3206 XP AK+

XP AK Auto Expulsion Plus Release

XP AK+ **Part Number: 3206**

Includes:

Valve
Housing with O-ring and retainer
Red Dummy for laminated sockets
Green Dummy for plastic sockets
Spanner wrench to tighten retainer to housing

INTENDED USE

The device is intended as a component of a prosthetic system that replaces a missing lower limb.
Suitability of the device for the prosthesis and the patient must be evaluated by a healthcare professional.
The device must be fitted and adjusted by a healthcare professional. Intended for single device use only, not to be reused on another device.
The device can be used for high impact use, e.g., walking, jogging, and running.

Indications For Use and Target Patient Population

- Lower limb loss, amputation, or deficiency
- No known contraindications

GENERAL SAFETY INSTRUCTIONS

The healthcare professional should inform the patient about everything in this document that is required for safe use of this device.
Warning: If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions, the patient should stop using the device and contact a healthcare professional.
The device is for single patient use.

DESCRIPTION

The device is an auto-expulsion valve with push button for suction release.
Components (Fig. 1)

1. Valve
2. Housing Retainer
3. O-ring
4. Housing
5. Dummy for Rigid Sockets (Red)
6. Dummy for Flexible Sockets (Green)

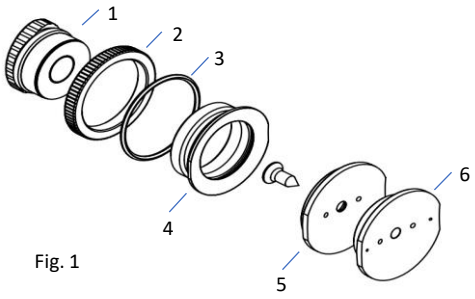

Fig. 1

ASSEMBLY INSTRUCTIONS

Cast rectification

1. Determine the Valve location on the plaster model and flatten the area to ensure the Dummy sits flush. In the center hole of the Dummy place a mark on the plaster model with an indelible marker.
2. Drill a 2 mm vacuum hole using a long drill.
3. Attach the Dummy to the plaster model, using the Nails provided.

Caution: For rigid socket choose Rigid Sockets dummy (6). For flexible inner sockets choose Flexible Sockets dummy (5).

Preparation for thermoplastic sockets (Green Dummy)

1. Drape the thermoplastic socket.
2. Guide the plastic around dummy to ensure proper molding.

Preparation for laminated sockets (Red Dummy)

1. Place the first PVA bag over the plaster model with dummy in place.
2. Place the reinforcing layers and second PVA bag over the dummy.
3. After mixing the resin apply the vacuum to remove trapped air.
4. Pour the resin.

Specifications:	
Overall Dimensions assembled:	
Diameter Base	39mm / 1.5in
Height	20mm / 0.78in
Weight:	41.2g/1.45oz

Finishing and installation

1. Expose Dummy by grinding away material until fully flat area is exposed.
2. Remove Dummy and insert Housing with O-ring.
3. Firmly hand tighten the Retainer to the Housing utilizing the spanner wrench. Make sure the O-ring is not visible from inside the socket, and be sure not to impinge the O-ring or may result in a leak.

USAGE

Cleaning and care Clean with a damp cloth and a mild soap.
Dry with a cloth after cleaning.

Environmental Conditions

The device is Waterproof. A Waterproof device can be used in a wet or humid environment and submerged in up to 3-meter-deep water for a maximum of 1 hour.
It can tolerate occasional contact with: Chlorinated water, perspiration, and mild soaps, but must be cleaned immediately or will void warranty if corrosion is present.
It can also tolerate minimal exposure to sand, dust, and dirt, but must be cleaned immediately to prevent damage to the valve seal mechanism.
Continuous exposure is not allowed.
Dry with a cloth after contact with fresh water or humidity.
Clean with fresh water after exposure to other liquids, chemicals, sand, dust, or dirt and dry with a cloth.

MAINTENANCE

Disassembly and cleaning

1. Unscrew Valve.
2. Clean under running water and clear airways with a gentle stream of air. Hold down the button in the cap while clearing airway.

Reassembly

Replace the valve body into the housing by applying gentle pressure, then gently twist the valve body into the housing. Do not overly tighten the valve body.
The device and the overall prosthesis should be examined by a healthcare professional. Interval should be determined based on patient activity.

REPORT OF SERIOUS INCIDENT

Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.

DISPOSAL

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

WARRANTY

Warranty: 6 months against manufacturing defect only.
Damage from misuse, exposure to non-allowed conditions will void the warranty.

LIABILITY

ST&G USA Corporation does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.

CE Conformity

This product meets the requirements Council EU 2017/1745 (MDR). MD
for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.

Specifications subject to change

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