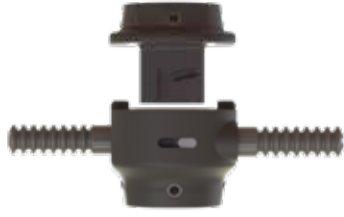


Instructions For Use, IFU Prosthetists

Xtend® Connect Shape A200



SIZE AND WEIGHT GUIDE

The maximum weight for Xtend Connect Shape is 220 lbs. Always verify that the patient's weight is correct. The maximum weight must never be exceeded. In case components with different weight limits are used in the prosthetic leg, it is the component with the lowest weight limit that never shall be exceeded.

PRODUCT DESCRIPTION

Xtend Connect Shape gives the prosthetic user possibility to disconnect a part in their prosthetic leg assembly, without changing any settings made by prosthetist. Xtend Connect Shape is compatible to use in a prosthetic leg assembly with leg cover.

INTENDED USE:

Xtend Connect Shape is a prosthetic component intended for use by above-knee or below-knee amputees, who want to remove or change prosthetic parts. Xtend Connect Shape is designed to be fitted between two prosthetic parts in a prosthetic leg and designed to fit standard connections according to common industry practice.

PATIENT INDICATIONS

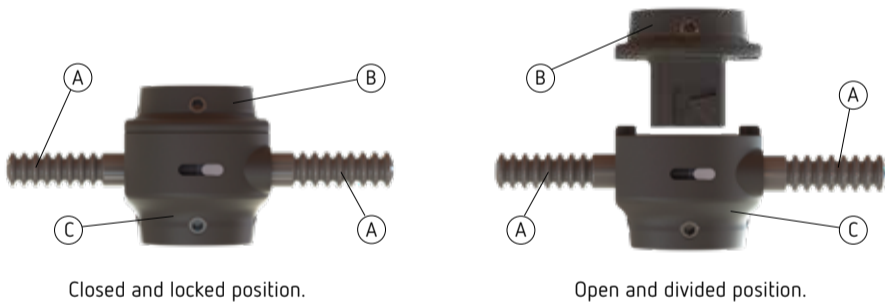
The prosthetic user is physically disabled, and the disability can vary from one leg amputated below knee to hip disarticulation on both legs.

CONTRAINDICATIONS

- The product shall NOT be used in the following types of applications:
- Patients weighing over 220 lbs shall not use the Xtend Connect Shape.
 - The product cannot be used in water.
 - The product is not suitable for users who engage in extreme sports and other high-impact activities.
 - The product is not to be altered or modified outside specification.
 - The product shall not be installed in a location where the user handles it in an unstable position.

XTEND® CONNECT SHAPE AND ITS DIFFERENT COMPONENTS

Xtend Connect Shape consists of two components:
Quick fit unit – the two buttons for locking mechanism open the unit for disconnecting the parts.
Base unit – fits into the quick fit unit.



- A) Buttons for locking mechanism
B) Base unit
C) Quick fit unit

Item number	Description
The parts are sold separately or as a kit.	
Quick fit unit	
A200-SQF	Xtend Connect Shape quick fit unit with a female pyramid adapter.
Base unit	
A200-SBF	Xtend Connect Shape base unit with a female pyramid adapter.
Kit of 1 + 1 pcs	
A200-SK	Xtend Connect Shape quick fit unit and base unit, both with female pyramid adapter.

Basic UDI number for Xtend Connect Shape: 735010414A200UQ

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GENERAL INSTRUCTIONS:

- Only authorised prosthetist may test and install the product on patients.
- Review the care, safety and user instructions with the patient at the time of fitting the product.
- When the Xtend Connect Shape parts are connected, there is a clicking sound heard at the connection point.
- ⚠ It is VERY IMPORTANT that the patient is seated while disconnecting and connecting Xtend Connect Shape. The patient may NEVER stand while connecting and disconnecting Xtend Connect Shape.
- Any worn-out device must be replaced by a prosthetist.
- Under no circumstances may the patient walk on Xtend Connect Shape if it is not correctly locked. This can cause the patient to fall and get injured.
- Before ordering Xtend Connect Shape, it is important to have analysed whether the patient is suited to using this type of quick fit connector and if he/she is able to follow the instructions.
- Before fitting the Xtend Connect Shape to the patient, assure that the joining components fits well to the interfaces of the Xtend Connect Shape. Test-lock the complete unit mounted on the prosthetic leg before fitting it to the patient. Only external components using industry standard may be used.
- Check that the foot/leg is properly locked with the Xtend Connect Shape by lifting the leg.
- Xtend Connect Shape cannot be used in water.
- All adverse events that occur and are related to this product should be reported to the manufacturer and the local authority in the country of occurred event.
- After finished life cycle, the product shall be disposed in metal recycling.

INSTALLATION

Only trained personnel such as a prosthetist may fit, install and regularly inspect the product on patients. Xtend Connect Shape can be fitted with the quick fit unit facing upwards and the base unit facing downwards as well as vice versa. When assembling with a pin lock, the base unit must face upwards. There are two pairs of buttons for the locking mechanism sent with the product: one pair to be used for fitting with the cover and one pair of buttons for final use.

