# ATMOS® Cup

<table>
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<tr>
<th>ATMOS® Cup, extraction cup silicone, Ø 50 mm</th>
<th>404.0194.B</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATMOS® Cup, extraction cup silicone, Ø 60 mm</td>
<td>404.0193.B</td>
</tr>
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Operating instructions

English
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For further information, accessories, consumables and spare parts, please contact:

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1.0 Introduction

1.1 Notes on operating instructions

These operating instructions contain important notes on how to operate the ATMOS® Cup safely, correctly and effectively. Their reading helps to avoid risks, and also to reduce repair costs and down-time. That increases, amongst other things, the reliability and service-life of the product. These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Reprints (also in extracts) only with permission in written form by ATMOS.

**These operating instructions must always be kept available near the device.**

Care and safety inspections in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS® Cup and are therefore a must besides regular cleaning.

- The ATMOS® Cup bears CE marking according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of appendix I of this directive.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 9001 and EN ISO 13485.
- The product ATMOS® Cup complies with all applicable requirements of the directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).
- The declaration of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.
- Prior to start-up please peruse chapter 2.0 “For your safety“, in order to be prepared for any possible dangerous situations.

1.2 Function

In case that it is not possible for the parturient to push out the baby from the uterus by herself, due to peridural anaesthesia, exhaustion, etc. a vacuum extraction with the suitable extraction cup can be performed.
1.3 Intended use

Name: ATMOS® Cup

Main functions: The ATMOS® Cups are used to support the birth process. It may only be used in human beings.

Med. indications/application: Support of the birth process.

Specification of the main function:
If a mother is unable to deliver her baby due to peridural anaesthesia, exhaustion etc. a vacuum extraction with the suitable extraction cup can be performed. The extraction cup is placed on the baby's head and the vacuum exerts temporarily on this part of the body. The application is only allowed under the following circumstances: Gravidity > 36 weeks, amnionic sac has broken, a completely dilated cervix, vertex presentation, correct diagnosis of the occiput presentation, steady contractions.

Application organ: Natural female orifices (vagina)

Application time: Temporary

Application site: In the clinic

Contraindications:
The ATMOS® Cup is used to support the child birth. It may only be used in human beings. The ATMOS® Cup is a product which should only be inserted into a natural body opening (vagina) and not into a surgical opening. The extraction cup is attached to the head of the baby (normally "above the minor fontanelle" Valet/Goerke/Steller, 1992) and temporarily a vacuum is applied to this part of the body.

The product is: not active

Sterility: Sterile usage

Single use product / reprocessing: Reprocessable

1.4 Explanation of pictures and symbols

- Warning, especial diligent notice
- Move in direction of the arrow
- Please read, important information
- Proceed in direction of the arrow
- Numeration
2.0 For your safety

- No warranty rights shall exist in the event of damage or failure caused by the use of non-ATMOS accessories or non-ATMOS consumables.

- Please also pay attention to the security advices of the connected device, as well as those stated in the following chapters.

- These operating instructions correspond to the design of the product and the status of basic safety engineering standards on going to press.

- The ATMOS® Cup may only be used by qualified personnel who is authorised and instructed in operation by ATMOS. It may only be used under supervision.

- Please check consignment on completeness and intactness.

- ATMOS will not be liable for damage to people or property if:
  → Any non-original ATMOS parts are used.
  → The instructions for use stated in these operating instructions have been disregarded.
  → Assembly, resetting, alterations, extensions and repairs have not been carried out by people authorised by ATMOS.

- The ATMOS® Cup should be disposed in case of discolouration or cracked surface, as this could be a sign of material fatigue.
2.0 For your safety

Please observe strictly!

In order to prevent from injuries, please note the following advices:

- Vacuum extraction may not be possible at elevated altitudes as it may not be possible to achieve the vacuum required. It is at the discretion of the specialist whether an operation using the suction unit can be carried out at the final vacuum obtained. If the vacuum is too low the extraction cup can tear off from the child's head and the child can be seriously injured.

- Prior to start up all connections must be checked on any damage. Hoses which are damaged must be exchanged!

- Never apply the extraction cup more than twice.

- The head must be completely delivered within 15 minutes from first applying the extraction cup.

- Do not pull three times, if the second pull fails to produce good descent.

Danger of injury!

- If the head is higher than "on the pelvic floor" when the extraction cup is applied, it must be at least "on the pelvic floor" by the end of the second pull.

- The head, not just the scalp, must descend with each pull.

- The head must be delivered, or almost completely delivered, with no more than three pulls.

- Do not pull twice, if the first pull fails to produce descent.

Indications for application

Child: Fetal distress in the second stage.

Pregnant woman: Maternal delay in the second stage. Maternal conditions requiring a short second stage.
3.0 Operation

3.1 Scope of supply

- ATMOS® Cup
- Hose

3.2 Connections

Connect the hose with the container of the vacuum source to be used.
3.3 Starting up

3.3.1 Requirements regarding the pump

The ATMOS® Cup has been developed for use in conjunction with an external vacuum source, capable of precise vacuum regulation to ensure proper vacuum levels. The vacuum source should be designed for medical purposes and may be either electric or manual.

