# INSTRUCTIONS FOR USE

## Accura Unblocker

## Aspiration Catheter

**STERILE:** Sterilized with ethylene oxide. Do not use if the sterile package is open or damaged.

**Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions; otherwise, complications may occur.**

**Use the product before expiration of the „Best-Before-Date" mentioned on**

**the packaging.**

## Product description

The Unblocker provided as set consists of a dual lumen rapid exchange aspiration catheter, compatible with 0.014" (0.36mm) guide wires.and related accessories. The proximal Luer-lock type hub allows the connection of a stopcock and of an aspiration syringe for blood aspiration and clot removal.

In order to facilitate Aspiration Catheter advancement through arterial vessels, a coating is present on the distal shaft.

***Lengths and sizes specified for the catheters are mentioned on the respective product label.***

Depending on the catheter:

- The usable catheter length varies between 135cm - 141cm.
- The guide wire lumen is located inside or outside of the catheter..
- The guide wire lumen length amounts 3 or 7.5cm depending on the catheter
- The smooth, soft, atraumatic tip has a radiopaque marker.
- The Aspiration catheter is compatible with 5F (min. ID 1.47mm), 6 F (min. ID 1.78mm) or 7 F (min. ID 2.06mm) guiding Catheter.

All versions are compatible to 0.014" (0.36mm) guide wires.

**Content:**

| Quantity | Material |
|---|---|
| 1 | Aspiration catheter |
| 2 | Syringes |
| 1 | Cell strainer (filter) |
| 1 | Stopcock with tubing assembly (extension tube) |

## Recommended storage

1. Keep in a cool, dark and dry place.
2. Use immediately after the sterile package is opened.
3. Refer to the symbol legend at the end of this document.

## Disposal instructions

After use, dispose product and packaging in accordance with hospital, administrative and/or local government policy.

## Indications

Deblokační katétr je určen pro odstraňování sraženiny a zbytků v koronárních nebo periferních arteriích perkutánním odsáváním.

## Contraindications

1. Single use only. Do not re-sterilize and/or reuse.
2. These components are contraindicated in the following lesion:
   - left main trunk lesion unprotected by bypass graft or collateral circulation
   - the venous system
   - cerebral vasculature.

3. These components are contraindicated in the following patients: patients who are responsive to surgical treatment, patients with lateral distal stenosis of the stent installed at the bifurcated lesion, patients with serious blood coagulation abnormality.
4. The catheter is contraindicated in the removal of fibrous, adherent or calcified material (e.g.atherosclerotic plaque, chronic clot).

## Warnings and precautions

1. This catheter may be used only by physicians skilled in percutaneous transluminal angioplasty.
2. Prior to use, the packaging and product should be inspected for signs of damage. Do not use if packaging is damaged.
3. Do not use agents containing organic solvents or oleaginous contrast media. Contact with these agents may lead to damage of the Aspiration catheter.
4. The Unblocker should be handled carefully. Prior to use inspect the Aspiration catheter carefully for bends, kinks, or other damage. Do not use a damaged Aspiration catheter.
5. Confirm the compatibility of the catheter diameter and length with the guide catheter and guide wire prior to use.
6. Check that all fittings are secure so that air is not introduced into the extension line or syringe during extraction.
7. Excessive tightening of a haemostatic valve onto the catheter shaft may result in damage to the catheter.
8. Since serious complications might arise when using this catheter, operation should be done in a medical institution where emergency procedures can be executed
9. When aspirating thrombus adjust the aspiration amount considering the diameter of the vessel from which the thrombus is sucked and the flow of blood into the target lesion (If the diameter of the vessel from which the Aspiration catheter sucked and the flow of blood into the target site is too small compared to the aspiration amount of this catheter, negative pressure may arise in the distal tip of the catheter).
10. If the guide catheter is wedged in the entrance of the coronary artery or there is stenosis in the upstream of the target lesion for suction, perform the procedure cautiously as the vessel or the implanted stent may be deformed by the negative pressure arising from the process of aspiration [If the flow of blood in to the target lesion from which the thrombus is sucked is too small compared to the aspiration amount of this catheter, negative pressure may arise in the distal tip of the catheter.
11. A distal protection device is mandatory when the Aspiration catheter is used in the treatment of thrombus within the carotid artery. Temporarily occlude distal side of the target lesion by such protection devices.
12. During insertion of this catheter into vessels, the guide catheter should be infused with heparinized saline for anticoagulation.
13. This catheter must be primed before use to remove any residual air inside the catheter and syringe.
14. This catheter can only be inserted with the use of a guide wire [Insertion of this catheter alone may lead to damage to the vascular wall or perforation of vessels.]
15. The guide wire must be completely advanced to reach towards the end of the vessel containing the lesion to be treated. [If guide wire is not completely advanced to the end, it may loosen from the guide wire lumen and it may even lead to damage to the vascular wall or perforation of vessels.]
16. If the guide wire is displaced from the guide wire lumen during operation, remove the catheter and reinsert the guide wire.
17. The location of the catheter and thrombus must be verified under fluoroscopy during operation. [During the insertion of this catheter into the area of the thrombus, this catheter may move the thrombus and cause it to disperse. In addition, during thrombus suction, attachment of the distal end of the catheter onto the inner wall of the vessel may lead to damage to the inner wall of the vessel.]
18. If abnormal or strong resistance is experienced during the operation the cause for such abnormality or Resistance should be verified and appropriate measures should be performed before proceeding [If such abnormality or resistance is ignored and excessive force is applied, it may lead to damage of the vessels or to the catheter shaft breaking and remaining inside the body]
19. In the case that this catheter is advanced to the area where the stent is placed, insertion or pulling out should be performed slowly to avoid the distal end of the catheter becoming stuck on a stent strut. The interface between this catheter and the guide wire may catch the stent strut, with could potentially damage the stent and this catheter. If any resistance is encountered, do not insert or remove the catheter forcefully. Check whether the catheter is caught and if so try to remove it from the strut by adjusting the position of the catheter and the guide wire.
20. Do not advance this catheter to the distal part of the site where a venous filter is implanted. [The strut of the venous filter may damage the catheter or break the catheter shaft leaving debris inside the body.]
21. During usage, the catheter shaft should be replaced if any, break or kink in the shaft occurs. [If the catheter continues to be used and such occurrence is ignored, suction may fail or the catheter shaft may be damaged and remain inside body.]

