* direction the Axor™ II is opened according to Figure 4.
- In the *rotational* direction the Axor™ II rotates around its axis in both clockwise and counter-clockwise directions according to Figure 5.

The two release mechanisms can be reset without using any tools.

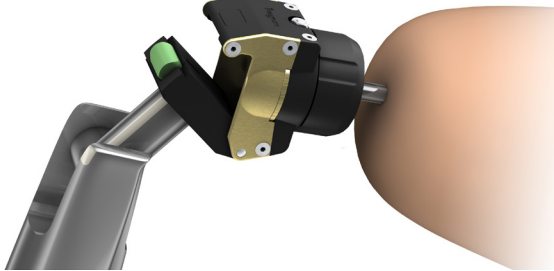


Figure 4. Bend release.



Figure 5. Rotation release.

## RESETTING THE AXOR™ II AFTER RELEASE IN BENDING/FLEXION

When the Axor™ II has released in bending/flexion direction it can be reset:

1. Sit on a chair or on the floor with the leg straight out and the heel of the prosthetic foot on a solid support. If needed, remove the prosthesis from the Abutment before resetting the Axor™ II.
2. Gently close the Axor™ II until the green release plunger makes contact with the edge of the housing.
3. Press down on the Axor™ II according to Figure 6 until it clicks back into the correct position. A moderate to high force may be required.

**CAUTION!** Avoid resetting the Axor™ II if there is any pain during the reset procedure. In case of pain, please contact your physician immediately. Please also contact your prosthetist for reset of the Axor™ II

**CAUTION!** Try to keep fingers away from the bend release mechanism during reset to avoid pinching the fingers.

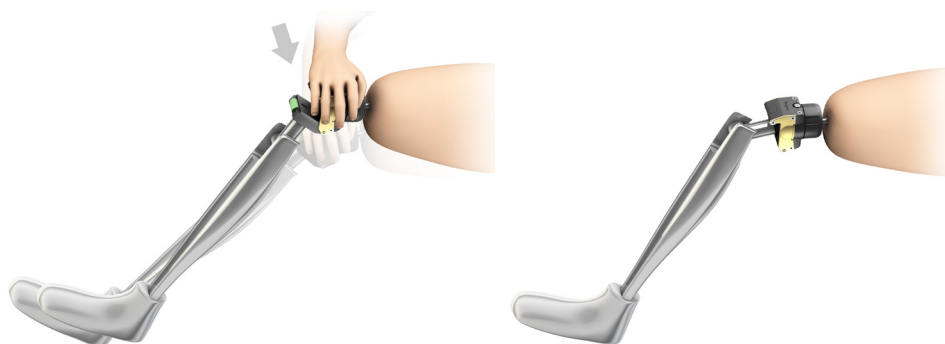


Figure 6. Resetting the Axor™ II after release in bending/flexion.

## RESETTING THE AXOR™ II AFTER RELEASE IN ROTATION

When the Axor™ II has released in rotation it is reset by turning the Axor™ II until the prosthetic leg is back in the normal position for walking (see Figure 7). A click is felt when the release mechanism is correctly reset.

**CAUTION!** A similar click is also felt when the leg is rotated 180 degrees, i.e. when the foot points straight backwards. If this happens, apply a force to turn the foot into the correct position.

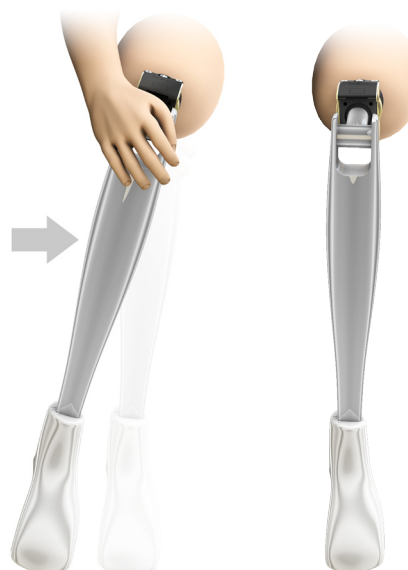


Figure 7. Resetting the Axor™ II after release in rotation.