⚠️ NOTE: Wall suction (central vacuum supply) may not be used.

3.3.2 Requirements regarding the hoses

The hose connections between the ATMOS® Cup and the vacuum source are vital for safe and proper function of the instrument. For this reason only original ATMOS hoses should be used.

3.3.3 Conditions for use of the extraction cup

- gestational age > 36 weeks
- amniotic sac is ruptured
- cervix is fully dilated
- vertex presentation
- head fully engaged
- no cephalopelvic disproportion
- good uterine contractions

3.3.4 Contraindications

- Malpresentation (face, brow, breech, transverse or oblique lie).
- Cephalopelvic disproportion.
- Cervix insufficiently dilated.
- Uncooperative patient.
- Active bleeding from a fetal blood sampling site.
3.0 Operation

IMPORTANT NOTE:
The physician is responsible for proper surgical procedures and techniques. The physician must evaluate the respective appropriateness of the procedure based on his or her own medical training and experience.

3.3.5 Technique

The level of the fetal head should be carefully assessed by abdominal palpation with the patient in the dorsal position. Assessment of level by vaginal examination is often wrong when there is moulding or caput, in which case the head always feels lower than it really is.

The ATMOS® Cup can be used with the patient in lithotomy, left or right lateral, or dorsal position. Dorsal position should not be used unless the fetal head is low and the patient’s buttocks are raised on a suitable support.

Adequate analgesia can be achieved by local infiltration or pudendal block. General anaesthesia should be avoided, because it prevents the patient from assisting the delivery by pushing.

The bladder should be emptied with a catheter if it is visibly or palpably full. Vaginal examination will indicate the type and size of extraction cup that should be used.

The hose end of the long silicone hose is connected to the cross handle of the extraction cup. The distal end of the long silicone rubber suction tube is handed to an assistant, who attaches it to the tube-connector-piece of the bottle of the vacuum pump. The pump must not be operated until the extraction cup has been correctly positioned.
3.0 Operation

3.3.5 Technique (continuation)

The ATMOS® Cup is gently edged into the vagina and firmly pushed towards the posterior fontanelle. The extraction cup is ideally positioned when its centre is directly over the posterior fontanelle. When the ATMOS® Cup has been correctly positioned it is pressed against the scalp with two fingers of one hand, while the index finger of the other hand is swept around the rim of the extraction cup to check that there is no maternal tissue between the ATMOS® Cup and the scalp (20 kpa).

![Image of the extraction process]

When the operator is completely satisfied with the application, the vacuum should be produced in one step as quick as possible and increased to a value of 60-80 kPa. Traction is applied at the onset of the next uterine contraction! Vacuum is to be controlled during childbirth with the manometer.

Traction is a two-handed exercise with the thumb of the non-pulling hand pressed firmly against the extraction cup near the rim and traction should be applied in the direction of the pelvic axis.

Traction is applied only throughout the contraction and no attempt should be made to rotate the fetal head by rotating the extraction cup.

Episiotomy may or may not be necessary, just as in normal delivery.

The vacuum is slowly (10-15 sec.) released and the extraction cup is removed, when the head has been completely delivered.
## 4.0 Cleaning and care

<table>
<thead>
<tr>
<th>Application site</th>
<th>Deposit the product preferably dry.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage/Transport</td>
<td>Transportation of used products in an unbreakable, leak-proof and well lockable container. This must be easy to clean and thermally disinfectable. To avoid encrustation and corrosion a prompt treatment is recommended.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manual processing</th>
<th>Mechanical processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-treatment</td>
<td>For the protection of the staff an immersion disinfection must be performed prior each cleaning. It is important to ensure that the product is fully submerged.</td>
</tr>
<tr>
<td></td>
<td>Cup and suction hose must always be reprocessed separately.</td>
</tr>
</tbody>
</table>

### Cleaning¹

- The extraction cups must always be completely immersed and then cleaned with a soft brush. Rinse cavities with a single use syringe (50 ml).
- Cleaning of the suction channel with a soft bottle brush.
- Water quality: drinking water
- Temperature: 37 – 42 °C

Cleaning agents²:
- a) MediClean forte
  - Conc.: 1 %
  - Duration: 20 min
- b) Sekusept Aktiv
  - Conc.: 1 %
  - Duration: 15 min

- Rinse the product under running water, pay attention to cavities and suction channel.
- Pay attention to personal protective equipment.

