

September 2022

**RE: Introduction of Diacap® Pro High Flux G-Article Codes in USA**

Dear Valued B. Braun Customer,

We are working on the implementation of Diacap® Pro article codes in order to comply with US standards and regulations. We want to inform you that the new article codes for the Diacap Pro product line will now be called Diacap Pro G. The article codes are listed below.

This change will be introduced in production in August 2022. This leads to the following availabilities in the US market:

- Diacap Pro 16H: September 2022
- Diacap Pro 19H: September 2022
- Diacap Pro 13H: October 2022

**WHICH ARTICLE CODES ARE AFFECTED?**

Product	Old Article Code	New Article Code	Description
<b>Diacap® Pro 13H</b>	720DH13	720DH13G	Diacap® Pro high flux 1.3 m <sup>2</sup>
<b>Diacap® Pro 16H</b>	720DH16	720DH16G	Diacap® Pro high flux 1.6 m <sup>2</sup>
<b>Diacap® Pro 19H</b>	720DH19	720DH19G	Diacap® Pro high flux 1.9 m <sup>2</sup>

Please note that the new article codes are fully identical to those already registered in terms of design, technical features, safety, performances, risks, and effectiveness.

**WHY IS THIS CHANGE NEEDED?**

The new article codes include the registration of **both** production facilities (Radeberg and Wilsdruff).

With the introduction of the new article codes, labels will clearly mention the manufacturing facility in which the product will be produced. Please see below as an example the Diacap Pro 16H labels for both production sites with the marked production address and article codes.

Box Label Site Wilsdruff

## Diacap® Pro 16H

vol. blood comp.: 100 ml  
surface: 1.6 m<sup>2</sup>

**20 units**

生产日期: YYY-MM-DD  
失效日期: YYY-MM-DD  
批号: X XXXX MM YY

**REF: 720DH16G**

製造日期及有效期限或保存期限: 如原標標示  
製造批號: 如原標標示  
其他內容詳見說明書 合格

GTIN: 04046955659647

place for DMC

CE 0123 30°C Rx only  
Symbol glossary in IFU  
Внутри стерильно, асепрично, нестерилизовано

Imported/Distributed by: 代理商及售后服务单位名称: 贝朗医疗(上海)贸易有限公司  
代理人住所: 中国(上海)自由贸易试验区新金桥路16号1901室 联系方式: 021-52143299  
注册证书: 国械注准: 202021100229

Manufacturer 注册人名称: 贝朗医疗股份公司  
B. Braun Avitum AG  
注册人住所: Schwarzenberger Weg 73-79,  
34212 Melsungen, Germany  
联系方式: Tel: +49-(0)5661-71-0

Manufacturing site: 生产企业名称: B. Braun Avitum Saxonia GmbH  
生产地址: Dresden-Tor 5,  
01723 Wilsdruff, Germany  
Made in Germany  
www.bbraun.com

High Flux

place for boxcoding

place for boxnumber

Box No. K323-001

**B | BRAUN**

New article code

New manufacturing address

Box Label Site Radeberg

## Diacap® Pro 16H

vol. blood comp.: 100 ml  
surface: 1.6 m<sup>2</sup>

**20 units**

生产日期: YYY-MM-DD  
失效日期: YYY-MM-DD  
批号: X XXXX MM YY

**REF: 720DH16G**

製造日期及有效期限或保存期限: 如原標標示  
製造批號: 如原標標示  
其他內容詳見說明書 合格

GTIN: 04046955659647

place for DMC

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Внутри стерильно, асепрично, нестерилизовано

Imported/Distributed by: 代理商及售后服务单位名称: 贝朗医疗(上海)贸易有限公司  
代理人住所: 中国(上海)自由贸易试验区新金桥路16号1901室 联系方式: 021-52143299  
注册证书: 国械注准: 202021100229

Manufacturer 注册人名称: B. Braun Avitum AG  
贝朗医疗股份公司  
注册人住所: Schwarzenberger Weg 73-79,  
34212 Melsungen, Germany  
联系方式: Tel: +49-(0)5661-71-0

Manufacturing site: 生产企业名称: B. Braun Avitum Saxonia GmbH  
生产地址: Jun-Gagarin-Strasse 13  
01454 Radeberg, Germany  
Made in Germany  
www.bbraun.com

High Flux

place for boxcoding

place for boxnumber

Box No. 1007-020

**B | BRAUN**

New article code

New manufacturing address

Product Label Site Wilsdruff

Product Label Site Radeberg



Please contact our customer service with any questions at 1-800-227-2862.

Kind Regards,

Brenda Flaherty  
Product Manager, Avitum  
B. Braun Medical Inc.