

3204

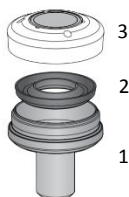
MD Medical Device

ST&G
USA CORPORATION

XP Release Valve Auto with push button

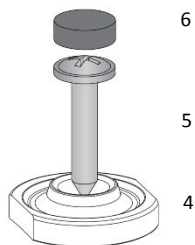


①



②

Flexible
Socket
Insert



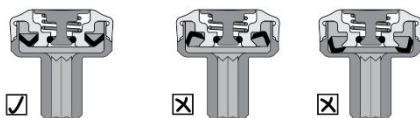
③



min 4mm (3/16")

Minimum residual thread body

④



CONTENT: (Fig 1 & 2)

1. Valve housing
2. Rubber membrane
3. Cap (remove with a rubber band for grip)
4. Socket insert
5. Set screw
6. Foam cap

TOOLS REQUIRED:

- 8.5mm drill bit
- M10x1.5 tap
- Hacksaw
- Caliper
- 5mm hex key
- Philips screwdriver
- Silicone adhesive. ST&G recommends:
Aqueon 100% Silicone Aquarium Sealant
SKU#: 100165004

VALVE INSTALLATION TO RIGID LAMINATED OR PLASTIC SOCKET:

Directly to the socket.

1. Fabricate the socket as usual.
2. Mark the position of the valve onto the socket.
3. Using an 8.5mm (5/16") drill bit, make a hole perpendicular to the socket wall.
4. Tap the hole using M10x1.5 tap.

NOTE: Cap can be unscrewed by hand when a rubber band is applied onto the outer perimeter of the Cap for grip.

5. Ensure the cap and rubber membrane have been disassembled off prior to shortening the threaded body to prevent debris lodging into the airway.
6. Measure socket wall thickness at insertion point with a caliper, and shorten the nozzle accordingly and smooth edges.

 **IMPORTANT:** Do not shorten the nozzle beyond 4 mm (3/16") as it may affect the seal and increase the risk of the valve breaking off.

It is recommended that the socket wall thickness at valve insertion point is to be equal or more than 4mm (3/16") in thickness. (Fig 3)

VALVE INSTALLATION TO RIGID OUTER WITH FLEXIBLE INNER SOCKET:

Using the socket insert. (Figure 2)

1. The socket insert is used as a fixation device for the valve, and should always be used when fabricating a flexible inner socket.
2. Prepare the plaster cast as usual.
3. Fix the socket insert to the cast using a screw. Ensure it sits flush to the cast.
4. Plaster may have to be removed or added.
5. Apply a foam cap to the screw to aid in removal and as a locator.
6. Fabricate the socket as usual.
7. Grind material away over the socket insert until the foam cap is fully exposed.
8. Unscrew the set screw to remove socket from cast.

NOTE: Cap can be unscrewed by hand when a rubber band is applied onto the outer perimeter of the Cap for grip.

9. Ensure the cap and rubber membrane have been disassembled off prior to shortening the threaded body to prevent debris lodging into the airway.
10. Measure socket wall and socket insert thickness at insertion point with a caliper, and shorten the nozzle accordingly and smooth edges.

 **IMPORTANT:** Do not shorten threaded body beyond 4 mm (3/16") as it may affect the seal and increase the risk of the valve breaking off. (Figure 3)

 **IMPORTANT:** It is recommended that valve be part of biannual inspection for proper function.

 **IMPORTANT:** This device is intended for single person use only, do not reuse for different application!



ASSEMBLY.

1. Apply silicone adhesive to the threads and housing, where it comes in contact with the socket. (Aqueon silicone is non-toxic and stays flexible. Epoxy or Urethane adhesive will cure hard, and can eventually compromise the seal)

 **NOTE:** It is not recommended to use epoxy or similar as it can compromise the seal.

2. Install disassembled valve body and hand tighten with a 5mm hex key. NOTE: Be careful not to over-tighten as it may damage the threads.

3. After installation distribute silicone adhesive around the valve / socket contact point to ensure an air tight seal.

4. Ensure the valve parts and valve body are free from debris before final assembly.

5. Replace rubber membrane to cap. Ensure the concave surface is facing the cap cavity. (Figure 4)

 **NOTE:** When reassembling ensure the membrane is **ON** the cap and **NOT** in the housing.

6. Screw the cap on.

DISASSEMBLY AND CLEANING

1. Unscrew the cap.

2. Remove the rubber membrane carefully.

3. Clean all parts with water and mild detergent.

4. Hold down the release button while cleaning airways.

REASSEMBLY

1. Replace rubber membrane to cap. Ensure the concave surface is facing the cap cavity. (Figure 4)

2. Screw the cap on.

 **NOTE:** When reassembling ensure the membrane is on the cap and not in the housing.

STORAGE & OPERATING:

- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
- Allowable relative humidity 0 % to 90 %, non-condensing



A weatherproof device allows use in a wet and/or humid environment but does not allow submersion. Fresh water splashing against the enclosure from any direction shall have no harmful effect. Dry thoroughly after contact with fresh water. Fresh water: Includes tap water. Not recommended for use in non-fresh water exposure, extreme temperatures, or extremely dusty environment.

IMPORTANT!



Do not utilize with certain items or in certain situations that can result in loss of suction, which could possibly lead to a fall scenario. Notify your prosthetist immediately so maintenance can be performed to clean out the valve assembly.

For example:

Talcum powder inside socket

Use in saltwater, as the salt water could leave particle residue

Use in very dusty conditions. Abrasive conditions can reduce the lifespan of the internal valve components and lead to leakage and loss of suction.

Warranty

Warranted for 6 months from the date of invoice by ST&G.

The user should be aware that changes or modifications will void the warranty.

Use in harsh conditions could void warranty.

Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for damage caused by the component combinations that were not authorized by the manufacturer.

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments

Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not store in wet or very hot environment.



Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics
cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, sand

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts

Cleaning agents containing solvents

CE Conformity

This product meets the requirements Council EU 2017/745 (EU) 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.

Useful Life

Service life of the product is covered by the warranty period.

Counter Indications

There are no counter indications.

Disposal

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

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