### Disinfection

- All surfaces must be covered by the disinfectant. Air bubbles must be removed. Consider the manufacturer’s information regarding contact time and the loss of active ingredients during several cycles.
- Water quality: drinking water
- Temperature: 20 – 25 °C

- Use a temperature of 93°C to disinfect the products.
## 4.0 Cleaning and care

<table>
<thead>
<tr>
<th>Manual processing</th>
<th>Mechanical processing</th>
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</thead>
<tbody>
<tr>
<td><strong>Disinfection</strong></td>
<td></td>
</tr>
<tr>
<td>Disinfectants⁴:</td>
<td>b) Sekusept Aktiv⁵</td>
</tr>
<tr>
<td>a) Septo 3000</td>
<td>Conc.: 2 %</td>
</tr>
<tr>
<td>Conc.: 1 %</td>
<td>Duration: 15 min</td>
</tr>
<tr>
<td>Duration: 30 min</td>
<td>Pay attention to personal protective equipment.</td>
</tr>
<tr>
<td>Rinse thoroughly with sterile demineralized water. All surfaces must be wet. All air bubbles must be removed.</td>
<td></td>
</tr>
<tr>
<td><strong>Drying</strong></td>
<td></td>
</tr>
<tr>
<td>Dry with a soft, lint-free, disposable cloth. Blow through cavities and suction channel with pressurized air (preferably microbiologically filtered air).</td>
<td></td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td></td>
</tr>
<tr>
<td>The extraction cups should be checked for functionality and cleanliness. Damaged cups must be eliminated. Products which are still dirty must be reprocessed.</td>
<td></td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td></td>
</tr>
<tr>
<td>The disassembled suction cup is packed in a peel bag. These must be large enough so that the sealing is not under tension.</td>
<td></td>
</tr>
<tr>
<td><strong>Sterilisation</strong></td>
<td></td>
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<tr>
<td>Sterilize the extraction cups with moist heat at 134°C (5 min 3x fractionated prevacuum).) with the pre-vacuum method. Use a sterilizer according to EN 285. The recommended limits for the ingredients of filling water and steam condensate are specified by the EN 285. Pay attention to the maximum loading of the sterilizer.</td>
<td></td>
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</table>

**Restriction of the durability**
The extraction cups have an expected durability of 2 years or 60 processing cycles, depending on what occurs first.

This processing manual is valid for the following products:
- REF 404.0194.0 ATMOS® Cup 50 mm
- REF 404.0193.0 ATMOS® Cup 60 mm

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¹ Do not use any organic solvents.
² As well as other agents which are approved by the manufacturer specifically for silicone.
³ As well as other agents which are approved by the manufacturer specifically for silicone.
⁴ As well as other agents which are approved by the manufacturer specifically for silicone.
⁵ Cleaning and disinfection in one step
5.0 Repair and service

Prior to each application, check the device's functions and its proper condition.
- The edge is smooth and undamaged
- The material does not show any cracks.

In the case you need maintenance and/or service, please contact:

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79853 Lenzkirch
Germany

Phone  +49 7653 689-222
Fax      +49 7653 689-292
E-mail  service@atmosmed.de
6.0 Technical specifications

6.1 General information

The ATMOS® Cup is made of medical grade silicone and is available in two sizes, with 50 mm and 60 mm inner diameter. The instrument is made in one piece and consists of a handle and a suction cup to be used with a pump and tubing. The cup has a smooth external surface, but there is a small longitudinal ridge, which makes it possible to observe any rotation. The inside of the cup is lined with small projections, 1 mm high and 4 mm in diameter, 3-5 mm from one another. The projections enable the air between the cup and the child's head to be evacuated and ensure that the cup sucks firmly against the child's head. The soft suction cup adapts to the shape of the head, thereby ensuring perfect adhesion and minimising trauma to the fetal scalp.

6.2 Equivalent negative gauge pressures

<table>
<thead>
<tr>
<th>kPA</th>
<th>Kg / cm²</th>
<th>mmHg</th>
<th>bar</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>0.13</td>
<td>100</td>
<td>0.13</td>
</tr>
<tr>
<td>27</td>
<td>0.27</td>
<td>200</td>
<td>0.26</td>
</tr>
<tr>
<td>40</td>
<td>0.41</td>
<td>300</td>
<td>0.39</td>
</tr>
<tr>
<td>53</td>
<td>0.54</td>
<td>400</td>
<td>0.53</td>
</tr>
<tr>
<td>67</td>
<td>0.68</td>
<td>500</td>
<td>0.66</td>
</tr>
<tr>
<td>80</td>
<td>0.82</td>
<td>600</td>
<td>0.79</td>
</tr>
<tr>
<td>93</td>
<td>0.95</td>
<td>700</td>
<td>0.92</td>
</tr>
<tr>
<td>101</td>
<td>1.03</td>
<td>760</td>
<td>1.00</td>
</tr>
</tbody>
</table>
7.0 Disposal

- The ATMOS® Cup does not contain any hazardous materials.
- The ATMOS® Cup is recyclable.
- Device and accessories must be decontaminated prior to disposal.
- Please take care on a careful separation of the different materials.
- Please observe national disposal regulations (e.g. waste incineration).

Disposal within the EC

The device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed of professional. According to the EC directives the product may not be disposed of in domestic waste. Please observe existing national laws and rules for disposal of old products.

Disposal within the Federal Republic of Germany

In order to guarantee a proper disposal of your old product, please either pass on your old product to your specialised dealer or send it directly to ATMOS MedizinTechnik for a professional disposal.

Before disposal respectively prior to transport all the parts, which came into contact with the patient must be thoroughly cleaned, disinfected.