



CE 0068

ISO 13485 : 2016

Revision date of the form format initially presented by the European Union: Rev 1: September 2018 (please note that this format is prepared by the European commission at this date this is not related to the field safety action)

FSN Ref: ARES-20210716-001-FSN

FSCA Ref: ARES-20210716-001-FSCA

For devices Ares Balloon Inflation Device (ref# BID6002)

Urgent Field Safety Notice

Ares Balloon Inflation Device (ref# BID6002)

Identification on labels, IFU and possible leakage problem of devices

For Attention of*: Agence nationale de sécurité du médicament et des produits de santé (ANSM)

143/147, boulevard Anatole France 93285 SAINT-DENIS CEDEX

Tel : +33 1 55 87 36 86 / +33 1 55 87 37 28

e-mail: dmdpt@ansm.sante.fr , dmtcos@ansm.sante.fr

Website: www.ansm.sante.fr

Contact details of local importer (name, e-mail, telephone, address etc.)*

Vytil

Address: 61 Av. Gallieni, 93170 Bagnolet, France

Phone: +33 1 49 88 22 07

Email: info@vytil.com

Web: www.vytil.com

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.

Aşık Veysel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE

Tel: +90 232 264 70 00

Fax: +90 232 264 90 00

E-mail: info@ares-medikal.com

Web: www.ares-medikal.com

Gaziemir V.D. 074 038 0394

Tic. Sic. No: 113178

Mersis No: 4545336122779750

Firma Tanımlayıcı No: 2667269009591

HALK BANKASI - Gaziemir Şb. - IBAN No: TR30 0001 2009 7460 0010 2603 77

• ZİRAAT BANKASI - Ege Tıp Şb. - IBAN No: TR10 0001 0014 4647 0931 6650 03



Urgent Field Safety Notice (FSN)
Ares Balloon Inflation Device (ref# BID6002)

Identification on labels, IFU and possible leakage problem of devices

| 1. Information on Affected Devices* | |
|-------------------------------------|---|
| 1 | 1. Device Type(s)* |
| . | Devices in question are balloon inflation devices intended for inflating balloon catheters. |
| 1 | 2. Commercial name(s) |
| . | Ares Balloon Inflation Device (ref# BID6002) |
| 1 | 3. Unique Device Identifier(s) (UDI-DI) |
| . | (01)08698907743797 (17)230701 (10)XG02-200701 |
| 1 | 4. Primary clinical purpose of device(s)* |
| . | Devices in question are balloon inflation devices intended for inflating balloon catheters. |
| 1 | 5. Device Model/Catalogue/part number(s)* |
| . | Ares Balloon Inflation Device (ref# BID6002) |
| 1 | 6. Software version |
| . | Only where relevant. |
| 1 | 7. Affected serial or lot number range |
| . | XG02200701 |
| 1 | 8. Associated devices |
| . | There are no associated devices under our manufacturing process for those devices with the same problems. |

| 2 Reason for Field Safety Corrective Action (FSCA)* | |
|---|--|
| 2 | 1. Description of the product problem* |
| . | It has been reported that the devices are leaking fluids and gases during operation after letting in the inflation medium of air and the air chamber release may realize some undesirable leakage, since they are tried before operation there are no incidents affecting human health so far. The status of the incident is a near miss. The devices include identification which may be misleading on their labels and instructions for use. |
| 2 | 2. Hazard giving rise to the FSCA* |
| . | Devices used during a balloon inflation for balloon catheters which are not manufactured by our company and balloon inflation devices are presented with defect will cause inefficient balloon catheter inflation which cause inefficient cardiovascular intervention and ultimately may result in restenosis. |
| 2 | 3. Probability of problem arising |
| . | The balloon inflation devices have been reported for their use in the operation room before the operation, if they are used without such a try the problem may occur if they are tried according to the required instructions for use. Probability of this risk is one in each ten thousand uses. |
| 2 | 4. Predicted risk to patient/users |
| . | The devices can result in harm regarding Severity dimension of risk 3 in 5 (indicating permanent damage due to injury to human body) and probability dimension of risk 2 in 5 (once in ten thousand |

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.