## CLEANING AND HYGIENE INSTRUCTIONS

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The Axor™ II should be cleaned on a regular basis, at least once per week and after any contact with body fluids. Cleaning should be carried out according to the following procedure:

1. Fill the square hole of the Axor™ II with water mixed with soap or detergent.
2. Let it rest for two minutes and rotate the grip back and forth several times.
3. Pour out the liquid from Axor™ II.
4. Pour alcohol based disinfectant into the square hole of the Axor™ II to dry out any residual water.
5. Let it rest for two minutes and rotate the grip back and forth several times.
6. Pour out the liquid from the Axor™ II.
7. A cotton swab can be used to wipe the surfaces inside the square hole.
8. Clean the Axor™ II on the outside using a soft brush. Put extra attention to screws and nuts. Wipe the outside of the Axor™ II using a cloth.

**CAUTION!** Not cleaning the Axor™ II can cause the Axor™ II to fall off the Abutment or damage the release function.

**CAUTION!** If the device is not clean, the risk for infection is increased.

Body fluids from the skin penetration area should not reach the Axor™ II. A protective tissue tied around the Abutment should preferably be used.

Patient usage and cleaning recommendation can also be found in our instructional video on Integrum's website; [www.integrum.se](http://www.integrum.se).

## MAINTENANCE

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- The Axor™ II must be cleaned, visually inspected and checked by your prosthetist annually for signs of damage, wear and fatigue.
- The release levels shall be checked and recorded by Integrum or certified prosthetist annually.

## WARNINGS

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- In configurations where short extension components are used between the Axor™ II and the prosthetic knee, the battery charger of certain prosthetic knee models (e.g. Otto Bock C-leg) may interfere with the Axor™ II when the knee is in the straight position. In these cases, please bend the knee to connect the charger.
- The use of stiff cosmetic covers may interfere with the function of the Axor™ II.
- The Axor™ II is not intended for use with the following physical activities:
  - » Do not run, jump or climb.
  - » It is recommended to use a cane or crutches for long walks.
  - » Do not lift or carry heavy items.
  - » Avoid subjecting the OPRA™™ Implant System to high torque (twisting motion or bending).
  - » While riding a bike, your knee joint might lock in the fully stretched position. This can seriously damage the Fixture. Always position the bike seat low enough that your knee cannot fully extend while cycling. Never stand up while you are cycling. Consult with your treating team before riding a bike for the first time.
- Handrails and/or other supports should be used when walking downstairs.
- Avoid contact with water (except during cleaning). If the Axor™ II is accidentally submerged in water, please contact your responsible prosthetist for service.
- Do not open the Axor™ II or unscrew any of the screws. In case of any problems, please contact your responsible prosthetist.
- Do not remove the plug in the front plate of the Axor™ II. The plug is only removed by the prosthetist when access to adjustment screws of the connecting prosthetic components is needed.
- Poor cleaning can cause the Axor™ II to fall off or damage the release function. It could also cause infection or cross contamination between patient and personnel.
- The Axor™ II is intended for patients with body weight equal or less than 100kg/220lb including prosthesis.
- If you are having an MRI scan, you must always remove the Axor™ II. Failure to do so may result in serious injury.

### **STOP USING THE AXOR™ II AND CONTACT YOUR RESPONSIBLE PROSTHETIST IF:**

- The Axor™ II does not release as intended, e.g. during overload, or releases unexpectedly. In these cases the responsible prosthetist must be contacted and the Axor™ II must be checked.
- The Axor™ II loosens from the Abutment or falls off during daily life activities.
- The Axor™ II is damaged in any way.
- The Axor™ II has been submerged in water.
- You hear sounds or feel play or vibration caused by the Axor™ II.
- You have any other concerns or questions.



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