22. If a great resistance is encountered during insertion, movement, or pulling out of this catheter, it should be verified that the guide wire is not tangled. If so, the tangling of the guide wire lumen of this catheter is short, the guide wire may wind around the catheter shaft. In addition, while drawing this catheter back into the guide catheter inside vessels, the wide-angel separation between the catheter shaft and guide wire may occur. Under this circumstance, a forced withdrawal may lead to damage to the guide wire or catheter.]
23. Due to the lack of conductivity of twist forces, the catheter shaft should not be twisted [If twisted, the catheter shaft may be damaged and then remain inside the body.]
24. The volume of thrombus suction should be decided by physicians for each lesion and adjusted via the suction syringe.
25. Air and sucked blood of thrombus in the suction syringe should never be injected into the body via the catheter.
26. This catheter should not be unreasonably inserted into or swiftly pulled out from lesions with highly tortuous vessels, bifurcated lesions, or calcified lesions. [The shaft at the distal end may then kink or be damaged, leading to vascular damage.]
27. Precaution should be taken to prevent any damage to the catheter by other equipment (such as scalpels, blades or scissors). Do not use a damaged catheter.
28. During the usage of this catheter, the temperature, blood pressure, pulse, and respiration of patients should be monitored. In case of any abnormality, the procedure should be stopped or appropriate measures taken based on the physician´s judgment.
29. Do not use the catheter for the delivery or infusion of diagnostic, embolic or therapeutic materials into blood vessels as it has not been designed for these uses.
30. Do not use the syringe, extension line, and stopcock inside the human body.
31. Refer to the instructions supplied with any interventional devices to be used in conjunction with the system for their intended uses, contraindications, warnings, precautions, and instructions for use.
32. If blood does not fill syringe during aspiration and catheter blockage is suspected, do not flush the catheter while in the patient.
33. Do not perform high pressure contrast injections around the Aspiration catheter while using a guide catheter. High pressure contrast injection may damage the Aspiration catheter, making it difficult to remove from the guide catheter.
34. If flow into the syringe stops or is restricted, do NOT attempt to flush the extraction lumen while the catheter is still inside the patient vasculature. Intravascular thrombus delivery, thromboembolic event and/or serious injury or death may result. Remove the catheter and, outside the patient, either flush the extraction lumen or use a new catheter.
35. Appropriate drug therapy (anticoagulant, vasodilator, etc.) should be administered to the patient according to standard protocols for percutaneous interventions before insertion of the Aspiration catheter.