Aşık Veyssel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 Fax: +90 232 264 90 00
E-mail: info@ares-medikal.com Web: www.ares-medikal.com

Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591



| | |
|---|--|
| | uses) resulting in the lower limit of AFAP risks (AFAP means reduced as far as possible yet it will still need actions implemented in before any precaution. |
| 2 | 5. Further information to help characterize the problem |
| . | The devices are instructed to be used after a try of the device before the operation in order to be safer by design. |
| 2 | 6. Background on Issue |
| . | The manufacturer has been notified of the leak during a near miss incident which has not resulted in any harm to the patient. |
| 2 | 7. Other information relevant to FSCA |
| . | The devices are to be recalled just in case they are faulty in the same lot. |

| | | |
|-----------|---|--|
| | 3. Type of Action to mitigate the risk* | |
| 3. | 1. Action To Be Taken by the User* | |
| | <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device | |
| | <input type="checkbox"/> On-site device modification/inspection | |
| | <input type="checkbox"/> Follow patient management recommendations | |
| | <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) | |
| | <input type="checkbox"/> Other <input type="checkbox"/> None | |
| | Provide further details of the action(s) identified. | |
| 3. | 2. By when should the action be completed? | Please return the devices in 4 weeks or 1 month. |
| 3. | 3. Particular considerations for: Balloon Inflation Devices | |
| | Is follow-up of patients or review of patients' previous results recommended? No | |
| | The devices are considered only during a limited period of time during the operation they do not require any follow up. | |
| 3. | 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | Yes. |
| 3. | 5. Action Being Taken by the Manufacturer | |
| | <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection | |
| | <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change | |
| | <input checked="" type="checkbox"/> Other <input type="checkbox"/> None | |

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.

Aşık Veyssel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 Fax: +90 232 264 90 00
E-mail: info@ares-medikal.com Web: www.ares-medikal.com

Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591



CE 0068

ISO 13485 : 2016

| | | | |
|----|---|--|--|
| | A number of devices are to be tried and tested for their efficiency and safety in order to see if there are any trending problems regarding the same risk. | | |
| 3 | 6. By when should the action be completed? | Action shall be complete at least 4 weeks after the completion of this recall. | |
| 3. | 7. Is the FSN required to be communicated to the patient / lay user? | No | |
| 3 | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | | |
| | No. Not appended to this FSN. | | |

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.

Aşık Veyssel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 Fax: +90 232 264 90 00
E-mail: info@ares-medikal.com Web: www.ares-medikal.com

Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591



| | | |
|----|--|--|
| | 4. General Information* | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | There are no previous FSN issued for this problem. |
| 4. | 3. For Updated FSN, key new information as follows: | |
| | This is not an updated FSN. | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | Not planned yet |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | Devices might be presented with inadequate label or instructions for use. | |
| 4 | 6. Anticipated timescale for follow-up FSN | The initial field safety corrective action is not completed yet. |
| 4. | 7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Ares Medikal San.Tic.Ltd.Sti. |
| | b. Address | Aşık Veyssel Mah. 5821/1 Sk. No: 6, İzmir Turkey asistan@ares-medikal.com +90 232 264 70 00 (The e-mail address is designated to and by the phone he French speaking personnel Miss Kubra Rana Gokdemir is reachable during the office hours between 0800 to 1700 in France. The designated phone number for mobile communication is +90 554 698 2956.) |
| | c. Website address | https://ares-medikal.com/ |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | ARES-20210716-001-FSCA |
| 4. | 10. Name/Signature | |

Transmission of this Field Safety Notice**ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.**

Aşık Veyssel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 Fax: +90 232 264 90 00
E-mail: info@ares-medikal.com Web: www.ares-medikal.com

Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591



CE 0068

ISO 13485 : 2016

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.

Aşık Veyssel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 **Fax:** +90 232 264 90 00
E-mail: info@ares-medikal.com **Web:** www.ares-medikal.com

Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591



CE 0068

ISO 13485 : 2016

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.

Aşık Veyssel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 **Fax:** +90 232 264 90 00
E-mail: info@ares-medikal.com **Web:** www.ares-medikal.com

Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591

HALK BANKASI - Gaziemir Şb. - IBAN No: TR30 0001 2009 7460 0010 2603 77 • ZİRAAT BANKASI - Ege Tıp Şb. - IBAN No: TR10 0001 0014 4647 0931 6650 03