

**Aesculap AG  
Quality Management**

Postfach 40  
78501 Tuttlingen  
Germany

Contact: Miriam Hoßfeld  
Fon: +49 7461 95-31701  
Fax: +49 7461 95-1555  
Email: [vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de)  
Internet: <http://www.bbraun.com>  
Date: December 13, 2017

**Field Safety Notice – Safety Information**

**Product Description: DS Titanium Ligation-Clips**

|         |        |         |         |         |         |         |         |         |         |
|---------|--------|---------|---------|---------|---------|---------|---------|---------|---------|
| FC171R  | FC174R | FC175R  | FC177R  | FC178R  | FC179R  | FC181R  | FC184R  | FC185R  | FC187R  |
| FC188R  | FC191R | FC194R  | FC195R  | FC196R  | FC197R  | FC198R  | FC199R  | FC204R  | FC205R  |
| FC206R  | FC207R | FC208R  | FC209R  | FC214R  | FC215R  | FC216R  | FC217R  | FC218R  | FC219R  |
| FC230R  | FC231R | PL450SU | PL452SU | PL453SU | PL459SU | PL462SU | PL465SU | PL468SU | PL471SU |
| PL475SU | PL801R | PL802R  | PL806R  | PL807R  | PL808R  | PL809R  | PL816R  | PL817R  | PL818R  |
| PL822R  | PL826R | PL827R  | PL828R  |         |         |         |         |         |         |

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Herewith, we would like to inform you that the instruction for use, chapter contraindications for the DS Titanium Ligation-Clips, has been extended with the "closure of the A./V. renalis during living kidney donation". This is a proactive action. We want to point out that there was no patient injury prior to this action. Enclosed please find the appropriate excerpt from the instruction for use.

Chairman of Supervisory Board:  
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:  
Dr. Joachim Schulz  
(Chairman)  
Dr. Jens von Lackum

Corporate Office: Tuttlingen  
Register Court: Stuttgart HRB 726261  
VAT reg. no. DE812160059  
WEEE-Reg.-No. DE 65109852

Bank Account:  
**Deutsche Bank AG Tuttlingen**  
BLZ 653 700 75 Konto 21 22 000 00  
IBAN DE44 6537 0075 0212 2000 00  
SWIFT / BIC DEUTDE33  
**Baden-Württembergische Bank**  
BLZ 600 501 01 Konto 487 1905  
IBAN DE31 6005 0101 0004 8719 05  
SWIFT / BIC SOLADEV33

Address:  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Germany

## 4. Contraindications

### 4.1 Absolute contraindications

DS titanium ligature clips (clip sizes SMALL to LARGE) and DS appendectomy clip (clip size X-LARGE)

Do not use:

- on the central circulatory system (in the aorta, truncus brachiocephalicus, carotid artery, cerebral arteries, coronary arteries and veins, pulmonary arteries and veins, vena cava)
- on the central nervous system
- in case of foreign-body sensitivity for titanium
- for contraceptive procedures such as tubal occlusion, vasectomy
- for closure of the A./V. renalis during living kidney donation
- DS appendectomy clip only: with highly inflammatory appendix with inclusion of the appendix base

### 4.2 Relative contraindications

Relative contraindications include, but are not limited to, medical and/or surgical conditions that could prevent the success of the implantation, e.g. disorders of the connective tissue (Marfan syndrome) or infections.

You can find the IFU with further remarks about the usage under the following links:

- TA013285, Laparoscopic DS clip applier forceps and DS titanium ligature clips  
<http://bbraun.info/013285>
- TA013409, DS clip applier forceps for open surgery and DS titanium ligature clips  
<http://bbraun.info/013409>

For any product-related request, kindly do not hesitate to contact our product manager:

Mr. Frank Radke

☎ + 49 7461- 95 – 2017

☎ + 49 171 – 6731808 (mobil)

[frank.radke@aesculap.de](mailto:frank.radke@aesculap.de)

Please ensure in your organization that all users of the affected devices are informed about this safety information.

If you have distributed the products to a third party, please forward a copy of this information or inform Aesculap AG ([vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de)).

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The Competent Authority BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte, has received a copy of this safety information.

With best regards,

Aesculap AG

i.V.

i.A.

Thorsten Barthelmes  
Safety Officer Medical Devices  
Director Quality Risk & Vigilance Management

Kerstin Rothweiler  
Dpt. Safety Officer Medical Devices  
Team Leader Quality

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| <p style="text-align: center;"><b>FEEDBACK FORM</b><br/><b>Field Safety Notice</b><br/><br/><b>DS Titanium Ligation-Clips</b></p> |
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\_\_\_\_\_ We acknowledge the receipt of the Field Safety Notice from B. Braun Aesculap / Germany.

Please mark:

We have take notice.

HOSPITAL \_\_\_\_\_ TOWN \_\_\_\_\_

NAME \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ TELEPHONE \_\_\_\_\_

\_\_\_\_\_ SIGNATURE \_\_\_\_\_

DATE \_\_\_\_\_

Please return this form by fax or e-mail to:

Fax: +49 7461-95 1555

E-Mail: [vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de)