WHAT YOU NEED FOR INSTALLATION

- Torque wrench 4 mm Allen key
- Thread locker e.g. Loctite 243

INSTALLATION OF FEMALE PYRAMID

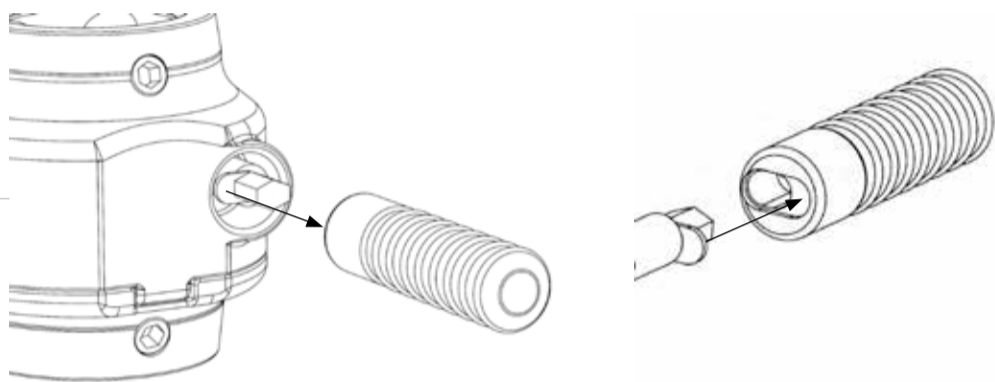
Part	Tightening torque	Thread locker
Adjusting screws	15 Nm	E.g. Loctite 243

Tighten the adjustment screws using the torque wrench once you have tested the product on the patient. When everything has been installed, use Loctite to lock each screw one at a time.



INSTALLATION WITH A COSMETIC FOAM COVER

1. Measure from the sole of the foot to the point where the Xtend Connect Shape will separate when disconnected.
2. Measure and mark where the holes for the locking mechanism buttons need to be placed on the cosmetic cover.
3. Fabricate the cosmetic cover according to standard procedures.
4. Using the measurement from step 1, measure from the sole of the foot and mark the level on the cosmetic cover where the Xtend Connect Shape will separate when disconnected.
5. Measure and mark the holes for the locking mechanism buttons on the cosmetic cover.
6. Remove cosmetic foam cover from the prosthesis.
7. Cut the cover at the marked level for Xtend Connect Shape separations point when disconnecting.
8. Make the holes for the locking mechanism buttons.
9. Reassemble the cosmetic cover to the prosthesis.
10. Tighten any set screws that were loosened to be able to remove the cosmetic cover, using Loctite and torque specifications.
11. Attach the locking mechanism buttons to define the length of them. See the guideline image.
12. To avoid accidental release, cut the locking mechanism buttons slightly below the surface of the cover. Do not cut the buttons closer to the unit than at the innermost immersion of the button. It may be easier to remove the buttons while cutting them.
13. Smooth any rough edges on the locking mechanism buttons to make sure no sharp edges remain.
14. Reinstall the locking mechanism buttons if you removed them before cutting them.
15. Check to make sure the locking mechanism buttons operate and that the Xtend Connect Shape operates properly. Also, check that nothing pushes against locking mechanism buttons after installation.



INSTALLATION WHEN NOT USING A COSMETIC FOAM COVER

1. After all set screws are tightened using Loctite and torque specifications, install the locking mechanism buttons and mark to the desired length.
2. Trim the locking mechanism buttons and smooth any rough edges to make sure no sharp edges remains. Do not cut the buttons closer to the unit than at the innermost immersion of the button. It might be easier to remove the buttons while cutting them.
3. Reinstall the locking mechanism buttons if you removed them before cutting them.
4. Check to make sure the locking mechanism buttons operate and that the Xtend Connect Shape operates properly.

REGULAR MAINTENANCE

We recommend having Xtend Connect Shape inspected by a prosthetist every six months. With very active use, shorter inspection interval may be necessary.

CLEANING INSTRUCTIONS

- During normal use, the device can be cleaned using warm water and a mild detergent whenever needed.
- Always clean the Xtend Connect Shape after contact with sand, to ensure proper function.

Steps for cleaning:

1. While seated, disconnect the Xtend Connect Shape from your prosthetic leg(s).
2. Clean all exposed areas of the Xtend Connect Shape by lightly scrubbing them with a damp lint-free cloth, paper or a cotton swab, and a mild detergent.
3. Wipe down all exposed parts with a dry lint-free cloth, paper or a cotton swab, so that all surfaces are clean and dry before reattachment.

⚠️ WARNINGS

⚠️ WARNINGS TO THE PATIENT

- It is VERY IMPORTANT that the patient is seated while disconnecting and connecting Xtend Connect Shape. The patient may NEVER stand while connecting and disconnecting Xtend Connect Shape.
- Keep fingers clear of the device during removal and attachment to avoid pinching.
- Parts of the device can become hot when exposed to high temperatures.

⚠️ OTHER WARNINGS

- The Xtend Connect Shape is a single patient, multiple use device. Do NOT reuse other persons prosthetic components due to unspecified history and use.
- The device may NOT be altered or modified in any way, shape, or form, outside of the specifications. Any other modifications to the device will void the guarantee.
- The Xtend Connect Shape must be inspected by a prosthetist if subjected to external violence or force.

WARRANTY

The Xtend Connect Shape is covered by a 12-month warranty, starting from the delivery date from Lindhe Xtend. Failure to follow the user instructions will invalidate the warranty. Failure to follow the weight recommendations or exposing the component to unreasonable loads such as heavy lifting or similar high-impact activities which could cause injury to a human body part, will invalidate the warranty.

Xtend Connect Shape A200 is covered by the following patents:

- Germany DE 602019020635.6
- European patent EP 3810040 in FR, GB, SE
- USA 11471305

Explanation of symbols

- REF Product Reference Number
- MD Medical Device
- UDI Unique Device Information
- SN Serial Number
- Consult Instruction For Use
- Warning
- Manufacturer
- Maximum weight