## Potential adverse events and Complications

Complications associated with the use of the Unblocker are similar to the ones associated with standard percutaneous interventional procedures. Adverse events may include, but are not limited to:
Infarction caused by occlusion of distal vessels or side branch

- Vasospasm
- Stripping of vascular endothelium
- Dissection of vascular intima
- Total occlusion or thrombosis of the vessel
- Vascular perforation
- Blood pressure fluctuation
- CVA/stroke or transient ischemic attacks
- Shock
- Intimal disruption
- Arterial thrombosis
- Distal embolization of blood clots and plaque
- Arterial dissection, perforation, rupture or injury
- Reaction to drugs
- Reaction to contrast media
- Renal insufficiency/renal failure
- Transient ischemia
- Air embolism
- Thromboembolism
- Internal bleeding
- Hematoma
- Infection

- Catheter fracture with tip separation and distal embolization
- Access site complication (i.e., AV fistula, dissection, hematoma, hemorrhage, pseudo aneurysm)
- Damage or migration of implanted stents and damage to drug coating of a freshly deployed drug eluting stent
- No or slow reflow of treated vessel
- etc.

These adverse events may cause:

- Emergent coronary bypass surgery or emergency surgical or percutaneous intervention
- Myocardial infarction
- Re-stenosis
- Cardiac tamponade
- Hemorrhage
- Haemolysis
- Emergent brain surgery
- Cerebral infarction
- Formation of vessel fistula
- Aneurysm
- Arrhythmia
- Ischemic infarction of tissue or organ
- Unstable angina
- Pain
- Death

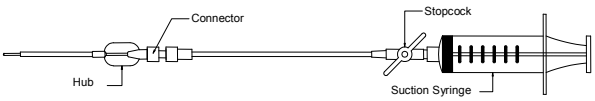
## Operators instructions Procedure

Preparations

1. Aseptically remove this catheter from the package container and carrier tube.
2. Remove protection wire
3. Prime the suction lumen and guide wire lumen of this catheter (using heparinized saline to replace the air)

Procedures for priming

a) Draw 10ml of heparinized saline into the suction syringe and expel any air inside the suction syringe.
b) Attach the Syringe kit onto the connector of the core wire of this catheter, as shown in the picture below.




c) Air inside this catheter and syringe kit is replaced with the full volume of heparinized saline inside the suction syringe. In the case of incomplete air replacement procedures a) – c) should be repeated, and after flushing, the stopcock should be closed.

d) Attach the flushing needle (not supplied in this set) onto another prepared syringe containing heparinized saline and fill the guide wire lumen of the distal tip of this catheter with the same heparinized saline.

Procedures for insertion into the body and suction

1) Prior to use, check if this catheter is compatible to the guide catheter (not supplied in this set), the Y-connector (not supplied in this set) and the guide wire (not supplied in this set) Tables on page 6.
2) Insert the guide catheter, and after the installation of the Y-connector, advance the guide wire beyond the lesion. In case of usage of distal protection device, advance it to the end of the lesion.
3) Insert the proximal end of the guide wire into the distal part of the guide wire lumen of this catheter.
4) Through the Y-connector, insert the catheter under fluoroscopy to make the radiopaque marker at the distal tip of the catheter reach the target site.
   To prevent kinking of the shaft, hold the catheter no more than two to three centimeters away from the y-connector and slowly insert the catheter into the introducer. Repeat this process until the catheter reaches the target site.

5) Moderately lock the Y-connector to prevent blood loss and resistance with catheter during the procedure.
6) Disconnect the Syringe kit from the connector; pull out the core wire from this catheter.
7) Reattach the Syringe kit to the hub of this catheter
8) After verifying the location of the catheter under fluoroscopy, pull the plunger of the suction syringe to the desired volume and reduce the pressure inside the suction syringe after locking the plunger.
9) Open the stopcock and start suction

In case of usage without protection balloon:
Open the stopcock and slowly advance this catheter towards the thrombus for thrombus suction. Slowly advance the catheter through the whole area of the thrombus. Then draw back the catheter to the proximal side of lesion.

In case of usage with protection balloon:
In accordance with Instruction for Use of protection balloon, temporarily occlude the target lesion. Then open the stopcock and slowly advance the catheter through the whole area of thrombus for suction.

10) Close the stopcock and remove the suction syringe. In case of usage with protection balloon, if urgent recanalization is necessary, deflate the protection balloon immediately according to its Instruction for Use.
11) If another aspiration is needed, after removing the aspirated materials from the suction syringe, reattach the suction syringe onto the stopcock and repeat procedures 8)-10)

Removal

1. Ensure the suction of the thrombus is completed
2. Ensure the stopcock is closed
3. Slowly remove the catheter
4. Ensure no thrombus remains inside the Y-connector. Any thrombus inside the Y-connector should be removed.
5. If reinsertion of this catheter is necessary, the insertion should be performed again from the priming procedure after the insertion of the core wire.

## Reuse precaution statement

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile seal is damaged. If damage is found call Accura GmbH representative.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

***References***

*The physician should consult recent literature on current medical procedures involving balloon dilatation, such as that published by international cardiologists' associations.*

## Warranty/Liability

The product and each component have been designed, manufactured, tested and packed with appropriate accuracy. The warning notices being contained in this Instruction of Use have to be considered particularly as an essential part of this clause. Accura grants a warranty on the products up to the mentioned "Best- Before-Date". A warranty exists only under the provision that the use of the product has been carried out in accordance with the Instruction of Use. Accura refuses each warranties or promises of a general usability for a certain purpose of the product. Accura is not liable for direct, indirect, incidental originated or secondary damages being caused by the product. With exception of a fault or of a considerable fault on the part of Accura a compensation of any damages which occur for the buyer will in no case be higher than the invoiced amount of the faulty product. The warranty contained in this clause considers and replaces the legal warranty for defects and compliance of the directives and excludes each other possibility of liability on the part of Accura howsoever this can be ascribed to the delivered products. This limitation of liability and warranty on the part of Accura does not gear towards to be in contradiction to compulsory regulations of applicable right. Should one of the clauses of the disclaimer of

liability be abrogated from a responsible court or should it be declared to be in contradiction to the applicable right the effectiveness of the further clauses of this user contract remain unaffected and valid in the greatest possible extend. In this case the undersigned commit themselves to agree a new arrangement which complies at best with the entitled interests of Accura to restrict their liability or warranty. No one has the authority to oblige Accura for any warranty or liability concerning the product.

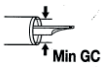
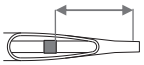
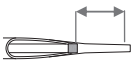
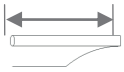
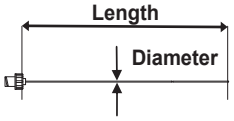
Product variants

| Catalogue No. | Compatible guiding catheter | Min. guiding catheter ID | Max. guide wire diameter |
|---|---|---|---|
| **AC5FE** | 5 F | 0.058“ 1.47 mm | 0.014“ 0.36 mm |
| **AC6FE** | 6 F | 0.070“ 1.78 mm | 0.014“ 0.36 mm |
| **AC7FE** | 7 F | 0.081“ 2.06 mm | 0.014“ 0.36 mm |

Specification

| Parameter | | AC5FE | AC6FE | AC7FE |
|---|---|---|---|---|
| Compatible Guide Catheter | | 5 F | 6 F | 7 F |
| Minimal Guiding Catheter ID - inner diameter [mm, inch] | | 1.47<br>0.058“ | 1.78<br>0.070“ | 2.06<br>0.081“ |
| Compatible Guidewire [mm, inch] | | 0.36<br>0.014“ | 0.36<br>0.014“ | 0.36<br>0.014“ |
| Usable Catheter Length (Tip Kink to Protection) [mm] | | 1410 | 1410 | 1410 |
| Rapid Exchange (RX) | Configuration: I = inner / O = outer | I | I | I |
| | Length [mm] | 75 | 75 | 75 |
| Length of the Aspiration Opening | | 4.8 | 4.8 | 4.8 |
| Distance Radiopaque Marker – Tip [mm] | | 3.5 | 3.5 | 3.5 |
| Distance Proximal End of Aspiration hole Radiopaque Marker [mm] | | 4.5 | 4.5 | 4.5 |
| ID Aspiration Lumen Proximal [mm] | | 0.838 | 1.10 | 1.30 |
| Minimum ID Aspiration Lumen Distal [mm] | | 0.23 | 0.48 | 0.69 |
| Shaft Diameter (OD) [mm] | Distal | 1.067 | 1.37 | 1.55 |
| | Central | | | |
| | Proximal | 1.12 | 1.42 | 1.55 |

Graphical Symbols for Medical Device Labeling

| | | | | |
|---|---|---|---|---|
|  Sterilized with ethylene oxide gas |  Lot number |  Catalogue number |  Manufacturer |  Quantity |
|  Expires |  Storage |  Conditions<br>Keep in a cool, dry and dark place |  Do not resterilize |  Do not re-use |
|  UCL Usable catheter length |  Guide wire lumen inside |  Guide wire lumen outside |  Min GC Min. guiding catheter ID | Ø GW Recommended guide wire diameter |
|  Distance Radiopaque Marker - Tip |  Distance Radiopaque Marker - Tip |  Délka rychlé výměny |  Length Diameter Rapid exchange length | |
|  Read instructions prior to use |  HYDROPHILIC Hydrophilic coating |  Do not use if package is damaged | | |

Conversion of dimension units: 1 French (F) = 0.333 mm; 1 inch (“) = 25.4 mm

## Manufacturer

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Germany

## Distributor

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281 63 Kostelec nad Černými Lesy
Czech Republic

**Stav: 2014-03-26**

CE 0297